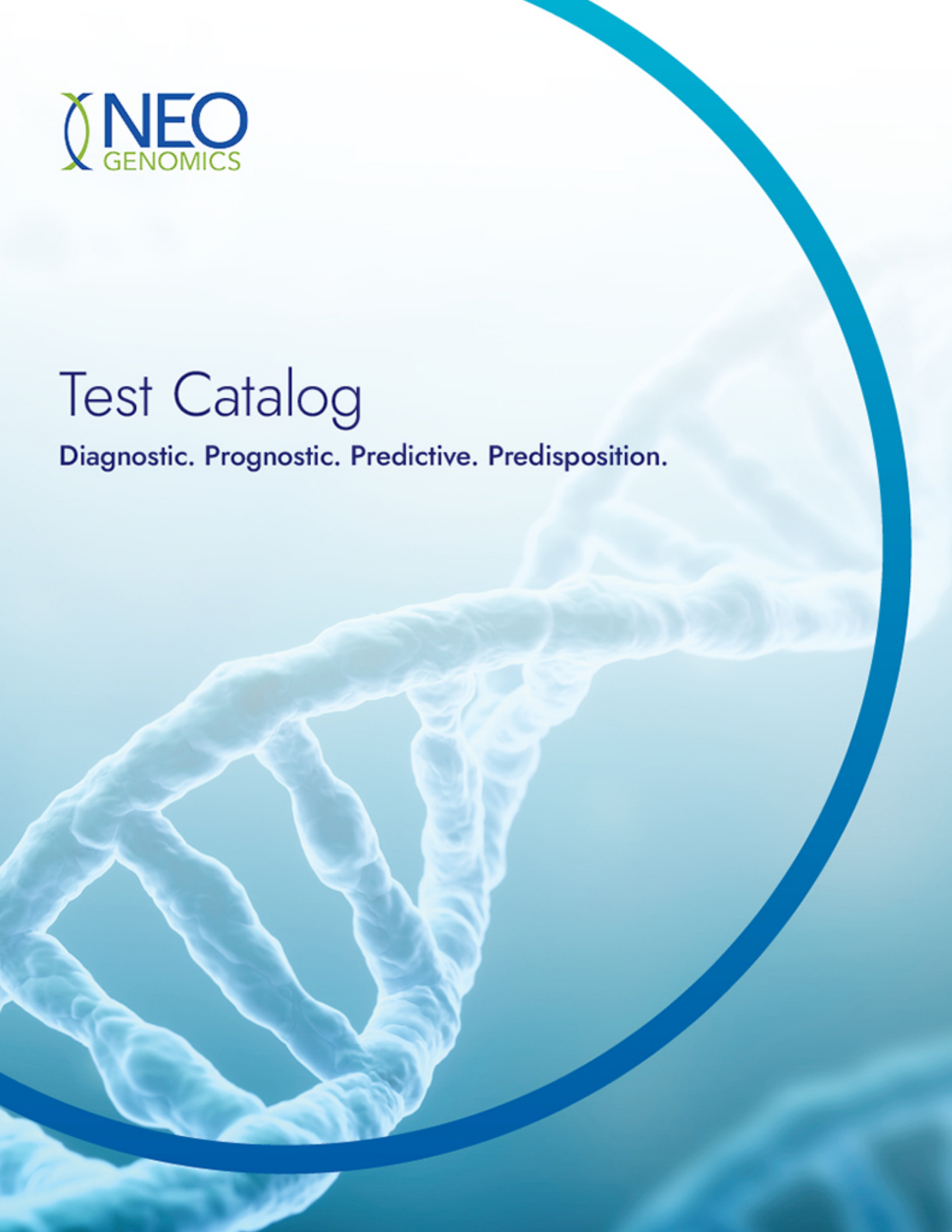
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



