HENRY FORD HEALTH
CENTER FOR PRECISION DIAGNOSTICS

PD-L1 Expression by ImmunoHistoChemistry (IHC): Clone 22C3

This test is an Immunohistochemistry (IHC) stain that detects PD-L1 22C3 clone protein expression in Formalin-fixed, paraffin-embedded (FFPE) tissue.

Testing Method and Background

PD-L1 IHC 22C3 pharmDx assay is a qualitative immunohistochemical assay using monoclonal mouse anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE).

PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. PD-L1 protein expression in gastric or GEJ adenocarcinoma, ESCC, cervical cancer, triple negative breast carcinoma, urothelial carcinoma and HNSCC is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100.

This assay has been FDA approved for patients with non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction (GEJ) adenocarcinoma, esophageal squamous cell carcinoma (ESCC), cervical cancer, triple negative breast carcinoma, urothelial carcinoma and head and neck squamous cell carcinoma (HNSCC) tissues using EnVision FLEX visualization system on Autostainer Link 48.

Highlights of PD-L1 Expression by ImmunoHistoChemistry (IHC): Clone 22C3

Targeted Region

PD-L1 Clone 22C3 Protein Expression

- **FDA approved IHC assay**
  This assay has been FDA approved for patients with non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction (GEJ) adenocarcinoma, esophageal squamous cell carcinoma (ESCC), cervical cancer, triple negative breast carcinoma, urothelial carcinoma and head and neck squamous cell carcinoma (HNSCC) tissues

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 22C3" (MOL800902)

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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