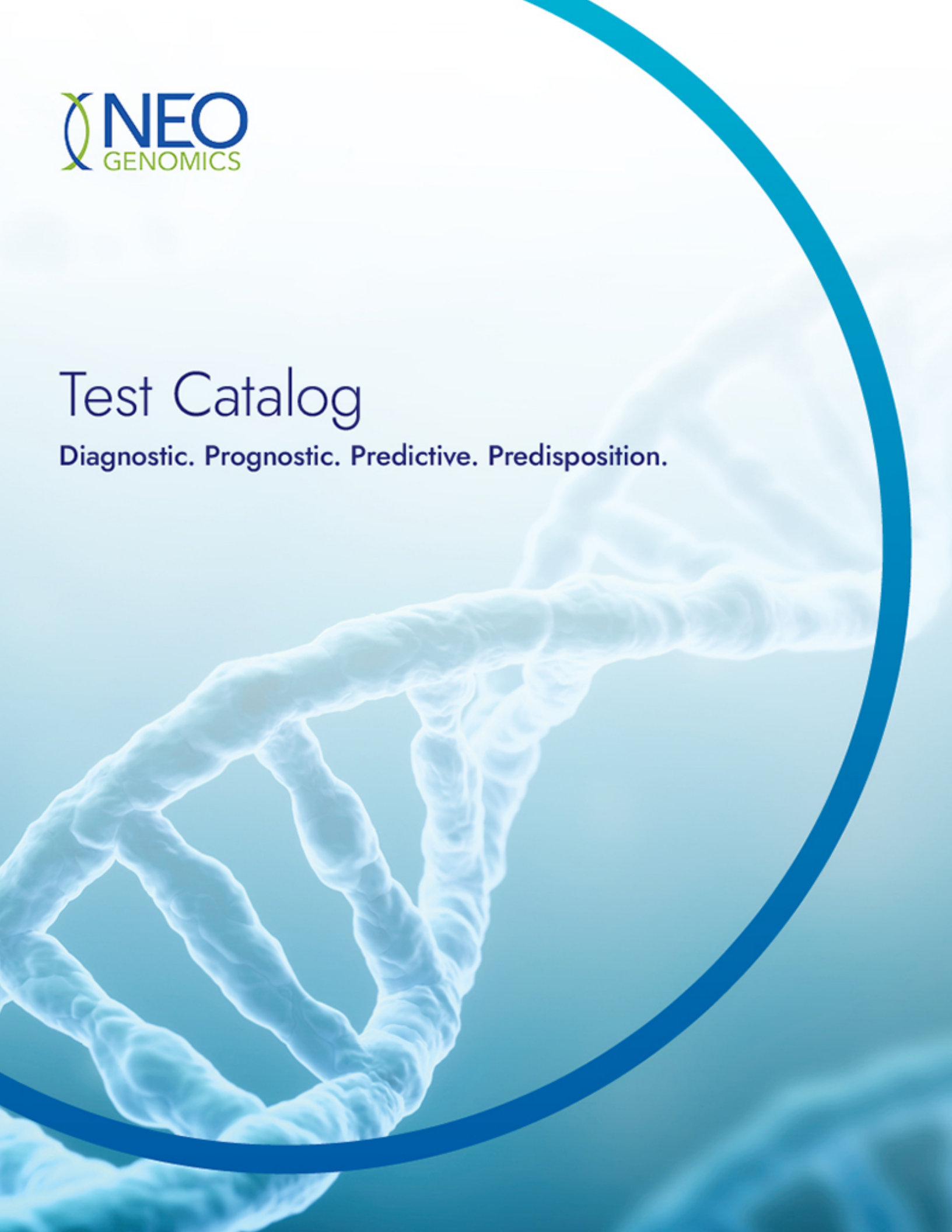
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



PD-L1 LDT

Methodology
Immunohistochemistry (IHC)

Test Description
Programmed cell death ligand 1 (PD-L1) is a transmembrane protein involved in cellular and humoral immune response regulation. PD-L1 expression has been found in a variety of cancers expressed on tumor and/or immune cells. This lab developed test uses the Zeta PD-L1 monoclonal antibody clone ZR3 to detect PD-L1 in formalin-fixed paraffin-embedded tissues. The utility of PD-L1 (ZR3) in predicting the response to anti-PD-1/PD-L1 has not been determined and no standardized scoring criteria currently exist. For therapies and indications that have an FDA-approved PD-L1 companion diagnostic, it is recommended to use the associated FDA approved PD-L1 test.

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

Scoring for this test is called "Total PD-L1 Expression" and is calculated by dividing the sum of the number of staining tumor cells and inflammatory cells by the total number of viable tumor cells. Results are reported as “detected” if the total score is ?1 and “not detected” if <1. This algorithm is comparable to Combined Positive Score used with PD-L1 22C3.

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 LDT 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

*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.

*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.

9490 NeoGenomics Way
Fort Myers, FL 33912
Phone: 239.768.0600/ Fax: 239.690.4237
neogenomics.com

Rev. 052024