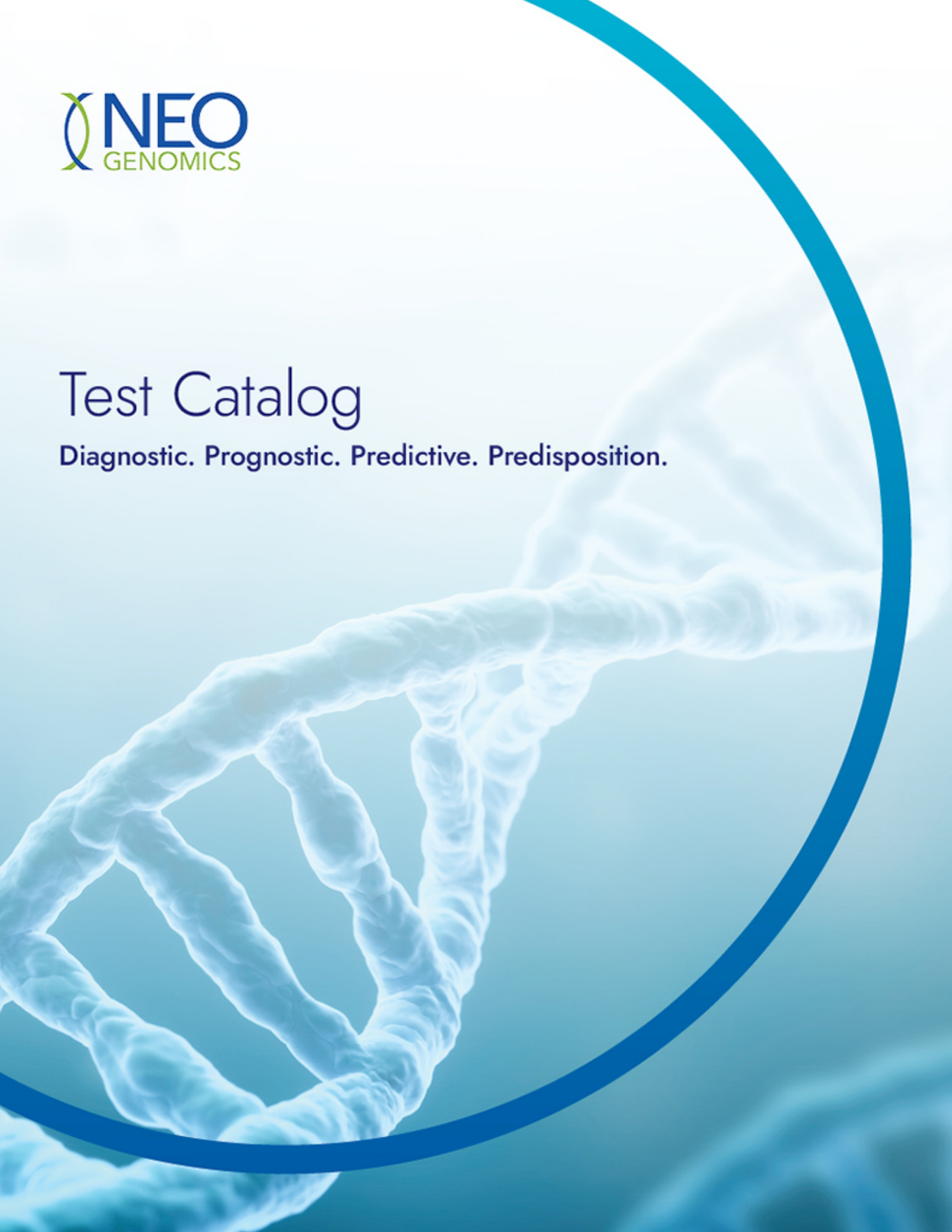
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



PD-L1 22C3 FDA (KEYTRUDA®) for TNBC (Breast)

Methodology
Immunohistochemistry (IHC)

Test Description
PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) triple-negative breast cancer (TNBC) tissue using EnVision FLEX visualization system on Autostainer Link 48. This test is indicated as an aid in identifying TNBC patients for treatment with KEYTRUDA® (pembrolizumab). Tissues with PD-L1 Combined Positive Score (CPS) ? 10 are considered positive.

Stain-only (tech-only) testing is available to clients who have completed the test kit manufacturer's online interpretation training.

All PD-L1 IHC test options may be viewed here.

Clinical Significance
PD-L1 22C3 FDA (KEYTRUDA®) for TNBC is a companion diagnostic (CDx) for certain triple-negative breast cancer patients. PD-L1 expression with ?10% Combined Positive Score (CPS) may be associated with increased progression-free survival in patients with metastatic or advanced, locally unresectable TNBC treated with KEYTRUDA® and chemotherapy.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.
- For PD-L1 22C3 evaluation, tissue submitted must have ?100 viable tumor cells present.

Storage & Transportation
Use cold pack for transport. Make sure cold pack is not in direct contact with specimen.

CPT Code(s)*
88360x1

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time

Global: 48 hours, Tech-Only (stain only): 24 hours

References

1. PD-L1 IHC 22C3 pharmDx [package insert]. Carpinteria, CA: Dako; PT0020/Rev F.
2. KEYTRUDA® (pembrolizumab) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc; usmg-mk3475-iv-2011r036

*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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