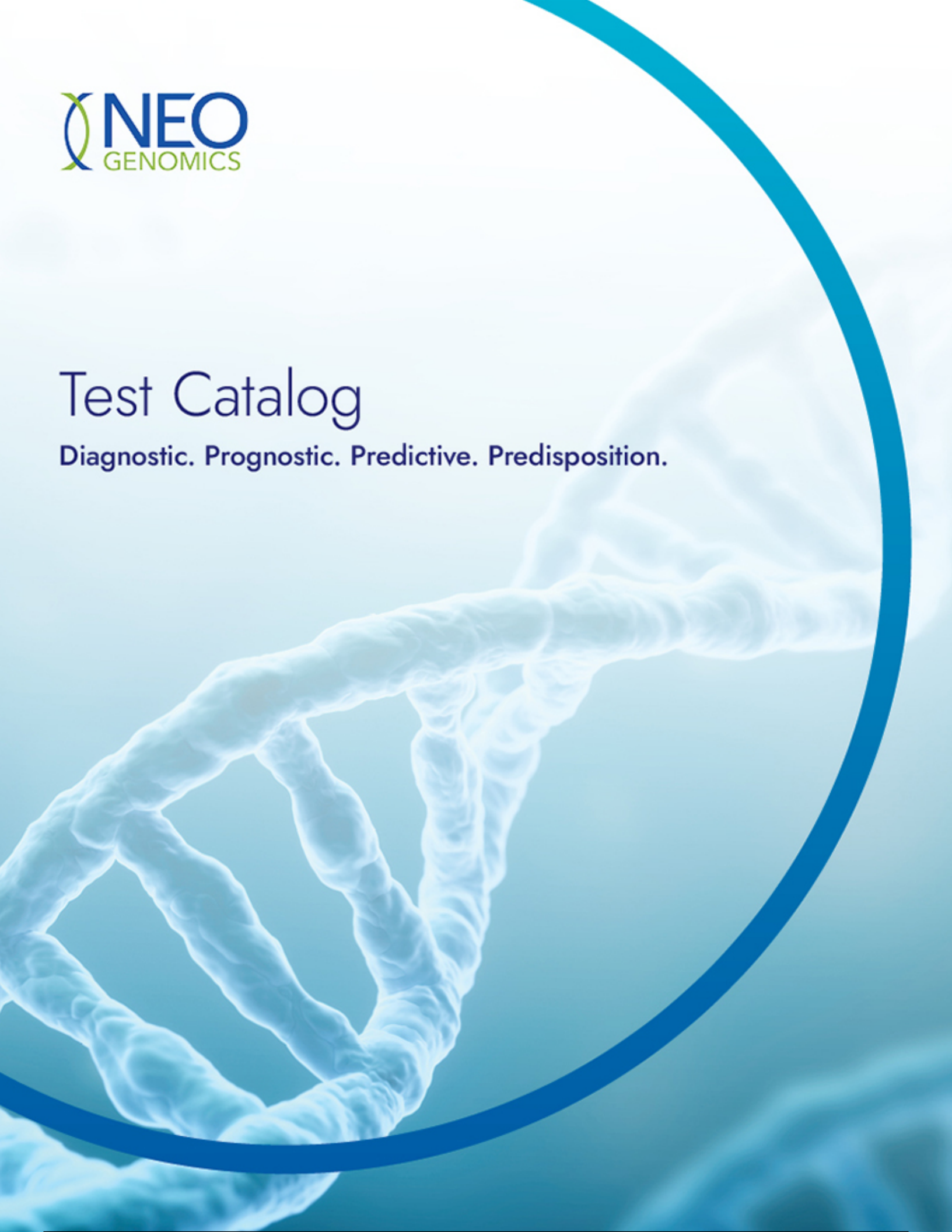
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



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 & 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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

References

1. Swerdlow SH, et al. WHO classification of tumors of hematopoietic and lymphoid tissues (Revised 4th edition). IARC Press, Lyon 2017
2. Salaverria I, et al. A recurrent 11q aberration pattern characterizes a subset of MYC-negative high-grade B-cell lymphomas resembling Burkitt lymphoma. *Blood.* 2014;123:1187-1198.
3. Ferreiro JF et al. Post-transplant molecularly defined Burkitt lymphomas are frequently MYC-negative and characterized by the 11q-gain/loss pattern. *Haematologica.* 2015;100:e275-e279.
4. Grygalewicz B, et al. The 11q-gain/loss aberration occurs recurrently in MYC-negative Burkitt-like lymphoma with 11q aberration, as well as MYC-positive Burkitt lymphoma and MYC-positive high-grade B-cell lymphoma, NOS.*Am J Clin Pathol.* 2018;149:17-28.

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Please direct any questions regarding coding to the payor being billed.

1p/19q Deletions for Glioma

Alternative Name
1/19 Co-deletion, 1p/1pq Tricolor 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 ependyomas, 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 oligodendrioglioma.

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 & 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

References

1. Louis DN, Perry A, Reifenberger G, et al. The 2016 World Health Organization Classification of Tumors of the Central Nervous System: a summary. *Acta Neuropathol*. DOI 10.1007/s00401-016-1545-1Published online May 9, 2016

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1p36 Deletion

Alternative Name
Deletion 1p36

Methodology
FISH

Test Description
Probes: TNFRSF14 (1p36)
Disease(s): Follicular Lymphoma (FL)

Clinical Significance
The TNFRSF14 (1p36) deletion test is used for the detection of deletion of the TNFRSF14 gene at chromosome 1p36.32. The 2017 WHO classification of lymphoid neoplasms recognizes diffuse follicular lymphomas negative for BCL2 translocation harboring a 1p36 aberration as a unique variant.

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 & 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. Codes may differ if manual analysis is performed.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

5 Days

References

1. Swerdlow SH, et al. WHO classification of tumors of hematopoietic and lymphoid tissues (Revised 4th edition). IARC Press, Lyon 2017.
2. Katzenberger T, et al. A distinctive subtype of t(14;18) negative nodal follicular non-Hodgkin lymphoma characterized by a predominantly diffuse growth pattern and deletions in the chromosomal region 1p36. *Blood*. 2009; 113: 1053-1061

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AAT

Alternative Name
alpha-1-antitrypsin

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

ABL1 Kinase Domain Mutation Analysis

Alternative Name
ABL1 Kinase

Methodology
Molecular

Test Description
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 all mutations recommended by guidelines, including the common T315I, Y253H, E255K/V, F359V/C/I, F317L/V/I/C, T315A, and V299L.

Clinical Significance
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.

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

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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 <7 days old preferred.

CPT Code(s)*
81170

New York Approved
Yes

Level of Service
Global

Turnaround Time
10 days

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

Adenovirus

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88312

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

AFP

Alternative Name
alpha-1-fetoprotein

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88365x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
48 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88313

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for both unfixed and FFPE specimens

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Please direct any questions regarding coding to the payor being billed.

ALK for NSCLC

Alternative Name
Anaplastic lymphoma kinase

Methodology
FISH

Test Description
Probes: ALK (2p23)
Disease(s): Non-small cell lung carcinoma (NSCLC)

Clinical Significance
ALK gene rearrangements are found in 3-5% of non-small cell lung carcinoma (NSCLC) and determine likelihood of response to crizotinib (Xalkori®) therapy.

Specimen Requirements
- **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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88377x1 manual.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time
3-5 days

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Please direct any questions regarding coding to the payor being billed.

ALK Mutation Analysis

Alternative Name
ALK Mutation

Methodology
Molecular

Test Description
Bi-directional Sanger sequencing of ALK is performed using PCR primers designed to target hotspot mutations in exons 23 and 25.

Clinical Significance
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 F1174V, F1174L, L1196M, and G1202R.

Note: This test is not designed to detect ALK fusions. To test for ALK rearrangement/fusions, either ALK for NSCLC FISH or Lung NGS Fusion Panel (Complete) are suggested.

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 & 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

New York Approved
No

Level of Service
Global

Turnaround Time

7-10 days

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Please direct any questions regarding coding to the payor being billed.

ALK-1 (for heme cases)

Alternative Name
ALK1 for lymphoma

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 7 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x7 automated. Codes may differ if manual analysis is performed.

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

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

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Please direct any questions regarding coding to the payor being billed.

ALL FISH Panel (Ph-Like)

Alternative Name
Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL)| Ph-like ALL

Methodology
FISH

Test Description
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) Panel. Probes may be ordered separately.
Disease(s): Philadelphia chromosome (Ph-like) acute lymphoblastic leukemia (ALL), B lymphoblastic leukemia/lymphoma.

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

Clinical Significance
The ALL FISH Panel (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.

Specimen Requirements
- **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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 5 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not Available
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x5 automated or 88377x5 manual. Codes may differ if manual analysis is performed.

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

ALL Pediatric 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) | ETV6/RUNX1 (TEL/AML1) t(12;21) | IgH (14q32)
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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 8 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x8 automated. Codes may differ if manual analysis is performed.

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

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

*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 stand-alone testing is only available for tech-only. 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.

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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

*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 Favorable-Risk Panel

Alternative Name
Acute myeloid leukemia

Methodology
FISH

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 3 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin block or cut slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x3 automated. Codes may differ if manual analysis is performed.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 panel since the standard number of events is collected.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 8 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin block or cut slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x8 automated. Codes may differ if manual analysis is performed.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

AML Standard FISH Panel

Alternative Name
Acute myeloid leukemia

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) | 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
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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 7 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x7 automated. Codes may differ if manual analysis is performed.

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

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

*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.

Amyloid A & Amyloid P

Alternative Name
Amyloid A, Amyloid P, Amyloid A&P Panel

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

Turnaround Time

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

*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.

Anaplastic Large Cell Lymphoma FISH Panel

Alternative Name
ALCL, Peripheral T-cell lymphoma (PTCL)

Methodology
FISH

Test Description
Probes: ALK (2p23) | TP63 (3q28) | TBL1XR1/TP63 [inv(3)(q26q28)] | DUSP22-IRF4 (6p25.3) Probes may be ordered separately except TP63 (3q28) and TBL1XR1/TP63 [inv(3)(q26q28)] are performed combined and reported as co-dependent for result and interpretation of TP63 rearrangement status.
Disease(s): Anaplastic Large Cell Lymphoma (ALCL), peripheral T-cell lymphoma (PTCL)

Clinical Significance
The ALCL FISH Panel is used for the detection of recurrent chromosome abnormalities observed in patients with anaplastic large cell lymphoma (ALCL) which may classify those patients into specific risk groups. This panel includes ALK (2p23) rearrangement testing. Patients with ALK-positive ALCL have a favorable prognosis compared to ALK-negative ALCL patients. This panel also includes two assays to detect TP63 rearrangements. Rearrangements of the TP63 gene encoding p63 fusion defines a subset of ALK-negative ALCL cases and are associated with aggressive course and poor outcome as compared to peripheral T-cell lymphoma without these rearrangements. The TBL1XR1/TP63 fusion [inv(3)] has also been reported in rare cases of peripheral T-cell lymphoma NOS, mycosis fungoides, diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma. This panel also includes the DUSP22-IRF4 rearrangement test which has been reported in CD30-positive, ALK-negative ALCL and is associated with favorable clinical outcome. DUSP22-IRF4 rearrangements have been also reported in patients with lymphomatoid papulosis (LyP).

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 4 unstained slides cut at 4 microns. Circle H&E for tech only.

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

CPT Code(s)*
88374x4 automated or 88377x4 manual

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

References

1. Pederson MB, Hamilton Dutoit SJ, Bendix K, et al. DUSP22 and TP63 rearrangements predict outcome of ALK-negative anaplastic large cell lymphoma: a Danish cohort study. *Blood*. 2017; 130:554-557.
2. Parrilla Castellar ER, Jaffe ES, Said JS, et al. ALK-negative anaplastic large cell lymphoma is a genetically heterogeneous disease with widely disparate clinical outcomes. *Blood*. 2014; 124:1473-1480.
3. Wada DA, Law ME, Hsi ED, et al. Specificity of IRF4 translocations for primary cutaneous anaplastic large cell lymphoma: a multicenter study of 204 skin biopsies. *Mod Pathol*. 2011; 24:596-605.
4. Peterson JF, Pearce KE, Meyer RG, et al. Fluorescence in-situ hybridisation for TP63 rearrangements in T cell lymphomas: single-site experience of 470 patients and implications for clinical testing. *Histopathology*. 2020;76(3):481-485. PMID: 31557339.

*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.

Annexin A1

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

AR

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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

CPT Code(s)*
88342x1 or 88341x1; or 88360x1; or 88361x1

New York Approved
Yes

Level of Service
Image Analysis, Stain Only, Global

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

*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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

ATRX

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

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

Notes
Global prognostic interpretation is available (TAT is 48 hours)

*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.

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 stand-alone testing is only available for tech-only. 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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

*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.

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. 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 panel since the standard number of events is collected.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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).

New York Approved

Yes

Level of Service

Technical

Turnaround Time

24 hours

*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.

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 CD304/CD73, CD45, CD19, CD34, CD38, CD10, CD22, CD58, CD66C/CD123, CD13/CD33, and CD20. Additional markers (CD13, CD14, CD16, CD45, and HLA-DR) are included for bone marrow samples to aid in evaluating the extent of hemodilution in bone marrow aspirates. 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:** 2-3 mL EDTA preferred. Sodium heparin is acceptable.
- **Peripheral blood:** 5-6 mL EDTA preferred. Sodium heparin is acceptable.
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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)*
Bone Marrow samples: 88184x1, 88185x13. Peripheral Blood samples: 88184x1, 88185x10. Add 88188x1 for global.

New York Approved
Yes

Level of Service

Global

Turnaround Time

24 hours

References

1. Gupta S, Devidas M, Loh ML, et al. Flow-cytometric vs. morphologic assessment of remission in childhood acute lymphoblastic leukemia: a report from the Children's Oncology Group (COG). *Leukemia*. 2018;32(6):1370-1379.
2. Borowitz MJ, Wood BL, Devidas M, et al. Prognostic significance of minimal residual disease in high risk B-ALL: a report from Children's Oncology Group study AALL0232. *Blood.*2015;126(8):964-71.
3. Brüggemann M, Kotrova M. Minimal residual disease in adult ALL: technical aspects and implications for correct clinical interpretation. *Blood Adv.* 2017;1(25):2456-2466.

*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.

B-Cell Gene Rearrangement

Alternative Name
B-Cell Translocations

Methodology
Molecular

Test Description
Detection of clonal IgH gene rearragements 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.

Clinical Significance
Detects monoclonal B-cell immunoglobulin gene rearrangement. Interpret in clinical context for diagnosis of leukemia, lymphoma, and plasma cell dyscrasia.

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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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

New York Approved
Yes

Level of Service

Global

Turnaround Time

7 days

*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.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

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

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

BCL2 (18q21)

Alternative Name
B-cell lymphoma

Methodology
FISH

Test Description
Probes: BCL2 (18q21)
Disease(s): B-cell lymphoma, non-Hodgkin lympoma (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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days (for both unfixed and FFPE specimens)

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

BCL6 (3q27)

Alternative Name
B-cell lymphoma

Methodology
FISH

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for both unfixed and FFPE specimens

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Please direct any questions regarding coding to the payor being billed.

BCL6/MYC t(3;8)

Alternative Name
BCL6/MYC Translocation

Methodology
FISH

Test Description
- **Probes**: BCL6/MYC t(3;8)
- **Disease(s)**: B-cell lymphoma, double-hit lymphoma, triple-hit lymphoma

Clinical Significance
BCL6/MYC translocation is observed recurrently in high-grade B-cell lymphoma, reported in the literature as “pseudo” double-hit or non-Ig/MYC translocation, which has a better prognosis than double hit/triple hit lymphomas with Ig/MYC translocations.

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
- **Bone Marrow/Peripheral Blood Smear or Fresh Tissue Preparation Slides:** minimum 1 slide labeled with specimen type.
- **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 & 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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 (e19a2) fusion proteins. Analytical sensitivity is 0.1%. Results are reported as Detected or Not Detected. Test can be ordered as a reflex when can be ordered as a reflex when BCR-ABL1 Standard p210, p190 is negative.

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. Sodium heparin acceptable.
- **Peripheral Blood:** 5 mL EDTA tube. Sodium heparin acceptable.

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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 <7 days old preferred.

CPT Code(s)*
81208

New York Approved
No

Level of Service
Global

Turnaround Time

7 days

*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.

BCR-ABL1 Standard p210, p190

Alternative Name
Philadelphia chromosome, BCR-ABL1 Major, BCR-ABL1 Minor, BCR/ABL1 Standard

Methodology
Molecular

Test Description
Real-time RT-PCR for quantitative detection of t(9;22) BCR-ABL1 fusion transcripts that result in major p210 (e13a2 and/or e14a2) or minor p190 (e1a2) fusion proteins with option to add p230 detection (micro or atypical variant). Analytical sensitivity is 0.002% for p210 and 0.005% for p190, depending on quality and quantity of the isolated RNA and absence of interfering substances. Log reduction score and percent abnormal are reported, and longitudinal data will appear as a NeoTRACK Result on the report. Testing is New York approved for p210 and p190 only. p230 testing may be ordered as a reflex if p210 and p190 are negative, or as a stand-alone test, BCR-ABL1 Non-Standard p230. For p230, results are reported as percent abnormal.

Clinical Significance
Useful for diagnosis and monitoring of Philadelphia chromosome-positive cases of CML and ALL. Also useful for monitoring minimal residual disease (MRD) for ALL and AML.

Specimen Requirements
- **Bone Marrow:** 2 mL EDTA tube. Sodium heparin acceptable.
- **Peripheral Blood:** 5 mL EDTA tube. Sodium heparin acceptable.

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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 <7 days old preferred.

CPT Code(s)*
81206, 81207

Medicare MolDX CPT Code(s)*
81479

New York Approved
Yes

Level of Service

Global

Turnaround Time

5 days

*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.

BCR/ABL1/ASS1 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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin or Cut Slides:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

BIRC3(API2)/MALT1 t(11;18)

Alternative Name
MALT lymphoma

Methodology
FISH

Test Description
Probes: BIRC3(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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time
3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 histiocyte-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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Bone Marrow Failure NGS Panel

Methodology
Molecular

Test Description
Testing is performed by Fulgent Genetics. Patient and physician or genetic counselor signatures on the Fulgent Genetics Informed Consent for Genetic Testing form are required. Testing will be put on hold until signatures are received. A complete test description, including list of genes tested, is available here.

Gene list: AP3B1, BRCA2, BRIP1, CSF3R, CXCR4, DKC1, ELANE, ERCC4, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, G6PC3, GATA1, GATA2, GFI1, HAX1, LAMTOR2, LYST, MPL, NHP2, NOP10, PALB2, RAB27A, RAC2, RAD51C, RBM8A, RMRP, RPL11, RPL15, RPL26, RPL35A, RPL5, RPS10, RPS17, RPS19, RPS24, RPS26, RPS7, RTEL1, RUNX1, SBDS, SLC37A4, SLX4, SRP72, TAZ, TERC, TERT, TINF2, USB1, VPS13B, VPS45, WAS, WRAP53 (60 genes).

Specimen Requirements
- **Peripheral blood:** two x 4 mL EDTA tubes

CPT Code(s)*
81165x1, 81216x1, 81242x1, 81334x1, 81345x1, 81455x1

Medicare MolDX CPT Code(s)*
81479

New York Approved
Yes

Level of Service
Global

Turnaround Time
21-37 days

*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.

BRAF Mutation Analysis by PCR

Alternative Name
BRAF V600

Methodology
Molecular

Test Description
BRAF Mutation Analysis Assay is based on PCR amplification and detection of target DNA using complementary primer pairs and oligonucleotide probes labeled with fluorsescent dyes. This assay is designed to detect V600 mutations E, K, D, R, and G. 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.

Clinical Significance
BRAF mutations are frequently found in human cancers. They are found most frequently in melanoma (50-70%), papillary thyroid cancer (36-40%) and almost all hairy cell leukemia. BRAF mutations are also found with low frequency in colorectal cancer (5-12%), non-small cell lung cancer (NSCLC), acute myeloid leukemia (AML), glioma, sarcoma, breast cancer, hepatoma, and ovarian cancer. The presence of BRAF V600E mutation in colon cancer with microsatellite instability (MSI) provides strong support for sporadic (non-Lynch) colon cancer.

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

Storage & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

*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.

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 & 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.

New York Approved
Yes

Level of Service

Global, Technical

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

BRAF V600E

Methodology
Immunohistochemistry (IHC)

Test Description
A monoclonal antibody (IHC600) 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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global (non-heme)

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

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

Brain NGS Fusion Panel

Alternative Name
Brain Tumor Fusion Panel

Methodology
Molecular

Test Description
The Brain Tumor NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects gene rearrangements (fusions) with known and novel fusion partners of these 28 genes: ALK, BRAF, CIC, EGFR including EGFRvIII, EML4, ETV6, EWSR1, FGFR1, FGFR2, FGFR3, FUS, KIAA1549, MAML2, MET, MN1, MYB, MYBL1, NTRK1, NTRK2, NTRK3, PRKCA, RAF1, ROS1, STAT6, TACC3, TFG, YAP1, and ZFTA (C11orf95).

Clinical Significance
The Brain Tumor NGS Fusion Panel is intended to detect gene fusions associated with brain tumors to aid in the diagnosis, disease classification, and therapy determination as outlined in the 2021 WHO Classification of Tumors of the CNS, 5th edition. Gliomas are the most common primary brain tumors with high recurrence and mortality rates. Gene fusions are identified in 30-50% of glioblastomas (GBMs). Potentially druggable gene fusions in all GBMs include FGFR (1.2%-8.3%), EGFR (2.2%-4%), and NTRK (1.2%-1.7%).

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81449

New York Approved
Yes

Level of Service
Global

Turnaround Time

21 Days

References

1. Louis DN et al. The 2021 WHO Classification of Tumors of the Central Nervous System: a summary.*Neuro-Oncology*. 2021;23(8):1231-1251. https://doi.org/10.1093/neuonc/noab106

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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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

*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 and BRCA2 Focus Panel (Germline)

Methodology
Molecular

Test Description
Testing is performed by Fulgent Genetics. Patient and physician or genetic counselor signatures on the Fulgent Genetics Informed Consent for Genetic Testing form are required. Testing will be put on hold until signatures are received. A complete test description, including list of genes tested, is available here.

Specimen Requirements
- **Peripheral blood:** two x 4 mL EDTA tubes

CPT Code(s)*
81162x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
10-16 days

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Please direct any questions regarding coding to the payor being billed.

BRCA1 Single Gene (Germline)

Methodology
Molecular

Test Description
Testing is performed by Fulgent Genetics. Patient and physician or genetic counselor signatures on the Fulgent Genetics Informed Consent for Genetic Testing form are required. Testing will be put on hold until signatures are received. A complete test description, including list of genes tested, is available here.

Specimen Requirements
- **Peripheral blood:** two x 4 mL EDTA tubes

CPT Code(s)*
81162x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
21-37 days

*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.

BRCA1/2 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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81163x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
14 days

References

1. Petrucelli N, Daly MB, Pal T. BRCA1- and BRCA2-Associated Hereditary Breast and Ovarian Cancer. GeneReviews. https://www.ncbi.nlm.nih.gov/books/NBK1247/ Updated December 15, 2016. Accessed February 21, 2019.
2. Meric-Bernstam F, Brusco L, Daniels M, et al. Incidental germline variants in 1000 advanced cancers on a prospective somatic germline profiling protocol. Ann Oncol. 2016;27:795-800.
3. Judkins T, Rosenthal E, Arnell C, et al. Clinical signficiance of large rearrangements in BRCA1 and BRCA2. Cancer. 2012; 118:5210-5216.
4. Ewald IP, Ribeiro PLI, Palmero EI, et al. Genomic rearrangements in BRCA1 and BRCA2: A literature review. Genet Mol Biol. 2009;32(3):437-446.;

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Please direct any questions regarding coding to the payor being billed.

BRCA2 Single Gene (Germline)

Methodology
Molecular

Test Description
Testing is performed by Fulgent Genetics. Patient and physician or genetic counselor signatures on the Fulgent Genetics Informed Consent for Genetic Testing form are required. Testing will be put on hold until signatures are received. A complete test description, including list of genes tested, is available here.

Specimen Requirements
- **Peripheral blood:** two x 4 mL EDTA tubes

CPT Code(s)*
81162x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
21-37 days

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Please direct any questions regarding coding to the payor being billed.

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., A Hologic Company. 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 & 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.

New York Approved

Yes

Level of Service

Global

Turnaround Time

10 days

References

1. Zhang Y, et al. *J Clin Oncol.* 2016; 34 (suppl abstr 541).
2. Sanft T, et al. *Breast Cancer Res Treat.* 2015;154(3):533-41.
3. Sgroi DC, et al. *Lancet Oncol.* 2013;14:1067 – 76.
4. Zhang Y, et al. *Clin Cancer Res.* 2013;19:4196-4205.
5. Sgroi DC, et al. *J Natl Cancer Inst.* 2013;105:1036-1042.
6. Ma X-J, et al. *Clin Cancer Res.* 2008;14:2601-2608.

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Please direct any questions regarding coding to the payor being billed.

Breast NGS Fusion Panel

Alternative Name
Breast Fusion Panel

Methodology
Molecular

Test Description
The Breast NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ACTL6A, AKT3, BRAF, CAPZA2, CCDC170 , CCDC6, COA5, CTNNBL1, ESR1, ETV5, FGFR3, KIAA1549, MAST1, MAST2, MET, MYB, NCOA4, NFIB, NOTCH1, NOTCH2, NTRK1, NTRK2, NTRK3, PIK3CA, RAF1, RASGEF1A, RET, RPS6KC1, and TACC3.

Clinical Significance
The Breast NGS Fusion Panel identifies the recurrent, targetable gene fusions in breast cancer for the purposes of prognosis and treatment management.

Managing the aggressive forms of breast cancer remains a challenge despite many targeted therapy approaches. Studies have shown that gene fusions may have become a precision medicine approach for the disease. Oncogenic fusions in ER-positive breast cancer may function as predictive biomarkers of clinical resistance to endocrine therapy. Fusion genes may in themselves be a biomarker of advanced and aggressive disease and are associated with some potentially targetable protein kinases. NTRK fusions are rare, but testing is of high interest due to possible treatment with specific TRK inhibitors (entrectinib, larotrectinib).

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81449

New York Approved
Yes

Level of Service

Global

Turnaround Time

21 Days

References

1. Natrajan, R. et al. Driver Oncogenes but Not as We Know Them: Targetable Fusion Genes in Breast Cancer.*Cancer Discov*; 8(3); 272–5. ©2018 AACR.

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Please direct any questions regarding coding to the payor being billed.

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

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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

CPT Code(s)*
88344 x 1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

BRG1 (SMARCA4)

Methodology
Immunohistochemistry (IHC)

Test Description
BRG1 (SMARCA4) is involved in chromatin remodeling, which regulates the binding of transcription factors to DNA. Immunhistochemical loss of expression of BRG-1 (SMARCA4) is associated with the diagnosis of small cell carcinoma of ovary, hypercalcemic type (SCCOHT).

Clone: Polyclonal
Staining pattern: Nuclear

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
- **Note:** Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 Hours

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Please direct any questions regarding coding to the payor being billed.

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.

Note: Test in DNA-based, suitable for Freeze & Hold option.

Storage & 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

New York Approved
No

Level of Service
Global

Turnaround Time

10 days

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Calcium Stain

Alternative Name
Von Kossa Stain

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

Caldesmon

Methodology
Immunohistochemistry (IHC)

Test Description
Caldesmon is a regulatory protein found in smooth muscle and tissues which interacts with actin, myosin, tryopomyosin and calmodulin. Caldesmon antibody detects smooth muscle and tumors of smooth muscle, myofibroblastic and myoepithelial differentiation. This antibody is also useful in the differentiation of epithelioid mesothelioma from serous papillary carcinoma of the ovary.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

CALR Mutation Analysis

Alternative Name
CALR, calreticulin

Methodology
Molecular

Test Description
Fragment analysis of exon 9 of the CALR (calreticulin) gene for enhanced detection of low levels of insertion/deletion mutations. Automatic reflex to bi-directional sequencing will be performed for positive samples that are not Type 1 and Type 2 mutations and results will be reported out in an addendum. 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.

Note: Test in DNA-based, suitable for Freeze & Hold option.

