11q Aberration in NHL

Alternative Name 11q Gain / Loss
Methodology FISH
Test Description Probes: CEN 11 (11p11.1-q11) | MLL (11q23) | 11qTel (11q25)
Disease(s): B-cell non-Hodgkin lymphoma
Clinical Significance This FISH panel detects proximal gains and distal losses of chromosome 11q which are recurrent abnormalities in MYC-negative high grade B-cell lymphomas resembling Burkitt lymphoma. “Burkitt-like lymphoma with 11q aberration” was recognized by the WHO in 2017 as a new provisional entity. This pattern of 11q abnormalities is also observed in MYC-positive Burkitt lymphomas and MYC-positive high-grade B-cell lymphomas, not otherwise specified.
Specimen Requirements Bone Marrow Aspirate: N/A
Peripheral Blood: N/A
Fresh, Unfixed Tissue: N/A
Fluids: N/A
Paraffin Block: H&E slide (required) plus paraffin block. Circle H&E for tech-only.
Cut Slides: H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.
Storage and Transportation Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.
CPT Code(s)* 88374x1 automated or 88377x1 manual
Turnaround Time 3-5 days
Level of Service Global ✓ Technical ✓

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Breast Cancer Index® (BCI)

Methodology

Molecular

Test Description

Breast Cancer Index (BCI) is an RT-PCR assay performed on FFPE breast tumor tissue that integrates two gene expression-based biomarkers: 1) the HOXB13:IL17BR ratio (H/I), which is associated with tumor responsiveness to endocrine therapy; and 2) Molecular Grade Index (MGI), which consists of the average expression of five cell cycle-associated genes (BUB1B, CENPA, NEK2, RACGAP1 and RRM2) and provides quantitative and objective molecular assessment of tumor proliferative status.

Clinical Significance

BCI Risk of Recurrence & Extended Endocrine Benefit is a molecular tool to help with the extended endocrine decision after primary adjuvant therapy in HR+ early-stage (TNM stage T1-3, N0-1) breast cancer patients. Breast Cancer Index provides information regarding a patient’s individualized risk for distant recurrence and prediction of likelihood of benefit from extended (>5 years) endocrine therapy.

The test is intended for use in women diagnosed with hormone receptor-positive (HR+), lymph node-negative (LN-) or lymph node positive (LN+; with 1-3 positive nodes) early-stage, invasive breast cancer who are distant recurrence-free. BCI provides two results based on unique gene signatures:

- **BCI Prognostic**: a quantitative assessment of the likelihood of late (post-5 years) and overall (0-10 year) distant recurrence* following an initial 5 years of endocrine therapy (LN- patients) or 5 years of endocrine therapy plus adjuvant chemotherapy (LN+ patients). Results are presented as percentage risk and categorized as high or low risk.
  
*0-10 year results apply if BCI is ordered at the time of diagnosis.

- **BCI Predictive**: prediction of likelihood of benefit from extended (>5 year) endocrine therapy. Results are presented as a high or low likelihood of benefit.

BCI results are adjunctive to the ordering physician’s workup; treatment decisions require correlation with all other clinical findings. Testing is approved for specimens from the state of New York.

Breast Cancer Index is performed, reported, and billed separately by Biotheranostics, Inc. For comprehensive details about Breast Cancer Index including sample reports, clinical studies, intended use and limitations, and Medicare Local Coverage Determination (LCD) criteria, visit www.breastcancerindex.com

Specimen Requirements

Testing is performed on breast primary invasive tumor.

**FFPE tissue**: Paraffin block is preferred. Alternatively, send 3-4 unstained, 10 micron thick sections on glass slides (an area of tumor that contains ≥40% neoplastic cells) and one H&E-stained slide.

**Note**: Cases with the following clinical or specimen characteristics are not acceptable: post-treatment (adjuvant or neoadjuvant) specimens, fine needle aspirations (FNA), fresh or frozen tissue, both ER- and PR-, ≥4 positive nodes, microinvasive carcinoma, metaplastic or metastatic breast cancer, carcinosarcoma, sarcoma, neuroendocrine carcinoma, adenoid cystic carcinoma, phyllodes tumor, male gender, T4 tumor, no evidence of invasive (ductal, lobular or mixed ductal lobular) carcinoma, biopsy site of chest wall, skin, axilla or lymph node.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

Please contact Biotheranostics, Inc. at 877-886-6739.
<table>
<thead>
<tr>
<th>Turnaround Time</th>
<th>10 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of Service</td>
<td>Global ✔</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*

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Prosigna® Assay

Alternative Name
PAM50 Risk of Recurrence, Prosigna Breast Cancer Prognostic Gene Signature Assay

Methodology
Molecular

Test Description
The Prosigna Assay measures tumor expression levels of 50 genes used in the PAM50 classification algorithm, weighted together with clinical variables, to predict the risk of distant breast cancer recurrence within 10 years.

Clinical Significance
The Prosigna Breast Cancer Prognostic Gene Signature Assay is FDA-cleared for use in certain early-stage breast cancer patients as a prognostic indicator for distant recurrence-free survival at 10 years. Results are tailored for nodal status and include:

- **Prosigna Score** - a numerical value on a 0 to 100 scale that correlates with the probability of distant recurrence
- **Risk groups** that use cutoffs related to clinical outcome in tested patient populations (high/low for node-positive and high/intermediate/low for node-negative)

**Patients/specimens must meet the following criteria:** post-menopausal female, invasive breast cancer treated or to be treated with adjuvant endocrine therapy alone, ER+ and/or PgR+, stage I or II with 0 positive lymph nodes OR stage II with 1-3 positive lymph nodes.

Specimen Requirements
Test is performed on breast cancer tissue specimens from surgical resections. Fresh, frozen, non-breast, needle biopsy, fine needle aspiration (FNA), and decalcified specimens are not acceptable.

**FFPE tissue:** Paraffin block is preferred. Alternatively, send 6 unstained slides cut at 10 microns and one H&E slide cut at 4-5 microns. Target area for testing must have tumor cellularity ≥10% and surface area on the slide of ≥4 mm². Please use positively-charged slides and 10% NBF fixative. Do not use zinc or other fixatives. **Note:** See Clinical Significance for required clinical and specimen characteristics.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81520x1

Turnaround Time
7 days

Level of Service
Global ✓

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1p/19q Deletions for Glioma

**Alternative Name**
1/19 Co-deletion

**Methodology**
FISH

**Test Description**

**Probes:** 1p36/1p12/1q25 |19q13/19q11q12/19p13

**Disease(s):** Oligodendroglioma

This assay employs one centromeric probe and two distal probes per chromosome to detect and differentiate whole-arm vs partial 1p and 19q deletions, and to detect polysomy.

**Clinical Significance**
Testing for 1p and 19q deletions in glial brain tumors, specifically oligodendrogliomas, has diagnostic and prognostic value. Whole-arm deletions of chromosomes 1p and 19q (with concurrent IDH1 or IDH2 mutation) are diagnostic for oligodendroglioma according to WHO classification. Co-deletion of both the 1p and 19q regions in adult oligodendroglioma patients is associated with improved response and longer survival in patients receiving radiation and/or chemotherapy. Results can help distinguish the oligodendroglioma subtype of diffuse gliomas from astrocytomas and from other tumor types with similar morphology such as clear cell ependymomas, central or extraventricular neurocytomas, and dysembryoplastic neuroepithelial tumors (DNETs). Partial deletions may be seen in high-grade glioblastomas. Polysomy in the presence of whole-arm co-deletions may occur in anaplastic oligodendroglioma.

**Specimen Requirements**
- **Paraffin Block:** Send paraffin block. Also send circled H&E slide for tech-only (required).
- **Cut Slides:** Send 4 unstained slides cut at 4-5 microns plus H&E slide (required). Circle H&E slide for tech-only.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88374x2 automated or 88377x2 manual. Codes may differ if manual analysis is performed.

**Turnaround Time**
4 days

**Level of Service**
Global ✔  Technical ✔
## AAT

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>alpha-1-antitrypsin</th>
</tr>
</thead>
</table>

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Alpha-1-Antitrypsin (AAT) is useful in the study of inherited AAT deficiency, benign and malignant hepatic tumors and yolk sac carcinoma. Sensitivity and specificity of the results have made this antibody a useful tool in the screening of patients with cryptogenic cirrhosis or other forms of liver disease with portal fibrosis of uncertain etiology.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only

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## ABL1 Kinase Domain Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>ABL1 Kinase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>RT-PCR and sequencing of the BCR-ABL1 fusion transcript for qualitative detection of mutations associated with resistance to Gleevec (imatinib) and other tyrosine kinase inhibitors. Analysis includes detection of the common T315I mutation.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Testing is recommended in CML with poor initial response to Gleevec (imatinib), relapse, or progression to accelerated/blast phase. Presence and identity of mutation may direct management to alternative drugs or stem cell transplant.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • **Peripheral blood**: 5 mL in EDTA tube.  
• **Bone marrow**: 2 mL in EDTA tube. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| CPT Code(s)*      | 81170       |
| Turnaround Time   | 10 days     |
| Level of Service  | Global ✓    |

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December 18, 2019
## Acid Phosphatase (AcP)

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Cytochemical stain.</td>
</tr>
</tbody>
</table>
| Specimen Requirements| • Minimum two slides fresh smear: bone marrow aspirate preferred, peripheral blood accepted  
                         • Slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*         | 88319x1                    |
| Turnaround Time      | 24 hours                   |
| Level of Service     | Stain Only ✓               |

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ACTH

Alternative Name: adrenocorticotropic hormone

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-adrenocorticotropic hormone (ACTH) is a useful marker in the classification of pituitary tumors and the study of pituitary disease. It reacts with ACTH-producing cells (corticotrophs). It also may react with other tumors (e.g., some small cell carcinomas of the lung) causing paraneoplastic syndromes by secreting ACTH.

Specimen Requirements:
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88342 x 1 or 88341 x 1

Turnaround Time: 24 hours

Level of Service: Stain Only ✓

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### Adenovirus

<table>
<thead>
<tr>
<th><strong>Methodology</strong></th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Description</strong></td>
<td>Adenoviruses are simple DNA-containing viruses that multiply in the cell nucleus. They induce latent infections in tonsils, adenoids and other lymphoid tissue of man, causing either unapparent or limited illnesses that are followed by complete recovery and persistent type-specific immunity. This antibody is directed against adenovirus, allowing for the rapid identification of viral infections in tissues.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
  - One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88342 x 1 or 88341 x 1 |
| **Turnaround Time** |  
  Global: 48 hours, Tech-Only (stain only): 24 hours |
| **Level of Service** |  
  Global  ✔  Stain Only  ✔  

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**AFB**

**Alternative Name**
Acid Fast Bacillus

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Special stain. Ziehl-Neelsen Acid-Fast Bacilli Stain is used to detect the presence of acid-fast mycobacteria in tissue sections. Acid-fast techniques are of value in the detection of mycobacteria, rod-shaped organisms that sometimes exhibit filamentous (fungus-like) growth. The most significant disease-producing mycobacteria are Mycobacterium tuberculosis and Mycobacterium leprae.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88312

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✔ Stain Only ✔
###AFP

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Alpha-1-fetoprotein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>Alpha-1-fetoprotein (AFP) is a 64 kD tumor-associated embryonal antigen produced by fetal liver, hepatocellular carcinoma, yolk sac tumor and several germ cell tumors of testicular and ovarian origin. Most non-seminomatous germ cell tumors produce AFP. AFP is of importance in diagnosing hepatocellular carcinoma.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*   | 88342x1 or 88341x1 |
| Turnaround Time | 24 hours |
| Level of Service | Stain Only ✓ |

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December 18, 2019
# Albumin RNA ISH

## Methodology
In Situ Hybridization (ISH)

## Test Description
Albumin RNA ISH is a sensitive and specific tool for distinguishing primary hepatocellular carcinoma and intrahepatic cholangiocarcinoma from metastatic adenocarcinoma to the liver or carcinoma of unknown origin in formalin fixed paraffin-embedded tissues. Positive results in this assay provide evidence of liver origin.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and three (3) positively charged unstained slides, all cut at 4-5 microns
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88365x1

## Turnaround Time
24 hours

## Level of Service
Stain Only ✓

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December 18, 2019
Alcian Blue

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain. Alcian blue is intended to identify weakly sulfated mucins in tissue samples.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88313

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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ALK (D5F3)

Methodology
Immunohistochemistry (IHC)

Test Description
VENTANA FDA approved ALK (D5F3) CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark XT or BenchMark ULTRA automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib) or ZYKADIA® (ceritinib).

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔ Stain Only ✔

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ALK for Lymphoma

Alternative Name
Anaplastic lymphoma kinase, (2p23)

Methodology
FISH

Test Description
Probes: ALK (2p23)
Disease(s): Anaplastic large cell lymphoma, NHL

Clinical Significance
ALK gene rearrangements are associated with anaplastic large-cell lymphoma (ALCL), and patients with ALK-positive ALCL have a favorable prognosis compared to patients with ALK-negative ALCL. This FISH probe detects ALK gene rearrangements irrespective of the partner gene. This probe is available separately or as part of the NHL FISH Panel.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88377x1 manual. Codes may differ if automated analysis is performed.

Turnaround Time
4 days for both unfixed and FFPE specimens

Level of Service
Global ✓ Technical ✓

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## ALK for NSCLC

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Anaplastic lymphoma kinase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>FISH</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td><strong>Probes:</strong> ALK (2p23)</td>
</tr>
<tr>
<td></td>
<td><strong>Disease(s):</strong> Non-small cell lung carcinoma (NSCLC)</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>ALK gene rearrangements are found in 3-5% of non-small cell lung carcinoma (NSCLC) and determine likelihood of response to crizotinib (Xalkori®) therapy.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>• <strong>Paraffin Block:</strong> Send paraffin block. Also send circled H&amp;E slide for tech-only (required).</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>88377x1 manual.</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>3-5 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓  Technical ✓</td>
</tr>
</tbody>
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# ALK Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>ALK Mutation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional Sanger sequencing of ALK is performed using PCR primers designed to target hotspot mutations in exons 23 and 25.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>ALK gene translocations are a well-known cause of gene deregulation and target of ALK inhibitors in non-small cell lung carcinoma (NSCLC). However, point mutations in the ALK tyrosine kinase domain, such as those detected by this test, are reported in patients who develop resistance to this therapy. Mutation analysis can help predict sensitivity or resistance to first and second generation inhibitors such as crizotinib, alectinib, and ceritinib. Reported mutations include L1152R, F1174V, F1245C, L1196M, and G1202R.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81479</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>7-10 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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# ALK-1 (for heme cases)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>ALK1 for lymphoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>The ALK1 (ALK1 cline) antibody labels normal human ALK protein and the NPM-ALK chimeric protein, and is a useful tool for the identification of the subgroup of anaplastic large-cell lymphomas (ALCL) that are ALK positive.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or&lt;br&gt;• One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered&lt;br&gt;• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88342 x 1 or 88341 x 1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Stain Only ✓</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.*

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ALL Adult FISH Panel

Alternative Name: Acute lymphoblastic leukemia

Methodology: FISH

Test Description:

**Probes:**
- TCF3/PBX1 (E2A/PBX1) t(1;19)
- Trisomy or Tetrasomy 4, 6, 10, 17 (Cen 4, Cen 6, Cen 10, Cen 17)
- MYC (8q24)
- BCR/ABL1/ASS1 t(9;22)
- MLL (11q23)
- IgH (14q32)

**Disease(s):** Acute lymphoblastic (lymphocytic) leukemia (B-cell ALL), B lymphoblastic lymphoma (LBL), adult

Probes may be ordered separately except Centromeres 4 and 17 are paired, and Centromeres 6 and 10 are paired.

**Note:** STAT processing is available by request for BCR-ABL1. Note STAT along with MD contact name and phone number to receive STAT results.

**Note:** CDKN2A (p16) Deletion FISH is also available and may be ordered separately. See details [here](#).

Clinical Significance:

The ALL Adult FISH Panel is used for the detection of recurrent chromosome abnormalities observed in adults with ALL of B-cell lineage and B lymphoblastic lymphoma (LBL). Identification of specific abnormalities helps predict disease aggressiveness and response to therapy. This panel differs from the ALL Pediatric FISH Panel in that this panel excludes probes for ETV6/RUNX1 t(12;21).

Specimen Requirements:

- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

Storage and Transportation:

Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*:

88374x7 automated. Codes may differ if manual analysis is performed.

Turnaround Time:

3-5 days. STAT results for BCR-ABL1, when requested, are reported 12-24 hours from receipt in the NeoGenomics laboratory.

Level of Service:

Global ✓ Technical ✓

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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December 18, 2019
# ALL FISH Panel (Ph-Like)

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL)</th>
<th>Ph-like ALL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>FISH</td>
<td></td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Probes: PDGFRb (5q32), BCR/ABL1-ASS1 t(9;22), JAK2 (9p24.1), EPOR (19p13.2) and CRLF2 (Xp22.33/Yp11.32) are included in the ALL FISH (Ph-like) Profile. Probes may be ordered separately. Disease(s): Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL), B lymphoblastic leukemia/lymphoma.</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>The ALL FISH Profile (Ph-like) detects cytogenetic abnormalities commonly associated with Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL). Patients with Ph-like B-ALL are associated with an unfavorable prognosis, but may potentially be amenable to inhibition with select tyrosine kinase inhibitors.</td>
<td></td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>• Bone Marrow Aspirate: 1-2 mL in sodium heparin tube. EDTA tube is acceptable. • Peripheral Blood: 2-5 mL sodium heparin tube. EDTA tube is acceptable. • Fresh, Unfixed Tissue: Tissue in RPMI • Fluids: Equal parts RPMI to specimen volume • Paraffin Block or Cut Slides: Not Available</td>
<td></td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen</td>
<td></td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>88374x5 automated or 88377x5 manual. Codes may differ if manual analysis is performed.</td>
<td></td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>3-5 days</td>
<td></td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔  Technical ✔</td>
<td></td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*
# ALL FISH Profile (Ph-Like)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL)</th>
<th>Ph-like ALL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
<td></td>
</tr>
<tr>
<td>Test Description</td>
<td><strong>Probes:</strong> PDGFRβ (5q32), BCR/ABL1-ASS1 t(9;22), JAK2 (9p24.1), EPOR (19p13.2) and CRLF2 (Xp22.33/Yp11.32) are included in the ALL FISH (Ph-like) Profile. Probes may be ordered separately. <strong>Disease(s):</strong> Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL), B lymphoblastic leukemia/lymphoma. See also the ALL FUSION PROFILE.</td>
<td></td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The ALL FISH Profile (ph-like) detects cytogenetic abnormalities commonly associated with Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL). Patients with Ph-like B-ALL are associated with an unfavorable prognosis, but may potentially be amenable to inhibition with select tyrosine kinase inhibitors.</td>
<td></td>
</tr>
</tbody>
</table>
| Specimen Requirements | • **Peripheral blood:** 3-5 mL in sodium heparin (green-top) tube or EDTA (purple-top) tube  
• **Bone marrow:** 2-3 mL in sodium heparin (green-top) tube or EDTA (purple-top) tube  
• **Lymphoid tissue:** Transport in RPMI  
• **FFPE tissue:** No decalcification. Two (2) x four (4) um thick slides for each probe ordered  
Note: Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen. DO NOT FREEZE.  
Probe Prioritization: If samples are insufficient to complete the whole FISH panel, NeoGenomics will prioritize testing in the following order: BCR/ABL1, CRLF2, JAK2, EPOR, and PDGFRβ, unless directed otherwise by the client. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 88377x5 |
| Turnaround Time | 6 days |
| Level of Service | Global ✓ |

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December 18, 2019
ALL Fusion Profile

Alternative Name
Philadelphia – like acute lymphoblastic leukemia (Ph-Like ALL)

Methodology
Molecular

Test Description
Detection of gene fusion transcripts in Acute Lymphoblastic Leukemia (ALL) from ribonucleic acid (RNA). RNA is isolated from bone marrow aspirates or peripheral blood and the cDNA sequence of targeted regions of the ABL1, ABL2, BCR, CRLF2, CSF1R, ETV6, IL2RB, IL3, JAK2, KMT2A, MEF2D, MLLT10, NUP98, PAX5, PDGFRB, PTK2B, RUNX1, TAL1, TCF3, TLX1, TLX3, TYK2, and ZNF384 genes is determined using next-generation sequencing (NGS) technology. This test will be performed at our Carlsbad location.

For comprehensive Ph-like ALL assessment consider ordering CRLF2 FISH & EPOR FISH concurrently. See also the ALL FISH PROFILE (Ph-Like)

Clinical Significance
Diagnostic Evaluation, Risk Assessment and Therapy Selection
Chromosome aberrations, in particular translocations and the corresponding gene fusions, have an important role in the initial steps of tumorigenesis. The identification of gene fusions in B Cell Acute Lymphoblastic Leukemia (B-ALL) are being recognized as an essential part of the diagnostic evaluation, risk assessment and optimal therapy selection. Within B-ALL, three major groups of fusions/rearrangements have been identified.

- BCR-ABL1 (aka Philadelphia chromosome “Ph+”)[1-3]
- Ph-Like (WHO 2016 Entity)[1-5]
  - ABL-class fusions: BCR, ABL1, ABL2, CSFR1, PDGFR-β
  - EPOR or JAK2 fusions
  - Cytokine receptor-like factor 2 (CRLF2) fusions
- Other Ph-Like fusions [6,7]
  - B ALL: DUX4, ETV6, IR2RB, KMT2A(MLL), MEF2D, MLLT10, NUP98, PAX5, PTK2B, RUNX1, TCF3, TSLP, TYK2, ZNF384
  - T ALL: TAL1, TLX1, TLX3

Specimen Requirements
Preferred:
- Peripheral blood: 2-3 mL in EDTA (purple-top) tube
- Bone marrow: 2-3 mL in EDTA (purple-top) tube

Acceptable:
- Peripheral blood: 2-3 mL in sodium heparin (green-top) tube
- Bone marrow: 2-3 mL in sodium heparin (green-top) tube
- Fixed cell pellets (3:1 methanol and acetic acid fixative)
**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. DO NOT FREEZE.

**CPT Code(s)**
81450x1, add 88377x2 if FISH is ordered.

**Turnaround Time**
15 days (NGS), 6 days (FISH)

**Level of Service**
Global ✓

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December 18, 2019
# ALL Pediatric FISH Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Acute lymphoblastic leukemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td>Test Description</td>
<td>Probes: TCF3/PBX1 (E2A/PBX1) t(1;19)</td>
</tr>
</tbody>
</table>

**Disease(s):** Acute lymphoblastic (lymphocytic) leukemia (B-cell ALL), B lymphoblastic lymphoma (LBL), pediatric

Probes may be ordered separately except Centromeres 4 and 17 are paired, and Centromeres 6 and 10 are paired.

**Note:** STAT processing is available by request for BCR-ABL1. Note STAT along with MD contact name and phone number to receive STAT results.

**Note:** CDKN2A (p16) Deletion FISH is also available and may be ordered separately. See details [here](#).

## Clinical Significance

The ALL Pediatric FISH Panel is used for the detection of recurrent chromosome abnormalities observed in infants and children with ALL of B-cell lineage and B lymphoblastic lymphoma (LBL). Identification of specific abnormalities helps predict disease aggressiveness and response to therapy. This panel differs from the ALL Adult FISH Panel in that this panel includes probes for ETV6/RUNX1 t(12;21).

## Specimen Requirements

- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

## Storage and Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88374x8 automated. Codes may differ if manual analysis is performed.

## Turnaround Time

3-5 days. STAT results for BCR-ABL1, when requested, are reported 12-24 hours from receipt in the NeoGenomics laboratory.

## Level of Service

- Global ✓
- Technical ✓

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*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*
AML Add-On Flow Panel

**Alternative Name**
Myeloid Leukemia Add-On Flow Panel

**Methodology**
Flow Cytometry

**Test Description**
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are cCD3, cCD22, cCD79, CD11b, CD123, CD34, CD45, CD117, cMPO, and nTdT (10 markers).

**Clinical Significance**
Used to diagnose AML and detect biphenotypic acute leukemia. Expression of CD11b is an unfavorable prognostic marker. CD123 can be added for specific cases.

**Specimen Requirements**
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

**Storage and Transportation**
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
Please contact NeoGenomics' Billing Department.

**Turnaround Time**
1 day

**Level of Service**
Global ✓ Technical ✓

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December 18, 2019
### AML Favorable-Risk Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Acute myeloid leukemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
</tbody>
</table>
| Test Description | Probes: RUNX1/RUNX1T1 (ETO/AML1) t(8;21) | PML/RARA t(15;17) | CBFB inv(16), t(16,16)  
|                  | Disease(s): Acute myeloid leukemia  
|                  | Probes may be ordered separately.  |
| Clinical Significance | The AML Favorable-Risk FISH Panel detects translocations associated with favorable prognosis.  |
| Specimen Requirements |  
|                  | Bone marrow aspirate: 1-2 mL sodium heparin tube. EDTA tube is acceptable.  
|                  | Peripheral blood: 2-5 mL sodium heparin tube. EDTA tube is acceptable.  
|                  | Fresh, unfixed tissue: Tissue in RPMI.  
|                  | Fluids: Equal parts RPMI to specimen volume.  
|                  | Paraffin block or cut slides: Not available.  |
| Storage and Transportation | Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.  |
| CPT Code(s)*     | 88374x3 automated. Codes may differ if manual analysis is performed.  |
| Turnaround Time  | 3-5 days               |
| Level of Service | Global ✓   Technical ✓ |

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December 18, 2019
# AML FISH Panel (New York)

**Alternative Name**  
Acute myeloid leukemia

**Methodology**  
FISH

**Test Description**  
**Probes:** 5q-, -5 (5p15.2, 5q33-34) | 7q-, -7 (7q31, Cen 7) | Trisomy 8 (Cen 8) | MLL (11q23) | RUNX1T1/RUNX1 (ETO/AML1) t(8;21) | PML/RARA t(15;17) | CBFB inv(16), t(16;16)
Probes may be ordered separately.

**Disease(s):** AML

**Note:** STAT processing is available by request for PML-RARA. Note STAT along with MD contact name and phone number to receive STAT results.

**Clinical Significance**  
The AML FISH panel is used for the detection of chromosome aberrations observed in AML, which aid in diagnosis, prognosis and/or therapy selection.

**Specimen Requirements**  
- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin or Cut Slides:** N/A

**Storage and Transportation**  
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88374x6, 88367x1 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**  
3-5 days. STAT results for PML-RARA, when requested, are reported 12-24 hours from receipt in the NeoGenomics laboratory

**Level of Service**  
Global ✅  Technical ✅

---

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AML Follow-Up Flow Panel

Alternative Name
Acute Myeloid Leukemia Follow-Up Flow Panel

Methodology
Flow Cytometry

Test Description
Available as global and tech-only. Please provide clinical history including the time after treatment. Prior immunophenotyping at NeoGenomics with Standard or Extended Flow Panel is strongly recommended. Clients who decline full phenotyping and order a global or push-to-global Follow-Up Panel are requested to provide details of the diagnosis by submitting at least one of the following: previous flow cytometry report, previous pathology report, and/or clinical history notes. Markers are cCD3, CD11b, CD13, CD14, CD16, CD19, cCD22, CD33, CD34, CD45, CD64, cCD79a, CD117, CD123, HLA-DR, cMPO, and nTdT (17 markers).

Clinical Significance
For acute myeloid leukemia (AML) monitoring after diagnosis is established. The standard number of flow events is collected, so this panel is best for diagnosis of relapse or >5% residual disease. This is not a minimal residual disease (MRD) panel since the standard number of events is collected.

Specimen Requirements
- **BM Aspirate:** 1mL EDTA; sodium heparin is acceptable; provide CBC
- **Peripheral Blood:** 1mL EDTA; sodium heparin is acceptable; provide CBC
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI and specimen volume

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184x1, 88185x16. Add 88189x1 for global.

Turnaround Time
1 day

Level of Service
Global ✔️  Technical ✔️

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# AML Non-Favorable Risk FISH Panel

**Alternative Name**  
Acute myeloid leukemia

**Methodology**  
FISH

**Test Description**  
**Probes:** RPN1, MECOM (3q21, 3q26.2) | 5q-, -5 (5p15, 5q31, 5q33) | 7q-, -7 (Cen 7, 7q22, 7q31) | Trisomy 8 (Cen 8) | DEK/NUP214 (CAN) t(6;9) | MLL (11q23) | ETV6 (12p13) | 17p-(TP53 17p13.1, NF1 17q11.2) | Probes may be ordered separately.

**Disease(s):** Acute myeloid leukemia

**Clinical Significance**  
The AML Non-Favorable Risk FISH Panel accommodates US and international cytogenetic risk classifications for intermediate and adverse risk groups. This Panel was formerly called AML Extended Panel.

**Specimen Requirements**

- **Bone marrow aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, unfixed tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin block or cut slides:** Not available.

**Storage and Transportation**  
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

- 88374x8 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**  
3-5 days

**Level of Service**  
Global [✓]  
Technical [✓]

---

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## AML Reflex Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>AML Prognostic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Routine cytogenetics with automatic addition of the NeoTYPE™ AML Prognostic Profile when cytogenetics results show intermediate risk including normal cytogenetics, +6, +8, -Y, or del(12p).</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The AML Reflex Panel combines cytogenetics and molecular testing to identify AML patients with intermediate-risk cytogenetic abnormalities that can benefit from molecular profiling. Use of the NeoTYPE AML Prognostic Profile in these patients can improve risk stratification by confirming intermediate risk or reclassifying patients to favorable or unfavorable risk categories.</td>
</tr>
</tbody>
</table>
| Specimen Requirements   | - **Peripheral blood**: 2-5 mL in sodium heparin tube and 2x5 mL in EDTA tube.  
                          - **Bone marrow**: 1-2 mL in sodium heparin tube and 2 mL in EDTA tube. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*            | 88235 or 88237, and 88291. With reflex to molecular testing, add molecular codes corresponding to the NeoTYPE AML Prognostic Profile. |
| Turnaround Time         | 12 days        |
| Level of Service        | Global ✓       |

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.*
# AML Standard FISH Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Acute myeloid leukemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
</tbody>
</table>
| Test Description | **Probes:** 5q-, -5 (5p15, 5q31, 5q33) | 7q-, -7 (Cen 7, 7q22, 7q31) | Trisomy 8 (Cen 8) | MLL (11q23) | 20q- (20q12, 20qter) | RUNX1/RUNX1T1 (ETO/AML1) t(8;21) | PML/RARA t(15;17) | CBFB inv(16), t(16;16)  
Probes may be ordered separately except +8 and 20q- which are combined.  
**Disease(s):** Acute myeloid leukemia Probes may be ordered separately except +8 and 20q- which are combined.  
**Note:** STAT processing is available by request for PML-RARA. Note STAT along with MD contact name and phone number to receive STAT results. |
| Clinical Significance | The AML Standard FISH Panel identifies the most frequent cytogenetic abnormalities associated with favorable, intermediate, and poor risk. See also the [AML Non-Favorable Risk Panel](#) and the [AML Favorable-Risk Panel](#). |
| Specimen Requirements | **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.  
**Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.  
**Fresh, Unfixed Tissue:** Tissue in RPMI.  
**Fluids:** Equal parts RPMI to specimen volume.  
**Paraffin Block or Cut Slides:** Not available. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 88374x7 automated. Codes may differ if manual analysis is performed. |
| Turnaround Time | 3-5 days. STAT results for PML-RARA, when requested, are reported 12-24 hours from receipt in the NeoGenomics laboratory |
| Level of Service | Global ✅  
Technical ✅ |

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### Amyloid A & Amyloid P

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Amyloid A, Amyloid P, Amyloid A&amp;P Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>Amyloid A and P react with amyloid deposits in many tissues. When accompanied by Congo Red, Amyloid A and P can be used to distinguish primary and secondary amyloidosis. Because these stains are interpreted in context of each other and Congo Red, testing options available to global and tech-only clients differ.</td>
</tr>
</tbody>
</table>
| Specimen Requirements     | • **Global orders**: Please order Amyloid A&P Panel and submit a Congo Red-stained slide for our reference (required). If Congo Red staining was not done or the slide is not available, please order a Consult instead so we can coordinate Congo Red staining followed by amyloid A and P staining as indicated. Individual orders for Amyloid A or Amyloid P are not available with global service.  
  • **Tech-only (stain only) orders**: Please order Amyloid A and/or Amyloid P as individual stains. The Panel combination is not available with tech-only service, nor is it necessary to submit a Congo Red-stained slide.  
  • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
  • One (1) unbaked, unstained slide for H&E staining (required) and two to four (2-4) positively charged unstained slides (all cut at 4-5 microns)  
  • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation| Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*              | Panel for global clients: (88342x1, 88341x1) or 88341x2. Single stain for tech-only clients: 88342x1 or 88341x1 for each stain |
| Turnaround Time           | Global: 48 hours, Tech-Only (stain only): 24 hours |
| Level of Service          | Global ✔️ Stain Only ✔️ |

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Androgen Receptor Mutation Analysis

Alternative Name: AR Mutation Analysis

Methodology: Molecular

Test Description: Bi-directional Sanger sequencing of the gene Androgen Receptor is performed using PCR primers designed to target hotspot mutations in exons 4, 5 and 8.

Clinical Significance: Androgen deprivation therapy (ADT) is very important therapeutic approach in the treatment of metastatic prostate cancer. Most of the current androgen deprivation drugs target the ligand binding domain (LBD) of the androgen receptor (AR). However, mutations in the AR gene as well as the expression of alternatively-spliced AR variant 7 (AR-V7) that lack the LBD lead to resistance to ADT. Furthermore, constitutional variations (mutations) and acquired mutations in AR lead to higher expression of the AR-V7 in castration-resistant prostate cancer. AR-V7 is inducible and detectable while the patient is on ADT. Our test is designed to predict resistance to enzalutamide and abiraterone in castration-resistant prostate cancers, irrespective if they are on therapy or not. This testing is recommended along with PTEN deletion testing by FISH for evaluating prognosis. Mutation analysis of the full AR coding sequence is available as a part of our NeoTYPE Discovery panel.

Specimen Requirements: FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation: Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

CPT Code(s): 81204

Turnaround Time: 14 days

Level of Service: Global

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# Annexin A1

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Annexin A1 (ANXA1), a gene related to phagocytosis, is found to be one of the most highly upregulated genes in hairy cell leukemia. Annexin A1 is strongly expressed on the cell membrane of 97% of hairy cell leukemia cases. Although Annexin A1 is negative in normal B-cells or B-cell tumors other than “classic” hairy cell leukemia, it stains myeloid cells, macrophages, and subsets of benign T-cells.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or • One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88342 x 1 or 88341 x 1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Stain Only ✓</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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December 18, 2019
### API2/MALT1 t(11;18)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MALT lymphoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
</tbody>
</table>
| Test Description | **Probes:** API2/MALT1 t(11;18)  
**Disease(s):** MALT lymphoma, NHL |
| Clinical Significance | Call Customer Care or your consulting NeoGenomics Pathologist. |
| Specimen Requirements |  
- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable  
Peripheral Blood: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable  
Fresh, Unfixed Tissue: Tissue in RPMI  
- **Fluids:** Equal parts RPMI to specimen volume.  
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.  
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only. |
| Storage and Transportation | Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 88374x1 automated. Codes may differ if manual analysis is performed. |
| Turnaround Time | 3-5 days |
| Level of Service | Global ✔  
Technical ✔ |

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**AR**

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Androgen receptor (AR) is responsible for the regulation of the growth of the prostate epithelial cells. In untreated prostate carcinoma, AR positive cells are more likely to be responsive to hormonal therapy. In patients with hormone refractory prostate carcinoma, the presence of AR has a negative prognostic impact. It is also commonly expressed in salivary duct carcinoma.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or&lt;br&gt;• One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered&lt;br&gt;• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88342 x 1 or 88341 x 1; 88361 x 1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓ Stain Only ✓</td>
</tr>
</tbody>
</table>

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December 18, 2019

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Arginase 1

Methodology

Immunohistochemistry (IHC)

Test Description

Arginase 1 (ARG1), also known as liver arginase, is a binuclear manganese metalloenzyme. ARG1 is abundantly expressed in liver and represents a sensitive and specific marker of benign and malignant hepatocytes that may be a useful diagnostic tool in routine surgical pathology practice.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓

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ASXL1 Mutation Analysis

Alternative Name  ASXL1 Gene Sequencing
Methodology  Molecular
Test Description  Bi-directional sequencing of the majority of exons 13 and 14 of ASXL1, corresponding to amino acids 406-1396.
Clinical Significance  ASXL1 is an epigenetic regulator of gene expression. Mutations are detected in approximately 14% of MDS, 11% of AML, 45% of CMML, 30% of PMF, and 4% of PV/ET. Mutations are generally associated with aggressive disease and poor outcome in these conditions.
Specimen Requirements  • Peripheral blood: 5 mL in EDTA tube.
                          • Bone marrow: 2 mL in EDTA tube.
Storage and Transportation  Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.
CPT Code(s)*  81175x1
Turnaround Time  14 days
Level of Service  Global

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December 18, 2019
**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
ATRX mutations predominantly occur in grade II/III astrocytoma and secondary glioblastoma multiforme (GBM) brain tumors. ATRX loss defines a subgroup of astrocytic tumors with a favorable prognosis.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
- 88342x1 or 88341x1

**Turnaround Time**  
Tech-Only (stain only): 24 hours

**Level of Service**  
Stain Only ✔
ATRX Mutation Analysis

Alternative Name: ATRX Gene Sequencing

Methodology: Molecular

Test Description: Bi-directional Sanger sequencing of ATRX is performed using PCR primers designed to target hotspot mutations in exons 8-10, 12-15, 17, 18, 21, 22, 26, 30-32, and 35.

Clinical Significance: This assay detects mutations in the gene ATRX, which encodes for a protein involved in chromatin remodeling and telomere biology. Mutations in ATRX have been reported in all types of cancers such as brain tumors. ATRX is mutated in 71% of grade II and III astrocytomas, 68% of oligoastrocytomas, and 57% of secondary glioblastoma. ATRX mutations in brain tumors are frequently detected with IDH1 and IDH2 mutations. The presence of these two mutations defines a specific subgroup of brain tumors that is important diagnostically. Patients with this molecularly characterized subtype have significantly longer survival. Mutations in ATRX have also been reported in 13% of MDS patients, 19% of pancreatic neuroendocrine tumors, 10% of endometrial tumors, 8% of colon cancers and 7% of lung cancers.

Specimen Requirements:
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.
- **FFPE solid tumor tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.
- **Fresh tissue**: 1 cm³ fresh tissue that is mostly tumor in RPMI.

Storage and Transportation: Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

CPT Code(s)*: 81479

Turnaround Time: 14 days

Level of Service: Global ✓

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December 18, 2019
B-ALL Add-On Flow Panel

Alternative Name: B-Cell Lymphoblastic Leukemia Add-On Panel. This panel was named ALL Flow Add-On Panel before June 18, 2018.

Methodology: Flow Cytometry

Test Description: Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are cCD3, cCD22, cCD79a, CD10, CD19, CD34, CD45, cMPO, and nTdt (9 markers).

Clinical Significance: Used to diagnose B-acute lymphoblastic leukemia/lymphoma and detect biphenotypic acute leukemia.

Specimen Requirements: Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

Storage and Transportation: Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: Please contact NeoGenomics' Billing Department.

Turnaround Time: 1 day

Level of Service: Global ✓ Technical ✓

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B-ALL Follow-Up Flow Panel

Alternative Name
B-Cell Acute Lymphoblastic Leukemia Flow Follow-Up Panel

Methodology
Flow Cytometry

Test Description
Available only as tech-only. Global clients, please refer to the B-ALL MRD Flow Panel. Prior immunophenotyping at NeoGenomics with Standard or Extended Flow Panel is strongly recommended. Tech-only clients who push cases to global will be asked to provide previous flow cytometry report, previous pathology report, and/or clinical history notes. Markers are cCD3, CD5, CD10, CD11c, CD19, CD20, cCD22, CD23, CD34, CD45, cCD79a, kappa, lambda, cMPO, and nTdT (15 markers).

Clinical Significance
For B-cell acute lymphocytic leukemia (B-ALL) monitoring after diagnosis is established. This is not a minimal residual disease (MRD) panel since the standard number of events is collected. MRD testing is available with the B-ALL MRD Flow Panel (global only).

Specimen Requirements
- **BM Aspirate**: 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Peripheral Blood**: 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Fresh Bone Marrow Core Biopsy**: 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue**: Tissue in RPMI
- **Fluids**: Equal parts RPMI and specimen volume

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184(x1), 88185(x14).

Turnaround Time
1 day

Level of Service
Technical ✓

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B-ALL MRD Flow Panel

Alternative Name: B-ALL Minimal Residual Disease Panel

Methodology: Flow Cytometry

Test Description: Available as global test only. Markers are CD3, CD9, CD10, CD13/CD33, CD19, CD20, CD34, CD38, CD45, CD58, CD71, and Syto16 (13 markers; Syto16 is not reported). This panel can detect MRD at the 0.01% level.

Clinical Significance: In patients with B-lymphoblastic leukemia, a combination of morphology and flow cytometry testing for minimal residual disease (MRD) is recommended when assessing response to therapy [1]. In both adult and pediatric patients with acute lymphoblastic leukemia, MRD during standard ALL chemotherapy is the strongest overall prognostic indicator and has therefore been used for refining initial treatment stratification [2, 3]. MRD positivity after the maintenance phase of treatment, pretransplant or post stem cell transplantation also provides prognostic information that may help guide therapeutic interventions [3]. This flow cytometry panel follows a consensus strategy and can detect MRD at the 0.01% level.

Specimen Requirements: Bone marrow aspirate or peripheral blood: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.

Storage and Transportation: Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88184x1, 88185x10. Add 88188x1 for global.

Turnaround Time: 1 day

Level of Service: Global ✓

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# B-Cell Gene Rearrangement

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>B-Cell Translocations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Detection of clonal IgH gene rearrangements by PCR of IgH framework regions 1, 2, 3 and joining regions. In addition, Ig Kappa gene rearrangement analysis is performed using specific oligonucleotides recognizing the Vk, intragenic and Jk regions. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Detects monoclonal B-cell immunoglobulin gene rearrangement. Interpret in clinical context for diagnosis of leukemia, lymphoma, and plasma cell dyscrasia.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • **Peripheral blood:** 5 mL in EDTA tube.  
• **Bone marrow:** 2 mL in EDTA tube.  
• **FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.  
• **Fresh tissue:** Two pieces minimum, 0.2 cm³ in RPMI. |
| Storage and Transportation | Refrigerate fresh tissue until shipping. For all specimens, use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 81261, 81264 |
| Medicare MolDX CPT Code(s)* | 81479 |
| Turnaround Time | 7 days |
| Level of Service | Global ✓ |

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B-Cell Lymphoma Follow-Up Flow Panel

Methodology
Flow Cytometry

Test Description
Available as global and tech-only. Please provide clinical history including the time after treatment. Prior immunophenotyping at NeoGenomics with Standard or Extended Flow Panel is strongly recommended. Clients who decline full phenotyping and order a global or push-to-global Follow-Up Panel are requested to provide details of the diagnosis by submitting at least one of the following: previous flow cytometry report, previous pathology report, and/or clinical history notes. Markers are CD5, CD10, CD11c, CD19, CD20, CD23, CD45, FMC-7, kappa, and lambda.

Clinical Significance
For B-cell lymphoma monitoring after diagnosis is established. This is not a minimal residual disease (MRD) panel since the standard number of events is collected.

Specimen Requirements
- **BM Aspirate**: 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Peripheral Blood**: 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Fresh Bone Marrow Core Biopsy**: 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue**: Tissue in RPMI
- **Fluids**: Equal parts RPMI and specimen volume

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184x1, 88185x9. Add 88188x1 for global.

Turnaround Time
1 day

Level of Service
Global ✔️ Technical ✔️

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B72.3

Methodology
Immunohistochemistry (IHC)

Test Description
This monoclonal antibody (B72.3) to tumor-associated glycoprotein recognizes a tumor-associated oncofetal antigen (TAG-72) expressed by a wide variety of human adenocarcinomas. This antigen is expressed by most invasive ductal breast, colonic, pancreatic, gastric, esophageal, lung, ovarian and endometrial adenocarcinomas. This antigen is also expressed on normal secretory endometrium, but not on other normal tissues.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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BAP1

Alternative Name
BRCA1-associated protein 1

Methodology
Immunohistochemistry (IHC)

Test Description
BAP1 IHC stain is a tool for detection of BAP1 mutations with subsequent inactivation. Loss of BAP1 by IHC is 100% specific for malignant mesothelioma in the context of mesothelioma vs. mesothelial hyperplasia. Loss of BAP1 may be seen in other neoplasms.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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# BCA-225

## Methodology
Immunohistochemistry (IHC)

## Test Description
This antibody recognizes a human breast carcinoma associated glycoprotein BCA-225 (220-225kD). This protein differs in size and distribution from other breast carcinoma antigens. It does not react with benign or malignant gastrointestinal tissues. It can be used to identify skin carcinomas with sweat gland and sebaceous differentiation.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1

## Turnaround Time
24 hours

## Level of Service
Stain Only ✓

---

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BCL1 Translocation, t(11;14)

**Alternative Name**
B-Cell Leukemia Translocation, B-Cell Leukemia Fusion

**Methodology**
Molecular

**Test Description**
Real-time PCR for quantitative detection of t(11;14) BCL1/IgH rearrangements. Analytical sensitivity is approximately 1 tumor cell in 1000 normal cells. Positive results are reported as a ratio between quantities of (11;14) DNA and a normal control gene. This translocation is also known as CCND1/IgH or BCL1/JH.

**Clinical Significance**
Testing may be used to confirm the diagnosis of mantle cell lymphoma, monitor therapy effectiveness, and detect minimal residual disease or relapse. This assay detects rearrangements involving the MTC (major translocation cluster) region. Due to breakpoint variations, this and other PCR-based assays cannot detect all BCL1/IgH translocations that are detected by FISH or cytogenetics.

**Specimen Requirements**
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.
- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
81401

**Turnaround Time**
7 days

**Level of Service**
Global ✔️

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December 18, 2019
# BCL1/Cyclin D1

## Methodology
Immunohistochemistry (IHC)

## Test Description
BCL1/Cyclin D1 is a nuclear protein detectable in formalin-fixed, paraffin-embedded (FFPE) sections and is found in the majority of mantle cell lymphomas. Hairy cell leukemia and plasmacytoma may also express BCL1 with a weaker signal. BCL1 is an oncogene acting as a cell cycle regulator.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1; 88361 x 1

## Turnaround Time
- Global: 48 hours
- Tech-Only (stain only): 24 hours

## Level of Service
- Global
- Stain Only

---

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December 18, 2019
BCL10

Methodology
Immunohistochemistry (IHC)

Test Description
BCL-10 is an N-terminal CARD (Caspase Recruitment Domain) containing protein that is involved in the adaptive immune response. It is also a substrate for MALT1. Mutations in the gene can lead to lymphoma, mucosa-associated lymphoid type. It is useful in the assessment of pancreatic tumors to distinguish acinar cell carcinoma from primitive neuroectodermal tumor (PNET), solid pseudopapillary tumor (SPT) and pancreatic blastoma (PB).

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔ Stain Only ✔

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.
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BCL2

Methodology
Immunohistochemistry (IHC)

Test Description
B-cell lymphoma 2 (BCL2) was the first of the translocation-associated proteins to be identified in lymphoma. Most cases of follicular lymphoma have a [t(14;18)] translocation, resulting in BCL2 overexpression. Overexpression of BCL2 in activated diffuse B-cell lymphoma may predict disease progression. BCL2 is also expressed in a wide range of other neoplasms. See also BCL2 (SP66) IHC.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1; 88360 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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## BCL2

### Alternative Name
B-cell lymphoma

### Methodology
FISH

### Test Description
- **Probes:** BCL2 (18q21)
- **Disease(s):** B-cell lymphoma, non-Hodgkin lymphoma (NHL), follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL)

### Clinical Significance
This BCL2 break-apart probe enables detection of BCL2 rearrangements at 18q21 irrespective of the partner gene. Detection of BCL2 rearrangement aids in diagnosis and classification of follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), and other aggressive B-cell lymphomas in conjunction with clinical, morphologic, and flow cytometric data. The most frequent rearrangement partner is IgH (14q32). Rarely, variant translocations involve the light chain genes Ig lambda (22q11) or Ig kappa (2p12), AFF3 (2q11), or the mu switch region. BCL2 functions in anti-apoptosis and its overexpression is implicated in oncogenesis.

### Specimen Requirements
- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.

### Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88377x1 manual or 88374x1 automated

### Turnaround Time
4 days (for both unfixed and FFPE specimens)

### Level of Service
Global ☑  Technical ☑

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BCL2 (SP66)

Methodology

Immunohistochemistry (IHC)

Test Description

BCL2 is a protein associated with apoptosis regulation produced by the BCL2 gene and is comprised of an alpha and beta chain. BCL2 (clone SP66) shows negative reaction on reactive germinal centers and positive staining of neoplastic follicles in follicular lymphoma. This is useful in distinguishing between reactive and neoplastic follicular proliferation in lymphoid lesions. This is a sensitive antibody that may stain a greater proportion of follicular lymphomas than other BCL2 antibodies. See also BCL2 IHC.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔

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## BCL2 Translocation, t(14;18)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>B-Cell Leukemia Translocation, B-Cell Leukemia Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>PCR and fragment analysis for quantitative detection of IGH-BCL2 translocations associated with 70-80% of follicular lymphoma and approximately 20% of diffuse large B-cell lymphoma. Translocations involving the major (MBR), minor (MCR), and 3' MBR sub-cluster regions of BCL2 are analyzed. Positive results quantify the ratio of mutant BCL2 to internal control DNA. Testing may be performed on plasma to increase sensitivity.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Useful to confirm diagnosis of follicular lymphoma, monitor therapy effectiveness, and detect minimal residual disease or recurrence.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Peripheral blood</strong>: 5 mL in EDTA tube.</td>
</tr>
<tr>
<td></td>
<td><strong>Bone marrow</strong>: 2 mL in EDTA tube.</td>
</tr>
<tr>
<td></td>
<td><strong>FFPE tissue</strong>: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transporting blood, marrow or block, making sure cold pack is not in direct contact with specimen. Slides can be packed at room temperature.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81402</td>
</tr>
<tr>
<td>Medicare MolDX CPT Code(s)*</td>
<td>81401</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>7 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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# BCL6

## Methodology

Immunohistochemistry (IHC)

## Test Description

BCL6 antibody stains the germinal center cells in lymphoid follicles, the follicular cells and interfollicular cells in follicular lymphoma, a subset of diffuse large B-cell lymphomas, and Burkitt lymphoma, as well as the majority of Reed-Sternberg cells in nodular lymphocyte predominant Hodgkin lymphoma. In contrast, BCL6 rarely stains mantle cell lymphoma and mucosa-associated lymphoid tissue (MALT) lymphoma. BCL6 expression is seen in approximately half of CD30+ anaplastic large cell lymphomas but is absent in other peripheral T-cell lymphomas.

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88342 x 1 or 88341 x 1

## Turnaround Time

24 hours

## Level of Service

Stain Only ✓

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December 18, 2019
# BCL6 (3q27)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>B-cell lymphoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
</tbody>
</table>
| Test Description     | **Probes:** BCL6 (3q27)  
**Disease(s):** Diffuse large B-cell lymphoma, NHL |
| Clinical Significance| Available separately or as part of the NHL FISH Panel. |
| Specimen Requirements| - **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable  
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable  
- **Fresh, Unfixed Tissue:** Tissue in RPMI  
- **Fluids:** Equal parts RPMI to specimen volume.  
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.  
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only. |
| Storage and Transportation | Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*         | 88374x1 automated. Codes may differ if manual analysis is performed. |
| Turnaround Time       | 4 days for both unfixed and FFPE specimens |
| Level of Service      | Global ✓  
Technical ✓ |

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December 18, 2019
**BCR-ABL1 Non-Standard p230**

**Alternative Name**  
BCR-ABL1 p230 Translocation, BCR/ABL1 Non-Standard

**Methodology**  
Molecular

**Test Description**  
Real-time RT-PCR for detection of t(9;22) BCR-ABL1 fusion transcripts that result in p230 fusion proteins. Analytical sensitivity is 1 tumor cell in 100,000 normal cells. BCR-ABL1 Standard p210, p190 may be ordered as a stand-alone test.

**Clinical Significance**  
Subsets of patients with Ph1+ chronic myeloid leukemia (CML) have a unique breakpoint within the BCR gene on chromosome 22. This breakpoint is 3’ to the more common breakpoints found in patients with CML and ALL and can lead to e19a2 fusion transcript. Thus, p230 BCR-ABL1 contains additional BCR coding sequences that are not found in the p190 or p210 variants. The incidence of this translocation is very rare, but may lead to falsely negative molecular testing when the molecular testing is designed to detect breakpoints in E1, E13 or E14. Although some studies suggested that the course of CML in patients with p230 is milder than that in average CML, response to therapy is similar. However, very little literature is available due to the rarity of this abnormality.

**Specimen Requirements**  
- **Bone Marrow:** 2 mL EDTA tube  
- **Peripheral Blood:** 5 mL EDTA tube

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**  
81208

**Turnaround Time**  
7 days

**Level of Service**  
Global

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December 18, 2019
**BCR-ABL1 Standard p210, p190**

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Philadelphia chromosome, BCR-ABL1 Major, BCR-ABL1 Minor, BCR/ABL1 Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Real-time RT-PCR for quantitative detection of t(9;22) BCR-ABL1 fusion transcripts that result in major p210 (E13, E14) or minor p190 (E1) fusion proteins with option to add p230 detection (micro or atypical variant). p230 testing may be ordered as a stand-alone test. For p210 and p190, analytical sensitivity is 1 tumor cell in 100,000 normal cells, log reduction score and percent abnormal are reported, and longitudinal data will appear as a NeoTRACK Result on the report. For p230, results are reported as percent abnormal. Testing is New York approved for p210 and p190 only.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Useful for diagnosis and monitoring of Philadelphia chromosome-positive cases of CML and ALL.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • Bone Marrow: 2 mL EDTA tube  
• Peripheral Blood: 5 mL EDTA tube |
| **Storage and Transportation** | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| **CPT Code(s)** | 81206, 81207 |
| **Medicare MolDX CPT Code(s)** | 81479 |
| **Turnaround Time** | 7 days |
| **Level of Service** | Global ✔ |

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**BCR/ABL1 t(9;22)**

**Alternative Name**
Philadelphia chromosome, Philadelphia translocation

**Methodology**
FISH

**Test Description**
Probes: ABL1 (9q34); ASS1 (9q34; BCR (22q11.2)
Disease(s): CML, ALL, MPN
Note: For suspected ALL, STAT processing is available by request. Note STAT along with MD contact name and phone number to receive STAT results.

**Clinical Significance**
Translocation 9;22 is seen in chronic myelogenous leukemia and acute lymphoblastic leukemia.

**Specimen Requirements**
- **Bone Marrow Aspirate**: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood**: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue**: Tissue in RPMI
- **Fluids**: Equal parts RPMI to specimen volume.
- **Paraffin or Cut Slides**: N/A

**Storage and Transportation**
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88374x1 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**
3-5 days. STAT results, when requested, are reported 12-24 hours from receipt in the NeoGenomics laboratory.

**Level of Service**
Global ✓ Technical ✓

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### BerEP4

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Ber-EP4 recognizes two glycoproteins of 34 and 49 kDa present on the surface and the cytoplasm of all epithelial cells except the superficial layers of squamous epithelial, hepatocytes and parietal cells. It does not label mesothelial cells and rarely marks mesotheliomas. It shows a broad spectrum of reactivity with human epithelial cells including simple epithelia and basal layers of stratified non-keratinized squamous epithelium and epidermis. Ber-EP4 reportedly distinguishes adenocarcinomas from pleural mesotheliomas.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only

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December 18, 2019
**Beta Catenin**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Beta-catenin is an important regulator of cell–cell adhesion and embryogenesis. Mutations of beta-catenin could lead to some human cancers. Normal cells show membrane staining for beta-catenin, while cytoplasmic and/or nuclear staining is abnormal. Dysregulation of beta-catenin occurs in Gardner syndrome, where it leads to both familial adenomatous polyposis and fibromatosis. Nuclear location of beta-catenin also occurs in colon and endometrioid ovarian carcinomas as well as in synovial sarcoma, osteosarcoma, liposarcoma, palisaded myofibroblastoma, and other sarcomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✔️

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December 18, 2019
**BG8**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
This antibody is specific for the Lewis Y (Type 2 Chain) carbohydrate antigen. Lewis Y has been evaluated as a clinical marker for the diagnosis and prognosis of cholangiocarcinoma, hepatocellular carcinoma and breast cancer. It was also shown that BG8 reacts predominantly with lung adenocarcinomas and is negative focally or weakly positive in epithelial mesotheliomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓
# Bladder Cancer

## Methodology

**FISH**

## Test Description

**Probes:** +3 (Cen 3) | +7 (Cen 7) | p16 (9p21) | +17 (Cen 17)

**Disease(s):** Bladder cancer

## Clinical Significance

This test is an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

## Specimen Requirements

- **Bone Marrow Aspirate:** N/A
- **Peripheral Blood:** N/A
- **Fresh, Unfixed Tissue:** N/A
- **Fluids:** N/A
- **Paraffin Block or Cut Slide:** N/A
- **Voided Urine:** 33-60 mL voided urine mixed 2:1 with supplied PreservCyt within 30 minutes of collection for total volume ≥50 mL

## Storage and Transportation

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88121x1 automated. Codes may differ if manual analysis is performed.

## Turnaround Time

3-5 days

## Level of Service

- Global ✓
- Technical ✓

---

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### BOB1

#### Methodology
Immunohistochemistry (IHC)

#### Test Description
BOB1 is present in all B-cells expressing Ig. The combination of BOB1 and OCT2 staining is helpful in distinguishing between classical Hodgkin lymphoma (at least one marker negative) and nodular lymphocyte predominant Hodgkin lymphoma or T-cell histioocyte-rich large B-cell lymphoma (both markers expressed).

#### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

#### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

#### CPT Code(s)*
88342 x 1 or 88341 x 1

#### Turnaround Time
24 hours

#### Level of Service
Stain Only ✓

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Bone Marrow Failure Syndrome Panel

Alternative Name
Hereditary Bone Marrow Failure

Methodology
Molecular

Test Description
Testing is performed by Blueprint Genetics. The Bone Marrow Failure Syndrome Panel includes next-gen sequencing of coding regions, exon-intron boundaries, and certain non-coding variants in 128 genes. Deletion/duplication analysis is performed to detect copy number variants (CNVs) ≥1 exon in size. Full test details including sample reports are available here. Note: Patient or parent signature on the Blueprint Genetics Informed Consent Form is required. Testing will be put on hold until a signed form is received.

Clinical Significance
This panel is for patients with a clinical suspicion of inherited bone marrow failure syndromes. Inherited bone marrow failure syndromes are a group of clinically and genetically heterogenous disorders. The genetic diagnosis is essential in management and surveillance of these diseases. The Blueprint Genetics Bone Marrow Failure Syndrome Panel covers classical genes associated with Hermansky-Pudlak syndrome, Diamond-Blackfan anemia, Fanconi anemia, Wiskott-Aldrich syndrome, Bloom syndrome, ELANE-related neutropenia, Shwachman-Diamond syndrome, Inherited bone marrow failure syndrome, familial hemophagocytic lymphohistiocytosis, severe congenital neutropenia and dyskeratosis congenita.

Specimen Requirements
Peripheral blood: 5 mL in EDTA tube

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81479x2

Turnaround Time
4 weeks

Level of Service
Global

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# BRAF Mutation Analysis

**Alternative Name**  
BRAF V600

**Methodology**  
Molecular

**Test Description**  
Bi-directional sequencing of exon 15 of the BRAF gene, which includes qualitative detection of V600 mutations E, K, D, and others, plus other significant exon 15 mutations. For solid tumors, tumor enrichment is performed before extraction. Expanded coverage for BRAF exons 11 & 15 is available in the RAS/RAF Panel. Testing is available separately or in combination with HRAS, KRAS, and NRAS in the RAS/RAF Panel. Testing is approved for specimens from the state of New York.

