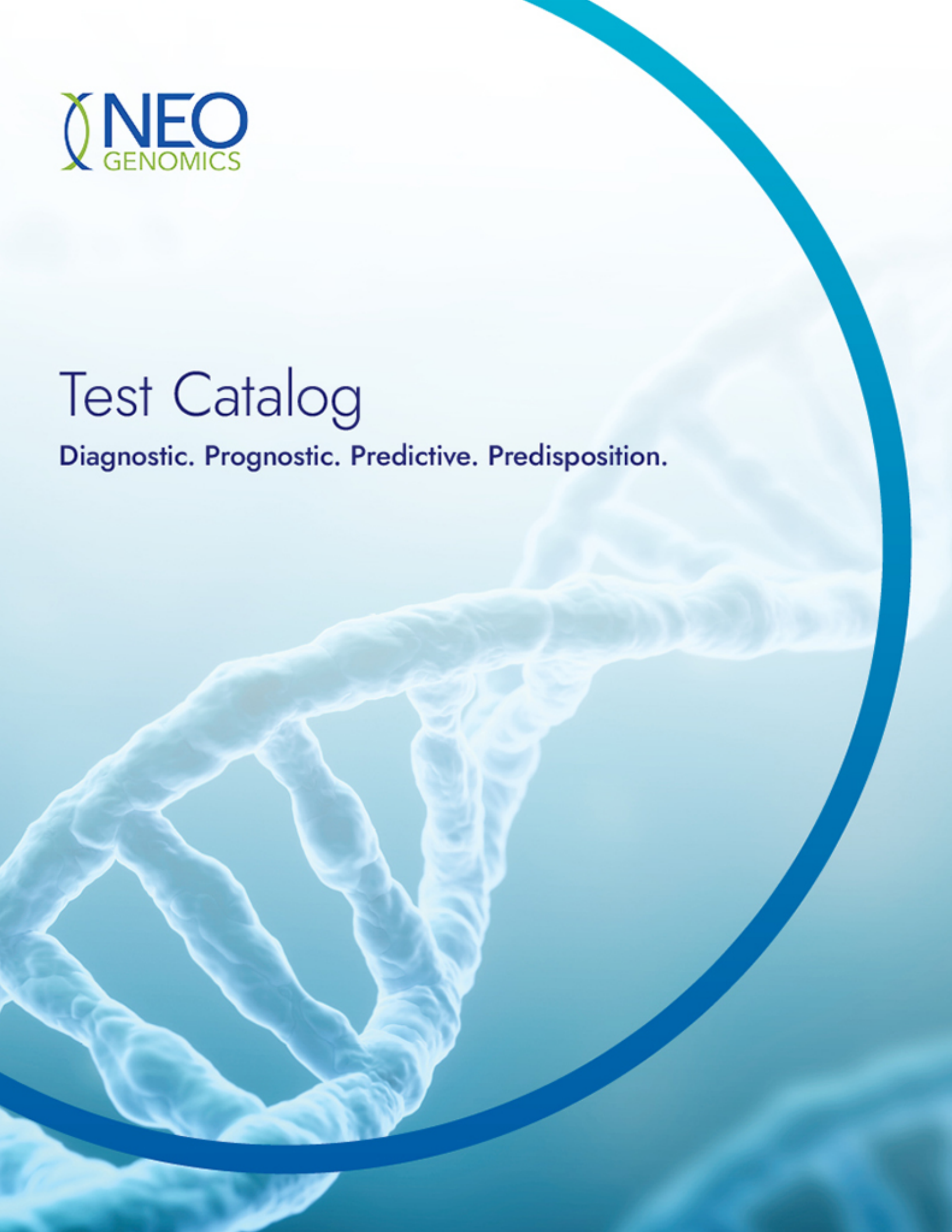
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



Neo Comprehensive - Solid Tumor

Methodology

Molecular

Test Description

Neo Comprehensive™ - Solid Tumor is a broad, next-generation sequencing panel for pan-solid tumor indications. The assay detects single nucleotide variants (SNV), insertions/deletions (InDels), copy number variants (CNV), and RNA fusions and splice variants in a total of 517 genes (517 genes analyzed by DNA, 55 genes by RNA), plus microsatellite instability (MSI*) and tumor mutational burden (TMB).