Storage & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

10 days

Medical Necessity Resource

Medical Necessity for NeoTYPE Myeloid Profiles

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88342x1or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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, reported and billed separately by 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 diagnosis[2] 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 NGS Solid Tumor Pathology Requisition.

Storage & 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.

New York Approved

Yes

Level of Service

Global

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.

References

1. Erlander M et al. *J Mol Diagn.* 2011;13(5):493-503.
2. Thomas SP et al. *J Clin Oncol*. 2015;33 (suppl 3; abst 249).

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Carcinoma Micromets

Alternative Name
Carcinoma micrometastases

Methodology
Immunohistochemistry (IHC)

Test Description
Carcinoma micrometastases (micromets) consist of small groups of cancer cells, originating from the original tumor site, that have spread through the lymphovascular system to another part of the body. The presence of metastasis in sentinel lymph nodes (SLN) may be the first indicator that cancer has spread to other sites in the body and is an important prognostic indicator.
Histologic evaluation of lymph nodes using a microscope is the most accurate way to assess for lymph node metastasis, since a significant number of patients have clinically negative lymph nodes. Histologic evaluation involves taking sectioning of the tissue block at three different levels and staining each level with H&E and one of the levels with Pan-Cytokeratin (AE1/AE3) immunohistochemical (IHC) stain. Pan-Cytokeratin is an epithelial cell marker and is used to highlight small tumor cell clusters that may be difficult to detect based on H&E-stain alone.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is the preferred specimen type
- Block identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

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

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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
Tech Only (Stain Only): 24 hours

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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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin or Cut Slides:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
3-5 days

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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, multiple myeloma

Clinical Significance
Available separately or as part of the NHL FISH Panel or Plasma Cell Myeloma IgH Complex FISH Panel

To learn more about FISH testing for IgH translocations in multiple myeloma, please visit Multiple Myeloma Cytogenetic Analysis resource page.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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)*
88374x1automated. Codes may differ if manual analysis is performed.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days for both unfixed and FFPE specimens

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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CD103

Methodology
Immunohistochemistry (IHC)

Test Description
CD103 antibody reacts with the integrin subunit CD103 cell surface antigen, which is expressed in intraepithelial T-lymphocytes, hairy cell leukemia, enteropathy associated T-cell lymphoma, and some splenic marginal zone lymphomas.

Staining description: Membranous

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 Hours

References

1. Morgan, EA, et al. Immunohistochemical Detection of Hairy Cell Leukemia in Paraffin Sections Using a Highly Effective CD103 Rabbit Monoclonal Antibody. Am J Clin Pathol. 2013 Feb;139(2):220-230

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

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

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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CD14

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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CD163

Methodology
Immunohistochemistry (IHC)

Test Description
CD163 antigen is restricted in its expression to the monocytic/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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 CD21and 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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 ollicular 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
  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
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Storage & Transportation
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Level of Service
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Turnaround Time
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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
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Level of Service
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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.

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CPT Code(s)*
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New York Approved
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Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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.

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New York Approved
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Level of Service
Stain Only

Turnaround Time
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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 & Transportation
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CPT Code(s)*
88342 x 1 or 88341 x 1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & Transportation
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CPT Code(s)*
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New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available

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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.

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CPT Code(s)*
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New York Approved
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Level of Service
Stain Only

Turnaround Time
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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 & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
Stain Only

Turnaround Time
24 hours

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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
Stain Only

Turnaround Time
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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.

Reference: Meyer KC, et al. An official American Thoracic Society clinical practice guideline: the clinical utility of bronchoalveolar lavage cellular analysis in interstitial lung disease. Am J Respir Crit Care Med. 2012;185(9):1004-14.

Specimen Requirements
- **BAL fluid:** 10-50 ml BAL fluid combined with equal volume of RPMI
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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. **Note: New York State samples must be received within 48 hours from collection per NYS requirements.** 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

New York Approved
No

Turnaround Time
24 hours

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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
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Storage & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
Stain Only

Turnaround Time
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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
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Storage & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
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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 & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
Stain Only

Turnaround Time
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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 & Transportation
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CPT Code(s)*
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New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
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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 & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
Stain Only

Turnaround Time
24 hours

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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 & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
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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
  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 & Transportation
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CPT Code(s)*
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New York Approved
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Level of Service
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Turnaround Time
24 hours

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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 vitronectrin. 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
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Storage & Transportation
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CPT Code(s)*
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New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

CDKN2A/B (p16) Deletion FISH for ALL

Methodology
FISH

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

Clinical Significance
Loss of the CDKN2A/B 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/B 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.

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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Global

Turnaround Time

3-5 days

References

1. Braun M, Pastorczak A, Fender W, et al. Biallelic loss of CDKN2A is associated with poor response to treatment in pediatric acute lymphoblastic leukemia. *Leuk Lymphoma.* 2017;58:1162-1171.
2. Messina M, Chiaretti S, Fedullo AL, et al. Clinical significance of recurrent copy number aberrations in B-lineage acute lymphoblasticleukaemia without recurrent fusion genes across age cohorts. *Brit J Haematol*. 2017;178(4):583-587.
3. Ribera J, Zamora L, Montesinos P, et al. Prognostic significance of copy number alterations in adolescent and adult patients with precursor B acute lymphoblastic leukemia enrolled in PETHEMA protocols. *Cancer*. 2015;121:3809-3817.

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Please direct any questions regarding coding to the payor being billed.

CDKN2A/B (p16) Deletion for Mesothelioma or Glioma

Methodology
FISH

Test Description
Probes: CDKN2A/B (p16) (9p21) | Centromere 9
Disease(s): Mesothelioma, Glioma

Clinical Significance
Detection of homozygous deletions of CDKN2A/B (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/B 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 & 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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
5 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88344 x 1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

CEA (Mono)

Alternative Name
CEA monoclonal

Methodology
Immunohistochemistry (IHC)

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 olangiocarcinomas 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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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CEBPA Mutation Analysis

Alternative Name
CEBPA

Methodology
Molecular

Test Description
Fragment length analysis of the relevant coding region 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.

Note: Test in DNA-based, suitable for Freeze & Hold option.

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

CPT Code(s)*
81218

New York Approved
No

Level of Service
Global

Turnaround Time

10 days

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Cholangio/Pancreatic Carcinoma NGS Fusion Panel

Methodology
Molecular

Test Description
The Cholangio/Pancreatic Carcinoma NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ALK, BRAF, CCDC6, FGFR2, NTRK1, NTRK2, NTRK3, NRG1, RAF1, RET, ROS1, and TACC3.

Clinical Significance
The Cholangio/Pancreatic Carcinoma NGS Fusion Panel is intended to detect gene fusions associated with cholangiocarcinoma and pancreatic carcinoma to aid in diagnosis, prognosis, and therapy selection.

Cholangiocarcinoma is an uncommon biliary tract cancer that typically presents at an advanced disease stage and is characterized by an aggressive disease course and poor clinical outcome. FGFR2 fusions are present up to 15% in cholangiocarcinoma and a prognostic indicator for survival and chemotherapy response.

Pancreatic cancer is a highly aggressive, recalcitrant malignancy with a 5-year survival of less than 9%. NRG1 fusions have been identified as a targetable oncogenic driver for pancreatic cancer. ALK and ROS1 fusions are also recommended for actionable targets.

NTRK fusions are rare in both cholangiocarcinoma and pancreatic cancers, but testing is of high interest due to possible treatment with specific TRK inhibitors (entrectinib, larotrectinib).

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81449

New York Approved
Yes

Level of Service

Global

Turnaround Time

21 Days

References

1. Jain, A. et al. Cholangiocarcinoma With FGFR Genetic Aberrations: A Unique Clinical Phenotype. *JCO Precision Oncology* 2018:2, 1-12.
2. Kuznar, W. FGFR2 Emerges as a Promising Target in Cholangiocarcinoma. *Targeted Oncology*. 2019:8
3. Demols A et al. NTRK gene fusions in bilio-pancreatic cancers. *Journal of Clinical Oncology* 2020 38:15_suppl, e16664-e16664

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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 submandibullar 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

CK14 (Cytokeratin 14)

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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CK20

Alternative Name
Cytokeratin 20

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 4 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block:** Send paraffin block. Also send circled H&E slide for tech-only (required). Note: Not approved for p53 probe. Not approved for NYS samples.
- **Cut Slides:** H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only. Note: Not approved for p53 probe. Not approved for NYS samples.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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, CD79b, CD81 (8 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.

Specimen Requirements
- **Bone marrow aspirate:** 2-3 mL EDTA preferred. Sodium heparin is acceptable.
- **Peripheral blood:** 5-6 mL EDTA preferred. Sodium heparin is acceptable.
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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(x7). Add 88187(x1) for global.

New York Approved
Yes

Level of Service
Global

Turnaround Time

24 hours

References

1. Rawstron AC, Fazi A, Agathangelidis A, et al. A complementary role of multiparameter flow cytometry and high-throughput sequencing for MRD detection in CLL: an European Research Initiative on CLL study.*Leukemia*. 2016;30:929-936.
2. Rawstron AC, Bottcher S, Letestu R, et al. Improving efficiency and sensitivity: European Research Initiative in CLL (ERIC) update on the international harmonised approach for flow residual disease monitoring in CLL.*Leukemia*. 2013;27:142-149.

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Please direct any questions regarding coding to the payor being billed.

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 stand-alone testing is only available for tech-only. Markers are CD3, CD5, CD19, CD22, CD36, CD43, CD45, CD52, and CD200 (9 markers). This panel is not for detection of minimal residual disease.

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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

24 hours

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cMET

Alternative Name
MET

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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CMV ISH

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

CPT Code(s)*
88365 x 1

New York Approved
Yes

Level of Service
Global, Stain Only

Turnaround Time
Global: 3 days, Tech-Only (stain only): 48 hours

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Please direct any questions regarding coding to the payor being billed.

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 (>40%) 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Colloidal Iron

Alternative Name
Hale Colloidal Iron

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Colorectal Cancer Focus Panel (Germline)

Methodology
Molecular

Test Description
Testing is performed by Fulgent Genetics. Patient and physician or genetic counselor signatures on the Fulgent Genetics Informed Consent for Genetic Testing form are required. Testing will be put on hold until signatures are received. A complete test description, including list of genes tested, is available here.

Gene list: APC, AXIN2, BMPR1A, CDH1, CHEK2, EPCAM, GREM1, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SMAD4, STK11, TP53 (18 genes)

Specimen Requirements
- **Peripheral blood:** two x 4 mL EDTA tubes

CPT Code(s)*
81432x1, 81433x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
14-23 days

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Colorectal NGS Fusion Panel

Alternative Name
Colorectal Fusion Panel

Methodology
Molecular

Test Description
The Colorectal NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: AKAP9, ALK, BRAF, CCDC6, EML4, ERBB2, ETV6, FGFR2, FGFR3, FGFR4, GOPC, LMNA, MKRN1, NCOA4, NTRK1, NTRK2, NTRK3, RET, ROS1, SLC34A2, STRN, TPM3, and TRIM24.

Clinical Significance
The Colorectal NGS Fusion Panel is intended to detect gene fusions associated with colorectal cancer to aid in diagnosis, prognosis, and therapy selection.

In colorectal cancer (CRC), gene fusions could play both a prognostic role, conferring the aggressiveness of the disease, and a predictive one, identifying which patients more likely prone to refractoriness.

- NTRK gene fusions indicate dismal prognosis with median overall survival in metastatic setting. They likely account for primary resistance to EGFR targeted therapies. NTRK fusions are more common in patients with high microsatellite instability status and mismatch repair deficiency.
- ALK and ROS1 rearrangements are in the subgroup of poor prognosis metastatic CRC (mCRC). Crizotinib, lorlatinib, and entrectinib are approved drugs with known activity against recurrent mCRC gene fusions.
- RET arrangements, although rare for mCRC, seem to be associated with significantly shorter overall survival in older patients.
- FGFR fusions are rare, but patients who harbor these specific alterations can benefit from an already available targeted treatment, erdafitinib.

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*

81449

New York Approved

Yes

Level of Service

Global

Turnaround Time

21 Days

References

1. Pagani F, Randon G, Guarini V, et al. The Landscape of Actionable Gene Fusions in Colorectal Cancer.*Int J Mol Sci*. 2019;20(21):5319. Published 2019 Oct 25. doi:10.3390/ijms20215319

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Please direct any questions regarding coding to the payor being billed.

COMPASS® Hematopathology Services

Alternative Name
COMPASS® Bone Marrow Evaluation, COMPASS® Peripheral Blood Evaluation

Methodology
Cytogenetics

FISH

Flow Cytometry

Immunohistochemistry (IHC)

Molecular

Test Description
COMPASS® is a comprehensive diagnostic solution, guided by a board-certified hematopathologist that provides an accurate, actionable, and definitive diagnosis for complex hematologic malignancies.

Includes COMPASS® consultation report, clinical pathology evaluation, bone marrow morphology, flow cytometry, cytogenetics and/or fluorescent in situ hybridization (FISH), and molecular tests as medically necessary.

Note: If an NGS profile is medically necessary and FLT3 by PCR is added on to provide faster results for the purpose of prompt therapy selection in cases of new or suspected AML diagnosis, the additional FLT3 test will be a client-bill only test. Please contact Client Services for more info.

Clinical Significance
Hematologic malignancies consist of more than 100 different subtypes of leukemias and lymphomas. Frequently, blood cancers require a comprehensive laboratory work-up with multiple test modalities in order to generate a differential diagnosis and render a definitive diagnosis.

COMPASS is a selected and personalized lab work-up to provide diagnostic clarity and often prognostic or predictive information to help inform effective patient care management.

Specimen Requirements
- **Peripheral Blood Kit:**
  - (1) 6 mL in EDTA tube AND
  - (2) 6 mL sodium heparin tubes AND
  - (2) bedside smears
- **Bone Marrow Kit:**
  - (3) 4 mL sodium heparin tubes AND

    - (1) 6 mL Peripheral Blood and (1) 4 mL Bone Marrow Aspirate (or Core Biopsy and/or Aspirate Clot of >1.5 cm in 10% NBF) in EDTA tubes AND
    - (2) Peripheral Blood bedside smears AND
    - (6) Bone Marrow smears AND
    - (2) Bone Marrow core touch prep slides
- **Lymph Node:** Not Available
- **NY Clients:** Please provide Date and Time of Collection.

Storage & Transportation

Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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)*

Refer to individual tests for CPT Code(s)

New York Approved

Yes

Level of Service

Global

Turnaround Time

8-10 Days (14 Days if NGS testing is included)

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Please direct any questions regarding coding to the payor being billed.

COMPASS® Select Hematopathology Services

Alternative Name
COMPASS® Select Bone Marrow Evaluation, COMPASS® Select Peripheral Blood Evaluation

Methodology
Cytogenetics

FISH

Flow Cytometry

Immunohistochemistry (IHC)

Molecular

Test Description
COMPASS® Select is a diagnostic solution optimized for pathologists who perform morphologic evaluation locally. Existing morphologic results are seamlessly integrated into the comprehensive laboratory assessment with only further medically necessary tests performed to render a definitive diagnosis. Each case is guided by a board-certified hematopathologist evaluating all clinical and laboratory information provided to deliver a final and actionable diagnosis with a summary assessment for every unique patient.

Includes COMPASS® consultation report, clinical pathology evaluation, flow cytometry, cytogenetics and/or fluorescent in situ hybridization (FISH), and molecular tests as medically necessary.

Note: If an NGS profile is medically necessary and FLT3 by PCR is added on to provide faster results for the purpose of prompt therapy selection in cases of new or suspected AML diagnosis, the additional FLT3 test will be a client-bill only test. Please contact Client Services for more info.

Clinical Significance
Hematologic malignancies consist of more than 100 different subtypes of leukemias and lymphomas. Frequently, blood cancers require a comprehensive laboratory work-up with multiple test modalities in order to generate a differential diagnosis and render a definitive diagnosis.

COMPASS Select incorporates existing morphologic results in a selected and personalized lab work-up to provide diagnostic clarity and often prognostic or predictive information to help inform effective patient care management.

Specimen Requirements
- **Peripheral Blood Kit:**
  - (1) 6 mL in EDTA tube AND
  - (2) 6 mL sodium heparin tubes AND
  - (2) bedside smears

- **Bone Marrow Kit:**
  - (3) 4 mL sodium heparin tubes AND
  - (1) 6 mL Peripheral Blood and (1) 4 mL Bone Marrow Aspirate (or Core Biopsy and/or Aspirate Clot of >1.5 cm in 10% NBF) in EDTA tubes AND
  - (2) Peripheral Blood bedside smears
- **Lymph Node:** Not Available
- **NY Clients:** Please provide Date and Time of Collection.

Storage & Transportation

Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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)*

Refer to individual tests for CPT Code(s)

New York Approved

Yes

Level of Service

Global

Turnaround Time

8-10 Days (14 Days if NGS testing is included)

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Please direct any questions regarding coding to the payor being billed.

Congo Red

Methodology
Immunohistochemistry (IHC)

Test Description
Special stain. Amyloidosis is a rare disease characterized by the deposition of insoluble misfolded proteins in various tissues and organs. Congo red stain is the gold standard for the demonstration of amyloid in tissue sections. The amyloid fibril Congo red complex demonstrates “apple green” birefringence using polarized light microscopy. For cases with positive Congo red staining, immunohistochemical stains for amyloid A, amyloid P and immunoglobulin light chains are available for further evaluation of the amyloid subtype, if clinically indicated.

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 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.
- **NOTE:** Clients should perform manual evaluation of the glass slide with polarized light for complete evaluation. Scanning at NeoGenomics is done with routine light microscopy.

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

CPT Code(s)*
88313 x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Copper Stain

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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

CPT Code(s)*
81479

New York Approved
No

Level of Service
Global

Turnaround Time
10 days

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Please direct any questions regarding coding to the payor being billed.

CXCL13

Alternative Name
BLC, BCA-1

Methodology
Immunohistochemistry (IHC)

Test Description
CXCL13 is useful marker in the diagnosis of angioimmunoblastic T-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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 as part of the NeoTYPE® CLL Prognostic Profile. 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.

Note: Test in DNA-based, suitable for Freeze & Hold option.

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

CPT Code(s)*
81479

New York Approved
Yes

Level of Service
Global

Turnaround Time

10 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 (*PDGFRA*) 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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DUSP22-IRF4 Rearrangement

Alternative Name
IRF4 Rearrangement

Methodology
FISH

Test Description
Probes: DUSP22-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.

DUSP22 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.

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 & 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

New York Approved
Yes

Level of Service

Global, Technical

Turnaround Time

3-5 days

References

1. Pedersen MB, Hamilton Dutoit SJ, Bendix K, et al. DUSP22 and TP63 rearrangements predict outcome of ALK-negative anaplastic large cell lymphoma: a Danish cohort study. Blood. 2017; 130:554-557.
2. Parrilla Castellar ER, Jaffe ES, Said JS, et al. ALK-negative anaplastic large cell lymphoma is a genetically heterogeneous disease with widely disparate clinical outcomes. Blood. 2014; 124:1473-1480.
3. Wada DA, Law ME, Hsi ED, et al. Specificity of IRF4 translocations for primary cutaneous anaplastic large cell lymphoma: a multicenter study of 204 skin biopsies. Mod Pathol. 2011; 24:596-605.

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Early-stage NSCLC Panel

Alternative Name
eNSCLC Panel

Methodology
FISH

Immunohistochemistry (IHC)

Molecular

Test Description
The Early-stage NSCLC Panel analyzes 4 relevant and actionable biomarkers through a combination of multi-modality methods: EGFR (PCR), ALK (FISH), ROS1 (FISH), and PD-L1 22C3 (IHC). EGFR alterations are detected using PCR amplification and detection of target DNA using complementary primer pairs and oligonucleotide probes with fluorescent dyes. The EGFR PCR component of this panel has been designed to detect EGFR highly recurrent somatic mutations in exons 18, 19, 20, and 21 of EGFR in eight reactions (Exon 18 G719X; Exon 19 deletions; Exon 20 T790M, C797S, Exon 20-Ins and S768I; Exon 21 L858R, L861Q). Some less common EGFR mutations are not detectable in this test. For a full list of EGFR variants detectable in this assay, please contact NeoGenomics client services. Test may be ordered with an opt out of PD-L1 22C3 (IHC).

Clinical Significance
The Early-stage NSCLC Panel is intended as an aid in diagnostic evaluation, prognostication, and therapy selection of early stage non-small cell lung cancer. It is appropriate for all early-stage NSCLC patients.

- Implementation of immunotherapy before molecular assessment increases toxicity. Genomic testing alongside PD-L1 expression informs immunotherapy eligibility in NSCLC[1]
- FDA approved adjuvant osimertinib after tumor resection in NSCLC with EGFR exon 19 deletion or exon 20 L858R mutations. ADAURA clinical trial demonstrated 73% of patients in the overall early-stage NSCLC population on the osimertinib arm were alive and disease-free at 48 months (95% CI HR of 0.27) vs 38% of those in the placebo group.
- Fewer patients had disease recurrence with osimertinib (27%) vs. placebo (60%)[2]

Specimen Requirements
- FFPE Tissue, Paraffin block preferred. Alternatively, clients can send 1 H&E slide plus 10 unstained slides cut at 4-5 microns.
- Use positively-charged slides, 10% NBF fixative. Do not use zinc fixative.

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

CPT Code(s)*

81235x1, 88377x2, 88360x1

New York Approved

Yes

Level of Service

Global

Turnaround Time

7 days

References

1. Gainor JF, Shaw AT, Sequist LV, Fu X, Azzoli CG, Piotrowska Z, Huynh TG, Zhao L, Fulton L, Schultz KR, Howe E, Farago AF, Sullivan RJ, Stone JR, Digumarthy S, Moran T, Hata AN, Yagi Y, Yeap BY, Engelman JA, Mino-Kenudson M. EGFR Mutations and ALK Rearrangements Are Associated with Low Response Rates to PD-1 Pathway Blockade in Non-Small Cell Lung Cancer: A Retrospective Analysis. Clin Cancer Res. 2016 Sep 15;22(18):4585-93. doi: 10.1158/1078-0432.CCR-15-3101. Epub 2016 May 25. PMID: 27225694; PMCID: PMC5026567.2 Lee CK, Man J, Lord S, Links M, Gebski V, Mok T, et al.. Checkpoint Inhibitors in Metastatic EGFR-mutated Non-Small Cell Lung Cancer- a Meta-Analysis. J Thorac Oncol (2017) 12:403–7. 10.1016/j.jtho.2016.10.007 3 Lee CK, Man J, Lord S, Cooper W, Links M, Gebski V, et al.. Clinical and Molecular Characteristics Associated With Survival Among Patients Treated With Checkpoint Inhibitors for Advanced Non-Small Cell Lung Carcinoma: A Systematic Review and Meta-Analysis. JAMA Oncol (2018) 4:210–6. 10.1001/jamaoncol.2017.4427
2. Herbst RS, Wu YL, John T, Grohe C, Majem M, Wang J, Kato T, Goldman JW, Laktionov K, Kim SW, Yu CJ, Vu HV, Lu S, Lee KY, Mukhametshina G, Akewanlop C, de Marinis F, Bonanno L, Domine M, Shepherd FA, Urban D, Huang X, Bolanos A, Stachowiak M, Tsuboi M. Adjuvant Osimertinib for Resected EGFR-Mutated Stage IB-IIIA Non-Small-Cell Lung Cancer: Updated Results From the Phase III Randomized ADAURA Trial. J Clin Oncol. 2023 Apr 1;41(10):1830-1840. doi: 10.1200/JCO.22.02186. Epub 2023 Jan 31. Erratum in: J Clin Oncol. 2023 Apr 27;:JCO2300658. PMID: 36720083; PMCID: PMC10082285.

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

Global (head and neck only): 3 days, Tech-Only (stain only): 48 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

EGFR Mutation Analysis by PCR

Alternative Name
EGFR, epidermal growth factor receptor

Methodology
Molecular

Test Description
EGFR Mutation Analysis Assay is based on PCR amplification and detection of target DNA using complementary primer pairs and oligonucleotide probes labeled with fluorescent dyes. This assay is designed to detect highly recurrent EGFR alterations in exon 18-21 (Exon 18 G719X; Exon 19 deletions; Exon 20 T790M, C797S, Exon20-Ins and S768I; Exon 21 L858R, L861Q); some less common EGFR mutations are not detectable in this test. For a full list of EGFR variants detectable in this assay, please contact NeoGenomics client services.

Clinical Significance
Epidermal growth factor receptor (EGFR) is a transmembrane glycoprotein which can activate downstream RAS/RAF/MAPK pathway. Activating mutations in the EGFR gene have been identified in approximately 20% of non-small cell lung cancer (NSCLC). Most EGFR mutations occur in exons 18–21 and are predictive biomarkers for clinical response or resistance to certain EGFR tyrosine kinase inhibitors (TKIs). Identifying NSCLC patients with EGFR mutation is critical in determining patient eligibility for targeted TKI therapies.

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 & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

Elastic Stain

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Eosinophilia FISH Panel

Methodology
FISH

Test Description
Probes: PDGFRa, CHIC2, FIP1L1 (4q12) | PDGFRb (5q33) | FGFR1 (8p11) | CBFB (16q22) | 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. PDGFRA and PDGFRB 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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 4 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*

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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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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, ER? and ERß. 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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

ERCC1

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

ERG

Methodology
Immunohistochemistry (IHC)

Test Description
ERG oncoprotein 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Erythroid-Mega Add-On Flow Panel

Alternative Name
Erythroid-Megakaryocyte 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 stand-alone testing is only available for tech-only. Markers are cCD41, cCD61, CD13, CD34, CD45, CD71, CD117, and CD235a (8 markers).

Clinical Significance
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).

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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Ewing Sarcoma NGS Fusion Panel

Alternative Name
NGS Ewing Sarcoma 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 genes EWSR1 and ERG.

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 chondromsarcoma, 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 & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

21 days

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Please direct any questions regarding coding to the payor being billed.

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 pathognomic 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 theNGS 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 & 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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

Extract and Hold Service, Hematologic Disorders

Alternative Name
Extract & Hold

Methodology
Nucleic acid extraction

Test Description
DNA, RNA or TNA (total nucleic acid: DNA and RNA together) will be isolated from viable cells and frozen. Analysis is not performed until clients order Molecular Testing. Processed samples are retained for 28 days.

Charges will be waived when testing is ordered on held specimens or a fee will be billed to client if no testing is ordered. For more information, please contact Client Services at 866.776.5907, option 3.

This specimen hold service is best used when it is known which test(s) may be ordered on the specimen. If possible, please make note of potential tests when ordering this service.

Below are specific tests for each extraction type.

Extract & Hold DNA

B-Cell Gene Rearrangement
BRAF Mutation Analysis by PCR
BTK Inhibitor Acquired Resistance Panel
CEBPA Mutation Analysis
CSF3R Mutation Analysis
CXCR4 Mutation Analysis
FLT3 Mutation Analysis
IDH1/IDH2 Mutation Analysis by PCR
IgH Clonality by NGS
JAK2 V617F Mutation Analysis - Quantitative
KIT (c-KIT) Mutation Analysis
MPL Mutation Analysis
MYD88 Mutation Analysis
NOTCH1 Mutation Analysis
NPM1 MRD Analysis
NPM1 Mutation Analysis
NRAS Mutation Analysis
Rapid AML Therapeutic Panel
T-Cell Receptor Beta Gene Rearrangement
T-Cell Receptor Gamma Gene Rearrangement
TP53 Mutation Analysis

Extract & Hold RNA

ABL1 Kinase Domain Mutation Analysis
BCR-ABL1 Non-Standard p230

BCR-ABL1 Standard p210, p190
IgVH Mutation Analysis
inv(16), CBFB-MYH11 Translocation
JAK2 Exon 12-13 Mutation Analysis
JAK2 V617F Mutation Analysis - Qualitative
PML-RARA Translocation, t(15;17)
RUNX1-RUNX1T1 (AML1-ETO) Translocation, t(8;21)

Note: If considering the MPN JAK2 V617F with Sequential Reflex to JAK2 Exon 12-13, CALR, and MPL assay as an add-on to either JAK2 V617F Mutation Analysis - Qualitative or JAK2 Exon 12-13 Mutation Analysis, we recommend adding Extract & Hold - DNA with Extract & Hold - RNA order.