**Clinical Significance**  
Useful in selection of melanoma patients for vemurafenib therapy, for determination of prognosis in thyroid and colon cancers, for predicting response to anti-EGFR therapy in colon cancer, and as aid to diagnosis of hairy cell leukemia.

**Specimen Requirements**

- **FFPE solid tumor tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.
- **Fine needle aspirate (FNA)**: Requisition must note specimen is FNA. Fresh cells in suspension, unstained air-dried smears (approx. 6-8 slides), or FFPE cell blocks are acceptable if pathologist attaches note verifying sample has >30% tumor or abnormal cells (required). Minimum 10^6 cells.
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

**CPT Code(s)**  
81210

**Turnaround Time**  
7 days

**Level of Service**  
Global ✓

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BRAF Rearrangement

Alternative Name: BRAF translocation

Methodology: FISH

Test Description:

**Probes:** BRAF (7q34)

**Disease(s):** Brain cancer, thyroid cancer, melanoma

Clinical Significance:

This test uses a break-apart BRAF probe to detect the BRAF-KIAA1549 fusion common in low-grade astrocytomas and to detect any other known and potential BRAF rearrangement partners. The BRAF-KIAA1549 fusion causes constitutive BRAF kinase activation and is found in about 70% of pilocytic astrocytomas and 15% of other low-grade gliomas. Frequency diminishes with patient age, from 80% in the first decade to <10% in pilocytic astrocytomas in patients over 40. The detection of a BRAF fusion is most suggestive of a low-grade glioma. Prognosis associated with BRAF fusions shows a positive trend. BRAF translocations have been reported in thyroid cancer and melanoma but are infrequent. MEK inhibitors, alone and in combination with BRAF inhibitors, are being investigated. BRAF inhibition alone may lead to activation of a feed-back loop with up-regulation and potential for further tumor growth.

BRAF Mutation Analysis is also available for detection of the V600E mutation (and others) found in non-pilocytic gliomas, thyroid cancer, and melanoma.

Specimen Requirements:

- **Bone marrow aspirate:** N/A
- **Peripheral blood:** N/A
- **Fresh, unfixed tissue:** N/A
- **Fluids:** N/A
- **Paraffin block:** Send paraffin block. Also send circled H&E slide for tech-only (required).
- **Cut slides:** H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation:

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88377x1 manual or 88374x1 automated.

Turnaround Time:

3-5 days

Level of Service:

Global ✔  Technical ✔

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BRAF V600E

Methodology
Immunohistochemistry (IHC)

Test Description
A monoclonal antibody (VE1) against mutant BRAF (V600E) permits fast assessment of the mutant protein expression throughout a tumor sample in hairy cell leukemia, some melanomas, and some thyroid carcinomas. BRAF mutation is a strong molecular marker of poor prognosis in colorectal carcinoma (CRC), and can be used as evidence of a sporadic mechanism of mismatch repair deficiency.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.
BRCA1

Methodology
Immunohistochemistry (IHC)

Test Description
BRCA1 (breast and ovarian cancer susceptibility protein 1) is a nuclear phosphoprotein that plays a role in maintaining genomic stability and acts as a tumor suppressor. This test detects expression of BRCA1 protein and is not intended to identify germline or somatic (tumor) mutations in BRCA1. Available molecular tests may be viewed here.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1; 88360 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓  Stain Only ✓

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BRCA1 Mutation & Del/Dup Analysis

**Alternative Name**  
BRCA1

**Methodology**  
Molecular

**Test Description**  
This test is performed by sequencing the entire BRCA1 gene using next-gen sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. This test may be ordered separately or in combination with BRCA2. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.

**Clinical Significance**  
Together, germline mutations in BRCA1 and BRCA2 cause hereditary breast-ovarian cancer syndrome (HBOC) and account for approximately 5-10% of all breast cancer cases, 13-18% of ovarian cancer, and 90% of familial breast and ovarian cancer. BRCA1 mutation carrier status confers higher ovarian cancer risk but lower pancreatic cancer and male breast cancer risks compared to BRCA2 positive status.

**Specimen Requirements**  
Peripheral blood: 5 mL in EDTA tube.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**  
81166

**Turnaround Time**  
21 days

**Level of Service**  
Global

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## BRCA1/2 Mutation & Del/Dup Analysis

### Alternative Name
BRCA1 and BRCA2

### Methodology
Molecular

### Test Description
This test is performed by sequencing the entire BRCA1 and BRCA2 genes using massive parallel sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. Tests for BRCA1 or BRCA2 may be ordered separately. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.

### Clinical Significance
Germline mutations in BRCA1 and BRCA2 cause hereditary breast-ovarian cancer syndrome (HBOC) and account for approximately 5-10% of all breast cancer cases, 13-18% of ovarian cancer, and 90% of familial breast and ovarian cancer. Mutations confer increased risk for early onset breast cancer, multiple breast primaries, male breast cancer, epithelial ovarian, Fallopian tube, primary peritoneal, pancreatic, and prostate cancers. BRCA2 mutations are also associated with increased risk for melanoma. BRCA mutation frequency is increased in triple-negative breast cancer, especially among younger patients. Prevalence of mutations is approximately 1/300 for BRCA1 and 1/800 for BRCA2 in the general population, with certain groups having higher prevalence due to founder mutations. Genetic testing facilitates therapy selection, surveillance planning, and identification of at-risk family members. Counseling and testing guidelines are available from multiple professional groups.

### Specimen Requirements
Peripheral blood: 5 mL in EDTA tube.

### Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

### CPT Code(s)*
81162

### Turnaround Time
21 days

### Level of Service
Global ✔️

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## BRCA1/2 Mutation Analysis for Tumors

**Methodology**  
Molecular

**Test Description**  
BRCA1 and BRCA2 mutation analysis is performed by next-generation sequencing of all coding exons of the BRCA1 and BRCA2 genes to detect point mutations and small insertions/deletions. This test does not detect large deletions or duplications.

This test is specifically for tumor specimens; please see our [Hereditary Cancer Testing menu](#) for germline (peripheral blood) testing requirements.

**Clinical Significance**  
BRCA1 and BRCA2 mutations account for a significant fraction of hereditary breast and ovarian cancer (HBOC) and impart increased risks for additional cancers including prostate, pancreatic, and melanoma. Both genes have roles in tumor suppression and DNA repair. Tumors with mutations may respond to PARP inhibitors and be sensitive to platinum-based therapy. Genetic counseling and germline testing may be considered if a tumor mutation is detected as tumor mutations may be somatic or germline. Large gene deletions and duplications account for approximately 10% of mutations and will not be detected by this test.

**Specimen Requirements**  
FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
81163x1

**Turnaround Time**  
14 days

**Level of Service**  
Global ✔

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BRCA2 Mutation & Del/Dup Analysis

Alternative Name  
BRCA2

Methodology  
Molecular

Test Description  
This test is performed by sequencing the entire BRCA2 gene using next-gen sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. This test maybe ordered separately or in combination with BRCA1. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.

Clinical Significance  
Together, germline mutations in BRCA1 and BRCA2 cause hereditary breast-ovarian cancer syndrome (HBOC) and account for approximately 5-10% of all breast cancer cases, 13-18% of ovarian cancer, and 90% of familial breast and ovarian cancer. BRCA2 mutation carrier status confers higher melanoma, pancreatic and male breast cancer risks but lower ovarian cancer risk compared to BRCA1 positive status.

Specimen Requirements  
Peripheral blood: 5 mL in EDTA tube.

Storage and Transportation  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*  
81167

Turnaround Time  
21 days

Level of Service  
Global ✓

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# Breast Triple Stain (CK5 + p63 + CK 8/18)

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>The combination of CK5 + P63 + CK8/18 (Breast Triple Stain) can be useful in distinguishing ductal carcinoma in situ (DCIS) from microinvasive breast carcinoma. This multiplex can decipher between a radial scar and infiltrating carcinoma. P63 (nuclear brown) and CK5/6 (cytoplasmic brown) stain myoepithelial cells, whereas CK8/18 labels the cytoplasm (red) of all ductal or lobular epithelium.</td>
</tr>
</tbody>
</table>
| Specimen Requirements| • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*         | 88344 x 1                   |
| Turnaround Time      | 24 hours                    |
| Level of Service     | Stain Only ✅               |

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BTK Inhibitor Acquired Resistance Panel

Alternative Name
BTK, BTK acquired resistance

Methodology
Molecular

Test Description
Concurrent bi-directional sequencing of hotpost regions in the BTK and PLC-gamma-2 genes. Analysis includes the BTK mutation C481S and surrounding regions corresponding to amino acids C464 to M509 and the following PLC-gamma-2 mutations and surrounding regions: R665W (W646 to S679), S707 (A681 to M743), and L845F (I839 to V860).

Clinical Significance
This panel detects mutations in BTK and PLC-gamma-2 which are associated with acquired ibrutinib resistance in certain B-cell neoplasms. This panel is appropriate for patients with B-cell neoplasms who have relapsed and/or show acquired (secondary) resistance after an initial response to BTK (Bruton tyrosine kinase) inhibitors.

Specimen Requirements
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.
- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81233, 81320

Medicare MolDX CPT Code(s)*
81479

Turnaround Time
10 days

Level of Service
Global ✓

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## BTK Inhibitor Primary Susceptibility Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>BTK, BTK primary susceptibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Concurrent analysis of the following by bi-directional sequencing: CARD11 exons 5 and 6, CD79B exon 5 including common Y196 mutations, CXCR4 C-terminus region, and MYD88 exon 5 including the L265P mutation.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>This panel detects mutations in four genes associated with primary (initial) susceptibility or resistance to BTK (Bruton tyrosine kinase) inhibitors in certain B-cell neoplasms. Mutations in MYD88 and CD79B are associated with inhibitor sensitivity, and mutations in CARD11 and CXCR4 are associated with primary resistance. Mutation presence may also have prognostic significance. This panel is appropriate for patients with B-cell neoplasms, particularly diffuse large B-cell lymphoma (DLBCL), who are candidates for BTK inhibitor therapy or are not responding to such therapy. Mutation detection can guide the selection of alternative therapeutic options.</td>
</tr>
</tbody>
</table>
| Specimen Requirements             | **Peripheral blood:** 5 mL in EDTA tube.  
**Bone marrow:** 2 mL in EDTA tube.  
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. |
| Storage and Transportation        | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*                      | 81305, 81479                    |
| Medicare MolDX CPT Code(s)*       | 81479                          |
| Turnaround Time                   | 10 days                        |
| Level of Service                  | Global ✓                      |

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December 18, 2019
# BTK Mutation Analysis

**Alternative Name**  
BTK, Bruton tyrosine kinase

**Methodology**  
Molecular

**Test Description**  
Bi-directional sequencing to detect the C481S mutation in exon 15 and other potential mutations within the amino acid range C464 to M509. Testing is available separately or in combination with PLC-gamma-2 in the BTK Inhibitor Acquired Resistance Panel. NeoGenomics recommends ordering the combination Panel.

**Clinical Significance**  
Bruton’s tyrosine kinase (BTK) is involved in multiple signaling pathways regulating proliferation, differentiation, and survival of B-lineage lymphoid cells. Multiple BTK inhibitors are in use (such as ibrutinib and dasatanib) and in clinical trials. Mutations are associated with acquired or secondary resistance to ibrutinib arising after initial response in B-cell disorders including CLL and mantle cell lymphoma.

**Specimen Requirements**
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.
- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
81233

**Turnaround Time**  
10 days

**Level of Service**  
Global ✓

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CA125

Methodology
Immunohistochemistry (IHC)

Test Description
CA125 reacts with most epithelial ovarian neoplasms of serous, endometrioid, clear cell and undifferentiated types. CA125 is a useful tumor marker for ovarian carcinomas; however, CA125 has also been described in other neoplasms such as seminal vesicle and anaplastic lymphomas. No reactivity has been shown for mucinous ovarian tumors. It reacts with both normal tissues and neoplasms of fallopian tube, endometrium, endocervix and mesothelioma. It does not react with colon cancer. Normal tissues such as breast, liver, skin, kidney and spleen are negative.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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CA19.9

Methodology
Immunohistochemistry (IHC)

Test Description
In normal tissues, the CA19.9 antigen has been demonstrated in ductal epithelium of the breast, kidney, salivary gland, sweat glands, respiratory epithelium of the lung, colon epithelium, pancreatic acini and ducts, biliary epithelium in the liver and prostate epithelium. Gastrointestinal carcinomas are positive, as well as transitional cell carcinomas of the bladder, endometrial adenocarcinomas, thyroid papillary, gallbladder carcinomas and lung carcinomas, including adenocarcinomas, bronchoalveolar cell carcinomas, squamous and small cell carcinomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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Calcitonin

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Calcitonin is secreted by thyroidal parafollicular cells of neuroectodermal origin, probably in response to hypercalcemia. The IHC demonstration of calcitonin is important: (1) For identification of early or microscopic medullary thyroid cancer (MTC), (2) To identify an MTC in the absence of amyloid deposits, (3) To distinguish non-typical forms of MTC (e.g., predominantly spindle cell or small cell patterns) from anaplastic carcinoma or malignant lymphoma, (4) To differentiate MTC with microfollicular or papillary patterns from thyroid follicular and papillary neoplasms and (5) To identify C-cell hyperplasia in association with hypercalcemia of diverse etiologies.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓
Calcium Stain

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88313x1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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Caldesmon

Methodology
Immunohistochemistry (IHC)

Test Description
Caldesmon is a developmentally regulated protein involved in smooth muscle and non-muscle contraction. Two closely related variants of human caldesmon have been identified. The h-caldesmon variant (120-150kDa) is predominantly expressed in smooth muscle and a subset of myoepithelial cells, whereas l-caldesmon (70-80kDa) is found in non-muscle tissue and cells. Neither of the two variants has been detected in skeletal muscle.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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## Calponin

### Methodology

Immunohistochemistry (IHC)

### Test Description

Calponin, a calmodulin, is involved in the regulation of smooth muscle contraction. The expression of calponin is restricted to smooth muscle cells. Two isoforms of calponin exist with molecular weights of 34kDa and 29kDa. Expression of the 29kDa form is primarily restricted to muscle of the urogenital tract. Calponin also labels myoepithelial cells and can be useful in distinguishing in situ from infiltrating breast carcinoma.

### Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*

88342 x 1 or 88341 x 1

### Turnaround Time

24 hours

### Level of Service

Stain Only ✔️

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December 18, 2019
**CALR Mutation Analysis**

**Alternative Name**
CALR, calreticulin

**Methodology**
Molecular

**Test Description**
Bi-directional sequencing of exon 9 of the CALR (calreticulin) gene with fragment length analysis for enhanced detection of low levels of insertion/deletion mutations. Testing is approved for specimens from the state of New York. Read more about the CALR Mutation Analysis.

**Clinical Significance**
CALR mutation analysis aids diagnostic confirmation of Philadelphia-chromosome negative and JAK2/MPL-mutation negative MPN. CALR mutations are mutually exclusive with JAK2 and MPL mutations, and are detected in peripheral blood in the majority (~70-85%) of essential thrombocythemia (ET) and primary myelofibrosis (PMF) cases that are JAK2- and MPL-mutation negative. CALR mutations are not reported in polycythemia vera (PV) and can distinguish ET and PMF from PV. Presence of CALR mutations is also associated with a better clinical course than JAK2 mutations.

**Specimen Requirements**
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**
81219

**Turnaround Time**
10 days

**Level of Service**
Global

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# Calretinin

## Methodology
Immunohistochemistry (IHC)

## Test Description
Calretinin is the most specific and reproducible positive marker of epithelial mesothelioma. Calretinin is a calcium-binding protein similar to S100 protein. It is found in the central and peripheral nervous system and in a wide spectrum of non-neural cells, including steroid-producing cells of ovaries and testes, fat cells, renal tubular epithelial cells, eccrine glands, thymic epithelial cells and mesothelial cells. Calretinin immunostaining is found in most epithelial mesotheliomas.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342x1 or 88341x1

## Turnaround Time
24 hours

## Level of Service
Stain Only

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CAM 5.2

Alternative Name: Cytokeratin LMW

Methodology: Immunohistochemistry (IHC)

Test Description: Anti-Cytokeratin (CAM 5.2) has a primary reactivity with human keratin proteins that correspond to Moll's peptides #7 and #8, Mr 48 and 52 Kd. Cytokeratin 8 is present on secretory epithelia of normal human tissue but not on stratified squamous epithelium. CAM 5.2 stains most epithelial derived tissue, including liver, renal tubular epithelium, hepatocellular and renal cell carcinomas. CAM 5.2 may not react with some squamous cell carcinomas.

Specimen Requirements:
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88342 x 1 or 88341 x 1

Turnaround Time: 24 hours

Level of Service: Stain Only ✓

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CancerTYPE ID® with reflex to NeoTYPE® Cancer Profile

Alternative Name
Used with Tumor of Unknown Origin (TUO), Cancer of Unknown Primary (CUP), occult primary

Methodology
Molecular

Test Description
CancerTYPE ID is a proprietary molecular cancer classifier used to identify unknown or unclear tumor types and subtypes in patients with metastatic cancer. When ordered through NeoGenomics, classification with CancerTYPE ID is followed by tumor profiling for actionable biomarkers using the NeoTYPE® Cancer Profile most appropriate for the tumor type identified by Cancer TYPE ID.† Tech-only options for FISH and IHC within the NeoTYPE Cancer Profile are available.

CancerTYPE ID is performed and billed separately by NeoGenomics’ contracted reference laboratory, Biotheranostics, Inc., an independent CLIA-licensed and CAP-accredited reference laboratory. The test uses quantitative RT-PCR to measure the expression of 92 genes in the patient’s specimen and classifies the tumor by matching the gene expression profile to a database of more than 2000 known tumor types and subtypes. Using this technology, CancerTYPE ID can identify 50 different tumor types and subtypes, covering >95% of all solid tumors based on incidence.¹ The test reports a main cancer type with the highest probability, as well as a list of tumor types that may be ruled out with 95% confidence.

†CancerTYPE ID may be ordered as a stand-alone test directly from Biotheranostics, Inc. Please see www.cancertypeid.com.

Clinical Significance
For difficult-to-diagnose metastatic cancer cases, CancerTYPE ID provides important tumor type information to resolve diagnostic dilemmas. It can help narrow a differential diagnosis so that clients may confidently report a single final diagnosis² and efficiently identify targetable mutations in genes pre-selected for their known impact in that tumor type.

Please see our Test Spotlight page for more information about CancerTYPE ID’s utility, performance, additional references, and which tumor-specific NeoTYPE Cancer Profile will be paired with each potential CancerTYPE ID result when ordered from NeoGenomics.

Specimen Requirements
FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixative.

Testing may be ordered through NeoGenomics via our online test order system or by using the current Solid Tumor Requisition or Oncology Office Solid Tumor Requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81540 for CancerTYPE ID. Add CPT Codes for the specific NeoTYPE Cancer Profile performed.

Turnaround Time
Approximately 21-23 days. CancerTYPE ID results can be expected 7-9 calendar days after receipt of specimen and required information into Biotheranostics' laboratory. NeoTYPE Cancer Profile results follow approximately 14 days later.

Level of Service
Global ✔

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Carbonic Anhydrase IX (CA IX)

Methodology
Immunohistochemistry (IHC)

Test Description
Carbonic anhydrase IX (CAIX) is a cell surface transmembrane protein, which is predominantly found in the gastrointestinal tract and gall bladder. The glandular regions of normal colon are reported to be negative, but in the case of adenocarcinoma, the glands are positive. CAIX is also expressed in common epithelial tumors such as carcinomas of the esophagus, lung, colon, kidney, cervix, and non-small cell lung carcinoma (NSCLC). In breast carcinomas, CAIX expression is associated with malignant tissue. Expression of CAIX is absent in normal kidney, chromophobe carcinomas or oncocytomas; however, it is specifically expressed in clear cell renal carcinomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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CBFB inv(16)

Methodology
FISH

Test Description
Probes: CBFB inv(16), t(16;16)
Disease(s): AML, AMML (AML-M4E)

Clinical Significance
Available separately or as part of the AML FISH Panel.

Specimen Requirements
- **Bone Marrow Aspirate**: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood**: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue**: Tissue in RPMI
- **Fluids**: Equal parts RPMI to specimen volume.
- **Paraffin or Cut Slides**: N/A

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x1 automated. Codes may differ if manual analysis is performed.

Turnaround Time
3-5 days

Level of Service
Global ✓  Technical ✓

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CCND1(BCL1)/IgH t(11;14)

Methodology
FISH

Test Description
Probes: CCND1/IgH t(11;14)
Disease(s): Mantle cell lymphoma, NHL

Clinical Significance
Available separately or as part of the NHL FISH Panel.

Specimen Requirements
- Bone Marrow Aspirate: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- Peripheral Blood: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- Fresh, Unfixed Tissue: Tissue in RPMI
- Fluids: Equal parts RPMI to specimen volume.
- Paraffin Block: H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- Cut Slides: H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x1 automated. Codes may differ if manual analysis is performed.

Turnaround Time
4 days for both unfixed and FFPE specimens

Level of Service
Global ✓  Technical ✓

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December 18, 2019
CD10

Methodology
Immunohistochemistry (IHC)

Test Description
CD10, also known as Common Acute Lymphocytic Leukemia Antigen (CALLA), is expressed in early lymphoid progenitors and normal germinal center cells. It is almost always present on the surface of precursor B-lymphoblastic and Burkitt lymphomas and much less frequently on precursor T-lymphoblastic leukemia-lymphoma. Many follicular lymphoma and some diffuse large B-cell lymphomas, along with multiple myeloma are positive. CD10 is also present on breast myoepithelial cells, bile canaliculi, fibroblasts and with especially high expression on the brush border of kidney and gut epithelial cells. CD10 is also a good marker of endometrial stomal sarcoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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Please direct any questions regarding coding to the payer being billed.
CD117 cKIT

Methodology
Immunohistochemistry (IHC)

Test Description
CD117 (cKIT) is a transmembrane receptor tyrosine kinase. It is expressed in many tissues and cells, such as tissue mast cells, skin basal cells, melanocytes, breast glandular epithelial cells, dermal sweat gland, esophageal glands, testicular and ovarian interstitial cells. Abnormal expression of cKit has been implicated in pathogenesis of myeloid leukemias. cKit expression has also been demonstrated in solid tumors including gastrointestinal stromal tumor (GIST), melanomas, breast carcinomas and small cell lung carcinoma. C-Kit pharmDXTM is indicated as an aid in the differential diagnosis of GIST. Accurate assessment of CD117 protein expression using cKIT testing is a critical factor in the diagnosis of GIST and is becoming increasingly important in clinical management, including the use of imatinib mesylate (Gleevec®) therapy.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Stain Only ✓

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CD11c

Methodology
Immunohistochemistry (IHC)

Test Description
In normal cells, CD11c is expressed on activated CD4/CD8+ T cells, granulocytes, lymphocytes, macrophages, and NK cells.

In diseased cells, CD11c is detected on acute myeloid leukemia (AML)-M4 and M5, hairy cell leukemia, lymphoplasmacytic lymphoma (81%), small lymphocytic lymphoma (SLL), splenic lymphoma, Langerhans cell histiocytosis, sinus histiocytosis, psoriatic skin lesions, and some follicular lymphomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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CD123

Methodology
Immunohistochemistry (IHC)

Test Description
CD123 labels plasmacytoid dendritic cells and is useful in diagnosing neoplasms derived from these cells as well as reactive conditions, such as histiocytic necrotizing lymphadentis.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only
CD138

Methodology
Immunohistochemistry (IHC)

Test Description
CD138 (Syndecan-1) positively stains normal tissue including B-cell precursors and plasma cells. Positive staining in tumors includes myeloma, primary effusion lymphoma. CD138 negative staining comprises mature B-cells and lymphomas (even plasmacytoid lymphomas). Many carcinomas also express CD138.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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**CD14**

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>CD14 stains normal macrophages/monocytes, granulocytes (weak), Langerhans cells, dendritic cells, and B cells. Positive staining in diseased cells comprises B-cell chronic lymphocytic leukemia (B-CLL), follicular center cell lymphoma, diffuse large B cell lymphoma (DLBCL), and acute myeloid leukemia (AML)-M4/M5.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 88342 x 1 or 88341 x 1 |
| Turnaround Time | 24 hours |
| Level of Service | Stain Only ✓ |

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December 18, 2019
# CD15

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD15 (X-Hapten) plays a role in mediating phagocytosis, bactericidal activity, and chemotaxis. It is present on granulocytes, including neutrophils and eosinophils, and to a lesser degree on monocytes. CD15 is also expressed in Reed-Sternberg cells and some epithelial cells. CD15 antibody is useful in the identification of Hodgkin lymphoma. CD15 is occasionally expressed in large cell lymphomas of both B- and T-phenotypes.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only

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CD163

Methodology

Immunohistochemistry (IHC)

Test Description

CD163 antigen is restricted in its expression to the monocyctic/macrophage lineage. It is present on all circulating monocytes and most tissue macrophages except those found in the mantle zone and germinal centers of lymphoid follicles, interdigitating reticulum cells and Langerhans cells.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔
**CD19**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD19 recognizes a 95kD cell surface glycoprotein which is expressed by cells of the B-cell lineage and follicular dendritic cells. CD19 is a co-receptor of CD21 and is an important signal transduction molecule which is involved in the regulation of B-lymphocyte development, activation and differentiation. CD19 may provide useful diagnostic information for the study of B-lymphoproliferative disorders.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✔️

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# CD1a

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

At least five CD1 genes (CD1a, b, c, d, and e) have been identified. CD1a is expressed on cortical thymocytes, Langerhans cells, and dendritic cells. It is absent on mature peripheral blood T-cells, but cytoplasmic expression is detected on activated T-lymphocytes. CD1a is found on a subset of T-lymphoblastic lymphoma-leukemia and cases of Langerhans cell histiocytosis.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✅

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CD2

Methodology

Immunohistochemistry (IHC)

Test Description

CD2, the E-rosette receptor, is an extremely broad T-cell marker. This antibody immunostains the vast majority of T-cells and a subset of natural killer (NK) - cell malignancies. Half of thymic B-cells are also CD2 positive.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓

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December 18, 2019
CD20

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Normal cell expression of CD20 is found on most B-cells (after CD19 and CD10 expression, before CD21/22 expression and surface immunoglobulin expression) and expression is retained on mature B-cells until plasma cell development, as well as follicular dendritic cells. In diseased cells, there is positive staining on most B-cell lymphomas, come pre-acute B lymphoblastic leukemia/ lymphoblastic lymphoma (B-ALL/LBL); lymphocyte predominant Hodgkin lymphoma, dimly expressed in T-cells (benign and neoplastic), and spindle cell thymomas. Rixtuximab treated patients may lose CD20 positivity in B cell lymphomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only
**CD21**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD21 (CR2, C3d receptor and EBV receptor) is expressed strongly on mature B-cells, follicular dendritic cells (FDC) and weakly on immature thymocytes and T-lymphocytes. In B-cell ontogeny, CD21 appears after the pre-B-stage, is maintained during peripheral B-cell development and is lost upon terminal differentiation into plasma cells. Immunohistological analysis of FDC in paraffin sections of Non-Hodgkin lymphoma (NHL) with this antibody demonstrates a nodular and usually dense and sharply defined FDC meshwork in follicular lymphomas and a loose, ill-defined FDC of varying size in some diffuse lymphoma types. Precursor B-cell lymphoma (lymphoblastic lymphomas), Burkitt lymphomas, plasmacytomas and hairy cell leukemias consistently lack CD21 expression. CD21 is expressed on follicular dendritic cell sarcoma.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only

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December 18, 2019
CD22

Methodology
Immunohistochemistry (IHC)

Test Description
CD22 expression is restricted to normal and neoplastic B-cells and is absent from other hemopoietic cell types. In B-cell ontogeny, CD22 is first expressed in the cytoplasm of pro-B and pre-B-cells and on the surface as B-cells mature to become IgD+. It is not expressed by plasma cells. CD22 is found highly expressed in follicular, mantle and marginal zone B-cells, while germinal center B-cells are relatively weak. Its expression roughly parallels that of CD19. It is strongly expressed in hairy cell leukemia.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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CD23

Methodology

Immunohistochemistry (IHC)

Test Description

CD23 is identical to low affinity IgE receptor found on B-cells. CD23 is expressed on a subpopulation of peripheral blood cells, B-lymphocytes and on EBV transformed B-lymphoblastoid cell lines. CD23 is most useful in distinguishing B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) from other entities and may remain present in CLL/SLL that has undergone large cell transformation.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔
CD25

Methodology
Immunohistochemistry (IHC)

Test Description
The interleukin-2 receptor is designated CD25. Originally isolated from T-lymphocytes, it is now known to be expressed on hairy cell leukemia and adult T-cell leukemia/lymphoma, classical Hodgkin lymphoma, and a subset of other peripheral T-cell lymphomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓
CD3

Methodology
Immunohistochemistry (IHC)

Test Description
The CD3 antigen is first detectable in early thymocytes and its appearance probably represents one of the earliest signs of commitment to the T-cell lineage. It has a cytoplasmic expression at early T-cell differentiation, then membranous expression. CD3 is the most specific T-cell antibody. CD3 is expressed in normal thymocytes, peripheral T-cells, NK cells, and Purkinje cells of cerebellum. In diseased cells, CD3 stains most T-cell lymphomas. Only rare B cell lymphomas may be positive for CD3.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
### CD30

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

CD30 is a lymphocyte activation antigen, related to tumor necrosis factor. It is expressed in activated B-, T- and NK cells. Positive staining is seen in infectious mononucleosis, lymphocytes infected with HIV, HTLV-1, EBV, HHV8 or hepatitis B, Reed-Sternberg cells, anaplastic large cell lymphomas (90%), lymphomatoid papulosis, peripheral T-cell lymphomas, and embryonal cell tumors.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only 

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December 18, 2019
CD31

Methodology
Immunohistochemistry (IHC)

Test Description
CD31 is a 130kDa transmembrane glycoprotein that is shared by vascular lining cells, megakaryocytes and platelets. This marker is highly restricted to endothelial neoplasms among all tumors of the soft tissue and its sensitivity is excellent. 100% of angiosarcomas and hemangiomas are CD31 positive. However, Kaposi’s sarcoma (KS) is labeled more consistently by CD34 than by CD31. CD31 has also been used as a prognostic marker measuring tumor angiogenesis. CD31 also stains histiocytes.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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December 18, 2019
CD33

Methodology  Immunohistochemistry (IHC)

Test Description  CD33 is a useful marker to identify cells of myeloid and monocytic lineage, leukemias and myeloproliferative neoplasms derived from these cells.

Specimen Requirements  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation  Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*  88342 x 1 or 88341 x 1

Turnaround Time  24 hours

Level of Service  Stain Only

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CD34

Methodology
Immunohistochemistry (IHC)

Test Description
CD34, a single chain transmembrane glycoprotein, is selectively expressed on human lymphoid and myeloid hematopoietic progenitor cells and endothelial cells. CD34 antibody labels many gastrointestinal stromal tumors (GIST), dermatofibrosarcoma protuberans, solitary fibrous tumor and a subset of sarcomas. CD34 staining has been also used to measure angiogenesis.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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### CD35

#### Methodology
- Immunohistochemistry (IHC)

#### Test Description
- CD35 antigen is a transmembrane protein of 160-250 kDa that binds complement components C3b and C4b. It mediates phagocytosis by neutrophils and monocytes. CD35 is found on erythrocytes, B-cells, a subset of T-cells, monocytes, macrophages cultured in vitro, neutrophils, eosinophils, glomerular podocytes and follicular dendritic cells. CD35 antibody is useful in the diagnosis of mucosa-associated lymphoid tissue (MALT) lymphoma and in the study of inflammatory disorders. It also labels follicular dendritic cell sarcoma.

#### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

#### Storage and Transportation
- Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

#### CPT Code(s)*
- 88342 x 1 or 88341 x 1

#### Turnaround Time
- 24 hours

#### Level of Service
- Stain Only ✓

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December 18, 2019
CD38

Methodology
Immunohistochemistry (IHC)

Test Description
CD38 is a transmembrane protein that is highly expressed on thymocytes. It is also present on activated T-cells and terminally differentiated B-cells (plasma cells). Other reactive cells include NK cells, monocytes, macrophages and dendritic cells. CD38 may be detected on cells from multiple myeloma, acute lymphoblastic leukemia (ALL, B and T) and some acute myeloid leukemia (AML).

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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CD4

Methodology
Immunohistochemistry (IHC)

Test Description
CD4, a single chain transmembrane glycoprotein, is found on a T-cell subset (helper/inducer). It is also present on a variety of monocyte-derived cells, including Langerhans and other dendritic cells. The CD4 epitope is absent from immature thymocytes and is expressed during T-cell development. Precursor T-lymphoblastic lymphomas are therefore variable in their expression of CD4, but most mature T-cell lymphomas are positive, with the exception of aggressive NK-cell leukemia, extranodal NK-cell lymphoma, gamma delta T-cell lymphomas, and enteropathy-type T-cell lymphoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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CD4/CD8 Ratio for BAL

Alternative Name
CD4/CD8 for Bronchoalveolar Lavage

Methodology
Flow Cytometry

Test Description
Available as global test only for bronchoalveolar lavage (BAL) specimens. Markers are CD3, CD4, CD8, and CD45 (4 markers). This test is not for quantitative immune status monitoring. (Tech-only testing is not offered as this test does not have a separate professional component.)

Clinical Significance
This panel can be helpful to differentiate sarcoidosis and hypersensitivity pneumonitis from other causes or types of interstitial lung disease.


Specimen Requirements
BAL fluid: 10-50 ml BAL fluid combined with equal volume of RPMI

Storage and Transportation
Please send specimens as soon as possible after collection. Ideally specimens should be received at NeoGenomics within 24 hours from collection for optimal sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184x1, 88185x3

Turnaround Time
1 day

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December 18, 2019
CD42b

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD42b stains normal platelets, megakaryocytes, and megakaryoblasts. In diseased cells, blasts in transient myeloproliferative disorder are positively stained. CD42b is used in diagnosis of acute myeloid leukemia (AML)-M7, distinguishing AML-M7 (CD42b+) from acute myelosis with myelofibrosis (usually CD42b negative).

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

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CD43

Methodology
Immunohistochemistry (IHC)

Test Description
CD43 (leukosialin, sialophorin, or leukocyte sialoglycoprotein) is a cell surface glycoprotein that is expressed on all thymocytes, T-cells, and cells of myeloid lineage. CD43 antibody can be useful in the diagnosis of T-cell lymphoma and a subset of B-cell lymphoma. CD43 expression in lymphomas is highly correlated with CD5; thus, most T-cell malignancies and a group of small lymphocyte B-cell malignancies (CLL/SLL, mantle cell lymphoma, and prolymphocytic leukemia (PLL)) are often positive, whereas follicular lymphoma is rarely positive. CD43 is also positive in about 50% of cases of Burkitt lymphoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔️

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December 18, 2019
CD44

Methodology
Immunohistochemistry (IHC)

Test Description
The CD44 family of glycoproteins exists in a number of variant isoforms, including hematopoietic variant (CD44s) and epithelial cells variant (CD44v). While many human tumors express CD44, a positive correlation between increased CD44 expression and tumor progression has been demonstrated in only some. The most practical application of CD44 immunostaining at present is the discrimination of urothelial transitional cell carcinoma-in-situ from non-neoplastic changes in the urothelium.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
CD45 (LCA)

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD45 (Leukocyte Common Antigen, LCA) is comprised of at least four isoforms (CD45RA, CD45RB, CD45RC and CD45RO) of membrane glycoproteins. CD45 is expressed on hematopoietic cells (human leukocytes, including lymphocytes, monocytes, and eosinophils), but is absent on normal and malignant non-hematopoietic tissues.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓
### CD45RO

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD45RO (an isoform of leukocyte common antigen) reacts with mature activated T-cells, most thymocytes, and a sub-population of resting T-cells within both CD4 and CD8 subsets. CD45RO antibody marks many T-cell lymphomas but also identifies granulocytes, histiocytes and some B-cells. It rarely stains B-cell lymphomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓
CD5

Methodology
Immunohistochemistry (IHC)

Test Description
CD5, a transmembrane protein, is found on most thymocytes and immature peripheral T-cells. It stains normal B-cells of mantle zone of spleen and lymph nodes, B-cells in peritoneal and pleural cavities, and almost all T-cells. In a fetus, most B-cells in spleen and cord blood are CD5 positive. It stains B-cell chronic lymphocytic leukemia/ small lymphocytic leukemia (CLL/SLL), mantle cell lymphoma (MCL), hairy cell leukemia (HCL), most T-malignancies, and most thymic carcinomas. CD5 is usually negative in spindle cell thymoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔️

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CD52 Analysis

Methodology
Flow Cytometry

Test Description
Available as global and tech-only. Available as stand-alone test (as described here) or as add-on to panels. Markers are CD3, CD19, CD45, and CD52. Additional markers may be necessary to identify a subset of abnormal cells in a background of normal cells.

Clinical Significance
Identifies CD52+ patients with B-CLL, other B-cell neoplasms, or T-cell neoplasms including mycosis fungoides (MF) and Sezary syndrome who may be considered for alemtuzumab (anti-CD52, Campath®) therapy. See also T-Cell Therapy Panel for more extensive analysis of 10 T-cell markers.

Specimen Requirements
- **BM Aspirate**: 1mL EDTA; sodium heparin is acceptable; provide CBC
- **Peripheral Blood**: 1mL EDTA; sodium heparin is acceptable; provide CBC
- **Fresh Bone Marrow Core Biopsy**: 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue**: Tissue in RPMI
- **Fluids**: Equal parts RPMI and specimen volume

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184(x1), 88185(x3). Add 88187(x1) for global.

Turnaround Time
24 hours

Level of Service
Global ✓ Technical ✓

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## CD56

### Methodology
Immunohistochemistry (IHC)

### Test Description
CD56 recognizes two proteins of the neural cell adhesion molecule, the basic molecule expressed on most neuroectodermally-derived cell lines, tissues and neoplasms (e.g. retinoblastoma, medulloblastomas, astrocytomas, and neuroblastomas). It is also expressed on some mesodermally-derived tumors (rhabdomyosarcoma) and on natural killer cells. CD56 can be used as a marker for NK cell neoplasms. Some benign and malignant plasma cells are also positive. CD56 is often positive in neuroendocrine carcinomas.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88342 x 1 or 88341 x 1

### Turnaround Time
24 hours

### Level of Service
Stain Only ✓

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December 18, 2019
**CD57**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD57 is expressed on subpopulations of peripheral blood mononuclear cells, NK active cells and T-cells. Hematopoietic malignancies that are CD57+ include a minority of T-lymphoblastic leukemias, roughly three quarters of the indolent T-cell large granular lymphocytic leukemias, and a small portion of NK-cell lymphomas. It can be used to highlight small lymphoid cells in nodular lymphocytic predominant Hodgkin lymphoma.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓
CD61

Methodology
Immunohistochemistry (IHC)

Test Description
CD61 (GPIIIa) is a glycoprotein found on megakaryocytes, platelets, and their precursors. CD61 antigen plays a role in platelet aggregation and also as a receptor for fibrinogen, fibronectin, von Willebrand factor, and vitronectin. This antibody is useful in detecting neoplastic platelet precursors, normal platelets, and most cases of megakaryocytic leukemias.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔️

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CD68

Methodology

Immunohistochemistry (IHC)

Test Description

CD68 is an antibody directed against lysosomes. It is important for identifying macrophages in tissue sections. It stains macrophages in a wide variety of human tissues, including Kupffer cells and macrophages in the red pulp of the spleen, lamina propria of the gut, lung alveoli, and bone marrow. This antibody reacts with myeloid precursors and peripheral blood granulocytes. It shows strong granular cytoplasmic staining of chronic and acute myeloid leukemia and also reacts with true histiocytic neoplasia. It also stains granular cell tumors and some cases of melanoma, renal cell carcinoma, and pleomorphic sarcoma. Tumors of lymphoid origin are usually not stained.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only

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CD7

Methodology

Immunohistochemistry (IHC)

Test Description

CD7 is expressed on the majority of immature and mature T-lymphocytes and T-cell leukemia. It is also found on natural killer cells, and a small subpopulation of normal and malignant B-cells. CD7 antibody can be useful for detection of T-cell leukemias and myeloid leukemias. CD7 expression is often lost in mycosis fungoides.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓
## CD71

### Methodology

Immunohistochemistry (IHC)

### Test Description

CD71 is useful in identifying erythroid precursors with no interference from mature erythrocytes and also in the determination of erythroid leukemia, benign erythroid proliferative disorders, and myelodysplastic syndrome.

### Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*

88342 x 1 or 88341 x 1

### Turnaround Time

24 hours

### Level of Service

Stain Only ✔

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December 18, 2019
CD79a

Methodology
Immunohistochemistry (IHC)

Test Description
CD79a first appears at the pre B-cell stage and persists until the plasma cell stage where it is found as an intracellular component. CD79a is found in the majority of acute leukemias of precursor B-cell type, B-cell lines, B-cell lymphomas, and in some myelomas. It is not present in myeloid cells or T-cells.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
**CD8**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
CD8 is a T-cell marker for the detection of cytotoxic/suppressor T-cells. CD8 is also detected on NK cells, most thymocytes, a subpopulation of null cells, and bone marrow cells. This antibody is useful in evaluating T-cell lymphomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only

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CD99

Methodology

Immunohistochemistry (IHC)

Test Description

CD99 (MIC2 gene product, E2) antigen is strongly expressed by Ewing sarcoma cells, primitive peripheral neuroectodermal tumors, and lymphoblastic leukemia/lymphoma.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only

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CDK4

Methodology
Immunohistochemistry (IHC)

Test Description
Among cyclin/CDK proteins, CDK4 and cyclin D1 are the most frequently activated by somatic genetic alterations in multiple tumor types. CDK4 antibody assists in distinguishing atypical lipomatous tumor well-differentiated liposarcoma (WDL) (positive) from benign adipocytic neoplasms (negative).

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔
CDKN2A (p16) Deletion FISH for ALL

Methodology

FISH

Test Description

Probes: CDKN2A (p16) (9p21) | Centromere 9
Disease(s): Acute Lymphoblastic Leukemia (ALL)

Clinical Significance

Loss of the CDKN2A gene (also called p16 or pINK4A) at 9p21 is frequently observed in acute lymphocytic leukemia (30-40% of cases) and requires a method more sensitive than cytogenetics (such as FISH) for reliable detection. CDKN2A gene deletion is associated with an adverse prognosis in pediatric, adolescent, and adult patients with B-cell ALL (B-cell precursor or BCP-ALL) due to increased risk for relapse, poor response to therapy, lower overall survival, and/or higher incidence of concurrent deletion of other genes. Reports vary whether the impact of heterozygous deletions is as severe as homozygous deletions.

References


Specimen Requirements

- **Bone Marrow Aspirate**: 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood**: 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue**: Tissue in RPMI.
- **Fluids**: Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides**: Not available.

Storage and Transportation

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88377x1 manual or 88374x1 automated

Turnaround Time

3-5 days

Level of Service

Global ✓

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December 18, 2019
CDKN2A (p16) Deletion for Mesothelioma

Methodology

FISH

Test Description

**Probes:** CDKN2A (p16) (9p21) | Centromere 9  
**Disease(s):** Mesothelioma

Clinical Significance

Detection of homozygous deletions of CDKN2A (also called p16) by FISH is useful to distinguish malignant pleural mesothelioma (MPM) and diffuse malignant peritoneal mesothelioma (DMPM) from reactive mesothelial hyperplasia (RMH) and epithelial ovarian cancer (EOC). While morphologic, immunocytochemical, and immunohistochemical analyses determine the mesothelial origin of such neoplasms, CDKN2A FISH enables differentiation of benign from malignant proliferations with high specificity and positive predictive value, particularly when combined with BAP-1 IHC. Homozygous deletions have been reported in 70-80% of MPM cases and are associated with shorter survival in these patients.

Specimen Requirements

- **Bone marrow aspirate:** N/A  
- **Peripheral blood:** N/A  
- **Fresh, unfixed tissue:** N/A  
- **Fluids:** N/A  
- **Paraffin block:** Send paraffin block. Also send circled H&E slide for tech-only (required).  
- **Cut slides:** H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88377(x1) Manual or 88374(x1) Automated

Turnaround Time

4 days

Level of Service

Global ✓  
Technical ✓

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CDX2

Methodology
Immunohistochemistry (IHC)

Test Description
CDX2 is an intestine specific transcription factor that regulates both the proliferation and differentiation of intestinal epithelial cells. It is expressed in the nuclei of epithelial cells throughout the intestine, from duodenum to rectum. The CDX2 protein is expressed in primary and metastatic colorectal carcinomas and has also been demonstrated in the intestinal metaplasia of the stomach and intestinal-type gastric cancer. It is not expressed in the normal gastric mucosa. CDX2 may be used in identifying metastatic carcinoma of colonic or other gastrointestinal tract origin in the setting of an unknown primary tumor.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
CDX2/CK7 Double Stain

Methodology
Immunohistochemistry (IHC)

Test Description
CDX2 is a transcription factor expressed in the nuclei of epithelial cells throughout the intestine, from duodenum to rectum. The CDX2 protein is expressed in primary and metastatic colorectal carcinomas and has also been demonstrated in the intestinal metaplasia of the stomach and intestinal-type gastric cancer. It is not expressed in the normal gastric mucosa. Cytokeratin 7 is a basic cytokeratin and is expressed in epithelial cells of ovary, lung, and breast, but not of the colon or gastrointestinal tract. This antibody cocktail of CDX2 and CK7 can be used simultaneously to distinguish stomach and colon cancers from breast, lung, and ovarian cancers.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88344 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
# CEA (Mono)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>CEA monoclonal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
</tbody>
</table>

## Test Description
Carcinoembryonic antigen (CEA) is usually demonstrated as a linear labeling of the apical poles of cells lining the glandular lumen and occasionally as weak staining near the apex of normal colonic epithelial cells. Tumors tend to display an increased cytoplasmic staining. In specific cases, CEA can be useful in tumor diagnosis. Pancreatic carcinomas, testicular tumors, gallbladder neoplasms and granular cell myoblastomas all stain positive for CEA, while malignant tumors of brain, prostate, skin, lymphoreticular tissues, hepatocellular carcinomas, esophageal squamous cell carcinomas and mesothelioma fail to stain for CEA.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1

## Turnaround Time
24 hours

## Level of Service
Stain Only

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December 18, 2019
CEA (Poly)

Alternative Name  
CEA polyclonal

Methodology  
Immunohistochemistry (IHC)

Test Description  
Polyclonal carcinoembryonic antigen (CEA) antibody stains a larger percentage of cholangiocarcinomas compared to hepatocellular carcinomas. Approximately 95% of cholangiocarcinomas are stained diffusely and strongly with polyclonal CEA, whereas show a canalicular staining pattern with this antibody.

Specimen Requirements  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*  
88342 x 1 or 88341 x 1

Turnaround Time  
24 hours

Level of Service  
Stain Only ✓
CEBPA Mutation Analysis

Alternative Name
CEBPA

Methodology
Molecular

Test Description
Bi-directional sequencing of the relevant coding region and fragment analysis for detection of sequence variant and internal tandem duplication mutations. The SNP genotype at rs34529039 is reported. Testing is performed on plasma for increased sensitivity whenever possible.

Clinical Significance
CEBPA mutations are detected in 7-15% of AML patients. Double mutations are associated with good prognosis in patients with intermediate risk and normal cytogenetics who do not have FLT3-ITD mutations. The genotype T at SNP rs34529039 has been associated with shorter event-free survival and time-to-relapse in one group of post-stem cell transplant AML patients with intermediate or adverse risk cytogenetics.

Specimen Requirements
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.
- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81218

Turnaround Time
10 days

Level of Service
Global ✔

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## Centromere 1 FISH for POC Ploidy

### Methodology
FISH

### Test Description
**Probes:** CEN 1 (1p11.1-q11.1)

**Disease(s):** Molar pregnancy vs. partial mole

This test is currently available on a global basis only.

### Clinical Significance
This FISH test analyzes copy number of the chromosome 1 centromere to assess triploidy (associated with partial molar pregnancy) vs. diploidy (associated with full molar pregnancy when pathology is consistent). This is an indirect analysis of products of conception (POC) ploidy based on the assumption that trisomy 1 indicates triploidy, as isolated trisomy 1 is extremely rare in POC. An alternative test that can assess ploidy of multiple chromosomes as well as maternal vs. paternal inheritance is the molecular Chimerism / DNA Fingerprinting Analysis. (A maternal blood sample is required for the molecular test to differentiate parental inheritance, but is not required for ploidy analysis alone.)

### Specimen Requirements
- **Note:** Specimen must contain villi and/or fetal tissue.
- **Paraffin block:** Send paraffin block.
- **Cut slides:** H&E slide (required) plus 4 unstained slides cut at 4-5 microns.

### Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88368x1 manual. Codes may differ if automated analysis is performed.

### Turnaround Time
5 days

### Level of Service
Global ✅

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Chloroacetate Esterase (CAE)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Cytochemical stain.

**Specimen Requirements**

- Minimum two slides fresh smear: bone marrow aspirate preferred, peripheral blood accepted
- Slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88319x1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓
Chromogranin A

Methodology
Immunohistochemistry (IHC)

Test Description
Chromogranin is present in several elements of the diffuse neuroendocrine system (DNES), including anterior pituitary, thyroid perifollicular C cells, parathyroid chief cells, pancreatic islet cells, intestinal enterochromaffin cells and tumors derived from these cells. Chromogranin immunoreactivity was also seen in thymus, spleen, lymph nodes, fetal liver, neurons, the inner segment of rods and cones, the submandibular gland and the central nervous system. This marker is useful in evaluating neuroendocrine tumors.

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
Chromosome Analysis

Alternative Name
Cytogenetics, karyotyping

Methodology
Cytogenetics

Test Description
A wide variety of abnormalities can be identified, providing both diagnostic and prognostic information. Acute leukemias, lymphomas and chronic myeloid and lymphoid disorders are examined cytogenetically in order to establish the exact nature of the acquired genetic change. Rearrangements, also known as translocations, inversions, and deletions, can usually be detected under a light microscope. In most leukemias and lymphomas, changes in chromosome number (ploidy) or chromosome structure (rearrangements) are often observed.

Clinical Significance
In some forms of cancer, especially hematological neoplasms, cytogenetic analysis can determine whether chromosomal changes, either structural or numerical, are present in the malignant cells, thereby facilitating diagnosis, prognosis and treatment options.

Specimen Requirements
- **BM Aspirate**: 1-2 mL sodium heparin tube.
- **Peripheral Blood**: 2-5 mL sodium heparin tube.
- **Fresh/Unfixed Tissue - Lymph Node or Solid Tumor Tissue Biopsy**: One thin cross-section of fresh node or one representative section of solid tumor with minimum 0.5 cm³ tissue. Collect under sterile conditions as if for microbiologic culture. Place tissue in RPMI and note type of tissue on test requisition. **Lymph nodes may be sent to our Aliso Viejo, CA or Nashville, TN facility. Send solid tumor samples to the Nashville, TN facility. Please see our contact page for shipping address.** Tissues placed in formalin are unacceptable for cytogenetics.
- **Note**: When submitting samples for cancer indications, please provide bone marrow transplantation status and (suspected) diagnosis on the requisition (and/or attach flow cytometry and morphology reports).
- **Fresh/Unfixed Tissue- Products of Conception (POC)**: Dissected chorionic villi or known fetal tissue(s) are preferred, but uterine contents or tissue of mixed fetal/maternal origin is acceptable and will be processed. Please include villi if sending tissue from a fetal demise. Place tissue in RPMI, note type(s) of tissue on test requisition, and send to our Nashville, TN facility. **Please see our contact page for shipping address.** Tissues placed in formalin are unacceptable for cytogenetics.
  - **POC cytogenetics only**: At least 50-100 mg villi or 1-1.5 cm³ fetal tissue(s).
  - **POC cytogenetics with reflex to NeoARRAY™ SNP/Cytogenetic Profile**: Same. At least 50-100 mg villi or 1-1.5 cm³ fetal tissue(s).

Storage and Transportation
Do not freeze. Use cold pack for transport, make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88237, 88262, 88291. Some cases require additional study and may use 88264, 88280, 88285.

Turnaround Time
Bone marrow aspirate/blood: 5 days (standard; 7 days for known or suspected plasma cell neoplasm) | Lymph node/node biopsy: 5 days | Solid tumor: 21 days | POC without array: 14-21 days | POC with reflex to array: 28-35 days

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December 18, 2019
# CK 10/13 (Cytokeratin 10/13)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Cytokeratins 10 and 13 are intermediate-size, acidic type I cytokeratins (molecular mass of 56.5 kDa). CK10/13 cocktail is expressed in all suprabasal cells of normal stratified squamous epithelium, although it is absent in the basal layer. CK10/13 expression can be lost in dysplastic lesions of the stratified squamous epithelium.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓

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December 18, 2019
CK HMW (CK903/34BE12)

Methodology

Immunohistochemistry (IHC)

Test Description

CK903 (34betaE12) is a high molecular weight cytokeratin present in all squamous epithelium and their carcinomas. This antibody recognizes cytokeratins 1, 5, 10 and 14 that are found in complex epithelia. There has been no reactivity with cells derived from simple epithelia, mesenchymal tumors, lymphomas, melanomas, neural tumors and neuroendocrine tumors. One useful application is the identification of the basal cell layer in prostate tissue in the determination of carcinoma.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only

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December 18, 2019
CK HMW/CK LMW Double Stain

Methodology
Immunohistochemistry (IHC)

Test Description
This cytokeratin cocktail can be useful in differentiation of the squamous cell carcinomas and adenocarcinomas. The 34bE12 clone recognizes cytokeratin (CK) 1, 5, 10 and 14. It is reactive with stratified epithelia, myoepithelial and basal cells of prostate and breast, and it stains squamous carcinomas and adenosquamous carcinomas (brown). Clone 5D3 recognizes cytokeratin (CK) 8 and 18 of all simple and glandular epithelium and adenocarcinomas (red).

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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**CK OSCAR**

**Alternative Name**
CK OSCAR (Pan Cytokeratin)

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Anti-cytokeratin clone OSCAR (CK OSCAR) demonstrates a broad spectrum of cytokeratin reactivity. In normal tissues, OSCAR is reactive with most epithelial types, including bile ducts and hepatocytes in liver, bladder epithelium, breast ducts, bronchial epithelium, endometrium, intestinal epithelium of stomach, duodenum, ileum, colon, rectum, pancreas, ovarian epithelium, pancreatic acini, pituitary acini, pneumocytes, prostate, thyroid, skin (positive on the basal layer and negative on the superficial layers of squamous epithelium), and apocrine and sweat glands. In tumors, OSCAR is reactive with most carcinomas, including breast, transitional cell (TCC), renal cell (RCC), lung adenocarcinoma, lung small cell, lung squamous cell, endometrial, prostate, ovarian, hepatocellular (HCC), colorectal CA, stomach and thyroid. It is negative in certain normal tissues, including brain, lymphocytes and all cells of hematolymphoid origin, muscle, brain, nerves, endothelium and in certain tumors including most melanomas, sarcomas, lymphomas, primitive neuroectodermal tumors (PNET)/Ewings and gastrointestinal stromal tumors (GIST). Positivity has been seen on some dendritic cells in lymph nodes, some endothelia, and some muscle cells.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✔️

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December 18, 2019
# CK14 (Cytokeratin 14)

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Cytokeratin 14 (CK14) belongs to the type A (acidic) subfamily of high molecular weight keratins and exists in combination with keratin 5. CK14 has been studied as a prognostic marker in breast cancer. CK14 distinguishes stratified epithelial cells from simple epithelial cells and has been reported useful in the identification of squamous cell carcinomas.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or&lt;br&gt;• One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered&lt;br&gt;• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88342 x 1 or 88341 x 1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>Global: 48 hours, Tech-Only (stain only): 24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✔ Stain Only ✔</td>
</tr>
</tbody>
</table>

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December 18, 2019
CK17

Alternative Name: Cytokeratin 17

Methodology: Immunohistochemistry (IHC)

Test Description: Cytokeratin 17 (CK17) is an effective marker to distinguish myoepithelial cells from luminal epithelium of various glands (mammary, sweat, salivary, bronchial, tracheal, laryngeal, esophageal) and benign from malignant forms of tumors, e.g. mammary gland tumors. Predominant expression of CK17 is the characteristic feature of basal cell carcinomas. It is often positive in carcinomas of pancreatic or biliary origin.

Specimen Requirements:
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88342 x 1 or 88341 x 1

Turnaround Time: 24 hours

Level of Service: Stain Only

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CK18 (Cytokeratin 18)

Methodology
Immunohistochemistry (IHC)

Test Description
Cytokeratin 18 (CK 18), a 45kDa protein, belongs to the acidic type of cytokeratins, and is typically expressed in simple, nonstratified epithelia. However, CK 18 is also expressed in basal and superficial cells of transitional epithelium, as well as in the luminal/secretory cells of complex epithelia.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
**CK19**

**Alternative Name**  
Cytokeratin 19

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Cytokeratin 19 (CK19) is a member of the type I acidic subfamily of keratins. It is expressed in various different human tissues. CK19 labels ductal and glandular epithelia, prostatic epithelia, and non-keratinizing squamous epithelia. This antibody is useful in the diagnosis of breast and cervical carcinoma. CK19 is not expressed in hepatocytes, therefore, antibody to CK19 is also useful in the distinction of liver metastasis from hepatocellular carcinomas.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only

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December 18, 2019
# CK20

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Cytokeratin 20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Cytokeratin 20 (CK20) positivity is seen in the majority of adenocarcinomas of the colon, mucinous ovarian carcinomas, transitional cell, and Merkel cell carcinomas, and frequently in adenocarcinomas of the stomach, bile system and pancreas. CK7/CK20 immunostaining patterns may be helpful in separating pulmonary from colonic adenocarcinomas.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
| | • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
| | • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88342 x 1 or 88341 x 1 |
| **Turnaround Time** | 24 hours |
| **Level of Service** | Stain Only ✓ |

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**CK5/6**

**Alternative Name**: Cytokeratin 5/6  

**Methodology**: Immunohistochemistry (IHC)  

**Test Description**: D5/16 B4 clone of CK5/6 antibody reacts strongly with cytokeratins 5 and 6. Cytokeratin 5/6 have been found valuable for the distinction between low differentiated squamous cell carcinoma and adenocarcinoma. It labels mesothelioma, and epithelial basal cells in prostate and tonsil. No reactivity with other mesodermally derived tissues, such as muscle and connective tissues, has been observed. Anti-CK 5/6 has also been found useful in the differential diagnosis of atypical proliferations of the breast.

**Specimen Requirements**:  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**:  
- 88342 x 1 or 88341 x 1

**Turnaround Time**: Tech-Only (stain only): 24 hours

**Level of Service**: Stain Only ✔️

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**CK7**

**Alternative Name**
Cytokeratin 7

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Cytokeratin 7 (CK7) antibody reacts with proteins that are found in most ductal, glandular and transitional epithelium of the urinary tract and bile duct epithelial cells. CK7 distinguishes between lung and breast epithelium that stain positive, and colon and prostate epithelial cells that are negative. It also reacts with many benign and malignant epithelial lesions, e.g. adenocarcinomas of the ovary, breast and lung. Transitional cell carcinomas are positive and most prostate cancers are negative. This antibody does not recognize other intermediate filament proteins.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓
CLL FISH Panel

**Alternative Name**  Chronic lymphocytic leukemia

**Methodology**  FISH

**Test Description**  

**Probes:** 6q- [SEC63 (6q21), MYB (6q23)] | ATM (11q22.3) | p53 (17p13.1) | Trisomy 12 (Cen 12) | 13q-/13 (13q14, 13q34) | CCND1/IgH t(11;14) | Probes may be ordered separately (except 12 and 13 are tested together, and ATM is tested with p53).  

