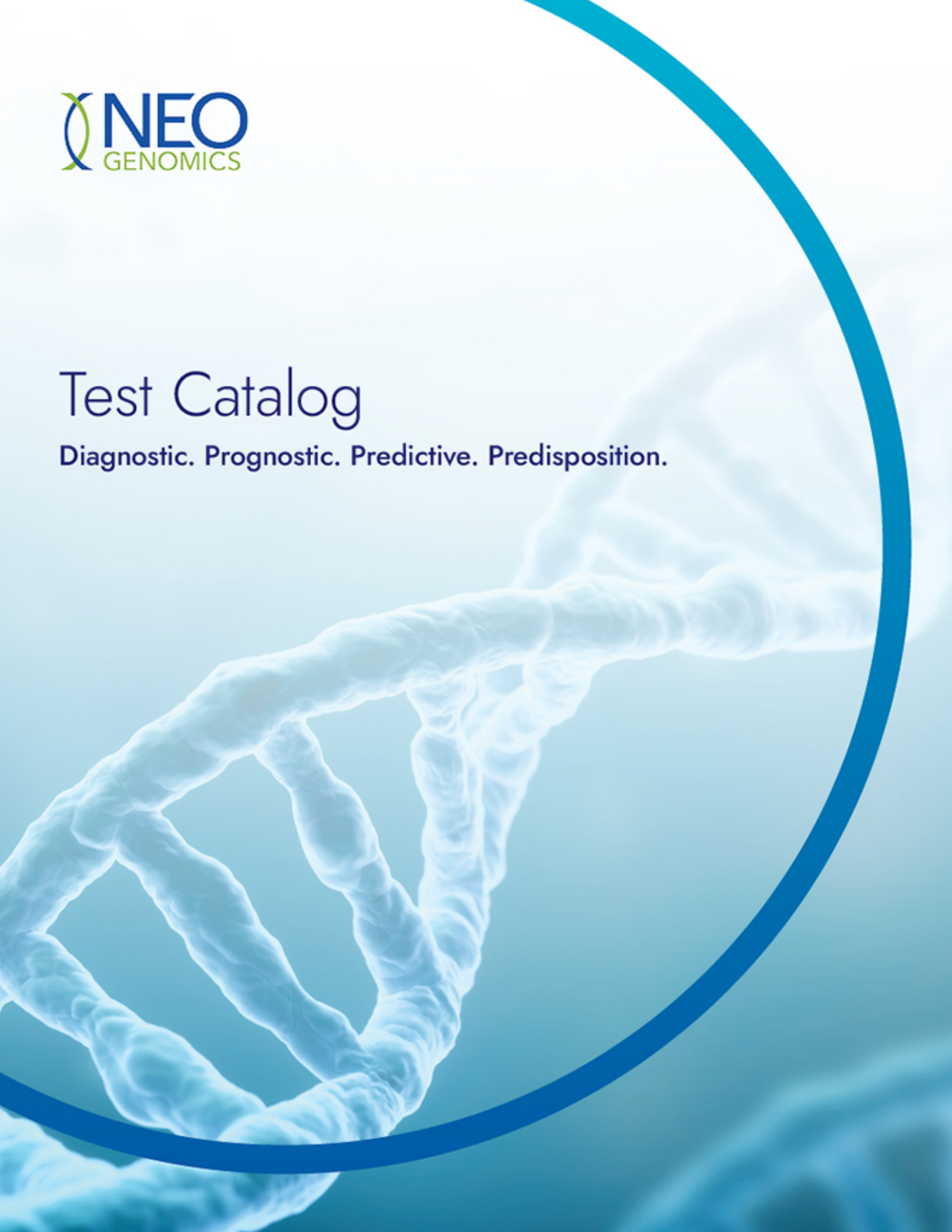
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



PD-L1 28-8 FDA for NSCLC

Alternative Name
Formerly named PD-L1 28-8 FDA (OPDIVO® + YERVOY®) for NSCLC

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) non-small cell lung cancer (NSCLC) tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 IHC 28-8 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with OPDIVO® (nivolumab) or OPDIVO in combination with YERVOY® (ipilimumab). Results are considered positive for either treatment when PD-L1 is expressed in ?1% of tumor cells (TC).

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

Please note: PD-L1 testing is not required for use of OPDIVO® in non-squamous NSCLC, head and neck squamous cell carcinoma or urothelial carcinoma, but may provide physicians more information and inform patient dialogue.

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 28-8 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 28-8 pharmDx [package insert]. Carpinteria, CA: Dako;

*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. 112224