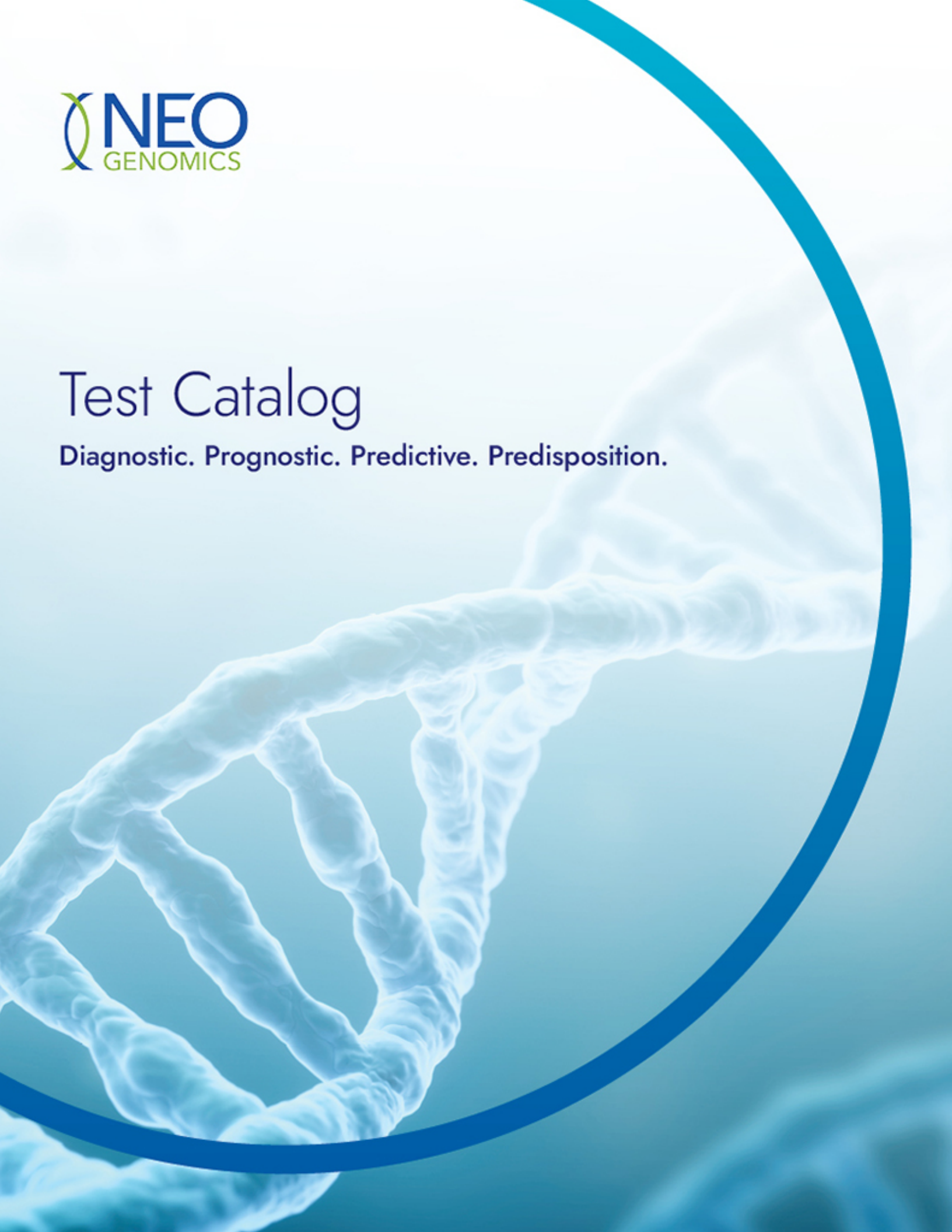
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



NeoTYPE® Discovery Profile for Solid Tumors

Alternative Name
Discovery Profile

Methodology
Molecular

Test Description
The NeoTYPE Discovery Profile analyzes 336 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. For non-breast tumors, HER2 (Other) w/ Breast Scoring will be added. For breast tumors, HER2 Breast IHC/FISH can be ordered separately, if clinically indicated. If global HER2 (Other) IHC w/Breast Scoring result is 2+, case will reflex to global HER2 (Other) FISH w/Breast 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% for colorectal specimens or ?40% with paired normal tissue available for non-colorectal specimens.

