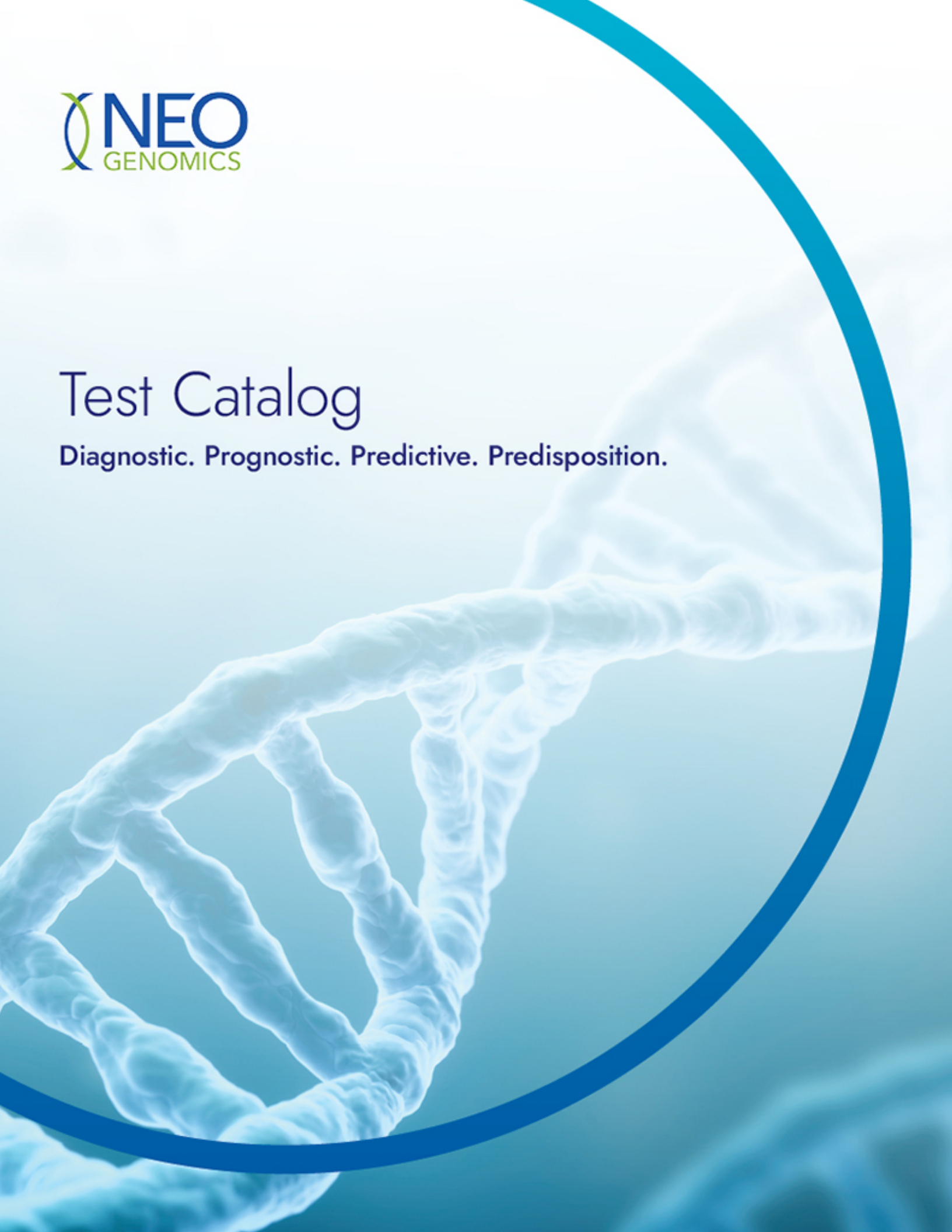
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



Early-stage NSCLC Panel

Alternative Name
eNSCLC Panel

Methodology
FISH

Immunohistochemistry (IHC)

Molecular

Test Description
The Early-stage NSCLC Panel analyzes 4 relevant and actionable biomarkers through a combination of multi-modality methods: EGFR (PCR), ALK (FISH), ROS1 (FISH), and PD-L1 22C3 (IHC). EGFR alterations are detected using PCR amplification and detection of target DNA using complementary primer pairs and oligonucleotide probes with fluorescent dyes. The EGFR PCR component of this panel has been designed to detect EGFR highly recurrent somatic mutations in exons 18, 19, 20, and 21 of EGFR in eight reactions (Exon 18 G719X; Exon 19 deletions; Exon 20 T790M, C797S, Exon 20-Ins and S768I; Exon 21 L858R, L861Q). Some less common EGFR mutations are not detectable in this test. For a full list of EGFR variants detectable in this assay, please contact NeoGenomics client services. Test may be ordered with an opt out of PD-L1 22C3 (IHC).

