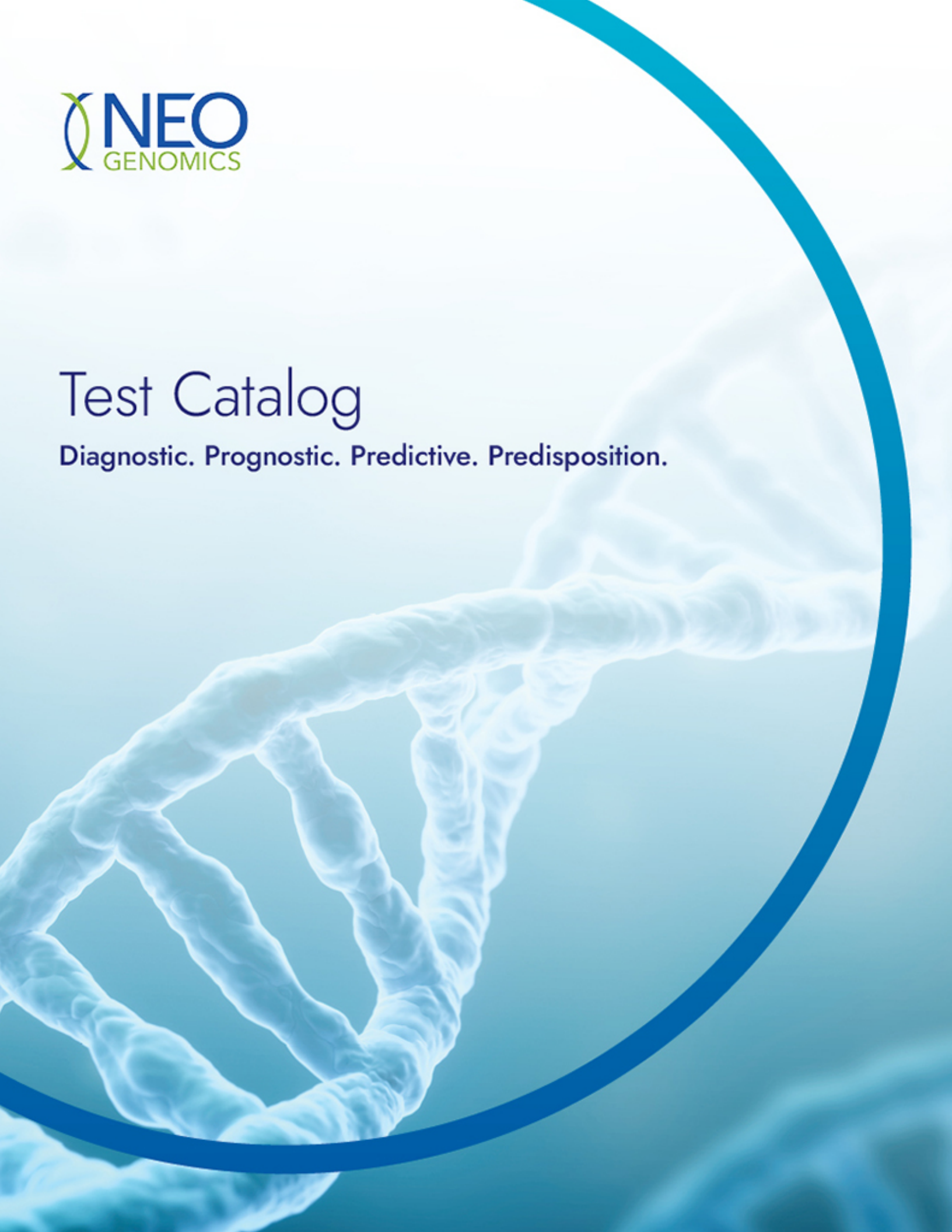
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



PD-L1 22C3 FDA (KEYTRUDA®) for ESCC (Esophageal Squamous Cell Carcinoma)

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) esophageal squamous cell carcinoma (ESCC) and certain other tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying ESCC patients for treatment with KEYTRUDA® (pembrolizumab). KEYTRUDA® is approved for use in some ESCC patients whose tumors express PD-L1 with Combined Positive Score (CPS) ? 10.

For other tumor types with approved indications for this test, please search our Test Menu for "22C3" to see available options.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 3-4 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; P03951_11/SK00621-5/2019.08
2. KEYTRUDA® (pembrolizumab) [package insert]. Whitehouse Station, NJ: Merck & C o., Inc: uspi-mk3475-iv-1907r029

*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. 050724