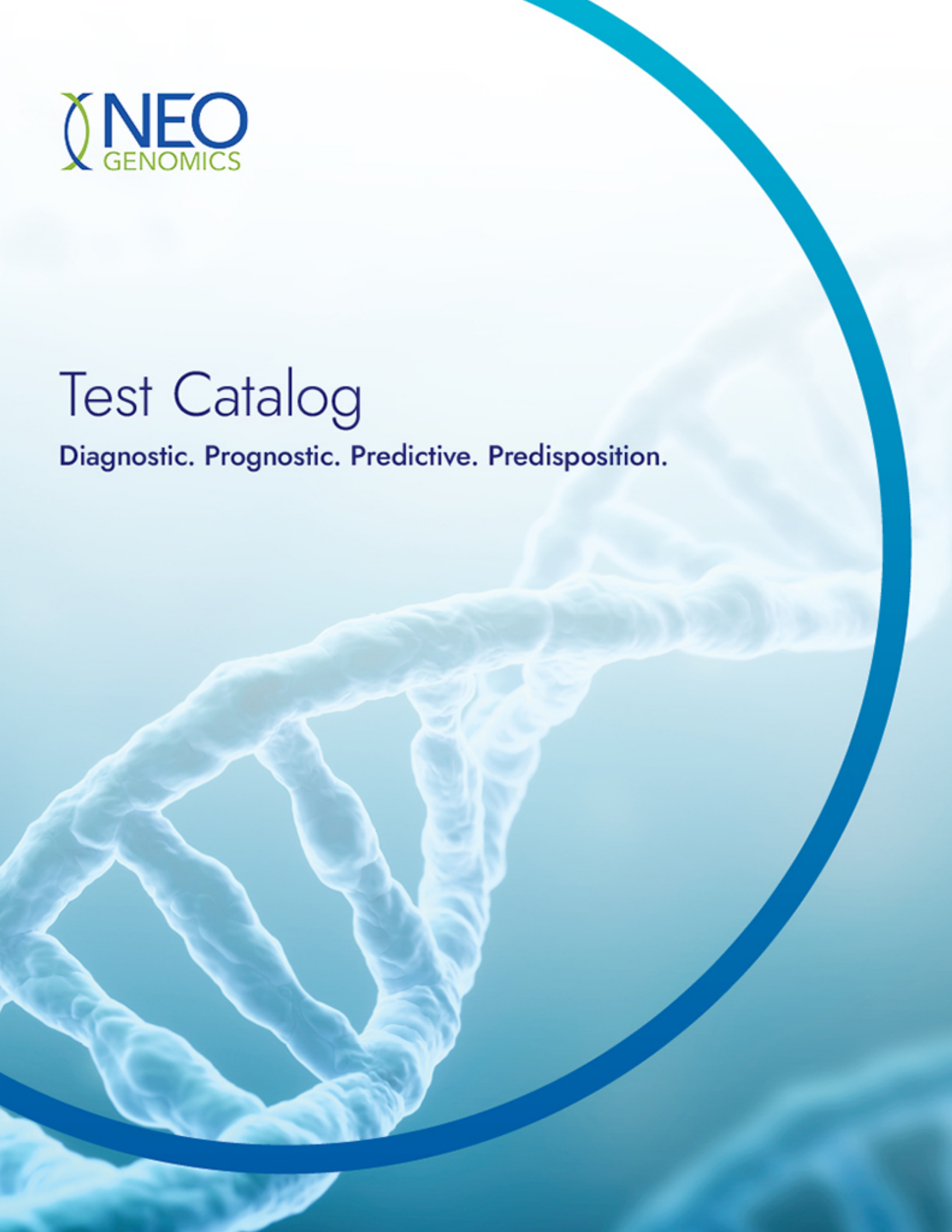
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



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.

*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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Rev. 052124