Clinical Significance
The Early-stage NSCLC Panel is intended as an aid in diagnostic evaluation, prognostication, and therapy selection of early stage non-small cell lung cancer. It is appropriate for all early-stage NSCLC patients.

- Implementation of immunotherapy before molecular assessment increases toxicity. Genomic testing alongside PD-L1 expression informs immunotherapy eligibility in NSCLC[1]
- FDA approved adjuvant osimertinib after tumor resection in NSCLC with EGFR exon 19 deletion or exon 20 L858R mutations. ADAURA clinical trial demonstrated 73% of patients in the overall early-stage NSCLC population on the osimertinib arm were alive and disease-free at 48 months (95% CI HR of 0.27) vs 38% of those in the placebo group.
- Fewer patients had disease recurrence with osimertinib (27%) vs. placebo (60%)[2]

Specimen Requirements
- FFPE Tissue, Paraffin block preferred. Alternatively, clients can send 1 H&E slide plus 10 unstained slides cut at 4-5 microns.
- Use positively-charged slides, 10% NBF fixative. Do not use zinc fixative.

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

CPT Code(s)*
81235x1, 88377x2, 88360x1

New York Approved

Yes

Level of Service

Global

Turnaround Time

7 days

References

1. Gainor JF, Shaw AT, Sequist LV, Fu X, Azzoli CG, Piotrowska Z, Huynh TG, Zhao L, Fulton L, Schultz KR, Howe E, Farago AF, Sullivan RJ, Stone JR, Digumarthy S, Moran T, Hata AN, Yagi Y, Yeap BY, Engelman JA, Mino-Kenudson M. EGFR Mutations and ALK Rearrangements Are Associated with Low Response Rates to PD-1 Pathway Blockade in Non-Small Cell Lung Cancer: A Retrospective Analysis. Clin Cancer Res. 2016 Sep 15;22(18):4585-93. doi: 10.1158/1078-0432.CCR-15-3101. Epub 2016 May 25. PMID: 27225694; PMCID: PMC5026567.2 Lee CK, Man J, Lord S, Links M, Gebski V, Mok T, et al.. Checkpoint Inhibitors in Metastatic EGFR-mutated Non-Small Cell Lung Cancer- a Meta-Analysis. J Thorac Oncol (2017) 12:403–7. 10.1016/j.jtho.2016.10.007 3 Lee CK, Man J, Lord S, Cooper W, Links M, Gebski V, et al.. Clinical and Molecular Characteristics Associated With Survival Among Patients Treated With Checkpoint Inhibitors for Advanced Non-Small Cell Lung Carcinoma: A Systematic Review and Meta-Analysis. JAMA Oncol (2018) 4:210–6. 10.1001/jamaoncol.2017.4427
2. Herbst RS, Wu YL, John T, Grohe C, Majem M, Wang J, Kato T, Goldman JW, Laktionov K, Kim SW, Yu CJ, Vu HV, Lu S, Lee KY, Mukhametshina G, Akewanlop C, de Marinis F, Bonanno L, Domine M, Shepherd FA, Urban D, Huang X, Bolanos A, Stachowiak M, Tsuboi M. Adjuvant Osimertinib for Resected EGFR-Mutated Stage IB-IIIA Non-Small-Cell Lung Cancer: Updated Results From the Phase III Randomized ADAURA Trial. J Clin Oncol. 2023 Apr 1;41(10):1830-1840. doi: 10.1200/JCO.22.02186. Epub 2023 Jan 31. Erratum in: J Clin Oncol. 2023 Apr 27;:JCO2300658. PMID: 36720083; PMCID: PMC10082285.

*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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