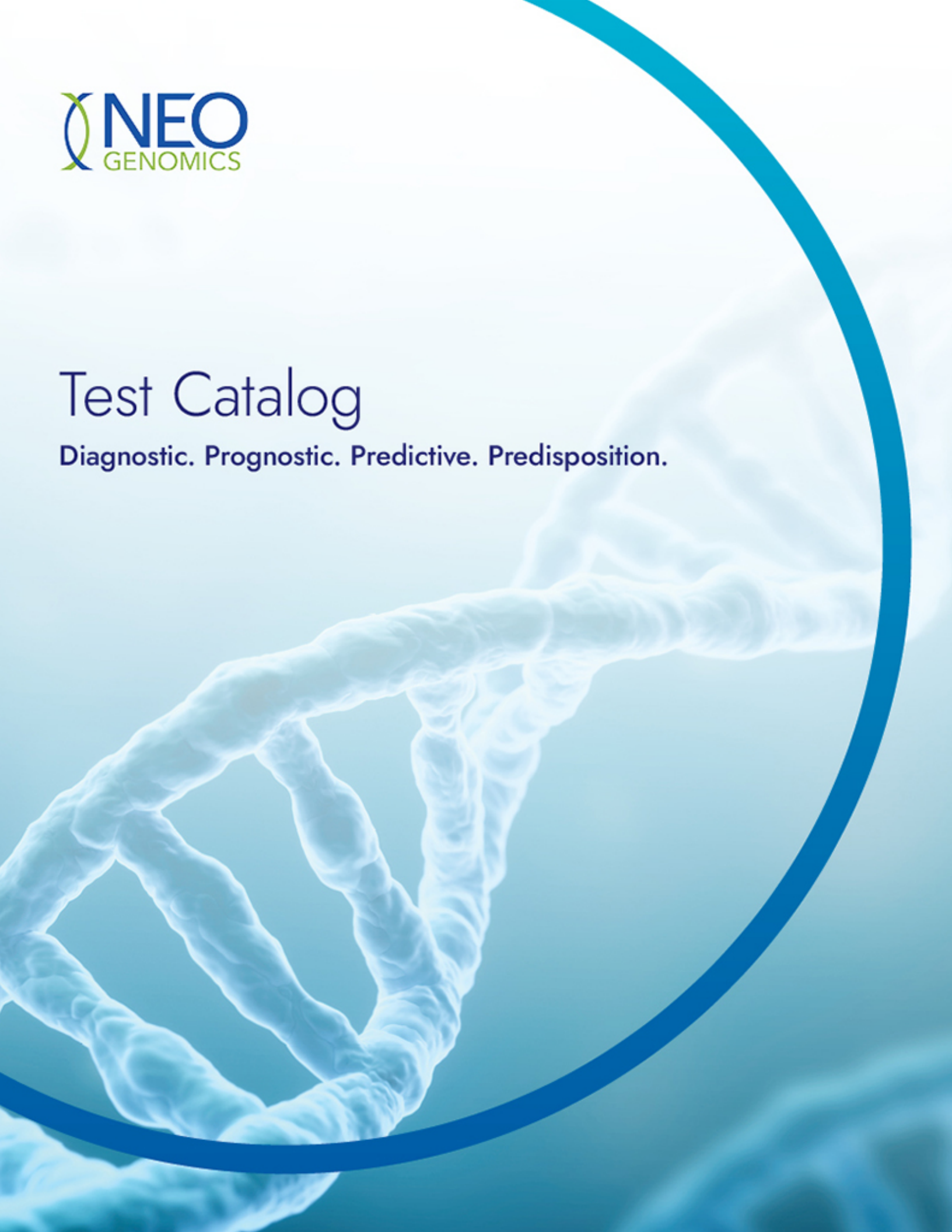
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



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.

*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.

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.

*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.

9490 NeoGenomics Way
Fort Myers, FL 33912
Phone: 239.768.0600/ Fax: 239.690.4237
neogenomics.com

Rev. 120424