**Disease(s):** Chronic lymphocytic leukemia  

**Note:** This test was previously called CLL FISH Panel (non-New York). It is now New York state-approved and available to all clients.

**Clinical Significance**  

The CLL FISH panel is used for the detection of chromosome aberrations observed in chronic lymphocytic leukemia/small lymphocytic lymphoma, which are useful in prognosis and prediction of time to treatment in CLL patients when used in combination with other clinical and diagnostic findings. CCND1/IgH is used to rule out mantle cell leukemia/lymphoma.

**Specimen Requirements**  

- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.  
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.  
- **Fresh, Unfixed Tissue:** Tissue in RPMI.  
- **Fluids:** Equal parts RPMI to specimen volume  
- **Paraffin Block or Cut Slides:** Not available.

**Storage and Transportation**  

Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  

88374x4 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**  

3-5 days

**Level of Service**  

Global ✓  Technical ✓
CLL MRD Flow Panel

Alternative Name
CLL Minimal Residual Disease Panel

Methodology
Flow Cytometry

Test Description
Available as global test only. Markers are CD3, CD5, CD19, CD20, CD22, CD43, CD45, CD79b, and CD81 (9 markers).

Clinical Significance
Monitoring of minimal residual disease (MRD) in chronic lymphocytic leukemia (CLL) has become increasingly important as treatments improve. This flow cytometry panel follows the strategy developed by the European Research Initiative in CLL (ERIC) and can detect MRD at the 0.01% level. Detection of MRD above 0.01% is reported to be an independent predictor of progression-free survival and overall survival in CLL patients treated with chemoimmunotherapy. The prognostic value of achieving MRD-negative status with other CLL therapies is under investigation in clinical trials.

References

Specimen Requirements
Bone marrow aspirate or peripheral blood: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184(x1), 88185(x8). Add 88188(x1) for global.

Turnaround Time
1 day

Level of Service
Global

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December 18, 2019
CLL/Mantle Cell Companion Add-On Flow Panel

Methodology
Flow Cytometry

Test Description
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD3, CD5, CD19, CD22, CD36, CD43, CD45, CD52, CD200, and FMC7 (10 markers). This panel is not for detection of minimal residual disease (MRD).

Clinical Significance
This panel is helpful in differentiating CLL from MCL; in small CD10+ lymphoma (usually negative for CD43) versus large cell lymphoma and Burkitt’s (40-60%+); in B-ALL vs. mature CD10+ lymphoma, especially in surface light chain negative cases; in HCL screening (extremely useful in rare CD5+ HCL cases); for evaluating heme versus nonheme cases (along with CD45) in ALCL, especially Null phenotype; and for granulocytic sarcomas (not all granulocytic sarcomas are CD34+, especially monocytic).

CD43 is useful in identifying the myeloid/monocyte populations (e.g. myeloid sarcomas) and immature B cells. CD43 is also useful as an additional T-cell antigen for aberrant loss in T-cell lymphomas, NK cell antigen (e.g. CD3-CD43+), and in mature B-cell non-Hodgkin lymphomas, especially CLL/MCL (usually CD43+), FCL (usually CD43-) and HCL (usually CD43-). In combination with CD11c (part of our main panel), FMC7 and CD200 are extremely useful in separating CLL (including atypical CLL) from MCL by flow.

Specimen Requirements
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
Please contact NeoGenomics’ Billing Department.

Turnaround Time
1 day

Level of Service
Global ✅  Technical ✅

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December 18, 2019
### cMET

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>MET</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>The cMET tyrosine kinase receptor, normally expressed by epithelial cells, is overexpressed and amplified in a variety of human tumors, including non-small cell lung carcinoma (NSCLC). High levels of intratumor cMET expression have been associated with a more aggressive biology and a worse prognosis in NSCLC. Engelman et al. reported that cMET amplification induced resistance to gefitinib in a gefitinib-sensitive lung cancer cell line. Moreover, cMET inhibition with a cMET tyrosine kinase inhibitor (PHA-665,752) restored gefitinib sensitivity.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or • One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>88342 x 1 or 88341 x 1; 88360 x 1</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>Global: 48 hours, Tech-Only (stain only): 24 hours</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓ Stain Only ✓</td>
</tr>
</tbody>
</table>

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CMV

Alternative Name Cytomegalovirus by ISH

Methodology In Situ Hybridization (ISH)

Test Description In situ hybridization for detection of cytomegalovirus (CMV) RNA.

Clinical Significance CMV is a herpesvirus capable of causing serious disease in immunocompromised / transplant patients and neonates. CMV ISH is useful for detection of primary, latent, and reactivated CMV infections in FFPE tissues.

Specimen Requirements

- **Cut Slides:** 4 cut slides. Sections must be wrinkle and artifact-free. No additives in the water bath. Cut sections at 4-5 microns, and place tissue at the center bottom of a positively charged slide.
- **Paraffin block:** Formalin-fixed paraffin-embedded tissue. Block should be sent with a cold pack. Block identifiers should be clearly written and match exactly with the specimen ID and the block labeling as noted on the requisition.
- **NOTE:** Please also send one H&E slide with global testing and consult requests.

Storage and Transportation Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)* 88365x1

Turnaround Time 48 hours

Level of Service

- Global ✓
- Stain Only ✓

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December 18, 2019
# CMV (Cytomegalovirus) by IHC

## Methodology
Immunohistochemistry (IHC)

## Test Description
Cytomegalovirus (CMV) is an opportunistic pathogen infecting lung, kidney, gut and other organs in situations where an individual is immunologically immature, such as the fetus and neonate. Infection also occurs in immunosuppressed patients, e.g. transplant patients, patients undergoing chemotherapy and HIV infected patients.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1

## Turnaround Time
- Global: 48 hours, Tech-Only (stain only): 24 hours

## Level of Service
- Global ✓
- Stain Only ✓

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December 18, 2019
cMyc

Methodology

Immunohistochemistry (IHC)

Test Description

cMyc protein is a transcription factor localized to the nucleus of the cell. Amplification of the cMyc gene has been found in several types of human tumors.
cMyc is amplified in 20-30% of breast cancer cases and is associated with HER-2 amplification and poor outcome. In Burkitt’s lymphoma, 90% of tumors have translocation of cMyc or variants. cMyc protein (>50%) is seen in a subset of cases of diffuse large B-cell lymphoma (DLBCL) and is correlated with Myc rearrangement. It is also positive in radiation-associated angiosarcoma.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✅
# COG Chromosome Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Children's Oncology Group Cytogenetics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Cytogenetics</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>NeoGenomics is approved to perform chromosome analysis for the Children’s Oncology Group (COG). COG-protocol cytogenetics is performed on blood and bone marrow specimens in our Fort Myers, Florida laboratory.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements**  | • **BM Aspirate**: 2-3 mL sodium heparin tube.  
• **Peripheral Blood**: 4-5 mL sodium heparin tube.  
• **Note**: Ship specimens directly to our Ft. Myers, FL facility. See Storage & Transportation. |
| **Storage and Transportation** | Please send COG Chromosome Analysis specimens directly to our Fort Myers, Florida laboratory. Shipping and contact information is available here.  
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**            | 88237, 88262, 88291. Some cases require additional study and may use 88264, 88280, 88285. |
| **Turnaround Time**        | **BM aspirate/blood cyto**: 10 days for cytogenetics results, 21 days for submission to COG |
| **Level of Service**       | Global ✓ |

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December 18, 2019
Collagen IV

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Collagen IV is a major constituent of the basement membranes along with laminins and enactins. In kidney, the antibody reacts with glomerular and tubular basement membranes, parts of the mesenchymal matrix, and the Bowman’s capsule. It also reacts with the basal lamina of capillaries and basement membranes in a variety of tissues. Antibody to collagen IV is useful in evaluating neural neoplasms.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓
**Colloidal Iron**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Hale Colloidal Iron</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>Special stain.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or&lt;br&gt;• One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered&lt;br&gt;• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88313x1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Stain Only ✓</td>
</tr>
</tbody>
</table>

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December 18, 2019
# Comprehensive Hereditary Cancer Panel

<table>
<thead>
<tr>
<th><strong>Methodology</strong></th>
<th>Molecular</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Description</strong></td>
<td>Testing is performed by Blueprint Genetics. The Comprehensive Hereditary Cancer Panel includes next-gen sequencing of coding regions, exon-intron boundaries, and certain non-coding variants in 146 genes. Deletion/duplication analysis is performed to detect copy number variants (CNVs) ≥1 exon in size. This panel is designed to detect heritable germline mutations and should not be used for the detection of somatic mutations in tumor tissue. Full test details are available <a href="#">here</a>. Note: Patient signature on the Blueprint Genetics Informed Consent Form is required. Testing will be put on hold until a signed form is received.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>This panel provides broad coverage of genes associated with germline susceptibility to cancer. Testing is appropriate for individuals with strong personal and/or family history of cancers.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>Peripheral blood: 5 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81432x1, 81433x1</td>
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<tr>
<td><strong>Turnaround Time</strong></td>
<td>4 weeks</td>
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<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔</td>
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December 18, 2019
Congo Red

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 10 microns
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88312x1, 88313x1

Turnaround Time
24 hours

Level of Service
Stain Only

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# Copper Stain

## Methodology
Immunohistochemistry (IHC)

## Test Description
Special stain.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88313x1

## Turnaround Time
24 hours

## Level of Service
Stain Only ✓

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**COX2**

**Alternative Name**
Cyclooxygenase-2

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Cyclooxygenase-2 (COX-2) plays a role in tumorigenesis through stimulating epithelial cell proliferation, inhibiting apoptosis, stimulating angiogenesis, enhancing cell invasiveness, mediating immune suppression, and by increasing the production of mutagens. COX-2 is expressed in breast cancer, transitional cell carcinoma of the bladder, high-grade endometrioid carcinoma, and ovarian cancer. Overexpression of COX-2 is associated with poor prognosis in cervical cancers after radiation and concurrent chemotherapy.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342x1 or 88341x1; 88360x1

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✓ Stain Only ✓
cREL

Methodology  
Immunohistochemistry (IHC)

Test Description  
Inactive cREL resides in the cytoplasm and translocates to the nucleus upon activation. Strong, homogeneous nuclear cREL staining has been observed in primary mediastinal large B-cell lymphoma whereas nuclear cREL expression is more variable in other forms of diffuse large B-cell lymphoma (DLBCL). Evaluation of cREL nuclear expression combined with germinal center B-cell (GCB) and non-GCB phenotyping by IHC may improve patient risk stratification in DLBCL.

Specimen Requirements  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*  
88342 x 1 or 88341 x 1

Turnaround Time  
24 hours

Level of Service  
Stain Only ✓

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# CSF3R Mutation Analysis

**Alternative Name**  
CSF3R

**Methodology**  
Molecular

**Test Description**  
Bi-directional sequencing of exons 14 and 17 of the CSF3R gene which includes detection of the common mutation T618I (also known as T595I).

**Clinical Significance**  
CSF3R mutations are newly-identified genetic markers detected in 59% of chronic neutrophilic leukemia (CNL) or atypical chronic myeloid leukemia (aCML) that are useful for diagnosis and classification of these disorders. Identification of specific mutations may suggest the class of kinase inhibitors to which the tumor will be sensitive. Mutations are also detected in 30-80% of leukemia in patients with severe congenital neutropenia (SCN).

**Specimen Requirements**  
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
81479

**Turnaround Time**  
10 days

**Level of Service**  
Global ✓

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December 18, 2019
<table>
<thead>
<tr>
<th><strong>CXCL13</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Alternative Name</strong></td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
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<tr>
<td><strong>Turnaround Time</strong></td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
</tr>
</tbody>
</table>

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CXCR4 Mutation Analysis

Alternative Name: CXCR4

Methodology: Molecular

Test Description: Bi-directional sequencing to detect nonsense, frameshift, and other mutations encoding the C-terminus of CXCR4. Analyzed range includes detection of the C1013G mutation and spans amino acids L301 to S352. Testing is available separately or in combination with three other contributory genes in the BTK Inhibitor Primary Susceptibility Panel. Testing is approved for specimens from the state of New York.

Clinical Significance: CXCR4 activates AKT1/MAPK pathways in B-lineage cells and facilitates cell migration in Waldenstrom macroglobulinemia (WM). Mutations are detected in nearly 30% of WM cases, and are associated with primary resistance and initial lack of response to BTK, PI3K, and mTOR inhibitors. The majority of these cases with CXCR4 mutations have concurrent MYD88 L265P mutations. The common C1013G mutation in CXCR4 and other somatic frameshift and nonsense mutations detected by this test are the same as or similar to the germline mutations associated with WHIM syndrome. Therapeutic antagonists to CXCR4 are in clinical trials.

Specimen Requirements:
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.
- **FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81479

Turnaround Time: 10 days

Level of Service: Global ✓

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D240

Methodology
Immunohistochemistry (IHC)

Test Description
D2 40 identifies a 40kDa O-linked sialoglycoprotein expressed by a variety of tissues, including fetal testes and testicular germ cell tumors. Anti-D2 40 has also been demonstrated to label lymphatic endothelium whereas it is unreactive with vascular endothelium. In neoplastic tissue, immunostaining of lymphatic endothelium by anti-D2 40 can be useful in identifying lymphatic invasion of primary tumors. It is also often positive on sarcomatoid malignant mesothelioma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✅

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DBA.44

Methodology

Immunohistochemistry (IHC)

Test Description

This antibody reacts with a subset of B-cells in the mantle zone and some immunoblasts outside the follicle. It reacts with most hairy cell leukemia cases. This antibody shows strong positive staining in some high grade B-cell lymphoma cases.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔

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December 18, 2019
# DDIT3 (CHOP)

## Alternative Name
CHOP

## Methodology
FISH

## Test Description
**Probes:** DDIT3 (CHOP) (12q13)

**Disease(s):** Myxoid-round cell liposarcoma (M/RCLS)

## Clinical Significance
The DDIT3 break-apart FISH test detects 12q13 rearrangements in myxoid-round cell liposarcoma (M/RCLS). The DDIT3 locus was formerly named CHOP. Fusion of DDIT3 and FUS genes in t(12;16)(q13;p11) is detected in >95% of cases. Occasionally observed is t(12;22)(q13;q12) in which DDIT3 and EWSR1 are fused. DDIT3 rearrangement partners will not be identified by this FISH test. For that purpose, please see the NGS Sarcoma Fusion Profile.

## Specimen Requirements
- **Bone marrow aspirate:** N/A
- **Peripheral blood:** N/A
- **Fresh, unfixed tissue:** N/A
- **Fluids:** N/A
- **Paraffin block:** Send paraffin block. Also send circled H&E slide for tech-only (required).
- **Cut slides:** H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only

## Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88377x1 manual or 88374x1 automated

## Turnaround Time
4 days

## Level of Service
- Global ✓
- Technical ✓

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December 18, 2019
### Desmin

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Desmin is an intermediate filament protein of both smooth and striated muscles. Antibody to desmin reacts with striated (skeletal and cardiac) as well as smooth muscle cells. Anti-desmin antibody is useful in identification of tumors of myogenic origin. It reacts with leiomyosarcomas (smooth muscle) as well as rhabdomyosarcomas (striated muscle).

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only ✔️

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## DNA Fingerprinting Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Specimen Identity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>STR (short tandem repeat) analysis by PCR and capillary electrophoresis (fragment analysis) is used to define sample identity and to identify mixtures of two or more genotypes within a single sample. Fifteen autosomal markers and one gender-based marker are analyzed.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>This test is useful to confirm specimen patient identity in cases of questionable sample labelling or origin and for differentiating partial moles from complete hydatidiform moles (molar pregnancy). Note: when used for specimen identity, this assay is not performed as a clinical assay for patient care.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | Notes: For analysis of suspected molar pregnancy, please submit a maternal blood sample along with the POC (products of conception) sample. For specimen ID confirmation, additional patient samples may be needed for comparison. Please call before sample submission to discuss details of atypical cases.  
* Peripheral blood: 5 mL in EDTA tube.  
* Bone marrow: 2 mL in EDTA tube.  
* FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.  
* Fresh tissue: Minimum two pieces 0.2 cm3, fresh in RPMI or frozen. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 81265x1 or 81266x1 or 81267x1 or 81268x1. Please contact our billing department for codes specific to your reason for referral and sample combination. |
| Turnaround Time | 10 days |
| Level of Service | Global ✔ |

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DNA Ploidy/Cell Cycle Analysis – POC/Solid Tumors

Methodology
Flow Cytometry

Test Description
Available as a global test only. DNA stain propidium iodide (PI) is used to determine S-phase cell cycle fraction and DNA index as indicators of DNA ploidy. Products of conception (POC) and solid tumors are accepted for this test. Please see DNA Ploidy/Cell Cycle Analysis – Heme for other indications.

Clinical Significance
DNA ploidy analysis in POC can detect diploid, triploid, and tetraploid cell populations to help distinguish hydatidiform molar, partial mole, and non-molar pregnancies. In cancer, S-phase and ploidy analysis have diagnostic and prognostic value in assessment of some tumors. In general, high S-phase fractions and/or aneuploidy may be associated with a more aggressive tumor.

Specimen Requirements
• **FFPE samples:** Please submit block. POC samples should contain villi or fetal tissue. Testing is not available on fresh (unfixed) tissue.

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88182

Turnaround Time
4 days

Level of Service
Global ✔

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# DNMT3A Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>DNMT3A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of exon 26, a mutation hotspot region containing R882 and other mutations. In hematological disease, testing may be performed on plasma to increase sensitivity. For solid tumors, tumor enrichment is performed before extraction.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>DNMT3A mutations are found in 20-25% of acute myeloid leukemia and are associated with poor outcome.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | - **Peripheral blood**: 5 mL in EDTA tube.  
- **Bone marrow**: 2 mL in EDTA tube.  
- **FFPE solid tumor tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 81403x1 |
| Turnaround Time | 7 days |
| Level of Service | Global ✔ |

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**DOG1**

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

DOG1 is a cell surface protein of unknown function selectively expressed in gastrointestinal stromal tumors (GIST). Among GIST cases with Kit mutations the DOG1 antibody identified 11% more cases than c-Kit antibody. DOG1 identifies the vast majority of both cKIT negative and Platelet-derived Growth Factor Receptor Alpha (PDGFRα) mutated GIST cases that may still benefit from imatinib mesylate (Gleevec®), an inhibitor of the Kit tyrosine kinase. In addition, DOG1 immunoreactivity is seen in fewer cases of mesanchymal, epithelial tumors and melanomas when compared with cKIT. The use of this highly sensitive and specific novel marker will increase the accuracy of GIST diagnosis.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only

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December 18, 2019
**DPC4**

**Alternative Name**
SMAD4

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
The gene *DPC4* (deleted in pancreatic carcinoma 4, also called SMAD4) was identified in 18q21.3. This gene is frequently mutated and deleted in pancreatic carcinomas (55%) and less frequently (20 - 22%) in colon carcinomas. Loss of expression is specific for pancreatic malignancy (in-situ or invasive) vs. benign process, particularly helpful in biopsies.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

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**DUSP22-IRF4 Rearrangement**

**Alternative Name**
IRF4 Rearrangement

**Methodology**
FISH

**Test Description**
**Probes:** DUPS22-IRF4 gene region at 6p25.3  
**Disease(s):** Anaplastic Large Cell Lymphoma (ALCL), large B-cell lymphoma

**Clinical Significance**
Gene rearrangements involving the DUSP22-IRF4 gene region have been reported in CD30-positive, ALK-negative anaplastic large cell lymphoma and are associated with a favorable clinical outcome. Rearrangement has been reported in a subset of patients with lymphomatoid papulosis (LyP). Testing may identify large B-cell lymphoma with IRF4 gene rearrangement, also with favorable outcome.

DUPS22 and IRF4 are adjacent genes at 6p25.3; this test does not identify the gene rearrangement partner. MUM1 is the protein expressed by the IRF4 gene. FISH for IRF4 rearrangements has greater specificity for cutaneous ALCL than MUM1 IHC.

**References**

**Specimen Requirements**
- **Bone Marrow Aspirate:** N/A
- **Peripheral Blood:** N/A
- **Fresh, Unfixed Tissue:** N/A
- **Fluids:** N/A
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.

**Storage and Transportation**
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88374x1 automated or 88377x1 manual

**Turnaround Time**
3-5 days

**Level of Service**
- Global ✓
- Technical ✓

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E-Cadherin

Methodology
Immunohistochemistry (IHC)

Test Description
E Cadherin is an adhesion protein that is expressed in cells of epithelial lineage. It stains positively in glandular epithelium, as well as adenocarcinomas of the lung, G.I. tract and ovary. It is useful in distinguishing adenocarcinoma from mesothelioma. It is also positive in some thyroid carcinomas. Breast carcinomas with ductal and lobular features show two staining patterns: (1) complete or almost complete lack of membrane staining in lobular carcinomas and (2) uniform membrane expression throughout the tumor in ductal carcinomas. Immunohistochemical detection of ECadherin expression can be a useful diagnostic tool for the differentiation of ductal and lobular carcinomas of the breast.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓
EBER

Alternative Name
Epstein-Barr Virus by ISH

Methodology
In Situ Hybridization (ISH)

Test Description
This probe set labels all latent EBV-infected cells, including EBV-positive lymphoblastoid cell lines and EBV infected B-cell immunoblasts in infectious mononucleosis. It also reacts with EBV-associated undifferentiated nasopharyngeal carcinomas and with Reed-Sternberg cells in almost all EBV-associated Hodgkin lymphoma cases. Global interpretation is available on head and neck specimens only; tech-only testing is available for all samples.

Clinical Significance
The Epstein-Barr virus (EBV) probe demonstrates latent EBV infection by hybridizing to abundantly expressed EBER transcripts which are concentrated in the nuclei of latently infected cells.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  - or
- One (1) unbaked, unstained slide for H&E staining (required) and three (3) positively charged unstained slides, all cut at 4-5 microns
  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88365 x 1 or 88364 x 1

Turnaround Time
Global (head and neck only): 72 hours, Tech-Only (stain only): 48 hours

Level of Service
Global ✅  Stain Only ✅

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# EBV (LMP1)

## Methodology
- Immunohistochemistry (IHC)

## Test Description
This antibody reacts strongly with Epstein Barr Virus (EBV)-positive lymphoblastoid cell lines and EBV infected B-cell immunoblasts in infectious mononucleosis. It also reacts with some EBV-associated neoplasms, particularly EBV-associated Hodgkin lymphoma.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
- 88342 x 1 or 88341 x 1

## Turnaround Time
- 24 hours

## Level of Service
- Stain Only

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EGFR

Methodology
Immunohistochemistry (IHC)

Test Description
Epidermal Growth Factor Receptor (EGFR) overexpression can occur in a variety of tumor types, including breast, prostate, ovarian, brain, lung and predominantly squamous cell carcinomas. Tumors that express EGFR are associated with a poor prognosis and a shorter disease-free survival. Most colon carcinomas will show expression of EGFR in more than 1% of the invasive tumor cells. Patients whose tumor expresses EGFR are eligible for cetuximab therapy although the response to therapy is independent of the intensity or percentage of cells staining.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔ Technical ✔ Stain Only ✔

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**EGFR (E746-A750del specific)**

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Epidermal Growth Factor Receptor (EGFR) is a 170 kDa transmembrane receptor tyrosine kinase that belongs to the HER/ErbB protein family. Somatic mutations in the tyrosine kinase domain of EGFR are present in a subset of lung adenocarcinomas. Two types of mutations account for approximately 90% of mutated cases: a specific point mutation, L858R, which occurs in exon 21 and short in-frame deletions in exon 19. A common lesion in exon 19 is the deletion of E746-A750, although other variants occur. IHC-based EGFR E746-A750del specific antibody is designed to detect deletion of E746-A750 in exon 19. Deletion in exon 19 is associated with response of non-small cell lung carcinoma (NSCLC) to gefitinib or erlotinib monotherapy.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**  
Global ✓ Stain Only ✓

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December 18, 2019
EGFR (L858R mutant specific)

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Epidermal Growth Factor Receptor (EGFR) is a 170 kDa transmembrane receptor tyrosine kinase that belongs to the HER/ErbB protein family. Somatic mutations in the tyrosine kinase domain of EGFR are present in a subset of lung adenocarcinomas. Two types of mutations account for approximately 90% of mutated cases: a specific point mutation (L858R) which occurs in exon 21 and short in-frame deletions in exon 19. IHC-based EGFR L858R mutant specific antibody is designed to detect the L858R missense mutation associated with response of non-small cell lung carcinoma (NSCLC) to gefitinib or erlotinib monotherapy.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✔ Stain Only ✔
EGFR Amplification

Alternative Name: Epidermal growth factor receptor
Methodology: FISH

Test Description:
Probes: EGFR (7p11.2) | Centromere 7
Disease(s): Brain, lung, colorectal, gastric, breast cancers

Clinical Significance:
FISH analysis for amplifications of EGFR (aka ERBB1 or HER1) can be used for prognostic and therapeutic consideration in various solid tumors such as glioblastoma, lung, colorectal, gastric, and breast. Amplifications are typically associated with poor prognosis, while presence and level of amplification may not correspond to level of protein expression or response to anti-EGFR therapy in gastrointestinal cancers. High gene copy number may indicate poor prognosis in gastric and triple-negative breast cancers. However, its role in treating breast cancer and other tumors with EGFR/HER2/HER4 inhibitors is under investigation.

Specimen Requirements:
- Bone marrow aspirate: N/A
- Peripheral blood: N/A
- Fresh, unfixed tissue: N/A
- Fluids: N/A
- Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required).
- Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation:
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88377x1 manual or 88374x1 automated.

Turnaround Time:
3-5 days

Level of Service
Global ✅ Technical ✅

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# EGFR Mutation Analysis

**Alternative Name**
EGFR, epidermal growth factor receptor

**Methodology**
Molecular

**Test Description**
Bi-directional sequencing of exons 18-21 of the EGFR gene for detection of EGFR-activating mutations and TKI resistance mutations (including T790M) in these exons. Tumor enrichment is performed before extraction. Testing is approved for specimens from the state of New York.

**Clinical Significance**
EGFR mutation analysis is recommended in non-small cell lung carcinoma (NSCLC) to detect mutations (commonly L858R and exon 19 deletions) associated with increased sensitivity to EGFR tyrosine kinase inhibitors. Detection of TKI resistance mutations such as T790M in patients being treated with a TKI is useful for planning alternate treatment.

**Specimen Requirements**
- **FFPE solid tumor tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.
- **Fine needle aspirate (FNA)**: Requisition must note specimen is FNA. FFPE cell blocks are acceptable if pathologist attaches note verifying sample has >30% tumor or abnormal cells (required). Minimum 10^6 cells.

**Storage and Transportation**
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

**CPT Code(s)**
- 81235

**Turnaround Time**
7 days

**Level of Service**
Global ✓

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# EGFR T790M Germline Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>EGFR T790M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bidirectional sequence analysis of EGFR exon 20 in peripheral blood for detection of T790M germline mutation. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Germline T790M mutations in the EGFR gene are estimated to be present in 1% of all patients with non-small cell lung carcinoma (NSCLC) and in approximately 50% of patients whose lung tumors have a baseline T790M mutation prior to anti-EGFR TKI therapy. As with somatic mutations, germline T790M variants are associated with resistance to such therapy except for third-generation EGFR inhibitors. Mutation detection can aid alternate therapy planning. Dominant inheritance of lung cancer predisposition has been described in some families with this mutation; genetic counseling is strongly recommended.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>&lt;ul&gt; &lt;li&gt;<strong>Peripheral blood</strong>: 5 mL in EDTA tube.&lt;/li&gt; &lt;/ul&gt;</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81235</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>7 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔️</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*
EGFRvIII Analysis

**Alternative Name**
EGFRvIII, epidermal growth factor receptor variant III

**Methodology**
Molecular

**Test Description**
The EGFRvIII Analysis test is a real-time quantitative RT-PCR assay that is capable of detecting the EGFRvIII mutation that results from an inframe deletion of 801 base pairs spanning exons 2-7 of the coding sequence. Expression of EGFRvIII is quantified by calculating the ratio of (EGFRvIII/EGFRvIII + wild-type EGFR) x 100.

**Clinical Significance**
The EGFRvIII Analysis assay is capable of detecting the EGFRvIII mutation. The mutant receptor is incapable of binding any known ligand. The pro-tumorigenic effects of EGFRvIII seem to rely directly on its ability to signal. EGFRvIII activates several downstream pathways, but a considerable amount of evidence indicates that it preferentially activates the PI3K/Akt signal transduction pathway. EGFRvIII is the most common mutation in glioblastoma multiforme (GBM), occurring in 25-64% of these tumors. It is also found in 20-36% of breast cancers and in about 33% of head and neck squamous cell carcinoma (HNSCC) patients. Compared with wild-type EGFR, EGFRvIII appears to be relatively resistant to treatment with conventional anti-EGFR agents. So the therapeutic potential of targeting EGFRvIII in brain and other tumors is becoming increasingly apparent, with agents against EGFRvIII.

**Specimen Requirements**
FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

**CPT Code(s)**
81479

**Turnaround Time**
10 days

**Level of Service**
Global ✓

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eIF4E

Methodology
Immunohistochemistry (IHC)

Test Description
eIF4E is a key regulator of translation of many cancer-related transcripts and its expression is altered in various cancers and has been associated with worse survival. High expression of eIF4E is associated with adverse tumor characteristics and predicts poor breast cancer-specific survival.

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
• or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1; 88360 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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December 18, 2019
## Elastic Stain

### Methodology
Immunohistochemistry (IHC)

### Test Description
Special stain.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88313x1

### Turnaround Time
24 hours

### Level of Service
Stain Only

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December 18, 2019
EMA

Alternative Name
Epithelial Membrane Antigen

Methodology
Immunohistochemistry (IHC)

Test Description
Epithelial Membrane Antigen (EMA) antibody stains normal and neoplastic cells from various tissues, including mammary epithelium, sweat glands and squamous epithelium. Hepatocellular carcinoma, adrenal carcinoma and embryonal carcinomas are consistently EMA negative, therefore, keratin positivity with negative EMA favors one of these tumors. EMA is frequently positive in meningioma, which can be useful when distinguishing it from other intracranial neoplasms, e.g. Schwannomas. The absence of EMA can also be of value since negative EMA is characteristic of tumors such as adrenal carcinoma, seminomas, paraganglioma and hepatoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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Eosinophilia FISH Panel

Methodology
FISH

Test Description
Probes: PDGFRα, CHIC2, FIP1L1 (4q12) | PDGFRβ (5q33) | FGFR1 (8p11) | CBFB inv(16), t(16;16) | Probes may be ordered separately.

Disease(s): Lymphoid and myeloid neoplasms with eosinophilia, including: Chronic eosinophilic leukemia, eosinophilia, MPN, AML-NOS, lymphoblastic lymphoma, CMML, AML with inversion 16

Clinical Significance
The eosinophilia FISH panel is used to aid in the diagnosis of myeloid and lymphoid neoplasms with eosinophilia and prediction of therapeutic response. The clinical and morphologic features of these diseases can overlap, but each mutation has a characteristic presentation. FIP1L1-PDGFRA rearrangement is generally found in CEL, but the presentation can be as AML, T-lymphoblastic lymphoma, or both simultaneously. Rearrangement is usually cryptic by routine cytogenetics. Myeloid neoplasms with PDGFRB usually present as chronic myelomonocytic leukemia, but may also present as atypical chronic myeloid leukemia (aCML), CEL, MPN with eosinophilia, AML and juvenile myelomonocytic leukemia (JMML). Myeloid and lymphoid neoplasms with FGFR1 are generally aggressive and may present as MPN, AML, T- or B-LBL/ALL, or mixed phenotype acute leukemia. PDGFRα and PDGFRβ mutations predict responsiveness to tyrosine kinase inhibitors, but MPN with FGFR1 rearrangement do not respond to imatinib and there is no currently established TKI therapy, although some promising new therapies have been reported. AML with inversion 16 may present with less than 20% blasts and can be a subtle abnormality by conventional cytogenetics, so confirmation with FISH is recommended.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x4 automated. Codes may differ if manual analysis is performed.

Turnaround Time
3-5 days

Level of Service
Global ✓  Technical ✓

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ER

Alternative Name Estrogen Receptor

Methodology Immunohistochemistry (IHC)

Test Description Estrogen Receptor (ER) belongs to a superfamily of nuclear hormone receptors and is expressed in about 85% of invasive breast cancers. There are two known isoforms of estrogen receptor, ERα and ERβ. It is a weak prognostic factor but a strong predictive factor for response to endocrine therapies, both in adjuvant and metastatic settings. The primary indication to assess ER in breast cancer is to predict response to hormonal therapies such as tamoxifen, other selective estrogen receptor modulators (SERMs) and aromatase inhibitors. In univariate analysis, moderate to strong staining in even 1% of the invasive tumor cells is associated with significant improvement in disease-free survival compared to those patients whose tumor lacks ER expression.

Specimen Requirements • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
• or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)* 88342 x 1 or 88341 x 1; 88361 x 1; 88360 x 1

Turnaround Time Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service Global ✓ Stain Only ✓

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<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>The Excision Repair Cross-Complementing Rodent Repair Deficiency, Complementation Group 1 (ERCC1) polypeptide is required for nucleotide excision repair (NER) of damaged DNA. Elevated levels of ERCC1 have also been reported in cisplatin-resistant cells.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
  • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*        | 88342 x 1 or 88341 x 1; 88360 x 1 |
| Turnaround Time      | Global: 48 hours, Tech-Only (stain only): 24 hours |
| Level of Service     | Global ✓  Stain Only ✓ |

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December 18, 2019
**Methodology**

Immunohistochemistry (IHC)

**Test Description**

ERG oncprotein expression has been shown to be a highly specific marker for prostate cancer. Given the lack of ERG expression in a wide variety of normal epithelial tissues and tumors, detection of ERG by IHC is a valuable tool for diagnosing prostate cancer or determining prostatic origin. ERG is also a highly specific and sensitive marker of endothelial cells and vascular tumors.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓
# Erythroid-Mega Add-On Flow Panel

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Erythroid-Megakaryocyte Add-On Flow Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Flow Cytometry</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are cCD41, cCD61, CD13, CD34, CD45, CD71, CD117, and CD235a (8 markers).</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>This is a select panel of flow markers to define/evaluate an acute myeloid leukemia (AML) subtypes with erythroid (FAB:AML-M6) or megakaryocytic differentiation (FAB:AML-M7).</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>Please contact NeoGenomics’ Billing Department.</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>1 day</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓ Technical ✓</td>
</tr>
</tbody>
</table>

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ETV6-RUNX1 (TEL-AML1) Translocation, t(12;21)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>TEL-AML1, ETV6-RUNX1, ETV6 translocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Real-time RT-PCR for quantitative detection of the t(12;21) ETV6-RUNX1 fusion transcript (formerly called TEL-AML1). Analytical sensitivity is 1 tumor cell in 100,000 normal cells. Positive results are reported as a percentage ratio between quantities of transcript of t(12;21) and the sum of t(12;21) plus a control gene.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The (12;21) translocation occurs in approximately 25-30% of pediatric B-cell acute lymphoblastic leukemia (B-ALL), but is rare in adult cases. This translocation is associated with a high rate of complete remission and good outcome. This assay is recommended for monitoring therapy effectiveness and for the detection of minimal residual disease (MRD) after confirming baseline detection. Due to breakpoint variations, this assay cannot detect all ETV6-RUNX1 translocations and FISH should be used if diagnostic confirmation is required.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • Peripheral blood: 5 mL in EDTA tube.  
• Bone marrow: 2 mL in EDTA tube. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| CPT Code(s)* | 81401 |
| Turnaround Time | 7 days |
| Level of Service | Global ✓ |

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**EWSR1**

**Alternative Name**
Ewing Sarcoma

**Methodology**
FISH

**Test Description**
Probes: EWSR1 (22q12)
Disease(s): Ewing sarcoma, primitive neuroectodermal tumor (PNET)

**Clinical Significance**
This EWSR1 break-apart FISH test is for diagnostic confirmation and classification of tumors diagnosed or suspected to be Ewing sarcoma/primitive neuroectodermal tumor (ES / PNET) based on morphology or immunohistologic studies. EWSR1 translocations are the hallmark and pathognomonic molecular findings of Ewing sarcoma (almost all ES) and "Ewing-like sarcoma". EWSR1 rearrangement partners will not be identified by this FISH test. For that purpose, please see the NGS Sarcoma Fusion Profile which may be ordered separately or as a reflex after positive FISH.

**Specimen Requirements**
- **Bone marrow aspirate**: N/A
- **Peripheral blood**: N/A
- **Fresh, unfixed tissue**: N/A
- **Fluids**: N/A
- **Paraffin block**: Send paraffin block. Also send circled H&E slide for tech-only (required)
- **Cut slides**: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only

**Storage and Transportation**
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88377x1 manual or 88374x1 automated

**Turnaround Time**
4 days

**Level of Service**
Global ✔️  Technical ✔️

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December 18, 2019
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Extended Leukemia/Lymphoma Panel - 31 markers

Methodology
Flow Cytometry

Test Description
Available as global and tech-only. Markers are CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD23, CD33, CD34, CD38, CD41, CD45, CD56, CD64, CD71, CD117, CD138, CD235a, FMC-7, HLA-DR, kappa, and lambda.

Clinical Significance
For diagnosis of leukemia, lymphoma, plasma cell neoplasms, and evaluation of myeloid maturation.

Specimen Requirements
- Bone marrow aspirate or peripheral blood: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- Bone marrow core: 1-2 cm minimum core length in RPMI.
- Fresh, unfixed tissue: 0.2 cm³ minimum in RPMI.
- Fluids and FNAs: Equal parts RPMI and specimen.

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184(x1), 88185(x30). Add 88189(x1) for global.

Turnaround Time
1 day

Level of Service
Global ✓ Technical ✓

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Factor VIII RA

Alternative Name: Factor VIII-related antigen

Methodology: Immunohistochemistry (IHC)

Test Description: Factor VIII-related antigen is a component of Factor VIII complex. Factor VIII-related antigen is one of the available immunohistochemical markers of endothelial cells. It has also been demonstrated in platelets and megakaryocytes. IHC staining of Factor VIII-related antigen is useful for diagnosis of vascular neoplasms and for identification of vascular invasion by neoplasms.

Specimen Requirements:
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88342 x 1 or 88341 x 1

Turnaround Time: 24 hours

Level of Service: Stain Only ✓

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Factor XIIIa

Methodology
Immunohistochemistry (IHC)

Test Description
Factor XIIIa is a dermal dendrocyte marker and shows variable reaction with these types of tumors. It can be used for histiocytic phenotyping and has been reported to mark capillary hemangiomas and tumors of the central nervous system. Factor XIIIa has also been used with CD34 to differentiate between dermatofibroma and dermatofibrosarcoma protuberans.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✅

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December 18, 2019
Fascin

Methodology
Immunohistochemistry (IHC)

Test Description
Human fascin is a highly conserved actin-bundling protein. It is expressed predominantly in dendritic cells. Lymphoid cells, myeloid cells and plasma cells are negative for staining. However, Reed-Sternberg cells in Hodgkin lymphoma are positive for fascin staining. Epstein-Barr virus may induce expression of fascin in B-cells.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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**FGFR CDx Molecular Analysis**

**Alternative Name**
therascreen® FGFR RGQ RT-PCR Kit

**Methodology**
Molecular

**Test Description**
FGFR CDx Molecular Analysis is a qualitative RT-PCR assay, FDA-approved for detection of four point mutations in the FGFR3 gene (p.R248C, p.S249C, p.G370C and p.Y373C) and two FGFR3 fusions (FGFR3:TACC3v1 and FGFR3:TACC3v3) to identify certain urothelial carcinoma patients for treatment with BALVERSA™ (erdafitinib). The test also detects and reports an additional FGFR3 fusion (FGFR3:BAIAP2L1) and two FGFR2 fusions (FGFR2:BICC1 and FGFR2:CASP7).

**Clinical Significance**
FGFR CDx Molecular Analysis is the first companion diagnostic test for identification of fibroblast growth factor receptor alterations in urothelial carcinoma. Patients with FGFR alterations identified by this test may be eligible for treatment with BALVERSA™ (erdafitinib) which is indicated for patients with locally advanced or metastatic urothelial carcinoma who have progressed on platinum-based chemotherapy.

FGFR plays an important role in cell development, differentiation, survival, migration, angiogenesis and carcinogenesis. FGFR aberrations can contribute to carcinogenic events by influencing PI3K/AKT, STAT and RAS/MAPK pathways. FGFR3 abnormalities accounts for ~70% of non-muscle-invasive bladder cancers and 10-20% of invasive bladder cancers. FGFR3 is considered as an important therapeutic target in both non-invasive and invasive UC.

**Specimen Requirements**
FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives. Required tissue is minimum 100mm². Required Tumor content is 80%. (This is higher than most molecular tests and the amount of tumor required is more than one typically sees in core needle biopsy specimens).

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
Prior to 12/31/2019 CPT Code 81479x1; as of 01/01/2020 CPT Code 0154U

**Turnaround Time**
8 business days / 10 calendar days

**Level of Service**
Global

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December 18, 2019
FGFR3/IgH t(4;14)

Methodology
FISH

Test Description
Probes: FGFR3/IgH t(4;14)
Disease(s): Multiple myeloma, MGUS

Clinical Significance
Available separately or as part of the Plasma Cell Myeloma FISH panels: Plasma Cell Myeloma IgH Complex FISH Panel (non-New York) and Plasma Cell Myeloma Prognostic FISH Panel (non-New York)

Specimen Requirements
- Bone Marrow Aspirate: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- Peripheral Blood: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- Fresh, Unfixed Tissue: Tissue in RPMI
- Fluids: Equal parts RPMI to specimen volume.
- Paraffin or Cut Slides: N/A

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x1 automated. Codes may differ if manual analysis is performed.

Turnaround Time
3-5 days

Level of Service
Global ✓  Technical ✓

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December 18, 2019
Fite (Leprosy) Stain

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88312x1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓
FLi-1

Methodology
Immunohistochemistry (IHC)

Test Description
Friend leukemia integration (FLI1) is a nuclear transcription factor and has been reported as the first nuclear marker of endothelial differentiation. FLI1 labels hemangiomas, angiosarcomas, Kaposis sarcoma, Ewings and Merkel cell carcinoma. FLI1 is expressed in normal endothelial cells, megakaryocytes, normal breast epithelia.

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔
# FLT3 Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>FLT3, FLT3 TKD, FLT3 ITD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Detection of internal tandem duplication and exon 20 tyrosine kinase domain (TKD) mutations using fragment-length analysis and bi-directional sequencing. Positive results identify specific TKD mutations or report ITD results quantitatively as percent abnormal ITD peak. Testing may be performed on plasma to increase sensitivity.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Testing for FLT3 and other gene mutations in AML patients with intermediate-risk cytogenetic abnormalities can improve risk stratification. The presence of an FLT3 mutation in a patient with AML implies aggressive disease.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • Peripheral blood: 5 mL in EDTA tube.  
• Bone marrow: 2 mL in EDTA tube.  
• FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 81245, 81246 |
| Medicare MolDX CPT Code(s)* | 81479 |
| Turnaround Time | 5 days |
| Level of Service | Global ✓ |

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Fontana Masson

Methodology

Immunohistochemistry (IHC)

Test Description

Special stain.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88313x1

Turnaround Time

24 hours

Level of Service

Stain Only ✔️

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December 18, 2019
## FOXP1

### Methodology

**Immunohistochemistry (IHC)**

### Test Description

FOX P1 (Forkheadbox-P1) is a transcription factor widely expressed in normal tissues. Its expression is commonly deregulated in malignancies. FOX P1 is differentially expressed in resting and activated B cells. FOX P1 expression has been demonstrated in a subset of diffuse large B-cell lymphomas (DLBCL) and is more common in the non-germinal center (non-GC), activated B-cell type. Loss of FOX P1 expression has been correlated with a poor prognosis in solid tumors, such as breast cancer. In contrast, high level expression of smaller isoforms of the FOX P1 protein identifies high risk patients with DLBCL. The study demonstrated a correlation between strong nuclear positivity and poor prognosis in a subset of patients with BCL2-positive, t(14;18)-negative, non-GC DLBCL.

### Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*

88342 x 1 or 88341 x 1

### Turnaround Time

24 hours

### Level of Service

Stain Only ✓

---

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December 18, 2019
# FOXP3

## Methodology

Immunohistochemistry (IHC)

## Test Description

FOX P3 is expressed at a high level in CD25 positive/CD4 positive regulatory T cells, at a low level in CD4 positive/CD25 negative cells, and is absent in CD4 negative/CD8 positive T cells. FOX P3 may be a master regulatory gene and a more specific marker of regulatory T cells than other T cells.

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88342 x 1 or 88341 x 1

## Turnaround Time

24 hours

## Level of Service

Stain Only ✅

---

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<table>
<thead>
<tr>
<th><strong>FSH</strong></th>
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<tr>
<td><strong>Alternative Name</strong></td>
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<tr>
<td><strong>Methodology</strong></td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
</tr>
</tbody>
</table>

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# Galectin 3

**Methodology**
- Immunohistochemistry (IHC)

**Test Description**
Galectins are a structurally-related family of proteins; 14 different galectins have been characterized. They are cytoplasmic proteins and can be translocated into the nucleus. Gal-3 has been found overexpressed in most malignant thyroid neoplasms. However, it was not detectable in normal and non-malignant tissue. Galectin 3 is a useful marker to differentiate benign from malignant (Galactin-3 positive) thyroid neoplasms.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342 x 1 or 88341 x 1

**Turnaround Time**
- 24 hours

**Level of Service**
- Stain Only ✓

---

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December 18, 2019
# Gastrin

## Methodology
- Immunohistochemistry (IHC)

## Test Description
Gastrin, a polypeptide hormone, occurs naturally in three forms: gastrin-14, gastrin-17 and gastrin-34. This antibody labels gastrin or gastrin-analogue producing cells in gastrin-secreting tumors and G cell hyperplasia.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
- Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
- 88342 x 1 or 88341 x 1

## Turnaround Time
- 24 hours

## Level of Service
- Stain Only ✓

---

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December 18, 2019
# GATA3

## Methodology

Immunohistochemistry (IHC)

## Test Description

GATA3 (GATA binding protein 3) is a member of the GATA family of transcription factors. Among several other roles, GATA3 is involved in luminal cell differentiation in the mammary gland and appears to control a set of genes involved in the differentiation and proliferation of breast cancer. The expression of GATA3 is associated with the expression of estrogen receptor-alpha (ER) in breast cancer. GATA3 has been shown to be a novel marker for bladder cancer. GATA3 stains almost all of urothelial carcinomas, but stained no prostate or renal carcinomas.

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88342 x 1 or 88341 x 1

## Turnaround Time

24 hours

## Level of Service

Stain Only ✔

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December 18, 2019
### GCDFP15

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Gross Cystic Disease Fluid Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>This antibody is specific to a 15kDa monomer protein called Gross Cystic Disease Fluid Protein-15 (GCDFP-15). GCDFP15 is expressed in apocrine epithelia, lacrimal, ceruminous and Moll’s glands, as well as in numerous serous cells of the submandibular, tracheal, bronchial, sublingual and minor salivary glands. It can be of use in the identification of breast carcinoma, salivary duct carcinoma and apocrine epithelia.</td>
</tr>
</tbody>
</table>
| Specimen Requirements             | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
                                       • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
                                       • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation        | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*                      | 88342 x 1 or 88341 x 1              |
| Turnaround Time                   | 24 hours                            |
| Level of Service                  | Stain Only ✓                        |

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December 18, 2019
GCET1

Methodology
Immunohistochemistry (IHC)

Test Description
The GCET1 gene codes for a serpin expressed in germinal center (GC) B-cells. GCET1 is highly restricted to a subset of GC B-cells and GC-derived lymphomas. It is preferentially expressed in follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) with GC B-cell differentiation.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Specimen Requirements
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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December 18, 2019
GFAP

Alternative Name  
Glial Fibrillary Acidic Protein

Methodology
Immunohistochemistry (IHC)

Test Description
Glial Fibrillary Acidic Protein (GFAP) is the major protein found in astrocytes and its expression is evidence of astroglial origin and differentiation. Gliomas are the most common cerebral neoplasm in adults and include astrocytomas, oligodendrogliomas and glioblastomas. It can also be demonstrated in ependymal cells, ependymomas, subependymomas, glioblastomas, mixed central nervous system neoplasms and gangliomas. It is detected in immature but not mature oligodendrocytes and neurons. Anti-GFAP antibodies do not cross-react with neurons, fibroblasts or muscle cells. Anti-GFAP antibodies are useful in differentiating primary gliomas from metastatic lesions in the brain and for documenting astrocytic differentiation in tumors outside the central nervous system.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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December 18, 2019
**GH**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Growth Hormone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>Growth Hormone (GH) is produced by the somatotroph cells in the pituitary. This marker is useful in classification of pituitary tumors and the study of pituitary disease (acromegaly).</td>
</tr>
</tbody>
</table>
| Specimen Requirements | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*     | 88342 x 1 or 88341 x 1 |
| Turnaround Time  | 24 hours |
| Level of Service | Stain Only ✓ |

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December 18, 2019
## Giemsa for sections

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Special stain.</td>
</tr>
</tbody>
</table>
| Specimen Requirements| • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
                        • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3)  
                          positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
                          • Block and slide identifiers should be clearly written and match exactly with the specimen ID  
                             and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*         | 88312x1                    |
| Turnaround Time      | 24 hours                   |
| Level of Service     | Stain Only ✓               |
Glucagon

Methodology
Immunohistochemistry (IHC)

Test Description
Glucagon antibody is used for the identification of tumors and hyperplasias of pancreatic islets. This antibody labels A cells of the endocrine mammalian pancreas. It reacts with glucagon in a large number of mammalian species.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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GLUT1

Methodology
Immunohistochemistry (IHC)

Test Description
Glucose transporter 1 (GLUT1) facilitates the transport of glucose across the plasma membranes of mammalian cells. GLUT-1 is expressed in many human tissues including those of the colon, lung, stomach, esophagus and breast. Overexpression of GLUT1 is associated with aggressive behavior in some cancers, including breast, renal, and bladder carcinoma. Expression of GLUT1 can help distinguish malignant mesothelioma from reactive mesothelial proliferations.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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## Glutamine Synthetase

<table>
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<th><strong>Alternative Name</strong></th>
<th>GS</th>
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</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Glutamine synthetase (GS) is strongly expressed in a majority of hepatocellular carcinoma, including cases of early HCC and low grade HCC.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td></td>
</tr>
<tr>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or</td>
<td></td>
</tr>
<tr>
<td>• One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered</td>
<td></td>
</tr>
<tr>
<td>• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
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<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
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<td><strong>CPT Code(s)</strong></td>
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<td><strong>Turnaround Time</strong></td>
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<tr>
<td><strong>Level of Service</strong></td>
<td>Stain Only ✔</td>
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Glycophorin A

Methodology

Immunohistochemistry (IHC)

Test Description

Glycophorin A (sialoglycoprotein alpha) is one of two transmembrane proteins exposed on the outer surface of normal human erythrocytes. This monoclonal antibody reacts with an epitope located on the extracellular domain of glycophorin A and does not cross-react with glycophorin D (glycophorin delta). In normal human erythrocytes, glycophorin A is expressed during all stages of differentiation, from the normoblast to the mature erythrocyte. Once maximally expressed, the quantity of glycophorin A in each red blood cell remains constant. Glycophorin A has also been located in the blast cells of cases of erythroleukemia. Cases of acute lymphoblastic and myeloblastic leukemia are not reactive.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only

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**Glypican-3**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
A useful marker to differentiate between benign (negative) and malignant (positive) liver diseases (HCCs).

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342x1 or 88341x1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

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### Gram Stain (Brown & Hopp modification)

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Special stain</td>
</tr>
</tbody>
</table>
| Specimen Requirements| • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation| Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*         | 88312x1                     |
| Turnaround Time      | Global: 48 hours, Tech-Only (stain only): 24 hours |
| Level of Service     | Global ✓ Stain Only ✓       |

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**Granzyme B**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Granzyme B antibody labels activated human cytotoxic T lymphocytes (CTL) and natural killer (NK) cells. This marker can be a useful tool for the identification of anaplastic large cell lymphoma, large granular lymphocytic leukemias, hepatosplenic T-cell lymphomas, intestinal T-cell lymphomas, NK-like T-cell lymphomas, NK-cell lymphomas, nasal T/NK-cell lymphomas, and subcutaneous panniculitic T-cell lymphomas of T or NK phenotype.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

---

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## Grocott Methanamine Silver (GMS)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Special stain. GMS (Grocott Methenamine-Silver Nitrate) Fungus Stain is used to demonstrate fungal organisms in tissue sections.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88312x1

**Turnaround Time**

Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**

Global ✔️ Stain Only ✔️

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December 18, 2019
### GST Pi

**Alternative Name**
- Glutathione S Transferase Pi

**Methodology**
- Immunohistochemistry (IHC)

**Test Description**
Glutathione S Transferase Pi (GSTpi) is a cytosolic enzyme that catalyzes the conjugation of toxic compounds to glutathione for transport out of the cell. Increased expression of GSTp has been demonstrated to show increased resistance to alkylating agents, such as cyclophosphamide, ifosfamide, and melphalan. GSTp is widely distributed throughout the body and has been identified in epithelial elements of thyroid, urinary, digestive track, and hepatic bile ducts. Adenocarcinomas of the stomach, kidney, uterus and ovary, as well as squamous cell tumors of the head and neck, melanomas, and carcinoid tumors of the lung all demonstrate reactivity with this antibody.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1, 88360 x 1

**Turnaround Time**
- Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
- Global ✔
- Stain Only ✔

---

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December 18, 2019
H. Pylori

Alternative Name
Helicobacter Pylori

Methodology
Immunohistochemistry (IHC)

Test Description
This antibody reacts with H. pylori on the surface and in the cytoplasm of epithelial cells of stomach biopsies. Studies have shown that H. pylori plays an important role in the etiology of chronic active gastritis and the development of peptic ulcer disease. Immunohistochemistry can provide rapid detection of this bacterium.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓  Stain Only ✓
# Hairy Cell Leukemia (HCL) Add-On Flow Panel

## Methodology
Flow Cytometry

## Test Description
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD11c, CD19, CD20, CD22, CD25, CD45, CD103, kappa, and lambda (9 markers).

## Clinical Significance
Used to diagnose hairy cell leukemia and hairy cell leukemia-variant.

## Specimen Requirements
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

## Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
Please contact NeoGenomics' Billing Department.

## Turnaround Time
1 day

## Level of Service
Global ✔️  Technical ✔️

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December 18, 2019
### Hairy Cell Leukemia (HCL) Follow-Up Flow Panel

**Methodology**

Flow Cytometry

**Test Description**

Available as global and tech-only. Please provide clinical history including the time after treatment. Prior immunophenotyping at NeoGenomics with Standard or Extended Flow Panel is strongly recommended. Clients who decline full phenotyping and order a global or push-to-global Follow-Up Panel are requested to provide details of the diagnosis by submitting at least one of the following: previous flow cytometry report, previous pathology report, and/or clinical history notes. Markers are CD11c, CD19, CD20, CD22, CD25, CD45, CD103, kappa, and lambda.

**Clinical Significance**

For hairy cell leukemia (HCL) monitoring after diagnosis is established. This is not a minimal residual disease (MRD) panel since the standard number of events is collected.

**Specimen Requirements**

- **BM Aspirate:** 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Peripheral Blood:** 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI and specimen volume

**Storage and Transportation**

Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88184(x1), 88185(x8). Add 88188(x1) for global.

**Turnaround Time**

1 day

**Level of Service**

Global ✓  Technical ✓

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Hall Bile Stain

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88313x1

Turnaround Time
24 hours

Level of Service
Stain Only

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December 18, 2019
HBME1

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
HBME1 is an anti-mesothelial monoclonal antibody that recognizes an unknown antigen on the microvilli of mesothelioma cells. It stains normal mesothelial cells as well as epithelial mesotheliomas in a thick membrane pattern. This antibody also reacts with some carcinomas showing cytoplasmic immunostaining.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only

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December 18, 2019
# HCG-Beta (Human Chorionic Gonadotropin Beta)

## Methodology
Immunohistochemistry (IHC)

## Test Description
HCG-beta is secreted in large quantities by the placenta and normally is found in maternal circulation during early fetal development. Polyclonal Rabbit Anti-Human Chorionic Gonadotropin is intended for use in immunocytochemistry. The antibody labels hCG-containing cells and may be used for the demonstration of trophoblastic elements, e.g. in germ cell tumors.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1

## Turnaround Time
24 hours

## Level of Service
Stain Only ✓

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December 18, 2019
# Hematogone Add-On Flow Panel

<table>
<thead>
<tr>
<th><strong>Methodology</strong></th>
<th>Flow Cytometry</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Description</strong></td>
<td>Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD10, CD19, CD20, CD22, CD34, CD38, CD43, CD45, and cTdT (9 markers).</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>This panel is designed to further evaluate immature B cells. Used to distinguish hematogones from B-lymphoblasts.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>Please contact NeoGenomics’ Billing Department.</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>1 day</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓  Technical ✓</td>
</tr>
</tbody>
</table>

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# Hemoglobin A

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Hemoglobin A antibody reacts with the alpha chain of adult hemoglobin A. This antibody is useful in the detection of red blood cell precursors. Immunohistochemical localization of hemoglobin is excellent as an erythroid marker for the detection of immature, dysplastic, and megaloblastic erythroid cells in myeloproliferative disorders, such as erythroleukemia. In contrast, myeloid cells, lymphoid cells, plasma cells, histiocytes, and megakaryocytes stain negative with anti-hemoglobin A. Anti-hemoglobin A, combined with antibodies against CD34, CD117, CD68, and MPO can be helpful in distinguishing between reactive extramedullary hematopoiesis and that seen in neoplastic myeloid disorders in spleen. Anti-hemoglobin A is limited to expression by erythroid precursors in bone marrow and is therefore of assistance in calculating percentages of erythroid precursors.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or&lt;br&gt;• One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered&lt;br&gt;• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88342 x 1 or 88341 x 1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Stain Only ✓</td>
</tr>
</tbody>
</table>

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December 18, 2019
# Hepatitis B Core Antigen

## Methodology
Immunohistochemistry (IHC)

## Test Description
Hepatitis B virus belongs to the hepatovirus family and causes type B hepatitis. Hepatitis B virus is spherical in shape with a diameter of 42 nm. Core antigens are localized within the nuclei, whereas the surface antigens are present in the cytoplasm of the infected cells. Antibodies to surface antigens appear in circulation at an early stage of infection, whereas the antibodies to the core antigens are detected in blood after several weeks. Hepatitis B core antibody targets Hepatitis B Virus Core Antigen in IHC applications.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1

## Turnaround Time
- Global: 48 hours
- Tech-Only (stain only): 24 hours

## Level of Service
- Global ✓
- Stain Only ✓

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December 18, 2019
Hepatitis B Surface Antigen

Methodology
Immunohistochemistry (IHC)

Test Description
Hepatitis B virus, belongs to the hepatovirus family, and causes type B hepatitis. It is spherical in shape with a diameter of 42 nm. It contains a 27 nm partially double stranded DNA core enclosed within a lipoprotein coat. The antigens in the outer surface are called hepatitis B virus surface antigens. Antibodies to surface antigens appear in circulation at an early stage of infection, whereas the antibodies to the core antigens are detected in blood after several weeks. Hepatitis B surface antibody targets Hepatitis B Virus Surface Antigen in IHC applications.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔ Stain Only ✔

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**HepPar1**

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Anti-Hepatocyte Specific Antigen (HepPar1) recognizes both benign and malignant liver derived tumors such as hepatoblastoma, hepatocellular carcinoma and hepatic adenoma. It recognizes both adult and fetal liver tissue. The typical pattern is a granular cytoplasmic staining. This antibody is useful in differentiating hepatocellular carcinomas from adenocarcinomas, either primary or metastatic. HepPar1 also can be used in differential diagnostic separation of hepatoblastoma versus other small round cell tumors. HepPar1 is also expressed in a subset of gastric carcinoma.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✔

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December 18, 2019
**HER2 Breast**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>HER2, HER-2/neu, PATHWAY HER2 (4B5), anti-Her2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>This test uses the Ventana PATHWAY anti-HER-2/neu antibody (clone 4B5) for the semi-quantitative detection of HER-2 antigen in sections of FFPE normal and neoplastic tissue. The test is FDA-approved with the indication as an aid in the assessment of breast cancer patients for whom Herceptin treatment is considered. Staining is performed according to the package insert. Scoring for breast cases is performed according to ASCO/CAP 2013 guidelines. Scoring for gastroesophageal and other tissues is according to the 2010 ToGA trial standards. HER2 is an oncogene that is over-expressed in a variety of cancers including some breast carcinomas. The expected breast cancer overexpression rate varies based on the grade and type of cancer. Known artifacts, such as edge artifact, tissue retraction and tissue crush may give the false impression of overexpression. Care should be taken to avoid assessing these areas, especially in needle core biopsies that generally harbor all of these artifacts.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or - One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88360x1; 88361x1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓  Stain Only ✓</td>
</tr>
</tbody>
</table>

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HER2 Breast Cancer

Alternative Name: HER2 neu
Methodology: FISH

Test Description:
- **Probes:** HER2 (17q11.2-q12) | 17 (Cen 17)
- **Disease(s):** Breast cancer

Clinical Significance: Determines anti-HER2 therapy.