- FISH (8 FISH): ALK, BRAF, MET, MYC, PDGFRA amplifications, PTEN, RET, ROS1 (tech-only available)
- IHC (3 biomarkers): HER2 (Other) w/Breast Scoring (non-breast tumors only), PD-L1 22C3 (breast, lung) or PD-L1 LDT (other), Pan-TRK (tech-only available for HER2 and PD-L1)
- NGS (323 genes + 2 biomarkers): ABL1, ABL2, ACVR1B, ADGRA2 (GPR124), AKT1, AKT2, AKT3, ALK, AMER1, APC, AR, ARAF, ARFRP1, ARID1A, ARID1B, ARID2, ASXL1, ATM, ATR, ATRX, AURKA, AURKB, AXIN1, AXL, BAP1, BARD1, BCL2, BCL2L1, BCL2L2, BCL6, BCOR, BCORL1, BLM, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BTG1, BTK, CARD11, CBFB, CBL, CCND1, CCND2, CCND3, CCN6 (WISP3), CCNE1, CD274, CD79A, CD79B, CDC73, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CHD2, CHD4, CHEK1, CHEK2, CIC, CREBBP, CRKL, CRLF2, CSF1R, CTCF, CTNNA1, CTNNB1, CUL3, CXCR4, CYLD, DAXX, DDR2, DICER1, DNMT3A, DOT1L, EGFR, EMSY (C11orf30), EP300, EPCAM, EPHA3, EPHA5, EPHA7, EPHB1, ERBB2, ERBB3, ERBB4, ERG, ERRFI1, ESR1, EZH2, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FAS, FAT1, FBXW7, FGF10, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLT1, FLT3, FLT4, FOXL2, FOXP1, FRS2, FUBP1, GABRA6, GATA1, GATA2, GATA3, GATA4, GATA6, GID4, GLI1, GNA11, GNA13, GNAQ, GNAS, GRIN2A, GRM3, GSK3B, HGF, HNF1A, HRAS, HSD3B1, HSP90AA1, H3-3A (H3F3A), H3C3 (HIST1H3C), IDH1, IDH2, IGF1R, IGF2, IKBKE, IKZF1, IL7R, INHBA, INPP4B, IRF2, IRF4, IRS2, JAK1, JAK2, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIT, KLHL6, KMT2A, KMT2C, KMT2D, KRAS (includes G12C mutation), LMO1, LRP1B, LYN, LZTR1, MAGI2, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, MET, Microsatellite Instability (MSI), MITF, MLH1, MPL, MRE11 (MRE11A), MSH2, MSH6, MTOR, MUTYH, MYC, MYCL, MYCN, MYD88, NBN, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NSD1, NTRK1, NTRK2, NTRK3, NUP93, PAK3, PALB2, PAX5, PBRM1, PDCD1LG2, PDGFRA, PDGFRB, PDK1, PIK3C2B, PIK3CA, PIK3CB, PIK3CG, PIK3R1, PIK3R2, PLCG2, PMS2, POLD1, POLE, PPP2R1A, PRDM1, PREX2, PRKAR1A, PRKCI, PRKDC, PRKN (PARK2), PRSS8, PTCH1, PTEN, PTPN11, QKI, RAC1, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RAF1, RANBP2, RARA, RB1, RBM10, RET, RICTOR, RNF43, ROS1, RPTOR, RUNX1, RUNX1T1, SDHA, SDHB, SDHC, SDHD, SETD2, SF3B1, SLIT2, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMO, SNCAIP, SOCS1, SOX10, SOX2, SOX9, SPEN, SPOP, SPTA1, SRC, STAG2, STAT3, STAT4, STK11, SUFU, SYK, TAF1, TBX3, TENT5C (FAM46C), TERC, TERT promoter, TET2, TGFBR2, TNFAIP3, TNFRSF14, TOP1, TOP2A, TP53, TSC1, TSC2, TSHR, U2AF1, VEGFA, VHL, WT1, XPO1, ZBTB2, ZNF217, ZNF703, Tumor Mutation Burden (TMB)

Clinical Significance

The NeoTYPE Discovery Profile for Solid Tumors combines NGS, FISH and IHC to allow for the accurate and sensitive detection of genomic alterations in the genes most relevant to various solid tumor cancers. These genomic alterations include SNP's, indels, rearrangements and other alterations. Testing can aid in the diagnosis of various diseases and provide information to develop strategies for the treatment and management of the underlying disease. In addition, the results obtained from the NeoTYPE Discovery Profile for Solid Tumors can also be used in current or future clinical research projects.

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. All slides can be packed at room temperature.

CPT Code(s)*

81455x1, 88377x8; 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 MolDX 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

*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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