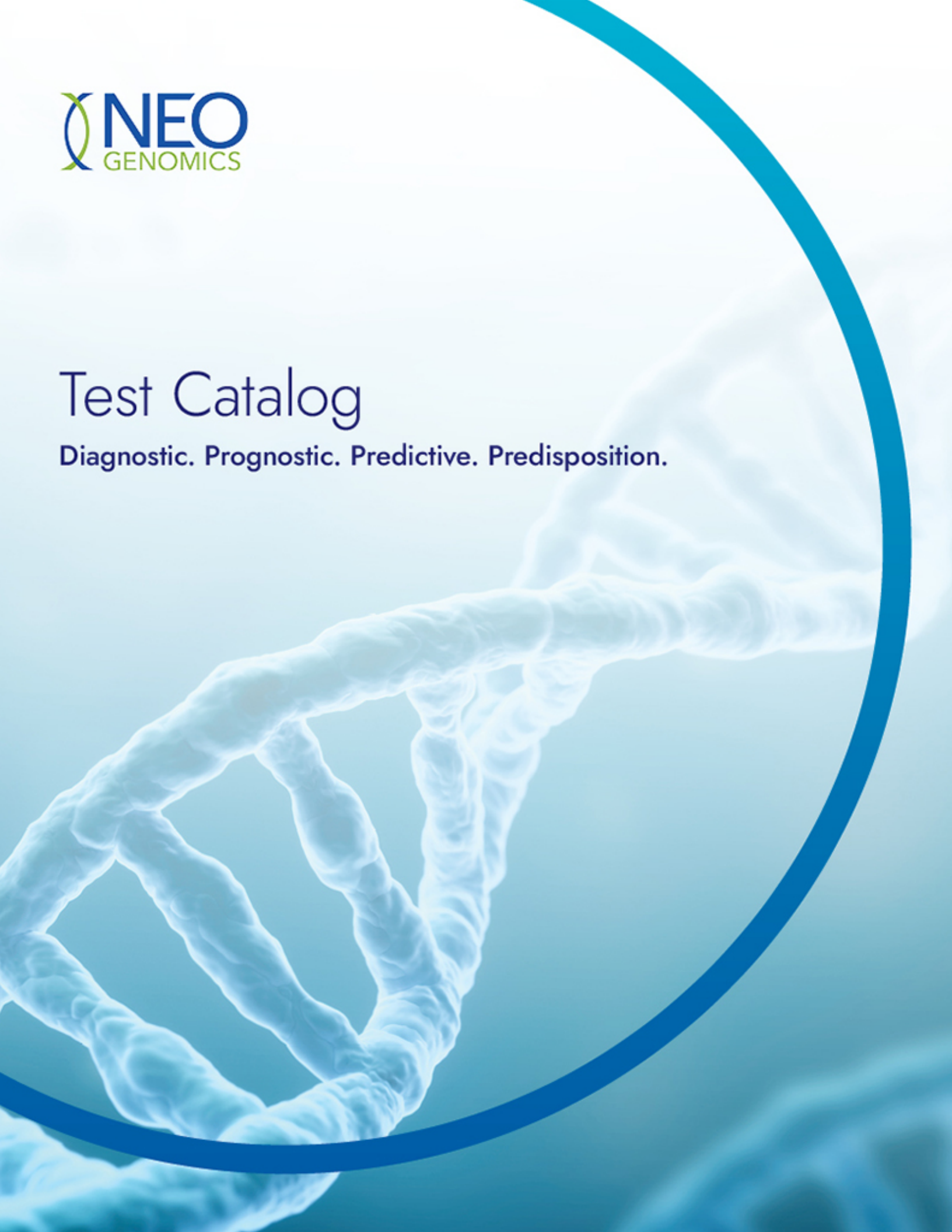
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



NeoTYPE® DNA & RNA - Lung

Methodology
Molecular

Test Description
NeoTYPE® DNA & RNA - Lung is a targeted next-generation sequencing profile that detects single nucleotide variants (SNV), insertions/deletions (InDels), copy number variants (CNV), and RNA fusions and splice variants in a total of 50 genes (44 genes analyzed by DNA and 19 by RNA), plus microsatellite instability (MSI) and tumor mutation burden (TMB). PD-L1 immunohistochemistry is optional. Results are summarized and details provided for prognostic findings, therapy susceptibility or resistance, available clinical trials, and more. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available. If the sample is insufficient to produce either DNA or RNA results, the available results will be reported and alternate CPT® Codes may apply.

- **SNVs/Indels/CNVs (44 genes):** AKT1, ALK, ARAF, ARID1A, ATM, ATR, ATRX, BRAF, CDKN2A, CDKN2B, EGFR, ERBB2*, ERBB3, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, FGFR4, KEAP1, KIT, KMT2D, KRAS, MAP2K1, MET*, NF1, NFE2L2, NOTCH1, NRAS, NTRK1, NTRK3, PDGFRA, PIK3CA, PTEN, RB1, RBM10, RET, ROS1, SMAD4, SMARCA4, SMO, STK11, TERT Promoter, and TP53
  * *CNV detection in addition to SNVs and indels.*
  The full coding sequence of each DNA gene is tested.
- **RNA Fusions (19 genes):** ALK, BRAF, FGFR1, FGFR2, FGFR3, FGFR4, MET** including METex14 skipping, NOTCH1, NOTCH2, NRG1, NTRK1, NTRK2, NTRK3, PDGFB, PDGFRA, PDGFRB, RAF1, RET, ROS1
  ** *Splice variant detection in addition to fusions.*
  The full coding sequence of each RNA gene is tested.
- **IHC**: PD-L1 22C3 FDA for NSCLC (tech-only available)
- **Other Markers**: Microsatellite Instability (MSI) and Tumor Mutation Burden (TMB) included.

Clinical Significance
NeoTYPE® DNA & RNA - Lung detects genomic alterations that are most relevant to therapy selection, prognosis, and clinical trial options in non-small cell lung cancer. It is appropriate for patients with newly diagnosed, recurrent, or resistant disease.

Specimen Requirements
A block is preferred for testing: ?20% tumor and ?10 mm^2 of tissue surface area for NGS (~500 tumor cells) (additional 100 neoplastic cells for PD-L1).

If submitting 5-micron unstained slides, the following number of slides are requested:

- **Samples with ? 25 mm^2 of tissue**: 10 unstained slides (2 sections per slide preferred)
- **Samples with 10-24 mm^2 of tissue:** 20 unstained slides (2 sections per slide preferred)

Please submit 1 additional unstained slide for H&E and 3 additional unstained slides if performing PD-L1 testing.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*

81445x1. Add 88360x1 for PD-L1 IHC.

Medicare MolDX CPT Code(s)*

81479x1. If sample is insufficient to produce RNA fusion results but DNA SNV/indel and/or CNV results are reported, 81479x1 still applies. If only RNA fusion results are reported, use 81445x1 instead. Add 88360x1 for PD-L1 IHC.

New York Approved

No

Level of Service

Global

Turnaround Time

8-10 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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