Specimen Requirements:
- Pathology Report: A copy of the pathology report is required for HER2 testing (global cases only).
- Bone Marrow Aspirate: N/A
- Peripheral Blood: N/A
- Fresh, Unfixed Tissue: N/A
- Fluids: N/A
- Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required).
- Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation: Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88374x1 automated. Codes may differ if manual analysis is performed.

Turnaround Time: 3-5 days

Level of Service:
- Global ✓
- Technical ✓

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HER2 Gastric & Non-Breast

Alternative Name
HER2 neu

Methodology
FISH

Test Description
Probes: HER2 (17q11.2-q12) | 17 (Cen 17)
Disease(s): Gastric cancer, gastroesophageal junction (GEJ) cancer, esophageal adenocarcinoma, and others

Clinical Significance
Determines anti-HER2 therapy.

Specimen Requirements
- Pathology Report: A copy of the pathology report is required for HER2 testing (global cases only).
- IHC Report with GEA Samples: For gastroesophageal specimens submitted for global HER2 Non-Breast FISH, we require a copy of the HER2 IHC report (if it is not available to us in NeoLINK™) so that we may interpret FISH results using 2016 CAP/ASCP/ASCO guidelines. Client Services will call your office or lab for missing IHC reports.
- Bone Marrow Aspirate: N/A
- Peripheral Blood: N/A
- Fresh, Unfixed Tissue: N/A
- Fluids: N/A
- Paraffin Block: Send paraffin block. Also send circled H&E slide for tech-only (required).
- Cut Slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x1 automated. Codes may differ if manual analysis is performed.

Turnaround Time
3-5 days

Level of Service
Global ✔  Technical ✔

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December 18, 2019
HGAL

Methodology
Immunohistochemistry (IHC)

Test Description
HGAL is specifically expressed in the cytoplasm of germinal center B-cells, but is absent in mantle and marginal zone. This antibody is highly specific for germinal center B-cells and it is an ideal marker for the detection of germinal center-derived B-cell lymphomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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HHV8

Alternative Name
Human Herpesvirus, Type 8

Methodology
Immunohistochemistry (IHC)

Test Description
Human Herpes Virus (HHV) 8 is the likely etiological agent of Kaposi’s sarcoma (KS), and is present in all cases. HHV 8 encodes a latent nuclear antigen (LANA) that is the product of the viral gene of 73. HHV8 has also been identified in multicentric Castleman disease (MCD), and primary effusion lymphoma (PEL).

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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High Sensitivity PNH Evaluation

Methodology
Flow Cytometry

Test Description
Markers are CD14, CD15, CD24, CD45, CD59, CD64, CD235a (Glycophorin A), and FLAER. In validation studies, this assay was shown to detect RBC and granulocyte PNH clones with frequency down to 0.01%.

Clinical Significance
Useful for diagnosis of PNH (paroxysmal nocturnal hemoglobinuria) and monitoring response to therapy. Small PNH clones may also be identified in patients with aplastic anemia and MDS who may respond to immune modulation therapy. Also identifies patients at increased risk of developing overt PNH. This assay is consistent with International Clinical Cytometry Society (ICCS) Guidelines. NeoGenomics no longer performs PNH testing on bone marrow specimens.

Specimen Requirements
• **Peripheral blood**: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow, no gel separator) is acceptable. Please provide a recent CBC report. Bone marrow specimens are not acceptable.

Storage and Transportation
Specimens should be received at NeoGenomics within 48 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184x1, 88185x7, 88187x1

Turnaround Time
1 day

Level of Service
Global ✓ Technical ✓

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High-Grade B-Cell Lymphoma Reflex FISH Panel (Non-New York)

Methodology
FISH

Test Description
Probes: MYC (8q24). If rearranged, reflex to concurrent BCL2 (18q21) and BCL6 (3q27).
Disease(s): B-cell lymphoma, double-hit lymphoma, triple-hit lymphoma
Note: This test is available on a global basis. Tech-only clients may order probes individually.

Clinical Significance
The High-Grade B-Cell Lymphoma Reflex Panel differentiates double-hit or triple-hit lymphomas (which have MYC rearrangements together with BCL2 and/or BCL6 rearrangements) from Burkitt lymphoma or diffuse large B-cell lymphoma. Double-hit and triple-hit lymphomas are difficult to classify morphologically without aid of cytogenetics/FISH or IHC, and are associated with an aggressive course. Testing is indicated when B-cell lymphoma patients experience transformation, relapse, or refractory disease. This reflex panel may be considered a cost-effective alternative to the High-Grade/Large B-Cell Lymphoma FISH Panel when clinical circumstances allow an additional few days for reflex testing if MYC is rearranged. IgH rearrangement may be inferred from positive results, but is not specifically identified.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block:** H&E slide (required) plus paraffin block.
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x1 automated or 88377x1 manual without reflex; with reflex add 88374x2 automated or 88377x2 manual

Turnaround Time
3-5 days

Level of Service
Global

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December 18, 2019
High-Grade/Large B-Cell Lymphoma Panel (NY and non-NY)

**Alternative Name**
Large B-Cell Lymphoma

**Methodology**
FISH

**Test Description**
Probes: BCL6 (3q27) | MYC (8q24) | IgH/BCL2 t(14;18) | Optional probes: MYC/IgH/CEN8 t(8;14) [available to all clients] and BCL2 (18q21) [non-New York clients only]

Disease(s): B-cell lymphoma, double-hit lymphoma, triple-hit lymphoma

**Clinical Significance**
This panel differentiates double-hit or triple-hit lymphomas (which have MYC rearrangements together with BCL2 and/or BCL6 rearrangements) from Burkitt lymphoma or diffuse large B-cell lymphoma. Double-hit and triple-hit lymphomas are difficult to classify morphologically without aid of cytogenetics/FISH or IHC, and are associated with an aggressive course. Testing is indicated when B-cell lymphoma patients experience transformation, relapse, or refractory disease. Clients may choose to add MYC/IgH/CEN8 t(8:14) and/or BCL2 breakapart testing to their initial test order. MYC/IgH/CEN8 will confirm heavy chain rearrangement when MYC is rearranged. BCL2 breakapart allows inclusion of BCL2 rearrangements other than IgH/BCL2 t(14;18).

Clients may want to consider the High-Grade B-Cell Lymphoma Reflex FISH Panel as a cost-effective alternative.

**Specimen Requirements**
- **Bone marrow aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, unfixed tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only. Testing on this specimen type is not yet available for NY specimens.
- **Cut slides:** H&E slide (required) plus 6 unstained slides cut at 4 microns. Circle H&E for tech-only. Testing on this specimen type is not yet available for NY specimens.

**Storage and Transportation**
Refrigerate fresh specimens. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88374x3 automated. Add 88374x1 for each of the two optional probes sets ordered. Codes may differ if manual analysis is performed.

**Turnaround Time**
4 days for both unfixed and FFPE specimens

**Level of Service**
Global ✔  Technical ✔

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December 18, 2019
HLADR

Methodology

Immunohistochemistry (IHC)

Test Description

This antibody to the human leukocyte antigen (HLA) MHC class II surface antigen stains a variety of cells expressing the HLADR antigen including B-lymphocytes, macrophages and dendritic cells. HLADR antibody is useful in the differentiation of lymphomas and leukemias and it discriminates most B-cell derived lymphomas from those of T-cell origin.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓

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# HMB45

## Methodology
Immunohistochemistry (IHC)

## Test Description
Antibody clone HMB45 recognizes a melanoma-specific antigen by reacting with melanoma cells, nevus cells and neonatal melanocytes. HMB45 is expressed on the majority of malignant melanoma cases as well as on tumors of melanocytic differentiation.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1

## Turnaround Time
24 hours

## Level of Service
Stain Only

---

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December 18, 2019
**HPL**

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Human Placental Lactogen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Human Placental Lactogen (HPL) is a polypeptide hormone synthesized in syncytiotrophoblastic cells of placenta and has been used as a tissue marker for certain trophoblastic tumors.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**      | 88342 x 1 or 88341 x 1 |
| **Turnaround Time**  | 24 hours |
| **Level of Service** | Stain Only ✓ |

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## HPV DNA Tissue Testing

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>HPV DNA, HPV genotyping (not for Pap), human papillomavirus, HPV Tissue Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>HPV DNA Tissue Testing is performed on FFPE tissue. It uses PCR and fragment analysis for qualitative detection and genotyping of human papillomavirus (HPV) low risk types 6/11 and high risk types 16, 18, 31, 33, 45, and 58. When detected, specific genotypes are identified except for 6 and 11 which cannot be distinguished from each other and are reported as positive for the combination 6/11.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>HPV DNA testing on FFPE tissue in head and neck squamous cell carcinomas (HNSCC), anogenital, and cervical lesions provides a complementary or alternative method to testing by p16 IHC or HPV ISH. In anogenital specimens, testing can distinguish presence of low-risk HPV types 6 and 11, associated with benign warts, from high-risk types which are associated with approximately 90% of anal cancers, 40% of vaginal cancers, and 40% of penile cancers. HPV is detected in up to 60-70% of oropharyngeal cancers and approximately 30% of HNSCC overall. HPV status serves as a prognostic marker head and neck cancer. Patients with HPV-positive cases have improved response to treatment and longer survival than patients with HPV-negative tumors in clinical trials.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>FFPE solid tumor tissue</strong>: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides with tissue area approximately 100 mm² cut at thickness of 5-10 microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>87624</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>5 - 7 DAYS</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global</td>
</tr>
</tbody>
</table>

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HPV RNA ISH

Alternative Name
HPV RNA ISH 16/18, HPV RNA ISH High Risk Cocktail, HPV RNA ISH Low Risk Cocktail

Methodology
In Situ Hybridization (ISH)

Test Description
In situ hybridization on FFPE tissues for qualitative detection of E6/E7 mRNA in up to 28 HPV subtypes with the complete panel: low risk (10 subtypes: 6, 11, 40, 44, 54, 69, 70, 71, 74) plus high risk (18 subtypes: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82). Testing with the complete panel is recommended, but orders for partial panels are accepted. Orderable components are (1) 16/18 High Risk; (2) High Risk Cocktail with all of the previously-named high risk subtypes; and (3) Low Risk Cocktail with all previously-named low risk subtypes. Reports will identify which component or cocktail is positive, but will not identify specific subtypes as positive. Testing is performed only on a global or consult basis at this time.

Clinical Significance
This test provides detection of human papilloma virus E6/E7 mRNA, histological localization of HPV within the tissue, and differentiation of low-risk vs. high-risk subtypes in formalin-fixed paraffin-embedded tissues. Positive results in this assay provide evidence of transcriptional activation of viral E6/E7 oncogenes and support the diagnosis of active infection. Studies have shown RNA ISH to have greater sensitivity and specificity than DNA ISH for HPV detection. RNA ISH may be useful in resolving cases with p16 overexpression that tested negative for HPV DNA by other methods. Testing is commonly performed on tissues of the uterine cervix, anus, and head and neck, particularly the oropharynx. HPV ISH may help resolve cervical cases with morphology discrepant from HPV status as determined from cytology specimens. Positive HPV status is associated with improved overall survival in oropharyngeal squamous cell carcinoma.

Specimen Requirements
- **Cut Slides:** Block is preferred over cut slides. Send 9-11 cut slides (minimum is 9) plus one H&E slide. Sections must be wrinkle and artifact-free. No additives in the water bath. Cut sections at 4-5 microns, and place tissue at the center bottom of a positively-charged slide.
- **Paraffin block:** Formalin-fixed paraffin-embedded tissue. Block should be sent with a cold pack. Block identifiers should be clearly written and match exactly with the specimen ID and the block labeling as noted on the requisition.
- **Note:** This test is not available on samples in ThinPrep® or SurePath™ Pap vials.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
Complete panel (16/18, high risk cocktail, and low risk cocktail): 88365x1, 88364x2. Partial panel: 88365x1 for first component/cocktail, 88364x1 for second component/cocktail.

Turnaround Time
5 days

Level of Service
Global

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HRAS Mutation Analysis

Alternative Name: HRAS, RAS testing

Methodology: Molecular

Test Description: Bi-directional sequencing of HRAS exons 2 and 3 which includes sites of common activating mutations in codons 12, 13, 59 and 61.

Clinical Significance: Samples are accepted for somatic and germline HRAS mutation testing. HRAS is highly homologous with KRAS and NRAS; all are members of the most frequently mutated family of oncogenes. HRAS mutations are found in a wide variety of solid tumors, including cancers of the bladder, thyroid, upper digestive tract, and melanoma. Germline HRAS mutations are associated with Costello syndrome, which confers a lifetime risk of approximately 15% for malignant tumors including rhabdomyosarcoma and neuroblastoma in childhood and bladder cancer in adolescence and young adulthood.

Specimen Requirements:
- Peripheral blood: 5 mL in EDTA tube.
- Bone marrow: 2 mL in EDTA tube.
- FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81403

Turnaround Time: 7 days

Level of Service: Global

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December 18, 2019
HSV I/II

Alternative Name  Herpes Simplex 1 Antigen, HSV1, Herpes Simplex 2 Antigen, HSV2

Methodology  Immunohistochemistry (IHC)

Test Description  This antibody cocktail reacts with Herpes Simplex Virus (HSV) type 1- or type 2-specific antigens and with antigens common to both types. The antibodies react with all the major glycoproteins present in the viral envelope and at least one core protein as determined by crossed immunoelectrophoresis. Neither antibody cross-reacts with cytomegalovirus or Epstein-Barr virus. The cocktail is well suited for the detection of HSV in human cellular material obtained from superficial lesions or biopsies and for the early identification of HSV in infected tissue cultures.

Specimen Requirements  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation  Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*  88342 x 1 or 88341 x 1

Turnaround Time  Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service  Global ✓  Stain Only ✓

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ICOS

**Alternative Name**  
CD278

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
ICOS (Inducible Co-Stimulator, CD278) is a member of the CD28 family that regulates T-cell activity and immune responses. ICOS is primarily expressed on activated CD4+ and CD8+ T-cells. It plays an important role in the diagnosis of T-cell lymphomas of follicular helper T-cell origin, and is useful when combined with multiple markers for follicular helper T-cells.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342x1 or 88341x1

**Turnaround Time**  
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**  
Global ✔  Stain Only ✔

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### IDH1

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>IDH1 R132H</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>IDH1 mutations are frequent genetic alterations in low-grade diffuse gliomas and secondary glioblastoma (70%). This alteration is observed in fewer than 10% of primary GBM cases. IDH1 IHC antibody is a diagnostic tool in assessing the IDH1 R132H mutational status and differentiating primary GBM tumors from the others.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
  • or  
  • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88342 x 1 or 88341 x 1 |
| **Turnaround Time** | Tech-Only (stain only): 24 hours |
| **Level of Service** | Stain Only ✓ |

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## IDH1 & IDH2 Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>IDH1 Mutation Analysis, IDH2 Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of the exon 4 mutation hotspot regions in both the IDH1 and IDH2 genes. IDH1 and IDH2 are analyzed concurrently. In hematological disease, testing may be performed on plasma to increase sensitivity. For solid tumors, tumor enrichment is performed before extraction.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>IDH1 or IDH2 mutations are detected in approximately 15-20% of acute myeloid leukemia (AML) and &gt;70% grade II or III brain gliomas. Patients with AML and mutations are likely to have aggressive disease, while mutations in gliomas are associated with better prognosis. Long-term survival after aggressive tumor resection has been reported for patients with IDH1-positive astrocytomas.</td>
</tr>
</tbody>
</table>
| Specimen Requirements             | • Peripheral blood: 5 mL in EDTA tube.  
• Bone marrow: 2 mL in EDTA tube.  
• FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. |
| Storage and Transportation        | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Slides can be packed at room temperature. |
| CPT Code(s)*                      | 81120, 81121 |
| Medicare MolDX CPT Code(s)*       | 81479 |
| Turnaround Time                   | 7 days |
| Level of Service                  | Global ✔️ |

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## IgA

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Immunoglobulin A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>IgA antibody reacts with immunoglobulin Ig alpha chains. It is useful in identifying leukemias, plasmacytomas and B-cell lineage lymphomas.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
  - One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**      | 88342 x 1 or 88341 x 1 |
| **Turnaround Time**  | 24 hours |
| **Level of Service** | Stain Only ✓ |

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## IgD

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Immunoglobulin D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>IgD antibody reacts with immunoglobulin Ig delta chains. This antibody is useful when identifying leukemias, plasmacytomas and B-cell lineage lymphomas (in particular marginal zone lymphoma). Cytoplasmic staining is easily identified on paraffin tissue. IgD staining is also seen in normal mantle zone B-lymphocytes.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*    | 88342 x 1 or 88341 x 1 |
| Turnaround Time | 24 hours |
| Level of Service| Stain Only ✓ |

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**IgG**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Immunoglobulin G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>IgG antibody reacts with immunoglobulin Ig gamma chains. This antibody may be useful in identifying plasma cytomas and B-cell lineage lymphomas, and in conjunction with IgG4 staining to assess for IgG4 associated disease.</td>
</tr>
</tbody>
</table>
| Specimen Requirements     | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
                              • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
                              • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation| Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*              | 88342 x 1 or 88341 x 1    |
| Turnaround Time           | 24 hours                  |
| Level of Service          | Stain Only ✓              |

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December 18, 2019
# IgG4 (Immunoglobulin G4)

## Methodology
- Immunohistochemistry (IHC)

## Test Description
Autoimmune pancreatitis typically produces an enlarged pancreas with narrowing of the pancreatic duct, and can mimic carcinoma. It was shown that the pancreatic tissue from patients with autoimmune pancreatitis often shows moderate or marked infiltration by IgG4-positive plasma. IgG4 staining in patients with chronic alcoholic pancreatitis and pancreatic ductal adenocarcinoma was rarely observed. IgG4-positive plasma cells are a useful marker for the tissue diagnosis of autoimmune pancreatitis. Elevated IgG4 to IgG plasma cell ratio (IgG4/IgG ratio) is helpful in distinguishing IgG4-related from non IgG4-related inflammatory conditions.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
- 88342 x 1 or 88341 x 1

## Turnaround Time
- 24 hours

## Level of Service
- Stain Only

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December 18, 2019
**IgH (14q32)**

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Immunoglobulin heavy chain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>FISH</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td><strong>Probes:</strong> IgH (14q32)</td>
</tr>
<tr>
<td></td>
<td><strong>Disease(s):</strong> Lymphoma, NHL, multiple myeloma, MGUS</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Available separately or as part of the following FISH panels: NHL, Plasma Cell Myeloma FISH Panel (non-New York)</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Bone Marrow Aspirate:</strong> 1-2mL Sodium Heparin Tube. EDTA tube is acceptable</td>
</tr>
<tr>
<td></td>
<td>• <strong>Peripheral Blood:</strong> 2-5mL Sodium Heparin Tube. EDTA tube is acceptable</td>
</tr>
<tr>
<td></td>
<td>• <strong>Fresh, Unfixed Tissue:</strong> Tissue in RPMI</td>
</tr>
<tr>
<td></td>
<td>• <strong>Fluids:</strong> Equal parts RPMI to specimen volume.</td>
</tr>
<tr>
<td></td>
<td>• <strong>Paraffin Block:</strong> H&amp;E slide (required) plus paraffin block. Circle H&amp;E for tech-only</td>
</tr>
<tr>
<td></td>
<td>• <strong>Cut Slides:</strong> H&amp;E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&amp;E for tech-only</td>
</tr>
</tbody>
</table>

| **Storage and Transportation** | Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)*** | 88374x1 automated. Codes may differ if manual analysis is performed. |
| **Turnaround Time** | 4 days for both unfixed and FFPE specimens |
| **Level of Service** | Global ✔ Technical ✔ |

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### IgH Clonality/MRD by NGS

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>IgH Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>The IgH Clonality/MRD by NGS assay detects clonal populations of B-lymphocytes in a given patient sample through the analysis of the VDJ segment of the immunoglobulin heavy chain (IgH) gene. *Note - Baseline testing of the original primary sample will need to be performed prior to testing on new samples submitted for monitoring of minimal residual disease.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The IgH Clonality/MRD by NGS test is designed to detect clonal populations of B-lymphocytes in a given patient sample through the analysis of the VDJ segment of the immunoglobulin heavy chain (IgH) gene. Detecting the presence of clonal B-lymphocyte populations is important for the diagnosis of B-cell lymphoma or leukemia. Additionally, this test provides important information on somatic hypermutations in the neoplastic clone as well as tumor heterogeneity. The presence of more than one clone or subclones within the B-cell lymphoma/leukemia cells can also be determined by this assay. The IgH Clonality/MRD by NGS test is specifically offered for monitoring patients with B-cell lymphoma/leukemia and for predicting minimal residual disease due to its high sensitivity and its quantitative nature. For proper MRD measurement, establishing the type of baseline clone(s) by testing a baseline sample is required. Furthermore, testing of cell-free DNA (cfDNA) in peripheral blood (liquid biopsy) using this technology has been reported to be reliable in monitoring patients with diffuse large B-cell lymphoma (DLBCL) and acute lymphoblastic lymphoma (ALL). This test should not be used as a replacement to our routine B-cell gene rearrangement clonality testing and should be reserved for special utilization as stated above.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | - **Peripheral blood**: 5 mL in EDTA tube  
- **Bone marrow**: 2 mL in EDTA tube  
- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.  
- **Fresh tissue**: Two pieces minimum, 0.2 cm³ in RPMI |
| Storage and Transportation | Refrigerate fresh tissue until shipping. For all specimens, use cold pack for transport. Make sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| CPT Code(s)* | 81263x1 |
| Turnaround Time | 14 days |
| Level of Service | Global 🔄 |

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.*
**IgH/BCL2 t(14;18)**

**Methodology**

FISH

**Test Description**

Probes: IgH/BCL2 t(14;18)  
Disease(s): Follicular lymphoma, NHL

**Clinical Significance**

Available separately or as part of the NHL FISH Panel.

**Specimen Requirements**

- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable  
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable  
- **Fresh, Unfixed Tissue:** Tissue in RPMI  
- **Fluids:** Equal parts RPMI to specimen volume.  
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.  
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.

**Storage and Transportation**

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88374x1 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**

4 days for unfixed or FFPE specimens

**Level of Service**

Global ✓ Technical ✓
IgH/MAF t(14;16)

Methodology  
FISH

Test Description  
**Probes:** IgH/MAF t(14;16)  
**Disease(s):** Multiple myeloma, MGUS

Clinical Significance  
Available separately or as part of the Plasma Cell Myeloma FISH panels: Plasma Cell Myeloma IgH Complex FISH Panel (non-New York) and Plasma Cell Myeloma Prognostic FISH Panel (non-New York)

Specimen Requirements  
- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable  
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable  
- **Fresh, Unfixed Tissue:** Tissue in RPMI  
- **Fluids:** Equal parts RPMI to specimen volume  
- **Paraffin or Cut Slides:** N/A

Storage and Transportation  
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*  
88374x1 automated. Codes may differ if manual analysis is performed.

Turnaround Time  
3-5 days

Level of Service  
Global ✔️  Technical ✔️

---

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# IgH/MAFB t(14;20)

## Methodology
FISH

## Test Description
**Probes:** IgH/MAFB t(14;20)
This probe combination may be ordered separately or added to any of our myeloma FISH panels.

## Clinical Significance
The translocation (14;20) is rare in multiple myeloma (MM) but associated with a poor prognosis for that diagnosis. In contrast, t(14;20) in patients with MGUS is associated with a long-term stable disease.

## Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

## Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88374x1 automated. Codes may differ if manual analysis is performed.

## Turnaround Time
3-5 days

## Level of Service
- Global ✔
- Technical ✔

---

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December 18, 2019
## IgM

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Immunoglobulin M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>IgM antibody reacts with immunoglobulin Ig mu chains. This antibody is useful when identifying leukemias, plasmacytomas and B-cell lineage lymphomas.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
  - One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**     | 88342 x 1 or 88341 x 1 |
| **Turnaround Time** | 24 hours |
| **Level of Service** | Stain Only 🔄 |

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December 18, 2019
IgVH Mutation Analysis

Methodology  Molecular

Test Description  RT-PCR and bi-directional sequencing of the variable region of the immunoglobulin heavy chain for detection of mutation from germline sequence. The mutated VH gene family is identified in positive reports (>3% sequence deviation). Mutation may not be detectable in specimens containing <10% clonal B-cells.

Clinical Significance  IgVH mutation is a significant prognostic marker in chronic lymphocytic leukemia (CLL). IgVH mutation analysis combined with FISH, ZAP-70, and beta-2 microglobulin measurement provide comprehensive prognostic assessment and may be used to determine the approach to therapy for all CLL patients.

Specimen Requirements  • Peripheral blood: 5 mL in EDTA tube.  • Bone marrow: 2 mL in EDTA tube.

Storage and Transportation  Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*  81263

Turnaround Time  10 days

Level of Service  Global ✓

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Inhibin

Methodology
Immunohistochemistry (IHC)

Test Description
Anti-Inhibin alpha is an antibody against a peptide hormone which has a demonstrated utility in differentiating between adrenocortical tumors and renal cell carcinoma. This antibody stains most adrenal tumors but no cases of renal cell carcinomas (RCC). Sex cord stromal tumors of the ovary, as well as trophoblastic tumors, also demonstrate cytoplasmic positivity with this antibody.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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**INI1**

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>hSNF5, SMARCB1, BAF47</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Lack of nuclear expression of INI1 is characteristic of malignant rhabdoid tumors and epithelioid sarcomas.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or</td>
</tr>
<tr>
<td></td>
<td>• One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered</td>
</tr>
<tr>
<td></td>
<td>• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>88342x1 or 88341x1</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Technical ✔ Stain Only ✔</td>
</tr>
</tbody>
</table>

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December 18, 2019
### INSM1

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Insulinoma-associated protein 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>INSM1 is a transcription factor that is a sensitive and specific marker for neuroendocrine tumors. It is a nuclear stain, and is as good if not better than synaptophysin and is superior to chromogranin. It is rarely expressed on adenocarcinoma or squamous cell carcinomas without neuroendocrine differentiation.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**      | 88342 x 1 or 88341 x 1          |
| **Turnaround Time**  | Tech-Only (stain only): 24 hours |
| **Level of Service** | Stain Only ✓                   |

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December 18, 2019
Insulin

Methodology
Immunohistochemistry (IHC)

Test Description
Insulin is composed of a and b chains connected through the C-peptide. The main storage site for insulin is the pancreatic islets. Antibodies to insulin are important as a marker of islet cell tumor of pancreas (insulinoma).

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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inv(16), CBFB-MYH11 Translocation

**Alternative Name**  
CBFB-MYH11 Fusion

**Methodology**  
Molecular

**Test Description**  
Real-time RT-PCR for quantitative detection of the inv(16) CBFB-MYH11 fusion transcript. Positive results are reported as ratio of the amount of fusion transcript with the amount of transcript from a normal control gene. This assay identifies type A fusions, which account for >90%. Analytical sensitivity is 1 tumor cell in 100,000 normal cells.

**Clinical Significance**  
The inv(16) occurs in about 10% of all acute myeloid leukemia and nearly all cases of AML with eosinophilia, subtype M4eo. The inversion is generally associated with relatively good outcome. This assay is recommended for diagnostic confirmation, for monitoring minimal residual disease, and for detection of relapse. c-KIT mutation testing may be considered for inv(16)-positive AML patients as c-KIT mutations are considered an adverse risk factor in these and other patients with core-binding factor AML.

**Specimen Requirements**  
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**  
81401

**Turnaround Time**  
7 days

**Level of Service**  
Global ✔

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## Iron

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Prussian Blue Iron, Ferric Iron</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Special stain. This iron stain is used to detect and identify ferric (Fe3+) iron in tissue preparations, blood smears, or bone marrow smears. Minute amounts of ferric acid are commonly found in bone marrow and in the spleen. Abnormal amounts of iron can indicate hemochromatosis and hemosiderosis. Lack of iron identification can indicate iron-deficient anemia.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88313x1 |
| **Turnaround Time** | 24 hours |
| **Level of Service** | Stain Only ✔ |

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**JAK2 Exon 12-14 Mutation Analysis**

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>JAK2 Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>RT-PCR and bi-directional sequencing to detect non-V617F mutations in exons 12-14 and most of exon 15, corresponding to the majority of the JAK2 pseudokinase domain. Exon deletion mutations are detectable. Testing is performed on plasma for increased sensitivity whenever possible. V617F analysis is recommended before or concurrently with this test. Exon 12-14 Mutation Analysis may be ordered separately, with concurrent V617F testing, by reflex after negative V617F testing, or as part of the MPN Reflex Panel. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>While the majority of polycythemia vera (PV) patients carry the V617F mutation (~90%), most of those who are negative carry one of over 40 additional JAK2 mutations in exons 12-15. RNA-based testing in this assay allows detection of deletions not detectable by DNA-based tests. Mutation analysis helps differentiate reactive conditions from malignant erythrocytosis.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • **Peripheral Blood**: 5mL EDTA tube  
• **Bone Marrow**: 2mL EDTA tube |
| **Storage and Transportation** | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| **CPT Code(s)** | 81403 |
| **Turnaround Time** | 7 days |
| **Level of Service** | Global ✓ |

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December 18, 2019
# JAK2 V617F Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>JAK2 Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Qualitative detection of the V617F mutation. The rare mutation V617I is also detected. Testing is performed on plasma for increased sensitivity whenever possible. V617F testing may be ordered separately, concurrently with full exon 12-14 sequencing, with reflex to exon 12-14 sequencing, or as part of the MPN Reflex Panel. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The JAK2 V617F mutation is present in approximately 90% of polycythemia vera (PV) cases and approximately 40% of primary myelofibrosis (PMF) or essential thrombocythemia (ET). Mutation analysis helps differentiate reactive conditions from myeloproliferative neoplasms (MPNs).</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • Peripheral Blood: 5 mL EDTA tube  
• Bone Marrow: 2 mL EDTA tube |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| CPT Code(s)*          | 81270                  |
| Turnaround Time       | 7 days                 |
| Level of Service      | Global ✔              |

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Kappa

Alternative Name
Kappa by ISH

Methodology
In Situ Hybridization (ISH)

Test Description
Each test contains a set of oligonucleotide probes. The intended target is the kappa light chain immunoglobulin messenger RNA (mRNA) in the cytoplasm of immunoblastic cells, plasma cells and plasmacytoid cells. Assessing the light chain immunoglobulin restriction is important in malignant lymphoma diagnosis. The relationship between monoclonal B-cell proliferation and light chain mRNA restriction aids in the distinction between neoplastic and reactive lymphoid proliferations and the evaluation of multiple myeloma, plasmacytoma, lymphomas with plasmacytoid features, immunoblastic lymphomas and reactive plasma cell proliferations.

Clinical Significance
Kappa and lambda probes are used to detect antibody producing B-cells or plasma cells in formalin-fixed, paraffin-embedded tissue. Restriction of light chain production to either kappa or lambda (monoclonality) can help distinguish between reactive and neoplastic B-cell and plasma cell proliferations.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type.
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered.
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88365 x 1 or 88364 x 1

Turnaround Time
48 hours

Level of Service
Stain Only ☑

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December 18, 2019
Kappa

**Alternative Name**
Kappa Light Chain by IHC

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Antibody to the kappa light chain of immunoglobulin is reportedly useful in the identification of leukemias, plasmacytomas and certain non-Hodgkin lymphomas. Demonstration of monotypism in lymphoid infiltrates is a surrogate for clonality, and therefore malignancy.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

---

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December 18, 2019
Ki67

Methodology
Immunohistochemistry (IHC)

Test Description
Ki67 is a nuclear protein that is expressed in proliferating cells. Ki67 is preferentially expressed during late G1, S, M, and G2 phases of the cell cycle, while cells in the G0 (quiescent) phase are negative for this protein. Increased proliferative activity is associated with more aggressive tumor and decreased disease-free survival period.

Note: Computer-assisted image analysis for Ki-67 is only validated for breast cancer and neuroendocrine carcinoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
- 88342 x 1 or 88341 x 1 (qualitative IHC) or 88360 (quantitative/semi-quantitative – manual) or 88361 x 1 (quantitative/semi-quantitative – computer assisted)

Turnaround Time
- Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓
## KIT (c-KIT) Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>c-KIT Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of KIT exons 8, 9, 11, 13 and 17 for detection of activating mutations including the common mutation D816V. For solid tumors, tumor enrichment is performed before extraction. In hematological disease, testing may be performed on plasma to increase sensitivity. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The four tested exons encompass the majority of mutations found in gastrointestinal stromal tumors (GIST), melanoma, core-binding factor AML (CBF-AML), mast cell disease (systemic mastocytosis), and germ cell tumors. Mutation identification is useful for planning TKI therapy and predicting clinical course.</td>
</tr>
</tbody>
</table>
| Specimen Requirements     | - **Peripheral blood:** 5 mL in EDTA tube.  
- **Bone marrow:** 2 mL in EDTA tube.  
- **Fixed cytogenetic cell pellet:** Send all available cells suspended in fixative.  
- **FFPE solid tumor tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. |
| Storage and Transportation| Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Slides can be packed at room temperature. |
| CPT Code(s)*              | 81272                                                        |
| Turnaround Time           | 7 days                                                       |
| Level of Service          | Global ✓                                                                 |

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December 18, 2019
## KRAS Exon 4 Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>KRAS Exon 4 Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of exon 4 of the KRAS gene corresponding to amino acids R97 through Q150. Codon 117 and 146 mutations are detected. For solid tumors, tumor enrichment is performed before extraction. This test may be ordered separately or by reflex after standard KRAS Mutation Analysis. Testing is available separately or in combination with BRAF, HRAS and NRAS in the RAS/RAF Panel. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>This assay complements the standard KRAS Mutation Analysis of exons 2 and 3. Mutations in exon 4 are detected in approximately 1-4% of colorectal cancers. Exon 4 analysis is appropriate for detecting activating mutations that may confer resistance to EGFR-targeted inhibitors and predicts sensitivity to MEK inhibition.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | - **FFPE solid tumor tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.  
- **Fine needle aspirate (FNA)**: Requisition must note specimen is FNA. Fresh cells in suspension, unstained air-dried smears (approx. 6-8 slides), or FFPE cells blocks are acceptable if pathologist attaches note verifying sample has >30% tumor or abnormal cells (required). Minimum 10^6 cells. |
| Storage and Transportation | Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature. |
| CPT Code(s)* | 81276 |
| Turnaround Time | 7 days |
| Level of Service | Global ✓ |

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## KRAS Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>KRAS Mutation Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of exons 2 and 3 of the KRAS gene. High-sensitivity sequencing is used for enhanced detection of mutations in codons 12, 13, 59, and 61. For solid tumors, tumor enrichment is performed before extraction. Testing is available separately or in combination with BRAF, HRAS and NRAS in the RAS/RAF Panel. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Testing is recommended in colorectal cancer as mutations are associated with resistance and shorter overall survival with EGFR-antagonist therapies such as cetuximab or panitumumab. Testing in non-small cell lung cancer may provide prognostic information and predict poor response to EGFR tyrosine kinase inhibitors.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td></td>
</tr>
</tbody>
</table>
  - **FFPE solid tumor tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.  
  - **Fine needle aspirate (FNA)**: Requisition must note specimen is FNA. Fresh cells in suspension, unstained air-dried smears (approx. 6-8 slides), or FFPE cell blocks are acceptable if pathologist attaches note verifying sample has >30% tumor or abnormal cells (required). Minimum 10^6 cells. |
| **Storage and Transportation** | Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature. |
| **CPT Code(s)*** | 81275, 81276 |
| **Medicare MolDX CPT Code(s)*** | 81479 |
| **Turnaround Time** | 7 days |
| **Level of Service** | Global ✓ |

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December 18, 2019
Lambda

Alternative Name
Lambda by ISH

Methodology
In Situ Hybridization (ISH)

Test Description
Each test contains a set of oligonucleotide probes. The intended target is the lambda light chain immunoglobulin messenger RNA (mRNA) in the cytoplasm of immunoblastic cells, plasma cells and plasmacytoid cells. Assessing the light chain immunoglobulin restriction is important in malignant lymphoma diagnosis. The relationship between monoclonal B-cell proliferation and light chain mRNA restriction aids in the distinction between neoplastic and reactive lymphoid proliferations and the evaluation of multiple myeloma, plasmacytoma, lymphomas with plasmacytoid features, immunoblastic lymphomas and reactive plasma cell proliferations.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88365x1 or 88364x1

Turnaround Time
48 hours

Level of Service
Stain Only ✔

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# Lambda (Lambda Light Chain IgG) by IHC

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Antibody to the lambda light chain of immunoglobulin is reportedly useful in the identification of leukemias, plasmacytomas and certain non-Hodgkin lymphomas. Demonstration of monotypism in lymphoid infiltrates is a surrogate for clonality, and therefore malignancy.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only

---

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December 18, 2019
# Langerin

## Methodology
Immunohistochemistry (IHC)

## Test Description
Langerin is a highly selective marker for Langerhans cells and the lesional cells of Langerhans cell histiocytosis. Langerin protein expression has utility in differentiating Langerhans cell histiocytosis from other non-Langerhans cell histiocytic proliferations.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1

## Turnaround Time
24 hours

## Level of Service
Stain Only ✓

---

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## LEF1

### Methodology
Immunohistochemistry (IHC)

### Test Description
LEF1 overexpression is highly associated with CLL/SLL among small B-cell lymphomas and may serve as a useful marker for diagnosis and differential diagnosis of the disease.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88342 x 1 or 88342 x 1

### Turnaround Time
24 hours

### Level of Service
Stain Only

---

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December 18, 2019
LH

**Alternative Name**  
Luteinizing Hormone

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Luteinizing Hormone (LH) is a tropic hormone that modulates the secretory activity of other endocrine glands. It is produced in the anterior hypophysis of the pituitary gland. LH antibody is useful for the labeling of normal gonadotropic cells of the pituitary and also for the classification of pituitary adenomas, as well as in the differential diagnosis of primary and metastatic tumors of the pituitary.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only ✔
LMO2

Methodology
Immunohistochemistry (IHC)

Test Description
LMO2 protein is expressed in normal human germinal-center (GC) and GC-derived lymphomas. In addition, it is also expressed at high levels in endothelial cells, spleen, hematopoietic precursors, and a significant proportion of acute lymphoblastic and myeloid leukemias. In diffuse large B-cell lymphoma (DLBCL), LMO2 protein expression is aligned with GC markers HGAL, CD10 and BCL6, indicating a potential role for LMO2 in the prognostic stratification of DLBCL patients. It is rarely expressed in mature T, natural killer (NK) and plasma cell neoplasms and is absent from non-hematolymphoid tissues, except for endothelial cells.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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Low-Grade/Small B-Cell Lymphoma FISH Panel

**Alternative Name**  
Small B-Cell Lymphoma

**Methodology**  
FISH

**Test Description**  
Probes: BCL6 (3q27) | CCND1/IgH t(11;14) IgH/BCL2 t(14;18) | MALT1 (18q21)
Probes may be ordered separately.
Disease(s): NHL, B-Cell Lymphoma, MCL, follicular lymphoma, MZL, MALT lymphoma

**Clinical Significance**  
This targeted panel is appropriate when clinical and morphologic evaluation is most suggestive of a low-grade/small B-cell lymphoma, and high-grade lymphomas (such as large cell anaplastic and Burkitt lymphoma) are not a diagnostic consideration. BCL6 evaluation (included in this panel) can provide further prognostic information in cases of follicular lymphoma since it can indicate a higher risk for transformation to aggressive lymphoma. Low-grade/small B-cell lymphomas include follicular lymphoma, mantle cell lymphoma (MCL), and marginal zone lymphoma (MZL)/MALT lymphomas. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) is also within this category, but typically has a peripheral blood lymphocytosis and is better evaluated by the CLL FISH Panel or NeoTYPE™ CLL Profile.

**Specimen Requirements**

- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only. Testing on this specimen type is not yet available for NY specimens. **Cut Slide:** H&E slide (required) plus 8 unstained slides cut at 4 microns for panel. Circle H&E for tech-only. Testing on this specimen type is not yet available for NY specimens.

**Storage and Transportation**  
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88374x4 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**  
4 days for both unfixed and FFPE specimens

**Level of Service**  
Global ✔  Technical ✔

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### Lung NGS Fusion Profile

**Alternative Name**  
NGS ALK, NTRK, RET, ROS1 Fusion Profile | NGS Lung Fusion Profile

**Methodology**  
Molecular

**Test Description**  
The Lung NGS Fusion Profile is an RNA-based next-generation sequencing panel that detects translocations and fusions of the genes ALK, NTRK1, NTRK2, NTRK3, RET and ROS1 with known and novel fusion partners. Point mutations in select exons of these six genes are also detected. Examples of some of the published fusions detectable in this test include EML4-ALK, KIF5B-ALK, NPM1-ALK, CD74-NTRK1, MPRIP-NTRK1, TPM3-NTRK1, TRIM24-NTRK2, PAN3-NTRK2, ETV6-NTRK3, CCD6-RET (aka RET-PTC1), KIF5B-RET, NCOA4-RET (aka RET-PTC3), CD74-ROS1, SLC34A2-ROS1, and TPM3-ROS1. This test may be used to select patients for therapy with the FDA-approved TRK inhibitor Vitrakvi® (larotrectinib).

We recommend FISH as the primary method of ALK, RET, and ROS1 rearrangement detection. We suggest using this test for NTRK analysis and/or cases that fail to provide conclusive FISH results. See also NTRK NGS Fusion Profile and NTRK & RET NGS Fusion Profile.

**Clinical Significance**  
Fusions of the ALK, NTRK1, NTRK2, NTRK3, RET and ROS1 kinase genes with various partner genes have been reported as oncogenic drivers in multiple cancer types including lung adenocarcinoma. Chimeric proteins resulting from the gene fusions may be overexpressed or constitutively activated and lead to progression of cancer. Patients whose tumors have such gene fusions may respond to various kinase inhibitors. In non-small cell lung carcinoma (NSCLC), these gene fusions are detected with the following approximate frequencies: ALK (4-6%), NTRK (1%), RET (1-2%), and ROS1 (1-2%).

**Specimen Requirements**  
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
81445

**Turnaround Time**  
14-21 days

**Level of Service**  
Global ✓
# Lynch Syndrome

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Lynch Syndrome Panel, Hereditary Lynch Syndrome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>This test is performed by sequencing the entire EPCAM, MLH1, MSH2, MSH6 and PMS2 genes using next-gen sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. Testing may be ordered for individual genes. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Lynch Syndrome is a hereditary cancer syndrome with prevalence of approximately 1 in 440 people. It is estimated to account for 1-3% of all colorectal cancer and up to 2% of all endometrial cancer cases. Patients are at increased risk for these tumors as well as those of the stomach, ovary, hepatobiliary tract, urinary tract, small intestine, brain, pancreas, prostate, and skin (sebaceous neoplasms). Lynch Syndrome is due to germline mutations of mismatch repair genes including MLH1 (responsible for ~50% of Lynch Syndrome), MSH2 (~40%), MSH6 (7-10%), PMS2 (~5%) and partial deletions of EPCAM (1-3%) which inactivate the MSH2 gene. Consideration of germline mutation testing is appropriate when tumor testing has identified mismatch repair defects and/or microsatellite instability, and for various other personal and family history indications as described by current guidelines.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>Peripheral blood: 5 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81445</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>21 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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Lysozyme

Methodology
Immunohistochemistry (IHC)

Test Description
Lysozyme is synthesized predominantly in reactive histiocytes rather than in resting, unstimulated phagocytes. This antibody labels myeloid cells, histiocytes, granulocytes, macrophages and monocytes. It is helpful in the identification of myeloid or monocytic nature of acute leukemia.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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December 18, 2019
MAL

Methodology
Immunohistochemistry (IHC)

Test Description
MAL is a distinct molecular marker of primary mediastinal large B-cell lymphoma subtype among diffuse large B-cell lymphomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1

Turnaround Time
Tech-Only (stain only): 24 hours

Level of Service
Stain Only ✓
# MALT1 (18q21)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MALT1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
</tbody>
</table>
| Test Description          | Probes: MALT1 (18q21)  
Disease(s): Marginal zone B-cell lymphoma, NHL |
| Clinical Significance     | Available separately or as part of the [NHL FISH Panel](#).            |
| Specimen Requirements     |  
• Bone Marrow Aspirate: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable  
• Peripheral Blood: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable  
• Fresh, Unfixed Tissue: Tissue in RPMI  
• Fluids: Equal parts RPMI to specimen volume  
• Paraffin Block: H&E slide (required) plus paraffin block. Circle H&E for tech-only.  
• Cut Slides: H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only. |
| Storage and Transportation| Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*              | 88374x1 automated. Codes may differ if manual analysis is performed. |
| Turnaround Time           | 4 days for unfixed or FFPE specimens                                    |
| Level of Service          | Global ✔  
Technical ✔                                                           |

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**Mammaglobin**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Mammaglobin is a breast-associated glycoprotein. In normal breast tissue, this antibody labels breast ductal and lobular epithelial cells. In tumor cells, they are reactive with all types of breast adenocarcinoma regardless of tumor differentiation and type. Adenocarcinomas from other organs rarely express mammaglobin. Mammaglobin can help in the identification of primary sites of carcinomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✔

---

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December 18, 2019
### Masson Trichrome

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Special stain.</td>
</tr>
</tbody>
</table>
| Specimen Requirements| • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  or  
                          • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3)  
                            positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
                          • Block and slide identifiers should be clearly written and match exactly with the specimen ID  
                            and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| Turnaround Time      | 24 hours                  |
| Level of Service     | Stain Only ✓              |

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## Mast Cell Add-On Flow Panel

### Methodology
Flow Cytometry

### Test Description
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD2, CD25, CD34, CD45, and CD117 (5 markers).

### Clinical Significance
Used to determine if mast cells are aberrantly expressing CD2 and CD25, which can indicate malignancy.

### Specimen Requirements
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

### Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
Please contact NeoGenomics’ Billing Department.

### Turnaround Time
1 day

### Level of Service
Global ✓  Technical ✓

---

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December 18, 2019
MDM2

Alternative Name
E3 ubiquitin ligase

Methodology
FISH

Test Description
Probes: MDM2 (12q15) | Centromere 12
Disease(s): Liposarcoma

Clinical Significance
This test detects amplifications of the MDM2 gene for classification of certain adipocytic tumors. MDM2 gene amplifications may appear microscopically as ring chromosomes, giant marker chromosomes, and double minutes. MDM2 amplifications are frequently detected in well-differentiated liposarcoma, which includes atypical lipomatous tumor (ALT/WDLS), and in dedifferentiated liposarcoma (DDLS). These tumors can be difficult to distinguish morphologically from other high-grade sarcomas and benign tumors. Amplifications are detected infrequently in other soft tissue sarcomas, and are not detected in benign lipomas. Drug targeting of MDM2 is an active area of clinical research.

Specimen Requirements
- Bone marrow aspirate: N/A
- Peripheral blood: N/A
- Fluids: N/A
- Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required).
- Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88377x1 manual or 88374x1 automated.

Turnaround Time
3-5 days

Level of Service
Global ✓ Technical ✓

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December 18, 2019
# MDM2 by IHC

## Methodology

Immunohistochemistry (IHC)

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88342 x 1 or 88341 x 1

## Turnaround Time

24 hours

## Level of Service

Stain Only ✓

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December 18, 2019
# MDS Add-On Flow Panel

**Alternative Name**
Myelodysplastic Syndrome Add-On Flow Panel

**Methodology**
Flow Cytometry

**Test Description**
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD11b, CD13, CD36, CD41, CD45, CD71, CD117, and CD235a (8 markers).

**Clinical Significance**
Used to help diagnose myeloid dysmaturation, which can be seen in some myelodysplastic syndromes in the appropriate clinical setting.

**Specimen Requirements**
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

**Storage and Transportation**
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
Please contact NeoGenomics’ Billing Department.

**Turnaround Time**
1 day

**Level of Service**
Global ✓  Technical ✓

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December 18, 2019
# MDS Extended FISH Panel

**Alternative Name**
Myelodysplastic syndrome

**Methodology**
FISH

**Test Description**
Probes: RPN1, MECOM (3q21, 3q26.2) | 5q-, -5 (5p15, 5q31, 5q33) | 7q-, -7 (Cen 7, 7q22, 7q31) | Trisomy 8 (Cen 8) | MLL (11q23) | ETV6 (12p13) | 17p- (TP53 17p13.1, NF1 17q11.2) | +19 (19p13.2, 19q13) | 20q- (20q12, 20qter)
Probes may be ordered separately except +8 and 20q- which are combined.

**Disease(s):** Myelodysplastic syndrome

**Clinical Significance**
The MDS Extended FISH Panel accommodates the 2012 Revised IPSS (IPSS-R) classification of five cytogenetic risk groups: very good, good, intermediate, poor, and very poor.

**Specimen Requirements**
- **Bone marrow aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, unfixed tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin block or cut slides:** Not available.

**Storage and Transportation**
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88374x8 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**
3-5 days

**Level of Service**
Global ✅  Technical ✅
MDS FISH Panel (New York)

Alternative Name: MDS NY Panel

Methodology: FISH

Test Description:
Probes: 5q-, -5 (5p15, 5q31, 5q33) | 7q-, -7 (7q31, Cen 7) | Trisomy 8 (Cen 8) | MLL (11q23) | 20q- (20q12, 20qter)

Probes may be ordered separately except +8 and 20q- which are combined.

Disease(s): Myelodysplastic syndrome

Clinical Significance:
The MDS FISH Panel (New York) identifies the most frequent cytogenetic abnormalities associated with favorable, intermediate, and poor risk.

Specimen Requirements:
- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

Storage and Transportation:
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*:
88374x4 automated. Codes may differ if manual analysis is performed.

Turnaround Time:
3-5 days

Level of Service:
Global ✓  Technical ✓

---

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December 18, 2019
MDS Standard FISH Panel

**Alternative Name**
Myelodysplastic syndrome

**Methodology**
FISH

**Test Description**
Probes: 5q-, -5 (5p15, 5q31, 5q33) | 7q-, -7 (Cen 7, 7q22, 7q31) | Trisomy 8 (Cen 8) | MLL (11q23) | 20q- (20q12, 20qter)
Probes may be ordered separately except +8 and 20q- which are combined.
**Disease(s):** Myelodysplastic syndrome

**Clinical Significance**
The MDS Standard FISH Panel identifies the most frequent cytogenetic abnormalities associated with favorable, intermediate, and poor risk according to IPSS guidelines (since revised). See also the separate listing for MDS Extended FISH Panel which accommodates the 2012 IPSS-Revised classification.

**Specimen Requirements**

- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88374x4 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**
3-5 days

**Level of Service**
Global ✓  Technical ✓
Melan A (Mart1)

Methodology
Immunohistochemistry (IHC)

Test Description
Melan A (Mart1, Melanoma Antigen Recognized by T-cells 1), is a differentiation antigen that is expressed in melanocytes, most melanomas. Melan A recognizes a subcellular fraction found in melanosomes. Melan A is a useful addition to melanoma panels since it is specific for melanocytic lesions. Both HMB 45 and Melan A are co-expressed in the majority of melanomas, as well as uniquely expressed in certain cases. Melan A antibody, A103 clone labels the tumor cells of a subset of adrenocortical carcinomas and sex cord tumors of the gonads.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔️

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Mesothelin

Methodology

Immunohistochemistry (IHC)

Test Description

Mesothelin is a 40kDa cell surface glycoprotein selectively expressed by mesothelial cells and malignant mesotheliomas, as well as by non-mucinous ovarian carcinomas, breast carcinomas, pancreatic carcinomas, and squamous tumors of the esophagus and cervix.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only

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December 18, 2019
# MET (c-MET) Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MET Mutation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional Sanger sequencing of MET is performed using PCR primers designed to target hotspot mutations in exons 14, 16, 17 and 19.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>This assay detects MET mutations, which are detected in 5% of colon cancers, 10% of upper digestive systems, 5% of kidney tumors, and 3% of lung cancers. MET deregulation in lung cancer is associated with poor outcome and resistance to anti-EGFR therapy. Multiple antibodies against MET and small molecule MET-inhibitors are currently in clinical trials for the treatment of various cancer types.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td><strong>FFPE solid tumor tissue</strong>: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81479</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>10 days</td>
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<tr>
<td>Level of Service</td>
<td>Global</td>
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## MET Exon 14 Deletion Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MET Exon 14 Skipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>MET Exon 14 Deletion Analysis is performed by real-time RT-PCR. The assay is designed to detect alternative splice junctions that lead to exon-skipping (deletion) of exon 14 of the gene MET. Note: Available as stand-alone test or as part of the NeoTYPE® Lung Tumor Profile.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The MET (mesenchymal-epithelial transition) tyrosine kinase receptor and its ligand the hepatocyte growth factor (HGF) play a major role in oncogenesis in various types of cancers. MET amplification and mutations have been reported in various types of tumors, especially lung cancer. MET amplification or mutation can be primary or acquired after treatment with EGFR kinase inhibitors. The expression of a defective MET mRNA that skips exon 14 is recently reported in 4% of lung cancers. This finding is very important, because it is actionable. Dramatic response to MET/ALK inhibitors (crizotinib and cabozantinib) can be seen in patients with lung cancer and METex14 abnormality. Testing for METex14 is now considered by multiple clinical investigators as a standard of care in patients with lung cancer. MET exon 14 deletion is also seen in a subset of gastric and gastrointestinal carcinomas and gliomas.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81479</td>
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<td>Turnaround Time</td>
<td>14 days</td>
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<tr>
<td>Level of Service</td>
<td>Global ✓</td>
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</table>

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MET FISH

Methodology

FISH

Test Description

Probes: MET (7q31) | Centromere 7
Disease(s): Multiple solid tumor cancers including lung (NSCLC), gastric, esophageal, endometrial

Clinical Significance

MET gene amplification, as detected by FISH, is one mechanism of MET overexpression. MET amplifications are detected in 3-7% of non-small cell lung cancer (NSCLC) and associated with resistance to EGFR inhibitors and shorter survival in this disease. MET amplifications are also detected in a wide variety of other solid tumors including gastric (up to 10%), esophageal (4%), and endometrial tumors. Clinical trials have demonstrated activity of MET inhibitors against numerous solid tumors such as lung, breast, melanoma, liver, prostate, renal, and ovarian, including tumor reduction in NSCLC and breast cancer patients who had developed resistance to EGFR inhibitors.

Specimen Requirements

- Bone marrow aspirate: N/A
- Peripheral blood: N/A
- Fresh, unfixed tissue: N/A
- Fluids: N/A
- Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required).
- Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88377x1 manual or 88374x1 automated.

Turnaround Time

7 days

Level of Service

Global ✔️  Technical ✔️

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# MGMT Promoter Methylation Analysis

**Alternative Name**  
MGMT Methylation

**Methodology**  
Molecular

**Test Description**  
Bisulfite modification of tumor DNA and real-time PCR are used to quantify CpG methylation within the MGMT gene promoter. Percentage of methylated DNA (compared to total DNA) is reported for positive results.

**Clinical Significance**  
Methylation (or hypermethylation) of the MGMT gene promoter down-regulates or inactivates the normal DNA-repair function of the MGMT enzyme, which can make tumors more susceptible to radiation or alkylating agent-based therapy. Testing is particularly useful in gliomas. About 45% of glioblastomas have MGMT methylation, and these patients show improved survival when treated with radiation and temzolomide over those patients with non-methylated tumors. Methylation has also been associated with improved survival in anaplastic gliomas, regardless of treatment. MGMT methylation has been reported in other tumors including colorectal, lung, and lymphoma, and alkylating agents and/or radiation therapy may be considered in these cases.

**Specimen Requirements**  
- **FFPE solid tumor tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**  
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

**CPT Code(s)**  
81287

**Turnaround Time**  
10 days

**Level of Service**  
Global ✔

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Microsatellite Instability Analysis (MSI)

**Alternative Name**  
MSI Analysis

**Methodology**  
Molecular

**Test Description**  
PCR and fragment analysis of paired normal and tumor tissue to determine microsatellite instability (MSI) at the standard five NCI-recommended loci. Positive results are reported as MSI-high (at least two markers are unstable) or MSI-low (one marker is unstable).

**Clinical Significance**  
MSI analysis and/or mismatch repair (MMR) IHC is recommended for all new colorectal cancer diagnoses to detect patients at increased risk of carrying germline mutations associated with Lynch Syndrome (HNPCC). MSI is also detected in sporadic colorectal cancer and its presence may imply better prognosis. MSI and MMR testing also serve as companion diagnostic tests in a wide range of solid tumors for selection of certain immuno-oncology therapies.

**Specimen Requirements**  
- **Note:** An additional patient sample from normal, non-tumor tissue is required for comparison testing in MSI Analysis. Please submit all specimens with one test requisition form.
- **Specimen requirements for normal tissue in order of preference are:**  
  1) 5 mL peripheral blood in EDTA tube OR 2) FFPE tissue slides or block containing only non-tumor tissue. Please label these as "normal tissue". OR 3) In cases where no alternative tissue is available, we can attempt to isolate non-tumor tissue from the tumor specimen submitted. Note "Use tumor sample for normal tissue" on requisition. See requirements below.
- **Specimen requirements for tumor tissue:** FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**  
Use cold pack for transporting block and/or blood, making sure cold pack is not in direct contact with specimen. Slides can be packed at room temperature.

**CPT Code(s)**  
81301

**Turnaround Time**  
7 days

**Level of Service**  
Global ✅

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December 18, 2019
MITF

Methodology  
Immunohistochemistry (IHC)

Test Description  
MITF (microphthalmia transcription factor) is a transcription factor that regulates the development and survival of melanocytes. MITF is restricted to the melanocyte cell lineage. Anti-MITF recognizes a nuclear protein that is expressed in the majority of primary and metastatic epithelioid malignant melanomas as well as in normal melanocytes, benign nevi and dysplastic nevi.

