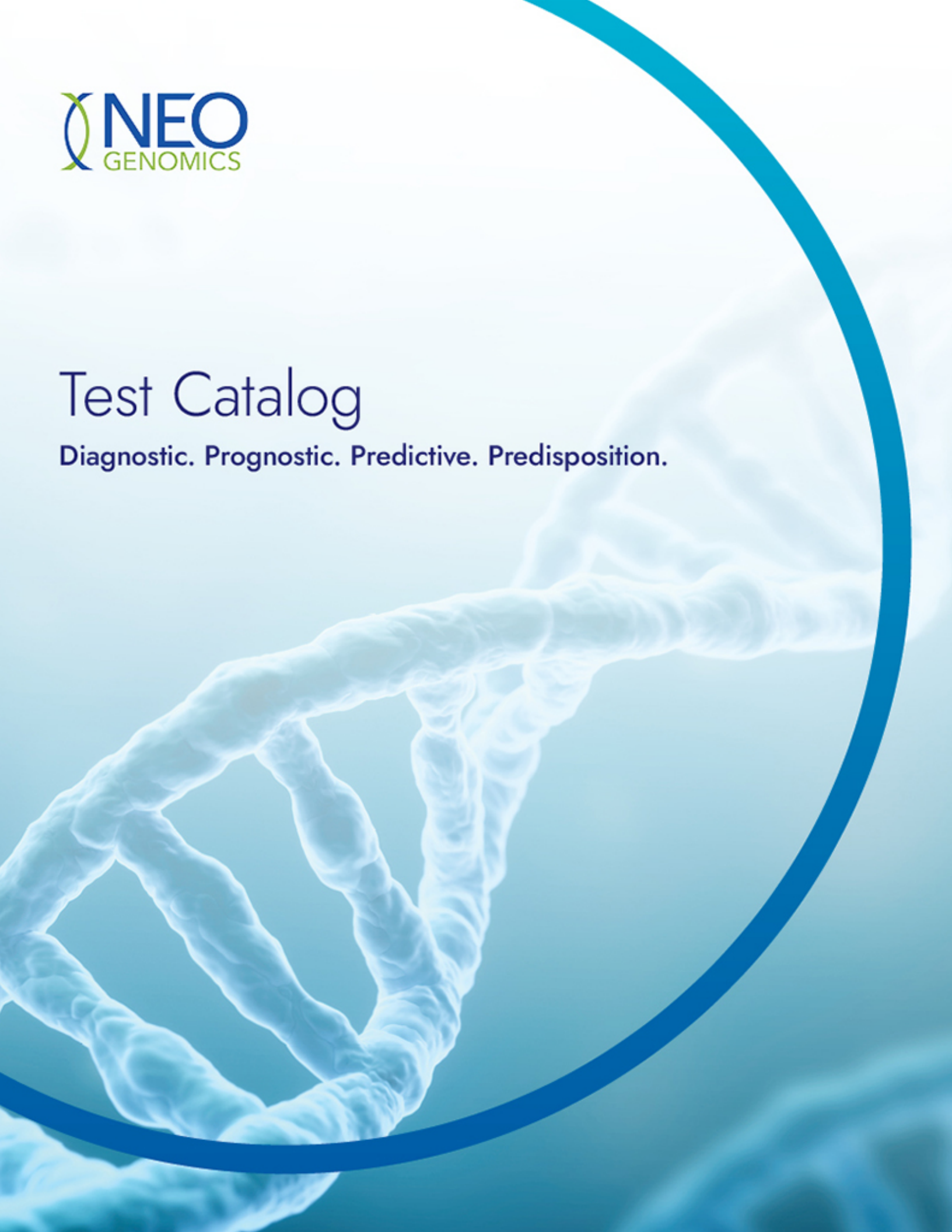
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



PD-L1 SP263 FDA for NSCLC

Methodology
Immunohistochemistry (IHC)

Test Description
The VENTANA PD-L1 (SP263) assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP263 intended for use in the assessment of the PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue on a VENTANA BenchMark ULTRA instrument. PD-L1 (SP263) is indicated as an aid in identifying NSCLC patients for treatment with TECENTRIQ® (atezolizumab) or LIBTAYO® (cemiplimab-rwlc). Results are considered positive for TECENTRIQ when tumors have PD-L1 expression on ? 1% of tumor cells (TC) at any intensity and positive for LIBTAYO when tumors have PD-L1 expression on ?50% of tumor cells (TC) at any intensity.

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

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 SP263 evaluation, tissue submitted must have ?50 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. TECENTRIQ® [package insert]. South San Francisco, CA: Genentech, Inc.;

*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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