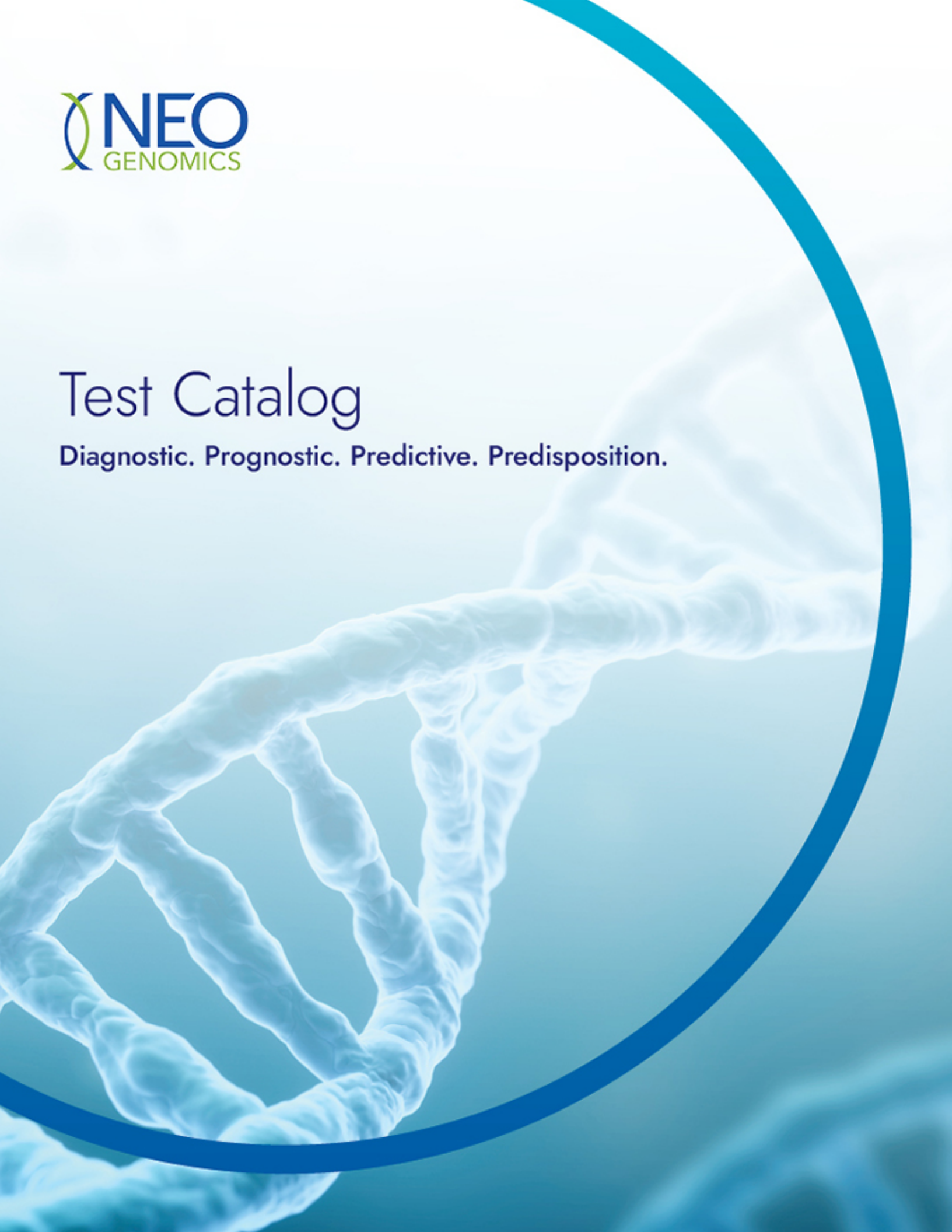
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



PD-L1 28-8 (OPDIVO®) for Gastric/GEJ/EAC

Alternative Name
PD-L1 28-8 (OPDIVO®) for Gastric/GEJ/Esophageal Adenocarcinoma

Methodology
Immunohistochemistry (IHC)

Test Description
PD-L1 IHC 28-8 pharmDx is a qualitative immunohistochemical assay using monoclonal rabbit anti-PD-L1, clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) gastric carcinoma, gastroesophageal junction carcinoma (GEJ) and esophageal adenocarcinoma (EAC) tissues using EnVision FLEX visualization system on Autostainer Link 48. Although PD-L1 testing has not received the FDA-approval for these tumor types, the CHECKMATE 649 Study showed that OPDIVO® (nivolumab) in combination with chemotherapy demonstrated superior overall survival (OS) and progression-free survival (PFS) when compared to chemotherapy alone.

Tissues with PD-L1 Combined Positive Score (CPS) ? 5 are considered to have PD-L1 expression.

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.

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.

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
Global, Stain Only

Turnaround Time

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

Notes

1. Janjigian YY, Shitara K, Moehler M, et al. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. Lancet. 2021;398(10294):27-40.

*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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