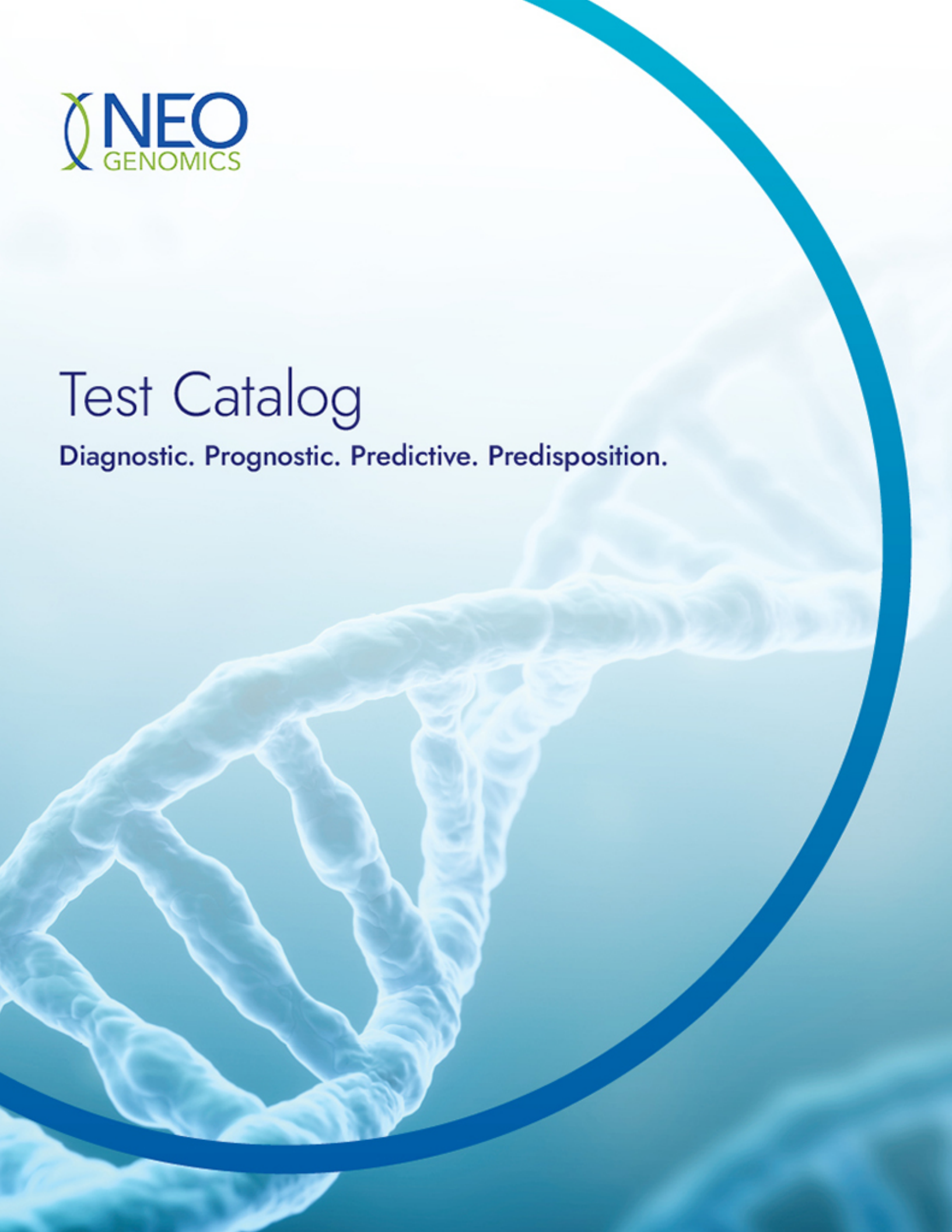




Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.





NeoTYPE® Colorectal Tumor Profile

Alternative Name

Colorectal Tumor Profile

Methodology

Molecular

Test Description

The NeoTYPE Colorectal Tumor Profile analyzes 44 biomarkers through a combination of next-generation sequencing (NGS), other molecular methods, FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. If global HER2 (Other) IHC w/Gastric Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/ Gastric Scoring unless reflex to tech-only FISH or reflex opt-out is requested. If Pan-TRK IHC is expressed or equivocal, reflex to either NTRK NGS Fusion Panel (Default) or NTRK 1-3 FISH Panel will be added. A microsatellite instability (MSI) NGS result of "indeterminate" will create a reflex to MSI by PCR as long as the tumor percentage is ≥20%.

- NGS (36 genes + 2 biomarkers): AKT1, ARID1A, APC, ATM, BRAF, EGFR, EPCAM, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, MSH2, MSH6, MUTYH, NOTCH1, NRAS, PDGFRA, PIK3CA, PMS2, POLD1, POLE, PTEN, RNF43, SMAD4, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB)
- FISH (3 FISH): MET, PTEN, RET (tech-only available)
- IHC (3 biomarkers): HER2 (Other) w/Gastric Scoring, PD-L1 LDT, Pan-TRK (tech-only available for HER2 and PD-L1)

Clinical Significance

The NeoTYPE Colorectal Tumor Profile characterizes primary or metastatic colorectal tumors of any histological subtype for the most significant genetic changes relevant to therapy decisions, prognosis, and clinical research. It is appropriate for patients with newly-diagnosed or recurrent disease, and for patients with resistant disease to explore options in clinical trials.

Specimen Requirements

- **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage & Transportation

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

CPT Code(s)*

81445x1, 88377x3, 88360x2, 88342x1; add 88374x1 if HER2 IHC is reflexed to FISH; add 81479x1 if reflexed to NTRK NGS Fusion Panel (default) or 88374x3 automated (88377x3 manual) if reflexed to NTRK 1-3 FISH Panel

Medicare MoIDX CPT Code(s)*

81479

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days; add 1-3 days if reflexed to NTRK NGS Fusion Profile

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.

*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.



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