Extract & Hold DNA and RNA (please order both Extract & Hold DNA and Extract & Hold RNA)

CALR Mutation Analysis
MPN JAK2 V617F with Sequential Reflex to JAK2 Exon 12-13, CALR, and MPL

Extract & Hold TNA

Neo Comprehensive - Heme Cancers
Neo Comprehensive - Myeloid Disorders
NeoTYPE ALL Profile
NeoTYPE ALL Profile for New York
NeoTYPE Follicular Lymphoma Profile
NeoTYPE® AITL/Peripheral T-Cell Lymphoma Profile
NeoTYPE® AML Prognostic Profile
NeoTYPE® CLL Profile
NeoTYPE® Lymphoid Disorders Profile
NeoTYPE® Lymphoma Profile
NeoTYPE® MDS/CMML Profile

Clinical Significance

This specimen hold option is useful for reserving specimens for which molecular testing requiring DNA, RNA, or TNA may be necessary at a future date.

Specimen Requirements

- Specimen requirements vary by tests. Please visit individual test pages for detailed information.
- General requirements:
    - **Bone Marrow:** 2-3 mL in EDTA. Sodium heparin acceptable.
    - **Peripheral Blood:** 3-5 mL in EDTA. Sodium heparin acceptable.

Storage & Transportation

Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <7 days old preferred.

New York Approved

No

Notes

New York Approved: Varies by tests. Please visit individual test pages for detailed information.

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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FGFR2 Rearrangement

Methodology
FISH

Test Description
Probes: FGFR2 (10q26.13)
Disease(s): Cholangiocarcinoma (bile duct cancer) and various solid tumors

Clinical Significance
FGFR2 fusions are under active clinical study in a range of solid tumors, with targeted therapy already available to certain cholangiocarcinoma patients. FGFR2 fusions occur at highest frequency in intrahepatic cholangiocarcinoma (iCCA), observed in 10-16% of patients. This lab-developed test uses a break-apart FISH probe to detect the presence of FGFR2 fusions (translocations). Fusion partners of FGFR2 are not specifically identified.

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

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
3-5 days

References

1. Newsroom page, published April 20, 2020. Am J Managed Care website. https://www.ajmc.com/newsroom/-fda-approves-orphan-drug-pemigatinib-for-rare-bile-duct-cancer-cholangiocarcinoma. Accessed June 20, 2020

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Please direct any questions regarding coding to the payor being billed.

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 and Plasma Cell Myeloma Prognostic FISH Panel.

To learn more about FISH testing for IgH translocations in multiple myeloma, please visit Multiple Myeloma Cytogenetic Analysis resource page.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin or Cut Slides:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

Fite (Leprosy) Stain

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

CPT Code(s)*
88312x1

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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FLT3 Mutation Analysis

Alternative Name
FLT3, FLT3 TKD, FLT3 ITD

Methodology
Molecular

Test Description
Detection of internal tandem duplication and exon 20 tyrosine kinase domain (TKD) mutations using fragment-length analysis and PCR. Positive results identify presence of TKD mutations or report ITD results quantitatively as allelic ratio.

Clinical Significance
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.

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.

Note: Test is suitable for Freeze & Hold option.

Storage & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

5 days

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Please direct any questions regarding coding to the payor being billed.

FOLR1 (non-STP)

Alternative Name
FOLR1 IHC, Folate Receptor alpha (FR?), FOLR1 (FOLR1-2.1) RxDx Assay

Methodology
Immunohistochemistry (IHC)

Test Description
The VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is an FDA-approved qualitative immunohistochemical assay using a mouse monoclonal anti-FOLR1 antibody intended for use in the assessment of Folate Receptor alpha (FR?) protein in formalin-fixed, paraffin-embedded (FFPE) ovarian cancer tissue on a VENTANA BenchMark ULTRA instrument. FOLR1 is indicated as an aid in identifying patients with ovarian cancer (including epithelial ovarian cancer, primary peritoneal cancer or primary fallopian tube cancer) who may be eligible for targeted therapy treatment.

Note: This test should be used for patient specimens that have already utilized the FOLR1 Sponsored Testing Program, have multiple specimens to test, or want to use in off-indication specimens.

If interested in utilizing the Sponsered Testing Program, Please visit the FOLR1 Ovarian Cancer Testing Program page for more information and to download the Test Request Form.

Clinical Significance
The FR? protein is expressed in 90% of ovarian cancers and has limited expression in normal tissue, making it an attractive therapeutic target.

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.
- For evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

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

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Please direct any questions regarding coding to the payor being billed.

FOLR1 FDA (ELAHERE™) for Ovarian Carcinoma

Alternative Name
FOLR1 IHC CDx, Folate Receptor alpha (FR?), FOLR1 (FOLR1-2.1) RxDx Assay

Methodology
Immunohistochemistry (IHC)

Test Description
The VENTANA FOLR1 (FOLR1-2.1) RxDx Assay is an FDA-approved qualitative immunohistochemical assay using a mouse monoclonal anti-FOLR1 antibody intended for use in the assessment of Folate Receptor alpha (FR?) protein in formalin-fixed, paraffin-embedded (FFPE) ovarian cancer tissue on a VENTANA BenchMark ULTRA instrument. FOLR1 is indicated as an aid in identifying patients with ovarian cancer (including epithelial ovarian cancer, primary peritoneal cancer or primary fallopian tube cancer), whose tumors have FR? expression in ?75% tumor cells staining at 2+/3+ intensity, who are eligible for treatment with ELAHERE™ (mirvetuximab soravtansine-gynx).

This test is available through the ImmunoGen-sponsored FOLR1 testing program initiative called FR-ASSIST™. A separate test request form is required. Please visit the FOLR1 Ovarian Cancer Testing Program page for more information and to download the Test Request Form.

Clinical Significance
The FR? protein is expressed in 90% of ovarian cancers and has limited expression in normal tissue, making it an attractive therapeutic target. In using the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay for the evaluation of ovarian cancer patients, approximately 35% of patients are considered to have high expression of FR?—as defined by the scoring criteria mentioned above— and thus eligible for treatment with ELAHERE™.

Specimen Requirements
- Ovarian cancer (including epithelial ovarian cancer, primary peritoneal cancer and primary fallopian tube cancer) tissue is required.
- 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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
Inquire for Testing Program details.

New York Approved

Yes

Level of Service

Global

Turnaround Time

48 hours

References

1. VENTANA FOLR1 (FOLR1-2.1) RxDx Assay. Package insert. Roche; 2022.
2. ELAHERE. Package insert. ImmunoGen, Inc.; 2022.

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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FSH

Alternative Name
Follicle Stimulating Hormone

Methodology
Immunohistochemistry (IHC)

Test Description
Follicle Stimulating Hormone (FSH) is a pituitary hormone involved in the maturation of ovarian follicles and estrogen secretion in females. In the pituitary gland, FSH is produced by gonadotrophs. In males, FSH stimulates the secretion of testosterone. This antibody is used in the identification of FSH 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

Full Comprehensive Cancer Panel (Germline)

Methodology
Molecular

Test Description
Testing is performed by Fulgent Genetics. Patient and physician or genetic counselor signatures on the Fulgent Genetics Informed Consent for Genetic Testing form are required. Testing will be put on hold until signatures are received. A complete test description, including list of genes tested, is available here.

Gene list: AIP, ALK, APC, ATM, ATR, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, BUB1B, CASR, CDC73, CDH1, CDK4, CDKN1B, CDKN1C, CDKN2A, CEBPA, CHEK2, CTC1, CTNNA1, CYLD, DDB2, DICER1, DIS3L2, DKC1, EGLN1, EPCAM, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, EXT1, EXT2, EZH2, FAN1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FH, FLCN, GALNT12, GATA2, GPC3, GREM1, HOXB13, HRAS, KIF1B, KIT, LZTR1, MAX, MC1R, MEN1, MET, MITF, MLH1, MLH3, MRE11, MSH2, MSH6, MUTYH, NBN, NF1, NF2, NHP2, NOP10, NTHL1, PALB2, PDGFRA, PHOX2B, PMS2, POLD1, POLE, POLH, POT1, PRKAR1A, PRSS1, PTCH1, PTCH2, PTEN, RAD50, RAD51C, RAD51D, RB1, RECQL4, RET, RUNX1, SDHA, SDHAF2, SDHB, SDHC, SDHD, SLC45A2, SLX4, SMAD4, SMARCA4, SMARCB1, SMARCE1, STK11, SUFU, TERC, TERT, TINF2, TMEM127, TP53, TSC1, TSC2, TYR, VHL, WRAP53, WRN, WT1, XPA, XPC, XRCC2 (127 genes)

Specimen Requirements
- **Peripheral blood:** two x 4 mL EDTA tubes

CPT Code(s)*
81162x1, 81437x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
14-23 days

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Please direct any questions regarding coding to the payor being billed.

Full Focus Cancer Panel (Germline)

Methodology
Molecular

Test Description
Testing is performed by Fulgent Genetics. Patient and physician or genetic counselor signatures on the Fulgent Genetics Informed Consent for Genetic Testing form are required. Testing will be put on hold until signatures are received. A complete test description, including list of genes tested, is available here.

Gene list: APC, ATM, AXIN2, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, GREM1, HOXB13, MLH1, MRE11, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTEN, RAD50, RAD51C, RAD51D, SMAD4, STK11, TP53 (30 genes)

Specimen Requirements
- **Peripheral blood:** two x 4 mL EDTA tubes

CPT Code(s)*
81162x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
14-23 days

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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 (Galectin 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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GCDFP15

Alternative Name
Gross Cystic Disease Fluid Protein

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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.

Storage & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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, subependyomas, 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

GH

Alternative Name
Growth Hormone

Methodology
Immunohistochemistry (IHC)

Test Description
Growth Hormone (GH) is produced by the somatotroph cells in the pituitary. This marker is a useful in classification of pituitary tumors and the study of pituitary disease (acromegaly).

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Glutamine Synthetase

Alternative Name
GS

Methodology
Immunohistochemistry (IHC)

Test Description
Glutamine synthetase (GS) is strongly expressed in a majority of hepatocellular carcinoma, including cases of early HCC and low grade HCC.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

Gram Stain (Brown & Hopp modification)

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

CPT Code(s)*
88312x1

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88312x1

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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H3K27me3

Methodology
Immunohistochemistry (IHC)

Test Description
H3K27me3 (trimethylation at lysine 27 of histone H3) is involved in the modification of DNA by protein Histone H3. Complete loss of H3K27me3 expression by immunohistochemistry can be useful in the diagnosis of malignant peripheral nerve sheath tumors (MPNST).

Clone: C36B11
Staining pattern: Nuclear

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
- **Note:** Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 Hours

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Please direct any questions regarding coding to the payor being billed.

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 stand-alone testing is only available for tech-only. 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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 panel since the standard number of events is collected.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available

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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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

HER2 (Other)

Alternative Name
HER2 (human epidermal growth factor receptor 2), HER-2/neu

Methodology
Immunohistochemistry (IHC)

Test Description
HER2, a member of the epidermal growth factor receptor family, is a transmembrane protein with tyrosine kinase activity. Gene amplification and protein overexpression of HER2 have been found in a variety of tumors. 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 tissues. Staining is performed according to the package insert. Scoring is performed using the following:

- **HER2 (Other) with Breast scoring** uses the 2023 CAP/ASCO guidelines for breast cancer for HER2 evaluation. Breast scoring is recommended indications such as endometrium cancer, salivary duct carcinoma, serous carcinoma, ovarian cancer, and other clinical indications without consensus guidelines.
- **HER2 (Other) with Gastric scoring** uses the 2016 CAP/ASCP/ASCO consensus guidelines for gastric/gastroesophageal adenocarcinoma for HER2 evaluation.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

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

References

1. Bartley AN, Washington MK, Ventura CB, et al. HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline From the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi:10.5858/arpa.2016-0331-CP
2. Cancer Protocol Templates- Biomarker Reporting. College of American Pathologists. https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates. Accessed November 24, 2020.
3. Wolff AC, Hammond MEH, Allison KH, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2018;142(11):1364-1382. doi:10.5858/arpa.2018-0902-SA

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Please direct any questions regarding coding to the payor being billed.

HER2 (Other)

Alternative Name
HER2 neu

Methodology
FISH

Test Description
Probes: HER2 (17q11.2-q12) | Centromere 17 (Cen 17)
Disease(s): Endometrial cancer, salivary duct carcinoma, ovarian cancer, serous carcinomas, and other various tumor types

Clinical Significance
HER2, a member of the epidermal growth factor receptor family, is a transmembrane protein with tyrosine kinase activity. Gene amplification and protein overexpression of HER2 have been found in a variety of tumors. This test provides HER2 amplification status to aid in determining anti-HER2 targeted therapies for patients. Scoring is performed using the following:

- **HER2 (Other) with Breast scoring** uses the 2018 CAP/ASCO guidelines for breast cancer for HER2 evaluation. Breast scoring is recommended for indications such as endometrium cancer, salivary duct carcinoma, serous carcinoma, and ovarian cancer as well as other clinical indications without consensus guidelines.
- **HER2 (Other) with Gastric scoring** uses the 2016 CAP/ASCP/ASCO consensus guidelines for gastric/gastroesophageal adenocarcinoma for HER2 evaluation.

Specimen Requirements
- **Pathology Report:** For global HER2 FISH cases we require a copy of the HER2 IHC pathology report (if it is not available to us in NeoLINK™). For HER2 (Other) with Breast Scoring, the HER2 IHC slide may also be required for intrepation of results. Client Services will call your office or lab for missing IHC reports or to request slides.
- **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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

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

New York Approved

Yes

Level of Service

Global, Technical

Turnaround Time

3-5 Days

References

1. Bartley AN, Washington MK, Ventura CB, et al. HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline From the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi:10.5858/arpa.2016-0331-CP
2. Cancer Protocol Templates- Biomarker Reporting. College of American Pathologists. https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates. Accessed November 24, 2020.
3. Wolff AC, Hammond MEH, Allison KH, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2018;142(11):1364-1382. doi:10.5858/arpa.2018-0902-SA

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Please direct any questions regarding coding to the payor being billed.

HER2 Breast

Alternative Name
HER2, HER-2/neu, PATHWAY HER2 (4B5), anti-Her2

Methodology
Immunohistochemistry (IHC)

Test Description
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 2023 guidelines.

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.

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

CPT Code(s)*
88360x1; 88361x1

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time
3-5 days

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Please direct any questions regarding coding to the payor being billed.

HER2 Gastric/GEA

Alternative Name
HER2 neu

Methodology
FISH

Test Description
Probes: HER2 (17q11.2-q12) | Centromere 17 (Cen 17)
Disease(s): Gastric cancer, Gastroesophageal Adenocarcinoma, Gastroesophageal junction (GEJ) cancer

Clinical Significance
HER2, a member of the epidermal growth factor receptor family, is a transmembrane protein with tyrosine kinase activity. Gene amplification and protein overexpression of HER2 have been found in a variety of tumors. This test provides HER2 amplification status to aid in determining anti-HER2 targeted therapies for patients with gastric cancer. Scoring for HER2 is performed according to 2016 CAP/ASCP/ACSO consensus guidelines for gastric/gastroesophageal adenocarcinoma.

Specimen Requirements
- **Pathology Report:** For global HER2 FISH cases we require a copy of the HER2 IHC pathology report (if it is not available to us in NeoLINK™). 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:** 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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

References

1. Bartley AN, Washington MK, Ventura CB, et al. HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline From the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi:10.5858/arpa.2016-0331-CP

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Please direct any questions regarding coding to the payor being billed.

HER2 Gastric/GEA

Alternative Name
HER2 (human epidermal growth factor receptor 2), HER-2/neu

Methodology
Immunohistochemistry (IHC)

Test Description
HER2, a member of the epidermal growth factor receptor family, is a transmembrane protein with tyrosine kinase activity. Gene amplification and protein overexpression of HER2 have been found in a variety of tumors, including gastric/gastroesophageal adenocarcinoma. 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 gastric/gastroesophageal adenocarcinoma. Staining is performed according to the package insert. Scoring for HER2 is performed according to 2016 CAP/ASCP/ACSO consensus guidelines for gastric/gastroesophageal adenocarcinoma.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Global, Stain Only

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

References

1. Bartley AN, Washington MK, Ventura CB, et al. HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline From the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi:10.5858/arpa.2016-0331-CP

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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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. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide a recent CBC report. Bone marrow specimens are also not acceptable.
- **NY Clients:** Please provide Date and Time of Collection and recent transfusion history.

Storage & Transportation
Specimens should be received at NeoGenomics within 48 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

High-Grade B-Cell Lymphoma Reflex FISH Panel

Methodology
FISH

Test Description
Probes: MYC (8q24) | MYC/IgH/CEN8 t(8;14)

Reflex Scheme:

- Reflex to BCL2 (18q21) and BCL6 (3q27) if MYC/IgH/CEN8 t(8;14) is positive
  OR
- Reflex to BCL2 (18q21), BCL6 (3q27), IGK/MYC t(2;8), IGL/MYC t(8;22), and BCL6/MYC t(3;8) if MYC (8q24) is positive and MYC/IgH/CEN8 t(8;14) is negative

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. MYC/IgH/CEN8 will confirm heavy chain rearrangement when MYC is rearranged.

IGK/MYC t(2;8), IGL/MYC t(8;22) and BCL6/MYC t(3;8) studies are useful to further subclassify lymphomas that are positive for MYC gene rearrangements, but negative for the most common IGH/MYC translocation. In addition, when both MYC and BCL6 gene rearrangements are present, but no IGH/MYC translocation is identified, these studies may help to differentiate between the double-hit/triple-hit lymphomas (D/T-HL), which have a poor prognosis, and DLBCL with BCL6/IGH translocation, representing a subset of GC B-cell lymphomas distinct from conventional D/T-HL and with better prognosis (so-called "pseudo-double-hit lymphoma").

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.

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum *3 slides* labeled with specimen type.
    - NOTE: Technically 1 TP is required since MYC would initially be ordered and other probes only reflexed if MYC was positive
- **Fluids:** Equal parts RPMI to specimen volume

- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block:** Paraffin block acceptable.
- **Cut Slides:** H&E slide (required) plus 4 unstained slides cut at 4 microns.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation

Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*

88374x2 automated or 88377x2 manual without reflex; with reflex option 1, add 88374x2 automated or 88377x2 manual; with reflex option 2, add 88374x5 automated or 88377x5 manual

New York Approved

Yes

Level of Service

Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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) | BCL2 (18q21) | MYC/IgH/CEN8 t(8;14)

Optional Reflex: IGK/MYC t(2;8) | IGL/MYC t(8;22) | BCL6/MYC t(3;8), if MYC (8q24) is positive and MYC/IgH/CEN8 t(8;14) is negative

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. MYC rearranges with an immunoglobulin partner in approximately 60% of MYC-rearranged DLBCL/HGBCL of which 75% are MYC/IgH fusion. MYC/IgH/CEN8 will confirm heavy chain rearrangement when MYC is rearranged.

IGK/MYC t(2;8), IGL/MYC t(8;22) and BCL6/MYC t(3;8) studies are useful to further subclassify lymphomas that are positive for MYC gene rearrangements, but negative for the most common IGH/MYC translocation. In addition, when both MYC and BCL6 gene rearrangements are present, but no IGH/MYC translocation is identified, these studies may help to differentiate between the double-hit/triple-hit lymphomas (D/T-HL), which have a poor prognosis, and DLBCL with BCL6/IGH translocation, representing a subset of GC B-cell lymphomas distinct from conventional D/T-HL and with better prognosis (so-called "pseudo-double-hit lymphoma").

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum *3-5 slides* labeled with specimen type.
    - NOTE: 3 slides needed for base 3 probe panel, 1 slide needed if optional 14;18 added, 1 slide needed if optional 8;14 added
- **Fluids:** Equal parts RPMI to specimen volume
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.

- **Paraffin block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut slides:** H&E slide (required) plus 8 unstained slides cut at 4 microns. Circle H&E for tech-only.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation

Refrigerate fresh specimens. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*

88374x4 automated. If reflex is added, add 88374x3. Codes may differ if manual analysis is performed.

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for both unfixed and FFPE specimens

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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HPL

Alternative Name
Human Placental Lactogen

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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HPV DNA Tissue Testing

Alternative Name
HPV DNA, HPV genotyping (not for Pap), human papillomavirus, HPV Tissue Testing

Methodology
Molecular

Test Description
HPV DNA Tissue Testing is peformed 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.

Clinical Significance
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.

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

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

CPT Code(s)*
87624

New York Approved
No

Level of Service
Global

Turnaround Time

5 - 7 DAYS

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Please direct any questions regarding coding to the payor being billed.

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, 43, 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 & 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.

New York Approved

Yes

Level of Service

Global

Turnaround Time

5 days

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HSV I/II

Alternative Name
HSV1/2, 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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available

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Please direct any questions regarding coding to the payor being billed.

IDH1

Alternative Name
IDH1 R132H

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

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

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

IDH1/IDH2 Mutation Analysis by PCR

Alternative Name
IDH1 Mutation Analysis, IDH2 Mutation Analysis

Methodology
Molecular

Test Description
Detection of mutations at IDH1 codons R132X and R100Q and at IDH2 codons R140X and R172X is performed using real-time PCR. IDH1 and IDH2 are analyzed concurrently. For solid tumors, tumor enrichment is performed before extraction.

Clinical Significance
Mutations in the enzyme isocitrate dehydrogenase 1 (IDH1) and IDH2 genes have been identified in a variety of tumors including central nervous system gliomas, cholangiocarcinoma, acute myeloid leukemia, blast-phase myeloproliferative neoplasms (MPNs) and chronic-phase primary myelofibrosis (PMF). Per professional practice guidelines, testing for IDH mutations has diagnostic and prognostic implications in the workup of gliomas and guides therapy selection in AML. AML patients with IDH mutations may respond to venetoclax-based therapy or IDH inhibitors.

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.

Note: NOT validated for Freeze & Hold option.

Storage & 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

New York Approved
Yes

Level of Service

Global

Turnaround Time

5 days

References

1. Han S, Liu Y, Cai SJ, et al. IDH mutation in glioma: molecular mechanisms and potential therapeutic targets. Br J Cancer. 2020;122(11):1580-1589. PMID: 32291392.
2. DiNardo CD, Stein AS, Stein EM, et al. Mutant isocitrate dehydrogenase 1 inhibitor ivosidenib in combination with azacitidine for newly diagnosed acute myeloid leukemia. J Clin Oncol. 2021;39(1):57-65. PMID: 33119479.
3. Stein EM, DiNardo CD, Fathi AT, et al. Molecular remission and response patterns in patients with mutant-IDH2 acute myeloid leukemia treated with enasidenib. Blood. 2019 Feb 14;133(7):676-687. PMID: 30510081.

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Please direct any questions regarding coding to the payor being billed.

IgA

Alternative Name
Immunoglobulin A

Methodology
Immunohistochemistry (IHC)

Test Description
IgA antibody reacts with immunoglobulin Ig alpha chains. It is useful in identifying leukemias, plasmacytomas and B-cell lineage 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

IgD

Alternative Name
Immunoglobulin D

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

IgG

Alternative Name
Immunoglobulin G

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

IgH (14q32)

Alternative Name
Immunoglobulin heavy chain

Methodology
FISH

Test Description
Probes: IgH (14q32)
Disease(s): Lymphoma, NHL, multiple myeloma, MGUS

Clinical Significance
Available separately or as part of the following FISH panels: NHL, Plasma Cell Myeloma 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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for both unfixed and FFPE specimens

*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.

IgH Clonality by NGS

Methodology
Molecular

Test Description
The IgH Clonality 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.

Clinical Significance
The IgH Clonality 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 by NGS test is also useful for monitoring patients with B-cell lymphoma/leukemia due to its high sensitivity and its quantitative nature. Using this technology has been reported to be reliable in monitoring patients with diffuse large B-cell lymphoma (DLBCL) and acute lymphoblastic lymphoma (ALL).

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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Note: Test in DNA-based, suitable for Freeze & Hold option.

Storage & 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

New York Approved
No

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days for unfixed or FFPE specimens

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Please direct any questions regarding coding to the payor being billed.

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 and Plasma Cell Myeloma Prognostic FISH Panel.

To learn more about FISH testing for IgH translocations in multiple myeloma, please visit Multiple Myeloma Cytogenetic Analysis resource page.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin or Cut Slides:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 mye
Disease(s): Myeloma, MGUSloma 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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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IGK/MYC t(2;8) Translocation

Alternative Name
IGK/MYC Translocation

Methodology
FISH

Test Description
Probes: IGK/MYC t(2;8)
Disease(s): B-cell lymphoma, double-hit lymphoma, triple-hit lymphoma

Clinical Significance
IGK/MYC translocation is observed recurrently in B-cell lymphomas, and when occurred concurrently with BCL2 and/or BCL6 rearrangement, is classified as double-hit/triple-hit lymphomas having a very poor prognosis.

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
- **Bone Marrow/Peripheral Blood Smear or Fresh Tissue Preparation Slides:** minimum 1 slide labeled with specimen type.
- **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 & 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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

IGL/MYC t(8;22) Translocation

Alternative Name
IGL/MYC Translocation

Methodology
FISH

Test Description
Probes: IGL/MYC t(8;22)
Disease(s): B-cell lymphoma, double-hit lymphoma, triple-hit lymphoma

Clinical Significance
IGL/MYC translocation is observed recurrently in B-cell lymphomas, and when occurred concurrently with BCL2 and/or BCL6 rearrangement, is classified as double-hit/triple-hit lymphomas having a very poor prognosis.

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
- **Bone Marrow/Peripheral Blood Smear or Fresh Tissue Preparation Slides:** minimum 1 slide labeled with specimen type.
- **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 & 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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

IgM

Alternative Name
Immunoglobulin M

Methodology
Immunohistochemistry (IHC)

Test Description
IgM antibody reacts with immunoglobulin Ig mu chains. This antibody is useful when identifying leukemias, plasmacytomas and B-cell lineage 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 (>2% 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 (Preferred); Sodium Heparin (Acceptable).
- **Bone marrow:** 2 mL in EDTA tube (Preferred); Sodium Heparin (Acceptable).

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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 <14 days old preferred.

CPT Code(s)*
81263

New York Approved
Yes

Level of Service
Global

Turnaround Time
10 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

INI1

Alternative Name
hSNF5, SMARCB1, BAF47

Methodology
Immunohistochemistry (IHC)

Test Description
Lack of nuclear expression of INI1 is characteristic of malignant rhabdoid tumors and epithelioid sarcomas.

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.

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only, Technical

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

INSM1

Alternative Name
Insulinoma-associated protein 1

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 10,000 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.

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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

New York Approved
No

Level of Service
Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

InVisionFirst®-Lung Liquid Biopsy

Methodology
Molecular

Test Description
The InVisionFirst®-Lung liquid biopsy test is a 37-gene next-generation sequencing assay performed on cell-free circulating tumor DNA in peripheral blood to detect oncogenic driver mutations and therapy targets in non-small cell lung cancer (NSCLC). This assay demonstrated 98% concordance with tissue in clinical validation. Testing is performed by Inivata.

- SNVs + indel hotspots: ALK, AKT1, BRAF, CCND1, CTNNB1, EGFR, ERBB2, ESR1, FGFR2, FGFR3, GATA3, GNA11, GNAQ, GNAS, HRAS, IDH1, IDH2, KRAS, KIT, MAP2K1, MET, MYC, NFE2L2, NRAS, NTRK1, NTRK3, PDGFRA, PIK3CA, PPP2R1A, ROS1, U2AF1
- SNVs + indel exon coverage: PTEN (70%), CDKN2A, STK11, TP53 (88-100%)
- Fusions: ALK, NTRK1, RET, ROS1
- CNV: EGFR, ERBB2, FGFR1, MET including exon 14 deletion

Clinical Significance
InVisionFirst®-Lung Liquid Biopsy enables discovery of actionable mutations in patients with advanced NSCLC at diagnosis or progression when results are needed more quickly than they can be obtained from tissue testing, or tissue is insufficient, unavailable, or not practical to obtain. Biomarker coverage includes oncogenic drivers and prognostic markers as recommended by current guidelines and literature. Positive results are quantified and delivered in an easy-to-read report annotating clinical trial opportunities, therapies approved in advanced NSCLC and in other indications, and associations with therapy resistance. Tissue testing is recommended over liquid biopsy when possible.