Specimen Requirements  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*  
88342 x 1 or 88341 x 1

Turnaround Time  
24 hours

Level of Service  
Stain Only ✓

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MLH1

Methodology
Immunohistochemistry (IHC)

Test Description
MLH1, a mismatch repair protein involved in maintaining the integrity of genetic information, alongside MSH2, MSH6 and PMS2. During DNA replication, strand misalignment can occur resulting in alterations to microsatellite repeats, often referred to as microsatellite instability (MSI). These defects in DNA repair pathways have been linked to human carcinogenesis. Mutations in the MLH1 gene have been reported to be found in tumors with MSI, such as some forms of colon cancer eg. Hereditary nonpolyposis colon cancer (HNPCC), a subset of sporadic carcinomas and breast cancer. Loss of expression of MLH1 has also been reported in acute lymphoblastic leukemia, endometrial carcinoma, gastric carcinoma and ovarian carcinoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1; 88360 x 1; 88361 x 1

Turnaround Time
Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔ Stain Only ✔
## MLH1 Mutation & Del/Dup Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>MLH1 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>This test is performed by sequencing the entire MLH1 gene using next-gen sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. Testing is also available in the Lynch Syndrome panel which includes EPCAM, MLH1, MSH2, MSH6, and PMS2. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>MLH1 is a DNA mismatch repair gene. Mutations in MLH1 account for approximately 50% of Lynch Syndrome cases. Testing for mutations in a single Lynch Syndrome-related gene is appropriate when mismatch repair and/or microsatellite instability testing in a patient's tumor has suggested which gene may be mutated, or if there are other personal or family history indications pointing to a particular gene.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>Peripheral blood: 5 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81292, 81294</td>
</tr>
<tr>
<td><strong>Medicare MolDX CPT Code(s)</strong></td>
<td>81294</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>21 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global</td>
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December 18, 2019
## MLH1 Promoter Methylation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MLH1 Methylation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>This assay is performed on tumor tissue to detect hypermethylation of the MLH1 gene promoter. Bisulfite modification of tumor DNA and real-time PCR are used to quantify CpG methylation within the promoter. Percentage of methylated DNA (compared to total DNA) is reported for positive results. Analysis should be considered in combination with IHC, BRAF, and/or MSI.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>MLH1 promoter methylation analysis is useful to distinguish sporadic from inherited colorectal and endometrial cancers in tumors that are MLH1-deficient by IHC staining and/or have high levels of microsatellite instability (MSI-H). The majority of MSI in sporadic cases of these tumors is caused by MLH1 promoter hypermethylation, while hypermethylation is rare in inherited cases. MLH1 promoter methylation analysis results should be considered with other clinical risk factors in determination of likelihood of HNPCC/Lynch Syndrome.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81288</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>10 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
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</table>

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### MLL (11q23)

**Alternative Name**  
Mixed-lineage leukemia

**Methodology**  
FISH

**Test Description**  
**Probes:** MLL (11q23)  
**Disease(s):** ALL, AML

**Clinical Significance**  
Available separately or as part of the AML FISH Panel.

**Specimen Requirements**
- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume
- **Paraffin or Cut Slides:** N/A

**Storage and Transportation**  
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88374x1 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**  
3-5 days

**Level of Service**  
Global ✓  Technical ✓

---

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*
MMR Panel by IHC (MLH1, MSH2, MSH6, PMS2)

Methodology

Immunohistochemistry (IHC)

Test Description

A well-defined subtype of colorectal cancer (CRC) is characterized by deficiencies in the mismatch repair (MMR) pathway. MMR status may impact prognosis and benefit of adjuvant chemotherapy. MLH1, MSH2, MSH6, and PMS2 protein expression (as assessed by IHC) and microsatellite instability analysis (MSI) assessed by PCR are well-established tools to screen for Lynch syndrome (LS), and such testing is recommended for all new colorectal cancer diagnoses. MMR IHC and molecular MSI testing also serve as companion diagnostic tests in a wide range of solid tumors for selection of certain immuno-oncology therapies.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and 4-8 (minimum 4) positively charged unstained slides (all cut at 4-5 microns) for panel, or 2-3 slides/stain for individual stains ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x1, 88341 x 3 or 88360 x 4 or 88361 x 4

Turnaround Time

Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service

Global ✓  Stain Only ✓

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December 18, 2019
**MOC31**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Monoclonal antibody MOC31 recognizes a membrane glycoprotein of 40kDa present on epithelial cells but not on mesothelial cells. MOC31 reacts with most adenocarcinomas of various origins, typically with strong staining pattern. Only rare cases of mesotheliomas show focal or weak staining. MOC31 antibody does not label liver as well as hepatocellular carcinoma, therefore, it will be helpful in the differential diagnosis of liver metastases versus hepatocellular carcinomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

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December 18, 2019
<table>
<thead>
<tr>
<th><strong>Monocyte Maturation Add-On Flow Panel</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
</tr>
</tbody>
</table>

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# MPL Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Myeloproliferative Leukemia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of exon 10 of the MPL gene to detect all possible mutations at the W515 and S505 codons, and other mutations throughout the exon. Testing is performed on plasma for increased sensitivity whenever possible. This test may be ordered separately or as part of the MPN Reflex Panel. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>MPL W515 mutations are present in JAK2-negative patients with primary myelofibrosis (PMF) or essential thrombocythemia (ET) at a frequency of approximately 1-5%, respectively. The S505 mutation is usually detected in patients with familial essential thrombocythemia. Mutation analysis helps differentiate reactive conditions from MPNs.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** |  *
| Peripheral blood: 5 mL in EDTA tube.  
| Bone marrow: 2 mL in EDTA tube.  |
| **Storage and Transportation** | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| **CPT Code(s)** | 81402 |
| **Turnaround Time** | 10 days |
| **Level of Service** | Global ✔ |

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December 18, 2019
MPN Extended Reflex Panel

**Alternative Name**
Myeloproliferative Neoplasms Extended Reflex Panel

**Methodology**
Molecular

**Test Description**
Sequential testing panel including qualitative detection of JAK2 V617F, JAK2 Exon 12-14, CALR exon 9, and MPL exon 10. Testing proceeds by reflex through the four-step panel until a mutation is identified, when the result is considered informative and no further testing is performed. Testing is performed on plasma for increased sensitivity whenever possible. Tests may also be ordered individually or as a three-step reflex panel without CALR in the MPN Standard Reflex Panel (see separate listing). Testing is approved for specimens from the state of New York.

**Clinical Significance**
Comprehensive testing to identify mutations associated with the myeloproliferative neoplasms polycythemia vera (PV), essential thrombocythemia (ET), and primary myelofibrosis (PMF). Mutation analysis helps differentiate reactive conditions from MPNs, may provide prognostic information, and may help distinguish ET and PMF from PV.

**Specimen Requirements**
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**
81270, 81403, 81219, 81402

**Medicare MolDX CPT Code(s)**
81479

**Turnaround Time**
10 days

**Level of Service**
Global ✅

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December 18, 2019
MPN FISH Panel

**Alternative Name**
Myeloproliferative neoplasms

**Methodology**
FISH

**Test Description**
Probes: PDGFRa, CHIC2, FIP1L1 (4q12) | PDGFRb (5q33) | FGFR1 (8p11) | BCR/ABL1 t(9;22) including ASS1 (9q34) | Probes may be ordered separately.

**Disease(s):** Myeloproliferative neoplasms

**Clinical Significance**
The MPN FISH panel is indicated in the diagnosis of myeloproliferative neoplasms with eosinophilia and as a guide to therapeutic selection. Patients with BCR-ABL, PDGFRA or PDGFRB rearrangements are responsive to tyrosine kinase inhibitors. There currently is no established TKI therapy for diseases with FGFR1 rearrangement, but some promising new therapies have been reported. If these FISH studies are negative, that does not exclude a myeloproliferative neoplasm and molecular studies for JAK2 and/or MPL mutations should also be considered in the work-up of a possible myeloproliferative neoplasm.

**Specimen Requirements**
- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88374x4 automated. Codes may differ if manual analysis is performed.

**Turnaround Time**
3-5 days

**Level of Service**
Global ✔️  Technical ✔️

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December 18, 2019
# MPO

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Myeloperoxidase by IHC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Myeloperoxidase (MPO) is an important enzyme used by granulocytes during phagocytic lysis of engulfed foreign particles. In normal tissues and in a variety of myeloproliferative disorders, myeloid cells of both neutrophilic and eosinophilic types, at all stages of maturation, exhibit strong cytoplasmic reactivity for MPO. MPO is useful in differentiating between myeloid and lymphoid leukemias.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88342x1 or 88341x1 |
| **Turnaround Time** | 24 hours |
| **Level of Service** | Stain Only ✓ |

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December 18, 2019
# MPO Cytochemical

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Myeloperoxidase special stain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Cytochemical stain. Myeloperoxidase (MPO) is present in granules of myeloid and monocytic cells, but absent from lymphocytes. Therefore MPO is an important marker for discriminating myeloid vs. lymphoid blasts. Staining is used to distinguish acute myeloid leukemia (AML) and other myeloid leukemias from lymphoid disorders.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • Minimum two slides fresh smear: bone marrow aspirate preferred, peripheral blood accepted  
• Slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**      | 88319x1                      |
| **Turnaround Time**  | 24 hours                     |
| **Level of Service** | Stain Only ✓                 |

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MSA

Alternative Name
muscle specific actin

Methodology
Immunohistochemistry (IHC)

Test Description
Muscle Specific Actin (MSA) antibody recognizes the alpha and gamma isotypes of skeletal, cardiac, and smooth muscle cells. It is non-reactive with other mesenchymal cells and all epithelial cells except for myoepithelium. This antibody is useful in the identification of tumors with muscle differentiation and detection of myoepithelial cells.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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**Methodology**

**Test Description**

Human mismatch repair protein 2 (MSH2) is involved in the initial recognition of mismatched nucleotides during the post replication mismatch repair process. Loss of MSH2 function leads to the accumulation of replication errors, which in turn may be responsible for the multiple mutations required for multistage carcinogenesis. Mutations in *MSH2* gene is linked to hereditary nonpolyposis colon cancer and to sporadic cancers which exhibit microsatellite instability.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

- 88342 x 1 or 88341 x 1
- 88360 x 1
- 88361 x 1

**Turnaround Time**

- Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**

- Global ✓
- Stain Only ✓
# MSH2 Mutation & Del/Dup Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MSH2 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>This test is performed by sequencing the entire MSH2 gene using next-gen sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. Testing is also available in the Lynch Syndrome panel which includes EPCAM, MLH1, MSH2, MSH6, and PMS2. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>MSH2 is a DNA mismatch repair gene. Mutations in PMS2 account for approximately 40% of Lynch Syndrome cases. Testing for mutations in a single Lynch Syndrome-related gene is appropriate when mismatch repair and/or microsatellite instability testing in a patient’s tumor has suggested which gene may be mutated, or if there are other personal or family history indications pointing to a particular gene.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>Peripheral blood: 5 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81295, 81297</td>
</tr>
<tr>
<td>Medicare MolDX CPT Code(s)*</td>
<td>81297</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>21 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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MSH6

Methodology

Immunohistochemistry (IHC)

Test Description

Mismatch repair (MMR) genes result in failure to repair errors in repetitive sequences that occur during DNA replication. The defects in DNA repair pathways have been related to tumor carcinogenesis. MSH6 mutations appear to be associated with atypical HNPCC and in particular with development of endometrial carcinoma or atypical endometrial hyperplasia, the presumed precursor of endometrial cancer. Defects in MSH6 are also found in familial colorectal cancers (suspected or incomplete HNPCC).

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1; 88360 x 1; 88361 x 1

Turnaround Time

Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service

Global ✓  Stain Only ✓

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December 18, 2019
**MSH6 Mutation & Del/Dup Analysis**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MSH6 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>This test is performed by sequencing the entire MSH6 gene using next-gen sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. Testing is also available in the Lynch Syndrome panel which includes EPCAM, MLH1, MSH2, MSH6, and PMS2. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>MHS6 is a DNA mismatch repair gene. Mutations in PMS2 account for approximately 7-10% of Lynch Syndrome cases. Testing for mutations in a single Lynch Syndrome-related gene is appropriate when mismatch repair and/or microsatellite instability testing in a patient's tumor has suggested which gene may be mutated, or if there are other personal or family history indications pointing to a particular gene.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>Peripheral blood: 5 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81298, 81300</td>
</tr>
<tr>
<td>Medicare MolDX CPT Code(s)*</td>
<td>81298</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>21 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global</td>
</tr>
</tbody>
</table>

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December 18, 2019
## MUC1

### Methodology
Immunohistochemistry (IHC)

### Test Description
Mucin 1 (MUC1) is a high molecular weight glycoprotein that is found on the apical surface of many glandular epithelia, including the gastrointestinal, respiratory, urinary, reproductive tracts and some hematopoietic cell lineages. MUC1 has been implicated in progression of numerous types of cancer, including breast, colon, lung, gastric and pancreatic cancers. MUC1 expression in tumors is greatly increased and accompanied by altered aberrant expression patterns that become more diffuse when compared to the normal apically restricted pattern.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88342 x 1 or 88341 x 1

### Turnaround Time
24 hours

### Level of Service
Stain Only ✓
MUC2

Methodology
Immunohistochemistry (IHC)

Test Description
Mucin 2 (MUC2) expression is detected in human tissues such as normal colon, breast, prostate, and salivary gland, as well as in gastrointestinal, colonic, breast and prostate neoplasia. This antibody labels MUC2 in normal colon and colonic carcinomas where it produces intense perinuclear staining in goblet cells.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
- 88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
MUC4

Methodology
Immunohistochemistry (IHC)

Test Description
MUC4 is useful in the identification of low-grade fibromyxoid sarcoma (LGFSMS) and sclerosing epithelioid fibrosarcoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1

Turnaround Time
24 hours

Level of Service
Stain Only
MUC5

Methodology
Immunohistochemistry (IHC)

Test Description
Mucin 5 (MUC5) is expressed in gastric mucosa, and in gall bladder epithelium. MUC5 antibody is recommended for use as part of a panel of antibodies for the characterization of mucin expression and in differentiation of intestinal metaplasia as well as gastric and pancreaticobiliary carcinomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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MUC6

Methodology
Immunohistochemistry (IHC)

Test Description
MUC6 is expressed mucopetic neck cells and pyloric glands of the gastric mucosa. MUC6 antibody is recommended for use as part of a panel of antibodies in differentiation of gastric cancer.

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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Mucicarmine

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain. Mucicarmine staining is used to identify epithelial mucins, namely acid mucopolysaccharides. Staining is useful to distinguishing mucin negative undifferentiated squamous cell lesions from mucin positive adenocarcinomas. In addition, this product will stain the mucopolysaccharide capsule of Cryptococcus neoformans.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88313

Turnaround Time
24 hours

Level of Service
Stain Only

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Multiple Myeloma IgH Complex FISH Panel (New York)

Methodology

FISH

Test Description

Probes: FGFR3/IgH t(4;14) | CCND1/IgH t(11;14) | IgH/MAF t(14;16) | Probes for each translocation may be ordered separately.

Disease(s): Plasma cell myeloma, multiple myeloma

Note: Plasma cell enrichment will be performed on bone marrow or blood samples unless our client directs us otherwise. (Peripheral blood is not recommended as a screening specimen unless increased plasma cells are seen on blood smear.) Specimens should be received in our laboratory within 72 hours of collection. If enriched samples are insufficient to complete the whole panel, NeoGenomics will prioritize t(4;14) testing unless directed otherwise by our client.

Clinical Significance

The Multiple Myeloma IgH Complex Reflex FISH panel is performed when IgH is rearranged. This panel is used to identify the IgH partner gene in myeloma, which has prognostic impact. IgH rearrangements are found in 55-70% of myelomas. Together t(4;14), t(11;14) and t(14;16) are found in approximately 35% of myelomas and in 90% of myelomas when there is an IgH gene rearrangement present.

Specimen Requirements

- Bone Marrow Aspirate: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- Peripheral Blood: Not recommended as a screening specimen unless increased plasma cells are seen on blood smear. 2-5mL sodium heparin tube. EDTA tube is acceptable.
- Fresh, Unfixed Tissue: Tissue in RPMI
- Fluids: Equal parts RPMI to specimen volume
- Paraffin Block or Cut Slide: N/A

Storage and Transportation

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Specimens should be received in our laboratory within 72 hours of collection.

CPT Code(s)*

88374x3 automated or 88377x3 manual

Turnaround Time

3-5 days

Level of Service

Global ✓  Technical ✓

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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December 18, 2019
## Multiple Myeloma-MGUS FISH Panel (New York)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>MM-MGUS NY Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td>Test Description</td>
<td>Probes: 1p-, 1q+, iso(1q): CDKN2C (1p32), CKS1B (1q21)</td>
</tr>
<tr>
<td></td>
<td>Disease(s): Plasma cell myeloma, multiple myeloma, MGUS</td>
</tr>
<tr>
<td></td>
<td>Note: Plasma cell enrichment will be performed on bone marrow or blood samples unless our client directs us otherwise. (Peripheral blood is not recommended as a screening specimen unless increased plasma cells are seen on blood smear.) Specimens should be received in our laboratory within 72 hours of collection. If enriched samples are insufficient to complete the whole panel, NeoGenomics will prioritize p53 testing unless directed otherwise by our client.</td>
</tr>
</tbody>
</table>

### Clinical Significance

The MM-MGUS FISH Panel (New York) is often used as an initial diagnosis/pre-treatment panel for the detection of FISH and chromosome aberrations useful in prognosis in plasma cell myeloma. As malignant plasma cells often have a low proliferation index, conventional cytogenetics frequently yields normal results. When this happens, interphase FISH studies can increase the abnormality detection rate.

### Specimen Requirements

- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** Not recommended as a screening specimen unless increased plasma cells are seen on blood smear. 2-5mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume
- **Paraffin Block or Cut Slide:** N/A

### Storage and Transportation

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Specimens should be received in our laboratory within 72 hours of collection.

### CPT Code(s)*

88374x5, 88367x1 automated or 8377x5, 88368x1 manual

### Turnaround Time

3-5 days

### Level of Service

Global ✓  Technical ✓

---

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Methodology

Immunohistochemistry (IHC)

Test Description

The MUM1 antibody is specific for the MUM1/IRF4 protein that is overexpressed in late plasma-cell-directed stages of B-cell differentiation. MUM1 is a powerful tool for understanding the histogenesis of B-cell lymphomas. MUM1 protein is an excellent marker for Hodgkin and Reed-Sternberg cells of classical Hodgkin lymphoma in combination with CD30. Furthermore, MUM1 seems to be a marker of prognostic value since it has been found that the expression of MUM1 is associated with the poor prognosis of patients with diffuse large B-cell lymphoma (DLBCL).

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓
### MYC (8q24)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>c-MYC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td>Test Description</td>
<td><strong>Probes:</strong> MYC (8q24)</td>
</tr>
<tr>
<td></td>
<td><strong>Disease(s):</strong> Lymphoma, NHL, B-ALL</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Available separately or as part of the <a href="#">NHL FISH Panel</a></td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• <strong>Bone Marrow Aspirate:</strong> 1-2mL Sodium Heparin Tube. EDTA tube is acceptable</td>
</tr>
<tr>
<td></td>
<td>• <strong>Peripheral Blood:</strong> 2-5mL Sodium Heparin Tube. EDTA tube is acceptable</td>
</tr>
<tr>
<td></td>
<td>• <strong>Fresh, Unfixed Tissue:</strong> Tissue in RPMI</td>
</tr>
<tr>
<td></td>
<td>• <strong>Fluids:</strong> Equal parts RPMI to specimen volume</td>
</tr>
<tr>
<td></td>
<td>• <strong>Paraffin Block:</strong> H&amp;E slide (required) plus paraffin block. Circle H&amp;E for tech-only.</td>
</tr>
<tr>
<td></td>
<td>• <strong>Cut Slides:</strong> H&amp;E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&amp;E for tech-only.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88374x1 automated. Codes may differ if manual analysis is performed.</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>4 days for unfixed or FFPE specimens</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✔ Technical ✔</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*

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MYC/IgH/Cen 8 t(8;14)

Methodology
FISH

Test Description
Probes: Trisomy 8 (Cen 8) | MYC/IgH t(8;14)
Disease(s): Burkitt lymphoma, NHL

Clinical Significance
Call Customer Care or your consulting NeoGenomics Pathologist regarding MYC/IgH/Cen 8 t(8;14).

Specimen Requirements
- **Bone marrow aspirate**: 1-2 mL in sodium heparin tube. EDTA tube is acceptable.
- **Peripheral blood**: 2-5 mL in sodium heparin tube. EDTA tube is acceptable.
- **Fresh tissue**: Tissue in RPMI.
- **Fluids**: Equal parts RPMI to specimen volume.
- **Paraffin block**: H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut slides**: H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x1 automated. Codes may differ if manual analysis is performed.

Turnaround Time
4 days for unfixed or FFPE specimens

Level of Service
Global ✓ Technical ✓

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**MYCN (n-MYC) Amplification**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>n-MYC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
</tbody>
</table>
| Test Description | Probes: MYCN (2p24.3) | Centromere 2  
|                  | Disease(s): Brain cancer, neuroblastoma, alveolar rhabdomyosarcoma, small-cell lung cancer, prostate cancer. |
| Clinical Significance | The MYCN gene, which encodes the n-myc protein, is a proto-oncogene with highest expression in the developing brain and insignificant expression in normal adult tissues. Gene amplification is detected in approximately 20% of neuroblastoma and a variety of other solid tumors including 5% medulloblastoma, glioblastoma multiforme, 25% alveolar rhabdomyosarcoma, 15-20% small-cell lung cancer, 40% neuroendocrine prostate cancer, and 5% prostate adenocarcinoma. MYCN amplifications are associated with aggressive disease and/or poor outcome. Detection can be useful to stratify patients for aggressive treatment. Numerous therapies are in development. |
| Specimen Requirements | Bone marrow aspirate: N/A  
|                      | Peripheral blood: N/A  
|                      | Fresh, unfixed tissue: N/A  
|                      | Fluids: N/A  
|                      | Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required).  
|                      | Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 88377x1 manual or 88374x1 automated. |
| Turnaround Time | 3-5 days |
| Level of Service | Global ✔  
|                  | Technical ✔ |

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MYD88 Mutation Analysis

**Alternative Name**  
Myeloid Differentiation Primary Response 88

**Methodology**  
Molecular

**Test Description**  
Bi-directional sequencing of exon 5 of the MYD88 gene which includes detection of the common L265P mutation. Testing is approved for specimens from the state of New York.

**Clinical Significance**  
MYD88 mutation is the most common genetic abnormality in the activated B-cell-like (ABC) subtype of diffuse large B-cell lymphoma (DLBCL), detected in 40% of cases. Mutations are rare in the germinal center B-cell-like (GCB) subtype, so mutation analysis can be useful to differentiate between the ABC and GCB subtypes. The L265P mutation is present in >90% of Waldenstrom’s macroglobulinemia (WM) and has been associated with increased risk of progression to WM in IgM MGUS patients. MYD88 is also implicated in susceptibility to BTK inhibitors in the treatment of B-cell neoplasms. Testing is available separately or in combination with three other contributory genes in the BTK Inhibitor Primary Susceptibility Panel.

**Specimen Requirements**
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.
- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.
- **Fresh tissue**: 0.5 - 1 cm³ in RPMI

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
81305

**Turnaround Time**  
7 days

**Level of Service**  
Global ✔

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December 18, 2019
MyoD1

Methodology
Immunohistochemistry (IHC)

Test Description
Nuclear expression of myogenic differentiation 1 (MyoD1) is restricted to skeletal muscle tissue and has been demonstrated to be a sensitive marker of myogenic differentiation. The antibody strongly labels the nuclei of myoblasts in developing skeletal muscle tissue, whereas the majority of adult skeletal muscle is negative. MyoD1 immunostaining has been demonstrated in the majority of rhabdomyosarcomas of various histological subtypes.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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Please direct any questions regarding coding to the payor being billed.
Myogenin

Methodology
Immunohistochemistry (IHC)

Test Description
Expression of myogenin is restricted to cells of skeletal muscle origin. It is a useful marker for tumors of the muscle lineage, being strongly expressed in alveolar rhabdomyosarcomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only
Myoglobin

Methodology
Immunohistochemistry (IHC)

Test Description
Myoglobin is found in skeletal and cardiac muscle but not in smooth muscle. Because myoglobin appears relatively late in the maturational sequence of striated muscle, it is typically undetectable immunohistologically in embryonic neoplasms that show differentiation toward that tissue. Accordingly, pleomorphic "adult"-type rhabdomyosarcoma and rhabdomyoma are the soft tissue tumors in which myoglobin is identified most often.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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# Naphthyl Acetate Esterase (NAE and NAE w/NAF)

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Naphthyl (Naphthol) Acetate Esterase with or without sodium fluoride inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Cytochemical stain.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • Minimum two slides fresh smear: bone marrow aspirate preferred, peripheral blood accepted  
  • Slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**      | 88319x1                                                                    |
| **Turnaround Time**  | 24 hours                                                                   |
| **Level of Service** | Stain Only                                                                 |

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Naphthyl Butyrate Esterase

Alternative Name  Naphthol Butyrate Esterase
Methodology     Immunohistochemistry (IHC)
Test Description Cytochemical stain.
Specimen Requirements
  • Minimum two slides fresh smear: bone marrow aspirate preferred, peripheral blood accepted
  • Slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition
Storage and Transportation Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.
CPT Code(s)*  88319x1
Turnaround Time  24 hours
Level of Service Stain Only ✓

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Napsin A

Methodology
Immunohistochemistry (IHC)

Test Description
Napsin A has a specific function in normal alveolar epithelium and is proposed to play a role in the proteolytic processing of surfactant precursors. Napsin A is reported to be predominantly expressed in lamellar bodies of type II pneumocytes, secondary lysosomes of alveolar macrophages, respiratory epithelium of terminal and respiratory bronchioles, plasma cells, and within a subset of lymphocytes in normal lung as well as in epithelial cells of renal tubules in normal kidney. It is weakly expressed in normal spleen. Past studies have also reported that Napsin A is expressed in most primary lung adenocarcinomas. Napsin A expression may also be seen in renal carcinoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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December 18, 2019
NeoARRAY™ SNP/Cytogenetic Profile

Alternative Name
SNP array, CGH array, microarray

Methodology
Cytogenetics

Test Description
The NeoARRAY SNP/Cytogenetic Profile is available for hematological, solid tumor, and pregnancy loss indications. With the best genome-wide coverage available, this test employs an enhanced SNP microarray with over 2.6 million SNP and non-polymorphic markers for detection of copy number variants (deletions, duplications, and amplifications) and loss of heterozygosity or uniparental disomy (LOH or UPD) in any chromosome. Sensitivity and specificity for detection of copy number variants >400 kb is >99%. Testing may not reliably detect abnormalities present in less than 20% of the cells tested. Balanced rearrangements, including translocations and inversions, are not detectable by this method. Clients may request NeoARRAY on POC as the sole test, or they may order POC cytogenetics with reflex to NeoARRAY if the POC culture fails or if cytogenetic results are normal. For reflex orders, if there is no cell attachment or growth after 14 days in culture, a cytogenetics failure report will be issued and NeoARRAY will be performed. If there is limited cell attachment after 14 days in culture, NeoGenomics will contact the client for instructions. When array testing is not performed, a fee will be charged for DNA extraction (which is performed upon specimen receipt).

Clinical Significance
This test provides genome-wide characterization of chromosomal imbalances at resolution approximately 10-25 times higher than conventional cytogenetics. Testing is appropriate in hematological disorders and solid tumors to obtain a detailed description of breakpoints and unidentified material in abnormal karyotypes, for detecting abnormalities in samples with normal karyotype, and for use after cytogenetics failure due to lack of growth or inadequate metaphases. Microarray testing such as the NeoARRAY is the only test for detection of copy-neutral loss of heterozygosity and uniparental disomy. Array testing is most often used in CLL, MDS, ALL, AML, and solid tumors.

Specimen Requirements
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.
- **Fresh tumor tissue:** 0.5-1 cm³ in RPMI.
- **Products of conception (without cytogenetics):**
  - **Dissected chorionic villi or known fetal tissue (preferred).** Please send at least 50-100 mg villi or 0.5-1 cm³ tissue(s) to our Aliso Viejo, CA laboratory.
  - **Uterine contents or tissue of mixed fetal/maternal origin:** Please send at least 50-100 mg villi or 0.5-1 cm³ tissue(s) to our Nashville, TN laboratory.
  - **Note:** Place tissue in RPMI. Note type of tissue(s) sent on the test requisition and whether it is fetal in origin or mixed maternal/fetal. Please see our contact page for the shipping addresses.
- **POC (cytogenetics reflex to NeoARRAY):** Please send at least 50-100 mg villi or 1-1.5 cm³ tissue(s) to our Nashville, TN laboratory.
  - **Note:** Place tissue in RPMI. Note type(s) of tissue on test requisition, and send to our Nashville, TN facility. Please see our contact page for the shipping address.
  - **Note:** Dissected chorionic villi or known fetal tissue(s) are preferred, but uterine contents or tissue of mixed fetal/maternal origin is acceptable and will be processed. Please include villi if sending tissue from a fetal demise. Tissues placed in formalin are unacceptable.
| **Storage and Transportation** | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <48 hours old preferred. |
| **CPT Code(s)** | 81229 |
| **Turnaround Time** | 14 days |
| **Level of Service** | Global ✔ |

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* December 18, 2019
**NeoARRAY™ SNP/Cytogenetic Profile**

**Alternative Name**  
SNP microarray

**Methodology**  
Molecular

**Test Description**  
The NeoARRAY SNP/Cytogenetic Profile is available for hematological, solid tumor, and pregnancy loss indications. With the best genome-wide coverage available, this test employs an enhanced SNP microarray with over 2.6 million SNP and non-polymorphic markers for detection of copy number variants (deletions, duplications, and amplifications) and loss of heterozygosity or uniparental disomy (LOH or UPD) in any chromosome. Sensitivity and specificity for detection of copy number variants >400 kb is >99%. Testing may not reliably detect abnormalities present in less than 20% of the cells tested. Balanced rearrangements, including translocations and inversions, are not detectable by this method. Clients may request NeoARRAY on POC as the sole test, or they may order POC cytogenetics with reflex to NeoARRAY if the POC culture fails or if cytogenetic results are normal. For reflex orders, if there is no cell attachment or growth after 14 days in culture, a cytogenetics failure report will be issued and NeoARRAY will be performed. If there is limited cell attachment after 14 days in culture, NeoGenomics will contact the client for instructions. When array testing is not performed, a fee will be charged for DNA extraction (which is performed upon specimen receipt).

**Clinical Significance**  
This test provides genome-wide characterization of chromosomal imbalances at resolution approximately 10-25 times higher than conventional cytogenetics. Testing is appropriate in hematological disorders and solid tumors to obtain a detailed description of breakpoints and unidentified material in abnormal karyotypes, for detecting abnormalities in samples with normal karyotype, and for use after cytogenetics failure due to lack of growth or inadequate metaphases. Microarray testing such as the NeoARRAY is the only test for detection of copy-neutral loss of heterozygosity and uniparental disomy. Array testing is most often used in CLL, MDS, ALL, AML, and solid tumors.

**Specimen Requirements**
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.
- **Fresh tumor tissue:** 0.5-1 cm$^3$ in RPMI.
- **Products of conception (without cytogenetics):**
  - **Dissected chorionic villi or known fetal tissue (preferred).** Please send at least 50-100 mg villi or 0.5-1 cm$^3$ tissue(s) to our Aliso Viejo, CA laboratory.
  - **Uterine contents or tissue of mixed fetal/maternal origin:** Please send at least 50-100 mg villi or 0.5-1 cm$^3$ tissue(s) to our Nashville, TN laboratory.
  - **Note:** Place tissue in RPMI. Note type of tissue(s) sent on the test requisition and whether it is fetal in origin or mixed maternal/fetal. Please see our contact page for the shipping addresses.

- **POC (cytogenetics reflex to NeoARRAY):** Please send at least 50-100 mg villi or 1-1.5 cm$^3$ tissue(s) to our Nashville, TN laboratory.
  - **Note:** Place tissue in RPMI. Note type(s) of tissue on test requisition, and send to our Nashville, TN facility. Please see our contact page for the shipping address.
  - **Note:** Dissected chorionic villi or known fetal tissue(s) are preferred, but uterine contents or tissue of mixed fetal/maternal origin is acceptable and will be processed. Please include villi if sending tissue from a fetal demise. Tissues placed in formalin are unacceptable.
<table>
<thead>
<tr>
<th><strong>Storage and Transportation</strong></th>
<th>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;48 hours old preferred.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81229</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>14 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔️</td>
</tr>
</tbody>
</table>
# NeoLAB™ AML Profile - Liquid Biopsy

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>AML Prognostic Profile, Acute Myeloid Leukemia Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>This test is performed by sequencing the entire coding regions of the genes listed using cell-free plasma DNA/RNA. ASXL1, BCOR, BRAF, CEBPA, CSF3R, DNMT3A, ETV6, EZH2, FLT3, HRAS, IDH1, IDH2, JAK2 V617F, JAK2 Exon 12+14, KIT, KMT2A (MLL), KRAS, NPM1, NRAS, PDGFRA, PHF6, PTPN11, RUNX1, SETBP1, STAG2, TET2, TP53 and WT1. Test orders include summary interpretation of all results together. For patients with therapy-related AML, AML that evolved from MDS, and AML with myelodysplasia, we recommend instead the NeoLAB™ MDS/CMML Profile- Liquid Biopsy.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Molecular profiling with the NeoLAB™ AML Profile- Liquid Biopsy is appropriate for AML patients with intermediate-risk cytogenetic abnormalities, which is a heterogeneous group. This Profile can refine and improve risk stratification by confirming intermediate risk or reclassifying patients to more favorable or unfavorable risk categories. This change in risk classification may have therapeutic implications. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available. For patients with therapy-related AML, AML that evolved from MDS, and AML with myelodysplasia, we recommend instead the NeoLAB™ MDS/CMML Profile- Liquid Biopsy. To rule out favorable-risk AML, we recommend performing NeoLAB™ PML-RARA Translocation, t(15;17) - Liquid Biopsy, NeoLAB™ RUNX1-RUNX1T1 (AML1-ETO) Translocation, t(8;21) - Liquid Biopsy, or NeoLAB™ inv(16), CBFB-MYH11 Translocation - Liquid Biopsy.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td><strong>Peripheral blood:</strong> 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81450x1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>14 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✔</td>
</tr>
</tbody>
</table>

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**NeoLAB™ BTK Inhibitor Acquired Resistance Panel - Liquid Biopsy**

**Alternative Name**

BTK Inhibitor Acquired Resistance Panel - Liquid Biopsy

**Methodology**

Molecular

**Test Description**

The NeoLAB™ BTK Inhibitor Acquired Resistance Panel is a blood test performed by modified proprietary bi-directional sequencing of the BTK and PLC-gamma-2 genes using cell-free circulating tumor DNA (ctDNA). This method allows detection of mutations with sensitivity of 10^-4. Analysis includes the BTK mutation C481S and surrounding regions corresponding to amino acids C464 to M509 and the following PLC-gamma-2 mutations and surrounding regions: R665W (W646 to S679), S707 (A681 to M743), and L845F (I839 to V860).

**Clinical Significance**

The NeoLAB BTK Acquired Resistance Panel detects mutations in Bruton tyrosine kinase (BTK) and PLC-gamma-2, which are two key driver genes in B-cell receptor pathway and play major role in lymphoproliferative neoplasms, especially in chronic lymphocytic leukemia (CLL), mantle cell lymphoma and diffuse large B-cell lymphoma (DLBL). Treating CLL with BTK inhibitors has been shown to be very effective. However, some patients with CLL and other types of B-cell lymphoma may develop resistance to BTK inhibitors by developing mutations in BTK or PLCG2 genes. The NeoLAB BTK Acquired Resistance Panel detects mutations in BTK and PLC-gamma-2 in the peripheral blood plasma cell-free DNA (cfDNA) approximately 2 to 12 months prior to the appearance of overt clinical resistance to therapy. The early detection of potential resistance may alert the treating physician to devise a new strategy for therapy or a combination therapy that may prevent overt resistance. Other indications for testing are for when a patient has few or no circulating cells.

**Specimen Requirements**

Peripheral blood: 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

81479x1

**Turnaround Time**

10 days

**Level of Service**

Global ✓

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# NeoLAB™ FLT3 Mutation Analysis - Liquid Biopsy

## Alternative Name
FLT3, FLT3 TKD, FLT3 ITD, FLT3 Liquid Biopsy Testing

## Methodology
Molecular

## Test Description
Detection of internal tandem duplication and exon 20 tyrosine kinase domain (TKD) mutations using bidirectional sequencing. Positive results identify specific TKD mutations or report ITD results quantitatively as percent abnormal ITD peak. Testing is performed on cell-free plasma DNA/RNA to increase sensitivity.

## Clinical Significance
Testing for FLT3 and other gene mutations in AML patients can improve risk stratification. The presence of an FLT3 mutation in a patient with AML implies aggressive disease. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. For FLT3-ITD, results are quantitative and help in monitoring. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available.

## Specimen Requirements
**Peripheral blood:** 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.

## Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

## CPT Code(s)*
81245, 81246

## Medicare MolDX CPT Code(s)*
81479

## Turnaround Time
7 days

## Level of Service
Global ✓

---

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**NeoLAB™ IDH1 Mutation Analysis - Liquid Biopsy**

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>IDH1 Liquid Biopsy Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of the exon 4 mutation hotspot region in the IDH1 gene. Testing is performed on cell-free plasma DNA/RNA to increase sensitivity.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>IDH1 or IDH2 mutations are detected in approximately 15-20% of acute myeloid leukemia (AML). Patients with AML and mutations are likely to respond to IDH inhibitors. This test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available. This test should not be used for solid tumors. Tissue-based testing is recommended for solid tumors.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Peripheral blood</strong>: 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81120</td>
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<td><strong>Turnaround Time</strong></td>
<td>7 days</td>
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<td><strong>Level of Service</strong></td>
<td>Global</td>
</tr>
</tbody>
</table>

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**NeoLAB™ IDH2 Mutation Analysis - Liquid Biopsy**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>IDH2 Liquid Biopsy Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of the exon 4 mutation hotspot region in the IDH2 gene. Testing is performed on cell-free plasma DNA/RNA to increase sensitivity.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>IDH1 or IDH2 mutations are detected in approximately 15-20% of acute myeloid leukemia (AML). Patients with AML and mutations are likely to respond to IDH inhibitors. This test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available. This test should not be used for solid tumors. Tissue-based testing is recommended for solid tumors.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td><strong>Peripheral blood:</strong> 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81121</td>
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<tr>
<td>Turnaround Time</td>
<td>7 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
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</tbody>
</table>

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NeoLAB™ inv(16), CBFB-MYH11 Translocation - Liquid Biopsy

Alternative Name: Liquid Biopsy CBFB-MYH11 Fusion Testing

Methodology: Molecular

Test Description: Real-time RT-PCR for quantitative detection of the inv(16) CBFB-MYH11 fusion transcript using cell-free plasma DNA/RNA. This assay identifies type A fusions, which account for >90%

Clinical Significance: The inv(16) occurs in about 10% of all acute myeloid leukemia and nearly all cases of AML with eosinophilia, subtype M4eo. The inversion is generally associated with relatively good outcome. This assay is recommended for diagnostic confirmation, for monitoring minimal residual disease, and for detection of relapse. c-KIT mutation testing may be considered for inv(16)-positive AML patients as c-KIT mutations are considered an adverse risk factor in these and other patients with core-binding factor AML. In addition, this test can be used for determining if a bone marrow biopsy is an absolute necessity. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available.

Specimen Requirements: Peripheral blood: 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*: 81401

Turnaround Time: 7 days

Level of Service: Global ✅

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# NeoLAB™ KIT (c-KIT) Mutation Analysis - Liquid Biopsy

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>c-KIT Liquid Biopsy Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of KIT exons 8, 9, 11, 13 and 17 for detection of activating mutations including the common mutation D816V. Testing is performed on cell-free plasma DNA/RNA to increase sensitivity.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>The four tested exons encompass the majority of mutations found in core-binding factor AML (CBF-AML) and mast cell disease (systemic mastocytosis). Mutation identification is useful for planning therapy and predicting clinical course. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available. This test should not be used for solid tumors. Tissue-based testing is recommended for solid tumors.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Peripheral blood</strong>: 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81272</td>
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<tr>
<td><strong>Turnaround Time</strong></td>
<td>7 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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December 18, 2019
# NeoLAB™ KRAS Mutation Analysis - Liquid Biopsy

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>KRAS Liquid Biopsy Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of exons 2 and 3 of the KRAS gene. High-sensitivity sequencing is used for enhanced detection of mutations in codons 12, 13, 59, and 61. Testing is performed on cell-free plasma DNA/RNA to increase sensitivity. Note - NeoLAB™ KRAS Mutation Analysis-Liquid Biopsy will only be performed for hematological diseases at this time.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Testing is recommended as a follow-up in patients with AML or MDS/CMML with confirmed KRAS mutations. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available. This test should not be used for solid tumors. Tissue-based testing is recommended for solid tumors.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Peripheral blood</strong>: 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81275, 81276</td>
</tr>
<tr>
<td><strong>Medicare MolDX CPT Code(s)</strong></td>
<td>81479</td>
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<tr>
<td><strong>Turnaround Time</strong></td>
<td>7 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔</td>
</tr>
</tbody>
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**NeoLAB™ MDS/CMML Profile - Liquid Biopsy**

**Alternative Name**
MDS/CMML Profile - Liquid Biopsy

**Methodology**
Molecular

**Test Description**
This test is performed by the sequencing the entire coding regions of the genes listed using cell-free plasma DNA/RNA. ASXL1, BCOR, BCORL1, BRAF, CBL, CEBPA, CUX1, DNMT3A, ETV6, EZH2, FLT3, HRAS, IDH1, IDH2, JAK2 V617F, JAK2 Exon 12+14, KIT, KRAS, NF1, NPM1, NRAS, PDGFRA, PPM1D, PTEN, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, TET2, TP53, U2AF1, and ZRSR2. Test orders include summary interpretation of all results together.

**Clinical Significance**
This molecular profile analyzes genes frequently mutated in myelodysplastic syndrome (MDS) and the related MDS/MPN overlap disease chronic myelomonocytic leukemia (CMML). Testing is useful to establish diagnosis and developing strategies for treatment and management, as mutations can signify poor or favorable prognosis and they inform of the underlying disease biology. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available. Molecular profiling in MDS and CMML complements and should be interpreted with cytogenetic/FISH test findings. This Profile may also be used in AML cases that evolved from MDS, therapy-related AML, and AML with myelodysplasia.

**Specimen Requirements**
**Peripheral blood:** 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**
81450x1

**Turnaround Time**
14 days

**Level of Service**
Global

---

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December 18, 2019
NeoLAB™ Myeloid Disorders Profile - Liquid Biopsy

Alternative Name
Myeloid Disorders Profile - Liquid Biopsy

Methodology
Molecular

Test Description
This test is performed on cell-free DNA/RNA in peripheral blood plasma by sequencing the entire coding regions of the genes listed. ABL1, ASXL1, ATRX, BCOR, BCORL1, BRAF, CALR, CBL, CBLB, CBLC, CDKN2A, CEBPA, CSF3R, CUX1, DNMT3A, ETV6, EZH2, FBXW7, FLT3, GATA1, GATA2, GNAS, HRAS, IDH1, IDH2, IKZF1, JAK2, JAK3, KDM6A, KIT, KMT2A (MLL), KRAS, MPL, MYD88, NF1, NOTCH1, NPM1, NRAS, PDGFRA, PHF6, PPM1D, PTEN, PTPN11, RAD21, RUNX1, SETBP1, SF3B1, SMC1A, SMC3, SRSF2, STAG2, TET2, TP53, U2AF1, WT1, ZRSR2. Test orders include summary interpretation of all results together.

Clinical Significance
The NeoLAB Myeloid Disorders Profile is a 56-gene panel that targets known mutations associated with acute myeloid leukemia (AML), myeloproliferative neoplasms (MPN), myelodysplastic syndrome (MDS), chronic myelogenous leukemia (CML), chronic myelomonocytic leukemia (CMML) and juvenile myelomonocytic leukemia (JMML). Testing using this panel can aid in making therapy decisions, predicting prognosis, and can be used in clinical research. This is a generic and comprehensive profiling of myeloid neoplasms. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available.

Specimen Requirements
Peripheral blood: 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
81450x1 (Effective as of 07/02/2018 | Prior to 07/2/2018 CPT Code was 81455x1)

Turnaround Time
14 days

Level of Service
Global ✓

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### NeoLAB™ NPM1 Mutation Analysis - Liquid Biopsy

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>NPM1 Liquid Biopsy Testing, Nucleophosmin (Nucleolar Phosphoprotein B23)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>PCR and fragment analysis of exon 12 of the NPM1 gene to detect small insertion mutations specific to AML. Positive results are reported quantitatively as percent abnormal DNA. Testing is performed on cell-free plasma DNA/RNA to increase sensitivity.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Testing for NPM1 and other gene mutations in AML patients with intermediate-risk cytogenetic abnormalities can improve risk stratification. NPM1 mutations can predict favorable prognosis in AML. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. Results are quantitative and help in monitoring. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Peripheral blood:</strong> 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
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<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81310</td>
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<tr>
<td><strong>Turnaround Time</strong></td>
<td>7 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓</td>
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</tbody>
</table>

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**NeoLAB™ NRAS Mutation Analysis - Liquid Biopsy**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>NRAS Liquid Biopsy Testing</th>
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</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of NRAS exons 2 and 3 which includes sites of common activating mutations in codons 12, 13, 59, and 61. Testing is performed on cell-free plasma DNA/RNA to increase sensitivity. Note - NeoLAB™ NRAS Mutation Analysis- Liquid Biopsy will only be performed for hematological diseases at this time.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>NRAS is highly homologous with KRAS; both are members of the most frequently mutated family of oncogenes. Mutations are found in MDS/CMML, AML, and in advanced systemic mastocytosis. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity, as well as monitoring disease status and response to therapy. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available. This test should not be used for solid tumors. Tissue-based testing is recommended for solid tumors.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td><strong>Peripheral blood:</strong> 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81311</td>
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<td>Turnaround Time</td>
<td>7 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✔️</td>
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</tbody>
</table>

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# NeoLAB™ PML-RARA Translocation, t(15;17) - Liquid Biopsy

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>PML-RARA Translocation Liquid Biopsy Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Real-time RT-PCR for quantitative detection of the t(15;17) PML-RARA fusion transcript using cell-free plasma DNA/RNA. Both long and short isoforms of the fusion transcript are detected.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>The (15;17) translocation occurs in nearly all cases of acute promyelocytic leukemia (APL, or AML subtype M3). The translocation is associated with a high rate of complete remission due to sensitivity of leukemic cells to all trans-retinoic acid (ATRA). This assay is recommended for diagnostic confirmation and initiation of ATRA therapy, for monitoring minimal residual disease, and for detection of relapse. In addition, this test can be used for screening and determining if a bone marrow biopsy is an absolute necessity. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td><strong>Peripheral blood:</strong> 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81315</td>
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<tr>
<td>Turnaround Time</td>
<td>7 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
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</table>

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**NeoLAB™ RUNX1-RUNX1T1 (AML1-ETO) Translocation, t(8;21) - Liquid Biopsy**

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>AML1-ETO Translocation Liquid Biopsy, AML1-ETO Fusion Liquid Biopsy, RUNX1-RUNX1T1 Translocation Liquid Biopsy, RUNX1-RUNX1T1 Fusion Liquid Biopsy</th>
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<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Real-time RT-PCR for quantitative detection of the t(8;21) RUNX1-RUNX1T1 fusion transcript (formerly called AML1-ETO) using cell-free plasma DNA/RNA.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>The (8;21) translocation occurs in approximately 5% of AML. These cases are usually considered core-binding factor AML (CBF-AML). The translocation is usually associated with a high rate of complete remission and longer overall survival in AML subtype M2. This assay is recommended for diagnostic confirmation of and for monitoring minimal residual disease. c-KIT mutation testing may be considered for t(8;21)-positive AML patients as c-KIT mutations are considered an adverse risk factor in these patients. In addition, this test can be used for determining if a bone marrow biopsy is an absolute necessity. It can also be used for performing molecular studies when a bone marrow sample is inadequate (dry tap, insufficient quantity, or not viable), or not available.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Peripheral blood:</strong> 2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81401</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>7 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*

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# NeoSITE™ BE Barrett's Esophagus FISH Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Barrett's Esophagus FISH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Probes: MYC (8q24)</td>
</tr>
<tr>
<td></td>
<td>This 4-probe FISH assay is performed on cytology brushings from Barrett esophagus to determine patterns of chromosomal gain and loss suggestive of esophageal adenocarcinoma/high-grade dysplasia vs. low grade dysplasia/non-dysplastic tissue. Sensitivity is 86% and specificity is 67% for differentiating the high-risk from the low-risk groups. Sensitivity and specificity are higher when only nodules rather than the entire esophagus are brushed. Cells from nodular surfaces will be tested first (if available) and reported as a final result if positive, or testing will reflex to the pan brushing sample if negative. Testing is approved for specimens from the state of New York.</td>
</tr>
<tr>
<td><strong>Disease(s):</strong></td>
<td>Barrett's esophagus, esophageal adenocarcinoma.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>This assay serves as an ancillary test in patients with Barrett's esophagus (BE) for determining risk of having high-grade dysplasia or esophageal cancer, for determining the prognosis of BE, and for differentiating low-grade dysplasia (LGD) from high-grade dysplasia (HGD).</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Collecting brushings:</strong></td>
</tr>
<tr>
<td></td>
<td>• Brushings are collected at endoscopy before biopsy. First brush any areas perceived to be nodular in contour, if present. Collect all cells from nodular surfaces onto a single brush. Process the brush as instructed below.</td>
</tr>
<tr>
<td></td>
<td>• Then collect a separate brushing from the entire involved esophageal mucosa throughout its length (pan brushing).</td>
</tr>
<tr>
<td></td>
<td>• A single pan brushing is acceptable if nodules are not seen.</td>
</tr>
<tr>
<td></td>
<td><strong>Processing the brushes:</strong></td>
</tr>
<tr>
<td></td>
<td>• Immediately after collection, place each brush into a separate vial of PreservCyt fixative that is labeled with patient ID and area brushed (nodular or pan).</td>
</tr>
<tr>
<td></td>
<td>• Free cells from brush into PreservCyt as quickly as possible by rotating the brush in the solution 10 times and then swirling the brush vigorously.</td>
</tr>
<tr>
<td></td>
<td>• Snip off the brush in the PreservCyt solution and tighten the cap.</td>
</tr>
<tr>
<td><strong>Note:</strong> Cytology studies are not performed at NeoGenomics and should be performed, as indicated, by the referring institution on additional samples. Please contact NeoGenomics for a printable set of detailed collection instructions for the endoscopist.</td>
<td></td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>88374x1 automated. Codes may differ if manual analysis is performed.</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>3-5 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓  Technical ✓</td>
</tr>
</tbody>
</table>

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# NeoSITE™ Cervical FISH Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Cervical FISH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
</tbody>
</table>
| Test Description            | **Probes:** TERC (3q26) | D5S630 (5p15) | CEN 7 (7p11.1-q11.1) | MYC (8q24) | ZNF217 (20q13)  
**Disease(s):** Cervical neoplasia, ASCUS, LSIL, HSIL, CIN, cervical cancer |
| Clinical Significance       | The NeoSITE Cervical FISH Panel, performed on ThinPrep® or SurePath™ cytology samples, determines copy numbers of five genomic loci that show non-random gains in pre-cancerous and cancerous cervical lesions including ASCUS, LSIL, HSIL, and CIN. This test serves as an adjunct to cytology and HPV nucleic acid analysis to aid diagnosis/classification, prognosis assessment, and monitoring of cervical lesions. In validation studies, this test detected genomic instability typical of high-grade, HPV+ lesions with sensitivity of 88.9% and specificity of 98.0%. |
| Specimen Requirements       | Cervical specimens. Acceptable specimen collection/transport containers are: -ThinPrep® Pap Vial -SurePath™ Pap Vial Do not use APTIMA® Specimen Transfer tubes for ThinPrep® or SurePath™ samples when ordering this test. |
| Storage and Transportation  | Use cold pack for transport if available, making sure cold pack is not in direct contact with specimen. Specimen must be delivered to NeoGenomics within 21 days of collection. |
| CPT Code(s)*                | 88374x2 automated or 88377x2 manual                |
| Turnaround Time             | 5 days                                            |
| Level of Service            | Global ✔ Technical ✔                              |

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# NeoSITE™ Melanoma

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Melanoma FISH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td>Test Description</td>
<td><strong>Probes:</strong> RREB1 (6p25)</td>
</tr>
<tr>
<td></td>
<td><strong>Disease(s):</strong> Melanoma</td>
</tr>
<tr>
<td></td>
<td>Read more about the NeoSITE Melanoma panel.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>NeoSITE Melanoma is a second-generation FISH assay that aids diagnostic discrimination between nevi and melanoma by informing of chromosomal gains or losses in four regions predictive of malignancy. This probe set has been modified from the prior version to improve classification of morphologically borderline lesions and detection of spitzoid melanoma, to control for tetraploidy, and to include 8q24 and 9p21 markers.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td><strong>Paraffin Block:</strong> Send block. For tech-only testing, include H&amp;E slide with target area circled (required).</td>
</tr>
<tr>
<td></td>
<td><strong>Cut Slides:</strong> Slides should be cut at 4 micron thickness. For global testing, send 5 unstained slides. For tech-only, send 4-5 unstained slides plus H&amp;E slide with target area circled (required).</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88377x2 manual or 88374x2 automated</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>5 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓ Technical ✓</td>
</tr>
</tbody>
</table>

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December 18, 2019
### NeoTYPE AITL/Peripheral T-Cell Lymphoma Profile

**Alternative Name**
Angioimmunoblastic/Peripheral T-Cell Lymphoma Profile

**Methodology**
Molecular

**Test Description**
The NeoTYPE AITL/Peripheral T-Cell Lymphoma Profile is performed by the sequencing of select exons in the genes BCL1 (CCND1), IDH1, IDH2, DNMT3A, TET2 and RHOA.

**Clinical Significance**
Angioimmunoblastic T-cell lymphoma (AITL) is a subtype of peripheral T-cell lymphoma (PTCL) and accounts for 20-25% of PTCLs. Peripheral T-cell lymphoma is known as an aggressive group of lymphoid malignancies and represent about 10-15% of non-Hodgkin lymphomas. Frequent mutations have been detected in the genes IDH1/2, DNMT3A, TET2 and RHOA in patients diagnosed with AITL. These mutations may play a role in the pathogenesis of AITL/PTCLs.

**Specimen Requirements**
- **Bone marrow (Preferred):** 2 mL in EDTA tube.
- **Peripheral blood:** 5 mL in EDTA tube.
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**
81479x1

**Turnaround Time**
14-21 days

**Level of Service**
Global ✔

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December 18, 2019
NeoTYPE AML Favorable-Risk Profile

Alternative Name: AML Favorable-Risk Profile

Methodology: Molecular

Test Description: This test is performed by sequencing of select exons of the genes FLT3 and KIT. Test orders include summary interpretation of all results together. Individual genes from a validated list of myeloid genes can be added-on.

Clinical Significance: Molecular profiling with the NeoTYPE AML Favorable-Risk Profile is appropriate for AML patients with core-binding factor leukemia-related cytogenetic abnormalities [namely t(8;21) and inv(16)] and t(15;17). The profile can improve risk stratification by confirming favorable risk or reclassifying patients to a less favorable risk category if gene mutations are present.

Specimen Requirements:
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81479x1

Turnaround Time: 10 days

Level of Service: Global ✔️

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# NeoTYPE Liposarcoma Fusion Profile

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Liposarcoma Fusions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>The NeoTYPE Liposarcoma Fusion Profile combines next-generation sequencing to detect translocations in the genes EWSR1, FUS, HMGA2, and PLAG1 with FISH testing for MDM2 to detect amplifications relevant in liposarcoma. FISH components of NeoTYPE Profiles may be ordered as “Tech-Only” by pathology clients who wish to perform the professional component.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>The diagnosis and classification of lipomatous lesions can be very challenging. Fortunately, reproducible cytogenetics have been identified in the most common lipomatous neoplasms. MDM2 amplification is a very consistent feature of well-differentiated liposarcoma/atypical lipomatous tumor and their dedifferentiated counterparts, while other abnormalities have been identified in lipoblastoma, lipoma, and myxoid/round cell liposarcoma. This panel, combining MDM2 FISH with selected NGS studies, has been designed to help in the diagnosis of the major lipomatous neoplasms and provide clear distinction from one another.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81479x1, 88374x1 automated or 88377x1 manual</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>21 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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# NeoTYPE® AML Prognostic Profile

**Alternative Name**  
AML Prognostic Profile

**Methodology**  
Molecular

**Test Description**  
This test is performed by sequencing the entire coding regions of the genes listed. ASXL1, BCOR, BRAF, CEBPA, CSF3R, DNMT3A, ETV6, EZH2, FLT3, HRAS, IDH1, IDH2, JAK2 including V617F and Exons 12+14, KIT, KMT2A (MLL), KRAS, NPM1, NRAS, PDGFRA, PHF6, PTPN11, RUNX1, SETBP1, STAG2, TET2, TP53 and WT1. FLT3 is performed by multiple methods. Individual genes from a validated list of myeloid genes can be added-on. Test orders include summary interpretation of all results together. The AML Prognostic Profile may also be ordered as reflex after intermediate cytogenetics in the AML Reflex Panel (see separate AML Reflex Panel listing). For patients with therapy-related AML, AML that evolved from MDS, and AML with myelodysplasia, we recommend instead the NeoTYPE MDS/CMML Profile.

**Clinical Significance**  
Molecular profiling with the NeoTYPE AML Prognostic Profile is appropriate for AML patients with intermediate-risk cytogenetic abnormalities, which is a heterogeneous group. This Profile can refine and improve risk stratification by confirming intermediate risk or reclassifying patients to more favorable or unfavorable risk categories. This change in risk classification may have therapeutic implications. For patients with therapy-related AML, AML that evolved from MDS, and AML with myelodysplasia, we recommend instead the NeoTYPE MDS/CMML Profile.

**Specimen Requirements**

- **Bone marrow (Preferred):** 2 mL in EDTA tube.
- **Peripheral blood:** 5 mL in EDTA tube.
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
81450x1

**Turnaround Time**  
14 days

**Level of Service**  
Global ✓

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NeoTYPE® Brain Tumor Profile

Alternative Name
Brain Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE Brain Tumor Profile analyzes 61 biomarkers through a combination of next-generation sequencing (NGS), other molecular methods, FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions.

- NGS (50 genes + 2 biomarkers): AKT1, APC, ATRX, BCOR, BCORL1, BRAF, CDK6, CDKN2A, CIC, CTNNB1, EGFR, EPCAM, ERBB2, ERBB4, FGFR1, FGFR1 fusions, FGFR2, FGFR2 fusions, FGFR3, FGFR3 fusions, FUBP1, H3F3A (H3-3A), HIST1H3C (H3C3), HRAS, IDH1, IDH2, KRAS, MAP2K1, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, MYC, MYCN, NF1, NF2, NRAS, NTRK1 fusions, NTRK2 fusions, NTRK3 fusions, PIK3CA, PMS2, PTCH1, PTEN, RAF1 fusions, RB1, SETD2, SMAD4, SM0, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB), VHL
- Other Molecular (2 genes): EGFRvIII Analysis, MGMT Promoter Methylation Analysis
- FISH (6 FISH): 1p/19q Deletion, BRAF, MET, MYCN, PDGFRA, PTEN (tech-only available)
- IHC (1 biomarker): PD-L1 22C3 (tech-only available)

Clinical Significance
The NeoTYPE Brain Tumor Profile characterizes primary or metastatic brain tumors of any histological subtype for the most significant genetic changes relevant to diagnosis, therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease and patients with an atypical clinical presentation.

Specimen Requirements
FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Slides can be packed at room temperature.

