Pediatric Oncology & Pathology Services

Diagnostic, Prognostic, Predictive, and Predisposition Testing

Molecular
FISH
Anatomic Pathology

Flow Cytometry
Cytogenetics
Pharma Services

NEO GENOMICS
**Pediatric Oncology & Pathology Services**

Neogenomics Laboratories is fully focused on propelling cancer diagnostics and research forward. Innovation and quality are two of our core company values. We fulfill them in two main ways:

- We provide unique, efficient multi-method cancer reference testing services that respect the time and cost pressures of these critical patient care situations.

- We put the highest priority on anticipating, creating, and continually improving a business that is a true partner to cancer care practitioners and researchers in academia and industry. From test development to specimen transport, client services, billing, and throughout the organization, we pay close attention to what our patients and customers need and want.

Pediatric oncology needs and deserves the best clinical diagnostic and research partners available. Molecular technology and immuno-oncology are providing new opportunities that, in combination with strong traditional diagnostics, are leading to significant progress. Neogenomics is CAP-accredited, CLIA-certified laboratory providing the full spectrum of cancer reference services: consultation, flow cytometry, IHC, cytogenetics, FISH, and molecular analysis. With 15 years’ experience serving pathologists and oncologists in all types of cancer, Neogenomics is renewing its focus on pediatric cancer to provide the best of these tools to the cancer community.

“The molecular and biological characteristics of pediatric cancers are different from those in adult cancer. Our mission is to define these characteristics and to help physicians to better treat and manage these cancers.”

Maher Albitar, MD

SVP, Chief Medical Officer & Director of R & D at Neogenomics
NeoGenomics' Advantages

Here are some of the reasons clients choose NeoGenomics.

• **Comprehensive**: We have expertise in all methodologies of cancer reference testing; molecular testing, FISH, IHC/ISH, cytogenetics, and flow cytometry. We also cover all hematologic and solid tumor cancer diagnoses. Having all techniques available in one lab allows efficiency in ordering, shipping, tracking, and reporting; most effective use and test prioritization on small specimens; and potential for better case coordination with reduced turnaround times.

• **Complete**: Our services are not just broad, but also deep with more than 600 orderable tests.
  - Most comprehensive molecular oncology menu in the US with over 155 tests for diagnostic, prognostic, predictive, and hereditary predisposition indications.
  - 10-color flow cytometry with numerous full panels and follow-up ‘short panel’ options.
  - Extensive libraries of heme FISH panels, solid tumor FISH probes, and IHC stains.

• **Liquid biopsy**: Options to bone marrow biopsy are especially important for pediatric patients. Our biopsy-free analyses target circulating hematologic or solid tumor DNA or RNA in easily-collected peripheral blood samples. We offer 14 hematologic disease liquid biopsies, and a 48-gene pan-cancer solid tumor profile.

• **COG Certification in Cytogenetics**: Confirming NeoGenomics’ high standards of quality in technical analysis and laboratory operations, we are certified to perform cytogenetics for the Children’s Oncology Group. We are actively preparing for certification in flow cytometry.

• **Rapidly-evolving test menu**: With one of the most rapid test development cycles in the industry, NeoGenomics quickly develops diagnostics for newly-recognized biomarkers and adapts to new and changed clinical guidelines. In the years 2015-2017, we launched or enhanced over 150 tests.

• **Ease of access**: Our professional staff and support services are available at any time. Throughout our growth, we have worked to maintain 'small lab' approachability and to make quick connections between our clients and our internal medical and technical team members.

• **Tech-only programs for pathologists**: Client pathologists working with NeoGenomics may choose to review and sign out flow cytometry, FISH, and/or IHC cases through our extensive technical-only or "TC/PC" program. Tech-only services are supported by live and recorded training, easy-to-follow User's Guides, custom reporting options, and a "push to global" option to refer especially complicated cases back to NeoGenomics pathologists for reporting.

• **Pharma Services**: Flexibility and rapid response all hallmarks of our Pharma Services. We support academic and industry researchers in all size and scope of projects. Commercial development efforts are simplified by access to our multiple CAP-accredited, CLIA-certified domestic labs as well as our European laboratory.
Pediatric Testing Highlights

As we frequently add new tests and enhance existing ones, please see our website to view the most current menu and to sign up for new test notifications. Here are selected tests in the most common pediatric cancer indications.