Specimen Requirements
- **Peripheral blood:** two x 10 mL Streck Cell-Free DNA BCT® tubes

Storage & Transportation
Do not refrigerate. Request collection kits from Client Services and see collection and shipping instructions here (also included in kit).

CPT Code(s)*
0388U

Medicare MolDX CPT Code(s)*
0388U (see NOTES for more info)

New York Approved
No

Level of Service

Global

Turnaround Time

7 days

Notes

Please review conditions for Medicare/Medicare Advantage coverage here. Advanced Beneficiary Notice (ABN) may be required.

References

1. Pritchett MA, Camidge DR, Patel M, et al. Prospective clinical validation of the InVisionFirst-Lung circulating tumor DNA assay for molecular profiling of patients with advanced non-squamous non-small cell lung cancer. *JCO Precis Oncol.* Published online April 25, 2019. DOI https://doi.org/10.1200/PO.18.00299.
2. Plagnol V, Woodhouse S, Howarth K, et al. Analytical validation of a next generation sequencing liquid biopsy assay for high sensitivity broad molecular profiling. *PLoS One*. Published online March 15, 2018. https://doi.org/10.1371/journal.pone.0193802

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Please direct any questions regarding coding to the payor being billed.

Iron

Alternative Name
Prussian Blue Iron, Ferric Iron

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

JAK2 (9p24.1)

Methodology
FISH

Test Description
Probe(s): JAK2 (9p24.1)
Disease(s): Eosinophilia
Also available as part of ALL FISH Panel (Ph-Like)

Clinical Significance
JAK2 (9p24.1) break-apart test by FISH is useful for detecting JAK2 rearrangements in eosinophilia workup. Eosinophilia is a common feature of the diseases that are recognized by the World Health Organization (WHO) category, “Myeloid/lymphoid neoplasms with eosinophilia and rearrangement of PDGFRA, PDGFRB, or FGFR1, or with PCM1-JAK2.”

For analysis of JAK2 mutations for suspected myeloproliferative neoplasms (MPN), consider JAK2 V617F Mutation Analysis with or without reflex to JAK2 Exon 12-14 Mutation Analysis by molecular.

Specimen Requirements
- **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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not Available
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x1 automated or 88377x1 if manual analysis is performed.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

5 Days

*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.

JAK2 Exon 12-13 Mutation Analysis

Alternative Name
JAK2 Mutation Analysis

Methodology
Molecular

Test Description
RT-PCR and bi-directional sequencing to detect mutations in exons 12-13, 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 12-13 Mutation Analysis may be ordered separately, with concurrent V617F testing, by reflex after negative V617F testing, or as part of the MPN JAK2 V617F with Sequential Reflex to JAK2 Exon 12-13, CALR, and MPL. Testing is approved for specimens from the state of New York.

Clinical Significance
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.

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

Note: Test in RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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 <7 days old preferred.

CPT Code(s)*
81279 (as of 01/01/2021); Prior to CPT Code was 81403

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

Medical Necessity Resource

Medical Necessity for NeoTYPE Myeloid Profiles

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Please direct any questions regarding coding to the payor being billed.

JAK2 V617F Mutation Analysis - Qualitative

Alternative Name
JAK2 Mutation Analysis

Methodology
Molecular

Test Description
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 12-13 sequencing, with reflex to exon 12-13 sequencing, or as part of the MPN JAK2 V617F with Sequential Reflex to JAK2 Exon 12-13, CALR, and MPL. Testing is approved for specimens from the state of New York.

Clinical Significance
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).

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

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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 <7 days old preferred.

CPT Code(s)*
81270

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

Medical Necessity Resource

Medical Necessity for NeoTYPE Myeloid Profiles

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Please direct any questions regarding coding to the payor being billed.

JAK2 V617F Mutation Analysis - Quantitative

Alternative Name
JAK2 V617F Quantitative Analysis

Methodology
Molecular

Test Description
Quantitative detection of the V617F mutation, which is commonly found in myeloproliferative neoplasms (MPN). DNA is isolated and subjected to allele-specific polymerase chain reaction (PCR) amplification. Test report includes a bar graph to trend the mutational load.

Clinical Significance
The JAK2 V617F mutation is present in approximately 90% of polycythemia vera (PV) cases and approximately half of primary myelofibrosis (PMF) or essential thrombocythemia (ET). Quantitation of V617F is useful for monitoring MPN patients' response to clinical treatment as V617F mutational load correlates with disease course, therefore can be used as a predictive marker.

Specimen Requirements
- **Bone Marrow Aspirate:** 2-3 mL in EDTA tube (Preferred); Heparin (Acceptable)
- **Peripheral Blood:** 3-5 mL in EDTA tube (Preferred); Heparin (Acceptable)

Note: Test in DNA-based, suitable for Freeze & Hold option.

Storage & 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 (x1)

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 Days

*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.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time

48 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Ki-67

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. For neuroendocrine/carcinoid cancer, please use Ki-67 NET. For all other tumor types, please use Tech-Only (stain only) Ki-67.

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 & 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)

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

Ki67 NET

Methodology
Immunohistochemistry (IHC)

Test Description
Ki67 is a nuclear protein expressed in proliferating cells. Ki67 is expressed in all phases of the cell cycle except for G0. In neuroendocrine tumors (NET), Ki67 is useful in grading well- differentiated neuroendocrine tumors.

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

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

New York Approved
Yes

Level of Service
Global, Stain Only

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

References

1. Jernman J, Välimäki MJ, Louhimo J, Haglund C, Arola J. The novel WHO 2010 classification for gastrointestinal neuroendocrine tumours correlates well with the metastatic potential of rectal neuroendocrine tumours. Neuroendocrinology. 2012;95(4):317-324. doi:10.1159/000333035
2. Yamaguchi T, Fujimori T, Tomita S, et al. Clinical validation of the gastrointestinal NET grading system: Ki67 index criteria of the WHO 2010 classification is appropriate to predict metastasis or recurrence. Diagn Pathol. 2013;8:65. Published 2013 Apr 22. doi:10.1186/1746-1596-8-65

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Please direct any questions regarding coding to the payor being billed.

KIT (c-KIT) Mutation Analysis

Alternative Name
c-KIT Mutation Analysis

Methodology
Molecular

Test Description
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.

Clinical Significance
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.

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.

Note: Test in DNA-based, suitable for Freeze & Hold option.

Storage & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

KMT2A (MLL) (11q23)

Alternative Name
Mixed-lineage leukemia

Methodology
FISH

Test Description
Probes: KMT2A (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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin or Cut Slides:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

KRAS Mutation Analysis

Alternative Name
KRAS Gene Sequencing, KRAS Exons 2-4 (includes G12C mutation)

Methodology
Molecular

Test Description
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 is available separately or in combination with BRAF, HRAS and NRAS in the RAS/RAF Panel.

KRAS testing in non-small cell lung cancer may provide prognostic information, predict poor response to EGFR tyrosine kinase inhibitors, and inform on possible response to targeted therapy such as sotorasib. Please see alsoKRAS (G12C) Mutation Analysis for NSCLC, part of a sponsored testing program for stage IV NSCLC patients.

Clinical Significance
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.

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):** FFPE cell blocks are acceptable. Requisition must note specimen is FNA. Fresh cells and smears are not acceptable.

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

CPT Code(s)*
81275, 81276

Medicare MolDX CPT Code(s)*
81479

New York Approved
Yes

Level of Service

Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88365x1 or 88364x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
48 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 4 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut Slide:** H&E slide (required) plus 8 unstained slides cut at 4 microns for panel. Circle H&E for tech-only.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for both unfixed and FFPE specimens

*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.

Lung NGS Fusion Panel (Complete or Limited)

Alternative Name
Lung NGS Fusion Profile, Lung Complete NGS Fusion Panel, Lung Limited NGS Fusion Panel

Methodology
Molecular

Test Description
The Lung NGS Fusion Panel (Complete or Limited) is an RNA-based next-generation sequencing panel that detects translocations and fusions of the genes ALK, MET including MET Exon 14 skipping, NTRK1, NTRK2, NTRK3, NRG1, RET and ROS1 with known and novel fusion partners. 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.

Lung Complete NGS Fusion Panel includes all genes listed above. Clients can opt out of ALK and ROS1 testing to receive the Lung Limited NGS Fusion Panel report.

This test may be used to select patients for the following FDA-approved therapies:

- ALK- ALECENSA® (alectinib), XALKORI® (crizotinib), ZYKADIA™ (ceritinib), ALUNBRIG® (brigatinib), LORBRENA® (lorlatinib)
- MET Exon 14- TABRECTA™ (capmatinib)
- NTRK- ROZLYTREK® (entrectinib), VITRAKVI® (larotrectinib)
- RET- GAVRETO™ (pralsetinib), RETEVMO™ (selpercatinib)
- ROS- XALKORI® (crizotinib), ROZLYTREK® (entrectinib)

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

CPT Code(s)*

81449

Medicare MolDX CPT Code(s)*

81449

New York Approved

Yes

Level of Service

Global

Turnaround Time

21 days

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Please direct any questions regarding coding to the payor being billed.

Lymphoma Consult

Methodology

FISH

Flow Cytometry

Immunohistochemistry (IHC)

Molecular

Morphologic Evaluation

Test Description

Lymphoma diagnoses may be challenging and often require expertise to manage the diagnostic complexities. Lymphoma Consult is a diagnostic solution managed by experienced, board-certified pathologists to direct evaluation and order medically necessary multi-modal testing to provide accurate diagnosis and prognosis.

Lymphoma Consult includes morphology, flow cytometry, and/or fluorescent in situ hybridization (FISH), and molecular tests as medically necessary. Results of ancillary testing are integrated within the morphology report either upfront or in an addendum.

Clinical Significance

There are more than 90 subtypes of nodal and extranodal lymphomas. Frequently, lymphoma diagnosis requires a comprehensive laboratory work-up with multiple test modalities in order to render a definitive diagnosis.

Lymphoma Consult is a selected and personalized lab work-up to provide diagnostic clarity and often prognostic or predictive information to help inform effective patient care management.

Specimen Requirements

- **Tissue/Lymph Node**
  - Fresh lymph node or needle core tissue biopsy in RPMI: 0.5-1 cm3 is recommended (minimum 0.5 cm3). To improve viability, tissues larger than 0.5 cm3 should be cut into smaller pieces and intact lymph nodes should be at least bisected. Collect under sterile conditions, as if for microbiologic culture.
  - Formalin-fixed, paraffin-embedded (FFPE) tissue block or tissue in 10% NBF
- **Note:** Fresh tissue, before submitting to Neo, must be split to RPMI (for flow studies) and 10% NBF (for morphology)
- **NY Clients:** Please provide Date and Time of Collection
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation

Specimens should be received at NeoGenomics within 48 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*

Refer to individual tests for CPT Code(s)

New York Approved

Yes

Level of Service

Global

Turnaround Time

2-5 Days

*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.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

MALT1 (18q21)

Alternative Name
MALT1

Methodology
FISH

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for unfixed or FFPE specimens

*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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88313 x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 stand-alone testing is only available for tech-only. 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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 8 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin block or cut slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x8 automated. Codes may differ if manual analysis is performed.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 4 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Melan A/Ki67

Methodology
Immunohistochemistry (IHC)

Test Description
A combination of Melan A/Ki67 is useful in the identification of proliferative index in melanocytic neoplasms. Melan A is a differentiation antigen that is expressed in melanomas, Ki67 is expressed in proliferating cells during late G1, S, M and G2 phases of the cell cycle.

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

CPT Code(s)*
88344x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Melanoma Micromets

Alternative Name
Melanoma micrometastases

Methodology
Immunohistochemistry (IHC)

Test Description
Melanoma micrometastases (micromets) consist of small groups of melanoma cancer cells, originating from the original tumor site, that have spread through the lymphovascular system to another part of the body. The presence of metastasis in sentinel lymph nodes (SLN) may be the first indicator that cutaneous melanoma has spread to other sites in the body and helps to guide physicians in the diagnosis, prognosis, and therapy of their patients. In patients with clinical stage I/II melanoma, SLN status is the strongest predictor of survival.

Histologic evaluation of lymph nodes using a microscope is the most accurate way to assess for lymph node metastasis, since a significant number of patients have clinically negative lymph nodes. Histologic evaluation for melanoma involves sectioning of the tissue block at three different levels and staining each level with H&E and one of the levels with HMB45 and Melan A immunohistochemical (IHC) stains. HMB45 is a protein that facilitates maturation of stage I pre-melanosomes to stage II and is expressed in the majority of malignant melanomas as well as in tumors with melanocytic differentiation. Melan A is a lineage specific marker that recognizes a cytoplasmic protein involved in formation of stage II melanosomes and aids in diagnosis of metastatic melanoma. Malignant melanoma may be negative for at least one lineage-specific marker, so using a combination of markers, such as HMB45 and Melan A, is helpful for melanoma micromet detection. Correlation of the IHC and H&E slides is recommended and comparison with the cytomorphology of the primary tumor may be helpful in difficult cases.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is the preferred specimen type
- Block identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

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

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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time

Tech Only (Stain Only): 24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

MET Exon 14 Deletion Analysis

Alternative Name
MET Exon 14 Skipping

Methodology
Molecular

Test Description
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.

Clinical Significance
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.

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 & 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

New York Approved
No

Level of Service
Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 temozolomide 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. A minimum of 40% tumor is required. If the tumor cannot be enriched to at least 40%, then testing will not be performed.

Storage & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

10 days

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Please direct any questions regarding coding to the payor being billed.

Microsatellite Instability (MSI) by PCR

Alternative Name
Microsatellite Instability 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). Testing requires paired normal tissue or blood analysis and at least 20% tumor content in tumor samples submitted (after macro-dissection).

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 & Transportation
Use cold pack for transporting block, making sure cold pack is not in direct contact with specimen. Slides can be packed at room temperature.

CPT Code(s)*
81301x1

New York Approved

Yes

Level of Service

Global

Turnaround Time

7 days

*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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

MLH1 Promoter Methylation Analysis

Alternative Name
MLH1 Methylation

Methodology
Molecular

Test Description
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.

Clinical Significance
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.

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

CPT Code(s)*
81288

New York Approved
Yes

Level of Service
Global

Turnaround Time
10 days

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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
  or
- 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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Molar Pregnancy Comprehensive Consultation

Alternative Name
CEN1/CEN11 and p57

Methodology
FISH

Immunohistochemistry (IHC)

Morphologic Evaluation

Test Description
Probes: Centromere 1 (1p11.1-q11.1) | Centromere 11 (11q12)
Antibody Marker: p57
Disease(s): Complete molar pregnancy vs. partial mole vs. abortus with hydropic changes

This test is available on a consult basis only.

Clinical Significance
Evaluation of products of conception to distinguish hydropic abortuses from complete or partial hydatidiform mole can be challenging. Molar Pregnancy Comprehensive Consultation offers a diagnostic solution where experienced, board-certified pathologists integrate the results of morphologic evaluation, p57 immunohistochemistry and Ploidy FISH for Molar Pregnancy to arrive at a final diagnosis.

Hydatiform moles (HM) are categorized as complete and partial and are usually considered the noninvasive form of gestational trophoblastic disease (GTD). While HM are typically deemed benign, they are premalignant and do have the potential to become malignant and invasive. Complete moles occur more frequently than partial moles and carry a higher risk of distant metastasis or choriocarcinoma. However, all molar pregnancies have the potential for persistent gestational trophoblastic neoplasia (GTN).

Ploidy FISH for Molar Pregnancy analyzes copy number of the chromosome 1 centromere and chromosome 11 centromere to assess triploidy vs. diploidy DNA content. Partial hydatidiform mole (PHM) shows triploid DNA content, complete hydatidiform mole (CHM) show predominately diploid DNA content, and normal non-molar placenta (NMP) can show diploid, triploid, or even tetraploid DNA content. Since morphologic features of hydatidiform moles (HMs) and hydropic abortus (HA) can often overlap, there is need for ancillary studies to help distinguish between the possibilities. The marker p57 is strongly paternally imprinted, being expressed from the maternal allele in most cases. Thus CHM, which contains paternal genes, shows absent or significantly reduced expression, serving as a reliable marker in addition to DNA ploidy testing for diagnosis.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
- FISH: One (1) unbaked, unstained slide for H&E staining (required) and four (4) positively charged unstained slides (all cut at 4-5 microns). IHC: One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) 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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88323x1, 88342x1, 88377x1

New York Approved
Yes

Level of Service
Global

Turnaround Time
5 Days

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Morphology for Blood and/or Bone Marrow

Methodology
Cytochemistry

Immunohistochemistry (IHC)

Test Description
Preparation of blood smears and/or bone marrow core/clot for staining, morphological identification, and enumeration of hematopoietic cells.

Specimen Requirements
- **Blood**
  - **Slides:** Two (2) bedside smears or 1 mL of peripheral blood in EDTA (purple-top) tube.
- **Bone Marrow**
  - **Bone marrow aspirate:** Four (4) to eight (8) bedside smears or 1 mL in EDTA (purple-top) tube.
  - **Bone marrow core:** > 1.0 cm (length) in 10% NBF fixative. Place vial in separate bag.
  - **Bone marrow clot:** > 1.0 cm (length) in 10% NBF fixative. Place vial in separate bag.

Storage & Transportation
Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen. DO NOT FREEZE.

CPT Code(s)*
Blood: 85060x1; Bone Marrow: 85097x1, 88305xN, 88311xN, 883112xN, 88313xN, 88341xN, 88342xN (see NOTES for more info)

New York Approved
Yes

Level of Service
Global

Turnaround Time
4 Days

Notes
85097 (x1) if bone marrow aspirate is evaluated and reported
88305 (xN) number of uniquely identified bone marrow biopsy specimens evaluated and reported (e.g., core and clot sections)
88311 (xN) number of uniquely identified bone marrow biopsies decalcified

88312 (xN) number of special stains, microorganisms, evaluated and reported
88313 (xN) number of special stains evaluated and reported per uniquely identified biopsy specimen
88341 (xN) number of immunohistochemical stains evaluated after initial stain
88342 (xN) Initial immunohistochemical single stain per uniquely identified biopsy specimen (e.g., core and clot sections)
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MPL Mutation Analysis

Alternative Name
Myeloproliferative Leukemia

Methodology
Molecular

Test Description
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.

Clinical Significance
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.

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

Note: Test in DNA-based, suitable for Freeze & Hold option.

Storage & 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)*
81339 (as of 01/01/2021); Prior to CPT Code was 81402

New York Approved
Yes

Level of Service
Global

Turnaround Time

10 days

Medical Necessity Resource

Medical Necessity for NeoTYPE Myeloid Profiles

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Please direct any questions regarding coding to the payor being billed.

MPN FISH Panel

Alternative Name
Myeloprofilerative 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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 4 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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MPN JAK2 V617F with Sequential Reflex to JAK2 Exon 12-13, CALR, and MPL

Alternative Name
MPN Reflex Test

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, with the next step triggered by a negative result or a weakly positive result of uncertain clinical significance; no further testing is performed once an informative result is obtained. Testing is performed on plasma for increased sensitivity whenever possible. Tests may also be ordered individually (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.

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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, 81279, 81219, 81339 (as of 01/01/2021); Prior CPT Codes were 81270, 81403, 81219, 81402

New York Approved
Yes

Level of Service
Global

Turnaround Time

10 days

Medical Necessity Resource

Medical Necessity for NeoTYPE Myeloid Profiles

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MPO

Alternative Name
Myeloperoxidase by IHC

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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MSH2

Methodology
Immunohistochemistry (IHC)

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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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MSH6

Methodology
Immunohistochemistry (IHC)

Test Description
Mismatch repair (*MMR*) genes results 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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

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

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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MUC4

Methodology
Immunohistochemistry (IHC)

Test Description
MUC4 is useful in the identification of low-grade fibromyxoid sarcoma (LGFMS) and sclerosing epithelioid fibrosarcoma.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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MUC6

Methodology
Immunohistochemistry (IHC)

Test Description
MUC6 is expressed mucopeptic 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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

CPT Code(s)*
88313

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

MUM1

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

MYC (8q24)

Alternative Name
c-MYC

Methodology
FISH

Test Description
Probes: MYC (8q24)
Disease(s): Burkitt lymphoma, Lymphoma, NHL, B-ALL

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for unfixed or FFPE specimens

*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.

MYC Amplification for Angiosarcoma

Alternative Name
c-MYC Amplification

Methodology
FISH

Test Description
Probes: MYC (8q24) | Centromere 8
Disease(s): Angiosarcoma

Clinical Significance
MYC gene dysregulation is frequently observed across various cancer types. In angiosarcoma, assessing MYC [c-MYC] amplification status provides diagnostic and prognostic information to distinguish post-radiation angiosarcoma from other angiosarcomas and non-neoplastic vascular proliferations.

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.
- **Bone Marrow Aspirate:** N/A
- **Peripheral Blood:** N/A
- **Fresh, Unfixed Tissue:** N/A
- **Fluids:** N/A

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

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

New York Approved
No

Level of Service
Global, Technical

Turnaround Time
3-5 Days

*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.

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
The MYC/IgH rearrangement is common in Burkitt lymphoma and diffuse large B-cell lymphoma, associated with a more aggressive tumor phenotype and a lower survival rate. MYC/IgH/CEN8 can confirm heavy chain rearrangement when MYC is rearranged.

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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days for unfixed or FFPE specimens

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Please direct any questions regarding coding to the payor being billed.

MYCN (n-MYC) Amplification

Alternative Name
n-MYC

Methodology
FISH

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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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. Note: not suitable for Freeze & Hold option.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Note: Test in DNA-based, suitable for Freeze & Hold option, except for Fresh Tissue samples.

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

CPT Code(s)*
81305

New York Approved
Yes

Level of Service

Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

Myeloma MRD Flow Panel

Alternative Name
MM MRD Flow Panel, MM Minimal Residual Disease Panel

Methodology
Flow Cytometry

Test Description
Markers include VS38c, CD19, CD20, CD27, CD45, CD56, CD81, CD117, CD138, CD269(BCMA), cKappa, and cLambda(12 markers).

Clinical Significance
The Myeloma MRD Panel by Flow Cytometry evaluates for the presence of minimal residual disease (MRD) in patients with previously diagnosed and treated multiple myeloma. The limit of detection is 0.01%.

Specimen Requirements
- **Bone marrow aspirate:** 3-4 mL EDTA preferred. Sodium heparin tube is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **NY Clients:** Please provide Date and Time of Collection.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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, 88185x11. Add 88188x1 for global

New York Approved
Yes

Level of Service
Global

Turnaround Time
24-48 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Neo Comprehensive - Solid Tumor

Methodology

Molecular

Test Description

Neo Comprehensive™ - Solid Tumor is a broad, next-generation sequencing panel for pan-solid tumor indications. The assay detects single nucleotide variants (SNV), insertions/deletions (InDels), copy number variants (CNV), and RNA fusions and splice variants in a total of 517 genes (517 genes analyzed by DNA, 55 genes by RNA), plus microsatellite instability (MSI*) and tumor mutational burden (TMB).

DNA GENE LIST: DETECTION OF SNVs, INDELS AND CNVs

ABL1, ABL2, ACVR1, ACVR1B, AKT1, AKT2*, AKT3, ALK*, ALOX12B, ANKRD11, ANKRD26, APC, AR*, ARAF, ARFRP1, ARID1A, ARID1B, ARID2, ARID5B, ASXL1, ASXL2, ATM*, ATR, ATRX, AURKA, AURKB, AXIN1, AXIN2, AXL, B2M, BAP1, BARD1, BBC3, BCL10, BCL2, BCL2L1, BCL2L11, BCL2L2, BCL6, BCOR, BCORL1, BCR, BIRC3, BLM, BMPR1A, BRAF*, BRCA1*, BRCA2*, BRD4, BRIP1, BTG1, BTK, C11orf30, CALR, CARD11, CASP8, CBFB, CBL, CCND1*, CCND2, CCND3*, CCNE1*, CD274, CD276, CD74, CD79A, CD79B, CDC73, CDH1, CDK12, CDK4*, CDK6*, CDK8*, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CENPA, CHD2, CHD4, CHEK1*, CHEK2*, CIC, CREBBP, CRKL, CRLF2, CSF1R, CSF3R, CSNK1A1, CTCF, CTLA4, CTNNA1, CTNNB1, CUL3, CUX1, CXCR4, CYLD, DAXX, DCUN1D1, DDR2, DDX41, DHX15, DICER1, DIS3, DNAJB1, DNMT1, DNMT3A, DNMT3B, DOT1L, E2F3, EED, EGFL7, EGFR*, EIF1AX, EIF4A2, EIF4E, EML4, EP300, EPCAM, EPHA3, EPHA5, EPHA7, EPHB1, ERBB2*, ERBB3*, ERBB4, ERCC1*, ERCC2*, ERCC3, ERCC4, ERCC5, ERG, ERRFI1, ESR1*, ETS1, ETV1, ETV4, ETV5, ETV6, EWSR1, EZH2, FAM123B, FAM175A, FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FAS, FAT1, FBXW7, FGF1*, FGF10*, FGF14*, FGF19*, FGF2*, FGF23*, FGF3*, FGF4*, FGF5*, FGF6*, FGF7*, FGF8*, FGF9*, FGFR1*, FGFR2*, FGFR3*, FGFR4*, FH, FLCN, FLI1, FLT1, FLT3, FLT4, FOXA1, FOXL2, FOXO1, FOXP1, FRS2, FUBP1, FYN, GABRA6, GATA1, GATA2, GATA3, GATA4, GATA6, GEN1, GID4, GLI1, GNA11, GNA13, GNAQ, GNAS, GPR124, GPS2, GREM1, GRIN2A, GRM3, GSK3B, H3F3A, H3F3B, H3F3C, HGF, HIST1H1C, HIST1H2BD, HIST1H3A, HIST1H3B, HIST1H3C, HIST1H3D, HIST1H3E, HIST1H3F, HIST1H3G, HIST1H3H, HIST1H3I, HIST1H3J, HIST2H3A, HIST2H3C, HIST2H3D, HIST3H3, HNF1A, HNRNPK, HOXB13, HRAS, HSD3B1, HSP90AA1, ICOSLG, ID3, IDH1, IDH2, IFNGR1, IGF1, IGF1R, IGF2, IKBKE, IKZF1, IL10, IL7R, INHA, INHBA, INPP4A, INPP4B, INSR, IRF2, IRF4, IRS1, IRS2, JAK1, JAK2*, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIF5B, KIT*, KLF4, KLHL6, KRAS*, LAMP1*, LATS1, LATS2, LMO1, LRP1B, LYN, LZTR1, MAGI2, MALT1, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MAP3K13, MAP3K14, MAP3K4, MAPK1, MAPK3, MAX, MCL1, MDC1, MDM2*, MDM4*, MED12, MEF2B, MEN1, MET*, MGA, MITF, MLH1, MLL, MLLT3, MPL, MRE11A, MSH2, MSH3, MSH6, MST1, MST1R, MTOR, MUTYH, MYB, MYC*, MYCL1*, MYCN*, MYD88, MYOD1, NAB2, NBN, NCOA3, NCOR1, NEGR1, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NKX3-1, NOTCH1, NOTCH2, NOTCH3, NOTCH4, NPM1, NRAS*, NRG1*, NSD1, NTRK1, NTRK2, NTRK3, NUP93, NUTM1, PAK1, PAK3, PAK7, PALB2, PARK2, PARP1, PAX3, PAX5, PAX7, PAX8, PBRM1, PDCD1, PDCD1LG2, PDGFRA*, PDGFRB*, PDK1, PDPK1, PGR, PHF6, PHOX2B, PIK3C2B, PIK3C2G, PIK3C3, PIK3CA*, PIK3CB*, PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIK3R3, PIM1, PLCG2, PLK2, PMAIP1, PMS1, PMS2, PNRC1, POLD1, POLE, PPARG, PPM1D, PPP2R1A, PPP2R2A, PPP6C, PRDM1, PREX2, PRKAR1A, PRKCI, PRKDC, PRSS8, PTCH1, PTEN*, PTPN11, PTPRD, PTPRS, PTPRT, QKI, RAB35, RAC1, RAD21, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RAF1*, RANBP2, RARA, RASA1, RB1, RBM10, RECQL4, REL, RET*, RFWD2, RHEB, RHOA, RICTOR*, RIT1, RNF43, ROS1, RPS6KA4, RPS6KB1*, RPS6KB2, RPTOR, RUNX1, RUNX1T1, RYBP, SDHA, SDHAF2, SDHB, SDHC, SDHD, SETBP1, SETD2, SF3B1, SH2B3, SH2D1A, SHQ1, SLIT2, SLX4, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMARCD1, SMC1A, SMC3, SMO, SNCAIP, SOCS1, SOX10, SOX17, SOX2, SOX9, SPEN, SPOP, SPTA1, SRC, SRSF2, STAG1, STAG2, STAT3, STAT4, STAT5A, STAT5B, STK11, STK40, SUFU, SUZ12, SYK, TAF1, TBX3, TCEB1, TCF3, TCF7L2, TERC, TERT, TET1, TET2, TFE3, TFRC*, TGFBR1, TGFBR2, TMEM127, TMPRSS2, TNFAIP3, TNFRSF14, TOP1, TOP2A, TP53, TP63, TRAF2, TRAF7, TSC1, TSC2, TSHR, U2AF1, VEGFA, VHL, VTCN1,

WISP3, WT1, XIAP, XPO1, XRCC2, YAP1, YES1, ZBTB2, ZBTB7A, ZFHX3, ZNF217, ZNF703, ZRSR2
**** Denotes genes with CNV detection***

RNA GENE LIST: DETECTION OF FUSIONS AND SPLICE VARIANTS
ABL1, AKT3, ALK, AR**, AXL, BCL2, BRAF, BRCA1, BRCA2, CDK4, CSF1R, EGFR**, EML4, ERBB2, ERG, ESR1, ETS1, ETV1, ETV4, ETV5, EWSR1, FGFR1, FGFR2, FGFR3, FGFR4, FLI1, FLT1, FLT3, JAK2, KDR, KIF5B, KIT, MET**, MLL, MLLT3, MSH2, MYC, NOTCH1, NOTCH2, NOTCH3, NRG1, NTRK1, NTRK2, NTRK3, PAX3, PAX7, PDGFRA, PDGFRB, PIK3CA, PPARG, RAF1, RET, ROS1, RPS6KB1, TMPRSS2
***** Denotes genes with splice variants including AR-V7, EGFRvIII, and MET exon 14 skipping.***

IMMUNOTHERAPY MARKERS
MSI, TMB

MSI-high is defined as ?20% of loci showing instability; microsatellite-stable (MSS) is defined as <20% of loci showing instability.*

Tumor Mutational Burden (TMB):

- **TMB-high** is defined as **?10.0 mut/Mb** (mutations per megabase)
- **TMB-low** is defined as **<10.0 mut/Mb**

*Samples exhibiting instability in >= 20% of microsatellites are reported as MSI-High. Samples below the 20% threshold are reported as MSI-Stable, except for endometrial tumors, which are reported as MSI-indeterminate. Additional confirmation test can be ordered to evaluate MSI-indeterminate results.

