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**Overview****Useful For**

Identification of neoplasms expressing programmed cell death 1-ligand 1(clone 28-8)

**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)

Reject Due To

Decalcified bone Wet/frozen tissue Cytology smears Nonformalin fixed tissue including alcohol-formalin-acetic acid (AFA), 95% ethanol, PREFER fixatives or Zinc formalin Nonparaffin embedded tissue Noncharged slides ProbeOn	Reject
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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 bladder, lung, gastric and gastroesophageal junction, colon, ovary, breast, kidney, and melanoma.

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**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 non-decalcified paraffin-embedded tissue specimens fixed in 10% neutral-buffered formalin. Recommended fixation time is between 6-48 hrs. This assay has not been validated on tissues subjected to the decalcification process or the 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. Garcia A, Recondo G, Greco M et al. Correlation between PD-L1 expression (clones 28-8 and SP263) and histopathology in lung adenocarcinoma. *Heliyon*. 2020;6(6):e04117
2. Kintslera S, Cassataroa MA, Drosch M, Holenya P, Knuechel R, Braunschweig T. Expression of programmed death ligand (PD-L1) in different tumors. Comparison of several current available antibody clones and antibody profiling. *Ann Diagn Pathol*. 2019;41:24-37
3. O'Malley DP, Yang Y, Boisot S, et al. Immunohistochemical detection of PD-L1 among diverse human neoplasms in a reference laboratory: observations based upon 62,896 cases. *Mod Pathol*. 2019;32(7):929-942
4. Koppel C, Schwellenbach H, Zielinski D, et al. Optimization and validation of PD-L1 immunohistochemistry staining protocols using the antibody clone 28-8 on different staining platforms. *Mod Pathol*. 2018;31(11):1630-1644
5. Phillips T, Simmons P, Inzunza HD, et al. Development of an automated PD-L1 immunohistochemistry (IHC) assay for non-small cell lung cancer. *Appl Immunohistochem Mol Morphol*. 2015;23(8):541-549
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 programmed cell death 1-ligand 1 (PD-L1) clone 28-8.(Unpublished Mayo method)

**PDF Report**

No

**Day(s) Performed**

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 [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 account representative. For assistance, contact [Customer Service](#).

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It 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
288PD	PD-L1 (28-8), SemiQuant IHC, Manual	85148-5

Result ID	Test Result Name	Result LOINC® Value
609995	Interpretation	83056-2
609996	Participated in the Interpretation	No LOINC Needed
609997	Report electronically signed by	19139-5
609998	Material Received	81178-6
609999	Disclaimer	62364-5
610000	Case Number	80398-1