Leukemia, Lymphoma & Myeloid Disorders

Selected Testing Indications:

• Acute lymphoblastic leukemia (ALL)
• Acute myeloid leukemia (AML)
• Acute promyelocytic leukemia (APL)
• Anaplastic large cell lymphoma (ALCL)
• Burkitt lymphoma
• Chronic myeloid leukemia (CML)
• Diffuse large B-cell lymphoma (DLBCL)
• Follicular lymphoma
• Hairy cell leukemia (HCL)
• Hodgkin lymphoma
• Juvenile myelomonocytic leukemia (JMML)
• Large granular lymphocytic (LGL) leukemia
• MALT lymphoma
• Mantle cell lymphoma (MCL)
• Marginal zone B-cell lymphoma (MZL)
• Mastocytosis
• Myelodysplastic syndrome (MDS)/Chronic myelomonocytic leukemia (CMML)
• Myeloproliferative neoplasm (MPN)
• Non-Hodgkin lymphoma (NHL)
• T-cell lymphoma

Highlighted Assays:

NeoLAB™ Liquid Biopsies

• AML Profile
• BTK Inhibitor Acquired Resistance Panel
• MDS/CMML Profile
• Myeloid Disorders Profile
• FLT3 Mutation Analysis
• IDH1 Mutation Analysis
• IDH2 Mutation Analysis
• Inv(16), CBFB-MYH11 Translocation
• KIT (c-KIT) Mutation Analysis
• KRAS Mutation Analysis
• NPM1 Mutation Analysis
• NRAS Mutation Analysis
• PML-RARA Translocation, t(15;17)
• RUNX1-RUNX1T1 (AML1-ETO) Translocation, t(8;21)

Molecular

• BCR-ABL1 Standard p210, p190
• NeoTYPE® AML Prognostic Profile
• NeoTYPE Lymphoma Profile
• NeoTYPE MDS/CMML Profile
• NeoTYPE Myeloid Disorders Profile

FISH

• ALK (2p23) for Lymphoma
• ALL Pediatric FISH Panel
• AML
• BCR-ABL1
• MDS
• MPN
• NHL
Brain Tumors

Selected Testing Indications:
• Glioblastoma
• Gliomas

Highlighted Assays:
Molecular
• ATRX Mutation Analysis
• EGFRvIII Analysis
• IDH1/2 Mutation Analysis
• MGMT Promoter Methylation Analysis
• NeoTYPE Brain Tumor Profile
• NeoTYPE Precision Profile for Solid Tumors

FISH
• BRAF Rearrangement
• EGFR Amplification
• MYCN (n-MYC) Amplification
• PDGFRA Amplification

Sarcoma

Selected Testing Indications:
• Osteosarcoma
• Ewing’s Sarcoma
• Rhabdomyosarcoma
• Pediatric Sarcoma

Highlighted Assays:
Molecular
• NGS Comprehensive Sarcoma Fusion Profile
• NGS Ewing Sarcoma Fusion Profile
• NGS Non-Ewing Sarcoma Fusion Profile
• NGS Pediatric Sarcoma Fusion Profile
• NGS Rhabdomyosarcoma Fusion Profile
• NeoTYPE Liposarcoma Fusion Profile

FISH
• DDIT3 (CHOP)
• EWSR1
• MDM2
• SS18 (SYT)

Melanoma

Highlighted Assays:
Molecular
• BRAF Mutation Analysis
• NeoTYPE Melanoma
• TERT Promoter Mutation Analysis

FISH
• BRAF Rearrangement
• NeoSITE® Melanoma

IHC
• PD-L1, 22C3 FDA (KEYTRUDA®)
• PD-L1 28-8 FDA

Solid Tumors, All Types

Highlighted Assays:
Molecular
• NeoLAB Solid Tumor Monitor – Liquid Biopsy
• NeoTYPE Discovery Profile for Solid Tumors
• NeoTYPE Precision Profile for Solid Tumors

Hereditary Cancer

Highlighted Assays:
Molecular
• Inherited Bone Marrow Failure Panel
• Hereditary Cancer Susceptibility for Pediatrics

All Cancers

Highlighted Assays:
Molecular
• Tumor Mutation Burden (TMB)
• Universal Fusion/Expression Profile (1385 Genes)

See our website for all 600+ available tests.
**Genes Evaluated (by molecular analysis unless otherwise noted)**

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**Methodology**

Nucleic acid is isolated from plasma, peripheral blood cells or bone marrow. The NeoTYPE™ Myeloid Disorders Profile A includes massive parallel sequencing and mutation analysis of the following 54 genes:

- **ABL1**: EX: 4-6 (AA: L184_R362)
- **ASXL1**: EX: 12 (AA: I574_R1541X)
- **ATRX**: EX: 8, 10-11 and 17-31 (AA: N199_C220, D1247_E1314, and K2283_V1568)
- **BCOR**: EX: All (AA: M1_W1755X)
- **BCORL1**: EX: All (AA: M1_1711X)
- **BRAF**: EX: 15 (AA: I582_M620)
- **CALR**: EX: 9 (AA: A352_L417)
- **CBL**: EX: 8 and 9 (AA: E366_K417)
- **CBLB**: EX: 9 and 10 (AA: E358_K469)
- **CBLC**: EX: 9 and 10 (AA: V429_V454)
- **CDKN2A**: EX: All (AA: M1_A167X)
- **CEBPA**: EX: All (AA: M1_A3580)
- **CSF3R**: EX: 14-17 (AA: A576_P830)
- **CUX1**: EX: (AA: M1_678X)
- **DNMT3A**: EX: All (AA: M1_V912X)
- **ETV6**: EX: All (AA: M1_C452X)
- **EZH2**: EX: All (AA: M1_P751X)
- **FBXW7**: EX: 9, 10 and 11 (AA: R473_G621)
- **FLT3**: EX: 13-15 and 20 (AA: S543_K647 and C807_N847)
- **GATA1**: EX: 2 (AA: M1_P73)
- **GATA2**: EX: 2-6 (AA: M1_G480X)
- **GNAS**: EX: 8 and 9 (AA: T105_Q176 and D196_D240)
- **HRAS**: EX: 2 and 3 (AA: M1_A83)
- **IDH1**: EX: 4 (AA: Y42_Q138)
- **IDH2**: EX: 4 (AA: F126_Q178)
- **IKZF1**: EX: All (AA: M1_S519X)
- **JAK2**: EX: 12 and 14 (AA: L509_F547 and S593_N622)
- **JAK3**: EX: 13 (AA: S596_L638)
- **KDM6A**: EX: All (AA: M1_S1401X)
- **KIT**: EX: 2, 8-11, 13 and 17 (AA: S24_R112, K412_F591, S593_N622, and C788_N828)
- **KRAS**: EX: 2 and 3 (AA: M1_Y96)
- **MLL (KMT2A)**: EX: 5-8 (AA: D1112_K1362)
- **MPL**: EX: 10 (AA: W491_Y521)
- **MYD88**: EX: 3-5 (AA: R192_P317X)
- **NOTCH1**: EX: 26-28 and 34 (AA: P1530_D1880, and E2061_K2555X)
- **NPM1**: EX: 12 (AA: A283_l294X)
- **NRAS**: EX: 2 and 3 (AA: M1_S87)
- **PDGFRA**: EX: 12, 14 and 18 (AA: K552_L595, L651_G668, and C814_S854)
- **PHF6**: EX: All (AA: M1_N365X)
- **PTEN**: EX: 5 and 7 (AA: A86_K164 and P213_K267)
- **PTPN11**: EX: 3 and 13 (AA: R47_R111 and V484_Q533)
- **RAD21**: EX: All (AA: M1_I631X)
- **RUNX1**: EX: All (AA: M1_481X)
- **SETBP1**: EX: 4 (AA: E858_Q919)
- **SF3B1**: EX: 13-16 (AA: E579_K741)
- **SMC1A**: EX: 2, 11, 16 and 17 (AA: K38_V99, V578_K637, and L808_N902)
- **SRSF2**: EX: 1 (AA: F57_R120)
- **STAG2**: EX: All (AA: M1_F1268X)
- **TET2**: EX: 3-11 (AA: M1_2002X)
- **TP53**: EX: 2-11 (AA: M1_Q331)
- **U2AF1**: EX: 2 and 6 (AA: K43_D72 and F117_M160)
- **WT1**: EX: 7 and 9 (AA: D367_T416 and V448_T477)
- **ZRSR2**: EX: All (AA: M1_483X)

When applicable, fragment length analysis is also performed on CALR and NPM1 to enhance the detection of low levels of insertion/deletion mutations. In addition, when applicable, confirmation of the presence or lack of mutation was performed using Sanger sequencing on the following genes: BRAF, HRAS, IDH1/2, KRAS, NRAS, PTEN and RUNX1. The sequencing method has a typical sensitivity of 5% for detecting mutations and the FLT3-ITD fragment analysis assay has a sensitivity of 5-10% for detecting FLT3-ITD in wildtype background. The CALR fragment analysis test has a sensitivity of 5% for detecting heterozygous insertion/deletions in the wild-type background. Various factors including quantity and quality of nucleic acid, sample preparation and sample age can affect assay performance.
Working with NeoGenomics

Clients appreciate working with NeoGenomics for our dedication to accuracy, service, and flexibility to resolve special challenges. Each department and program has dedicated staff and management, quality measures, and ongoing training.

Billing: NeoGenomics offers client, third-party, and patient billing. Online payment options and patient payment programs are available. We are also contracted with a large number of private insurance plans and managed care organizations.

Specimen Transport: We routinely use our own employee couriers with our company fleet of hybrid cars, highly-vetted contracted couriers, and commercial air/ground services to carefully coordinate pick-up, transportation, and receipt of patient specimens. Checkpoints and safeguards are monitored throughout the transport process.

Client Services: Live telephone coverage is available 24/7 with extended coverage of all four US continental time zones. Client Service Advocates are cross-trained in multiple functions and support clients in all geographical regions.

Online Ordering: NeoGenomics encourages clients to use our Online Ordering system as a green initiative, and because it improves our clients' efficiency and ours. Phone calls back to our clients' offices for missing information are reduced by 93% with use of Online Ordering.

Get Started Now

Call us at 866.776.5907 to speak with one of our physicians, lab directors, lab managers, Client Service Advocates, or Territory Business Managers.

We’d love to learn how we might help enhance and simplify your testing process and help you in the care of your patients.
Recent Company Publications

As an innovator, NeoGenomics is both an avid consumer and frequent contributor to the scientific literature. Please see below selected recent publications by NeoGenomics authors and collaborators. The full list is available on our website, along with downloadable files or links to contact us for copies.

Publications


Poster Presentations


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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