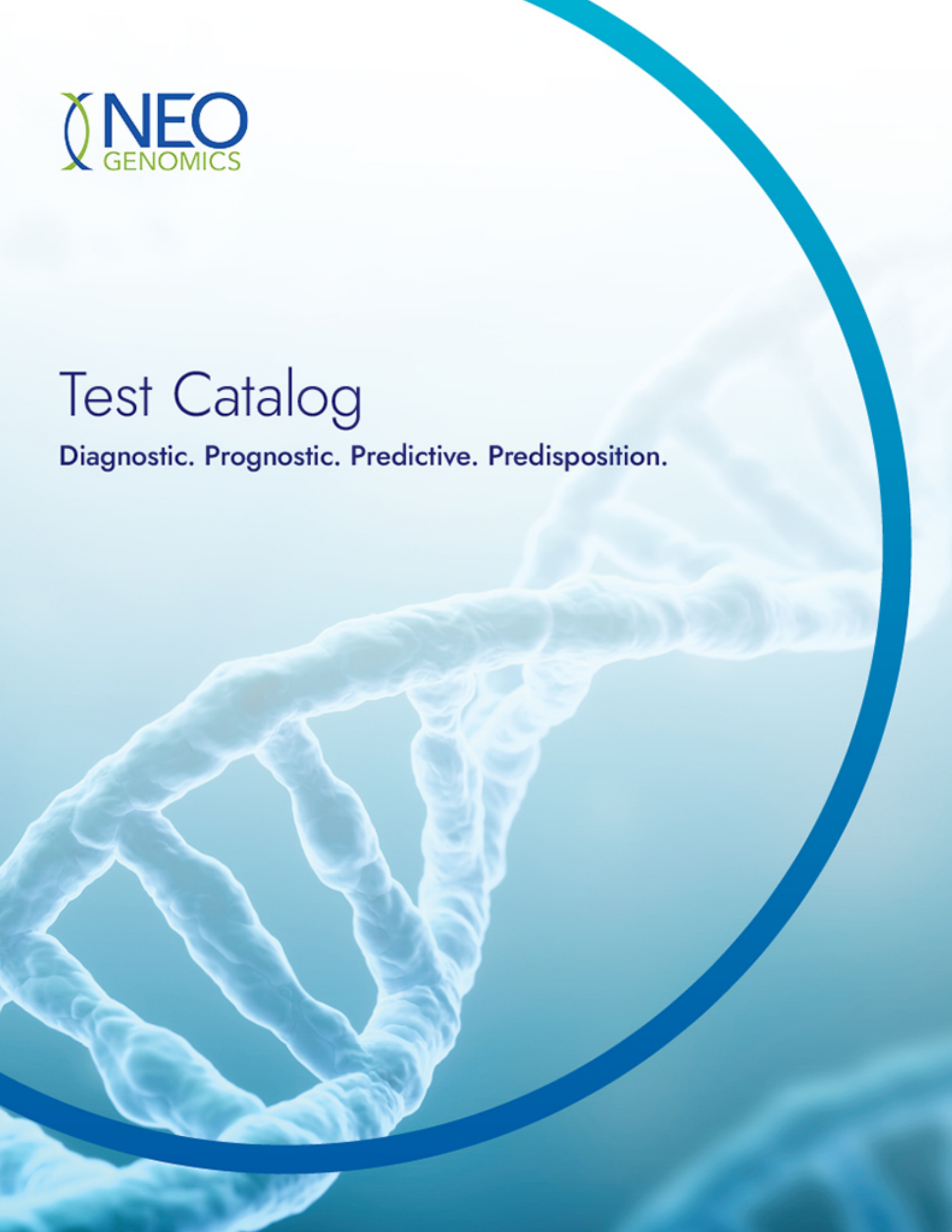
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



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.

Note: Test in TNA-based. Please select Extract & Hold - TNA if specimen hold service is desired.

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.

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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