NeoTYPE® DNA & RNA - Brain

Alternative Name
Brain Tumor Profile

Methodology
Molecular

Test Description
NeoTYPE® DNA & RNA - Brain uses targeted next-generation sequencing (NGS) to detect single nucleotide variants, insertions/deletions, and gene fusions in 83 unique genes (62 genes analyzed by DNA and 28 by RNA), plus microsatellite instability (MSI) and tumor mutational burden (TMB). In addition, FISH is performed to detect nine key copy number alterations and PD-L1 immunohistochemistry is performed. MGMT Promoter Methylation Analysis by PCR is an optional add-on. Results are incorporated into one report providing diagnostic, prognostic, and therapeutic implications, as well as potential clinical trial options. A microsatellite instability 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 both DNA and RNA results, the available results will be reported and alternate CPT® Codes may apply.

- **SNVs/Indels (62 genes):** AKT1, APC, ATRX, BAP1, BCOR, BCORL1, BRAF, CDK6, CDKN2A, CDKN2B, CIC, CTNNB1, DICER1, EED, EGFR, EPCAM, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, FUBP1, GNA11, GNAQ, H3F3A (H3-3A), HIST1H3C (H3C3), HRAS, IDH1, IDH2, KDM6A, KRAS, MAP2K1, MET, MLH1, MSH2, MSH6, MYC, MYCN, NOTCH1, NF1, NF2, NRAS, PDGFRA, PIK3CA, PMS2, PTCH1, PTEN, RB1, SETD2, SF3B1, SMAD4, SMARCA4, SMARCB1, SMO, SRC, SUFU, SUZ12, TERT Promoter, TP53, TSC1, TSC2, and VHL
- **RNA Fusions (28 genes):** ALK, BRAF, CIC, EGFR including EGFRvIII, EML4, ETV6, EWSR1, FGFR1, FGFR2, FGFR3, FUS, KIAA1549, MAML2, MET, MN1, MYB, MYBL1, NTRK1, NTRK2, NTRK3, PRKCA, RAF1, ROS1, STAT6, TACC3, TFG, YAP1, and ZFTA (C11orf9)
- **CNVs by FISH (9 CNVs):** 1p/19q co-deletion, +7/-10 (trisomy 7, monosomy 10), CDKN2A (p16) deletion, EGFR amplification, MET amplification, MYCN amplification, PDGFRa amplification, and PTEN deletion (FISH is global only)
- **IHC:** PD-L1 LDT (tech-only available)
- **Other Biomarkers:** Microsatellite Instability (MSI) and Tumor Mutation Burden (TMB) included. MGMT Promoter Methylation Analysis may be added.

Clinical Significance
NeoTYPE® DNA & RNA – Brain is intended to provide a tumor genomic profile that includes the most clinically significant genomic alterations according to the 2021 WHO Classification of Tumors of the CNS, 5th edition. These genomic findings may help inform diagnosis, prognosis, therapeutic decisions, and clinical trial options. This profile is appropriate for patients with newly diagnosed, recurrent, or resistant disease.

Specimen Requirements
FFPE solid tumor tissue: Minimum surface area 10mm^2 with ?20% tumor content. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

- **Paraffin block:** Preferred.
- **Cut slides:** Send ?25 unstained sections cut at 5 microns plus one H&E slide (which NeoGenomics will keep). No additional slides are needed if ordering MGMT Promoter Methylation Analysis.

Storage & Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen. Slides can be packed at room temperature.

CPT Code(s)*

81455x1, 88377x8, 88360x1. Add 81287x1 if ordering MGMT Promoter Methylation Analysis.

Medicare MolDX CPT Code(s)*

81479x1, 88377x8, 88360x1. 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 of 81479x1. (SEE NOTES)

New York Approved

Yes

Turnaround Time

14 days

Notes

Add 81287x1 if ordering MGMT Promoter Methylation Analysis.

References

1. Louis DN et al. The 2021 WHO Classification of Tumors of the Central Nervous System: a summary. Neuro-Oncology. 2021;23(8):1231-1251. https://doi.org/10.1093/neuonc/noab106

*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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Rev. 120922