DNA GENE LIST: DETECTION OF SNVs, INDELS AND CNVs

ABL1, ABL2, ACVR1, ACVR1B, AKT1, AKT2*, AKT3, ALK*, ALOX12B, ANKRD11, ANKRD26, APC, AR*, ARAF, ARFRP1, ARID1A, ARID1B, ARID2, ARID5B, ASXL1, ASXL2, ATM*, ATR, ATRX, AURKA, AURKB, AXIN1, AXIN2, AXL, B2M, BAP1, BARD1, BBC3, BCL10, BCL2, BCL2L1, BCL2L11, BCL2L2, BCL6, BCOR, BCORL1, BCR, BIRC3, BLM, BMPR1A, BRAF*, BRCA1*, BRCA2*, BRD4, BRIP1, BTG1, BTK, C11orf30, CALR, CARD11, CASP8, CBFB, CBL, CCND1*, CCND2, CCND3*, CCNE1*, CD274, CD276, CD74, CD79A, CD79B, CDC73, CDH1, CDK12, CDK4*, CDK6*, CDK8*, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CENPA, CHD2, CHD4, CHEK1*, CHEK2*, CIC, CREBBP, CRKL, CRLF2, CSF1R, CSF3R, CSNK1A1, CTCF, CTLA4, CTNNA1, CTNNB1, CUL3, CUX1, CXCR4, CYLD, DAXX, DCUN1D1, DDR2, DDX41, DHX15, DICER1, DIS3, DNAJB1, DNMT1, DNMT3A, DNMT3B, DOT1L, E2F3, EED, EGFL7, EGFR*, EIF1AX, EIF4A2, EIF4E, EML4, EP300, EPCAM, EPHA3, EPHA5, EPHA7, EPHB1, ERBB2*, ERBB3*, ERBB4, ERCC1*, ERCC2*, ERCC3, ERCC4, ERCC5, ERG, ERRFI1, ESR1*, ETS1, ETV1, ETV4, ETV5, ETV6, EWSR1, EZH2, FAM123B, FAM175A, FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FAS, FAT1, FBXW7, FGF1*, FGF10*, FGF14*, FGF19*, FGF2*, FGF23*, FGF3*, FGF4*, FGF5*, FGF6*, FGF7*, FGF8*, FGF9*, FGFR1*, FGFR2*, FGFR3*, FGFR4*, FH, FLCN, FLI1, FLT1, FLT3, FLT4, FOXA1, FOXL2, FOXO1, FOXP1, FRS2, FUBP1, FYN, GABRA6, GATA1, GATA2, GATA3, GATA4, GATA6, GEN1, GID4, GLI1, GNA11, GNA13, GNAQ, GNAS, GPR124, GPS2, GREM1, GRIN2A, GRM3, GSK3B, H3F3A, H3F3B, H3F3C, HGF, HIST1H1C, HIST1H2BD, HIST1H3A, HIST1H3B, HIST1H3C, HIST1H3D, HIST1H3E, HIST1H3F, HIST1H3G, HIST1H3H, HIST1H3I, HIST1H3J, HIST2H3A, HIST2H3C, HIST2H3D, HIST3H3, HNF1A, HNRNPK, HOXB13, HRAS, HSD3B1, HSP90AA1, ICOSLG, ID3, IDH1, IDH2, IFNGR1, IGF1, IGF1R, IGF2, IKBKE, IKZF1, IL10, IL7R, INHA, INHBA, INPP4A, INPP4B, INSR, IRF2, IRF4, IRS1, IRS2, JAK1, JAK2*, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIF5B, KIT*, KLF4, KLHL6, KRAS*, LAMP1*, LATS1, LATS2, LMO1, LRP1B, LYN, LZTR1, MAGI2, MALT1, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MAP3K13, MAP3K14, MAP3K4, MAPK1, MAPK3, MAX, MCL1, MDC1, MDM2*, MDM4*, MED12, MEF2B, MEN1, MET*, MGA, MITF, MLH1, MLL, MLLT3, MPL, MRE11A, MSH2, MSH3, MSH6, MST1, MST1R, MTOR, MUTYH, MYB, MYC*, MYCL1*, MYCN*, MYD88, MYOD1, NAB2, NBN, NCOA3, NCOR1, NEGR1, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NKX3-1, NOTCH1, NOTCH2, NOTCH3, NOTCH4, NPM1, NRAS*, NRG1*, NSD1, NTRK1, NTRK2, NTRK3, NUP93, NUTM1, PAK1, PAK3, PAK7, PALB2, PARK2, PARP1, PAX3, PAX5, PAX7, PAX8, PBRM1, PDCD1, PDCD1LG2, PDGFRA*, PDGFRB*, PDK1, PDPK1, PGR, PHF6, PHOX2B, PIK3C2B, PIK3C2G, PIK3C3, PIK3CA*, PIK3CB*, PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIK3R3, PIM1, PLCG2, PLK2, PMAIP1, PMS1, PMS2, PNRC1, POLD1, POLE, PPARG, PPM1D, PPP2R1A, PPP2R2A, PPP6C, PRDM1, PREX2, PRKAR1A, PRKCI, PRKDC, PRSS8, PTCH1, PTEN*, PTPN11, PTPRD, PTPRS, PTPRT, QKI, RAB35, RAC1, RAD21, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RAF1*, RANBP2, RARA, RASA1, RB1, RBM10, RECQL4, REL, RET*, RFWD2, RHEB, RHOA, RICTOR*, RIT1, RNF43, ROS1, RPS6KA4, RPS6KB1*, RPS6KB2, RPTOR, RUNX1, RUNX1T1, RYBP, SDHA, SDHAF2, SDHB, SDHC, SDHD, SETBP1, SETD2, SF3B1, SH2B3, SH2D1A, SHQ1, SLIT2, SLX4, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMARCD1, SMC1A, SMC3, SMO, SNCAIP, SOCS1, SOX10, SOX17, SOX2, SOX9, SPEN, SPOP, SPTA1, SRC, SRSF2, STAG1, STAG2, STAT3, STAT4, STAT5A, STAT5B, STK11, STK40, SUFU, SUZ12, SYK, TAF1, TBX3, TCEB1, TCF3, TCF7L2, TERC, TERT, TET1, TET2, TFE3, TFRC*, TGFBR1, TGFBR2, TMEM127, TMPRSS2, TNFAIP3, TNFRSF14, TOP1, TOP2A, TP53, TP63, TRAF2, TRAF7, TSC1, TSC2, TSHR, U2AF1, VEGFA, VHL, VTCN1, WISP3, WT1, XIAP, XPO1, XRCC2, YAP1, YES1, ZBTB2, ZBTB7A, ZFHX3, ZNF217, ZNF703, ZRSR2