CPT Code(s)*
81455x1, 88377x6, 88360x1

Turnaround Time
14 days

Level of Service
Global ✓

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December 18, 2019
NeoTYPE® Breast Tumor Profile

Alternative Name: Breast Tumor Profile

Methodology: Molecular

Test Description: The NeoTYPE Breast Tumor Profile analyzes 60 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (54 genes + 2 biomarkers): AKT1, ARID1A, ATM, ATR, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDH1, CDK12, CHEK1, CHEK2, CTNNB1, EGFR, ESR1, ERBB2, ERBB4, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCL, FGFR1, FGFR2, FGFR3, GATA3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, MRE11A (MRE11), MSH2, MSH6, NBN, NRAS, PALB2, PIK3CA, PMS2, PTEN, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- FISH (2 FISH): MET, PTEN (tech-only available)
- IHC (2 biomarkers): PD-L1 SP142, Pan-TRK (tech-only available for PD-L1)

Clinical Significance: The NeoTYPE Breast Tumor Profile characterizes primary or metastatic breast tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements: FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81455x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time: 14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

Level of Service: Global

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NeoTYPE® Cervical Tumor Profile

Alternative Name
Cervical Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE Cervical Tumor Profile analyzes 43 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (37 genes + 2 biomarkers): AKT1, ARID1A, ATM, ATR, ATRX, BRAF, BRCA1, BRCA2, BRIP1, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, HRAS, KRAS, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, NOTCH1, NRAS, PDGFRA, PIK3CA, PMS2, PTEN, RAD50, SMAD4, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- FISH (2 FISH): MET, PTEN (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE Cervical Tumor Profile characterizes primary or metastatic cervical tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements
**FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

CPT Code(s)*
81445x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

Level of Service
Global ✓

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December 18, 2019
NeoTYPE® CLL Prognostic Profile

Alternative Name: CLL Prognostic Profile

Methodology: Molecular

Test Description: This test is performed by sequencing the entire coding regions of the genes ATM, BIRC3, BTK, CARD11, CD79B, CXCR4, MYD88, NOTCH1, SF3B1, TP53, plus IgVH Mutation Analysis and the CLL FISH Panel as noted. Test orders include summary interpretation of all results together. Individual genes from a validated list of genes can be added-on. Test orders include summary interpretation of all results together. FISH components of NeoTYPE Profiles may be ordered as "Tech-Only" by pathology clients who wish to perform the professional component.

Clinical Significance: The clinical course of chronic lymphocytic leukemia (CLL) is heterogenous, and it ranges from very indolent with a nearly normal life expectancy to rapidly progressive leading to early death. Genomic alterations in the TP53, BIRC3, NOTCH1, and SF3B1 genes, unmutated IgVH and 17p deletion by FISH are associated with adverse outcomes, and their presence or absence can improve risk stratification and treatment selection beyond clinical staging and other prognostic biomarkers. However, the most powerful biomarkers in this profile are IgVH mutation status and 17p deletion as determined by FISH.

SF3B1 mutations occur in 10-15% of CLL patients and serve as independent predictors of shortened time to treatment and poorer overall survival in CLL. NOTCH1 mutations occur in a similar proportion of CLL patients and are associated with poor prognosis, comparable to TP53 abnormalities. Genomic alterations in the ATM gene, which is located on 11q22-q23, are also associated with an adverse outcome, particularly when both ATM mutation and 11q deletion are present. However, the most powerful biomarkers in this profile are IgVH mutation status and 17p deletion as determined by FISH.

Mutations in CARD11, CD79B, CXCR4 and MYD88 are associated with primary (initial) susceptibility or resistance to BTK (Bruton tyrosine kinase) inhibitors in certain B-cell neoplasms. Mutations in MYD88 and CD79B are associated with inhibitor sensitivity, and mutations in CARD11 and CXCR4 are associated with primary resistance. Mutations in BTK and PLCG2 are associated with acquired ibrutinib resistance in patients with B-cell neoplasms who have relapsed and/or show acquired (secondary) resistance after an initial response to BTK (Bruton tyrosine kinase) inhibitors. PLC-Gamma-2 (PLCG2) mutation analysis is available separately, if clinically indicated.

Specimen Requirements:

- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.
- **Fresh tissue:** 0.5 - 1 cm³ in RPMI.

Storage and Transportation: Refrigerate specimen. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible.

CPT Code(s)*: 88374x4; 81445x1

Turnaround Time: 14 days

Level of Service: Global

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# NeoTYPE® Colorectal Tumor Profile

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Colorectal Tumor Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
</tbody>
</table>
| **Test Description** | The NeoTYPE Colorectal Tumor Profile analyzes 44 biomarkers through a combination of next-generation sequencing (NGS), other molecular methods, FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.  
  - NGS (36 genes + 2 biomarkers): AKT1, ARID1A, APC, ATM, BRAF, EGFR, EPCAM, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, MUTYH, NOTCH1, NRAS, PDGFRA, PIK3CA, PMS2, POLD1, POLE, PTEN, RNF43, SMAD4, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB)  
  - Other Molecular (1 biomarker): MLH1 Promoter Methylation  
  - FISH (3 FISH): MET, PTEN, RET (tech-only available)  
  - IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1) |
| **Clinical Significance** | The NeoTYPE Colorectal Tumor Profile characterizes primary or metastatic colorectal tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials. |
| **Specimen Requirements** | FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives. |
| **Storage and Transportation** | Refrigerate fresh tissue in RPMI until shipping. For all specimens, use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 81445x1, 88377x3, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile |
| **Turnaround Time** | 14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile |
| **Level of Service** | Global ✓ |

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*

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December 18, 2019
### NeoTYPE® Discovery Profile for Solid Tumors

<table>
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<th>Alternative Name</th>
<th>Discovery Profile</th>
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<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
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</tbody>
</table>

The NeoTYPE Discovery Profile analyzes 336 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- **FISH (9 FISH):** ALK, BRAF, HER2, MET, MYC, PDGFRA amplifications, PTEN, RET, ROS1 (tech-only available)
- **IHC (2 biomarkers):** PD-L1 22C3 (or for breast tissue: PD-L1 SP142 FDA (TECENTRIQ®) for TNBC), Pan-TRK (tech-only available for PD-L1)
- **NGS (323 genes + 2 biomarkers):**
  - ABL1, ABL2, ACVR1B, AKT, AKT2, AKT3, ALK, AMER1, APC, AR, ARAF, ARFRP1, ARID1A, ARID1B, ARID2, ASXL1, ATM, ATR, ATRX, AURKA, AURKB, AXIN1, AXL, BAP1, BARD1, BCL2, BCL2L1, BCL6, BCO, BCOR, BCR, BRAF, BRCA1, BRCA2, BRD4, BRF1, BTK, C11orf30 (EMSY), CARD11, CBFB, CBL, CCND1, CCND2, CCNE1, CD79A, CD79B, CDH1, CDK, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CEBPA, CHD2, CHK1, CHK2, CIC, CREBBP, CRKL, CRLF2, CSF1R, CTCF, CTNNB1, CTNNB1, CUX1, CXCR4, CYLD, DAXX, DDR2, Dicer1, DNM3A, DOT1L, EGFR, EP300, EPCAM, EPHA3, EPHA5, EPHB1, ERBB2, ERBB3, ERBB4, ERG, ERRF1, ESR1, EZH2, FAM46C (TENT5C), FANCA, FANCC, FANC2, FANCE, FANCF, FANC, FANCL, FAS, FAT1, FBXW7, FGF10, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGF8, FGF9, FKBP12, FLG, FLCN, FLT1, FLT3, FLTR4, FOXL2, FUBP1, GABRA6, GABA1, GATA2, GATA3, GATA6, GID4, GLI1, GNA11, GNA13, GNAQ, GNAS, GPR124 (ADGRA2), GRIN2A, GRM3, GSK3B, H3F3A (H3-3A), HGF, HIST1H3C (H3C3), HNF1A, HRAS, HSD3B1, HSP90AA1, IDH, IDH2, IGFR, IGF2, IL1R, INHBA, INPP4B, IRF2, IRF4, IRF7, JAK1, JAK2, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIT, KLHL6, KMT2A, KMT2B, KMT2D, KRAS, LMO1, LRP1B, LYN, LRZTR1, MAGI2, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, MNT, Microsatellite Instability (MSI), MIF, MLH1, MSH2, MSH6, MTO1, MUTYH, MYC, MYCL1, MYCN, MYD88, NBN, NF1, NF2, NFE2L2, NFKBIA, NFKB2, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NTRK1, NTRK2, NTRK3, NUP93, PAK3, PAK4, PARK2, PARK2, PARK2, PARK2, PARK2, PARK2, PD1LG1, PDGFR, PDGFRB, PDK, PI3K, PI4K, PIK3CB, PIK3CG, PIK3R1, PIK3R2, PLCG2, PMS2, POLD1, POLE, PPP2R1A, PRDM1, PREX2, PRKAR1A, PRKCI, PRKDC, PRSS8, PTCH1, PTPN11, QKI, RAC1, RAD50, RAD51, RAD51B, RAD51D, RAD54L, RAF1, RANBP2, RASA, RB1, RBM10, RET, RICTOR, RNF43, ROS1, RPTOR, RUNX1, RUNX1T1, SDHA, SDHB, SDHC, SDHD, SETD2, SF3B1, SIT2, SMAD2, SMAD3, SMAD4, SMERCA4, SMERCA5B, SMO, SNAIP, SOCS1, SOX10, SOX2, SOX9, SPEN, SPOP, SPTA1, SRC, STAG2, STAT3, STAT4, STK11, SUFU, SYK, TAF1, TBX3, TERC, TERT promoter and coding sequence, TET2, TGFBR2, TNFAIP3, TNFRSF14, TOP1, TOP2A, TP53, TSC1, TSC2, TSHR, U2AF1, VEGFA, VHL, WISP3 (CCN6), WT1, XPO1, ZBTB2, ZNF217, ZNF703, Tumor Mutation Burden (TMB)
Clinical Significance

The NeoTYPE Discovery Profile for Solid Tumors combines NGS, FISH and IHC to allow for the accurate and sensitive detection of genomic alterations in the genes most relevant to various solid tumor cancers. These genomic alterations include SNP’s, indels, rearrangements and other alterations. Testing can aid in the diagnosis of various diseases and provide information to develop strategies for the treatment and management of the underlying disease. In addition, the results obtained from the NeoTYPE Discovery Profile for Solid Tumors can also be used in current or future clinical research projects.

Specimen Requirements

FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

CPT Code(s)*

81455x1, 88374x1, 88377x8; 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time

22 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

Level of Service

Global ✓
NeoTYPE® Endometrial Tumor Profile

Alternative Name
Endometrial Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE Endometrial Tumor Profile analyzes 38 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (40 genes + 2 biomarkers): AKT1, APC, ARID1A, ATM, ATR, ATRX, BRAF, BRCA1, BRCA2, CDH1, EGFR, EPCAM, ESR1, FBXW7, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, MTO, MUTH, NRAS, PDGFR, PIK3CA, PIK3R1, PMS2, POLE, PTEN, PTPN11, SMAD4, SMARCA4, SMO, SRC, TERT, Promoter, TP53, Tumor Mutation Burden (TMB)
- FISH (2 FISH): MET, PTEN (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE Endometrial Tumor Profile characterizes primary or metastatic endometrial tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements
- **FFPE tissue**: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

CPT Code(s)*
81445x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

Level of Service
Global ✓

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# NeoTYPE® Esophageal Tumor Profile

**Alternative Name**
Esophageal Tumor Profile

**Methodology**
Molecular

**Test Description**
The NeoTYPE Esophageal Tumor Profile analyzes 38 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- **NGS (32 genes + 2 biomarkers):** AKT1, ALK, APC, ARID1A, BLM, BRAF, BRCA1, BRCA2, CHD1, CDKN2A, CTNNB1, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), NFE2L2, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMARCA4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- **FISH (2 FISH):** MET, PTEN (tech-only available)
- **IHC (2 biomarkers):** PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

**Clinical Significance**
The NeoTYPE Esophageal Tumor Profile characterizes esophageal and gastroesophageal junction (GEJ) tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

**Specimen Requirements**
- **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

**CPT Code(s)**
81445x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

**Turnaround Time**
14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

**Level of Service**
Global ✓

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NeoTYPE® Gastric Tumor Profile

Alternative Name: Gastric Tumor Profile

Methodology: Molecular

Test Description: The NeoTYPE Gastric Tumor Profile analyzes 39 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (33 genes + 2 biomarkers): AKT1, ARID1A, BRAF, CDH1, CDK2NA, EGFR, ERBB2, ERBB3, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, NOTCH1, NRAS, PDGFRα, PIK3CA, PMS2, PREX2, PTEN, RNF43, SMAD4, SMO, SRC, TGFBR2, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- FISH (2 FISH): MET, PTEN (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance: The NeoTYPE Gastric Tumor Profile characterizes gastric tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements:

- FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation: Refrigerate fresh tissue in RPMI until shipping. For all specimens, use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81445x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time: 14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

Level of Service: Global

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December 18, 2019
NeoTYPE® GI Predictive Profile

Methodology
Molecular

Test Description
The NeoTYPE GI Predictive Profile analyzes 10 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (5 genes + 2 biomarkers): BRAF, HRAS, KRAS, Microsatellite Instability (MSI), NRAS, TERT Promoter, Tumor Mutation Burden (TMB)
- FISH (1 FISH): HER2 (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE GI Predictive Profile characterizes GI tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is especially relevant to colorectal or gastroesophageal tumors. It is appropriate for patients with new-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements
- **FFPE tissue**: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

CPT Code(s)*
81445x1, 88374x1, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

Level of Service
Global ✔

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December 18, 2019
NeoTYPE® GIST and Soft Tissue Tumor Profile

Alternative Name
Soft Tissue Tumor Profile, Gastrointestinal Stromal Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE GIST/Soft Tissue Tumor Profile analyzes 43 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions.
- **NGS (38 genes + 2 biomarkers):** AKT1, AKT2, AKT3, ARID1A, ATM, BRAF, CDKN2A, CTNNB1, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, GNAS, HRAS, KIT, KRAS, MAP2K1, MET, Microsatellite Instability (MSI), NF1, NRAS, NTRK1 fusions, NTRK2 fusions, NTRK3 fusions, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, SDHA, SDHB, SDHC, SDHD, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- **FISH (2 FISH):** MET, PTEN (tech-only available)
- **IHC (1 biomarker):** PD-L1 22C3 (tech-only available)

Clinical Significance
The GIST and Soft Tissue Tumor Profile characterizes primary or metastatic gastrointestinal stromal tumors, sarcomas, and other soft tissue primary or metastatic tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, patients with an atypical clinical presentation, and patients with resistant disease to explore options in clinical trials.

Specimen Requirements
- **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 88377x2, 88360x1

Turnaround Time
14 days

Level of Service
Global ✔

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December 18, 2019
NeoTYPE® Head & Neck Tumor Profile

Alternative Name
Head & Neck Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE Head & Neck Tumor Profile analyzes 34 biomarkers through a combination of next-generation sequencing (NGS), other molecular methods, FISH, and IHC as listed below. Test orders include summary interpretation of all results that help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- **NGS (27 genes + 2 biomarkers):** AKT1, ATM, BRAF, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, HRAS, IDH1, IDH2, KRAS, MET, Microsatellite Instability (MSI), NFE2L2, NOTCH1, NRAS, PIK3CA, PTEN, RB1, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- **Other Molecular (1 biomarker):** HPV DNA
- **FISH (3 FISH):** MET, PTEN, RET (tech-only available)
- **IHC (2 biomarkers):** PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE Head and Neck Tumor Profile characterizes head and neck tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements
- **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 88377x3, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days

Level of Service
Global ✔

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December 18, 2019
**NeoTYPE® HRD+ Profile**

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<th>Alternative Name</th>
<th>Homologous Recombination Deficiency / Repair (HRD / HRR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>The NeoTYPE HRD+ Profile analyzes 30 genes by next-generation sequencing (NGS) as listed below.</td>
</tr>
<tr>
<td></td>
<td>• NGS (30 genes): ATM, ATR, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, MLH1, MRE11A, MSH2, MSH6, NBN, PALB2, PMS2, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, TP53</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Homologous recombination deficiency (HRD) is a type of genomic instability caused by mutations in genes involved in repair of double-stranded DNA breaks. BRCA1, BRCA2, ATM, PALB2, and RAD51 are among the best-known genes in this repair complex; 26 such genes are included in the NeoTYPE HRD+ Profile which is a tumor profile for somatic mutation detection. PARP inhibition targets HRD-mutated cells by further crippling DNA repair and inducing synthetic lethality of tumor cells. PARP inhibition is an active area of clinical trial research across a wide variety of tumors. Breast, ovarian, pancreatic, and prostate are the cancers most studied for response to FDA-approved and off-label therapy uses. Some tumors with HRD mutations have shown susceptibility to platinum-based chemotherapy. This Profile also includes four genes associated with Lynch Syndrome, another cause of genomic scarring due to mismatch repair deficiency and microsatellite instability. Checkpoint inhibitor therapy may be considered for patients whose tumors express these defects.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81445x1</td>
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<td>Turnaround Time</td>
<td>14 days</td>
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<tr>
<td>Level of Service</td>
<td>Global ✓</td>
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</table>

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December 18, 2019
NeoTYPE® JMML Profile

Alternative Name: JMML Profile, Juvenile Myelomonocytic Leukemia Profile

Methodology: Molecular

Test Description: This test is performed by sequencing the entire coding regions of the genes listed: BRAF, CBL, CEBPA, FLT3, HRAS, JAK2 including V617F and Exons 12+14, JAK3, KIT, KRAS, NPM1, NRAS, PDGFRA, PTEN, PTPN11, and SETBP1. FLT3 is performed by multiple methods. Individual genes from a validated list of myeloid genes can be added-on. Test orders include summary interpretation of all results together.

Clinical Significance: The NeoTYPE JMML Profile detects mutations that diagnose and assess prognosis of juvenile myelomonocytic leukemia. Testing helps differentiate JMML from leukemoid reactions or other reactive processes. PTPN11 mutations are associated with worse prognosis than other mutations including NRAS and KRAS. Conversely, NRAS or KRAS mutations may be linked to more favorable outcomes.

Specimen Requirements:
- **Bone marrow (Preferred):** 2 mL in EDTA tube.
- **Peripheral blood:** 5 mL in EDTA tube.
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81450x1

Turnaround Time: 14 days

Level of Service: Global

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NeoTYPE® Liver/Biliary Tumor Profile

Alternative Name
Liver/Biliary Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE Liver/Biliary Tumor Profile analyzes 38 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (32 genes + 2 biomarkers): AKT1, APC, ARID1A, ATM, BAP1, BRAF, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, IDH1, IDH2, KRAS, MET, Microsatellite Instability (MSI), NF1, NOTCH1, NRAS, PBRM1, PIK3CA, PTEN, SMAD4, SMO, SRC, TERT Promoter, TP53, TSC1, TSC2, Tumor Mutation Burden (TMB)
- FISH (2 ISH): MET, PTEN (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE Liver/Biliary Tumor Profile characterizes liver/biliary tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements
- **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445*1, 88377*2, 88360*1, 88342*1; add 81479*1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days

Level of Service
Global

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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December 18, 2019
NeoTYPE® Lung Tumor Profile

Alternative Name
Lung Tumor Profile, Lung Cancer Profile

Methodology
Molecular

Test Description
The NeoTYPE Lung Tumor Profile analyzes 46 biomarkers through a combination of next-generation sequencing (NGS), other molecular methods, FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (37 genes + 2 biomarkers): AKT1, ARID1A, ATM, ATR, ATRX, BRAF, CCND1, CDKN2A, CDKN2B, EGFR, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, KEAP1, KIT, KMT2D, KRAS, MET, Microsatellite Instability (MSI), NF1, NFE2L2, NOTCH1, NRAS, PDGFRα, PIK3CA, PTEN, RB1, RBM10, SMARCA4, SMAD4, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- Other Molecular (1 biomarker): MET Exon 14 Deletion Analysis
- FISH (6 FISH): ALK, HER2, MET, PTEN, RET, ROS1 (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE Lung Tumor Profile characterizes primary or metastatic non-small cell tumors for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements
- **FFPE tissue**: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 88374x1, 88377x5, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days

Level of Service
Global ✔

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NeoTYPE® Lymphoma Profile

Alternative Name  Lymphoma Profile
Methodology  Molecular
Test Description  This test is performed by multiple methods to detect mutations in the following genes BCL1, BCL2, BCL6, BRAF, CARD11, CD79B, EZH2, MYD88, NOTCH1, NOTCH2, NRAS and TP53. The test is performed by sequencing the entire coding regions of the genes listed unless otherwise noted. BCL1/ IgH translocation t(11;14) is performed by real-time PCR and BCL2 t(14;18) is performed by fragment length analysis. Test orders include summary interpretation of all results together.

Clinical Significance  Genes analyzed in this profile have known roles in lymphoma pathogenesis. Testing is useful for diagnosis, classification, prognosis, and treatment decisions. It is also useful to distinguish between activated B-cell-like (ABC) and germinal center (GC) subtypes, especially in diffuse large B-cell lymphoma (DLBCL).

Specimen Requirements
- **Bone marrow (Preferred):** 2 mL in EDTA tube.
- **Peripheral blood:** 5 mL in EDTA tube.
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

Storage and Transportation  Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*  81450x1

Turnaround Time  14 days

Level of Service  Global ✓

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NeoTYPE® MDS/CMML Profile

Alternative Name
MDS/CMML Profile

Methodology
Molecular

Test Description
This test is performed by sequencing the entire coding regions of the genes listed unless another method is noted. ASXL1, BCOR, BCORL1, BRAF, CBL, CEBPA, CUX1, DNMT3A, ETV6, EZH2, FLT3, HRAS, IDH1, IDH2, JAK2 including V617F and Exons 12+14, KIT, KRAS, NF1, NPM1, NRAS, PDGFRA, PPM1D, PTEN, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, TET2, TP53, U2AF1, and ZRSR2. FLT3 is performed by multiple methods. Individual genes from a validated list of myeloid genes can be added-on. Test orders include summary interpretation of all results together.

Clinical Significance
This molecular profile analyzes genes frequently mutated in myelodysplastic syndrome (MDS) and the related MDS/MPN overlap disease chronic myelomonocytic leukemia (CMML). Testing is useful to establish diagnosis and develop strategies for treatment and management, as mutations can signify poor or favorable prognosis and they inform of the underlying disease biology. Molecular profiling in MDS and CMML complements and should be interpreted with cytogenetic/FISH test findings. This Profile may also be used in AML cases that evolved from MDS, therapy-related AML, and AML with myelodysplasia.

Specimen Requirements
- **Bone marrow (Preferred):** 2 mL in EDTA tube.
- **Peripheral blood:** 5 mL in EDTA tube.
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
81450x1

Turnaround Time
14 days

Level of Service
Global

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December 18, 2019
# NeoTYPE® Melanoma Profile

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Melanoma Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
</tbody>
</table>
| **Test Description** | The NeoTYPE Melanoma Tumor Profile analyzes 28 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.  
  - NGS (22 genes + 2 biomarkers): AKT1, BAP1, BRAF, CDK4, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, KIT, Microsatellite Instability (MSI), NBN, NF1, NRAS, PDGFRA, SMO, SRC, TERT Promoter, Tumor Mutation Burden (TMB)  
  - FISH (1 FISH): PTEN (tech-only available)  
  - IHC (2 biomarkers): PD-L1 28-8, Pan-TRK (tech-only available for PD-L1) |
| **Clinical Significance** | The NeoTYPE Melanoma Profile assesses the most commonly-mutated driver mutations in primary or metastatic melanoma to determine prognosis and identify established and clinical trial-based therapeutic options. This NeoTYPE Profile is for histologically-confirmed melanoma and is not appropriate for differentiating melanoma from ambiguous melanocytic lesions. For that indication, please see the separate listing for the MelanoSITE™ Melanoma FISH Panel. |
| **Specimen Requirements** | FFPE tissue: Paraffin block (preferred). Please use 10% buffered formalin fixative. Do not use zinc fixatives. |
| **Storage and Transportation** | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature. |
| **CPT Code(s)** | 81445x1, 88377x1, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile |
| **Turnaround Time** | 14 days |
| **Level of Service** | Global ✓ |

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NeoTYPE® Myeloid Disorders Profile

Alternative Name
Myeloid Disorders Profile

Methodology
Molecular

Test Description
This test is performed by the sequencing the entire coding regions of the genes listed. ABL1, ASXL1, ATRX, BCOR, BCORL1, BRAF, CALR, CBL, CBLB, CBLC, CDKN2A, CEBPA, CSF3R, CUX1, DNMT3A, ETV6, EZH2, FBXW7, FLT3, GATA1, GATA2, GNAS, HRAS, IDH1, IDH2, IKZF1, JAK2 including V617F and Exons 12+14, JAK3, KDM6A, KIT, KRAS, MPL, MYD88, NF1, NOTCH1, NPM1, NRAS, PDGFRA, PHF6, PPM1D, PTEN, PTPN11, RAD21, RUNX1, SETBP1, SF3B1, SMC1A, SMC3, SRSF2, STAG2, TET2, TP53, U2AF1, WT1, ZRSR2. CALR and FLT3 are performed by multiple methods. Test orders include summary interpretation of all results together.

Clinical Significance
The NeoTYPE Myeloid Disorders Profile is a 56 gene panel that targets known mutations associated with acute myeloid leukemia (AML), myeloproliferative neoplasms (MPN), myelodysplastic syndrome (MDS), chronic myelogenous leukemia (CML), chronic myelomonocytic leukemia (CMML) and juvenile myelomonocytic leukemia (JMML). Testing using this panel can aid in making therapy decisions, predicting prognosis, and can be used in clinical research. This is a generic and comprehensive profiling of myeloid neoplasms.

Specimen Requirements
- **Bone marrow (Preferred):** 2 mL in EDTA tube.
- **Peripheral blood:** 5 mL in EDTA tube.
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
81450x1 (Effective as of 07/02/2018 | Prior to 07/2/2018 CPT Code was 81455x1)

Turnaround Time
14 days

Level of Service
Global

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December 18, 2019
# NeoTYPE® Other Solid Tumor Profile

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Other Solid Tumor Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
</tbody>
</table>
| Test Description       | The NeoTYPE Other Solid Tumor Profile analyzes 30 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.  
  - NGS (24 genes + 2 biomarkers): AKT1, BRAF, EGFR, FGFR1, FGFR2, FGFR3, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PDGFRα, PIK3CA, PTEN, PTPN11, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB)  
  - FISH (2 FISH): MET, PTEN (tech-only available)  
  - IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1) |
| Clinical Significance  | The NeoTYPE Other Solid Tumor Profile characterizes primary or metastatic tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. This test can be used for tumors arising from various tissues including liver, pancreas, prostate, kidney, head and neck, or other tumors that do not match any subtypes of the 13 other tumor-specific NeoTYPE Profiles. These other profiles are available for specific tumors including brain, breast, colorectal, lung, thyroid, and others; please see separate listings for descriptions. The NeoTYPE Other Solid Tumor Profile is recommended for patients with resistant disease to explore options in clinical trials. This test is not for determining a tumor's tissue of origin. |
| Specimen Requirements  | **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*          | 81445x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile |
| Turnaround Time        | 14 days                   |
| Level of Service       | Global ✓                 |

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Neotype® Ovarian Tumor Profile

Alternative Name
Ovarian Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE Ovarian Tumor Profile analyzes 68 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.

- NGS (58 genes + 2 biomarkers): AKT1, ARID1A, ATM, ATR, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDK12, CDKN2A, CDKN2B, CHEK1, CHEK2, CTNNB1, EGFR, ERBB2, ERBB4, ESR1, FANCA, FANCC, FANCD2, FANCE, FANC, FANC, FANCL, FGFR1, FGFR2, FGFR3, HRAS, KIT, Kras, MET, Microsatellite Instability (MSI), MLH1, MRE11A (MRE11), MSH2, MSH6, NBN, NF1, NRAS, PALB2, PIK3CA, POLE, PMS2, PTEN, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RB1, SMAD4, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- FISH (6 FISH): EGFR Amplification, HER2, MET, MYC, PTEN, RET (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE Ovarian Tumor Profile characterizes primary or metastatic ovarian tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and patients with resistant disease to explore options in clinical trials.

Specimen Requirements
- FFPE tissue: Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

CPT Code(s)*
81455x1, 88374x1, 88377x5, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days

Level of Service
Global ✔

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### NeoTYPE® Pancreas Tumor Profile

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Pancreas Tumor Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
</tbody>
</table>
| Test Description       | The NeoTYPE Pancreas Tumor Profile analyzes 69 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.  
  - **NGS (63 genes + 2 biomarkers):** ACVR1B, ARID1A, ATM, ATR, BARD1, BRAF, BRCA1, BRCA2, BRIP1, CDK12, CDKN2A, CDKN2B, CHEK1, CHEK2, EGFR, ERBB2, ERBB4, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FGFR1, FGFR2, FGFR3, FGFR4, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MEN1, MET, Microsatellite Instability (MSI), MLH1, MRE11A (MRE11), MSH2, MSH6, NBN, NF1, NOTCH1, NRAS, PALB2, PBRM1, PIK3CA, PMS2, PTEN, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RNF43, SMAD4, SMO, STK11, TGFBR2, TERT Promoter, TP53, Tumor Mutation Burden (TMB), VHL  
  - **FISH (3 FISH):** HER2, MET, PTEN (tech-only available)  
  - **IHC (2 biomarkers):** PD-L1 22C3, Pan-TRK (tech-only available for PD-L1) |
| Clinical Significance  | The NeoTYPE Pancreas Tumor Profile characterizes pancreatic tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials. |
| Specimen Requirements  | **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*           | 81455x1, 88377x3, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile |
| Turnaround Time         | 14 days                |
| Level of Service        | Global ✓              |

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# NeoTYPE® Precision Profile for Solid Tumors

<table>
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<tr>
<th><strong>Alternative Name</strong></th>
<th>Solid Tumor Profile, Precision Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>The NeoTYPE Precision Profile analyzes 83 biomarkers through a combination of next-generation sequencing (NGS) and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.</td>
</tr>
<tr>
<td></td>
<td>- NGS (79 genes + 2 biomarkers): AKT1, ALK, APC, ARAF, ATM, ATR, BARD1, BRAF, BRCA1, BRCA2, BRI2, CDH1, CDK12, CDKN2A, CHEK1, CHEK2, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, ESR1, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FBXW7, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, KDR, KIT, KRAS, MAP2K1, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, MRE11A (MRE11), MTR, NBN, NF1, NOTCH1, NRAS, PALB2, PDGFRA, PIK3CA, PMS2, PCH1, PTEN, PTPN11, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TSC1, TSC2, TERT Promoter, TP53, Tumor Mutation Burden (TMB), VHL</td>
</tr>
<tr>
<td></td>
<td>- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Molecular profiling with the NeoTYPE™ Precision Profile for Solid Tumors allows for the accurate and sensitive detection of somatic mutations in the genes most relevant to various solid tumor cancers. Testing can aid in the diagnosis of various diseases and provide information to develop strategies for the treatment and management of the underlying disease. In addition, the results obtained from the NeoTYPE™ Precision Profile for Solid Tumors can also be used in current or future clinical research projects.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>• FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81455x1, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>14 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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December 18, 2019
NeoTYPE® Thyroid Profile

Alternative Name
Thyroid Profile

Methodology
Molecular

Test Description
The NeoTYPE Thyroid Tumor Profile analyzes 32 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If Pan-TRK IHC is expressed or equivocal, NTRK NGS Fusion Profile for NTRK1 fusions, NTRK2 fusions, and NTRK3 fusions will be added by reflex.
- NGS (26 genes + 2 biomarkers): AKT1, ALK, ARID1A, ATM, BRAF, CDKN2A, CTNNB1, ERBB2, ERBB4, HRAS, KRAS, MEN1, MET, Microsatellite Instability (MSI), NF1, NF2, NRAS, PIK3CA, PTEN, RET, SMAD4, SMO, SRC, TERT Promoter, TP53, TSC1, TSC2, Tumor Mutation Burden (TMB)
- FISH (2 FISH): MET, RET (tech-only available)
- IHC (2 biomarkers): PD-L1 22C3, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
The NeoTYPE Thyroid Profile is useful to classify fine needle aspirates of thyroid nodules that are indeterminate or suspicious on cytology. Presence of mutations or gene rearrangements as detected by FISH predicts malignancy with varying degrees of specificity depending on the gene mutated and histological subtype. BRAF mutation V600E is associated with poor prognosis in papillary thyroid carcinoma (PTC).

Specimen Requirements
- **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

CPT Code(s)*
81445x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Profile

Turnaround Time
14 days

Level of Service
Global ✔

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December 18, 2019
NeuN

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

NeuN is a sensitive and specific marker of neuronal differentiation in brain tumors.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓

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**NF (Neurofilament)**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Neurofilaments (NFs) are the intermediate filaments of neurons and their processes. NFs are expressed in tumors of neural origin or tumors displaying neuronal differentiation, such as neuroblastoma, medulloblastoma and retinoblastoma. This antibody labels neurons, neuronal processes and peripheral nerves, as well as sympathetic ganglion cells and adrenal medulla. The cell body of neurons, containing the non-phosphorylated neurofilament, is weakly stained.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

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December 18, 2019
NGFR

Alternative Name: P75NTR, CD271

Methodology: Immunohistochemistry (IHC)

Test Description: Nerve Growth Factor Receptor (NGFR), also known as P75NTR or CD271, is a neurotrophin receptor belonging to the tumor necrosis factor receptor family. NGFR is expressed mainly in Schwann cells and neurons, as well as a number of other non-neuronal cell types, and functions during central and peripheral nervous system development. It is useful in the diagnosis of brain tumors, peripheral nerve sheath sarcoma, melanoma, and breast malignancy.

Specimen Requirements:
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88342x1 or 88341x1

Turnaround Time: Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service: Global ✓ Stain Only ✓

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# NGS Comprehensive Sarcoma Fusion Profile

**Methodology**
Molecular

**Test Description**
The NGS Comprehensive Sarcoma Fusion Profile is a targeted next-generation sequencing panel that can detect 134 different translocations relevant in sarcomas in the genes ALK, CAMTA1, CCNB3, CIC, EPC1, EWSR1, FOXO1, FUS, GLI1, HMGA2, JAZF1, MEAF6, MKL2, NCOA2, NTRK3, PDGFB, PLAG1, ROS1, SS18, STAT6, TAF15, TCF12, TFE3, TFG, USP6, and YWHAE.

**Clinical Significance**
Sarcoma is a connective tissue cancer of mesenchymal origin which accounts for more than 20% of pediatric solid tumor malignancies but is rare in adults. The majority of sarcomas are classified as soft tissue sarcomas and approximately 10% are malignant bone tumors. Genomic rearrangements called translocations are present in approximately 20-30% of sarcomas and are associated with different subtypes of sarcomas. Identification of translocations can be useful for diagnosis, disease subclassification, and determining therapy. Compared to FISH, molecular detection of sarcoma translocations, as provided in this test, requires less tumor sample for a much broader and therefore more cost-effective screen. See the NGS Comprehensive Sarcoma Fusion test spotlight for more information.

**Specimen Requirements**
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

**CPT Code(s)**
81445

**Medicare MolDX CPT Code(s)**
81479

**Turnaround Time**
21 days

**Level of Service**
Global ✓

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# NGS Ewing Sarcoma Fusion Profile

**Alternative Name**  
EWSR1 NGS Fusion Profile

**Methodology**  
Molecular

**Test Description**  
The NGS Ewing Fusion Profile is a targeted next-generation sequencing panel that can detect various translocations relevant in Ewing's sarcoma in the gene EWSR1.

**Clinical Significance**  
Many different soft tissue sarcomas are characterized by the presence of a translocation involving the EWS gene. This test is designed to determine the partner gene in cases that have been determined to contain an EWS translocation by FISH studies. It will identify Ewing sarcoma/primitive neuroectodermal tumor (PNET) and six of its translocation variants, including all of the most common ones. It will also distinguish cases of EWS-translocation positive desmoplastic small round-cell tumor, clear cell sarcoma, Ewing-like bone sarcoma, myoepithelial tumor of soft tissue and bone, extraskeletal myxoid chordoma, myxoid/round cell liposarcoma, pulmonary myxoid sarcoma, and angiomatoid fibrous histiocytoma from Ewing sarcoma/PNET, and most often will allow distinction of these cases from one another. These studies are most useful for specific diagnosis, and identification of specific translocations may also be useful in determining therapy.

**Specimen Requirements**  
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**  
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

**CPT Code(s)**  
81479

**Turnaround Time**  
21 days

**Level of Service**  
Global

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December 18, 2019
NGS Non-Ewing Sarcoma Fusion Profile

Methodology
Molecular

Test Description
The NGS Non-Ewing Sarcoma Fusion Profile is a targeted next-generation sequencing panel that can detect various translocations unrelated to Ewing’s sarcoma in the genes ALK, CAMTA1, CCNB3, CIC, EPC1, FOXO1, FUS, GLI1, HMGA2, JAZF1, MEAF6, MKL2, NCOA2, NTRK3, PDGFB, PLAG1, STAT6, TAF15, TCF12, TFE3, TFG, USP6, and YWHAE.

Clinical Significance
Many sarcomas, including sarcomas classically regarded as spindle cell sarcomas are associated with translocations not involving the EWS gene. This test is designed to determine the specific genetic abnormalities in cases that either have been determined to be negative for an EWS translocation by FISH studies or cases in which a EWS translocation is not suspected. This fusion profile has been designed to detect the common genetic abnormalities in a large number of sarcomas and other soft tissue or bone tumors, including aneurysmal bone cyst, angiofibroma, angiomatoid fibrous histicocytoma, alveolar rhabdomyosarcoma, alveolar soft-part sarcoma, chondroid lipoma, congenital/infantile fibrosarcoma, dermatofibrosarcoma protuberans/giant cell fibroblastoma, endometrial stromal sarcoma, epithelioid hemangioendothelioma, primitive neuroectodermal tumor, Ewing-like bone sarcoma, Extraskeletal myxoid chondrosarcoma, inflammatory myofibroblastic tumor, lipoblastoma, lipoma, low-grade fibromyxoid sarcoma, meningeal hemangiopericytoma, mesenchymal chondrosarcoma, myoepithelial tumor of soft tissue and bone, nodular fasciitis, pericytoma, sclerosing epithelioid fibrosarcoma, solitary fibrous tumor, spindle cell rhabdomyosarcoma, and undifferentiated small round blue cell tumor.

Specimen Requirements
FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

CPT Code(s)*
81445

Medicare MolDX CPT Code(s)*
81479

Turnaround Time
21 days

Level of Service
Global ✓

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December 18, 2019
# NGS Pediatric Sarcoma Fusion Profile

## Methodology
Molecular

## Test Description
The NGS Pediatric Sarcoma Fusion Profile is a targeted next-generation sequencing panel that can detect various translocations related to pediatric sarcomas in the genes ALK, EWSR1, FUS, GLI1, NTRK3, and USP6.

## Clinical Significance
The precise diagnosis of pediatric soft tissue tumors is very important for prognosis and treatment purposes. Unfortunately, many of these neoplasms are difficult to distinguish from one another, even after careful morphologic and immunohistochemical study. This fusion profile has been designed to aid in the diagnosis of some of the more common (and difficult to recognize) soft tissue proliferations which occur with relatively high frequency in the pediatric age group. The fusion profile will detect the common translocations found in angiomatoid fibrous histiocytoma, congenital/infantile fibrosarcoma, inflammatory myofibroblastic tumor, nodular fasciitis, and pericytoma.

## Specimen Requirements
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

## Storage and Transportation
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

## CPT Code(s)*
81445

## Medicare MolDX CPT Code(s)*
81479

## Turnaround Time
21 days

## Level of Service
Global

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December 18, 2019
# NGS Rhabdomyosarcoma Fusion Profile

**Methodology**
Molecular

**Test Description**
The NGS Rhabdomyosarcoma Fusion Profile is a targeted next-generation sequencing panel that can detect various translocations related to rhabdomyosarcoma in the genes FOXO1, NCOA2, and TFE3.

**Clinical Significance**
The diagnosis and subclassification of rhabdomyosarcoma is very important for diagnostic, prognostic and treatment purposes. Several genetic abnormalities are associated with specific subtypes of rhabdomyosarcoma. In addition, alveolar soft part sarcoma is a soft tissue sarcoma that may be easily confused with certain types of rhabdomyosarcoma. This fusion profile is designed to aid in the diagnosis and subclassification of rhabdomyosarcoma and to identify cases of alveolar soft part sarcoma.

**Specimen Requirements**
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

**CPT Code(s)**
81401, 81479

**Medicare MolDX CPT Code(s)**
81479

**Turnaround Time**
21 days

**Level of Service**
Global ✔️

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**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Homeobox protein NKX2.2 plays a critical role in neuroendocrine/glial differentiation. The NKX2.2 gene was recently identified as a target of EWS-FLI-1, the fusion protein specific to Ewing sarcoma. NKX2.2 is a valuable marker for Ewing sarcoma with a sensitivity of 93% and a specificity of 89%, and aids in the differential diagnosis of small round cell tumors.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only

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NKX3.1

Methodology

Immunohistochemistry (IHC)

Test Description

NKX3.1 is a protein encoded by the NKX3.1 gene located on chromosome 8. NKX3.1 protein has been found to be positive in the vast majority of primary prostatic adenocarcinomas. NKX3.1 stains nuclei in both normal and prostate cancer and along with other prostate-restricted markers, may be a valuable marker to definitively determine prostatic origin in poorly differentiated metastatic carcinomas.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓

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Non-Hodgkin's Lymphoma (NHL) FISH Panel

Alternative Name
NHL FISH

Methodology
FISH

Test Description
Probes: ALK (2p23) | BCL6 (3q27) | MYC (8q24) | CCND1/IgH t(11;14) | IgH (14q32) | IgH/BCL2 t(14;18) | MALT1 (18q21)
Probes may be ordered separately.
Disease(s): NHL

Clinical Significance
The NHL FISH panel is used for the detection of chromosome aberrations observed in lymphoma.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut Slide:** H&E slide (required) plus 12 unstained slides cut at 4 microns for panel, or 2 unstained slides cut at 4 microns for single abnormalities. Circle H&E for tech-only.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374x7 automated. Codes may differ if manual analysis is performed.

Turnaround Time
4 days

Level of Service
Global ✔  Technical ✔

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December 18, 2019
## NOTCH1 Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>NOTCH1 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of exons 26, 27, and 34 is performed for detection of sequence variant mutations. Testing can be performed on plasma when adequate leukemic cells are not available.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>NOTCH1 mutations are common in T-ALL, CLL, and mantle cell lymphoma. Mutations in ALL are associated with good prognosis, while mutations in CLL and mantle cell lymphoma are associated with poor prognosis.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | * Peripheral blood: 5 mL in EDTA tube.  
* Bone marrow: 2 mL in EDTA tube. |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 81407 |
| Turnaround Time | 10 days |
| Level of Service | Global ✓ |

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NPM1 MRD Analysis

Alternative Name
NPM1 Minimal Residual Disease

Methodology
Molecular

Test Description
NPM1 MRD Analysis is performed by PCR and fragment analysis of exon 12 of the NPM1 gene to detect small insertion mutations. Testing is performed on plasma with a PCR modification to improve sensitivity. The lower limit of detection of mutated NPM1 in this assay is $5 \times 10^{-3}$ (0.5%). Positive results are reported quantitatively if the percentage of mutated DNA is $\geq 1\%$, and they are reported qualitatively if $<1\%$.

Clinical Significance
High-sensitivity testing to detect residual NPM1 mutation in AML may be useful for further refining prognosis and for early detection of relapse.

Specimen Requirements
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.
- **FFPE tissue**: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81310

Turnaround Time
7 days

Level of Service
Global ✔️

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NPM1 Mutation Analysis

Alternative Name  Nucleophosmin (Nucleolar Phosphoprotein B23)
Methodology  Molecular
Test Description  PCR and fragment analysis of exon 12 of the NPM1 gene to detect small insertion mutations specific to AML. Positive results are reported quantitatively as percent abnormal DNA. Testing may be performed on plasma to increase sensitivity.
Clinical Significance  Testing for NPM1 and other gene mutations in AML patients with intermediate-risk cytogenetic abnormalities can improve risk stratification. NPM1 mutations can predict favorable prognosis in AML with normal karyotype.
Specimen Requirements  • Peripheral blood: 5 mL in EDTA tube.
• Bone marrow: 2 mL in EDTA tube.
• FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.
Storage and Transportation  Use cold pack for transport, making sure cold pack is not in direct contact with specimen.
CPT Code(s)*  81310
Turnaround Time  7 days
Level of Service  Global ✓

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December 18, 2019
Page 413 of 578
### Methodology
Molecular

### Test Description
Bi-directional sequencing of NRAS exon 4 is performed using PCR primers designed to target hotspot mutations in codons 117 and 146, among other regions in exon 4. Testing is available separately or in combination with BRAF, KRAS and HRAS in the RAS/RAF Panel. Testing is approved for specimens from the state of New York.

### Clinical Significance
NRAS is highly homologous with KRAS; both are members of the most frequently mutated family of oncogenes. NRAS Mutations are found in a wide variety of solid tumors, in advanced systemic mastocytosis, and in myeloid neoplasias. Mutations in codon 117 and 146 are also believed to have similar effects as other mutations in RAS that involve exons 2 and 3. Patients with any known KRAS mutation or NRAS mutation may be resistant to certain tyrosine kinase inhibitors.

### Specimen Requirements
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

### Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

### CPT Code(s)*
81403

### Turnaround Time
7 days

### Level of Service
Global

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NRAS Mutation Analysis

Alternative Name: NRAS Gene Sequencing

Methodology: Molecular

Test Description: Bi-directional sequencing of NRAS exons 2 and 3 which includes sites of common activating mutations in codons 12, 13, 59, and 61. Testing is approved for specimens from the state of New York.

Clinical Significance: NRAS is highly homologous with KRAS; both are members of the most frequently mutated family of oncogenes. NRAS Mutations are found in a wide variety of solid tumors, in advanced systemic mastocytosis, and in myeloid neoplasias.

Specimen Requirements:
- Peripheral blood: 5 mL in EDTA tube.
- Bone marrow: 2 mL in EDTA tube.
- FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81311

Turnaround Time: 7 days

Level of Service: Global ✔

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NSE (Neuron Specific Enolase)

Methodology

Immunohistochemistry (IHC)

Test Description

In normal tissue, most neurons and their axonal and dendritic processes stain strongly positive for Neuron Specific Enolase (NSE), with the exception of Purkinje cells. Schwann cells, cells of the adrenal medulla, and paraganglia also contain NSE. Endocrine cells of the skin (Merkel cells), respiratory and GI tract epithelium, pituitary parathyroid, and pancreatic islets and C cells of thyroid all stain positively for NSE. NSE is expressed in ganglioneuromas, neuroblastomas, Schwannomas and malignant melanomas. It is also present in pheochromocytomas and paragangliomas. Carcinoids, medullary thyroid carcinomas, pituitary adenomas and endocrine tumors of the pancreas and GI tract all show positive immunoreactivity for NSE. NSE is found in neuroendocrine carcinoma of the skin (Merkel cell tumor) and small cell carcinoma of the lung.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✅

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December 18, 2019
### NTRK & RET NGS Fusion Profile

**Methodology**
Molecular

**Test Description**
The NTRK & RET NGS Fusion Profile is an RNA-based next-generation sequencing panel that detects translocations and fusions of the genes NTRK1, NTRK2, NTRK3 and RET with known and novel fusion partners. Point mutations in select exons of these four genes are also detected. Examples of some of the published fusions detectable in this test include CD74-NTRK1, LMNA-NTRK1, MPRIP-NTRK1, TPM3-NTRK1, SQSTM1-NTRK1, PPL-NTRK1, AFAP1-NTRK2, PAN3-NTRK2, TRIM24-NTRK2, BTBD1-NTRK3, ETV6-NTRK3, CCD6-RET (aka RET-PTC1), KIF5B-RET, and NCOA4-RET (aka RET-PTC3).

This test may be used to select patients for therapy with the FDA-approved TRK inhibitor Vitrakvi® (larotrectinib).

See also [NTRK NGS Fusion Profile](#) and [Lung NGS Fusion Profile](#).

**Clinical Significance**
NTRK gene fusion is the primary mechanism of oncogenic activation of TRK proteins. Gene fusions have been reported in >20 tumor types. They occur in >90% of certain rare tumors and are considered essentially pathognomonic in secretory breast cancer, congenital fibrosarcoma, congenital mesoblastic nephroma, and mammary analogue secretory carcinoma (MASC).

Tumors with intermediate NTRK fusion frequencies (5-25%) include papillary thyroid cancer (PTC), GIST without KIT/PDGFRA/RAS mutations, Spitzoid neoplasms, and certain pediatric gliomas. NTRK fusions are detected in <5% of a wide range of common tumors including non-small cell lung cancer (NSCLC, ~1%); pancreatic adenocarcinoma; head and neck squamous cell; breast, colorectal, and renal cell carcinoma; melanoma; and adult brain tumors such as astrocytoma and glioblastoma.

RET translocations detected in this test are common in papillary thyroid carcinoma (>20%) and are also seen in 1-2% of NSCLC.

Numerous TRK and RET inhibitor therapies are in various stages of clinical availability, trial, and development.

**Specimen Requirements**
**FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
81479

**Turnaround Time**
14-21 days

**Level of Service**
Global ✓

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NTRK 1, 2, 3 FISH Panel

Alternative Name: NTRK FISH Panel

Methodology: FISH

Test Description:
- **Probes:** NTRK1 (1q23.1), NTRK2 (9q21.33), NTRK3 (15q25.3)
- **Disease(s):** Various solid tumors.

Clinical Significance:
The NTRK 1, 2, 3 FISH Panel provides simultaneous analysis of NTRK1, NTRK2, and NTRK3 for gene rearrangements (fusions) to identify TRK-inhibitor therapy and clinical trial options using break-apart probes. This panel is useful for screening solid tumors. Approximately 1% of solid tumors overall will have a positive FISH panel result. FISH-negative results in any tumor type may be confirmed with the NTRK NGS Fusion Profile. Pan-TRK IHC testing is also available to screen most tumors with low fusion frequencies. See also NTRK3 FISH for tumors with very high NTRK3 fusion frequencies. Fusion partners of the NTRK gene are not identified by this FISH panel but are identified by the NTRK NGS Fusion Profile.

Specimen Requirements:
- **Bone marrow aspirate:** N/A
- **Peripheral blood:** N/A
- **Fresh, unfixed tissue:** N/A
- **Fluids:** N/A
- **Paraffin block:** Send paraffin block. Also send circled H&E slide for tech-only (required).
- **Cut slides:** H&E slide (required) plus 5 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation:
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*:
- 88377x3 manual or 88374x3 automated

Turnaround Time:
3-5 days

Level of Service:
Global ✔️  Technical ✔️

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NTRK NGS Fusion Profile

Methodology
Molecular

Test Description
The NTRK NGS Fusion Profile is an RNA-based next-generation sequencing panel that detects translocations and fusions of the Neurotrophic Tropomyosin-Related Kinase (NTRK) genes NTRK1, NTRK2, and NTRK3 with known and novel fusion partners. Point mutations in select exons of these three genes are also detected. Examples of some of the published fusions detectable in this test include CD74-NTRK1, LMNA-NTRK1, MPRIP-NTRK1, TPM3-NTRK1, SQSTM1-NTRK1, PPL-NTRK1, AFAP1-NTRK2, PAN3-NTRK2, TRIM24-NTRK2, BTBD1-NTRK3, and ETV6-NTRK3.

This test may be used to select patients for therapy with the FDA-approved TRK inhibitor Vitrakvi® (larotrectinib).

See also Lung NGS Fusion Profile and NTRK & RET NGS Fusion Profile.

Clinical Significance
NTRK gene fusion is the primary mechanism of oncogenic activation of TRK proteins. Gene fusions have been reported in >20 tumor types. They occur in >90% of certain rare tumors and are considered essentially pathogenic in secretory breast cancer, congenital fibrosarcoma, congenital mesoblastic nephroma, and mammary analogue secretory carcinoma (MASC).

Tumors with intermediate NTRK fusion frequencies (5-25%) include papillary thyroid cancer (PTC), GIST without KIT/PDGFR/A/PDGFRA/RAS mutations, spitzoid neoplasms, and certain pediatric gliomas. NTRK fusions are detected in <5% of a wide range of common tumors including non-small cell lung cancer (NSCLC, ~1%); pancreatic adenocarcinoma; head and neck squamous cell; breast, colorectal, and renal cell carcinoma; melanoma; and adult brain tumors such as astrocytoma and glioblastoma.

Numerous TRK inhibitor therapies are in various stages of clinical availability, trial, and development.

Specimen Requirements
FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81479

Turnaround Time
14-21 days

Level of Service
Global

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December 18, 2019
NTRK3 FISH

Methodology
FISH

Test Description
Probes: NTRK3 (15q25.3)
Disease(s): Various solid tumor cancers with high incidence in IFS, MASC, SBC, CMN

Clinical Significance
NTRK3 FISH is useful in confirming diagnoses and/or screening for TRK inhibitor options in infantile (congenital) fibrosarcoma (IFS), mammary analogue secretory carcinoma (MASC), secretory breast carcinoma (SBC), and congenital mesoblastic nephroma (CMN). FISH panel testing for NTRK1, 2, and 3 rearrangements (coming soon) is recommended for pediatric glioma, papillary thyroid carcinoma (PTC) and other tumors. The NTRK3 gene encodes Trk-C protein.

Specimen Requirements
- Bone marrow aspirate: N/A
- Peripheral blood: N/A
- Fresh, unfixed tissue: N/A.
- Fluids: N/A
- Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required).
- Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88377x1 manual or 88374x1 automated

Turnaround Time
3-5 days

Level of Service
Global ✓ Technical ✓

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NUP98

Alternative Name
Nucleoporin 98

Methodology
FISH

Test Description
Disease(s): Acute Myeloid Leukemia
Probes: NUP98 (11p15.4)

Clinical Significance
Fusions of the nucleoporin 98 (NUP98) gene with more than 30 partner genes are noted in a variety of hematologic malignancies including AML, MDS, and T-ALL. Recurring NUP98 fusions, such as NUP98-NSD1, NUP98-JARID1A, and NUP98-HOXA9, have been reported in pediatric and adult cytogenetically normal AML (CN-AML) and some have been associated with poor prognosis. Detection of NUP98 rearrangement may be useful to further classify prognostic risk in AML and guide therapy selection. Screening for NUP98 rearrangement in pediatric AML patients at the time of diagnosis has been suggested. This NUP98 break-apart FISH test is designed to detect NUP98 rearrangements with potentially any known or novel translocation partner.

References

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Paraffin Block or Cut Slides:** Not available.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88377x1 manual or 88374x1 automated

Turnaround Time
3-5 days

Level of Service
Global ✓ Technical ✓

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**NUT**

**Alternative Name**  
Nuclear protein in testis

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Expression of nuclear protein in testis (NUT) is generally confined to the germ cells of the testis and ovary. NUT midline carcinomas are aggressive tumors with non-diagnostic morphology that overlaps with many other poorly differentiated tumors. In these tumors, rearrangement of the NUT gene at chromosome 15q14 causes NUT protein overexpression. IHC staining with NUT antibody may serve as a diagnostic alternative to FISH or molecular confirmation of 15q14 rearrangement.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342x1 or 88341x1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only ✓

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OCT2

Methodology
Immunohistochemistry (IHC)

Test Description
Octamer Binding Transcription Factor 2 (OCT2) is present in all B-cells expressing Ig. The combination of BOB1 and OCT2 stains is helpful in distinguishing between classical Hodgkin lymphoma (at least one marker negative) and nodular lymphocyte predominant Hodgkin lymphoma (both markers expressed). Classical Hodgkin lymphoma stains as BOB1-OCT2+ or BOB1+ OCT2-, while nodular lymphocyte predominant Hodgkin lymphoma (NLPHL) or diffuse large B-cell lymphoma (DLBCL) stains BOB1+ OCT2+.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Octamer Binding Transcription Factor 4 (OCT4, also known as OCT3/4, POU51) is a transcription factor and is expressed by early embryonic cells, germ cells, and stem cells. OCT4 is a nuclear marker of classical seminoma and embryonal carcinoma. It has excellent sensitivity and specificity for these two tumors, and can be used as the ‘screen’ for these neoplasms when dealing with a metastatic tumor of unknown origin.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓
## Olig2

### Methodology
Immunohistochemistry (IHC)

### Test Description
Olig2, a transcription factor, is involved in oligodendrogial specification. Olig2 expression has been reported in most glial tumors, such as oligodendrogliomas and astrocytomas. Olig2 is negative in the non-glial tumors including neuroepithelial tumors, ependymomas, subependymomas, medulloblastomas, and nonneuroepithelial tumors, such as CNS lymphomas, meningiomas, schwannomas, atypical teratoid/rhabdoid tumor, and haemangioblastomas.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88342 x 1 or 88341 x 1

### Turnaround Time
24 hours

### Level of Service
Stain Only ✓

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December 18, 2019
**Oncomine™ Dx Target Test**

**Methodology**
Molecular

**Test Description**
The Oncomine Dx Target Test is a next-gen sequencing assay designed to detect variants in 23 genes associated with non-small cell lung cancer (NSCLC). Abnormalities targeted are ROS1 gene fusions and 367 sequence variant "hotspot" mutations in the following genes: AKT1, ALK, BRAF, CDK4, DDR2, EGFR, ERBB2, ERBB3, FGFR2, FGFR3, HRAS, KIT, KRAS, MAP2K1 (aka MEK1), MAP2K2 (aka MEK2), MET, MTOR, NRAS, PDGFRα, PIK3CA, RAF1, RET, and ROS1.

**Clinical Significance**
This test is an FDA-approved companion diagnostic indicated as an aid for selecting NSCLC patients for three targeted therapies:

1. **Tafinlar®** in combination with Mekinist® (dabrafenib/trametinib) in the presence of BRAF V600E mutation
2. **Xalkori®** (crizotinib) with ROS1 fusions; and
3. **Iressa®** (gefitinib) with EGFR L858R mutation or exon 19 deletions.

Other detected abnormalities may reveal additional therapeutic or clinical trial opportunities.


**Specimen Requirements**
- **FFPE tissue**: Paraffin block is preferred. Alternatively, for slides please send the following in 5 micron sections. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. Decalcified specimens are not acceptable.
  - Surgical or resection biopsy: 9 unstained slides plus 1 H&E slide
  - Core-needle biopsy: 14 unstained slides plus 1 H&E slide

**Note on tumor type**: This test is indicated for patients with non-small cell lung cancer. Specimens submitted must be NSCLC, either from primary site or metastasis. Testing requested on other tumor types will be cancelled.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
0022U

**Turnaround Time**
5-9 days

**Level of Service**
Global ✔

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p120 Catenin

Methodology

Immunohistochemistry (IHC)

Test Description

P120 Catenin is a tyrosine kinase which binds to E-cadherin within the cell membrane. It is detectable in the cell membranes of a wide variety of cells, but predominates in virtually all types of epithelia. When E-cadherin is absent, P120ctn moves to the cell cytoplasm. P120ctn can be useful in the diagnostic distinction between lobular (cytoplasmic staining pattern) and ductal (membranous) breast neoplasia.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔

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p16

Methodology
Immunohistochemistry (IHC)

Test Description
p16 (p16 -INK4a, p16-MTS1, inhibitor of CDK4) is the product of the CDKN2 gene. It inhibits the progression of the cell cycle through the G1 phase. p16 is a candidate tumor suppressor, whose gene is frequently deleted or mutated in tumors such as melanomas, gliomas, esophageal, pancreatic, lung, and urinary bladder carcinomas, and some types of leukemias. p16 expression is associated with high-risk human papillomavirus in cervical cancer and head and neck tumors.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔ Stain Only ✔

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p21

Methodology
Immunohistochemistry (IHC)

Test Description
p21 is a cyclin dependent protein kinase inhibitor and is a member of a family of proteins that functions to slow down cell division. p21 is found in t cells as they transitions from G1 phase to S phase. Low nuclear expression of p21 has been associated with poor prognosis in colon and prostate carcinomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1 (qualitative IHC) or 88360 x 1 (quantitative/semi-quantitative – manual)
or 88361 x 1 (quantitative/semi-quantitative – computer assisted)

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓  Stain Only ✓
### Methodology
Immunohistochemistry (IHC)

### Test Description
p27 (KIP1) belongs to the family of cell cycle regulators that cause cell cycle arrest in G1 phase. p27 promotes apoptosis, plays a role in terminal differentiation of some tissues and mediates chemosensitivity in solid tumors. Decreased p27 KIP1 expression in tumors is associated with a more aggressive tumor phenotype such as poor histologic grade, presence of lymphovascular invasion and higher growth fraction. These findings have been validated on various cancers such as breast, colon, esophagus, stomach, lung and prostate.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
- 88342 x 1 or 88341 x 1 (qualitative IHC) or 88360 x 1 (quantitative/semi-quantitative – manual)
- 88361 x 1 (quantitative/semi-quantitative – computer assisted)

### Turnaround Time
- Global: 48 hours
- Tech-Only (stain only): 24 hours

### Level of Service
- Global ✓
- Stain Only ✓

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p40

Methodology  Immunohistochemistry (IHC)

Test Description  p40 antibody recognizes ΔNp63—a p63 isoform. It is equivalent to p63 in sensitivity for squamous cell carcinoma, but it is markedly superior to p63 in specificity, which eliminates a potential pitfall of misinterpreting a p63-positive adenocarcinoma as squamous cell carcinoma. These findings strongly support the routine use of p40 for the diagnosis of pulmonary squamous cell carcinoma.

