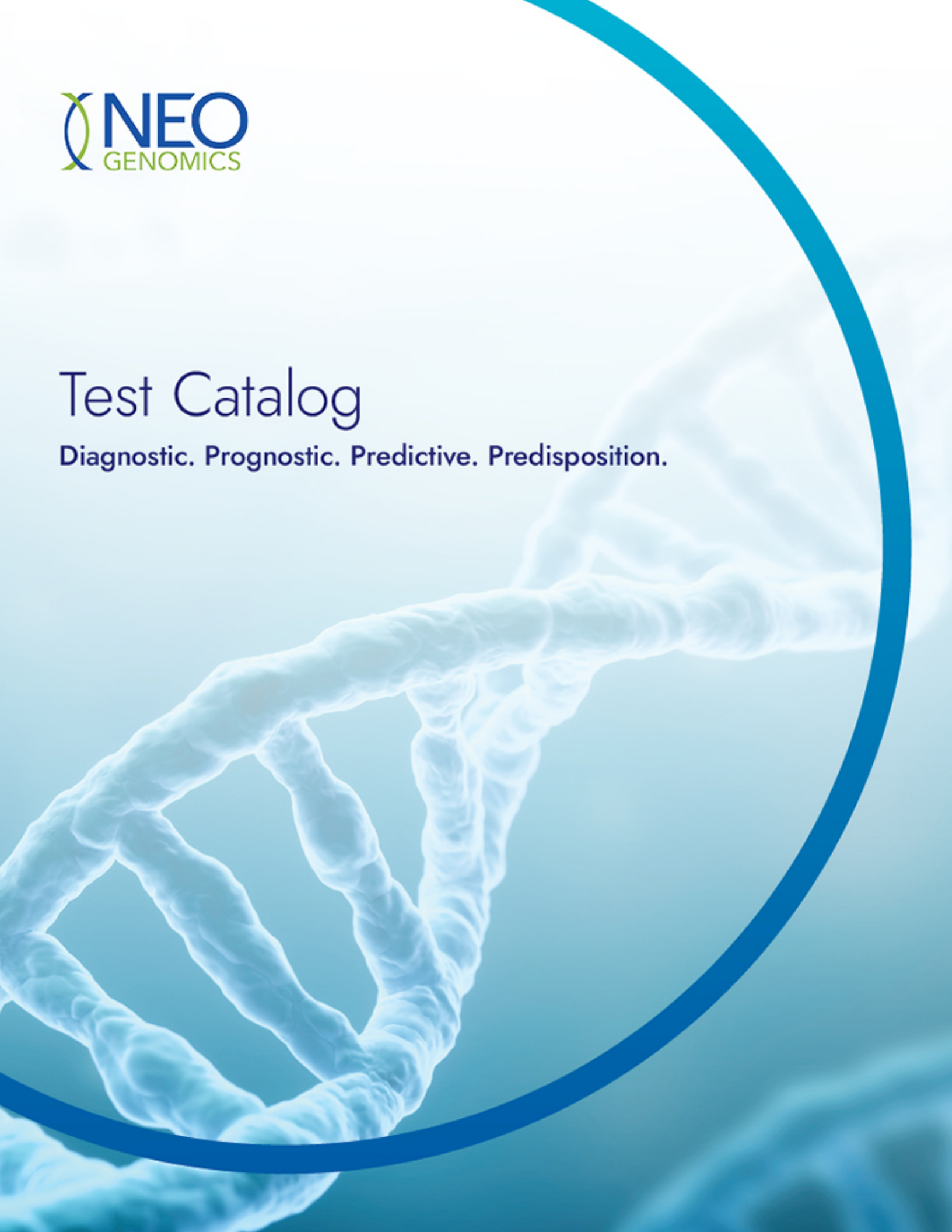
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



NeoTYPE® HRR Profile

Alternative Name
Homologous Recombination Repair/ Deficiency (HRR / HRD)

Methodology
Molecular

Test Description
The NeoTYPE HRR Profile analyzes 31 biomarkers through a combination of next-generation sequencing (NGS) and IHC as listed below.

- NGS (30 genes): ATM, ATR, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, MLH1, MRE11A, MSH2, MSH6, NBN, PALB2, PMS2, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, TP53
- IHC (1 biomarker): PD-L1 LDT (tech-only available for PD-L1)

Clinical Significance
Homologous recombination repair (HRR) is a pathway where mutations in genes involved in the repair of double-stranded DNA breaks have lost the ability to repair DNA and thus may lead to diseases such as cancer. BRCA1, BRCA2, ATM, PALB2, and RAD51 are among the best-known genes in this repair complex; 26 such genes are included in the NeoTYPE HRR Profile which is a tumor profile for somatic mutation detection. PARP inhibition targets HRR/HRD-mutated cells by further crippling DNA repair and inducing synthetic lethality of tumor cells. PARP inhibition is an active area of clinical trial research across a wide variety of tumors. Breast, ovarian, pancreatic, and prostate are the cancers most studied for response to FDA-approved and off-label therapy uses. Some tumors with HRR/HRD mutations have shown susceptibility to platinum-based chemotherapy.

This Profile also includes four genes associated with Lynch Syndrome, another cause of genomic scarring due to mismatch repair deficiency and microsatellite instability. Checkpoint inhibitor therapy may be considered for patients whose tumors express these defects.

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; 88360x1

Medicare MolDX CPT Code(s)*
81445

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 days

References

1. O'Kane GM, Connor AA, Gallinger S. Characterization, detection, and treatment approaches for homologous recombination deficiency in cancer. *Trends Mol Med.* 2017;23(12):1121-1137.
2. Faraoni I, Graziani G. Role of BRCA mutations in cancer treatment with poly(ADP-ribose) polymerase (PARP) inhibitors. *Cancers*. 2018;10:487; doi:10.3390/cancers10120487

*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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