Clinical Significance
Neo Comprehensive - Solid Tumor detects genomic alterations that are most relevant to diagnosis, therapy selection, prognosis, and clinical trial options in solid tumors. It Is appropriate for patients with newly diagnosed, recurrent, or resistant disease.

Specimen Requirements
A block is preferred for testing: ?20% tumor and ?10 mm² of tissue surface area for NGS (~500 tumor cells)
(if PD-L1 is ordered, at least 100 neoplastic cells are required)

If submitting 5 ?m unstained slides, the following number of slides are requested:

- Samples with ? 25 mm² of tissue: 10 unstained slides (2 sections per slide preferred)
- Samples with 10-24 mm² of tissue: 20 unstained slides (2 sections per slide preferred)

Please submit 1 additional unstained slide for H&E and 3 additional unstained slides if performing PD-L1 testing. Please use positively charged slides and 10% NBF fixative. Do not use zinc fixatives

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

CPT Code(s)*
81455x1. Add 88360x1 for PD-L1 IHC.

Medicare MolDX CPT Code(s)*
81479x1. If sample is insufficient to produce RNA fusion results but DNA SNV/indel and/or CNV results are reported, 81479x1 still applies. If only RNA fusion results are reported, use 81456x1 instead. Add 88360x1 for PD-L1 IHC.

New York Approved

No

Turnaround Time

8-10 days

*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.

Neo Comprehensive™ - Heme Cancers

Alternative Name

Neo Comprehensive Heme, Neo Comp Heme, Heme CGP

Methodology

Molecular

Test Description

The Neo Comprehensive™ - Heme Cancers assay analyzes 433 genes to detect DNA and RNA alterations through next-generation sequencing (NGS) as noted below. Test reports include a summary interpretation of all results together.

DNA Sequencing

- SNVs/InDels (302 genes): ABL1, ABL2, AKT1, AKT2, AKT3, ALK, ANKRD26, APC, ARAF, ARHGEF1, ARID1A, ARID1B, ARID2, ASXL1, ASXL2, ATG2B, ATM, ATP2A2, ATRX, AXL, B2M, BAP1, BCL2, BCL2L11, BCL6, BCOR, BCORL1, BCR, BIRC3, BLM, BRAF, BRCA1, BRCA2, BRINP3, BRIP1, BTK, C17orf97, CALR, CARD11, CBFB, CBL, CBLB, CBLC, CCND1, CCND2, CCND3, CD274, CD33, CD79A, CD79B, CDC25C, CDK2, CDK4, CDK6, CDKN1B, CDKN2A, CDKN2B, CEBPA, CHEK2, CIC, CIITA, CREBBP, CRLF2, CSF1R, CSF3R, CTC1, CTCF, CTNNB1, CUX1, CXCR4, CYLD, DAXX, DCK, DDX3X, DDX41, DIS3, DKC1, DNMT1, DNMT3A, EBF1, EED, EGFR, EGLN1, EGR1, ELANE, EP300, EPCAM, EPHA2, EPHA7, EPOR, ERBB2, ERBB3, ERCC4, ETNK1, ETV6, EZH2, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FAS, FAT1, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, FOXO1, FUBP1, G6PC3, GAB2, GATA1, GATA2, GATA3, GFI1, GNA12, GNA13, GNAI2, GNAQ, GNAS, GNB1, GSKIP, H1-4, HAX1, HIF1A, HNRNPK, HRAS, ID3, IDH1, IDH2, IGF1R, IKBKB, IKZF1, IKZF3, IL7R, IRAK4, IRF4, ITPKB, JAK1, JAK2, JAK3, KDM6A, KDR, KEAP1, KIT, KLF2, KLHL6, KMT2A, KMT2C, KMT2D, KRAS, LUC7L2, MALT1, MAP2K1, MAP3K1, MAP3K14, MAPK1, MCL1, MDM2, MDM4, MED12, MEF2B, MET, MLH1, MPL, MSH2, MSH6, MTOR, MYC, MYCN, MYD88, NBN, NCAPH, NF1, NFKBIE, NHP2, NOP10, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NSD1, NT5C2, NTRK1, NTRK2, NTRK3, NUP214, NUP98, P2RY8, PALB2, PAX5, PDCD1LG2, PDGFRA, PDGFRB, PHF6, PIGA, PIK3CA, PIK3CD, PIK3R1, PIM1, PLCG1, PLCG2, PML, PMS2, POT1, PPM1D, PRDM1, PRPF40B, PRPF6, PRPF8, PRPS1, PTCH1, PTEN, PTPN11, PTPRC, RAC1, RAD21, RAD51C, RAD51D, RB1, RBBP6, REL, RHEB, RHOA, RICTOR, RIPK1, RIT1, RPL11, RPL35A, RPL5, RPN1, RPS10, RPS15, RPS17, RPS26, RPS7, RTEL1, RUNX1, S1PR2, SAMD9, SAMD9L, SAMHD1, SBDS, SETBP1, SETD2, SF1, SF3A1, SF3B1, SGK1, SH2B3, SLX4, SMAD4, SMARCB1, SMC1A, SMC3, SMO, SOCS1, SPEN, SRP72, SRSF2, STAG2, STAT3, STAT5B, STAT6, STK11, SUZ12, TBL1XR1, TCF3, TENT5C, TERC, TERT, TET2, TET3, THPO, TINF2, TLR2, TNFAIP3, TNFRSF14, TP53, TP63, TRAF2, TRAF3, TSC1, TSC2, U2AF1, U2AF2, UBR5, VHL, WAS, WRAP53, WT1, XPO1, ZFHX4, ZMYM3, ZRSR2
- Copy Number Variants (CNV) (24 genes): ABL1, ASXL1, ATM, BRAF, CBL, CD274, CDKN1B, CDKN2A, DNMT1, EPOR, ETV6, EZH2, FLT3, IKZF1, JAK2, KMT2A, KRAS, MYC, PAX5, RAD21, REL, TNFRSF14, TP53, XPO1

RNA Sequencing

- Fusions (184 genes): ABI1, ABL1, ABL2, ACTN4, ADAMTS17, AFDN, AFF1, AFF3, AGGF1, ALK, ARHGAP26, ARHGEF12, ATF7IP, ATIC, ATP2A1, ATP5MG, BCL11B, BCL2, BCL6, BCR, BIN2, BIRC3, CALR, CAPRIN1, KNL1, CBFB, CBL, CCDC6, CCDC88C, CCND1, CCND2, CCND3, CDK6, CEP43, CEP85L, CHD1, CHIC2, CIITA, CNTRL, COL1A1, CPSF6, CREBBP, CRLF2, CSF1R, CXCR4, DEK, DTD1, DUSP22, EBF1, EIF4A1, ELL, EML1, EP300, EPOR, EPS15, ERC1, ERG, ERVK3, ETV6, FGFR1, FGFR1OP2, FIP1L1, FLT3, FNBP1, FOXO4, FOXP1, FRYL, FUS, GAS7, GIT2, GLIS2, GOLGA4, GPHN, HIP1, HLF, HNRNPA2B1, IKZF1, IKZF2, IKZF3, JAK2, KANK1, KAT6A,

KLF2, KMT2A, LAIR1, LMNA, LRRFIP1, MALT1, MAML2, MAP4, MECOM, MEF2D, MRTFA, MLF1, MLLT1, MLLT10, MLLT11, MLLT3, MLLT6, MYB, MYC, MYH11, MYO18A, MYO1F, NDE1, NF1, NFKB2, NIN, NOTCH1, NOTCH2, NPM1, NRIP1, NTRK1, NTRK2, NTRK3, NUP214, NUP98, P2RY8, PAG1, PAX5, PBX1, PCM1, PDCD1LG2, PDE4DIP, PDGFRA, PDGFRB, PICALM, PLAG1, PML, PRDM16, PRDM9, PRKG2, PTK2B, PVT1, RABEP1, RARA, RBM15, RBM6, RCSD1, ROS1, RPN1, RUNX1, RUNX1T1, SART3, SEMA6A, SEPTIN2, SEPTIN3, SEPTIN5, SEPTIN6, SEPTIN9, SET, SETD2, SNX2, SPECC1, SPTBN1, SQSTM1, SSBP2, STIL, SYNRG, TACC1, TAL1, TBL1XR1, TCF3, TERF2, TET1, TFG, TLX1, TLX3, TP53BP1, TP63, TPM3, TPR, TRIM24, TRIP11, TYK2, UBE2R2, WDR48, ZBTB16, ZCCHC7, ZEB2, ZMIZ1, ZMYM2, ZNF384, ZNF703

Note: FLT3 by PCR (via FLT3 Mutation Analysis) is available to be ordered, as Client-Bill only, in conjunction with the Neo Comprehensive - Heme Cancers. It is reported separately from the Neo Comprehensive profile for the purpose of prompt therapy selection in patients with a new diagnosis of AML.

Clinical Significance

The Neo Comprehensive - Heme Cancers profile is a DNA (302 genes) + RNA (184 genes) panel that detects known mutations, CNVs and RNA fusions associated with most forms of hematologic malignant disorders, such as acute myeloid leukemia (AML), myeloproliferative neoplasms (MPN), myelodysplastic syndromes (MDS), chronic myelogenous leukemia (CML), angioimmunoblastic T-cell lymphoma (AITL)/peripheral T-cell lymphoma (PTCL), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), T/NK-large granular lymphocytic leukemia, among others.

Testing using this panel can provide key diagnostic information, including critical molecular determinations affecting therapeutic approaches, can aid in risk stratification and predicting prognosis, and can also be used in clinical research.

Specimen Requirements

- **Bone Marrow Aspirate:** 2-3 mL in EDTA tube
- **Peripheral Blood:** 3-5 mL in EDTA tube
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 10-14 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.

Note: Test is NOT suitable for Freeze & Hold option

Storage & Transportation

Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <7 days old preferred.

Important! To ensure sample stability, ship samples directly to NeoGenomics Aliso Viejo.

CPT Code(s)*

81455

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 Days

*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.

Neo Comprehensive™ - Myeloid Disorders

Alternative Name

Comprehensive Myeloid Disorders, Myeloid CGP, Comprehensive Myeloid

Methodology

Molecular

Test Description

The Neo Comprehensive™ - Myeloid Disorders assay analyzes 164 genes to detect DNA and RNA alterations through next-generation sequencing (NGS) as noted below. Test reports include a summary interpretation of all results together.

DNA sequencing

- SNVs/Indels (126 genes): ABL1, ANKRD26, APC, ARAF, ASXL1, ATM, ATRX, BCOR, BCORL1, BLM, BRAF, BRCA1, BRCA2, BRIP1, CALR, CBL, CBLB, CBLC, CDKN2A, CEBPA, CHEK2, CSF3R, CTC1, CUX1, CXCR4, DDX41, DKC1, DNMT3A, ELANE, EPCAM, ERCC4, ETNK1, ETV6, EZH2, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FBXW7, FLT3, G6PC3, GATA1, GATA2, GFI1, GNAS, GNB1, HAX1, HRAS, IDH1, IDH2, IKZF1, IKZF3, ITPKB, JAK2, JAK3, KDM6A, KIT, KMT2A, KRAS, MAP2K1, MET, MLH1, MPL, MSH2, MSH6, MYD88, NF1, NHP2, NOP10, NOTCH1, NPM1, NRAS, PALB2, PDGFRA, PHF6, PIGA, PML, PMS2, PPM1D, PTEN, PTPN11, RAD21, RAD51C, RB1, RPL11, RPL35A, RPL5, RPS10, RPS17, RPS26, RPS7, RTEL1, RUNX1, SAMD9, SAMD9L, SBDS, SETBP1, SETD2, SF3B1, SH2B3, SLX4, SMC1A, SMC3, SRP72, SRSF2, STAG2, STAT3, STAT5B, SUZ12, TERC, TERT, TET2, TINF2, TP53, U2AF1, VHL, WAS, WRAP53, WT1, ZRSR2
- Copy Number Variants (CNV) (17 genes): ABL1, ASXL1, ATG2B, BRAF, CBFB, CDKN1B, CDKN2A, DNMT1, ETV6, EZH2, GSKIP, JAK2, KMT2A, KRAS, MYC, RAD21, TP53

RNA sequencing

- Fusions (40 genes): ABL1, AFDN, AFF1, ALK, BCL11B, CBFB, CEP43, CPSF6, CREBBP, DEK, ELL, EP300, ETV6, FGFR1, FLT3, GLIS2, JAK2, KMT2A, MECOM, MLLT1, MLLT3, MRTFA, MYB, MYH11, NTRK3, NUP214, NUP98, PCM1, PDGFRA, PDGFRB, PICALM, PML, PRDM16, RARA, RBM15, RPN1, RUNX1, RUNX1T1, TCF3, ZNF384

Note: FLT3 by PCR (via FLT3 Mutation Analysis) is available to be ordered, as Client-Bill only, in conjunction with the Neo Comprehensive – Myeloid Disorders. It is reported separately from the Neo Comprehensive profile for the purpose of prompt therapy selection in patients with a new diagnosis of AML.

Clinical Significance

The Neo Comprehensive - Myeloid Disorders assay detects relevant aberrations for the purpose of diagnostic evaluation, prognosis, risk stratification, and therapy guidance. It covers a wide spectrum of myeloid neoplasms, including acute myeloid leukemia (AML); chronic myeloid leukemia (CML); chronic myelomonocytic leukemia (CMML); myelodysplastic neoplasms (MDS); myeloproliferative neoplasms (MPN), e.g., polycythemia vera (PV), primary myelofibrosis (PMF), and essential thrombocythemia (ET); myeloid neoplasms with eosinophilia and defining gene rearrangement; histiocytic neoplasms, such as Langerhans cell histiocytosis (LCH) or Erdheim-Chester Disease (ECD); mastocytosis; myeloid precursor lesions.

Specimen Requirements

- **Bone Marrow Aspirate:** 2-3 mL in EDTA tube
- **Peripheral Blood:** 3-5 mL in EDTA tube
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 10-14 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.

Note: Test is NOT suitable for Freeze & Hold option

Storage & Transportation

Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen. Ship same day as drawn whenever possible; specimens <7 days old preferred.

Important! To ensure sample stability, ship samples directly to NeoGenomics Aliso Viejo.

CPT Code(s)*

81455

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

*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.

NeoLAB® Solid Tumor Liquid Biopsy

Methodology
Molecular

Test Description
The NeoLAB Solid Tumor Liquid Biopsy is a next-gen sequencing assay designed to detect mutations in cell-free circulating tumor DNA of patients with solid tumors (pan-cancer). Analytic validation demonstrated accuracy of 98.0%, sensitivity of 95.1%, and specificity of 98.8%.

- SNVs and indels (969 mutations across these 44 genes): AKT1, ALK, APC, AR, ARAF, BRAF, CHEK2, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ESR1, FBXW7, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, GNA11, GNAQ, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1 (aka MEK1), MAP2K2 (aka MEK2), MET, MTOR, NRAS, NTRK1, NTRK3, PDGFRA, PIK3CA, PTEN, RAF1, RET, ROS1, SF3B1, SMAD4, SMO, and TP53.

NOTE: Not available for samples from New York.

Clinical Significance
Liquid biopsy (also called plasma testing) is appropriate for situations when tissue is insufficient, unavailable, or not practical to obtain, or when results are needed more quickly than they can be obtained from tissue analysis. The NeoLAB® Solid Tumor Liquid Biopsy includes targets significant to a wide variety of solid tumors including colorectal, pancreas, prostate, melanoma, head & neck, bladder, thyroid, kidney, ovarian, liver, thyroid, breast, and lung*. Tissue testing is recommended over plasma testing when possible.

*See also our other liquid biopsy InVisionFirst®-Lung for lung.

Specimen Requirements
- **Peripheral blood:** two x 10 mL Streck Cell-Free DNA BCT® tubes

Storage & Transportation
Do not refrigerate. Request collection kits from Client Services and see collection and shipping instructionshere (also included in kit).

CPT Code(s)*
81445

Medicare MolDX CPT Code(s)*
81445

New York Approved
No

Level of Service

Global

Turnaround Time

7 days

*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.

NeoSITE™ Melanoma

Alternative Name
Melanoma FISH

Methodology
FISH

Test Description
Probes: RREB1 (6p25) | MYC (8q24) | CDKN2A p16 (9p21) | Centromere 9 | CCND1 (11q13)
Disease(s): Melanoma

Clinical Significance
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.

Specimen Requirements
- **Paraffin Block:** Send block. For tech-only testing, include H&E slide with target area circled (required).
- **Cut Slides:** 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&E slide with target area circled (required).

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

CPT Code(s)*
88377x2 manual or 88374x2 automated

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
5 days

*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.

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 all exons in the genes 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 10-14 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 & 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 <7 days old preferred.

CPT Code(s)*
81450x1

Medicare MolDX CPT Code(s)*
81479

New York Approved
No

Level of Service

Global

Turnaround Time

14 days

*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.

NeoTYPE® ALL Profile

Alternative Name
NeoTYPE ALL, ALL Profile

Methodology
FISH

Molecular

Test Description
The NeoTYPE ALL Profile analyzes 38 genes to detect DNA and RNA alterations through a combination of next-generation sequencing (NGS) and FISH as noted below. Test reports include a summary interpretation of all results together. FISH components may be ordered as “Tech-Only” by pathology clients who wish to perform the professional component. Test may be ordered as “Molecular only” by clients who wish to opt out of the FISH components.

- **DNA Sequencing:**
  - SNVs/InDels (21 Genes): ABL1, ABL2, CDKN2A, CRLF2, CSF1R, EPOR, FGFR2, FGFR3, FLT3, IKZF1, IL7R, JAK1, JAK2, JAK3, NTRK1, NTRK2, NTRK3, PDGFRA, PDGFRB, SH2B3, and TP53
  - Copy Number Variations (3 Genes): CDKN2A, IKZF1, and TP53
    Note: Only copy number loss is reported as it is a clinically relevant abnormality for these tumor suppressor genes.
- **RNA Sequencing:**
  - Fusions (30 Genes): ABL1, ABL2, BCR, CRLF2, CSF1R, EPOR, ETV6, FGFR1, FLT3, IKZF1, JAK2, KMT2A, MEF2D, MLLT10, NTRK1, NTRK2, NTRK3, NUP98, PAX5, PBX1, PDGFRA, PDGFRB, PTK2B, RUNX1, TAL1, TCF3, TLX1, TLX3, TYK2, and ZNF384
  - Gene Overexpression (2 Genes): CRLF2 and EPOR
    Note: Analysis not available for FFPE samples
- **FISH (2 Genes):** CRLF2 (Xp22.33/Yp11.32) | EPOR (19p13.2)

Clinical Significance
The NeoTYPE ALL Profile is intended as an aid in diagnostic subtyping, risk assessment, and therapy selection of acute lymphoblastic leukemia (ALL) with a focus on Ph+ and Ph-like B-ALL subtypes. It is appropriate for both adult and pediatric ALL patients.

Comprehensive genetic information is of critical importance for disease management of ALL.

- 25% of B-ALL cases have the BCR-ABL1 fusion (Philadelphia chromosome-positive, or Ph+), with historically poor outcomes, but improved with tyrosine kinase inhibitors[1].
- Approximately 20-25% of B-ALL cases are characterized as Ph-Like and associated with a highly unfavorable prognosis[2,3].
- Many fusions, such as those involving ABL1, ABL2, CSF1R, PDGFRB, JAK2, or EPOR, may be responsive to certain tyrosine kinase inhibitors[2].
- Oncogenic RNA overexpression, often resulting from gene fusions, may provide prognostic information for ALL. High expression of CRLF2 or EPOR correlates with an unfavorable prognosis and poor response to conventional therapy[4,5].

- Copy number variations are increasingly relevant as risk stratification markers for ALL. Deletions of tumor suppressor genes, such as CDKN2A, IKZF1 and TP53, are generally associated with poor clinical outcomes[6,7,8].

Specimen Requirements

- **Bone Marrow Aspirate:** 2-3 mL in EDTA tube
- **Peripheral Blood:** 3-5 mL in EDTA tube
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 10-14 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. **Note:** not validated for the FISH portion.

Storage & Transportation

Use refrigerated 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)*

81450x1, 88374x2

New York Approved

No

Level of Service

Global

Turnaround Time

14 Days

Notes

Tech-only option available for FISH component

References

1. Sánchez, R., Ribera, J., Morgades, M. et al. A novel targeted RNA-Seq panel identifies a subset of adult patients with acute lymphoblastic leukemia with BCR-ABL1-like characteristics. *Blood Cancer J.* 10, 43 (2020).
2. Jain N, et al. Ph-like acute lymphoblastic leukemia: a high-risk subtype in adults. *Blood*. 2017;129(5):572-581.
3. Terwilliger T , Abdul-Hay M. Acute lymphoblastic leukemia: a comprehensive review and 2017 update. *Blood Cancer Journal* (2017) 7, e577;
4. Iacobucci I, Li Y, Roberts KG, et al. Truncating Erythropoietin Receptor Rearrangements in Acute Lymphoblastic Leukemia. *Cancer Cell*. 2016;29(2):186-200.
5. Dou H, Chen X, Huang Y, et al. Prognostic significance of P2RY8-CRLF2 and CRLF2 overexpression may vary across risk subgroups of childhood B-cell acute lymphoblastic leukemia. *Genes Chromosomes Cancer*. 2017;56(2):135-146.
6. Zhang W, Kuang P, Liu T. Prognostic significance of CDKN2A/B deletions in acute lymphoblastic leukaemia: a meta-analysis. *Ann Med*. 2019;51(1):28-40.
7. Marke, R, van Leeuwen F, Scheijen B. The many faces of IKZF1 in B-cell precursor acute lymphoblastic leukemia. *Haematologica*. Vol.103 No. 4 (2018): April, 2018
8. Stengel A. et al. TP53 mutations occur in 15.7% of ALL and are associated with MYC-rearrangement, low hypodiploidy, and a poor prognosis. *Blood* (2014) 124 (2):251-258.

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® ALL Profile for New York

Alternative Name
NeoTYPE ALL, ALL Profile

Methodology
FISH

Molecular

Test Description
The NeoTYPE ALL Profile analyzes 38 genes to detect DNA and RNA alterations through a combination of next-generation sequencing (NGS) and FISH as noted below. Test reports include a summary interpretation of all results together. FISH components may be ordered as “Tech-Only” by pathology clients who wish to perform the professional component.

- **DNA Sequencing:**
  - **SNVs/InDels (21 Genes):** ABL1, ABL2, CDKN2A, CRLF2, CSF1R, EPOR, FGFR2, FGFR3, FLT3, IKZF1, IL7R, JAK1, JAK2, JAK3, NTRK1, NTRK2, NTRK3, PDGFRA, PDGFRB, SH2B3, and TP53
  - Copy Number Variations (3 Genes): CDKN2A, IKZF1, and TP53
    Note: Only copy number loss is reported as it is a clinically relevant abnormality for these tumor suppressor genes.
- **RNA Sequencing:**
  - **Fusions (30 Genes):** ABL1, ABL2, BCR, CRLF2, CSF1R, EPOR, ETV6, FGFR1, FLT3, IKZF1, JAK2, KMT2A, MEF2D, MLLT10, NTRK1, NTRK2, NTRK3, NUP98, PAX5, PBX1, PDGFRA, PDGFRB, PTK2B, RUNX1, TAL1, TCF3, TLX1, TLX3, TYK2, and ZNF384
- **FISH (2 Genes):** CRLF2 (Xp22.33/Yp11.32) | EPOR (19p13.2)

Clinical Significance
The NeoTYPE ALL Profile is intended as an aid in diagnostic evaluation, prognostication, and therapy selection of acute lymphoblastic leukemia (ALL) with a focus on Ph+ and Ph-like B-ALL subtypes. It is appropriate for both adult and pediatric ALL patients.

Comprehensive genetic information is of critical importance for disease management of ALL.

- 25% of B-ALL cases have the BCR-ABL1 fusion (Philadelphia chromosome-positive, or Ph+), with historically poor outcomes, but improved with tyrosine kinase inhibitors[1].
- Approximately 20-25% of B-ALL cases are characterized as Ph-Like and associated with a highly unfavorable prognosis[2,3].
- Many fusions, such as those involving ABL1, ABL2, CSF1R, PDGFRB, JAK2, or EPOR, may be responsive to certain tyrosine kinase inhibitors[2].
- Copy number variations are increasingly relevant as risk stratification markers for ALL. Deletions of tumor suppressor genes, such as CDKN2A, IKZF1 and TP53, are generally associated with poor clinical outcomes[4,5,6].

Specimen Requirements

- **Bone Marrow Aspirate:** 2-3 mL in EDTA tube
- **Peripheral Blood:** 3-5 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. **Note:** not validated for the FISH portion.

Storage & Transportation

Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*

81450x1, 88374x2

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 Days

References

1. Sánchez, R., Ribera, J., Morgades, M. et al. A novel targeted RNA-Seq panel identifies a subset of adult patients with acute lymphoblastic leukemia with BCR-ABL1-like characteristics. *Blood Cancer J.* 10, 43 (2020).
2. Jain N, et al. Ph-like acute lymphoblastic leukemia: a high-risk subtype in adults. *Blood*. 2017;129(5):572-581.
3. Terwilliger T , Abdul-Hay M. Acute lymphoblastic leukemia: a comprehensive review and 2017 update. *Blood Cancer Journal* (2017) 7, e577;
4. Zhang W, Kuang P, Liu T. Prognostic significance of CDKN2A/B deletions in acute lymphoblastic leukaemia: a meta-analysis. *Ann Med*. 2019;51(1):28-40.
5. Marke, R, van Leeuwen F, Scheijen B. The many faces of IKZF1 in B-cell precursor acute lymphoblastic leukemia. *Haematologica*. Vol.103 No. 4 (2018): April, 2018
6. Stengel A. et al. TP53 mutations occur in 15.7% of ALL and are associated with MYC-rearrangement, low hypodiploidy, and a poor prognosis. *Blood* (2014) 124 (2):251-258.