Specimen Requirements  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation  Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*  88342 x 1 or 88341 x 1

Turnaround Time  24 hours

Level of Service  Stain Only ✓

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P501S

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>P501S protein, also called the prostein, is a type IIIa plasma membrane protein which is exclusively expressed in cells of normal and malignant prostate. P501S expression has not been detected in other normal or malignant glandular tissues.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
                          • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
                          • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*       | 88342 x 1 |
| Turnaround Time    | 24 hours |
| Level of Service   | Stain Only ✓ |

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P504S

Methodology

Immunohistochemistry (IHC)

Test Description

Expression of P504S protein, or Alpha-methylacyl-CoA Racemase (AMACR), is found in prostatic adenocarcinoma but not in benign prostatic tissue. It has also been found to stain premalignant lesions of the prostate, high-grade prostatic intraepithelial neoplasia (PIN) and atypical adenomatous hyperplasia. P504S stains the vast majority of prostate cancers, and P504S has been shown to stain numerous other tumor types, such as hepatoma, breast carcinoma, pancreatic islet tumor and desmoplastic small round cell tumor.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓

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Methodology

Immunohistochemistry (IHC)

Test Description

The product of the p53 gene is a nuclear phosphoprotein that regulates cell proliferation. Excess accumulation of the mutant p53 gene product results in inactivation of its tumor suppressor function and cellular transformation. Overexpression of mutant p53 gene has also been associated with high proliferative rates and poor prognosis in breast, colon, lung, and brain cancer, as well as in some leukemias and lymphomas.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1 (qualitative IHC) or 88360 x 1 (quantitative/semi-quantitative – manual) or 88361 x 1 (quantitative/semi-quantitative – computer assisted)

Turnaround Time

Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service

Global ✔ Stain Only ✔
## Methodology

Immunohistochemistry (IHC)

## Test Description

p57 (Kip 2, CDKN 1C) is an inhibitor of several G1 cyclin complexes and is a negative regulator of cell proliferation. The gene encoding human p57 is located on chromosome 11p15.5, a region implicated in both sporadic cancers, Wilm's tumor, and Beckwith Wiedemann syndrome (BWS, a cancer syndrome) making it a tumor suppressor candidate. p57 is useful in differentiating between complete hydatidiform mole (no nuclear p57 expression) and partial hydatidiform mole or spontaneous abortion (normal expression).

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only

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Methodology

Immunohistochemistry (IHC)

Test Description

p63 is a homologue of the p53 gene and is necessary for normal breast and prostate development. Unlike other markers of myoepithelial cells and basal cells, p63 immunoreactivity is localized to the nucleus of the cells, which can offer distinct advantages over cytoplasmic labeling in certain types of cases. p63, as a marker of myoepithelial and basal cells, is extremely useful in diagnostic surgical pathology, particularly when examining difficult breast biopsies and prostate biopsies. p63 is also a marker of squamous cell and endothelial carcinomas.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔

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pAKT (Phosphorylated AKT)

Methodology
Immunohistochemistry (IHC)

Test Description
AKT is a signal transduction protein that plays a central role in inhibiting apoptosis in a variety of tumor types. Constitutive activation of AKT (phosphorylated) has been observed in several human cancers, including lung, breast and prostate. pAKT is associated with poor prognosis as well as chemotherapy and radiotherapy resistance.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1; 88360 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✅  Stain Only ✅

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## Pan Melanoma (S100 + Melan A + Tyrosinase)

### Methodology
Immunohistochemistry (IHC)

### Test Description
The Pan Melanoma staining combination increases sensitivity for melanomas. Since many skin biopsies are small, the triple stain conserves valuable tissue while saving time. Melan A (brown cytoplasmic) is a useful addition to melanoma panels as it is specific for melanocytic lesions. Tyrosinase (brown cytoplasmic) is a key enzyme involved in the initial stages of melanin biosynthesis. Tyrosinase is a more sensitive marker when compared to HMB45 and MART-1. It also labels a higher percentage of desmoplastic melanomas than HMB45. S100 stains Schwannomas, ependymomas, astrogliomas, almost all benign and malignant melanomas and their metastases. S100 (nuclear red) protein is also expressed in antigen presenting cells, such as the Langerhans cells in skin and interdigitating reticulum cells in the paracortex of lymph nodes.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88344 x 1

### Turnaround Time
24 hours

### Level of Service
Stain Only

---

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December 18, 2019
Pan Melanoma/Ki67

Methodology
Immunohistochemistry (IHC)

Test Description
Pan Melanoma/Ki67 serves as a tool to identify the proliferation rate of melanocytic lesions. A high Ki67 rate of a melanocytic lesion raises the possibility of malignancy.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88344 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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### Pan-Cytokeratin

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>CK AE1/AE3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Monoclonal antibodies AE1 and AE3 recognize the acidic and basic subfamilies of cytokeratin, respectively, thus the combination of these two antibodies can be used to detect almost all human epithelia. In surgical pathology, it is an important marker for carcinoma as well as some special tumor types which have an epithelial component or differentiation. This cocktail has been used to differentiate epithelial from non-epithelial tumors.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
  - or  
  - One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**     | 88342 x 1 or 88341 x 1 |
| **Turnaround Time** | 24 hours |
| **Level of Service** | Global ✔   Stain Only ✔ |

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.*

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## Pan-TRK

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>TRKA, TRKB, TRKC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>Pan-TRK (clone EPR17341) is directed against the C-terminal region of TRK (tropomyosin receptor kinase) A, B, and C proteins, which are encoded by NTRK1, NTRK2, and NTRK3 genes respectively. Pan-TRK IHC staining is a useful screen for identification of NTRK protein overexpression caused by gene fusions. Correlation of IHC staining with molecular detection of TRK fusions is moderate; discrepant cases have been described. IHC screening is not recommended in neuroendocrine tumors, GISTs, gliomas, or adult sarcomas, as these tissues show positive staining in the absence of an NTRK translocation. Published sensitivity rates of IHC staining for detection of NTRK fusions (detected by molecular testing) are 95% and above. Follow-up molecular testing is available to confirm positivity and identify the specific NTRK gene rearranged and its fusion partner gene.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>NTRK gene fusions have been reported in &gt;20 tumor types. They occur in &gt;90% of certain rare tumors and are considered essentially pathogenic in secretory breast cancer, congenital fibrosarcoma, congenital mesoblastic nephroma, and mammary analogue secretory carcinoma (MASC). Tumors with intermediate NTRK fusion frequencies (5-25%) include papillary thyroid cancer (PTC), GIST without KIT/PDGFRA/RAS mutations, spitzoid neoplasms, and certain pediatric gliomas. NTRK fusions are detected in &lt;5% of a wide range of common tumors including non-small cell lung cancer (NSCLC, ~1%); pancreatic adenocarcinoma; head and neck squamous cell; breast, colorectal, and renal cell carcinoma; melanoma; and adult brain tumors such as astrocytoma and glioblastoma. Testing for NTRK fusions identifies patients who may be candidates for NTRK inhibitor therapy.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or • One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88342 x 1 or 88341 x 1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>48 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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December 18, 2019
### Parafibromin

**Methodology**
- Immunohistochemistry (IHC)

**Test Description**
- Complete absence of nuclear staining for parafibromin is diagnostic of parathyroid carcinoma or an HPT-JT-related tumor (hyperparathyroidism-jaw tumor syndrome).

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
- Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342x1 or 88341x1

**Turnaround Time**
- 24 hours

**Level of Service**
- Stain Only

---

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### Parvovirus

**Methodology**
- Immunohistochemistry (IHC)

**Test Description**
- This monoclonal antibody clone, R92F6, recognizes a capsid protein of human parvovirus B19. Therefore, this antibody will be useful in detection of parvovirus infected cells.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
- Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342 x 1 or 88341 x 1

**Turnaround Time**
- Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
- Global ✓
- Stain Only ✓

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December 18, 2019
**PAX2**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Paired Box 2 (PAX2) is a transcription factor that is essential for kidney development. In kidneys of normal adult, Pax2 protein expression is limited to nuclei of collecting ducts and to a lesser extent in distal tubules. PAX2 is expressed in early kidney organogenesis as well as in Wilms' tumor and renal cell carcinoma. PAX2 can be useful in the diagnosis of renal cell carcinoma.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✔️

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## PAX5

### Methodology

**Immunohistochemistry (IHC)**

### Test Description

Paired Box 5 (PAX5) is a B-cell specific activator protein (BSAP). In early stages of B-cell development, PAX5 influences the expression of several B-cell specific genes, such as CD19 and CD20. PAX5 is expressed primarily in pro-, pre-, and mature B-cells, but not in plasma cells. There is an excellent correlation between CD20 and PAX5 expression; however, anti-PAX5 exceeds the specificity and sensitivity of L26 (CD20) because of its earlier expression in B-cell differentiation and its ability to detect all committed B-cells, including classic Hodgkin lymphoma. It is very specific to B-cell lineage and does not stain T-cells.

### Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type.
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered.
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*

88342 x 1 or 88341 x 1

### Turnaround Time

24 hours

### Level of Service

Stain Only ✓

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December 18, 2019
**PAX8**

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

The PAX8 gene is a member of the paired box (PAX) family of transcription factors. This family plays critical roles during fetal development and cancer growth. PAX8 is involved in kidney cell differentiation, and thyroid development. PAX8 has been shown to be expressed in three of the most common types of renal cell carcinoma including clear cell, chromophobe and papillary carcinoma. PAX8 stains nuclei exclusively and performs well in formalin-fixed paraffin-embedded (FFPE) tissues. PAX8 has been shown to be positive in thyroid and ovarian carcinomas.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✔

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December 18, 2019
## PD-L1 22C3 FDA (KEYTRUDA®) for Cervical

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) cervical squamous cell carcinoma tissue using EnVision FLEX visualization system on Autostainer Link 48.

PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying patients with recurrent or metastatic cervical cancer for treatment with KEYTRUDA® (pembrolizumab).

For gastric or GEJ cancer, please order PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA. For urothelial (bladder) carcinoma, please order PD-L1 22C3 FDA (KEYTRUDA®) for Urothelial Carcinoma. For non-small cell lung carcinoma (NSCLC), please order PD-L1 22C3 FDA (KEYTRUDA®) for NSCLC.

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer’s online interpretation training.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88360x1

**Turnaround Time**

Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**

Global ✔ Stain Only ✔

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PD-L1 22C3 FDA (KEYTRUDA®) for ESCC (Esophageal Squamous Cell Carcinoma)

Methodology

Immunohistochemistry (IHC)

Test Description

PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) esophageal squamous cell carcinoma (ESCC) and certain other tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying ESCC patients for treatment with KEYTRUDA® (pembrolizumab). KEYTRUDA® is approved for use in some ESCC patients whose tumors express PD-L1 with Combined Positive Score (CPS) ≥ 10. For other tumor types with approved indications for this test, please search our Test Menu for "22C3" to see available options.

Clinical Significance

none for IHC

Specimen Requirements

• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88360x1

Turnaround Time

Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service

Global ✓ Stain Only ✓

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December 18, 2019
PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA

Alternative Name
PD-L1, 22C3 FDA (KEYTRUDA®) for Gastric/GEA

Methodology
Immunohistochemistry (IHC)

Test Description
PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) gastric or gastroesophageal junction adenocarcinoma (GEJ, GEA) tissue using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying patients with metastatic gastric or GEJ cancer for treatment with KEYTRUDA® (pembrolizumab).

For cervical cancer, please order PD-L1 22C3 FDA (KEYTRUDA®) for Cervical. For urothelial (bladder) carcinoma, please order PD-L1 22C3 FDA (KEYTRUDA®) for Urothelial Carcinoma. For non-small cell lung carcinoma (NSCLC), please order PD-L1 22C3 FDA (KEYTRUDA®) for NSCLC.

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer’s online interpretation training.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88360 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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December 18, 2019
PD-L1 22C3 FDA (KEYTRUDA®) for HNSCC (Head & Neck)

Alternative Name
PD-L1, 22C3, KEYTRUDA

Methodology
Immunohistochemistry (IHC)

Test Description
PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) head and neck squamous cell carcinoma (HNSCC) and certain other tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying HNSCC patients for treatment with KEYTRUDA® (pembrolizumab). KEYTRUDA® is approved for use in some HNSCC patients whose tumors express PD-L1 with Combined Positive Score (CPS) ≥ 1.

For other tumor types with approved indications for this test, please search our Test Menu for “22C3” to see available options.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88360x1

Turnaround Time
Global: 48 hours

Level of Service
Global ✓ Stain Only ✓

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December 18, 2019
**PD-L1 22C3 FDA (KEYTRUDA®) for NSCLC**

**Alternative Name**
PD-L1, 22C3 FDA (KEYTRUDA®)

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). For gastric or GEJ cancer, please order PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA. For cervical cancer, please order PD-L1 22C3 FDA (KEYTRUDA®) for Cervical. For urothelial (bladder) carcinoma, please order PD-L1 22C3 FDA (KEYTRUDA®) for Urothelial Carcinoma. Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer’s online interpretation training.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88360 x 1

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✓ Stain Only ✓

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PD-L1 22C3 FDA (KEYTRUDA®) for Urothelial Carcinoma

Methodology
Immunohistochemistry (IHC)

Test Description
PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma and certain other tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying urothelial carcinoma patients for treatment with KEYTRUDA® (pembrolizumab). Keytruda® is approved for use in some urothelial carcinoma patients whose tumors express PD-L1 with Combined Positive Score (CPS) ≥ 10.

For gastric or GEJ cancer, please order PD-L1 22C3 FDA (KEYTRUDA®) for Gastric/GEA. For cervical cancer, please order PD-L1 22C3 FDA (KEYTRUDA®) for Cervical. For non-small cell lung carcinoma (NSCLC), please order PD-L1 22C3 FDA (KEYTRUDA®) for NSCLC. Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer's online interpretation training.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88360x1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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December 18, 2019
**PD-L1 28-8 FDA (OPDIVO®)**

**Alternative Name**
PD-L1, 28-8 FDA (OPDIVO®)

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
PD-L1 IHC 28-8 pharmDx is a qualitative immunohistochemical assay using Monoclonal Rabbit Anti-PD-L1, clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-squamous non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (SCCHN), and urothelial carcinoma tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is defined as the percentage of tumor cells exhibiting positive membrane staining at any intensity. Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer's online interpretation training.

**Clinical Significance**
Testing is not required for use of OPDIVO® in NSCLC, head and neck squamous cell carcinoma, or urothelial carcinoma, but may provide physicians more information and inform patient dialogue. In non-squamous NSCLC, PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx may be associated with enhanced survival from OPDIVO®.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88360 x 1

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✓ Stain Only ✓

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December 18, 2019
PD-L1 SP142 FDA (TECENTRIQ®) for NSCLC

**Alternative Name**  
PD-L1, SP142

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
The VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue on a VENTANA BenchMark ULTRA instrument. Evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity. Primary or metastatic NSCLC tissues may be submitted. For bladder cancer, please order PD-L1 SP142 FDA (TECENTRIQ®) for Urothelial Carcinoma. For triple-negative breast cancer, please order PD-L1 SP142 FDA (TECENTRIQ®) for TNBC (Breast).

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer’s online interpretation training.

**Clinical Significance**  
PD-L1 expression in ≥50% tumor cells or ≥ 10% tumor infiltrating immune cells as determined by this assay in NSCLC tissue may be associated with enhanced overall survival from TECENTRIQ (atezolizumab). This test is a complementary diagnostic for use of Tecentriq in certain NSCLC cases.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**Turnaround Time**  
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**  
Global ✓  Stain Only ✓
PD-L1 SP142 FDA (TECENTRIQ®) for TNBC (Breast)

Methodology
Immunohistochemistry (IHC)

Test Description
The VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) triple-negative breast carcinoma (TNBC) tissue on a VENTANA BenchMark ULTRA instrument. Evaluation is based on the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity. Primary or metastatic TNBC tissues may be submitted. Tissues with ≥1% IC are considered positive. For non-small cell lung cancer, please order PD-L1 SP142 FDA (TECENTRIQ®) for NSCLC. For bladder cancer, please order PD-L1 SP142 FDA (TECENTRIQ®) for Urothelial Carcinoma.

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer’s online interpretation training.

Clinical Significance
PD-L1 expression in ≥1% tumor-infiltrating immune cells as determined by this assay in triple-negative breast carcinoma may be associated with increased progression-free survival in patients with advanced, locally unresectable or metastatic TNBC treated with TECENTRIQ® (atezolizumab) and chemotherapy. This test is a companion diagnostic for use of Tecentriq in certain TNBC cases.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88360x1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓  Stain Only ✓

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December 18, 2019
# PD-L1 SP142 FDA (TECENTRIQ®) for Urothelial Carcinoma

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>PD-L1, SP142</th>
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<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>The VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma tissue on a VENTANA BenchMark ULTRA instrument. Evaluation is based on the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity. Primary or metastatic urothelial carcinoma (bladder cancer) Primary or metastatic NSCLC tissues may be submitted. For non-small cell lung cancer, please order PD-L1 SP142 FDA (TECENTRIQ®) for NSCLC. For triple-negative breast cancer, please order PD-L1 SP142 FDA (TECENTRIQ®) for TNBC (Breast). Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer’s online interpretation training.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>PD-L1 expression in ≥5% tumor-infiltrating immune cells as determined by this assay in urothelial carcinoma tissue is associated with increased objective response rate (ORR) to TECENTRIQ® (atezolizumab) in a non-randomized study. This test is a companion diagnostic for use of Tencertiaq in certain urothelial carcinoma cases.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or • One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88360x1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>Global: 48 hours, Tech-Only (stain only): 24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓ Stain Only ✓</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed. © 2019 NeoGenomics Laboratories, Inc. All Rights Reserved. All other trademarks are the property of their respective owners. December 18, 2019 Page 456 of 578*
PD-L1 SP263 FDA (IMFINZI™)

**Alternative Name**
PD-L1, SP263 FDA (IMFINZI™)

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
The VENTANA PD-L1 (SP263) assay is an FDA-approved complementary diagnostic IHC test for PD-L1 status in patients with locally advanced or metastatic urothelial carcinoma (mUC) who are being considered for treatment with IMFINZI™ (durvalumab). This is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) urothelial carcinoma tissue stained with OptiView DAB IHC Detection Kit on a VENTANA BenchMark ULTRA instrument. PD-L1 high expression status as determined by this assay was associated with increased objective response rate (ORR) in a single arm study of durvalumab. Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer’s online interpretation training.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88360x1

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✓ Stain Only ✓
PD1

Alternative Name
Programmed Death 1

Methodology
Immunohistochemistry (IHC)

Test Description
Programmed death-1 (PD-1) is expressed on activated T-cells, B-cells, and myeloid cells. Anti-PD-1 is a marker of angioimmunoblastic lymphoma and suggests a unique cell of origin for this neoplasm. Unlike CD10 and BCL6, PD-1 is expressed by few B-cells, so anti-PD-1 may be a more specific and useful diagnostic marker in angioimmunoblastic lymphoma. In addition, PD-1 expression provides evidence that angioimmunoblastic lymphoma is a neoplasm derived from germinal center-associated T-cells. PD-1 expression in angioimmunoblastic lymphoma lends further support to this model of T-cell oncogenesis, in which specific subtypes of T-cells may undergo neoplastic transformation and result in specific distinct histologic, immunophenotypic, and clinical subtypes of T-cell neoplasia. Programmed Death 1 (PD1) is expressed on most T-cells and a small subset of B-cells in the light zone of germinal centers and is a useful marker of angioimmunoblastic lymphoma.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Global ✔ Stain Only ✔

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Please direct any questions regarding coding to the payor being billed.
PDGFRA Amplification

Alternative Name  PDGFR Alpha Amplification
Methodology  FISH
Test Description  Probes: PDGFRA (4q12) | Centromere 4
Disease(s): Brain cancer
Clinical Significance  Amplifications of PDGFRA as detected by FISH occur in approximately 30% of pediatric and 20% of adult high-grade astrocytomas. In de novo adult glioblastoma multiforme (GBM), the co-occurrence of PDGFRA amplification with IDH1 mutation is associated with significantly worse overall survival compared to patients negative for amplification. Clinical trials with tyrosine kinase inhibitors targeting activated or over-expressed PDGFRA are in progress.
Specimen Requirements  Bone marrow aspirate: N/A Peripheral blood: N/A Fresh, unfixed tissue: N/A Fluids: N/A Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required). Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.
Storage and Transportation  Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.
CPT Code(s)*  88377x1 manual or 88374x1 automated.
Turnaround Time  3-5 days
Level of Service  Global 的技术

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# PDGFRa Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>PDGFR Alpha Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of exons 12 and 18 of the PDGFRA (platelet-derived growth factor alpha) gene. These exons are mutation hotspots that account for the majority of PDGFRA mutations detected in gastrointestinal stromal tumors (GISTs) including the common TKI-resistance mutation D842V. Solid tumor enrichment is performed before extraction.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>PDGFRa mutations are found in soft-tissue sarcomas including gastrointestinal stromal tumors (GISTs). Identification of mutations is informative for sensitivity or resistance to tyrosine kinase inhibitor (TKI) therapy.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• <strong>FFPE solid tumor tissue</strong>: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81314</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>10 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global</td>
</tr>
</tbody>
</table>

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December 18, 2019
# PDGFRA Rearrangement

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>PDGFR Alpha Rearrangement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>FISH</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td><strong>Probes:</strong> PDGFRA</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>FISH for FIP1L1-PDGFR is generally found in chronic eosinophilic leukemia, but the presentation can be as acute myeloid leukemia, T-lymphoblastic lymphoma or both simultaneously. Detection of this abnormality predicts responsiveness to tyrosine kinase inhibitors. PDGFRA rearrangement is usually cryptic by routine cytogenetic analysis.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>Bone Marrow Aspirate: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable Peripheral Blood: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable Fresh, Unfixed Tissue: Tissue in RPMI Fluids: Equal parts RPMI to specimen volume. Paraffin block: Send paraffin block. Also send circled H&amp;E slide for tech-only (required). Cut slides: H&amp;E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&amp;E slide for tech-only.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong>*</td>
<td>88374x1 automated or 88377x1 manual.</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>3-5 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✓ Techncial ✓</td>
</tr>
</tbody>
</table>

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Perforin

Methodology
Immunohistochemistry (IHC)

Test Description
Perforin is a protein found in cytoplasmic granules of cytotoxic T-lymphocytes (CTLs). CTLs bind to cells that express foreign antigens and induce them to lyse. Perforin expression is significantly induced in CD8 positive T-cells, but to lesser extent in gamma/delta T-cells and NK cells. This antibody may be of value in the detection of perforin in CTLs in severe cases of graft versus host disease, chronic renal rejection and peripheral T-cell lymphomas. In addition, perforin antibody may also be useful for the detection of NK cell lymphomas, all of which express the perforin protein.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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December 18, 2019
Periodic Acid Schiff (PAS) for fungus (PASF)

Methodology
- Immunohistochemistry (IHC)

Test Description
- Special stain.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
- Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
- 88312x1

Turnaround Time
- Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
- Global ✓  Stain Only ✓

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Periodic Acid Schiff (PAS) with digestion (PASD)

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88313x1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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Periodic Acid Schiff (PAS)- HEME

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Special stain.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88313x1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✅

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Periodic Acid Schiff (PAS)- Non HEME

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain.

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88313x1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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PgR

Alternative Name
Progesterone Receptor

Methodology
Immunohistochemistry (IHC)

Test Description
Progesterone Receptor (PR) belongs to a superfamily of nuclear hormone receptors. Estrogen Receptor (ER) induces PR expression, therefore, PR status serves as an indicator of an intact ER pathway. There are two known isoforms of PR; PRα and PRβ. The current assays in clinical breast cancer measure both isoforms. PR is expressed in about 60-70% of invasive breast cancers. It is a weak prognostic factor by itself but a modest predictive factor that adds to the predictive value of ER for response to endocrine therapies, both in adjuvant and metastatic settings. The primary indication to assess PR in breast cancer is to predict response to hormonal therapies, such as tamoxifen, other selective estrogen receptor modulators (SERMs) and aromatase inhibitors.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1 (qualitative IHC) or 88360 (quantitative/semi-quantitative – manual) or 88361 x 1 (quantitative/semi-quantitative – computer assisted)

Turnaround Time
Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔ Stain Only ✔

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**pHistone H3 (PHH3)**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Phosphohistone H3 (PHH3) is a marker of cells in the late G2-M phase of the cell cycle. It is not expressed in apoptotic cells which may be confused with mitotic figures on a routine H&E stained slide. PHH3 can be used as a surrogate of mitotic activity or as an independent prognostic marker in breast carcinomas.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88361 x 1; 88360 x 1

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✔ Stain Only ✔

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December 18, 2019
PIK3CA CDx Mutation Analysis by PCR

Alternative Name: QIAGEN therascreen® PIK3CA RGQ PCR

Methodology: Molecular

Test Description: PIK3CA CDx Mutation Analysis by PCR is an FDA-approved qualitative companion diagnostic assay performed on DNA extracted from FFPE breast tissue to detect 11 mutations in exons 7, 9, and 20 of the PIK3CA gene. Completion of the PIK3CA Mutation CDx Test Request Form with provider's signature is required for this CDx test.

Clinical Significance: This test is intended to identify PIK3CA mutations in patients with advanced hormone receptor-positive, HER2-negative (HR+/HER2-) breast cancer who may be candidates for therapy with the PI3Kalpha-specific inhibitor PIQRAY® (alpelisib). In results from the phase III SOLAR-1 study, patients with PIK3CA mutations and prior endocrine therapy had significantly improved progression-free survival when treated with alpelisib and fulvestrant compared to fulvestrant alone (11.0 vs. 5.7 months). Patients without a PIK3CA mutation did not obtain the survival benefit of alpelisib found in the mutation-positive group.

Approximately 70% of breast cancer cases are HR+/HER2-, and approximately 40% of these carry a PIK3CA mutation.

Specimen Requirements: FFPE tissue: Breast tumor tissue (either primary or metastatic) is required; non-breast tumors are not accepted for this test. Paraffin block is preferred. Alternatively, send 1 H&E slide plus 6-12 unstained slides for core needle biopsy (or 5-10 slides for resection) cut at 5 microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. Decalcified specimens are not accepted.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: Inquire for Testing Program details.

Turnaround Time: 7 days

Level of Service: Global

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# PIK3CA LDT Mutation Analysis by Sequencing

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>PI3K Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of PIK3CA exons 1, 9, and 20 which are the most commonly-mutated regions of the gene.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>The PIK3CA gene encodes the p110 alpha catalytic subunit of PI3K enzymes. Mutations occur in a wide variety of tumors and may have prognostic and therapeutic significance, depending on tumor type. Numerous PI3K-pathway inhibitors are in development.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>FFPE solid tumor tissue:</strong> Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>Prior to 12/31/2019 CPT Code 81404; as of 01/01/2020 CPT Code 81309</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>10 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔</td>
</tr>
</tbody>
</table>

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PLAP

Alternative Name: Placental Alkaline Phosphatase

Methodology: Immunohistochemistry (IHC)

Test Description: Normally human Placental Alkaline Phosphatase (PLAP) is produced by syncytiotrophoblasts after the twelfth week of pregnancy. PLAP is expressed by both malignant somatic and germ cell tumors. PLAP can be useful in distinguishing seminoma and embryonal carcinomas from undifferentiated malignant tumors.

Specimen Requirements:
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation: Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 88342 x 1 or 88341 x 1

Turnaround Time: 24 hours

Level of Service: Stain Only ✓

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Plasma Cell Add-On Flow Panel

**Methodology**  
Flow Cytometry

**Test Description**  
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD19, CD20, CD38, CD45, CD56, CD117, CD138, cKappa, and cLambda (9 markers).

**Clinical Significance**  
Useful for diagnosis of multiple myeloma and other plasma cell dyscrasias. Normal plasma cells express a polyclonal pattern of kappa and lambda immunoglobulin (Ig) light chains. Clonal expression of either kappa or lambda light chains indicates an expansion of a clone of plasma cells and is consistent with a plasma cell dyscrasia.

**Specimen Requirements**  
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

**Storage and Transportation**  
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
Please contact NeoGenomics’ Billing Department.

**Turnaround Time**  
1 day

**Level of Service**  
Global ✔️  Technical ✔️

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Plasma Cell Follow-Up Flow Panel

Methodology
Flow Cytometry

Test Description
Available as global and tech-only. Please provide clinical history including the time after treatment. Prior immunophenotyping at NeoGenomics with Standard or Extended Flow Panel is strongly recommended. Clients who decline full phenotyping and order a global or push-to-global Follow-Up Panel are requested to provide details of the diagnosis by submitting at least one of the following: previous flow cytometry report, previous pathology report, and/or clinical history notes. Markers are CD19, CD20, CD38, CD45, CD56, CD117, CD138, cKappa, and cLambda (9 markers).

Clinical Significance
For plasma cell and MGUS monitoring after diagnosis is established. This is not a minimal residual disease (MRD) panel since the standard number of events is collected.

Specimen Requirements
- **Bone marrow aspirate or peripheral blood**: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- **Bone marrow core**: 1-2 cm minimum core length in RPMI
- **Fresh, unfixed tissue**: 0.2 cm³ minimum in RPMI
- **Fluids and FNAs**: Equal parts RPMI and specimen

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184x1, 88185x8, Add 88188x1 for global.

Turnaround Time
1 day

Level of Service
Global ✓  Technical ✓

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Plasma Cell Myeloma FISH Panel (non-New York)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Multiple Myeloma-MGUS, MM-MGUS FISH Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td>Test Description</td>
<td>Probes: 1p-, 1q+, iso(1q): CDKN2C (1p32), CKS1B (1q21)</td>
</tr>
<tr>
<td></td>
<td>Probes may be ordered separately except +5, +9 and +15 which are combined.</td>
</tr>
<tr>
<td></td>
<td>Global cases with IgH rearrangement will automatically reflex to the Plasma Cell Myeloma IgH Complex FISH Panel unless client has opted out.</td>
</tr>
<tr>
<td>Disease(s):</td>
<td>Plasma cell myeloma, multiple myeloma</td>
</tr>
<tr>
<td>Note:</td>
<td>Plasma cell enrichment will be performed on bone marrow or blood samples unless our client directs us otherwise. (Peripheral blood is not recommended as a screening specimen unless increased plasma cells are seen on blood smear.) Specimens should be received in our laboratory within 72 hours of collection. If enriched samples are insufficient to complete the whole panel, NeoGenomics will prioritize p53 testing unless directed otherwise by our client.</td>
</tr>
</tbody>
</table>

| Specimen Requirements                  | Bone Marrow Aspirate: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable |
|                                       | Peripheral Blood: Not recommended as a screening specimen unless increased plasma cells are seen on blood smear. 2-5mL Sodium Heparin Tube. EDTA tube is acceptable |
|                                       | Fresh, Unfixed Tissue: Tissue in RPMI |
|                                       | Fluids: Equal parts RPMI to specimen volume |
|                                       | Paraffin Block or Cut Slide: N/A |

| Storage and Transportation             | Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Specimens should be received in our laboratory within 72 hours of collection. |

| CPT Code(s)*                          | 88374x5 automated or 88377x5 manual without reflex; with reflex add 88374x4 automated or 88377x4 manual |

| Turnaround Time                       | 3-5 days. Add 3-5 days if reflexed. |

| Level of Service                      | Global ✓  Technical ✓ |

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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# Plasma Cell Myeloma IgH Complex FISH Panel (non-New York)

**Alternative Name**

Multiple Myeloma (MM) IgH Complex FISH Panel

**Methodology**

FISH

**Test Description**

**Probes:**
- FGFR3/IgH t(4;14)
- CCND1/IgH t(11;14)
- IgH/MAF t(14;16)
- IgH/MAFB t(14;20)

Probes for each translocation may be ordered separately.

This panel is available separately or by reflex after the Plasma Cell Myeloma FISH Panel if it detects IgH rearrangement.

**Disease(s):** Plasma cell myeloma, multiple myeloma

**Note:** Plasma cell enrichment will be performed on bone marrow or blood samples unless our client directs us otherwise. (Peripheral blood is not recommended as a screening specimen unless increased plasma cells are seen on blood smear.) Specimens should be received in our laboratory within 72 hours of collection. If enriched samples are insufficient to complete the whole panel, NeoGenomics will prioritize t(4;14) testing unless directed otherwise by our client.

**Specimen Requirements**

- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** Not recommended as a screening specimen unless increased plasma cells are seen on blood smear. 2-5mL sodium heparin tube. EDTA tube is acceptable.
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume
- **Paraffin Block or Cut Slide:** N/A

**Storage and Transportation**

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Specimens should be received in our laboratory within 72 hours of collection.

**CPT Code(s)**

- 88374x4 automated or 88377x4 manual

**Turnaround Time**

3-5 days

**Level of Service**

Global ✔️  Technical ✔️
# Plasma Cell Myeloma Prognostic FISH Panel (New York)

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>PCM Prognostic Panel for New York clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td>Test Description</td>
<td>Probes: 1p-, 1q+, iso(1q): CDKN2C (1p32), CKS1B (1q21)</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> Plasma cell enrichment will be performed on bone marrow or blood samples unless our client directs us otherwise. (Peripheral blood is not recommended as a screening specimen unless increased plasma cells are seen on blood smear.) Specimens should be received in our laboratory within 72 hours of collection. If enriched samples are insufficient to complete the whole panel, NeoGenomics will prioritize t(4;14) and TP53 testing unless directed otherwise by our client.</td>
</tr>
<tr>
<td>Disease(s)</td>
<td>Plasma cell myeloma, multiple myeloma</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>This panel may be useful post-diagnosis or post-treatment. It has predominantly non-favorable prognostic markers with the exception of t(11;14) which is generally considered to be a favorable prognostic marker.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>Bone Marrow Aspirate: 1-2 mL sodium heparin tube. EDTA tube is acceptable.</td>
</tr>
<tr>
<td></td>
<td>Peripheral Blood: Not recommended as a screening specimen unless increased plasma cells are seen on blood smear. 2-5mL sodium heparin tube. EDTA tube is acceptable.</td>
</tr>
<tr>
<td></td>
<td>Fresh, Unfixed Tissue: Tissue in RPMI</td>
</tr>
<tr>
<td></td>
<td>Fluids: Equal parts RPMI to specimen volume</td>
</tr>
<tr>
<td></td>
<td>Paraffin Block or Cut Slide: N/A</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Specimens should be received in our laboratory within 72 hours of collection.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88374x5, 88367x1 automated or 88377x5, 88368x1 manual</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>3-5 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓ Technical ✓</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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Plasma Cell Myeloma Prognostic FISH Panel (non-New York)

Alternative Name: PCM Prognostic Panel for non-New York clients

Methodology: FISH

Test Description: Probes: 1p-, 1q+, iso(1q): CDKN2C (1p32), CKS1B (1q21) | FGFR3/IgH t(4;14) | CCND1/IgH t(11;14) | 13q- (13q14, 13q34) | IgH/MAF t(14;16) | IgH/MAFB t(14;20) | 17p- (TP53 17p13.1, NF1 17q11.2) |
Probes may be ordered separately.

Disease(s): Plasma cell myeloma, multiple myeloma

Note: Plasma cell enrichment will be performed on bone marrow or blood samples unless our client directs us otherwise. (Peripheral blood is not recommended as a screening specimen unless increased plasma cells are seen on blood smear.) Specimens should be received in our laboratory within 72 hours of collection. If enriched samples are insufficient to complete the whole panel, NeoGenomics will prioritize t(4;14) and TP53 testing unless directed otherwise by our client.

Specimen Requirements: Bone Marrow Aspirate: 1-2 mL sodium heparin tube. EDTA tube is acceptable.

Peripheral Blood: Not recommended as a screening specimen unless increased plasma cells are seen on blood smear. 2-5mL sodium heparin tube. EDTA tube is acceptable.

Fresh, Unfixed Tissue: Tissue in RPMI

Fluids: Equal parts RPMI to specimen volume

Paraffin Block or Cut Slide: N/A

Storage and Transportation: Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Specimens should be received in our laboratory within 72 hours of collection.

CPT Code(s)*: 88374x7 automated or 88377x7 manual

Turnaround Time: 3-5 days

Level of Service: Global ✓ Technical ✓

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# PLC-Gamma-2 Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>PLCG2 Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing to detect mutations in exons 19, 20, and 24, covering amino acid ranges W646 to S679, A681 to M743, and I839 to V860. Testing is available separately or in combination with the BTK Inhibitor Acquired Resistance Panel. NeoGenomics recommends ordering the combination Panel.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>PLC-gamma-2 is immediately downstream of BTK in B-cell regulation pathways. Mutations in PLCG2 are associated with acquired or secondary resistance to ibrutinib arising after initial response in CLL.</td>
</tr>
</tbody>
</table>
| Specimen Requirements            | **Peripheral blood:** 5 mL in EDTA tube. Bone marrow: 2 mL in EDTA tube.  
|                                  | **FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives. |
| Storage and Transportation       | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*                     | 81320                   |
| Turnaround Time                  | 10 days                 |
| Level of Service                 | Global ✓                |

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*

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December 18, 2019
PML-RARA Translocation, t(15;17)

**Alternative Name**
PML-RARA Translocation, PML-RARA Fusion

**Methodology**
Molecular

**Test Description**
Real-time RT-PCR for quantitative detection of the t(15;17) PML-RARA fusion transcript. Both long and short isoforms of the fusion transcript are detected. Positive results identify the isoform and quantify it as a ratio with the amount of transcript from a normal control gene. Analytical sensitivity is 1 tumor cell in 10,000 normal cells.

**Clinical Significance**
The (15;17) translocation occurs in nearly all cases of acute promyelocytic leukemia (APL, or AML subtype M3). The translocation is associated with a high rate of complete remission due to sensitivity of leukemic cells to all trans-retinoic acid (ATRA). This assay is recommended for diagnostic confirmation and initiation of ATRA therapy, for monitoring minimal residual disease, and for detection of relapse.

**Specimen Requirements**
Bone marrow (preferred): 2 mL in EDTA tube. Peripheral blood (acceptable): 5 mL in EDTA tube.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**
81315

**Turnaround Time**
7 days

**Level of Service**
Global ✓

---

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## PML/RARA t(15;17)

### Methodology

FISH

### Test Description

**Probes:** PML/RARA t(15;17)

**Disease(s):** AML, APL (AML-M3)

**Note:** PML-RARA FISH is performed STAT when ordered as a stand-alone test (outside a panel). Note MD contact name and phone number to receive STAT results.

### Clinical Significance

Available separately or as part of the AML Standard FISH Panel and AML Favorable-Risk Panel.

### Specimen Requirements

- **Bone Marrow Aspirate:** 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** 2-5mL Sodium Heparin Tube. EDTA tube is acceptable
- **Fresh, Unfixed Tissue:** Tissue in RPMI
- **Fluids:** Equal parts RPMI to specimen volume
- **Paraffin Block or Cut Slides:** N/A

### Storage and Transportation

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

### CPT Code(s)*

88374x1 automated. Codes may differ if manual analysis is performed.

### Turnaround Time

STAT results are reported 12-24 hours from receipt in the NeoGenomics laboratory.

### Level of Service

Global ✓  Technical ✓

---

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December 18, 2019
PMS2

Methodology
Immunohistochemistry (IHC)

Test Description
PMS2, also known as PMS1 protein homologue 2, is a DNA mismatch repair (MMR) protein. The PMS2 protein forms a heterodimer with the MLH1 protein which is then activated in the presence of ATP; this complex coordinates the binding of other proteins that repair DNA errors arising during cell preparation for cell division. The loss of PMS2 expression in tumors can be helpful in identifying hMLH1 mutation carriers. PMS2 gene defects account for a small but significant proportion of colorectal cancers and for a substantial proportion of tumors with microsatellite instability.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1 (qualitative IHC) or 88360 (quantitative/semi-quantitative – manual) or 88361 x 1 (quantitative/semi-quantitative – computer assisted)

Turnaround Time
Global: 48 hours, Image Analysis (tech-only): 36 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✔️ Stain Only ✔️

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# PMS2 Mutation & Del/Dup Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>PMS2 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>This test is performed by sequencing the entire PMS2 gene using next-gen sequencing complemented by conventional Sanger sequencing or other molecular methodologies to detect point mutations, small insertions/deletions, and large deletions/duplications. Testing is also available in the Lynch Syndrome panel which includes EPCAM, MLH1, MSH2, MSH6, and PMS2. Note: Patient and physician or genetic counselor signatures on the NeoGenomics Consent for Hereditary Cancer Genetic Testing form are required. Testing will be put on hold until signatures are received.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>PMS2 is a DNA mismatch repair gene. Mutations in PMS2 account for approximately 5% of Lynch Syndrome cases. Testing for mutations in a single Lynch Syndrome-related gene is appropriate when mismatch repair and/or microsatellite instability testing in a patient's tumor has suggested which gene may be mutated, or if there are other personal or family history indications pointing to a particular gene.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>Peripheral blood: 5 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81317, 81319</td>
</tr>
<tr>
<td>Medicare MolDX CPT Code(s)*</td>
<td>81317</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>21 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global</td>
</tr>
</tbody>
</table>

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# Pneumocystis Carinii (Jiroveci)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

This antibody is specific to *P. carinii* (*P. Jiroveci*). It stains *P. carinii* distinctly. The staining pattern is visualized as homogeneous rings corresponding to individual cyst walls. In addition, free extra-cystic *P. carinii* (trophozoites) are stained.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**

Global ✔  Stain Only ✔

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**Prealbumin (TTR)**

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Prealbumin (Transthyretin, TTR) is a hormone-binding protein that participates in the plasma transport of both thyroxine and retinol (vitamin A). The vast majority are inherited in an autosomal dominant manner and are related to amyloid deposition, affecting predominantly peripheral nerves and/or the heart. A small portion of prealbumin mutations are apparently non-amyloidogenic. The human amyloid disorders, including familial amyloid polyneuropathy, familial amyloid cardiomyopathy and senile systemic amyloidosis, are caused by insoluble prealbumin fibrils. This antibody also stains pancreatic islet cells and carcinoids.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓

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December 18, 2019
Prolactin

Methodology
Immunohistochemistry (IHC)

Test Description
Prolactin is a growth factor secreted by the anterior pituitary that is necessary for the proliferation and differentiation of the mammary glands. Prolactin antibody is useful in the identification of prolactin in pituitary adenomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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Prostate Triple Stain

Methodology
Immunohistochemistry (IHC)

Test Description
The combination of p63 + CK HMW + P504S (PIN-4 cocktail) can be extremely useful for diagnosing prostatic intraepithelial neoplasia (PIN) and/or prostate carcinoma, especially in difficult cases with limited tissue. P504 stains (cytoplasm red) prostate adenocarcinoma and atypical adenomatous hyperplasia. p63 (nuclear brown) and cytokeratin high molecular weight (HMW, cytoplasmic brown) stain basal cells of all normal (negative markers) and benign prostate glands.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88344 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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**PSA**

**Alternative Name**  
Prostate Specific Antigen

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Prostate specific antigen (PSA) is a glycoprotein with a molecular weight of 33-34kDa. It is restricted to the cytoplasm of acinar and ductal epithelia of normal, benign or malignant prostate tissue. Furthermore, PSA from prostatic cancers has been shown to be immunologically and biochemically similar to that of normal prostate tissue. The antibody reacts against primary and metastatic prostatic neoplasms, but not against tumors of non-prostatic origin. This antibody is useful for determining if an isolated metastasis is of prostatic origin.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only ✓

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*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*

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December 18, 2019
## PSAP/HPAP

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Prostate Acid Phosphatase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Prostate specific acid phosphatase/human prostatic acid phosphatase (PSAP/HPAP) is a 100kDa glycoprotein present in high concentration in the prostate gland and its secretions. PSAP is specific to the benign or malignant epithelial cells of the prostate gland. Prostatic stroma, urethra and the basal cells stain negatively. Also, epithelial cells injured due to inflammation, infarction, etc. and areas of squamous metaplasia of the prostatic acini show loss of PSAP activity. Nearly all metastases of prostatic carcinoma, irrespective of site, demonstrate PSAP immunoreactivity.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88342 x 1 or 88341 x 1 |
| **Turnaround Time** | 24 hours |
| **Level of Service** | Stain Only ✔ |

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December 18, 2019
PSMA

Alternative Name
Prostate Specific Membrane Antigen

Methodology
Immunohistochemistry (IHC)

Test Description
Prostate specific membrane antigen (PSMA) is a 750 amino acid type II membrane glycoprotein with folate hydrolase and neuropeptidase activity. PSMA is expressed in normal and malignant prostatic epithelium and in a subset of non-prostatic tissues. In prostate cancer, PSMA expression has been shown to correlate with disease progression, with the highest levels expressed in hormone-refractory and metastatic disease. PSMA expression has also been reported on the neovasculature of a variety of non-prostatic solid tumors.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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PTEN

Methodology
FISH

Test Description
Probes: PTEN (10q23) | Centromere 10
Disease(s): Prostate cancer, melanoma, squamous cell carcinoma of the head and neck, cervix (PTEN deletions)
This test may be ordered separately and is included in the majority of NeoTYPE Solid Tumor Profiles.

Clinical Significance
PTEN is one of the most commonly mutated tumor suppressors in human cancer. Large or complete gene deletions have been reported in prostate cancer, melanoma, and squamous cell carcinoma of the head and neck, CNS, cervix, and at lower frequencies, a variety of other tumors. This FISH test detects large deletions.

Specimen Requirements
Paraffin Block: Send paraffin block. Also send circled H&E slide for tech-only (required). Cut Slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88377x1 manual or 88374x1 automated.

Turnaround Time
3-5 days

Level of Service
Global ✔️  Technical ✔️

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December 18, 2019
PTEN

Methodology
Immunohistochemistry (IHC)

Test Description
Phosphatase and tensin homolog (PTEN) is a tumor suppressor gene that is mutated in a wide range of cancers. PTEN plays a role in cell proliferation, apoptosis and migration. Reduced expression of PTEN has been reported in a variety of malignancies, including breast, prostate and endometrial cancer. In breast and prostate cancer, loss of PTEN expression has been shown to correlate positively with advanced stage disease. Recent studies have reported that PTEN may be a powerful predictor of response to Herceptin in HER2 positive breast cancer.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1; 88360 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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### PTH

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Parathyroid Hormone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Parathyroid hormone (PTH) is expressed in normal parathyroid, parathyroid adenomas and primary and secondary hyperplasia of parathyroid. This antibody is useful in the differential diagnosis of autoimmune disorders involving parathyroid gland resulting in the production of anti-PTH &amp; hypo-parathyroidism.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  or  - One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>88342 x 1 or 88341 x 1</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Stain Only ✓</td>
</tr>
</tbody>
</table>

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PTPN11 Mutation Analysis

Alternative Name: Protein Tyrosine Phosphatase, Non-Receptor Type 11

Methodology: Molecular

Test Description: Bi-directional sequencing of exons 2-4 of PTPN11.

Clinical Significance: Samples are accepted for somatic and germline PTPN11 mutation testing. Somatic mutations are detected in 34% of juvenile myelomonocytic leukemia (JMML) and 3-4% of AML, ALL, and MDS/CMML. Mutations in JMML patients are associated with worse prognosis. Germline PTPN11 mutations are detected in 50% of Noonan syndrome and are a significant cause of the LEOPARD syndrome of multiple lentigines with anomalies.

Specimen Requirements: Peripheral blood: 5 mL in EDTA tube. Bone marrow: 2 mL in EDTA tube.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s): 81406x1

Turnaround Time: 14 days

Level of Service: Global

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December 18, 2019
# RARA Break-Apart

## Methodology
FISH

## Test Description
**Disease(s):** APL, AML  
**Probes:** RARA (17q21)

## Clinical Significance
This RARA break-apart probe is useful for detecting variant RARA translocations with partners other than PML such as t(5;17) and t(11;17). Testing is recommended when FISH for t(15;17) is negative but extra RARA signals are seen to distinguish variant RARA translocations from trisomy 17. If indicated, follow-up metaphase FISH may be added to identify rearrangement partner chromosomes as an aid to therapy selection. Testing is also useful for verifying RARA status when morphology is suspicious for APL but t(15;17) FISH is negative.

## Specimen Requirements
- Bone marrow aspirate: 1-2 mL sodium heparin tube. EDTA tube is acceptable.  
- Peripheral blood: 2-5 mL sodium heparin tube. EDTA tube is acceptable.  
- Fresh, unfixed tissue: Tissue in RPMI.  
- Fluids: Equal parts RPMI to specimen volume.  
- Paraffin block or cut slides: Not available.

## Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88377x1 manual or 88374x1 automated.

## Turnaround Time
3-5 days

## Level of Service
Global ✅  
Technical ✅

---

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# RAS/RAF Panel

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>RAS Mutation Analysis, RAF Mutation Analysis, RAS RAF, RAS RAF Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>The RAS/RAF Panel is an NGS-based assay performed by sequencing the entire coding region (full gene) of BRAF, HRAS, KRAS and NRAS genes. The panel reports mutations detected in the full gene including mutations in the most common hotspots, if present. The common hotspots include KRAS (exons 2-4, including codons 12, 13, 59, 61, 117, and 146), NRAS (exons 2-4, including codons 12, 13, 59, 61, 117, and 146), HRAS (exons 2-3, including codons 12, 13, 59, and 61), and BRAF (exons 11, 15 including codon V600).</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>KRAS, NRAS, HRAS, and BRAF are members of the RAS/RAF/MAPK pathway. Current guidelines recommend KRAS and NRAS testing in metastatic colorectal cancer for determination of anti-EGFR therapy, and recommend BRAF testing as a marker of poor prognosis. BRAF mutations may predict lack of response to anti-EGFR therapy; evidence is mixed.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• FFPE tissue: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81479x1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>10-14 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✅</td>
</tr>
</tbody>
</table>

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December 18, 2019
# RB (Retinoblastoma Protein)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Retinoblastoma (RB) is a tumor suppressor gene which functions as a negative regulator of the cell cycle by interacting with transcription factors including E2F1, PU1, ATF2, UBF, Elf1 and cAbl. RB protein may act by regulating transcription and loss of its function leads to uncontrolled cell growth. Aberrations in the RB gene have been implicated in cancers of breast, colon, prostate, kidney, nasopharynx, and leukemia.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1; 88360 x1

**Turnaround Time**

Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**

Global ✔ Stain Only ✔

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December 18, 2019
### RCC1

**Alternative Name**  
Renal Cell Carcinoma 1

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
In normal kidney, renal cell carcinoma (RCC1, gp200) is localized along the brush border of the proximal tubule. In other normal tissues, RCC is also localized along the luminal surfaces of breast lobules and ducts, the luminal surface of the epididymal tubular epithelium, within the cytoplasm of parathyroid parenchymal cells and focally within the colloid of thyroid follicles. Other normal tissues do not express similar or cross-reacting antigens. RCC1 is expressed by most primary and metastatic renal cell carcinomas.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only ✓
Methodology

FISH

Test Description

Probes: RET (10q11.2)
Disease(s): Lung cancer, thyroid cancer

Clinical Significance

RET gene rearrangements that result in growth-promoting chimeric or fusion proteins are found in 1-2% of adenocarcinoma-containing non-small cell lung cancer (NSCLC) and 20-40% of sporadic papillary thyroid carcinoma (PTC). In lung cancer, the most common rearrangement partner is KIF5B, followed by PTC1 and PTC3 rearrangements which are the most common in PTC. RET rearrangements in NSCLC are generally mutually exclusive of mutations in EGFR, KRAS, ALK, and ROS1. Patients tend to be younger (<60) and lack smoking history. Early clinical studies in NSCLC show response to multi-kinase inhibitors. By identifying PTC, RET rearrangements are one of several genetic markers useful for classifying indeterminate thyroid FNA cytology results. Sequence-variant mutations in the RET gene associated with MEN2 syndrome or sporadic medullary thyroid carcinoma (MTC) will not be detected by FISH; next-gen sequencing for the RET gene may be considered instead.

Specimen Requirements

Bone marrow aspirate: N/A
Peripheral blood: N/A
Fresh, unfixed tissue: N/A
Fluids: N/A
Paraffin block: Send paraffin block. Also send circled H&E slide for tech-only (required). Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88377x1 manual or 88374x1 automated.

Turnaround Time

7 days

Level of Service

Global ✓ Technical ✓

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# Reticulin

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>Reticular Nuclear Fast Red Stain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Special stain.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td></td>
</tr>
</tbody>
</table>
  - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
  - One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** |  
  Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)**      | 88313x1                          |
| **Turnaround Time**  | 24 hours                         |
| **Level of Service** | Stain Only ✓                     |

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RHOA Mutation Analysis

Methodology
Molecular

Test Description
Bi-directional sequencing of the gene RHOA. The locked nucleic acid (LNA) technique is used to increase detection sensitivity for the G17V mutation. Note - Available as stand-alone or as part of the NeoTYPE AITL/Peripheral T-Cell Lymphoma Profile.

Clinical Significance
RHOA mutations are common in angioimmunoblastic T-cell lymphoma (AITL), a subtype of peripheral T-cell lymphoma. AITL makes up about 20% of T-cell lymphoma cases. AITL patients with a G17V mutation in RHOA have also been shown to have TET2 mutations, which may play a role in the pathogenesis of AITL. Testing for RHOA mutations using the RHOA Mutation Analysis assay may aid in the diagnostic assessment of a patient.

Specimen Requirements
- **Peripheral blood**: 5 mL in EDTA tube.
- **Bone marrow**: 2 mL in EDTA tube.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
81479

Turnaround Time
10-14 days

Level of Service
Global

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## ROS1

### Methodology
- Immunohistochemistry (IHC)

### Test Description
ROS1 gene rearrangements are reported in 1% to 2% of lung adenocarcinomas and are associated with a response to the multi-targeted tyrosine kinase inhibitor crizotinib. ROS1 rearrangement can be detected by using IHC for ROS1 protein as an alternate screening test. We recommend that any positive results be confirmed by ROS FISH studies.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
- Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
- 88342 x 1 or 88341 x 1

### Turnaround Time
- Global: 48 hours, Tech-Only (stain only): 24 hours

### Level of Service
- Global ✔️
- Stain Only ✔️

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December 18, 2019
### Methodology
- **FISH**

### Test Description
**Probes:** ROS1 (6q22.1)
**Disease(s):** Non-small cell lung carcinoma (NSCLC)

### Clinical Significance
ROS1 gene rearrangements are found in 1-2% of non-small cell lung carcinoma (NSCLC). Pre-clinical and early clinical evidence suggests ROS1-rearranged tumors may be sensitive to the dual ALK/MET inhibitor crizotinib.

### Specimen Requirements
Paraffin Block: Send paraffin block. Also send circled H&E slide for tech-only (required).

### Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
- 88377x1 manual or 88374x1 automated.

### Turnaround Time
3-5 days

### Level of Service
- Global ✅
- Technical ✅

---

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December 18, 2019
RRM1

Methodology
Immunohistochemistry (IHC)

Test Description
RRM1 is crucial for DNA synthesis and damage repair. High levels of RRM1 are associated with G2 cell cycle arrest and increased apoptosis in vitro.

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1 qualitative; 88360x1 quantitative

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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December 18, 2019
RUNX1-RUNX1T1 (AML1-ETO) Translocation, t(8;21)

**Alternative Name**
RUNX1-RUNX1T1 Translocation, RUNX1-RUNX1T1 Fusion, AML1-ETO Translocation, AML1-ETO Fusion

**Methodology**
Molecular

**Test Description**
Real-time RT-PCR for quantitative detection of the t(8;21) RUNX1-RUNX1T1 fusion transcript (formerly called AML1-ETO). Analytical sensitivity is 1 tumor cell in 100,000 normal cells. Positive results are reported as a ratio between quantities of (8;21) transcript and a normal control gene.

**Clinical Significance**
The (8;21) translocation occurs in approximately 5% of AML. These cases are usually considered core-binding factor AML (CBF-AML). The translocation is usually associated with a high rate of complete remission and longer overall survival in AML subtype M2. This assay is recommended for diagnostic confirmation of and for monitoring minimal residual disease. c-KIT mutation testing may be considered for t(8;21)-positive AML patients as c-KIT mutations are considered an adverse risk factor in these patients.

**Specimen Requirements**
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.

**Storage and Transportation**
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

**CPT Code(s)**
81401

**Turnaround Time**
7 days

**Level of Service**
Global ✓

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### RUNX1T1/RUNX1 (ETO/AML1) t(8;21)

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>AML1-ETO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>FISH</td>
</tr>
</tbody>
</table>
| **Test Description** | Probes: RUNX1T1/RUNX1 (ETO/AML1) t(8;21)  
Disease(s): AML-M2 |
| **Clinical Significance** | Available separately or as part of the AML Standard FISH Panel and AML Favorable-Risk Panel. |
| **Specimen Requirements** | Bone Marrow Aspirate: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable  
Peripheral Blood: 2-5mL Sodium Heparin Tube. EDTA tube is acceptable  
Fresh, Unfixed Tissue: Tissue in RPMI Fluids: Equal parts RPMI to specimen volume. Paraffin or Cut Slides: N/A |
| **Storage and Transportation** | Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88374x1 automated. Codes may differ if manual analysis is performed. |
| **Turnaround Time** | 3-5 days |
| **Level of Service** | Global ✅  
Technical ✅ |

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S100

Methodology
Immunohistochemistry (IHC)

Test Description
S100 belongs to the family of calcium binding proteins. Antibody to S100 stains Schwannomas, ependymomas, astrogliomas, almost all benign melanocytic lesions, melanomas and their metastases. S100 protein is also expressed in the Langerhans cells in skin and interdigitating reticulum cells in the paracortex of lymph nodes.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
S100p

Methodology

Immunohistochemistry (IHC)

Test Description

Expression of S100P, a member of the S100 family, is increased in a number of tumors, including pancreas, lung, breast, and ovary carcinomas. S100P can be seen in many pancreatic ductal carcinoma, and it displays no staining in the benign pancreatic ducts and acinar glands.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✅

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SALL4

Methodology
Immunohistochemistry (IHC)

Test Description
SALL4, a newly identified zinc-finger transcriptional factor, is required for the maintenance of embryonic stem cell pluripotency by modulating OCT4. SALL4 is a novel sensitive and highly specific marker for metastatic germ cell tumors, and is particularly useful for detecting metastatic yolk sac tumors.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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### SAT B2

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>SATB2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>SATB2 stains colonic and osteogenic cells and their neoplasms.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
  • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*    | 88342 x 1 or 88341 x 1 |
| Turnaround Time | 24 hours |
| Level of Service | Stain Only ✓ |

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Serotonin

Methodology

Immunohistochemistry (IHC)

Test Description

Serotonin is synthesized in serotonergic neurons in the central nervous system and enterochromaffin cells in the gastrointestinal tract and serotonin-containing carcinoid tumors. Serotonin may be a useful tool for characterization of carcinoids.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔

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December 18, 2019
### Sezary T-Cell Add-On Flow Panel

**Methodology**
Flow Cytometry

**Test Description**
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD3, CD4, CD5, CD7, CD8, CD19, CD26, CD43, and CD45 (9 markers).

**Clinical Significance**
The Sezary T-Cell Add-On Panel is designed to detect abnormal circulating T-cells seen in Sezary syndrome, a disseminated form of cutaneous T-cell lymphoma.

