

Overview

Useful For

Identification of neoplasms expressing programmed cell death 1-ligand 1 (clone SP263)

Special Instructions

- [PD-L1 by Immunohistochemistry: Options for Companion and Complementary Diagnostic Assays](#)

Method Name

Immunohistochemistry (IHC)

NY State Available

Yes

Specimen

Specimen Type

Special

Advisory Information

For information on selection of programmed cell death 1-ligand 1 (PD-L1) testing, see PD-L1 by [Immunohistochemistry: Options Companion and Complementary Diagnostic Assays](#) in Special Instructions.

Shipping Instructions

Attach the green pathology address label included in the kit to the outside of the transport container.

Necessary Information

A pathology/diagnostic report and a brief history, including primary site of neoplasm, are required.

Specimen Required

Supplies: Pathology Packaging Kit (T554)

Specimen Type: Formalin-fixed, paraffin-embedded tissue block; or 3 unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue

Additional Information: One slide will be stained with hematoxylin and eosin and returned.

Reject Due To

Tissue/Slides	Wet/frozen tissue Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides
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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Special	Ambient (preferred)		
	Refrigerated		

Clinical and Interpretive

Clinical Information

Programmed cell death 1-ligand 1 (PD-L1), also known as B7 homolog 1 (B7-H1) or CD274, is a transmembrane protein involved in the regulation of cell-mediated immune responses through interaction with the receptor programmed death protein-1 (PD-1). PD-L1 has been identified as both a prognostic and theranostic marker in a variety of neoplasms. Overexpression of PD-L1 has been observed in carcinomas of the urinary bladder, lung, thymus, colon, pancreas, ovary, breast, kidney, and in melanoma and glioblastoma.

Interpretation

The results of the test will be reported in form of scores. The scoring system is based on type and origin of tumor. If additional interpretation or analysis is needed, order PATHC / Pathology Consultation along with this test.

Cautions

Preclinical studies suggest that positive programmed cell death 1-ligand 1 (PD-L1) immunohistochemistry in tumor cells may predict tumor response to therapy with immune checkpoint inhibitors. This result should not be used as the sole factor in determining treatment, as other factors (eg, tumor mutation burden and microsatellite instability) have also been studied as predictive markers.

This test has been validated for nondecalcified paraffin-embedded tissue specimens fixed in 10% neutral-buffered formalin. This assay has not been validated on tissues subjected to the decalcification process or use of alternative fixatives for bone and bone marrow specimens or cell blocks.

Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen-dependent. Best practice is for paraffin sections to be cut fresh.

Clinical Reference

- Rimm DL, Han, G, Taube JM, et al: A prospective, multi-institutional, pathologist-based assessment of 4 immunohistochemistry assay for PD-L1 expression in non-small cell lung cancer. *JAMA Oncol* 2017 August 1;3(8):1051-1058 doi: 10.1001
- Gaule P, Smithy JW, Toki M, et al: A quantitative comparison of antibodies to programmed cell death 1 Ligand 1. *JAMA Oncol* 2017;3(2):256-259
- Sunshine JC, Nguyen P, Kaunitz G, et al: PD-L1 expression in melanoma: A quantitative immunohistochemical antibody comparison. *Clin Can Res* 2017 April 20
- D'Incecco A, Andreozzi M, Ludovini V, et al: PD-1 and PD-L1 expression in molecularly selected non-small-cell lung cancer patients. *Br J Cancer* 2015;112(1):95-102
- Mansfield AS, Roden AC, Peikert T, et al: B7-H1 expression in malignant pleural mesothelioma is associated with sarcomatoid histology and poor prognosis. *J Thorac Oncol* 2014;9(7):1036-1040

Performance

Method Description

Immunohistochemistry on sections of paraffin-embedded tissue using Ventana PD-L1 clone SP263.(Unpublished Mayo method)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday

Analytic Time

5 days

Maximum Laboratory Time

7 days

Specimen Retention Time

Until reported

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

88360

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
SP263	PD-L1 (SP263) SemiQuant IHC, Manual	In Process

Result ID	Test Result Name	Result LOINC Value
603756	Interpretation	59465-5



Result ID	Test Result Name	Result LOINC Value
603757	Participated in the Interpretation	No LOINC Needed
603758	Report electronically signed by	19139-5
603759	Material Received	81178-6
603760	Disclaimer	62364-5
603761	Case Number	80398-1