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Please direct any questions regarding coding to the payor being billed.

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, KIT, KMT2A (MLL), KRAS, NPM1, NRAS, PDGFRA, PHF6, PML, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, TET2, TP53, U2AF1, WT1 and ZRSR2. For patients with therapy-related AML, AML that evolved from MDS, and AML with myelodysplasia, we recommend instead the NeoTYPE MDS/CMML Profile.

Note: FLT3 by PCR (via FLT3 Mutation Analysis) is available to be ordered, as Client-Bill only, in conjunction with the NeoTYPE AML Prognostic Profile. It is reported separately from the NeoTYPE Profile for the purpose of prompt therapy selection in patients with a *new* diagnosis of AML.

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 10-14 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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81450x1

Medicare MolDX CPT Code(s)*

81450

New York Approved
Yes

Level of Service
Global

Turnaround Time
14 days

Medical Necessity Resource
Medical Necessity for NeoTYPE Myeloid Profiles

*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.

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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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, FANCG, 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 22C3, 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 & 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 Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

*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.

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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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 & 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 Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

*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.

NeoTYPE® Cholangiocarcinoma Profile

Alternative Name
Cholangiocarcinoma Profile

Methodology
FISH

Immunohistochemistry (IHC)

Molecular

Test Description
The NeoTYPE Cholangiocarcinoma Profile analyzes 19 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. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- NGS (15 genes + 2 biomarkers): APC, ARID1A, BAP1, BRAF, EGFR, ERBB2, HRAS, IDH1, IDH2, KRAS, MET (c-MET), NRAS, PBRM1, SMAD4, TP53, plus Microsatellite instability (MSI) and Tumor Mutation Burden (TMB).
- FISH (1 biomarker): FGFR2
- IHC (1 biomarker): PD-L1 LDT

Clinical Significance
The NeoTYPE Cholangiocarcinoma Profile is intended to detect genetic aberrations reported in cholangiocarcinoma to aid in diagnosis and prognosis of the disease.

Cholangiocarcinoma (CCA) is an uncommon biliary tract cancer that typically presents at an advanced disease stage and is characterized by an aggressive disease course and poor clinical outcome. The most commonly mutated genes include KRAS, BRAF, BAP1, and SMAD4, associated with cell signaling pathways (MAPK signaling), cell cycle control and chromatin dynamics. Many potential therapies have been identified, including lapatinib (ERBB2), cetuximab and panitumumab (EGFR). Other potential targets include IDH1/2 and PD-L1.jab

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

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

CPT Code(s)*
81445, 88360, 88374x1 or 88377x1

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 Days

References

1. Jain, A. et al. Cholangiocarcinoma With FGFR Genetic Aberrations: A Unique Clinical Phenotype. *JCO Precision Oncology* 2018:2, 1-12.
2. Zhou, M., Zhu, Y., Hou, R., Mou, X., & Tan, J. (2019). Identification of candidate genes for the diagnosis and treatment of cholangiocarcinoma using a bioinformatics approach. *Oncology Letters*, 18, 5459-5467. https://doi.org/10.3892/ol.2019.10904
3. Labib, P.L., Goodchild, G. & Pereira, S.P. Molecular Pathogenesis of Cholangiocarcinoma. *BMC Cancer* 19, 185 (2019). https://doi.org/10.1186/s12885-019-5391-0

*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.

NeoTYPE® CLL Profile

Alternative Name
CLL Profile

Methodology
Molecular

Test Description
This NeoTYPE® CLL Profile analyzes 12 genes through next-generation sequencing (NGS) and the CLL FISH Panel as noted below. 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.

- **NGS (12 genes):** ATM, BCL2, BIRC3, BTK, CARD11, CD79B, CXCR4, MYD88, NOTCH1, PLCG2, SF3B1, TP53
- **FISH 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)
- **Optional Add-on:** IgVH Mutation Analysis

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 SFB31 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 are IgVH mutation status (available as optional add-on) 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.

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. Acquisition of the G101V mutation in the BCL2 gene may associate with resistance to venetoclax in CLL patients.

Specimen Requirements
- **Peripheral blood:** 5 mL in EDTA tube.
- **Bone marrow:** 2 mL in EDTA tube.
- **Fresh tissue:** 0.5 - 1 cm^3 in RPMI (Note: not acceptable for NYS samples).
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 10-14 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. Note: not acceptable for IgVH Mutation Analysis if added on.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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; 81450x1; 81263x1 (if IgVH Mutation Analysis is added)

Medicare MolDX CPT Code(s)*
81479x1; 88374x4; 81263x1 (if IgVH Mutation Analysis is added)

New York Approved
Yes

Level of Service
Global

Turnaround Time
14 days

*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.

NeoTYPE® Colorectal Tumor Profile

Alternative Name
Colorectal Tumor Profile

Methodology
Molecular

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 global HER2 (Other) IHC w/Gastric Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/ Gastric Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?20%.

- 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)
- FISH (3 FISH): MET, PTEN, RET (tech-only available)
- IHC (3 biomarkers): HER2 (Other) w/Gastric Scoring, PD-L1 LDT, Pan-TRK (tech-only available for HER2 and 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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 88377x3, 88360x2, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

*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.

NeoTYPE® Discovery Profile for Solid Tumors

Alternative Name
Discovery Profile

Methodology
Molecular

Test Description
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. For non-breast tumors, HER2 (Other) w/ Breast Scoring will be added. For breast tumors, HER2 Breast IHC/FISH can be ordered separately, if clinically indicated. If global HER2 (Other) IHC w/Breast Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/Breast Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?20% for colorectal specimens or ?40% with paired normal tissue available for non-colorectal specimens.

- FISH (8 FISH): ALK, BRAF, MET, MYC, PDGFRA amplifications, PTEN, RET, ROS1 (tech-only available)
- IHC (3 biomarkers): HER2 (Other) w/Breast Scoring (non-breast tumors only), PD-L1 22C3 (breast, lung) or PD-L1 LDT (other), Pan-TRK (tech-only available for HER2 and PD-L1)
- NGS (323 genes + 2 biomarkers): ABL1, ABL2, ACVR1B, ADGRA2 (GPR124), AKT1, AKT2, AKT3, ALK, AMER1, APC, AR, ARAF, ARFRP1, ARID1A, ARID1B, ARID2, ASXL1, ATM, ATR, ATRX, AURKA, AURKB, AXIN1, AXL, BAP1, BARD1, BCL2, BCL2L1, BCL2L2, BCL6, BCOR, BCORL1, BLM, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BTG1, BTK, CARD11, CBFB, CBL, CCND1, CCND2, CCND3, CCN6 (WISP3), CCNE1, CD274, CD79A, CD79B, CDC73, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CHD2, CHD4, CHEK1, CHEK2, CIC, CREBBP, CRKL, CRLF2, CSF1R, CTCF, CTNNA1, CTNNB1, CUL3, CXCR4, CYLD, DAXX, DDR2, DICER1, DNMT3A, DOT1L, EGFR, EMSY (C11orf30), EP300, EPCAM, EPHA3, EPHA5, EPHA7, EPHB1, ERBB2, ERBB3, ERBB4, ERG, ERRFI1, ESR1, EZH2, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FAS, FAT1, FBXW7, FGF10, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLT1, FLT3, FLT4, FOXL2, FOXP1, FRS2, FUBP1, GABRA6, GATA1, GATA2, GATA3, GATA4, GATA6, GID4, GLI1, GNA11, GNA13, GNAQ, GNAS, GRIN2A, GRM3, GSK3B, HGF, HNF1A, HRAS, HSD3B1, HSP90AA1, H3-3A (H3F3A), H3C3 (HIST1H3C), IDH1, IDH2, IGF1R, IGF2, IKBKE, IKZF1, IL7R, INHBA, INPP4B, IRF2, IRF4, IRS2, JAK1, JAK2, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIT, KLHL6, KMT2A, KMT2C, KMT2D, KRAS (includes G12C mutation), LMO1, LRP1B, LYN, LZTR1, MAGI2, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, MET, Microsatellite Instability (MSI), MITF, MLH1, MPL, MRE11 (MRE11A), MSH2, MSH6, MTOR, MUTYH, MYC, MYCL, MYCN, MYD88, NBN, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NSD1, NTRK1, NTRK2, NTRK3, NUP93, PAK3, PALB2, PAX5, PBRM1, PDCD1LG2, PDGFRA, PDGFRB, PDK1, PIK3C2B, PIK3CA, PIK3CB, PIK3CG, PIK3R1, PIK3R2, PLCG2, PMS2, POLD1, POLE, PPP2R1A, PRDM1, PREX2, PRKAR1A, PRKCI, PRKDC, PRKN (PARK2), PRSS8, PTCH1, PTEN, PTPN11, QKI, RAC1, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RAF1, RANBP2, RARA, RB1, RBM10, RET, RICTOR, RNF43, ROS1, RPTOR, RUNX1, RUNX1T1, SDHA, SDHB, SDHC, SDHD, SETD2, SF3B1, SLIT2, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMO, SNCAIP, SOCS1, SOX10, SOX2, SOX9, SPEN, SPOP, SPTA1, SRC, STAG2, STAT3, STAT4, STK11, SUFU, SYK, TAF1, TBX3, TENT5C (FAM46C), TERC, TERT promoter, TET2, TGFBR2, TNFAIP3, TNFRSF14, TOP1, TOP2A, TP53, TSC1, TSC2, TSHR, U2AF1, VEGFA, VHL, 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 & 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, 88377x8; 88360x2, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

*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.

NeoTYPE® DNA & RNA - Brain

Alternative Name
Brain Tumor Profile

Methodology
Molecular

Test Description
NeoTYPE® DNA & RNA - Brain uses targeted next-generation sequencing (NGS) to detect single nucleotide variants, insertions/deletions, and gene fusions in 83 unique genes (62 genes analyzed by DNA and 28 by RNA), plus microsatellite instability (MSI) and tumor mutational burden (TMB). In addition, FISH is performed to detect nine key copy number alterations and PD-L1 immunohistochemistry is performed. MGMT Promoter Methylation Analysis by PCR is an optional add-on. Results are incorporated into one report providing diagnostic, prognostic, and therapeutic implications, as well as potential clinical trial options. A microsatellite instability NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available. If the sample is insufficient to produce both DNA and RNA results, the available results will be reported and alternate CPT® Codes may apply.

- **SNVs/Indels (62 genes):** AKT1, APC, ATRX, BAP1, BCOR, BCORL1, BRAF, CDK6, CDKN2A, CDKN2B, CIC, CTNNB1, DICER1, EED, EGFR, EPCAM, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, FUBP1, GNA11, GNAQ, H3F3A (H3-3A), HIST1H3C (H3C3), HRAS, IDH1, IDH2, KDM6A, KRAS, MAP2K1, MET, MLH1, MSH2, MSH6, MYC, MYCN, NOTCH1, NF1, NF2, NRAS, PDGFRA, PIK3CA, PMS2, PTCH1, PTEN, RB1, SETD2, SF3B1, SMAD4, SMARCA4, SMARCB1, SMO, SRC, SUFU, SUZ12, TERT Promoter, TP53, TSC1, TSC2, and VHL
- **RNA Fusions (28 genes):** ALK, BRAF, CIC, EGFR including EGFRvIII, EML4, ETV6, EWSR1, FGFR1, FGFR2, FGFR3, FUS, KIAA1549, MAML2, MET, MN1, MYB, MYBL1, NTRK1, NTRK2, NTRK3, PRKCA, RAF1, ROS1, STAT6, TACC3, TFG, YAP1, and ZFTA (C11orf95)
- **CNVs by FISH (9 CNVs):** 1p/19q co-deletion, +7/-10 (trisomy 7, monosomy 10), CDKN2A (p16) deletion, EGFR amplification, MET amplification, MYCN amplification, PDGFRa amplification, and PTEN deletion (FISH is global only)
- **IHC:** PD-L1 LDT (tech-only available)
- **Other Biomarkers:** Microsatellite Instability (MSI) and Tumor Mutation Burden (TMB) included. MGMT Promoter Methylation Analysis may be added.

Clinical Significance
NeoTYPE® DNA & RNA – Brain is intended to provide a tumor genomic profile that includes the most clinically significant genomic alterations according to the 2021 WHO Classification of Tumors of the CNS, 5th edition. These genomic findings may help inform diagnosis, prognosis, therapeutic decisions, and clinical trial options. This profile is appropriate for patients with newly diagnosed, recurrent, or resistant disease.

Specimen Requirements
FFPE solid tumor tissue: Minimum surface area 10mm^2 with ?20% tumor content. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

- **Paraffin block:** Preferred.

- **Cut slides:** Send ?25 unstained sections cut at 5 microns plus one H&E slide (which NeoGenomics will keep). No additional slides are needed if ordering MGMT Promoter Methylation Analysis.

Storage & 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, 88377x8, 88360x1. Add 81287x1 if ordering MGMT Promoter Methylation Analysis.

Medicare MolDX CPT Code(s)*

81479x1, 88377x8, 88360x1. If sample is insufficient to produce RNA fusion results but DNA SNV/indel and/or CNV results are reported, 81479x1 still applies. If only RNA fusion results are reported, use 81445x1 instead of 81479x1. (SEE NOTES)

New York Approved

Yes

Turnaround Time

14 days

Notes

Add 81287x1 if ordering MGMT Promoter Methylation Analysis.

References

1. Louis DN et al. The 2021 WHO Classification of Tumors of the Central Nervous System: a summary. Neuro-Oncology. 2021;23(8):1231-1251. https://doi.org/10.1093/neuonc/noab106

*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.

NeoTYPE® DNA & RNA - Lung

Methodology
Molecular

Test Description
NeoTYPE® DNA & RNA - Lung is a targeted next-generation sequencing profile that detects single nucleotide variants (SNV), insertions/deletions (InDels), copy number variants (CNV), and RNA fusions and splice variants in a total of 50 genes (44 genes analyzed by DNA and 19 by RNA), plus microsatellite instability (MSI) and tumor mutation burden (TMB). PD-L1 immunohistochemistry is optional. Results are summarized and details provided for prognostic findings, therapy susceptibility or resistance, available clinical trials, and more. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available. If the sample is insufficient to produce either DNA or RNA results, the available results will be reported and alternate CPT® Codes may apply.

- **SNVs/Indels/CNVs (44 genes):** AKT1, ALK, ARAF, ARID1A, ATM, ATR, ATRX, BRAF, CDKN2A, CDKN2B, EGFR, ERBB2*, ERBB3, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, FGFR4, KEAP1, KIT, KMT2D, KRAS, MAP2K1, MET*, NF1, NFE2L2, NOTCH1, NRAS, NTRK1, NTRK3, PDGFRA, PIK3CA, PTEN, RB1, RBM10, RET, ROS1, SMAD4, SMARCA4, SMO, STK11, TERT Promoter, and TP53
  * *CNV detection in addition to SNVs and indels.*
  The full coding sequence of each DNA gene is tested.
- **RNA Fusions (19 genes):** ALK, BRAF, FGFR1, FGFR2, FGFR3, FGFR4, MET** including METex14 skipping, NOTCH1, NOTCH2, NRG1, NTRK1, NTRK2, NTRK3, PDGFB, PDGFRA, PDGFRB, RAF1, RET, ROS1
  ** *Splice variant detection in addition to fusions.*
  The full coding sequence of each RNA gene is tested.
- **IHC**: PD-L1 22C3 FDA for NSCLC (tech-only available)
- **Other Markers**: Microsatellite Instability (MSI) and Tumor Mutation Burden (TMB) included.

Clinical Significance
NeoTYPE® DNA & RNA - Lung detects genomic alterations that are most relevant to therapy selection, prognosis, and clinical trial options in non-small cell lung cancer. It is appropriate for patients with newly diagnosed, recurrent, or resistant disease.

Specimen Requirements
A block is preferred for testing: ?20% tumor and ?10 mm^2 of tissue surface area for NGS (~500 tumor cells) (additional 100 neoplastic cells for PD-L1).

If submitting 5-micron unstained slides, the following number of slides are requested:

- **Samples with ? 25 mm^2 of tissue**: 10 unstained slides (2 sections per slide preferred)
- **Samples with 10-24 mm^2 of tissue:** 20 unstained slides (2 sections per slide preferred)

Please submit 1 additional unstained slide for H&E and 3 additional unstained slides if performing PD-L1 testing.

Storage & Transportation

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

CPT Code(s)*

81445x1. Add 88360x1 for PD-L1 IHC.

Medicare MolDX CPT Code(s)*

81479x1. If sample is insufficient to produce RNA fusion results but DNA SNV/indel and/or CNV results are reported, 81479x1 still applies. If only RNA fusion results are reported, use 81445x1 instead. Add 88360x1 for PD-L1 IHC.

New York Approved

No

Level of Service

Global

Turnaround Time

8-10 days

*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.

NeoTYPE® Endometrial Tumor Profile

Alternative Name
Endometrial Tumor Profile

Methodology
Molecular

Test Description
The NeoTYPE Endometrial Tumor Profile analyzes 47 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 global HER2 (Other) IHC w/Breast Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/Breast Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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, MTOR, MUTYH, NRAS, PDGFRA, 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 (3 biomarkers): HER2 (Other) IHC w/Breast Scoring, PD-L1 LDT, Pan-TRK (tech-only available for HER2 and 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 & 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, 88360x2, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

*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.

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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- NGS (32 genes + 2 biomarkers): AKT1, ALK, APC, ARID1A, BLM, BRAF, BRCA1, BRCA2, CDH1, 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 & 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 Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® Follicular Lymphoma Profile

Alternative Name
Follicular Lymphoma Profile

Methodology
FISH

Molecular

Test Description
The NeoTYPE® Follicular Lymphoma Profile analyzes 16 genes through a combination of next-generation sequencing (NGS) and FISH as noted below. Test reports include a summary interpretation of all results together. FISH components may be ordered as “Tech-Only” by pathology clients who wish to perform the professional component.

- **NGS (16 Genes):** ARID1A, BCL2, BCL6, CDKN2A, CREBBP, EP300, EZH2, FAS, KMT2D, MAP2K1, MEF2B, PIK3CA, SOCS1, STAT6, TNFAIP3, and TNFRSF14
  For EZH2, the test can detect relevant mutations in Exons 16 and 18, including Y646N, Y646H, Y646F, Y646S, Y646C, A682G, and A692V.
- **FISH probes:** IgH/BCL2 t(14;18) | DUSP22-IRF4 (6p25.3) | TNFRSF14 (1p36)

Clinical Significance
Conventional follicular lymphoma (FL) is a common form of non-Hodgkin lymphoma (NHL) that stems from germinal center B-lymphocytes and is typically characterized by diffuse lymphadenopathy, splenomegaly, and bone marrow involvement, as well as occasional involvement in other extranodal sites. Histologic grade correlates with prognosis with grade 1-2 being indolent and not usually curable. Grade 3 conventional FL has a more aggressive clinical course, but may respond to systemic therapies. Frequent recurrent genetic abnormalities in conventional FL include rearrangements of BCL2 (80%) and BCL6 (15%).

Pediatric-type follicular lymphoma (PTFL) most commonly presents in children age 7.4-14 years, but can be seen in young adults and more rarely older adults. PTFL occurs as localized disease of the head and neck lymph nodes or tonsils and is characteristically negative for BCL2 and BCL6 rearrangements. Although most cases meet conventional criteria for grade 3B FL, PTFL has a good prognosis after local excision alone. The molecular profile of PTFL differs from conventional FL, as PTFL only has rare mutations in CREBBP, EZH2 and KMT2D, which are commonly found in conventional FL. PTFL frequently has mutations in TNFRSF14 and MAP2K1. Follicular lymphoma with EZH2 mutation may respond to EZH2 inhibitors. The NeoTYPE® Follicular Lymphoma Profile has been developed to include a number of genes which are associated with lymphoma pathogenesis. Results from this test will aid in patient diagnosis, classification, prognosis, as well as treatment decisions.

Specimen Requirements
- **FFPE tissue:** Paraffin block. 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 & 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)*

81450x1; 88374x3 or 88377x3

New York Approved

No

Level of Service

Global

Turnaround Time

14 Days

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Please direct any questions regarding coding to the payor being billed.

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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- NGS (33 genes + 2 biomarkers): AKT1, ARID1A, BRAF, CDH1, CDKN2A, EGFR, ERBB2, ERBB3, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, NOTCH1, NRAS, PDGFRA, 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 (6 biomarkers): MMR (opt-out available), PD-L1 22C3, Pan-TRK (tech-only available for MMR and 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 & 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 88361x4 if MMR IHC is selected; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® GI Predictive Profile

Methodology
Molecular

Test Description
The NeoTYPE GI Predictive Profile analyzes 10 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. HER2 (Other) IHC w/Gastric Scoring (default) and HER2 Gastric/GEA options are available. If global HER2 (Other) IHC w/Gastric Scoring is selected and the result is 2+, the case will reflex to global HER2 (Other) FISH w/Gastric Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If global HER2 Gastric/GEA is selected and the result is 2+, the case will reflex to global HER2 Gastric/GEA FISH unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?20% for colorectal specimens or ?40% with paired normal tissue available for non-colorectal specimens.

- NGS (5 genes + 2 biomarkers): BRAF, HRAS, KRAS, Microsatellite Instability (MSI), NRAS, TERT Promoter, Tumor Mutation Burden (TMB)
- IHC (3 biomarkers): HER2 (Other) w/Gastric Scoring (default) or HER2 Gastric/GEA, PD-L1 22C3, Pan-TRK (tech-only available for HER2 and 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 & 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, 88360x2, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

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Please direct any questions regarding coding to the payor being billed.

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. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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 LDT (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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 88377x2, 88360x1

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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 Methodology (1 biomarker): HPV RNA ISH 16/18 (High Risk)
- 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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 88377x3, 88360x1, 88342x1, 88365x1; add 81194x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479x1, 88377x3, 88360x1, 88342x1, 88365x1; add 81194x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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NeoTYPE® HRR Profile

Alternative Name
Homologous Recombination Repair/ Deficiency (HRR / HRD)

Methodology
Molecular

Test Description
The NeoTYPE HRR Profile analyzes 31 biomarkers through a combination of next-generation sequencing (NGS) and IHC as listed below.

- 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
- IHC (1 biomarker): PD-L1 LDT (tech-only available for PD-L1)

Clinical Significance
Homologous recombination repair (HRR) is a pathway where mutations in genes involved in the repair of double-stranded DNA breaks have lost the ability to repair DNA and thus may lead to diseases such as cancer. BRCA1, BRCA2, ATM, PALB2, and RAD51 are among the best-known genes in this repair complex; 26 such genes are included in the NeoTYPE HRR Profile which is a tumor profile for somatic mutation detection. PARP inhibition targets HRR/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 HRR/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.

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

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

CPT Code(s)*
81445x1; 88360x1

Medicare MolDX CPT Code(s)*

81445

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

References

1. O'Kane GM, Connor AA, Gallinger S. Characterization, detection, and treatment approaches for homologous recombination deficiency in cancer. *Trends Mol Med.* 2017;23(12):1121-1137.
2. Faraoni I, Graziani G. Role of BRCA mutations in cancer treatment with poly(ADP-ribose) polymerase (PARP) inhibitors. *Cancers*. 2018;10:487; doi:10.3390/cancers10120487

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® Liposarcoma Fusion Profile

Alternative Name
Liposarcoma Fusions

Methodology
Molecular

Test Description
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.

Clinical Significance
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 lipopomatous neoplasms and provide clear distinction from one another.

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

CPT Code(s)*
81406x1, 88374x1 automated or 88377x1 manual

New York Approved
No

Level of Service
Global

Turnaround Time

21 days

*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.

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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- NGS (32 genes + 2 biomarkers): AKT1, APC, ARID1A, ATM, BAP1, BRAF, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1 (mutations), FGFR2 (mutations), FGFR3 (mutations), 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 (3 FISH): FGFR2 rearrangement, MET, PTEN (tech-only available)
- IHC (2 biomarkers): PD-L1 LDT, 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 & 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 Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® Lung Tumor Profile

Alternative Name
Lung Tumor Profile, Lung Cancer Profile (includes KRAS G12C mutation)

Methodology
Molecular

Test Description
The NeoTYPE Lung Tumor Profile analyzes 49 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 global HER2 (Other) IHC w/Breast Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/Breast Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- NGS (40 genes + 2 biomarkers): AKT1, ALK, ARID1A, ATM, ATR, ATRX, BRAF, CCND1, CDKN2A, CDKN2B, EGFR, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, KEAP1, KIT, KMT2D, KRAS (includes G12C mutation), MET, Microsatellite Instability (MSI), NF1, NFE2L2, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, RB1, RBM10, RET, ROS1, SMARCA4, SMAD4, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- Other Molecular (1 biomarker): MET Exon 14 Deletion Analysis
- FISH (5 biomarkers): ALK, MET, PTEN, RET, ROS1 (tech-only available)
- IHC (3 biomarkers): HER2 (Other) IHC w/Breast Scoring, PD-L1 22C3, Pan-TRK (tech-only available for HER2 and 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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 88377x5, 88360x2, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

No

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® Lymphoid Disorders Profile

Alternative Name
NeoTYPE Lymphoid, Lymphoid Disorders Profile

Methodology
Molecular

Test Description
The NeoTYPE Lymphoid Disorders Profile detects DNA mutations (SNVs and InDels) in 128 genes across multiple lymphoma/leukemia subtypes through next-generation sequencing (NGS): ABL1, ABL2, ALK, ARHGEF1, ARID1A, ARID2, ASXL1, ATM, B2M, BCL2, BCL6, BCOR, BIRC3, BRAF, BTK, CARD11, CCND1, CCND2, CCND3, CD274, CD79A, CD79B, CDKN1B, CDKN2A, CDKN2B, CIITA, CREBBP, CRLF2, CSF1R, CTCF, CTNNB1, CXCR4, DDX3X, DIS3, DNMT3A, EBF1, EGR1, EP300, EPOR, ETV6, EZH2, FAM46C, FAS, FAT1, FBXW7, FGFR3, FOXO1, GATA3, GNA13, GNAI2, HIST1H1E, HRAS, ID3, IDH1, IDH2, IKBKB, IKZF1, IKZF3, IRAK4, ITPKB, JAK1, JAK2, JAK3, KLF2, KMT2D, KRAS, MALT1, MAP2K1, MAP3K14, MAPK1, MED12, MEF2B, MYC, MYCN, MYD88, NF1, NFKBIE, NOTCH1, NOTCH2, NOTCH3, NRAS, NT5C2, P2RY8, PDGFRB, PHF6, PIK3CA, PIK3CD, PIK3R1, PIM1, PLCG1, PLCG2, POT1, PPM1D, PRDM1, PRPS1, PTEN, PTPN11, RB1, REL, RHOA, RIPK1, RPS15, RUNX1, S1PR2, SAMHD1, SETD2, SF3B1, SGK1, SH2B3, SOCS1, SPEN, STAT3, STAT5B, STAT6, TBL1XR1, TCF3, TET2, TLR2, TNFAIP3, TNFRSF14, TP53, TRAF2, TRAF3, UBR5, WT1, XPO1, ZFHX4, and ZMYM3. Test reports include a summary of all results together.

Clinical Significance
The NeoTYPE Lymphoid Disorders Profile is intended as an aid in the diagnosis and subclassification of lymphoid neoplasms as well as to identify potential therapies based on the patient's unique molecular drivers. The profile includes analysis of genes known to be recurrently mutated in chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Richter's syndrome (RS), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), lymphoplasmacytic lymphoma (LPL), hairy cell leukemia (HCL), follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), double-hit lymphoma (DHL), and various T-cell neoplasms.

Specimen Requirements
- **Bone Marrow Aspirate:** 2-3 mL in EDTA tube
- **Peripheral Blood:** 3-5 mL in EDTA tube
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 10-14 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 & Transportation
Use refrigerated cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81455x1

Medicare MolDX CPT Code(s)*

81450x1

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 Days

*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.

NeoTYPE® Lymphoma Profile

Alternative Name
Lymphoma Profile

Methodology
Molecular

Test Description
The NeoTYPE® Lymphoma Profile analyzes 12 genes through a combination of next-generation sequencing (NGS) and FISH as noted below. Test reports include a summary interpretation of all results together.

