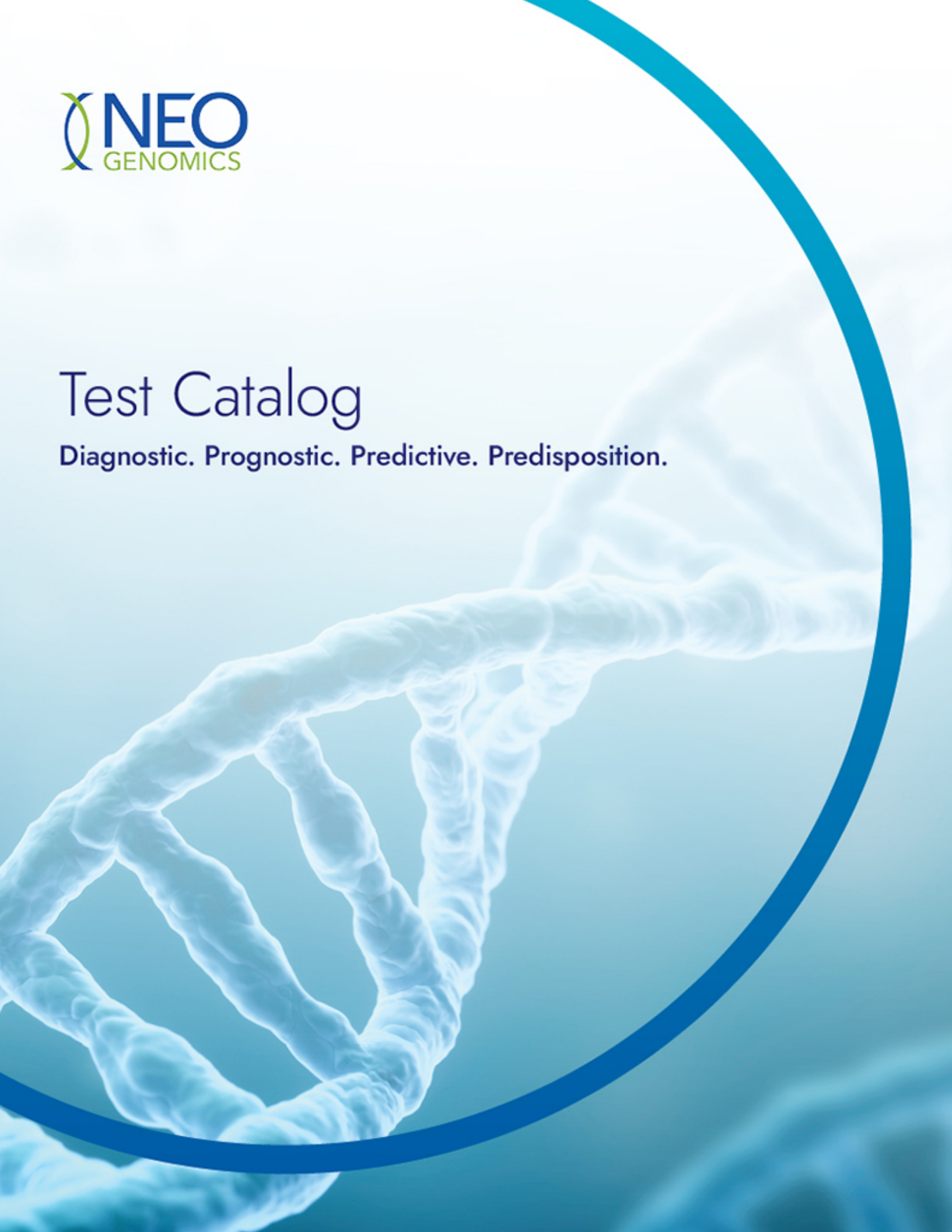
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



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 instructionshere (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

*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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