HENRY FORD HEALTH
CENTER FOR PRECISION DIAGNOSTICS

PD-L1 Expression by ImmunoHistoChemistry (IHC): Clone 28-8

This test is an Immunohistochemistry (IHC) stain that detects PD-L1 28-8 clone protein expression in Formalin-fixed, paraffin-embedded (FFPE) tissue.

Testing Method and Background

PD-L1 IHC 28-8 pharmDx assay 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-squamous non-small cell lung cancer (NSCLC) and melanoma tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is defined as the percentage of tumor cells exhibiting positive membrane staining at any intensity.

Evidence suggests the level of PD-L1 expression in the tumor cell population is a major predictor of response to nivolumab. The scoring system that has been approved for this assay considers positive tumors as those with a tumor proportion score (TPS) of > 1%. Levels of expression of PD-L1 in other tumors may also be predictive of response to nivolumab. This assay has been FDA approved as a "complementary diagnostic" test for the assessment of patients with non-small cell lung cancers (NSCLC) and melanoma who are being considered for treatment with OPDIVOe (nivolumab), a drug that targets PD-1, a receptor for PD-L1 found on immune cells.

Highlights of PD-L1 Expression by ImmunoHistoChemistry (IHC): Clone 28-8

Targeted Region

PD-L1 Clone 28-8 Protein Expression

- **FDA approved as a "complementary diagnostic" test**
  This assay has been FDA approved as a "complementary diagnostic" test for the assessment of patients with non-small cell lung cancers (NSCLC) and melanoma who are being considered for treatment with OPDIVOe (nivolumab).

Ordering Information

Get started (non-HFHS): Print a Molecular Solid Tumor Requisition form online at www.HenryFord.com/HFCPD

Get started (HFHS): Order through Epic using test " PD-L1 Expression by ImmunoHistoChemistry (IHC): Clone 28-8" (MOL800901)

Specimen requirements:
A surgical pathologist should confirm the presence of adequate tumor in materials submitted for analysis.

- Formalin-fixed, paraffin-embedded tissue, preferably no older than 2 years

Cause for Rejection: Fresh unfixed tissue, paraffin materials that do not contain tumor cells, improperly labeled specimens.

TAT: 3-5 business days

Mail test material to:
Henry Ford Center for Precision Diagnostics
Pathology and Laboratory Medicine
Clinic Building, K6, Core Lab, E-655
2799 W. Grand Blvd., Detroit, MI 48202

CPT Codes: 88360, G0452

Contact us: Client Services, Account and Billing Set-up, and connect with a Molecular Pathologist at (313) 916-4DNA (4362)

For more information on Comprehensive Molecular Services, visit our website
www.HenryFord.com/HFCPD

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