**Specimen Requirements**
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

**Storage and Transportation**
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
Please contact NeoGenomics’ Billing Department.

**Turnaround Time**
1 day

**Level of Service**
Global ✓  Technical ✓
SF1

Alternative Name
Steroidogenic Factor 1

Methodology
Immunohistochemistry (IHC)

Test Description
SF1 is expressed in all steroidogenic tissues, including the adrenal cortex, testicular Sertoli cells, and Leydig cells, ovarian theca, hypothalamus, and anterior pituitary. SF1 is highly valuable marker to determine adrenocortical origin.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only

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## SF3B1 Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>SF3B1 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>RT-PCR and bi-directional sequencing of exons 14-17 of the SF3B1 gene. More than 90% of reported mutations are detected in these exons. This test detects mutations present at 10-15% or more in a wild-type background.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>SF3B1 mutations occur in 10-15% of CLL patients and serve as independent predictors of shortened time to treatment and poorer overall survival in CLL. Mutations are also detected in approximately 28% of MDS and 19% of myelodysplastic/myeloproliferative neoplasms. In MDS/MPN, most mutations were found in refractory anemia with ring sideroblasts (the RARS subtype).</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td><strong>Peripheral blood:</strong> 5 mL in EDTA tube. <strong>Bone marrow:</strong> 2 mL in EDTA tube.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81479</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>10 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✓</td>
</tr>
</tbody>
</table>

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Simian Virus 40 (SV40) Immunohistochemistry (IHC)

Methodology

Test Description

Simian Virus 40 (SV40) is a polyomavirus that is found in both monkeys and humans. Like other polyomaviruses, SV40 is a DNA virus that has the potential to cause tumors. SV40 is believed to suppress the tumor-suppressing p53 in humans. A mutated p53 gene may contribute to uncontrolled cellular proliferation, leading to a tumor. The hypothesis that SV40 might cause cancer in humans has been a particularly controversial area of research. Some research has suggested that SV40 is associated with brain tumors, bone cancers, non-Hodgkin lymphoma and malignant mesothelioma. This antibody shows cross-reactivity to BK and JC virus, and some use it a surrogate to detect these viruses.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service

Global ✔ Stain Only ✔

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.
SMA

**Alternative Name**  
smooth muscle actin

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Smooth muscle actin antibody binds to smooth muscle cells and myoepithelial cells. It stains the muscularis propria and muscularis mucosae of the gastrointestinal tract, the uterine myometrium, medial layer of blood vessels, myoepithelial cells of salivary glands and other organs. The antibody does not stain skeletal and cardiac muscle, endothelium, connective tissue, epithelium or nerve. The antibody can be used to identify smooth muscle tumors (leiomyomas and leiomyosarcomas).

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only

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**SMMHC**

**Alternative Name**  
Smooth Muscle Myosin, Heavy Chain

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Smooth Muscle Myosin, Heavy Chain (SMMS-1) is an antibody to smooth muscle myosin, heavy chain that reacts with human visceral and vascular smooth muscle cells. The antibody also reacts with human myoepithelial cells. It is very helpful in distinguishing between benign sclerosing breast lesions and infiltrating carcinomas in difficult cases since it strongly stains the myoepithelial layer in the benign lesions while it is negative in the infiltrating carcinomas.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only  

---

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Smoothelin

Methodology
Immunohistochemistry (IHC)

Test Description
Smoothelin is a novel cytoskeletal protein that reacts with the 59 kDa and 100 kDa proteins corresponding to Smoothelin A and B, respectively, which are exclusively found in smooth muscle cells (SMC). Cells with SMC-like characteristics, such as myofibroblasts and myoepithelial cells, as well as skeletal and cardiac muscle do not contain Smoothelin. Smoothelin is exclusively expressed in fully differentiated (contractile) smooth muscle cells and could be used as a tool to differentiate muscularis propria from muscularis mucosa.

Specimen Requirements
• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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**Somatostatin**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Somatostatin is a useful marker of D-cells of pancreatic islet cells. D-cells are used to identify hyperplasia of the pancreatic islets. Most of these tumors are malignant, giving rise to somatostatinomas. Somatostatin suppresses gastric acid secretion, gallbladder contractions and pancreatic insulin secretion; therefore, the most common clinical manifestations of patients with these tumors are mild diabetes.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

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# Somatostatin (Receptor Type 2)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Somatostatin receptor type 2 (sstr2) is a receptor for somatostatins-14 and -28. This antibody has a great value in the assessment of sst2A status in human neuroendocrine tumors. Overexpression of somatostatin receptor 2 (Sst2r) in neuroendocrine tumors is diagnostically helpful and may have therapeutic implications.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓

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SOX10

Methodology
Immunohistochemistry (IHC)

Test Description
SOX10 is a sensitive marker of melanoma, including conventional, spindled, and desmoplastic subtypes. It is also a useful marker in detecting both the in situ and invasive components of desmoplastic melanoma. SOX10 is diffusely expressed in schwannoma, neurofibroma, and granular cell tumor. SOX10 was not identified in any other mesenchymal and epithelial tumors except for myoepitheliomas and diffuse astrocytomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type.
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered.
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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**SOX11**

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Nuclear protein expression of SOX-11 is highly associated with both cyclin D1-positive and negative mantle cell lymphoma (MCL). SOX-11 IHC is useful for identifying true cyclin D1-negative MCL and further defining pathologic features of CD5+ DLBCL. Routine use of anti-SOX-11 in cases of suspected CD5+ DLBCL might help identify additional cases of cyclin D1-negative blastoid MCL. SOX-11 can also be detected in some BL, LBL, and T-PLL, although the different morphological and phenotypic features of these malignancies allow easy recognition of the cases of cyclin D1-negative MCL.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 (or 88341 if not the first single antibody per specimen)

**Turnaround Time**
1 day: tech only. 2 days: with interpretation. 4 days: with consult report.

**Level of Service**
Stain Only ✔

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SOX2

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
SOX2 stains all embryonal carcinomas and is highly specific for squamous cell carcinoma.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✓

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Spirochete

Methodology

Immunohistochemistry (IHC)

Test Description

Spirochete (Treponema pallidum) is the causative agent of syphilis. In the past, localization of the spirochete agent was achieved with silver stains such as Steiners and/or Warthin-Starry. Treponema pallidum can now be successfully localized with IHC techniques in FFPE tissue. The antibody consists of a rabbit purified IgG fraction and is highly specific for spirochete. Treponema pallidum also cross-reacts with Borrelia burgdorferi (Lyme disease).

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service

Global ✔ Stain Only ✔

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December 18, 2019
SRSF2 Mutation Analysis

Alternative Name: SRSF2 Gene Sequencing

Methodology: Molecular

Test Description: Bi-directional sequencing of the mutation hotspot region in exon 1 of the SRSF2 gene corresponding to amino acids 57-120.

Clinical Significance: SRSF2 is a component of the RNA splicing complex, the spliceosome. Mutations are frequent in myeloid disorders including 12% MDS, 44% CMML, and 17% primary myelofibrosis (PMF), and are associated with poorer prognosis in these patients. Testing is useful for establishing diagnosis by distinguishing myeloid neoplasms from a reactive process and for assessing prognosis.

Specimen Requirements: Peripheral blood: 5 mL in EDTA tube. Bone marrow: 2 mL in EDTA tube.

Storage and Transportation: Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*: 81479

Turnaround Time: 14 days

Level of Service: Global ✓

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**SS18 (SYT)**

**Alternative Name**  
SYT

**Methodology**  
FISH

**Test Description**  
Probes: SS18 (SYT) (18q11.2)  
Disease(s): Synovial sarcoma

**Clinical Significance**  
SS18 break-apart FISH testing detects rearrangements of SS18 (also known as SYT or SSXT) in synovial sarcoma. SS18 rearrangements are found exclusively in this tumor and have been widely used to establish an accurate diagnosis. The major translocation in synovial sarcoma is t(X;18)(p11.2;q11.2) which results in fusion of SS18 with one of the SSX genes on the X chromosome. This translocation or complex variants are present in >95% of all cases, often as the sole abnormality. SS18 rearrangement partners will not be identified by this FISH test. For that purpose, please see the [NGS Comprehensive Sarcoma Fusion Profile](#).

**Specimen Requirements**  
- **Bone marrow aspirate**: N/A  
- **Peripheral blood**: N/A  
- **Fresh, unfixed tissue**: N/A  
- **Fluids**: N/A  
- **Paraffin block**: Send paraffin block. Also send circled H&E slide for tech-only (required)  
- **Cut slides**: H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only

**Storage and Transportation**  
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88377x1 manual or 88374x1 automated

**Turnaround Time**  
4 days

**Level of Service**  
Global ✔  
Technical ✔

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December 18, 2019  
Page 525 of 578
# Standard Leukemia/Lymphoma Panel - 24 markers

## Methodology
Flow Cytometry

## Test Description
Available as global and tech-only. Markers are CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD13, CD14, CD16, CD19, CD20, CD23, CD33, CD34, CD38, CD45, CD56, CD64, CD117, HLA-DR, kappa, and lambda.

## Clinical Significance
Useful to aid in diagnosis of leukemia and lymphoma, and for post-treatment follow-up.

## Specimen Requirements
- **Bone marrow aspirate or peripheral blood:** 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- **Bone marrow core:** 1-2 cm minimum core length in RPMI.
- **Fresh, unfixed tissue:** 0.2 cm³ minimum in RPMI.
- **Fluids and FNAs:** Equal parts RPMI and specimen.

## Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88184(x1), 88185(x23). Add 88189(x1) for global.

## Turnaround Time
1 day

## Level of Service
- Global ✅
- Technical ✅

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# STAT3 Mutation Analysis

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>STAT3 Gene Sequencing, Signal Transducer and Activator of Transcription 3 Mutation Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Molecular</td>
</tr>
<tr>
<td>Test Description</td>
<td>Bi-directional sequencing of STAT3 exons 13-21 encompassing the DNA binding and SH2 domains.</td>
</tr>
<tr>
<td>Clinical Significance</td>
<td>Samples are accepted for somatic and germline STAT3 mutation testing. Somatic mutations are detected in 42% of T-cell large granular lymphocytic (T-LGL) and natural killer (NK) cell leukemias, and 5% of diffuse large B-cell lymphoma (DLBCL). STAT3 inhibitor therapies for multiple cancers are being evaluated in clinical trials. Germline STAT3 mutations are identified in &gt;95% of cases of autosomal dominant hyper-IgE syndrome (AD-HIES, or Job’s syndrome).</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>Peripheral blood: 5 mL in EDTA tube. Bone marrow: 2 mL in EDTA tube</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens &lt;72 hours old preferred.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>81405</td>
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<tr>
<td>Turnaround Time</td>
<td>10 days</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✅</td>
</tr>
</tbody>
</table>

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STAT6

Methodology
Immunohistochemistry (IHC)

Test Description
STAT6 is a highly sensitive and specific immunohistochemical marker for solitary fibrous tumor (SFT) and can be helpful to distinguish this tumor type from histologic mimics.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1

Turnaround Time
24 hours

Level of Service
Stain Only

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December 18, 2019
Surfactant

Methodology
Immunohistochemistry (IHC)

Test Description
Pulmonary surfactant apoproteins play essential roles in keeping alveoli from collapsing at the end of expiration. SP-A is located mainly in type II pneumocytes and has been demonstrated in bronchiolo-alveolar carcinomas and adenocarcinomas of the lung. Mesotheliomas show no positive staining with this antibody. Surfactant can be helpful in the differential diagnosis of pulmonary adenocarcinomas and mesotheliomas.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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December 18, 2019
Synaptophysin

Methodology
Immunohistochemistry (IHC)

Test Description
Antibody to synaptophysin reacts with neuroendocrine neoplasms of neural as well as epithelial types. In combination with chromogranin A and NSE antibodies, the antibody to synaptophysin is very useful in the identification of normal neuroendocrine cells and neuroendocrine neoplasms.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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T&B Tissue Flow Panel

Methodology
Flow Cytometry

Test Description
Stand-alone test. Markers are CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD19, CD20, CD23, CD34, CD38, CD45, CD56, kappa, and lambda (17 markers).

Clinical Significance
This panel is designed for basic evaluation and phenotypic subclassification of B- and T-cell lymphoproliferative disorders. Together with CD45/side scatter gating strategy, this panel may also be utilized to identify a subset of granulocytic sarcomas and lymphoblastic lymphomas. Additional tests can also be ordered in conjunction with this panel for further subclassification and confirmation of the results, if needed.

Specimen Requirements
Bone marrow aspirate or peripheral blood: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
Bone marrow core: 1-2 cm minimum core length in RPMI.
Fresh, unfixed tissue: 0.2 cm³ minimum in RPMI.
Fluids and FNAs: Equal parts RPMI and specimen.

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184x1, 88185x16, Add 88189x1 for global.

Turnaround Time
1 day

Level of Service
Global ✓  Technical ✓

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December 18, 2019
T-ALL Add-On Flow Panel

**Alternative Name**
T-Cell Acute Lymphoblastic Leukemia/Lymphoma Add-On Panel

**Methodology**
Flow Cytometry

**Test Description**
Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD1a, CD3, CD7, CD11b, CD19, CD43, CD45, cMPO, and nTdT (9 markers).

**Clinical Significance**
Used to diagnose T-acute lymphoblastic leukemia/lymphoma and detect biphenotypic acute leukemia.

**Specimen Requirements**
Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.

**Storage and Transportation**
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
Please contact NeoGenomics’ Billing Department.

**Turnaround Time**
1 day

**Level of Service**
Global ✔️  Technical ✔️

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# T-ALL Follow-Up Flow Panel

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>T-Cell Acute Lymphoblastic Leukemia/Lymphoma Follow-Up Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Flow Cytometry</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Available as global and tech-only. Please provide clinical history including the time after treatment. Prior immunophenotyping at NeoGenomics with Standard or Extended Flow Panel is strongly recommended. Clients who decline full phenotyping and order a global or push-to-global Follow-Up Panel are requested to provide details of the diagnosis by submitting at least one of the following: previous flow cytometry report, previous pathology report, and/or clinical history notes. Markers are CD1a, CD2, CD3, cCD3, CD4, CD5, CD7, CD8, CD11b, CD19, CD38, CD43, CD45, CD56, cMPO, and nTDT (16 markers).</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>For T-cell acute lymphocytic leukemia (T-ALL) monitoring after diagnosis is established. This is not a minimal residual disease (MRD) panel since the standard number of events is collected.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • Bone marrow aspirate or peripheral blood: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.  
  • Bone marrow core: 1-2 cm minimum core length in RPMI.  
  • Fresh, unfixed tissue: 0.2 cm³ minimum in RPMI.  
  • Fluids and FNAs: Equal parts RPMI and specimen. |
| **Storage and Transportation** | Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88184(x1), 88185(x15). Add 88189(x1) for global. |
| **Turnaround Time** | 1 day |
| **Level of Service** | Global ✓  
  Technical ✓ |

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## T-Cell Lymphoma Follow-Up Flow Panel

### Methodology
Flow Cytometry

### Test Description
Available as global and tech-only. Please provide clinical history including the time after treatment. Prior immunophenotyping at NeoGenomics with Standard or Extended Flow Panel is strongly recommended. Clients who decline full phenotyping and order a global or push-to-global Follow-Up Panel are requested to provide details of the diagnosis by submitting at least one of the following: previous flow cytometry report, previous pathology report, and/or clinical history notes. Markers are CD2, CD3, CD4, CD5, CD7, CD8, CD19, CD38, CD45, and CD56.

### Clinical Significance
For T-cell lymphoma monitoring after diagnosis is established. This is not a minimal residual disease (MRD) panel since the standard number of events is collected.

### Specimen Requirements
- Bone marrow aspirate or peripheral blood: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- Bone marrow core: 1-2 cm minimum core length in RPMI.
- Fresh, unfixed tissue: 0.2 cm³ minimum in RPMI.
- Fluids and FNAs: Equal parts RPMI and specimen.

### Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Ship same day as drawn whenever possible. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
88184(x1), 88185(x9). Add 88188(x1) for global.

### Turnaround Time
1 day

### Level of Service
- Global ✓
- Technical ✓

---

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T-Cell Receptor Beta Gene Rearrangement

**Alternative Name**
T-Cell Beta Gene Rearrangement

**Methodology**
Molecular

**Test Description**
This test provides qualitative detection of monoclonal T-cell receptor (TCR) beta gene rearrangements by PCR and fragment analysis according to BIOMED-2 consensus primer design. This test may be ordered concurrently with or after negative results in our T-Cell Receptor Gamma Gene Rearrangement assay for gamma gene rearrangements to improve TCR rearrangement detection by ~5% in T-cell leukemias/lymphomas.

**Clinical Significance**
T-cell receptor (TCR) gene rearrangement analysis is commonly used for determining clonality in the diagnostic evaluation of T-cell lymphomas and leukemias. TCR gamma gene (tested separately) and beta gene rearrangement analysis (as provided in this test) together will detect most clonal TCR rearrangements in patients with T-cell lymphomas/leukemias. Results should be interpreted in clinical context for diagnosis of T-cell lymphoproliferative disorders.

**Specimen Requirements**
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.
- **FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.
- **Fresh tissue:** Two pieces minimum, 0.2 cm^3 in RPMI.

**Storage and Transportation**
Refrigerate fresh tissue until shipping. For all specimens, use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 81340

**Turnaround Time**
7 days

**Level of Service**
Global

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## T-Cell Receptor Gamma Gene Rearrangement

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>T-Cell Gamma Gene Rearrangement, TCRG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Detection of clonal T-cell receptor gamma (TCRG) gene rearrangements by PCR of variable and joining regions. T-Cell Receptor Beta Gene Rearrangement is offered separately and may be added to this gamma gene test.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>Detects monoclonal T-cell receptor gamma gene rearrangement. Interpret in clinical context for diagnosis of T-cell lymphoproliferative disorders.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | • **Peripheral blood:** 5 mL in EDTA tube.  
• **Bone marrow:** 2 mL in EDTA tube.  
• **FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.  
• **Fresh tissue:** Two pieces minimum, 0.2 cm^3 in RPMI. |
| **Storage and Transportation** | Refrigerate fresh tissue until shipping. For all specimens, use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 81342 |
| **Turnaround Time** | 7 days |
| **Level of Service** | Global ✔ |

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# T-Cell Receptor/LGL Add-On Flow Panel

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>T-Cell Receptor/Large Granular Lymphocyte (TCR/LGL) Add-On Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Flow Cytometry</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Available as global and tech-only. This add-on panel is available to clarify findings on samples currently having flow cytometry analysis at NeoGenomics and is not available for stand-alone testing. Markers are CD3, CD4, CD7, CD8, CD16, CD45, CD56, CD57, TCR alpha/beta, and TCR gamma/delta (10 markers).</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>This panel differentiates gamma/delta from alpha/beta T cells and evaluates aberrant immunophenotypic expression of LGLs and NK cells. CD1a and CD30 can be added for specific cases.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>Flow cytometry testing can be performed on bone marrow aspirate, peripheral blood, fresh bone marrow core biopsy, unfixed tissue, and body fluids. Please see full specimen requirements for either Standard Leukemia/Lymphoma Analysis or Extended Leukemia/Lymphoma Analysis as this add-on panel is available in combination with either of those full panels.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong>*</td>
<td>Please contact NeoGenomics’ Billing Department.</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>1 day</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔️ Technical ✔️</td>
</tr>
</tbody>
</table>

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# T-Cell Therapy Flow Panel

**Methodology**

Flow Cytometry

**Test Description**

Available as global and tech-only. Available as stand-alone test (as described here) or as add-on to panels. Markers are CD3, CD4, CD7, CD8, CD25, CD26, CD30, CD45, CD52, and CD279 (10 markers).

**Clinical Significance**

This panel assesses T-cells for the presence of targetable antigens to guide therapeutic decisions. Expression of some markers may also help with differential diagnosis of various T-cell lymphomas or leukemias.

**Specimen Requirements**

- **BM Aspirate**: 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Peripheral Blood**: 1mL EDTA: sodium heparin is acceptable; provide CBC
- **Fresh Bone Marrow Core Biopsy**: 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue**: Tissue in RPMI
- **Fluids**: Equal parts RPMI and specimen volume

**Storage and Transportation**

Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88184x1, 88185x3. Add 88187x1 for global.

**Turnaround Time**

1 day

**Level of Service**

Global ✓  Technical ✓

---

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### TCL1

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>T-cell leukemia 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>FISH</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td></td>
</tr>
<tr>
<td>Probes:</td>
<td>TCL1 (14q32.1)</td>
</tr>
<tr>
<td>Disease(s):</td>
<td>mature T-cell leukemia, T-cell prolymphocytic leukemia (T-PLL), adult T-cell leukemia/lymphoma (ATLL)</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td></td>
</tr>
<tr>
<td>This breakapart probe covers breakpoint regions in the TCL1 (T-cell leukemia) gene cluster on chromosome 14q32 which encompasses TCL1A, TCL1B, and other genes. TCL1 translocations and inversions occur in mature T-cell leukemias including T-cell prolymphocytic leukemia (T-PLL) and adult T-cell leukemia/lymphoma (ATLL). These rearrangements cause gene overexpression due to juxtaposition with TCR-alpha or TCR-beta regulatory elements and contribute to oncogenesis.</td>
<td></td>
</tr>
</tbody>
</table>

| **Specimen Requirements** |                  |
| Bone Marrow Aspirate:     | 1-2 mL sodium heparin tube. EDTA tube is acceptable. |
| Peripheral Blood:          | 2-5 mL sodium heparin tube. EDTA tube is acceptable. |
| Fresh, Unfixed Tissue:     | Tissue in RPMI. |
| Fluids:                   | Equal parts RPMI to specimen volume. |
| Paraffin block:           | Send paraffin block. Also send circled H&E slide for tech-only (required). |
| Cut slides:               | H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only. |

| **Storage and Transportation** |                  |
| Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |

| **CPT Code(s)**          | 88377x1 manual or 88374x1 automated. |
| **Turnaround Time**      | 4 days for unfixed or FFPE specimens |
| **Level of Service**     | Global ✓  Technical ✓ |

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# TCL1

**Alternative Name**  
T Cell Leukemia/Lymphoma Protein 1

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
T-cell leukemia/lymphoma protein 1 (TCL1) is normally found in the nucleus and cytoplasm of lymphoid lineage cells during early embryogenesis. Chromosomal translocations may lead to overexpression of TCL1, resulting in T-cell leukemia and B-cell lymphoma. TCL1 is expressed in more differentiated B-cells, under both reactive and neoplastic conditions, from antigen committed B-cells and in germinal center B-cells. It is down-regulated in the latest stage of B-cell differentiation. The most useful application of TCL1 antibody is the discrimination of B-cell lymphomas from T-cell lymphomas, CD30+ anaplastic large cell lymphomas, multiple myeloma, and marginal zone B-cell lymphoma.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only

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December 18, 2019
**TCR Delta IHC**

**Test Description**

T-cell receptor delta (TCR delta) is used as a phenotypic marker for TCR delta-expressing T-cells. TCR is a heterodimer composed of either alpha/beta or gamma/delta. TCR delta is expressed by thymocytes and a majority of peripheral (gamma/delta TCR-bearing) T-cells. Evaluation may help in the differential diagnosis of T-cell lymphomas.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 3-4 microns for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342x1 or 88341x1

**Turnaround Time**

48 hours

**Level of Service**

Stain Only ✔

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December 18, 2019
# TCRβF1

## Methodology

**Immunohistochemistry (IHC)**

## Test Description

T Cell Receptor beta (TCRβ) is used as a phenotypic marker for TCRβ expressing T-cells. TCRβ is expressed by thymocytes and a majority of peripheral (α/β TCR-bearing) T-cells. This antibody does not cross-react with γ/Δ TCR-bearing T-cells.

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88342 x 1 or 88341 x 1

## Turnaround Time

24 hours

## Level of Service

Stain Only ✓

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**TdT (Terminal Deoxynucleotidyl Transferase)**

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Description</strong></td>
<td>TdT is a highly specific marker for the diagnosis and classification of acute lymphoblastic lymphoma/leukemias. The determination of TdT expression is most valuable when it is important to differentiate histologically between lymphoblastic lymphoma and Burkitt lymphoma.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or • One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>88342 x 1 or 88341 x 1</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>24 hours</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Stain Only ✓</td>
</tr>
</tbody>
</table>

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TERT Promoter Mutation Analysis

Alternative Name: TERT Promoter Mutation

Methodology: Molecular

Test Description: Bi-directional Sanger sequencing is performed using PCR primers designed to target mutations in the promoter region of TERT.

Clinical Significance: TERT gene promoter mutations lead to constitutive activation and expression. This in turn leads to replication and proliferation of cancer cells. Mutations in the TERT promoter are found in approximately 70% of melanomas, 80–90% of glioblastoma multiforme, 60% of hepatocellular carcinoma, 60% of bladder cancer, 70% of basal cell carcinoma, 50% of cutaneous squamous cell carcinoma and up to 30% of thyroid cancers. In thyroid cancers, TERT promoter mutations are detected in approximately 10% of papillary, 40% of poorly differentiated, and 70% of anaplastic carcinomas. In papillary thyroid carcinomas, the co-presence of mutations in the TERT promoter region and BRAF are associated with significantly more aggressive disease and shorter survival. Similarly, TERT promoter mutations in melanoma are associated with more aggressive disease, especially when associated with a BRAF mutation.

Specimen Requirements: FFPE solid tumor tissue: Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage and Transportation: Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

CPT Code(s)*: 81345

Medicare MolDX CPT Code(s)*: 81479

Turnaround Time: 14 days

Level of Service: Global ✓

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# TET2 Mutation Analysis

## Methodology
Molecular

## Test Description
Bi-directional sequencing of the entire coding sequence of the TET2 transcript variant A (2002 amino acids in length).

## Clinical Significance
TET2 functions in DNA methylation as a part of epigenetic regulation of gene expression. Mutations are detected in myeloid cancers including 19% of MDS, 12% of MPN, 16% of AML, and 22% of CMML, and are associated with poor overall survival in intermediate-risk AML. Mutations are also detected in 38% of peripheral T-cell lymphoma and 47% of angioimmunoblastic T-cell lymphoma. In these lymphomas, TET2 mutations are associated with aggressive disease and poor outcome.

## Specimen Requirements
**Peripheral blood:** 5 mL in EDTA tube. **Bone marrow:** 2 mL in EDTA tube.

## Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred.

## CPT Code(s)*
81479

## Turnaround Time
14 days

## Level of Service
Global ✅

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TFE3

Methodology

Immunohistochemistry (IHC)

Test Description

Overexpression of TFE3 is a sensitive and specific marker of Xp11 translocation in renal cell carcinomas. TFE3 is also expressed in alveolar soft part sarcoma the hallmark of which is a chromosomal rearrangement at 17q25 and Xp11.2 engendering an ASPSCR1–TFE3 fusion gene. Use of this antibody is an aid in the recognition of Xp11 translocation renal cell carcinoma and alveolar soft part sarcoma within the context of an antibody panel.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✔

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# Thrombomodulin (TM)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Thrombomodulin (TM) is a plasma membrane-related glycoprotein that has anticoagulant activity. TM antigen is found in several cell types, including megakaryocytes, mesangial cells, synovial cells, mesothelial cells, endothelial cells, and some squamous epithelial cells and their associated tumors. TM antibody labels most mesotheliomas with thick membranous staining pattern and about half of pulmonary adenocarcinomas, showing cytoplasmic immunostaining. Thrombomodulin is also a marker of urinary bladder epithelium.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓
# Thyroglobulin (TGB)

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

This antibody labels thyroglobulin (TGB) in follicular epithelial cells of the thyroid and colloid. Thyroglobulin antibody is useful in positive identification of thyroid carcinomas of the papillary and follicular types. Demonstration of thyroglobulin in a metastatic lesion establishes the thyroid origin of the tumor.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓

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December 18, 2019
TIA1

Methodology
Immunohistochemistry (IHC)

Test Description
TIA1 (T-cell intracytoplasmic antigen) monoclonal antibody reacts with a 15 kDa cytoplasmic granule-associated protein, expressed in lymphocytes processing cytolytic potential. Most anaplastic large cell lymphomas react with TIA1. TIA1 also reacts with most large granular lymphocytic leukemias, hepatosplenic T-cell lymphomas, intestinal T-cell lymphomas, NK-like T-cell lymphomas, NK-cell lymphomas, nasal T/NK-cell lymphomas, subcutaneous T-cell lymphomas and pulmonary angiocentric lymphomas of T or NK phenotype. All B-cell lymphomas, Hodgkin and lymphoblastic leukemias are negative for TIA1.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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December 18, 2019
## TLE1

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Expression of the transducing-like receptor (TLE) genes, TLE1, TLE2, TLE3 and TLE4, correlate with immature epithelial cells that are progressing toward a terminally differentiated state. TLE1 antibody is an excellent discriminator of synovial sarcoma from other sarcomas, including histologically similar tumors such as malignant peripheral nerve sheath tumor.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✔️

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**TOP2A**

**Alternative Name**  
Topo2A, topoisomerase IIa

**Methodology**  
FISH

**Test Description**

**Probes:** TOP2A (17q21-q22) | Cen 17 (17p11.1-q11.1)  
**Disease(s):** Breast cancer  
**Note:** Available as a global test only.

**Clinical Significance**  
TOP2A (topoisomerase IIa) amplification has been associated with positive response to anthracycline therapy in breast cancer patients.

**Specimen Requirements**

- Pathology Report: A copy of the pathology report is required for TOP2A testing  
- Bone Marrow Aspirate: N/A  
- Peripheral Blood: N/A  
- Fresh, Unfixed Tissue: N/A  
- Fluids: N/A  
- Paraffin block: Send paraffin block  
- Cut slides: H&E slide (required) plus 4 unstained slides cut at 4-5 microns

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

- 88377x1 manual or 88374x1 automated

**Turnaround Time**

4 days

**Level of Service**

Global ✅

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**TOP01**

**Alternative Name**  
Topo I

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Topoisomerase I (TOPO1) is essential nuclear enzyme for replication and transcription during cell reproduction and DNA repair. Upregulation of TOPO1 increases with disease stage in colorectal and pancreatic cancers.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
- 88342x1 or 88341x1 qualitative; 88360x1 quantitative

**Turnaround Time**  
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**  
Global ✔  Stain Only ✔

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Toxoplasma

Methodology
Immunohistochemistry (IHC)

Test Description
Toxoplasma is a crescent shaped sporozoan that lives as an intracellular parasite in various tissues of vertebrates and completes its life cycle in a single host. This antibody helps to identify the toxoplasma in FFPE tissues.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓  Stain Only ✓

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## TP53 Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>TP53 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of TP53 exons 4-9.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>TP53 mutations are detected in at least 50% of all adult tumors and are generally associated with a poor prognosis. The TP53 gene encodes the tumor suppressor p53. Germline mutations in TP53 are the cause of Li-Fraumeni Syndrome.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Peripheral blood</strong>: 5 mL in EDTA tube. <strong>Bone marrow</strong>: 2 mL in EDTA tube. <strong>FFPE solid tumor tissue</strong>: Paraffin block is preferred. Alternatively, send 1 H&amp;E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81405</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>10 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔️</td>
</tr>
</tbody>
</table>

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TP63 Rearrangement

**Alternative Name**
TBL1XR1/TP63

**Methodology**
FISH

**Test Description**

- **Probes:** TP63 (3q28) | TBL1XR1/TP63 [inv(3)(q26q28)]
- **Disease(s):** Anaplastic large cell lymphoma (ALCL), peripheral T-cell lymphoma (PTCL)
- **Note:** Probes are not orderable separately; concurrent analysis is necessary due to proximity of breakpoints in the most common fusion rearrangement.

**Clinical Significance**
TP63 gene rearrangements encoding p63 fusion proteins define a subset of ALK-negative anaplastic large cell lymphoma (ALCL) cases and are associated with aggressive course and poor outcome compared to peripheral T-cell lymphoma (PTCL) cases without these rearrangements. This test includes targeted analysis for the TBL1XR1/TP63 fusion, which has also been reported in diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma. Positive results will be reported for this fusion or TP63 gene rearrangement with another partner not identified by this assay.

**Specimen Requirements**
- **Bone Marrow Aspirate:** N/A
- **Peripheral Blood:** N/A
- **Fresh, Unfixed Tissue:** N/A
- **Fluids:** N/A
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech-only.

**Storage and Transportation**
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88377x2 manual or 88374x2 automated

**Turnaround Time**
3-5 days

**Level of Service**
Global ☑️  Technical ☑️

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December 18, 2019
## TRAcP

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Tartrate Resistant Acid Phosphatase, TRAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>TRAP IHC is of use in the identification of hairy cell leukemia, but it is not a completely specific marker.</td>
</tr>
</tbody>
</table>
| Specimen Requirements  | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
|                        | • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
|                        | • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*           | 88342 x 1 or 88341 x 1                   |
| Turnaround Time        | 24 hours                                 |
| Level of Service       | Stain Only ✓                             |

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# Trichrome

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Special stain. Trichrome stains are frequently used to differentiate between collagen and smooth muscle in tumors and to identify increases in collagenous tissue in diseases such as cirrhosis of the liver.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88313

**Turnaround Time**

24 hours

**Level of Service**

Stain Only

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December 18, 2019
Tryptase

Methodology
Immunohistochemistry (IHC)

Test Description
This antibody labels a mast cell tryptase. It will also show reactivity to basophils, but to a lesser degree.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔️

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December 18, 2019
## TS (Thymidylate Synthase)

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Antibody MAB4130 recognizes a 36 kDa protein identified as Thymidylate Synthase [TS], which is a target for the fluoropyrimidine group of antineoplastic drugs used to treat solid tumors. Expression of TS is associated with response to 5-fluorouracil (5-FU) in human breast, colorectal, gastric, head and neck carcinomas.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>• A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or • One (1) unbaked, unstained slide for H&amp;E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88342 x 1 or 88341 x 1 (qualitative IHC) or 88360 x 1 (quantitative/semi-quantitative – manual)</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>Global: 48 hours, Tech-Only (stain only): 24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Global ✔ Stain Only ✔</td>
</tr>
</tbody>
</table>

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December 18, 2019
# TSH

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Thyroid Stimulating Hormone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>Thyroid Stimulating Hormone (TSH) is a pituitary hormone of 28 kDa that stimulates thyroid growth and production of thyroid hormones. This antibody labels thyrotropic cells of the pituitary and may be useful in the classification of pituitary adenomas and the differential identification of primary and metastatic tumors of the pituitary.</td>
</tr>
</tbody>
</table>
| Specimen Requirements | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
• One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
• Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 88342 x 1 or 88341 x 1 |
| Turnaround Time | 24 hours |
| Level of Service | Stain Only ✔ |

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**TTF1**

<table>
<thead>
<tr>
<th>Alternative Name</th>
<th>Thyroid Transcription Factory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodology</td>
<td>Immunohistochemistry (IHC)</td>
</tr>
<tr>
<td>Test Description</td>
<td>Thyroid Transcription Factory (TTF1) is found predominantly in lung and thyroid neoplasms. The utility of TTF1 becomes apparent in the differential diagnosis of primary versus metastatic carcinomas, especially in the lung. This clone is sensitive and may show weak staining in non-lung tissues.</td>
</tr>
</tbody>
</table>
| Specimen Requirements       | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
                               • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
                               • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation  | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*                | 88342 x 1 or 88341 x 1        |
| Turnaround Time             | 24 hours                      |
| Level of Service            | Stain Only ✓                 |

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December 18, 2019
# Tuberculosis

## Methodology

- Immunohistochemistry (IHC)

## Test Description

*Mycobacterium tuberculosis* is the most common cause of tuberculosis. Immunohistochemical demonstration of mycobacterial antigens is not only useful in establishing mycobacterial etiology, but can also be used as an alternative method to the conventional Ziehl-Neelsen method.

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type.
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered.
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88342 x 1 or 88341 x 1 or 88341 x 1

## Turnaround Time

- Global: 48 hours, Tech-Only (stain only): 24 hours

## Level of Service

- Global ✓
- Stain Only ✓

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Tyrosinase

Methodology

Immunohistochemistry (IHC)

Test Description

Tyrosinase is a copper-containing metalloglycoprotein that catalyzes several steps in the melanin pigment biosynthetic pathway. Mutations of the tyrosinase gene occur in various forms of albinism. Tyrosinase is one of the targets for cytotoxic T-cell recognition in melanoma patients. Staining of melanomas with this antibody showed tyrosinase in melanotic as well as amelanotic variants.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ✓

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## UGT1A1 Genotyping

### Methodology
Molecular

### Test Description
Lengths of the TA repeat polymorphism in the promoter region of the UGT1A1 gene are determined by fragment analysis using capillary electrophoresis. The alleles detected include the common normal allele *1 (with 6 TA repeats) and the common abnormal allele *28 (7 repeats). The patient's genotype is reported along with the associated high, intermediate, or low risk for toxicity from the quinolone-based alkaloids.

### Clinical Significance
Polymorphisms in the gene UGT1A1 can reduce expression of the enzyme UDP glucuronosyl transferase 1A1 and lead to toxicity from incomplete metabolism of the drug irinotecan, which is used in the treatment of colorectal and gastric cancers. There is increased risk for hematologic and gastrointestinal toxicity (especially neutropenia and diarrhea) with irinotecan therapy in patients who carry one or two copies of the abnormal allele UGT1A1*28. Testing for UGT1A1 genotype before initiating irinotecan therapy is recommended so initial doses can be adjusted. This test may also be used for diagnostic confirmation of Gilbert and Crigler-Najjar hyperbilirubinemia syndromes.

### Specimen Requirements
**Peripheral blood:** 5 mL in EDTA tube.

### Storage and Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
81350

### Turnaround Time
14 days

### Level of Service
Global ✔

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Uroplakin II

Methodology
Immunohistochemistry (IHC)

Test Description
Uroplakin II is a 15 kDa protein component of urothelial plaques. Uroplakin II mRNA was found in both bladder cancer tissues and peripheral blood of patients with primary and metastatic urothelial carcinoma of the bladder. Uroplakin II antibody [BC21] is a highly specific antibody that may be useful in identifying tumors of urothelial origin.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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# Uroplakin III

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Uroplakins (UPs) are a family of transmembrane proteins (UPs Ia, Ib, II and III) that are specific differentiation products of urothelial cells. In non-neoplastic urothelium, UPIII is expressed in the luminal surface plasmalemma of superficial (umbrella) cells. UPIII detects half of urothelial carcinomas, whereas many non-urothelial carcinomas were UPIII-negative. Recent studies of UP gene expression in normal urothelium and bladder cancer specimens found that UP expression was absent after malignant transformation. Thus, UP expression might reflect the malignant potential of urothelial cancer cells as well as being cytodifferential markers of urothelial cells.

**Specimen Requirements**  
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type  
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88342 x 1 or 88341 x 1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only ✓
### V-Beta T-Cell Clonality

**Methodology**  
Flow Cytometry

**Test Description**  
Available as global test only. Markers are VB1, VB2, VB3, VB4, VB5.1, VB5.2, VB5.3, VB7.1, VB7.2, VB8, VB9, VB11, VB12, VB13.1, VB13.2, VB13.6, VB14, VB16, VB17, VB18, VB20, VB21.3, VB22, and VB23 (24 markers). Two additional T-cell markers are used to identify the population of interest and the markers vary from case to case.

**Clinical Significance**  
Useful in identification of clonal T-cell populations to aid in diagnosis of T-cell lymphoproliferative disorders. Clonal T-cell populations can be identified in some reactive conditions and in some healthy elderly patients. Correlation with morphology, clinical history, and other diagnostic information is necessary for diagnosis.

**Specimen Requirements**
- **Bone marrow aspirate or peripheral blood:** 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- **Bone marrow core:** 1-2 cm minimum core length in RPMI.
- **Fresh, unfixed tissue:** 0.2 cm³ minimum in RPMI.
- **Fluids and FNAs:** Equal parts RPMI and specimen.

**Storage and Transportation**  
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88184(x1), 88185(x23), 88189(x1).

**Turnaround Time**  
1 day

**Level of Service**  
Global ✅

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## Varicella Zoster Virus (VZV)

### Methodology
- Immunohistochemistry (IHC)

### Test Description
Varicella Zoster Virus (VZV), a member of the human herpes virus family, causes two distinct clinical manifestations: chickenpox and shingles. Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including encephalitis or pneumonia. This antibody detects VZV in FFPE tissues.

### Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

### Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

### CPT Code(s)*
- 88342 x 1 or 88341 x 1

### Turnaround Time
- Global: 48 hours, Tech-Only (stain only): 24 hours

### Level of Service
- Global ✔
- Stain Only ✔

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.
Vascular Endothelial Growth Factor (VEGF)

**Methodology**
Immunohistochemistry (IHC)

**Test Description**
Vascular endothelial growth factor (VEGF) is a glycoprotein involved in angiogenesis that promotes tumor progression and metastasis. VEGF is a mitogen for vascular endothelial cells derived from arteries, veins and lymphatics, but it is devoid of consistent mitogenic activity for other cell types. VEGF is expressed in many human tumor cells, including adenocarcinomas, such as pancreatic, hepatocellular, renal cell carcinoma and fibrosarcoma. In normal tissues, VEGF expression has been observed in activated macrophages, keratinocytes, hepatocytes, smooth muscle cells, Leydig cells, embryonic fibroblasts and bronchial and choroids plexus epithelium, renal glomerular visceral epithelium, and mesangial cells.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1 or 88341 x 1; 88360 x 1

**Turnaround Time**
Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**
Global ✓ Stain Only ✓

---

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*
# Villin

## Methodology

Immunohistochemistry (IHC)

## Test Description

This antibody recognizes villin, a cytoskeletal filament protein of 58 kDa found in human renal epithelial cells. Villin antibody is useful for the study of gastrointestinal cells in normal and tumor tissues.

## Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88342 x 1 or 88341 x 1

## Turnaround Time

24 hours

## Level of Service

Stain Only ✓

---

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December 18, 2019
Vimentin

Methodology
Immunohistochemistry (IHC)

Test Description
Vimentin is the major intermediate filament in a variety of mesenchymal cells, including endothelial cells, all fibroblastic cells, macrophages, Sertoli cells, melanocytes, lymphocytes and ovarian granulosa cells. Vimentin is found in all types of sarcomas and lymphomas. Positive staining for vimentin is seen in most cells of fibrosarcomas, liposarcomas, malignant fibrous histiocytomas, angiosarcomas, chondrosarcomas and lymphomas. All melanomas and Schwannomas are strongly vimentin-positive.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✓

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Warthin Starry

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain. Warthin Starry stain is intended to identify Helicobacter pylori in tissue samples.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88312

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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# Wright Giemsa

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Cytochemical stain. The Wright Giemsa stain is used to stain peripheral blood and bone marrow smears for study of blood cell morphology.

**Specimen Requirements**  
- Minimum two slides fresh smear: bone marrow aspirate preferred, peripheral blood accepted  
- Slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**  
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**  
88313x1

**Turnaround Time**  
24 hours

**Level of Service**  
Stain Only ✓

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December 18, 2019
WT1

**Alternative Name**  
Wilms Tumor

**Methodology**  
Immunohistochemistry (IHC)

**Test Description**  
Wilms tumor susceptibility gene 1 protein (WT1) has diagnostic utility in the distinction of mesothelioma from adenocarcinoma in tissue sections of pleural tumors. WT1 diffusely stains most ovarian serous carcinomas and all Wilms tumors.

**Specimen Requirements**
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**
88342 x 1 or 88341 x 1

**Turnaround Time**
24 hours

**Level of Service**
Stain Only ✔️

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X/Y FISH for Engraftment

Methodology
FISH

Test Description
Probes: Centromere X | DYZ1
Disease(s): Sex-mismatched stem cell transplant

Clinical Significance
This panel assesses level of engraftment (chimerism) after sex-mismatched allogeneic hematopoietic stem cell transplant (HSCT). Molecular analysis for chimerism is also available at NeoGenomics.

Specimen Requirements
- Bone marrow aspirate: 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- Peripheral blood: 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- Fresh, unfixed tissue: Tissue in RPMI.
- Fluids: Equal parts RPMI to specimen volume.
- Paraffin block or cut slides: Not available.

Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88374xX1 automated. Codes may differ if manual analysis is performed.

Turnaround Time
3-5 days

Level of Service
Global ✓  Technical ✓

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December 18, 2019
# X/Y FISH for Molar Pregnancy

<table>
<thead>
<tr>
<th>Methodology</th>
<th>FISH</th>
</tr>
</thead>
</table>
| Test Description | Probes: Centromere X | Centromere Y  
**Note:** Testing is performed only on a global basis at this time.  
**Disease(s):** Molar pregnancy (hydatidiform mole), partial mole, triploidy |
| Clinical Significance | Along with morphological exam, FISH for chromosomes X and Y can be useful in differentiating true molar pregnancy (46, XX) from partial molar triploid pregnancy (69, XXY or XYY). |
| Specimen Requirements | • Fresh, unfixed tissue: N/A  
• Paraffin block: Send paraffin block |
| Storage and Transportation | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| CPT Code(s)* | 88377x1 manual or 88374x1 automated |
| Turnaround Time | 5-7 days |
| Level of Service | Global ✔ |

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*December 18, 2019*
ZAP-70 Lymphoid Panel

Methodology
Flow Cytometry

Test Description
Available as global and tech-only. Markers are CD3, CD5, CD19, CD45, and ZAP-70.

Clinical Significance
Over-expression of ZAP-70 is a poor prognostic marker in CLL/SLL.

Specimen Requirements
- **Bone marrow aspirate or peripheral blood:** 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- **Bone marrow core:** 1-2 cm minimum core length in RPMI.
- **Fresh, unfixed tissue:** 0.2 cm³ minimum in RPMI.
- **Fluids and FNAs:** Equal parts RPMI and specimen.

Storage and Transportation
Specimens must be received at NeoGenomics within 48 hours of collection. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184, 88185(x4). Add 88187(x1) for global.

Turnaround Time
1 day

Level of Service
Global ✓ Technical ✓

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ZAP70

Methodology
Immunohistochemistry (IHC)

Test Description
A prognostic factor in CLL/SLL.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

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December 18, 2019
NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.
### U2AF1 Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>U2AF1 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of exons 2 and 7 of the U2AF1 gene (also called U2AF35).</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>U2AF1 is a component of the RNA splicing complex, the spliceosome. Mutations are detected in myeloid disorders including 6% MDS, 4% AML, and 11% CMML. In MDS, mutations indicate risk for reduced overall survival and shorter time to AML transformation. Testing is useful for establishing diagnosis by distinguishing myeloid neoplasms from a reactive process and for assessing prognosis.</td>
</tr>
<tr>
<td><strong>Specimen Requirements</strong></td>
<td><strong>Peripheral blood</strong>: 5 mL in EDTA tube. <strong>Bone marrow</strong>: 2 mL in EDTA tube.</td>
</tr>
<tr>
<td><strong>Storage and Transportation</strong></td>
<td>Use cold pack for transport, making sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td><strong>CPT Code(s)</strong></td>
<td>81479x1</td>
</tr>
<tr>
<td><strong>Turnaround Time</strong></td>
<td>14 days</td>
</tr>
<tr>
<td><strong>Level of Service</strong></td>
<td>Global ✔</td>
</tr>
</tbody>
</table>

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October 07, 2019
UGT1A1 Genotyping

**Methodology**

Molecular

**Test Description**

Lengths of the TA repeat polymorphism in the promoter region of the UTG1A1 gene are determined by fragment analysis using capillary electrophoresis. The alleles detected include the common normal allele *1 (with 6 TA repeats) and the common abnormal allele *28 (7 repeats). The patient’s genotype is reported along with the associated high, intermediate, or low risk for toxicity from the quinolone-based alkaloids.

**Clinical Significance**

Polymorphisms in the gene UGT1A1 can reduce expression of the enzyme UDP glucuronosyl transferase 1A1 and lead to toxicity from incomplete metabolism of the drug irinotecan, which is used in the treatment of colorectal, stomach, lung, brain, and breast cancers. There is increased risk for hematologic and gastrointestinal toxicity (especially neutropenia and diarrhea) with irinotecan therapy in patients who carry one or two copies of the abnormal allele UGT1A1*28. Testing for UGT1A1 genotype before initiating irinotecan therapy is recommended so initial doses can be adjusted. This test may also be used for diagnostic confirmation of Gilbert and Crigler-Najjar hyperbilirubinemia syndromes.

**Specimen Requirements**

Peripheral blood: 5 mL in EDTA tube.

**Storage and Transportation**

Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

81350x1

**Turnaround Time**

14 days

**Level of Service**

Global ✓
# Uroplakin II

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Uroplakin II is a 15 kDa protein component of urothelial plaques. Uroplakin II mRNA was found in both bladder cancer tissues and peripheral blood of patients with primary and metastatic urothelial carcinoma of the bladder. Uroplakin II antibody [BC21] is a highly specific antibody that may be useful in identifying tumors of urothelial origin.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88342 x 1 or 88341 x 1 or 88341 x 1

**Turnaround Time**

24 hours

**Level of Service**

Stain Only ✓

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Uroplakin III

Methodology
Immunohistochemistry (IHC)

Test Description
Uroplakins (UPS) are a family of transmembrane proteins (UPs Ia, Ib, II and III) that are specific differentiation products of urothelial cells. In non-neoplastic urothelium, UPIII is expressed in the luminal surface plasmalemma of superficial (umbrella) cells. UPIII detects half of urothelial carcinomas, whereas many non-urothelial carcinomas were UPIII-negative. Recent studies of UP gene expression in normal urothelium and bladder cancer specimens found that UP expression was absent after malignant transformation. Thus, UP expression might reflect the malignant potential of urothelial cancer cells as well as being cytodifferential markers of urothelial cells.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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V-Beta T-Cell Clonality

Methodology
Flow Cytometry

Test Description
Available as global test only. Markers are VB1, VB2, VB3, VB4, VB5.1, VB5.2, VB5.3, VB7.1, VB7.2, VB8, VB9, VB11, VB12, VB13.1, VB13.2, VB13.6, VB14, VB16, VB17, VB18, VB20, VB21.3, VB22, and VB23 (24 markers). Two additional T-cell markers are used to identify the population of interest and the markers vary from case to case.

Clinical Significance
Useful in identification of clonal T-cell populations to aid in diagnosis of T-cell lymphoproliferative disorders. Clonal T-cell populations can be identified in some reactive conditions and in some healthy elderly patients. Correlation with morphology, clinical history, and other diagnostic information is necessary for diagnosis.

Specimen Requirements
- **Bone marrow aspirate or peripheral blood:** 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- **Bone marrow core:** 1-2 cm minimum core length in RPMI.
- **Fresh, unfixed tissue:** 0.2 cm³ minimum in RPMI.
- **Fluids and FNAs:** Equal parts RPMI and specimen.

Storage and Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88184(x1), 88185(x23), 88189(x1).

Turnaround Time
1 day

Level of Service
Global ✓

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Varicella Zoster Virus (VZV)

Methodology
Immunohistochemistry (IHC)

Test Description
Varicella Zoster Virus (VZV), a member of the human herpes virus family, causes two distinct clinical manifestations: chickenpox and shingles. Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including encephalitis or pneumonia. This antibody detects VZV in FFPE tissues.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

Level of Service
Global ✓ Stain Only ✓

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.
# Vascular Endothelial Growth Factor (VEGF)

## Methodology
Immunohistochemistry (IHC)

## Test Description
Vascular endothelial growth factor (VEGF) is a glycoprotein involved in angiogenesis that promotes tumor progression and metastasis. VEGF is a mitogen for vascular endothelial cells derived from arteries, veins and lymphatics, but it is devoid of consistent mitogenic activity for other cell types. VEGF is expressed in many human tumor cells, including adenocarcinomas, such as pancreatic, hepatocellular, renal cell carcinoma and fibrosarcoma. In normal tissues, VEGF expression has been observed in activated macrophages, keratinocytes, hepatocytes, smooth muscle cells, Leydig cells, embryonic fibroblasts and bronchial and choroids plexus epithelium, renal glomerular visceral epithelium, and mesangial cells.

## Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

## Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88342 x 1 or 88341 x 1 or 88341 x 1; 88360 x 1

## Turnaround Time
Global: 48 hours, Tech-Only (stain only): 24 hours

## Level of Service
- Global
- Stain Only

---

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Villin

Methodology
Immunohistochemistry (IHC)

Test Description
This antibody recognizes villin, a cytoskeletal filament protein of 58 kDa found in human renal epithelial cells. Villin antibody is useful for the study of gastrointestinal cells in normal and tumor tissues.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342 x 1 or 88341 x 1

Turnaround Time
24 hours

Level of Service
Stain Only ✔

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October 07, 2019
Vimentinin

Methodology

Immunohistochemistry (IHC)

Test Description

Vimentin is the major intermediate filament in a variety of mesenchymal cells, including endothelial cells, all fibroblastic cells, macrophages, Sertoli cells, melanocytes, lymphocytes and ovarian granulosa cells. Vimentin is found in all types of sarcomas and lymphomas. Positive staining for vimentin is seen in most cells of fibrosarcomas, liposarcomas, malignant fibrous histiocytomas, angiosarcomas, chondrosarcomas and lymphomas. All melanomas and Schwannomas are strongly vimentin-positive.

Specimen Requirements

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

Storage and Transportation

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*

88342 x 1 or 88341 x 1

Turnaround Time

24 hours

Level of Service

Stain Only ☑
**Warthin Starry**

**Methodology**

Immunohistochemistry (IHC)

**Test Description**

Special stain. Warthin Starry stain is intended to identify Helicobacter pylori in tissue samples.

**Specimen Requirements**

- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

**Storage and Transportation**

Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

**CPT Code(s)**

88312

**Turnaround Time**

Global: 48 hours, Tech-Only (stain only): 24 hours

**Level of Service**

Global ✓ Stain Only ✓

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*Please direct any questions regarding coding to the payor being billed.*

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October 07, 2019
# Wright Giemsa

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>Cytochemical stain. The Wright Giemsa stain is used to stain peripheral blood and bone marrow smears for study of blood cell morphology.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>Minimum two slides fresh smear: bone marrow aspirate preferred, peripheral blood accepted. Slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.</td>
</tr>
<tr>
<td>Storage and Transportation</td>
<td>Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.</td>
</tr>
<tr>
<td>CPT Code(s)*</td>
<td>88313x1</td>
</tr>
<tr>
<td>Turnaround Time</td>
<td>24 hours</td>
</tr>
<tr>
<td>Level of Service</td>
<td>Stain Only</td>
</tr>
</tbody>
</table>

*The CPT codes provided with our test descriptions are based onAMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

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<table>
<thead>
<tr>
<th><strong>WT1</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alternative Name</strong></td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | - A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type or  
  - One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered  
  - Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| **Storage and Transportation** | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 88342 x 1 or 88341 x 1 |
| **Turnaround Time** | 24 hours |
| **Level of Service** | Stain Only ✓ |

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# WT1 Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>WT1 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of exons 7 and 9 is performed for detection of sequence variant mutations. Fragment analysis of exon 7 is also performed for enhanced detection of heterozygous insertion/deletion mutations. The SNP genotype at rs16754 is reported. Testing is performed on plasma for increased sensitivity whenever possible.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>WT1 mutations occur in approximately 12% of acute myeloid leukemia (AML) cases and are associated with poor outcome in cytogenetically normal AML. Within exon 7, the G allele at SNP rs16754 is associated with better prognosis in cytogenetically normal AML, especially in patients with high-risk NPM1/FLT3-ITD mutation status.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | **Peripheral blood**: 5 mL in EDTA tube.  
**Bone marrow**: 2 mL in EDTA tube. |
| **Storage and Transportation** | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. |
| **CPT Code(s)** | 81405 (effective July 2019) | Prior CPT Code was 81479 (before July 2019) |
| **Turnaround Time** | 14 days |
| **Level of Service** | Global ✔ |

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# X/Y FISH for Engraftment

## Methodology
FISH

## Test Description
**Probes:** Centromere X | DYZ1  
**Disease(s):** Sex-mismatched stem cell transplant

## Clinical Significance
This panel assesses level of engraftment (chimerism) after sex-mismatched allogeneic hematopoietic stem cell transplant (HSCT). Molecular analysis for chimerism is also available at NeoGenomics.

## Specimen Requirements
- Bone marrow aspirate: 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- Peripheral blood: 2-5 mL sodium heparin tube. EDTA tube is acceptable.
- Fresh, unfixed tissue: Tissue in RPMI.
- Fluids: Equal parts RPMI to specimen volume.
- Paraffin block or cut slides: Not available.

## Storage and Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88374xX1 automated. Codes may differ if manual analysis is performed.

## Turnaround Time
3-5 days

## Level of Service
Global ✔  Technical ✔

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# X/Y FISH for Molar Pregnancy

## Methodology

FISH

## Test Description

**Probes:** Centromere X | Centromere Y  
**Note:** Testing is performed only on a global basis at this time.  
**Disease(s):** Molar pregnancy (hydatidiform mole), partial mole, triploidy

## Clinical Significance

Along with morphological exam, FISH for chromosomes X and Y can be useful in differentiating true molar pregnancy (46, XX) from partial molar triploid pregnancy (69, XXY or XYY).

## Specimen Requirements

- Fresh, unfixed tissue: N/A  
- Paraffin block: Send paraffin block

## Storage and Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*

88377x1 manual or 88374x1 automated

## Turnaround Time

5-7 days

## Level of Service

Global ✔

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# ZAP-70 Lymphoid Panel

## Methodology
Flow Cytometry

## Test Description
Available as global and tech-only. Markers are CD3, CD5, CD19, CD45, and ZAP-70.

## Clinical Significance
Over-expression of ZAP-70 is a poor prognostic marker in CLL/SLL.

## Specimen Requirements
- **Bone marrow aspirate or peripheral blood**: 1-2 mL EDTA preferred. 1-2 mL minimum in sodium heparin tube or ACD (pale yellow/no gel separator) is acceptable. Please provide recent CBC report.
- **Bone marrow core**: 1-2 cm minimum core length in RPMI.
- **Fresh, unfixed tissue**: 0.2 cm³ minimum in RPMI.
- **Fluids and FNAs**: Equal parts RPMI and specimen.

## Storage and Transportation
Specimens must be received at NeoGenomics within 48 hours of collection. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
88184, 88185(x4). Add 88187(x1) for global.

## Turnaround Time
1 day

## Level of Service
Global ✓  Technical ✓

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October 07, 2019
ZAP70

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Immunohistochemistry (IHC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Description</td>
<td>A prognostic factor in CLL/SLL.</td>
</tr>
</tbody>
</table>
| Specimen Requirements      | • A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
|                            | • One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
|                            | • Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition. |
| Storage and Transportation | Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. |
| CPT Code(s)*               | 88342 x 1 or 88341 x 1 |
| Turnaround Time            | Global: 48 hours, Tech-Only (stain only): 24 hours |
| Level of Service           | Global ✓ Stain Only ✓ |

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October 07, 2019
# ZRSR2 Mutation Analysis

<table>
<thead>
<tr>
<th><strong>Alternative Name</strong></th>
<th>ZRSR2 Gene Sequencing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology</strong></td>
<td>Molecular</td>
</tr>
<tr>
<td><strong>Test Description</strong></td>
<td>Bi-directional sequencing of exons 5 and 7-11 of the ZRSR2 gene.</td>
</tr>
<tr>
<td><strong>Clinical Significance</strong></td>
<td>ZRSR2 is a component of the RNA splicing complex, the spliceosome. Mutations are detected in 8% of MDS and 4% of CMML. Mutations in MDS have been associated with shorter overall survival and an increased rate of transformation to AML. Testing is useful for establishing diagnosis by distinguishing myeloid neoplasms from a reactive process and for assessing prognosis.</td>
</tr>
</tbody>
</table>
| **Specimen Requirements** | - **Peripheral blood**: 5 mL in EDTA tube.  
- **Bone marrow**: 2 mL in EDTA tube. |
| **Storage and Transportation** | Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <72 hours old preferred. |
| **CPT Code(s)**     | 81479x1               |
| **Turnaround Time** | 14 days               |
| **Level of Service** | Global ✓              |

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Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.