**** Denotes genes with CNV detection***

RNA GENE LIST: DETECTION OF FUSIONS AND SPLICE VARIANTS

ABL1, AKT3, ALK, AR**, AXL, BCL2, BRAF, BRCA1, BRCA2, CDK4, CSF1R, EGFR**, EML4, ERBB2, ERG, ESR1, ETS1, ETV1, ETV4, ETV5, EWSR1, FGFR1, FGFR2, FGFR3, FGFR4, FLI1, FLT1, FLT3, JAK2, KDR, KIF5B, KIT, MET**, MLL, MLLT3, MSH2, MYC, NOTCH1, NOTCH2, NOTCH3, NRG1, NTRK1, NTRK2, NTRK3, PAX3, PAX7, PDGFRA, PDGFRB, PIK3CA, PPARG, RAF1, RET, ROS1, RPS6KB1, TMPRSS2

***** Denotes genes with splice variants including AR-V7, EGFRvIII, and MET exon 14 skipping.***

IMMUNOTHERAPY MARKERS

MSI, TMB

MSI-high is defined as ?20% of loci showing instability; microsatellite-stable (MSS) is defined as <20% of loci showing instability.*

Tumor Mutational Burden (TMB):

- **TMB-high** is defined as **?10.0 mut/Mb** (mutations per megabase)
- **TMB-low** is defined as **<10.0 mut/Mb**

*Samples exhibiting instability in >= 20% of microsatellites are reported as MSI-High. Samples below the 20% threshold are reported as MSI-Stable, except for endometrial tumors, which are reported as MSI-indeterminate. Additional confirmation test can be ordered to evaluate MSI-indeterminate results.

Clinical Significance

Neo Comprehensive - Solid Tumor detects genomic alterations that are most relevant to diagnosis, therapy selection, prognosis, and clinical trial options in solid tumors. It Is appropriate for patients with newly diagnosed, recurrent, or resistant disease.

Specimen Requirements

A block is preferred for testing: ?20% tumor and ?10 mm² of tissue surface area for NGS (~500 tumor cells)
(if PD-L1 is ordered, at least 100 neoplastic cells are required)

If submitting 5 ?m unstained slides, the following number of slides are requested:

- Samples with ? 25 mm² of tissue: 10 unstained slides (2 sections per slide preferred)
- Samples with 10-24 mm² 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. Please use positively charged slides and 10% NBF 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)*

81455x1. 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 81456x1 instead. Add 88360x1 for PD-L1 IHC.

New York Approved

No

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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