- **NGS (12 Genes):** BCL2, BCL6, BRAF, CARD11, CCND1 (BCL1), CD79B, EZH2, MYD88, NOTCH1, NOTCH2, NRAS, and TP53
- **FISH (2 Genes):** CCND1 (BCL1)/IgH t(11;14) | BCL2/IgH t(14;18)

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 10-14 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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81450x1; 88374x2 or 88377x2

Medicare MolDX CPT Code(s)*
81450

New York Approved
No

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

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, CALR, CBL, CEBPA, CUX1, DDX41, DNMT3A, ETNK1, ETV6, EZH2, FLT3, GATA2, GNB1, HRAS, IDH1, IDH2, JAK2, KIT, KRAS, MPL, NF1, NPM1, NRAS, PDGFRA, PHF6, PIGA, PPM1D, PTEN, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, STAT3, STAT5B, TET2, TP53, U2AF1, WT1, and ZRSR2.

Note: FLT3 by PCR (via FLT3 Mutation Analysis) is available to be ordered, as Client-Bill only, in conjunction with the NeoTYPE MDS/CMML Profile. It is reported separately from the NeoTYPE Profile for the purpose of prompt therapy selection in patients with a *new* diagnosis of AML.

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 10-14 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 & 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 <7 days old preferred.

CPT Code(s)*
81450x1

Medicare MolDX CPT Code(s)*

81450

New York Approved
Yes

Level of Service
Global

Turnaround Time
14 days

Medical Necessity Resource
Medical Necessity for NeoTYPE Myeloid Profiles

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® Melanoma Profile

Alternative Name
Melanoma Profile

Methodology
Molecular

Test Description
The NeoTYPE Melanoma 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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- NGS (24 genes + 2 biomarkers): AKT1, BAP1, BRAF, CDK4, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, HRAS, KIT, KRAS, 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 IHC, 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 & 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 Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® Other Solid Tumor Profile

Alternative Name
Other Solid Tumor Profile

Methodology
Molecular

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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?20% for colorectal specimens or ?40% with paired normal tissue available for non-colorectal specimens.

- NGS (24 genes + 2 biomarkers): AKT1, BRAF, EGFR, FGFR1, FGFR2, FGFR3, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PDGFRA, 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 LDT, 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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445x1, 81479x1, 88377x2, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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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 global HER2 (Other) IHC w/Breast Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/Breast Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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, FANCF, FANCG, 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 (5 FISH): EGFR Amplification, MET, MYC, PTEN, RET (tech-only available)
- IHC (4 biomarkers): FOLR1 FDA, HER2 (Other) IHC w/Breast Scoring, PD-L1 LDT, Pan-TRK (tech-only available for HER2 and PD-L1, opt out available for FOLR1 and HER2)

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 & 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)*
81479x1, 88377x5, 88360x3, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel.

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

NeoTYPE® Pancreas Tumor Profile

Alternative Name
Pancreas Tumor Profile

Methodology
Molecular

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 global HER2 (Other) IHC w/Breast Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/Breast Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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 (2 FISH): MET, PTEN (tech-only available)
- IHC (3 biomarkers): HER2 (Other) IHC w/Breast Scoring, PD-L1 LDT, Pan-TRK (tech-only available for HER2 and 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 & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81455x1, 88377x2, 88360x2, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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NeoTYPE® Precision Profile for Solid Tumors

Alternative Name
Solid Tumor Profile, Precision Profile

Methodology
Molecular

Test Description
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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?20% for colorectal specimens or ?40% with paired normal tissue available for non-colorectal specimens.

- NGS (79 genes + 2 biomarkers): AKT1, ALK, APC, ARAF, ATM, ATR, BARD1, BRAF, BRCA1, BRCA2, BRIP1, 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 (includes G12C mutation), MAP2K1, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, MRE11A (MRE11), MTOR, NBN, NF1, NOTCH1, NRAS, PALB2, PDGFRA, PIK3CA, PMS2, PTCH1, 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
- IHC (2 biomarkers): PD-L1 LDT, Pan-TRK (tech-only available for PD-L1)

Clinical Significance
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.

Specimen Requirements
- **FFPE solid tumor tissue:** Paraffin block is preferred. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

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

CPT Code(s)*

81455x1, 88360x1, 88342x1; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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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, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- 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 LDT, 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 & 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 Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

NKX2.2

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Non-Ewing Sarcoma NGS Fusion Panel

Alternative Name
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, SS18, 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 histiocytoma, alveolar rhabdomyosarocma, alveolar soft-part sarcoma, chondroid lipoma, congenital/infantile fibrosaroma, 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 & Transportation
Use cold pack for transporting block during summer to prevent block from melting. Slides can be packed at room temperature.

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

21 days

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Please direct any questions regarding coding to the payor being billed.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 7 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

CPT Code(s)*
88374x7 automated. Codes may differ if manual analysis is performed.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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NOTCH1 Mutation Analysis

Alternative Name
NOTCH1 Gene Sequencing

Methodology
Molecular

Test Description
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.

Clinical Significance
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.

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

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

CPT Code(s)*
81407

New York Approved
No

Level of Service
Global

Turnaround Time
10 days

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Please direct any questions regarding coding to the payor being billed.

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 x 10^-3 (0.5%). Positive results are reported quantitatively if the percentage of mutated DNA is ?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.

Note: Test in DNA-based, suitable for Freeze & Hold option.

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

CPT Code(s)*
81310

New York Approved
No

Level of Service
Global

Turnaround Time

7 days

References

1. Schnittinger S, Kern W, Tschulik C, et al. Minimal residual disease levels assessed by NPM1 mutation–specific RQ-PCR provide important prognostic information in AML. *Blood*. 2009; 114:2220-2231.
2. Krönke J, Schlenk RF, Jensen KO, et al. Monitoring of minimal residual disease in NPM1-mutated acute myeloid leukemia: a study from the German-Austrian acute myeloid leukemia study group. *J Clin Oncol.* 2011; 29(19):2709-16.

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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.

Note: Test in DNA-based, suitable for Freeze & Hold option.

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

CPT Code(s)*
81310

New York Approved
No

Level of Service
Global

Turnaround Time
7 days

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NRAS Mutation Analysis

Alternative Name
NRAS Gene Sequencing, NRAS Exons 2-4

Methodology
Molecular

Test Description
Bi-directional sequencing of NRAS exons 2, 3, and 4 including codons 12, 13, 59, 61, 117, and 146.

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. Patients with any known KRAS mutation or NRAS mutation may be resistant to certain tyrosine kinase inhibitors. Testing is available separately or in combination with BRAF, HRAS and KRAS in the RAS/RAF Panel.

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

CPT Code(s)*
81311, 81403

Medicare MolDX CPT Code(s)*
81479

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

NTRK & RET NGS Fusion Panel

Alternative Name
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 the following FDA-approved therapies:

- NTRK- ROZLYTREK® (entrectinib), VITRAKVI® (larotrectinib)
- RET- GAVRETO™ (pralsetinib), RETEVMO™ (selpercatinib)

See also NTRK NGS Fusion Panel and Lung NGS Fusion Panel (Complete or Limited).

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 pathognomic 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 & Transportation

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

CPT Code(s)*

81194, 81479 (as of 01/01/2021); Prior to CPT Code was 81479

Medicare MolDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

21 days

References

1. Cocco E, Scaltriti M, Drilon A. NTRK fusion-positive cancers and TRK inhibitor therapy.*Nat Rev Clin Onco*. 2018;15:731-747.
2. Chen Y, Chi P. Basket trial of TRK inhibitors demonstrates efficacy in TRK fusion-positive cancers.*J Hematol Oncol*. 2018;11:78.
3. Farago AF, Taylor MS, Doebele RC et al. Clinicopathologic features of non-small-cell lung cancer harboring an ntrk gene fusion. *JCO Precis Oncol*. 2018: 10.1200/PO.18.00037.

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

References

1. Cocco E, Scaltriti M, Drilon A. NTRK fusion-positive cancers and TRK inhibitor therapy. *Nat Rev Clin Oncol.* 2018;15:731-747.
2. Chen Y, Chi P. Basket trial of TRK inhibitors demonstrates efficacy in TRK fusion-positive cancers. *J Hematol Oncol.* 2018;11:78.

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NTRK NGS Fusion Panel

Alternative Name
NTRK NGS Fusion Profile

Methodology
Molecular

Test Description
The NTRK NGS Fusion Panel 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 the following FDA-approved therapies: ROZLYTREK® (entrectinib), VITRAKVI® (larotrectinib).

See also Lung NGS Fusion Panel (Complete or Limited) and NTRK & RET NGS Fusion Panel.

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

CPT Code(s)*
81194 (as of 01/01/2021); Prior to CPT Code was 81479

Medicare MolDX CPT Code(s)*

81194

New York Approved

Yes

Level of Service

Global

Turnaround Time

21 days

References

1. Cocco E, Scaltriti M, Drilon A. NTRK fusion-positive cancers and TRK inhibitor therapy.*Nat Rev Clin Oncol. 2018;15:731-747.*
2. Chen Y, Chi P. Basket trial of TRK inhibitors demonstrates efficacy in TRK fusion-positive cancers.*J Hematol Oncol.* 2018;11:78.
3. Farago AF, Taylor MS, Doebele RC et al. Clinicopathologic features of non-small-cell lung cancer harboring an ntrk gene fusion. *JCO Precis Oncol.* 2018: 10.1200/PO.18.00037

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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 & 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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time
3-5 days

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Please direct any questions regarding coding to the payor being billed.

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.

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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

References

1. Ostronoff F, Othus M, Gerbing RB, et al. NUP98/NSD1 and FLT3/ITD coexpression is more prevalent in younger AML patients and leads to induction failure: a COG and SWOG report. *Blood*. 2014;124(15):2400-2407.
2. Hollink I, van den Heuvel-Eibrink M, Arentsen-Peters S, et al. NUP98/NSD1 characterizes a novel poor prognostic group in acute myeloid leukemia with a distinct HOX gene expression pattern. *Blood.* 2017;118(13):3645-3656.
3. Romana SP, Radford-Weiss I, Ben Abdelali R, et al. NUP98 rearrangements in hematopoietic malignancies: a study of the Groupe Francophone de Cytogenetique Hematologique. *Leukemia.* 2006;20:696-706.

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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, but are characterized by rearrangement of the NUTM1 (NUT) gene at chromosome 15q14 with BRD4/3 (and rarely NSD3, ZNF532 or ZNF592), which causes NUT protein overexpression. IHC staining with NUT antibody may serve as a diagnostic alternative to FISH or molecular confirmation of 15q14 rearrangement. However, NUT overexpression by IHC may also be seen in other diseases NUTM1 rearrangement, such as porocarcinoma with YAP1-NUTM1 gene fusion (PMID: 32436169), so a diagnosis of NUT midline carcinoma should not be based on NUT IHC positivity alone.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

References

1. Agaimy A, Tögel L, Haller F, Zenk J, Hornung J, Märkl B. YAP1-NUTM1 Gene Fusion in Porocarcinoma of the External Auditory Canal. *Head Neck Pathol*. 2020;14(4):982-990.
2. Napolitano M, Venturelli M, Molinaro E, Toss A. NUT midline carcinoma of the head and neck: current perspectives. *Onco Targets* Ther. 2019;12:3235-3244.
3. Park HS, Bae YS, Yoon SO, et al. Usefulness of Nuclear Protein in Testis (NUT) Immunohistochemistry in the Cytodiagnosis of NUT Midline Carcinoma: A Brief Case Report. *Korean J Pathol*. 2014;48(4):335-338.

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

OCT4

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Olig2

Methodology
Immunohistochemistry (IHC)

Test Description
Olig2, a transcription factor, is involved in oligodendroglial 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Oncology Chromosome Analysis

Alternative Name
Oncology Cytogenetics, Oncology Karyotyping

Methodology
Cytogenetics

Test Description
Cytogenetic analysis can provide an important clinical understanding for diagnosis, prognosis, and available therapies in a wide variety of hematologic tumors. Chromosomal changes can consist of additions and deletions of whole chromosomes or structural changes such as insertions, inversions, translocations, and deletions. In leukemias and lymphomas, chromosomal translocations are identified as a common karyotypic change aiding in disease diagnosis.

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.
- **CSF:** 1-3 mL
- **Lymph Node and BM Cores (Fresh/Unfixed):** One thin cross-section of fresh node 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 and BM cores may be sent to our Aliso Viejo, CA facility. Tissues placed in formalin are unacceptable for cytogenetics.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

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

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

New York Approved
Yes

Level of Service

Global

Turnaround Time

Bone marrow aspirate/blood: 6 days (standard; 8 days for known or suspected plasma cell neoplasm) | Lymph node/node biopsy: 6 days

References

1. Sandberg AA. Cancer cytogenetics for clinicians. American Cancer Society Journals. https://acsjournals.onlinelibrary.wiley.com/doi/abs/10.3322/canjclin.44.3.136. Published December 31, 2008. Accessed January 11, 2021.

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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p40

Methodology
Immunohistochemistry (IHC)

Test Description
p40 antibody recognizes ?Np63—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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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P501S

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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

CPT Code(s)*
88342 x 1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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p53

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

CPT Code(s)*
88360 x 1

New York Approved
Yes

Level of Service
Stain Only, Global

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

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p57

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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p63

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 erothelial 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available

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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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Pan-Cytokeratin

Alternative Name
CK AE1/AE3

Methodology
Immunohistochemistry (IHC)

Test Description
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.

Note: Global interpretation is only available for sentinel nodes. For Pan-Cytokeratin performed on sentinel nodes, please refer to Carcinoma Micromets testing.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Pan-TRK

Alternative Name
TRKA, TRKB, TRKC

Methodology
Immunohistochemistry (IHC)

Test Description
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.

Clinical Significance
NTRK 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/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. Testing for NTRK fusions identifies patients who may be candidates for NTRK inhibitor 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 & 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

New York Approved

Yes

Level of Service

Global

Turnaround Time

48 hours

References

1. Albert CM, Davis JL, Federman H, et al. TRK fusion cancers in children: A clinical review and recommendations for screening. *J Clin Oncol.*2018;doi: 10.1200/JCO.18.00573.
2. Rudzinski ER, Lockwood CM, Stohr BA, et al. Pan-Trk IHC identifies NTRK rearrangements in pediatric mesenchymal tumors. *Am J Surg Pathol.* 2018; 42(7):927-935
3. Hechtman JF, Benayed R, Hyman DM, et al. Pan-Trk IHC is an efficient and reliable screen for the detection of NTRK fusions. *Am J Surg Pathol.*2017;41(11):1547-1551.
4. Cocco E, Scaltriti M, Drilon A. NTRK fusion-positive cancers and TRK inhibitor therapy*Nat Rev Clin Oncol.* 2018;15:731-747.
5. Chen Y, Chi P. Basket trial of TRK inhibitors demonstrates efficacy in TRK fusion-positive cancers.*J Hematol Oncol.* 2018;11:78.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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).

PD-L1 22C3 test for other indications may be viewed.

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.
- For PD-L1 22C3 evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

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.

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.
- For PD-L1 22C3 evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

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

References

1. PD-L1 IHC 22C3 pharmDx [package insert]. Carpinteria, CA: Dako; P03951_11/SK00621-5/2019.08
2. KEYTRUDA® (pembrolizumab) [package insert]. Whitehouse Station, NJ: Merck & C o., Inc: uspi-mk3475-iv-1907r029

*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.

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).

PD-L1 22C3 test for other indications may be viewed.

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.
- For PD-L1 22C3 evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360 x 1

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

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

*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.

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.
- For PD-L1 22C3 evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

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

*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.

PD-L1 22C3 FDA (KEYTRUDA®) for TNBC (Breast)

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) triple-negative breast cancer (TNBC) tissue using EnVision FLEX visualization system on Autostainer Link 48. This test is indicated as an aid in identifying TNBC patients for treatment with KEYTRUDA® (pembrolizumab). Tissues with PD-L1 Combined Positive Score (CPS) ? 10 are considered positive.

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer's online interpretation training.

All PD-L1 IHC test options may be viewed here.

Clinical Significance
PD-L1 22C3 FDA (KEYTRUDA®) for TNBC is a companion diagnostic (CDx) for certain triple-negative breast cancer patients. PD-L1 expression with ?10% Combined Positive Score (CPS) may be associated with increased progression-free survival in patients with metastatic or advanced, locally unresectable TNBC treated with KEYTRUDA® and 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.
- For PD-L1 22C3 evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service

Stain Only, Global

Turnaround Time

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

References

1. PD-L1 IHC 22C3 pharmDx [package insert]. Carpinteria, CA: Dako; PT0020/Rev F.
2. KEYTRUDA® (pembrolizumab) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc; usmg-mk3475-iv-2011r036

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Please direct any questions regarding coding to the payor being billed.

PD-L1 22C3 FDA for NSCLC

Alternative Name
Formerly named PD-L1 22C3 FDA (KEYTRUDA®) for NSCLC

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) or LIBTAYO® (cemiplimab-rwlc). Results are considered positive for KEYTRUDA when Tumor Proportion Score (TPS) is ?1% and for LIBTAYO when TPS is ?50%.

PD-L1 22C3 tests for other indications may be viewed here.

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.
- For PD-L1 22C3 evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360 x 1

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

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

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Please direct any questions regarding coding to the payor being billed.

PD-L1 28-8 (OPDIVO®) for Gastric/GEJ/EAC

Alternative Name
PD-L1 28-8 (OPDIVO®) for Gastric/GEJ/Esophageal Adenocarcinoma

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) gastric carcinoma, gastroesophageal junction carcinoma (GEJ) and esophageal adenocarcinoma (EAC) tissues using EnVision FLEX visualization system on Autostainer Link 48. Although PD-L1 testing has not received the FDA-approval for these tumor types, the CHECKMATE 649 Study showed that OPDIVO® (nivolumab) in combination with chemotherapy demonstrated superior overall survival (OS) and progression-free survival (PFS) when compared to chemotherapy alone.

Tissues with PD-L1 Combined Positive Score (CPS) ? 5 are considered to have PD-L1 expression.

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer's online interpretation training.

All PD-L1 IHC test options 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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service

Global, Stain Only

Turnaround Time

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

Notes

1. Janjigian YY, Shitara K, Moehler M, et al. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. Lancet. 2021;398(10294):27-40.

*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.

PD-L1 28-8 FDA for NSCLC

Alternative Name
Formerly named PD-L1 28-8 FDA (OPDIVO® + YERVOY®) for NSCLC

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-small cell lung cancer (NSCLC) tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 28-8 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with OPDIVO® (nivolumab) or OPDIVO in combination with YERVOY® (ipilimumab). Results are considered positive for either treatment when PD-L1 is expressed in ?1% of tumor cells (TC).

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer's online interpretation training.

Please note: PD-L1 testing is not required for use of OPDIVO® in non-squamous NSCLC, head and neck squamous cell carcinoma or urothelial carcinoma, but may provide physicians more information and inform patient dialogue.

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.
- For PD-L1 28-8 evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

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

References

1. PD-L1 IHC 28-8 pharmDx [package insert]. Carpinteria, CA: Dako;

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Please direct any questions regarding coding to the payor being billed.

PD-L1 LDT

Methodology
Immunohistochemistry (IHC)

Test Description
Programmed cell death ligand 1 (PD-L1) is a transmembrane protein involved in cellular and humoral immune response regulation. PD-L1 expression has been found in a variety of cancers expressed on tumor and/or immune cells. This lab developed test uses the Zeta PD-L1 monoclonal antibody clone ZR3 to detect PD-L1 in formalin-fixed paraffin-embedded tissues. The utility of PD-L1 (ZR3) in predicting the response to anti-PD-1/PD-L1 has not been determined and no standardized scoring criteria currently exist. For therapies and indications that have an FDA-approved PD-L1 companion diagnostic, it is recommended to use the associated FDA approved PD-L1 test.

All PD-L1 IHC test options may be viewed here.

Scoring for this test is called "Total PD-L1 Expression" and is calculated by dividing the sum of the number of staining tumor cells and inflammatory cells by the total number of viable tumor cells. Results are reported as “detected” if the total score is ?1 and “not detected” if <1. This algorithm is comparable to Combined Positive Score used with PD-L1 22C3.

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.
- For PD-L1 LDT evaluation, tissue submitted must have ?100 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

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

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Please direct any questions regarding coding to the payor being billed.

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.

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.
- For PD-L1 SP142 evaluation, tissue submitted must have ?50 viable tumor cells present.

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

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

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

References

1. TECENTRIQ® [package insert]. South San Francisco, CA: Genentech, Inc.; Revised 7/2018

*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.

PD-L1 SP263 FDA for NSCLC

Methodology
Immunohistochemistry (IHC)

Test Description
The VENTANA PD-L1 (SP263) assay 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) non-small cell lung cancer (NSCLC) tissue on a VENTANA BenchMark ULTRA instrument. PD-L1 (SP263) is indicated as an aid in identifying NSCLC patients for treatment with TECENTRIQ® (atezolizumab) or LIBTAYO® (cemiplimab-rwlc). Results are considered positive for TECENTRIQ when tumors have PD-L1 expression on ? 1% of tumor cells (TC) at any intensity and positive for LIBTAYO when tumors have PD-L1 expression on ?50% of tumor cells (TC) at any intensity.

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.
- For PD-L1 SP263 evaluation, tissue submitted must have ?50 viable tumor cells present.

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

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

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

References

1. TECENTRIQ® [package insert]. South San Francisco, CA: Genentech, Inc.;

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time

24 hours

Notes

Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

PDGFB Rearrangement (22q13)

Alternative Name
Platelet-derived growth factor beta

Methodology
FISH

Test Description
Probe(s): PDGFB (22q13.1)
Disease(s): Dermatofibrosarcoma protuberans (DFSP)

Clinical Significance
Dermatofibrosarcoma protuberans (DFSP) commonly has the COL1A1-PDGFB fusion gene and other variants of PDGFB fusion that are related to DFSP pathogenesis and targeted therapies.

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.
- **Bone Marrow Aspirate:** N/A
- **Peripheral Blood:** N/A
- **Fresh, Unfixed Tissue:** N/A
- **Fluids:** N/A

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

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

New York Approved
No

Level of Service
Global, Technical

Turnaround Time
3-5 Days

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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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

PDGFRa Mutation Analysis

Alternative Name
PDGFR Alpha Mutation Analysis

Methodology
Molecular

Test Description
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.

PDGFRA Amplification by FISH is available for detection of PDGFRA amplifications, which occur in approximately 30% of pediatric and 20% of adult high-grade astrocytomas, and may have prognostic and/or therapeutic implications.

PDGFRA Rearrangement by FISH is also available for detection of FIP1L1-PDGFRA fusion, which may be found in myeloid/lymphoid neoplasms with eosinophilia. Bone marrow and peripheral blood are acceptable specimens.

Clinical Significance
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.

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

CPT Code(s)*
81314

New York Approved
No

Level of Service
Global

Turnaround Time

10 days

*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.

PDGFRA Rearrangement

Alternative Name
PDGFR Alpha Rearrangement

Methodology
FISH

Test Description
Probes: PDGFRA | CHIC2 | FIP1L1 (4q12)
Disease(s): Chronic eosinophilic leukemia, MPN

Clinical Significance
FISH for FIP1L1-PDGFRA 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.

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:** 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.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88312x1

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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; PR? and PRß. 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
  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 & 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)

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

PIK3CA LDT Mutation Analysis by Sequencing

Alternative Name
PI3K Mutation Analysis

Methodology
Molecular

Test Description
Bi-directional sequencing of PIK3CA exons 1, 9, and 20 which are the most commonly-mutated regions of the gene.

Clinical Significance
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.

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 & 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 81404; as of 01/01/2020 CPT Code 81309

New York Approved
No

Level of Service
Global

Turnaround Time
10 days

*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.

PIT1

Alternative Name
POU1F1, GHF-1, growth hormone factor-1

Methodology
Immunohistochemistry (IHC)

Test Description
PIT1 is a transcription factor critical in the normal development of the anterior pituitary. IHC staining of PIT1 is useful in the classification of pituitary adenomas of anterior pituitary origin. The staining pattern is nuclear.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 stand-alone testing is only available for tech-only. 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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 npanel since the standard number of events is collected.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

Plasma Cell Myeloma FISH Panel

Alternative Name
Multiple Myeloma-MGUS, MM-MGUS FISH Panel

Methodology
FISH

Test Description
Probes: 1p-, 1q+, iso(1q): CDKN2C (1p32), CKS1B (1q21) | +5, hyperdiploidy (5p15) | +9, hyperdiploidy (9q22) | +15, hyperdiploidy (15q22) | 13q- (13q14, 13q34) | IgH (14q32) | 17p- (TP53 17p13.1, NF1 17q11.2)
Probes may be ordered separately except +5, +9 and +15 which are combined.
Global cases with IgH rearrangement will automatically reflex to the Plasma Cell Myeloma IgH Complex FISH Panel unless client has opted out.
Disease(s): Plasma cell myeloma, multiple myeloma
Note: Plasma cell enrichment will be performed on bone marrow 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.

Clinical Significance
The panel is used 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:** Plasma cell enrichment was not validated using peripheral blood; therefore, it is 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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 5 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slide:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days. Add 3-5 days if reflexed.

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Please direct any questions regarding coding to the payor being billed.

Plasma Cell Myeloma IgH Complex FISH Panel

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 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.

Clinical Significance
The 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), t(14;16) and t(14;20) are found in approximately 35% of myelomas and in 90% of myelomas when there is an IgH gene rearrangement present.

To learn more about the importance of FISH testing with plasma cell enrichment in multiple myeloma, please visitMultiple Myeloma Cytogenetic Analysis resource page.

Specimen Requirements
- **Bone Marrow Aspirate**: 1-2mL Sodium Heparin Tube. EDTA tube is acceptable
- **Peripheral Blood:** Plasma cell enrichment was not validated using peripheral blood; therefore, it is 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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 4 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slide:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

Plasma Cell Myeloma Prognostic FISH Panel

Alternative Name
PCM Prognostic Panel

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 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.

Clinical Significance
This panel may be useful for prognostic purposes. It has predominantly non-favorable prognostic markers with the exception of t(11;14) which is generally considered to be a standard risk and may help guide therapy.

To learn more about the importance of FISH testing with plasma cell enrichment in multiple myeloma, please visitMultiple Myeloma Cytogenetic Analysis resource page.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** Plasma cell enrichment was not validated using peripheral blood; therefore, it is 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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 7 slides labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slide:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & 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

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

Ploidy FISH for Molar Pregnancy

Alternative Name
CEN1/CEN11

Methodology
FISH

Test Description
Probes: Centromere 1 (1p11.1-q11.1) | Centromere 11 (11q12)
Disease(s): Complete molar pregnancy vs. partial mole
This test is available on a global basis only.

Clinical Significance
Ploidy FISH for Molar Pregnancy analyzes copy number of the chromosome 1 centromere and chromosome 11 centromere to assess triploidy (associated with partial molar pregnancy) vs. diploidy (associated with complete molar pregnancy when pathology is consistent).This is an indirect analysis of products of conception (POC) ploidy based on the assumption that trisomy 1 along with trisomy 11 indicates triploidy. An isolated trisomy 1 is extremely rare event and trisomy 11 is an almost negligible incidence; therefore the presence of a combination of the two in the absence of triploidy is expected to be a nearly non-existent event.

Specimen Requirements
- **Bone Marrow Aspirate:** N/A
- **Peripheral Blood:** N/A
- **Fresh, Unfixed Tissue:** N/A
- **Paraffin Block:** H&E slide (required) plus paraffin block.
- **Cut Slides:** H&E slide (required) plus 4 unstained slides cut at 4-5 microns.
- **Note:** Specimen must contain villi and/or fetal tissue.

Storage & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

5 days

*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.

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 (MRD), and for detection of relapse

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

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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 <7 days old preferred.

CPT Code(s)*
81315

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

*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.

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin Block or Cut Slides:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

4 days. STAT results are reported 12-24 hours from receipt in the NeoGenomics laboratory.

*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.

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 & 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)

New York Approved
Yes

Level of Service
Image Analysis, Stain Only, Global

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

*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.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

*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.

PRAME

Methodology
Immunohistochemistry (IHC)

Test Description
PRAME (PReferentially expressed Antigen in MElanoma) is expressed in about 90% among melanoma subtypes, while negative in about 85% of cutaneous melanocytic nevi. Immunohistochemical analysis of PRAME may be useful for diagnostic purposes to support diagnosis of melanoma.

