

Programmed Death-Ligand 1 (PD-L1) (SP142), Semi-Quantitative Immunohistochemistry, Manual

#### Overview

#### **Useful For**

Identification of neoplasms expressing programmed cell death 1-ligand 1 (clone SP142)

#### **Method Name**

Immunohistochemistry (IHC)

#### **NY State Available**

Yes

## Specimen

## **Specimen Type**

Special

#### **Ordering Guidance**

In patients with specific tumor types, programmed death-ligand 1 (PD-L1) immunohistochemistry (IHC) is indicated to predict response to treatment with PD-L1 inhibitors. The specific PD-L1 clone, scoring method, and eligibility requirements depend on the tumor type, stage of malignancy, previous treatment outcomes, and specific PD-L1 inhibitor under consideration. For assistance with PD-L1 test selection as well as answers to frequently asked questions, see PD-L1 Immunohistochemistry Testing on MayoClinicLabs.com.

#### **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

Specimen Type: Tissue

Supplies: Pathology Packaging Kit (T554)

Collection Instructions: 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.

## **Forms**

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen: Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763)

Oncology Test Request (T729)



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## **Reject Due To**

Decalcified	Reject
bone	
Wet/frozen	
tissue	
Cytology	
smears	
Nonformalin	
fixed tissue	
including	
alcohol-formali	
n-acetic acid	
(AFA), 95%	
ethanol,	
PREFER	
fixatives or	
Zinc formalin	
Nonparaffin	
embedded	
tissue	
Noncharged	
slides	
ProbeOn slides	

## **Specimen Stability Information**

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

## **Clinical & 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-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



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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. Recommended fixation time is between 6 and 48 hours. 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 within 6 weeks.

## **Clinical Reference**

- 1. 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;3(8):1051-1058. doi: 10.1001/jamaoncol.2017.0013
- 2. 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. doi: 10.1001/jamaoncol.2016.3015
- 3. Sunshine JC, Nguyen P, Kaunitz G, et al. PD-L1 expression in melanoma: A quantitative immunohistochemical antibody comparison. Clin Can Res. 2017;23(16):4938-4944. doi:10.1158/1078-0432.CCR-16-1821
- 4. 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. doi: 10.1038/bjc.2014.555
- 5. 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. doi: 10.1097/JTO.000000000000177 6. Magaki S, Hojat SA, Wei B, So A, Yong WH. An introduction to the performance of immunohistochemistry. Methods Mol Biol. 2019;1897:289-298. doi:10.1007/978-1-4939-8935-5\_25

## **Performance**

## **Method Description**

Immunohistochemistry on sections of paraffin-embedded tissue using Ventana PD-L1 clone SP142.(Unpublished Mayo method)

## **PDF Report**

No

## Day(s) Performed



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Monday through Friday

## **Report Available**

5 to 7 days

## **Specimen Retention Time**

Until reported

## **Performing Laboratory Location**

Mayo Clinic Laboratories - Rochester Main Campus

## **Fees & Codes**

#### **Fees**

- Authorized users can sign in to <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact <u>Customer Service</u>.

### **Test Classification**

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

#### **CPT Code Information**

88360

## **LOINC®** Information

Test ID	Test Order Name	Order LOINC® Value
SP142	PD-L1 (SP142) SemiQuant IHC,	85149-3
	Manual	

Result ID	Test Result Name	Result LOINC® Value
603770	Interpretation	59465-5
603771	Participated in the Interpretation	No LOINC Needed
603772	Report electronically signed by	19139-5
603773	Material Received	81178-6
603774	Disclaimer	62364-5
603775	Case Number	80398-1