Clone: EPR20330
Staining pattern: Nuclear

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
- **Note:** Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 Hours

References

1. Lezcano, C. et al. PRAME Expression in Melanocytic Tumors. *Am J Surg Pathol.* 2018 Nov;42(11):1456-1465.

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

Prostate NGS Fusion Panel

Alternative Name
Prostate Fusion Panel

Methodology
Molecular

Test Description
The Prostate NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ACSL3, BRAF, CANT1, DDX5, ERG, ESRP1, ETV1, ETV4, ETV5, EWSR1, FLI1, FOXP1, HERPUD1, HMGN2P46, HNRNPA2B1, KLK2, KRAS, NDRG1, NTRK1, NTRK2, NTRK3, RAF1, RET, SLC45A3, SNURF, TMPRSS2, and UBTF.

Clinical Significance
The Prostate NGS Fusion Panel is intended to detect gene fusions associated with prostate cancer to aid in diagnosis and prognosis of the disease.

Gene fusions play critical roles in the development and progression of prostate cancer, and have been used as molecular biomarkers for diagnosis of the malignant disease. Approximately 50%-60% of prostate cancers harbor recurrent gene fusions, typically involving members of the ETS family of transcription factors (ERG, ETV1, ETV4, and ETV5). TMPRSS2-ERG is the most common fusion in prostate cancer, serving as a driver of prostate cancer progression. NTRK fusions are rare, but testing is of high interest due to possible treatment with specific TRK inhibitors (entrectinib, larotrectinib).

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81449

New York Approved
Yes

Level of Service

Global

Turnaround Time

21 Days

References

1. Yang J. et al. Identification and characterization of novel fusion genes in prostate cancer by targeted RNA capture and next-generation sequencing. *Acta Biochimica et Biophysica Sinica*, Vol 50, Iss 11, November 2018, Pages 1166–1172, https://doi.org/10.1093/abbs/gmy112
2. Song, C., Chen, H. Predictive significance of TMRPSS2-ERG fusion in prostate cancer: a meta-analysis.*Cancer Cell Int* 18, 177 (2018). https://doi.org/10.1186/s12935-018-0672-2

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

CPT Code(s)*
88344 x 1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

PSAP/HPAP

Alternative Name
Prostate Acid Phosphatase

Methodology
Immunohistochemistry (IHC)

Test Description
Prostate specific acid phosphatase/human prostatic acid phosphatse (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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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, and may be observed in Cowden syndrome tumors. 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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time
3-5 days

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Please direct any questions regarding coding to the payor being billed.

PTH

Alternative Name
Parathyroid Hormone

Methodology
Immunohistochemistry (IHC)

Test Description
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 & hypo-parathyroidism.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

Rapid AML Therapeutic Panel

Alternative Name
Rapid AML Panel

Methodology
FISH

Molecular

Test Description
The Rapid AML Therapeutic Panel analyzes 13 biomarkers through a combination of bi-directional Sanger sequencing, PCR, and FISH as listed below.

- Sanger sequencing (1 gene): TP53
- PCR/Fragment Analysis (5 genes): FLT3 (ITD and TKD), IDH1/IDH2, NPM1, and CEBPA
- FISH probes: 5q-, -5 (5p15, 5q31, 5q33) | 7q-, -7 (Cen 7, 7q22, 7q31) | RUNX1/RUNX1T1 (ETO/AML1) t(8;21) | MLL (11q23) | PML/RARA t(15;17) | CBFB inv(16), t(16;16) | 17p- (TP53 17p13.1, NF1 17q11.2)

Test reports include a summary of all results together.

Clinical Significance
The Rapid AML Therapeutic Panel identifies genetic abnormalities associated with Acute Myeloid Leukemia (AML) that are useful for risk stratification and therapeutic decision making. This panel utilizes a combination of bi-directional Sanger sequencing, PCR and FISH with a fast turnaround time. AML is usually an in-patient hematologic diagnosis and prompt time to treatment assignment can improve patient outcomes significantly.

Specimen Requirements
- **Bone Marrow Aspirate:** 2-3 mL sodium heparin tube. EDTA tube is acceptable.
- **Peripheral Blood:** 3-5 mL sodium heparin tube. EDTA tube is acceptable.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Note: Test in DNA-based, suitable for Freeze & Hold option.

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

CPT Code(s)*
Molecular: Client-bill only, if ordered concurrently with Neo Comprehensive™ – Myeloid Disorders, or one of the NeoTYPE® Heme Profiles, such as Myeloid Disorders Profile, AML Prognostic Profile, or MDS/CMML Profile. See Notes if ordered alone.

New York Approved

No

Level of Service

Global

Turnaround Time

4-5 Days for FLT3, IDH1/IDH2, and FISH. 7-10 Days for NPM1, CEBPA, and TP53.

Notes

If ordered alone: 81245x1, 81246 x1, 81310 x1, 81218 x1, 81120 x1, 81121 x1, 81405 x1. FISH: 88374x7

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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.
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin block or cut slides:** Not available.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

RAS/RAF Panel

Alternative Name
RAS Mutation Analysis, RAF Mutation Analysis, RAS RAF, RAS RAF Panel

Methodology
Molecular

Test Description
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).

Clinical Significance
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.

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

CPT Code(s)*
81404 - HRAS, 81405 - KRAS, 81406 - BRAF, 81479 - NRAS

Medicare MolDX CPT Code(s)*
81479

New York Approved
Yes

Level of Service
Global

Turnaround Time

10-14 days

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88360 x1

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

RET FISH

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 & 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

Reticulin

Alternative Name
Reticular Nuclear Fast Red Stain

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Rhabdomyosarcoma NGS Fusion Panel

Alternative Name
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 & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

21 days

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

ROS1

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:** 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 & 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.

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time
3-5 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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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 (MRD). 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.

Note: Test is RNA-based, NOT suitable for Freeze & Hold option.

Storage & 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

New York Approved
No

Level of Service
Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

RUNX1T1/RUNX1 (ETO/AML1) t(8;21)

Alternative Name
AML1-ETO

Methodology
FISH

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
- **Bone Marrow/ Peripheral Blood Smear or Fresh Tissue Touch Preparation Slides:** minimum 1 slide labeled with specimen type.
- **Fluids:** Equal parts RPMI to specimen volume.
- **Fixed Cell Suspension:** A client fixed cell suspension may be submitted for testing as long as it is received in 3:1 Methanol:Glacial Acetic Acid.
- **Paraffin or Cut Slides:** N/A
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Refrigerate specimen. Do not freeze. Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Salivary Gland NGS Fusion Panel

Alternative Name
Salivary Gland Fusion Panel

Methodology
Molecular

Test Description
The Salivary Gland NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ARID1A, ATF1, CRTC1, CRTC3, DDX3X, ETV6, EWSR1, HMGA2, MAML1, MAML2, MYB, MYBL1, MYH9, NCOA4, NFIB, NTRK1, NTRK2, NTRK3, PLAG1, PRKD1, PRKD2, PRKD3, RET, and USP6.

Clinical Significance
The Salivary Gland NGS Fusion Panel detects gene fusions that may aid in the classification of the disease and selection of patients for available therapies.

Salivary gland tumors have been reported to harbor gene fusions, such as ETV6-NTRK3, MYB-NFIB, EWSR1-ATF1, CRTC1-MAML2, and CRTC3-MAML2. Studies suggest these fusions could be therapeutic targets.

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81449

New York Approved
Yes

Level of Service
Global

Turnaround Time

21 Days

References

1. Inaki R, Abe M, Zong L, et al. Secretory carcinoma - impact of translocation and gene fusions on salivary gland tumor. *Chin J Cancer Res.* 2017;29(5):379-384. doi:10.21147/j.issn.1000-9604.2017.05.01

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Sarcoma Comprehensive NGS Fusion Panel

Alternative Name
NGS Comprehensive Sarcoma Fusion Profile

Methodology
Molecular

Test Description
The Sarcoma Comprehensive NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ACTB, AHRR, ALK, ASPSCR1, ATF1, ATIC, BCOR, BRAF, C11orf95, CAMTA1, CARS1, CCNB3, CDH11, CIC, CLTC, CNBP, COL1A1, COL1A2, CREB1, CREB3L1, CREB3L2, CSF1, CTNNB1, DDIT3, DUX4, EML4, EPC1, ERG, ETV1, ETV4, ETV6, EWSR1, FEV, FLI1, FOXO1, FRK, FUS, GLI1, HAS2, HEY1, HMGA2, IL2RB, ITK, JAZF1, LMNA, LPP, MEAF6, MRTFB, MYH9, MYLK, NAB2, NCOA1, NCOA2, NFATC2, NFIB, NR4A3, NTRK1, NTRK2, NTRK3, NUTM2A, NUTM2B, OMD, PAX3, PATZ1, PAX7, PBX1, PDGFB, PDGFRB, PHF1, PLAG1, POU5F1, RAD51B, RANBP2, ROS1, SEC31A, SRF, SS18, SSX1, SSX2, SSX4B, STAT6, SUZ12, SYK, TAF15, TCF12, TEAD1, TFE3, TFG, THRAP3, TPM3, TPM4, USP6, WT1, WWTR1, YAP1, YWHAE and ZNF444.

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.

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

CPT Code(s)*
81456

Medicare MolDX CPT Code(s)*
81449

New York Approved

Yes

Level of Service

Global

Turnaround Time

21 days

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Please direct any questions regarding coding to the payor being billed.

SAT B2

Alternative Name
SATB2

Methodology
Immunohistochemistry (IHC)

Test Description
SATB2 stains colonic and osteogenic cells and their 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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)

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 palladium 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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

3-5 days

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Please direct any questions regarding coding to the payor being billed.

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:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

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

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Surgical Pathology Consultation

Alternative Name
Pathology consults, second opinions, morphology consults

Methodology
Immunohistochemistry (IHC)

In Situ Hybridization (ISH)

Molecular

Morphologic Evaluation

Test Description
A NeoGenomics pathologist will select medically necessary tests, with any exceptions noted by the client, to provide comprehensive analysis and a final pathology diagnosis for histologic slides and FFPE materials submitted.

Clinical Significance
- Send relevant consult material including:
  - H&E stained slides
  - Appropriate histochemical and/or immunostained slides
  - Pathology report (Final or Preliminary)
  - Patient demographic and insurance information
- FFPE Tissue Blocks (formalin fixed, paraffin embedded) containing lesional tissue (preferred)
  - 10 unbaked, positively charged unstained slides for staining (cut at 4-5 microns) may be submitted as a backup option to tissue blocks. Please note that delays may occur if additional material is needed.
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

CPT Code(s)*
Refer to individual tests for CPT Code(s)

New York Approved
Yes

Level of Service
Global

Turnaround Time

3-5 Days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 neeeded.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

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 stand-alone testing is only available for tech-only. 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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

T-ALL Follow-Up Flow Panel

Alternative Name
T-Cell Acute Lymphoblastic Leukemia/Lymphoma Follow-Up 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 CD1a , CD2, CD3, cCD3, CD4, CD5, CD7, CD8, CD11b, CD19, CD38, CD43, CD45, CD56, cMPO, and nTDT (16 markers).

Clinical Significance
For T-cell acute lymphocytic leukemia (T-ALL) monitoring after diagnosis is established. This is not a minimal residual disease panel since the standard number of events is collected.

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL EDTA. &Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved

Yes

Level of Service

Technical, Global

Turnaround Time

24 hours

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Please direct any questions regarding coding to the payor being billed.

T-Cell Receptor Beta Gene Rearrangement

Alternative Name
T-Cell Clonality Assessment (Beta)

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 ~10% 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 with at least 5mm2 of tissue size is preferred. Alternatively, send 1 H&E slide plus 4-5 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. Note: not suitable for Freeze & Hold option.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Note: Test in DNA-based, suitable for Freeze & Hold option, except for Fresh Tissue samples.

Storage & Transportation
For fresh specimens, use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81340

New York Approved
Yes

Level of Service

Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

T-Cell Receptor Gamma Gene Rearrangement

Alternative Name
T-Cell Gamma Gene Rearrangement, TCRG

Methodology
Molecular

Test Description
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.

Clinical Significance
Detects monoclonal T-cell receptor gamma gene rearrangement. Interpret 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 4-5 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. Note: not suitable for Freeze & Hold option.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Note: Test in DNA-based, suitable for Freeze & Hold option, except for Fresh Tissue samples.

Storage & 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

New York Approved
Yes

Level of Service
Global

Turnaround Time

7 days

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Please direct any questions regarding coding to the payor being billed.

Targeted Solid Tumor NGS Fusion Panel

Alternative Name
Targeted Solid Tumor Fusion Panel

Methodology
Molecular

Test Description
The Targeted Solid Tumor NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ALK, BRAF, FGFR1, FGFR2, FGFR3, FGFR4, MET including MET Exon 14 skipping, NOTCH1, NOTCH2, NRG1, NTRK1, NTRK2, NTRK3, PDGFB, PDGFRA, PDGFRB, RAF1, RET, and ROS1.

Clinical Significance
Gene fusion events that deregulate protein expression or generate a chimeric protein are associated with the pathology of several cancer types. The Targeted Solid Tumor NGS Fusion Panel is intended to identify gene fusions that have been reported as oncogenic drivers in multiple solid tumors, including but not limited to NSCLC, urothelial carcinoma, cholangiocarcinoma, and thyroid carcinoma. Patients with the gene fusions may respond to select kinase inhibitors that have been approved by the FDA, including crizotinib, ceritinib, imatinib, larotrectinib, entrectinib, pemigatinib, and selpercatinib.

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81449

New York Approved
Yes

Level of Service
Global

Turnaround Time

21 Days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

TCL1 ***

Alternative Name
T-cell leukemia 1

Methodology
FISH

Test Description
Probes: TCL1 (14q32.1)
Disease(s): mature T-cell leukemia, T-cell prolymphocytic leukemia (T-PLL), adult T-cell leukemia/lymphoma (ATLL)

Clinical Significance
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.

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). ****** Testing on this specimen type is not yet available for NY specimens.******
- **Cut slides:** H&E slide (required) plus 4 unstained slides cut at 4-5 microns. Circle H&E slide for tech-only.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen. For fresh samples: ship same day as drawn whenever possible; specimens <72 hours old preferred.

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

New York Approved
Yes

Level of Service

Technical, Global

Turnaround Time

3-5 days for unfixed or FFPE specimens

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TCR Delta

Methodology
Immunohistochemistry (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 & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88342x1 or 88341x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

TCR?F1

Methodology
Immunohistochemistry (IHC)

Test Description
T Cell Receptor beta (TCR?) is used as a phenotypic marker for TCR? expressing T-cells. TCR? is expressed by thymocytes and a majority of peripheral (?/? TCR-bearing) T-cells. This antibody does not cross-react with ?/? 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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TdT (Terminal Deoxynucleotidyl Transferase)

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
No

Level of Service

Global

Turnaround Time

14 days

*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.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

TFE3 Rearrangement

Alternative Name
Transcription factor E3

Methodology
FISH

Test Description
Probe(s): TFE3 (Xp11.2)
Disease(s): Renal cell carcinoma (RCC), alveolar soft part sarcoma (ASPS)

Clinical Significance
Chromosome Xp11.2 translocations causing TFE3 gene rearrangement and fusions define the "MiT family translocation RCC" category in the 2016 WHO renal call carcinoma classification. Alveolar soft part sarcoma (ASPS) is a rare soft tissue tumor caused by balanced or unbalanced translocation between TFE3 and the ASPL gene on chromosome 17. FISH may be used to diagnose RCC subtype and ASPS, and FISH has been reported to be more reliable in detecting translocations than TFE3 IHC.

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

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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

5 days 3 for tech-only

References

1. Argani P. *Semin Diagn Pathol.* 2015:32(2):103-13.
2. Pei J et al. *Mod Pathol.* 2019;32:710-716.
3. Pradhan D et al. *Diagn Pathol.* 2015;10:179+.

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Thyroid NGS Fusion Panel

Alternative Name
Thyroid Fusion Panel

Methodology
Molecular

Test Description
The Thyroid NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ALK, AXL, BRAF, CCND1, FGFR1, FGFR2, FGFR3, GLIS3, MET, NRG1, NTRK1, NTRK2, NTRK3, PAX8, PPARG, RAF1, RET, ROS1, and THADA.

Clinical Significance
The Thyroid NGS Fusion Panel is intended to detect gene fusions associated with thyroid cancer to aid in diagnosis, disease classification, prognosis, and therapy selection.

The spectrum and prevalence of gene fusions in thyroid cancer ranges from single cases up to 80%, depending on the specific type of cancer. Fusions of tyrosine kinases activating the MAPK pathway, such as RET, BRAF, NTRK1, NTRK2, NTRK3, and ALK, can be found in 6-46% of sporadic papillary thyroid carcinoma (PTC) while PPARG and THADA gene fusions are found dominantly in follicular thyroid carcinoma, follicular adenomas, and follicular variants of PTC. Medullary thyroid carcinoma (MTC) cells harbor RET and ALK gene fusions. While RET mutations are the primary drivers of medullary thyroid carcinoma (MTC), ALK and RET fusions have been reported. For radioactive iodine (RAI)-refractory thyroid cancer, several FDA-approved tyrosine kinase inhibitors have shown efficacy in improving progression-free survival, including sorafenib and lenvatinib for progressive DTC, and vandentanib and cabozantinib for MTC.

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

CPT Code(s)*
81449

Medicare MolDX CPT Code(s)*
81449

New York Approved
Yes

Level of Service

Global

Turnaround Time

21 Days

References

1. Yakushina VD, Lerner LV, Lavrov AV. Gene Fusions in Thyroid Cancer. *Thyroid*. 2018 Feb;28(2):158-167. doi: 10.1089/thy.2017.0318. PMID: 29281951.

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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
  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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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Please direct any questions regarding coding to the payor being billed.

TP53 Mutation Analysis

Alternative Name
TP53 Gene Sequencing

Methodology
Molecular

Test Description
Bi-directional sequencing of TP53 exons 4-9.

Clinical Significance
The TP53 gene encodes the tumor suppressor p53. TP53 mutations are detected in at least 50% of all adult tumors and are generally associated with a poor prognosis. For patients with chronic lymphocytic leukemia (CLL), TP53 sequencing, in addition to FISH for 17p deletion, aids in prognosis and/or therapy selection. Germline mutations in TP53 are the cause of Li-Fraumeni Syndrome.

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

CPT Code(s)*
81352 (as of 01/01/2021); Prior to CPT Code was 81405

New York Approved
No

Level of Service
Global

Turnaround Time
7 days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service

Global, Technical

Turnaround Time

3-5 days

References

1. Pedersen MB et al. DUSP22 and TP63 rearrangements predict outcome of ALK-negative anaplastic large cell lymphoma: a Danish cohort study. *Blood*. 2017;130:554-557.
2. Parrilla Castellar ER et al. ALK-negative anaplastic large cell lymphoma is a genetically heterogeneous disease with widely disparate clinical outcomes. *Blood*. 2014;124:1473-80.
3. Vasmatzis G et al. Genome-wide analysis reveals recurrent structural abnormalities of TP63 and other p53-related genes in peripheral T-cell lymphomas. *Blood*. 2012;120:2280-2289.
4. Scott DW et al. TBL1XR1/TP63: a novel recurrent gene fusion in B-cell non-Hodgkin lymphomas. *Blood*. 2012;119 4949-4952.

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Please direct any questions regarding coding to the payor being billed.

TRAcP

Alternative Name
Tartrate Resistant Acid Phosphatase, TRAP

Methodology
Immunohistochemistry (IHC)

Test Description
TRAP IHC is of use in the identification of hairy cell leukemia, but it is not a completely specific marker.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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TRBC1/LGL Add-On Flow Panel

Alternative Name
T-Cell Receptor/Large Granular Lymphocyte (TCR/LGL) 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 stand-alone testing is only available for tech-only. Markers are CD3, CD4, CD7, CD8, CD16, CD45, CD56, CD57, TRBC1, and TCR gamma/delta (10 markers).

Clinical Significance
This panel evaluates aberrant immunophenotypic expression of LGLs and NK cells. TRBC1 is a reliable means to identify T-cell clonality. CD1a and CD30 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 & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

TRBC1/T-Cell Lymphoma Companion 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, CD279, and TRBC1 (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 (including Mycosis fungoides/Sézary syndrome, anaplastic large cell lymphoma, angioimmunoblastic T cell lymphoma, etc.).

Specimen Requirements
- **Bone Marrow Aspirate:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Peripheral Blood:** 1-2 mL EDTA. Sodium heparin is acceptable. Lithium heparin or ACD (pale yellow/no gel separator) is not acceptable. Please provide recent CBC report.
- **Fresh Bone Marrow Core Biopsy:** 1-2cm core (length) tissue in RPMI
- **Fresh/Unfixed Tissue:** 0.2 cm3 minimum in RPMI
- **Fluids and FNAs:** Equal parts RPMI and specimen volume
- **CSF:** 1-2 mL recommended
- **NY Clients:** Please provide Date and Time of Collection.
- **Note:** Please exclude biopsy needles, blades, and other foreign objects from transport tubes. These can compromise specimen viability and yield, and create hazards for employees.

Storage & Transportation
Specimens should be received at NeoGenomics within 72 hours from collection to assure sample integrity and acceptable cell viability. Note: New York State samples must be received within 48 hours from collection per NYS requirements. 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.

New York Approved
Yes

Level of Service
Technical, Global

Turnaround Time

24 hours

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

CPT Code(s)*
88342 x1 or 88341 x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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TS (Thymidylate Synthase)

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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)

New York Approved
Yes

Level of Service
Stain Only, Global

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

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Please direct any questions regarding coding to the payor being billed.

TSH

Alternative Name
Thyroid Stimulating Hormone

Methodology
Immunohistochemistry (IHC)

Test Description
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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

Notes
Global prognostic interpretation is available (TAT is 48 hours)

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TTF1

Alternative Name
Thyroid Transcription Factory

Methodology
Immunohistochemistry (IHC)

Test Description
Thyroid Transcription Factory (TTF1) is found 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.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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. Please note this antibody is reactive with other Mycobacterium species including: M. avium, M. phlei, and M. parafortuitum.

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 & 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

New York Approved
Yes

Level of Service
Stain Only, Global

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

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

Universal Solid Tumor NGS Fusion Panel

Alternative Name
Universal Solid Tumor Fusion Panel

Methodology
Molecular

Test Description
The Universal Solid Tumor NGS Fusion Panel is an RNA-based next-generation sequencing panel that detects translocations and fusions with known and novel fusion partners of these genes: ABL1, ACSL3, ACTB, ACTL6A, AFDN, AFF1, AFF3, AFF4, AHRR, AKAP9, AKT3, ALK, AR, ARID1A, ASPSCR1, ATF1, ATIC, AXL, BCOR, BCR, BRAF, BRCA1, BRCA2, BRD4, C11orf95, CAMTA1, CANT1, CAPZA2, CARS1, CBFA2T3, CCDC170, CCDC6, CCNB3, CCND1, CCND2, CCND3, CD274, CD74, CDH11, CDK4, CDK6, CDKN2D, CHCHD7, CIC, CIITA, CLTC, CNBP, COA5, COL1A1, COL1A2, CREB1, CREB3L1, CREB3L2, CREBBP, CRTC1, CRTC3, CSF1, CTLA4, CTNNB1, CTNNBL1, DDIT3, DDX3X, DDX5, DHH, DNAJB1, DUX4, EGFR, EGFRvIII, ELK4, ELL, EML4, EPC1, EPS15, ERBB2, ERG, ESR1, ESRP1, ETV1, ETV4, ETV5, ETV6, EWSR1, EZR, FAM131B, FEV, FGFR1, FGFR2, FGFR3, FGFR4, FLI1, FLT3, FOXO1, FOXP1, FRK, FUS, GLI1, GLIS1, GLIS2, GLIS3, GNAS, GOPC, HAS2, HERPUD1, HEY1, HIP1, HMGA2, HMGN2P46, HNRNPA2B1, IL2RB, IRF4, ITK, JAK2, JAZF1, KAT6A, KDM5A, KIAA1549, KIF5B, KIT, KLK2, KMT2A, KNL1, KRAS, LIFR, LMNA, LPP, MAML1, MAML2, MAST1, MAST2, MEAF6, MET, MET Exon 14 skipping, MKRN1, MLLT1, MLLT10, MLLT11, MLLT3, MN1, MPRIP, MRTFB, MSH2, MYB, MYBL1, MYC, MYH9, MYLK, NAB2, NCOA1, NCOA2, NCOA4, NDRG1, NFATC2, NFIB, NOTCH1, NOTCH2, NPM1, NR4A3, NRG1, NTRK1, NTRK2, NTRK3, NUP214, NUP98, NUTM1, NUTM2A, NUTM2B, OMD, PAN3, PATZ1, PAX3, PAX7, PAX8, PBX1, PCM1, PDGFB, PDGFRA, PDGFRB, PHF1, PIK3CA, PLAG1, PML, POU5F1, PPARG, PRCC, PRKACA, PRKAR1A, PRKD1, PRKD2, PRKD3, PTPRK, RAD51B, RAF1, RANBP2, RARA, RASGEF1A, RET, RHEBL1, ROS1, RPS6KC1, RSPO3, RUNX1, RUNX1T1, SDC4, SEC31A, SEPTIN6, SEPTIN9, SET, SLC34A2, SLC45A3, SND1, SNURF, SRF, SRGAP3, SS18, SSX1, SSX2, SSX4B, STAT6, STIL, STRN, SUZ12, SYK, TACC3, TAF15, TAL1, TBL1XR1, TCF12, TCF3, TCF7L2, TEAD1, TEAD2, TEAD3, TFE3, TFG, THADA, THRAP3, TMPRSS2, TP63, TPM3, TPM4, TPR, TRIM24, UBTF, USP6, VTI1A, WDFY2, WIF1, WT1, WWTR1, YAP1, YWHAE, and ZNF444 (total 250 genes and 2 variants).

Clinical Significance
Genomic rearrangements called gene fusions are present in approximately 20-30% of all cancers. Identification of translocations can be useful for diagnosis, disease sub-classification, and therapy determination.

The Universal Solid Tumor NGS Fusion Panel detects gene fusions across multiple solid tumors, including lung, brain, breast, thyroid, salivary gland, prostate, sarcoma, colorectal, cholangiocarcinoma, and pancreas. Compared to FISH, molecular detection of gene fusions, as provided in this test, requires less tumor sample for a much broader and therefore more cost-effective screen.

This test should be considered for difficult-to-diagnose tumors of uncertain histogenesis, particularly in younger patients (<50 years of age).

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 & Transportation

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

CPT Code(s)*

81456

Medicare MolDX CPT Code(s)*

81449

New York Approved

Yes

Level of Service

Global

Turnaround Time

21 Days

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Please direct any questions regarding coding to the payor being billed.

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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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Please direct any questions regarding coding to the payor being billed.

USP6 Rearrangement

Alternative Name
Ubiquitin specific peptidase 6

Methodology
FISH

Test Description
Probe(s): USP6 (17p13.2)
Disease(s): Nodular fasciitis, aneurysmal bone cysts

Clinical Significance
USP6 gene rearrangements (fusions) are commonly found in nodular fasciitis (NF), aneurysmal bone cysts (ABC), myositis ossificans (MO), fibro-osseous pseudotumor of digit (FOTD), and fibroma of tendon sheath. Presence of a USP6 rearrangement can serve as a valuable marker for differentiating these neoplasms, many of which are self-limiting, from other neoplasms and malignancies with similar histological appearance.

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.
- **Reminder about decalcified specimens:** Testing will be attempted but most decalcification solutions are incompatible with FISH. Limited acid decalcification (<24 hours) in 5% formic acid or EDTA decalcification may better preserve DNA for FISH.

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

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

New York Approved
Yes

Level of Service
Global, Technical

Turnaround Time

5 days 3 for tech-only

References

1. Hiemcke-Jiwa L, van Gorp JM, Fisher C, et al. USP6-associated neoplasms: A rapidly expanding family of lesions.*Int J Surg Path*. 2020;28(8):816-825.

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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 & 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

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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
  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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 histocytomas, 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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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

CPT Code(s)*
88313x1

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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 & 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

New York Approved
Yes

Level of Service
Stain Only

Turnaround Time
24 hours

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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.

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