Test Definition: 22C3

Programmed Death-Ligand 1 (PD-L1) (22C3), Semi-Quantitative Immunohistochemistry, Manual

Overview

Useful For
Identification of neoplasms expressing programmed cell death 1-ligand 1 (clone 22C3)

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 "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

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

Specimen Required
This assay requires at least 100 viable tumor cells.

Specimen Type: Tissue
Supplies: Pathology Packaging Kit (T554)
Submit:
Formalin-fixed, paraffin-embedded tissue block
OR
3 Unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue

Additional Information:

1. One slide will be stained with hematoxylin and eosin and returned.
2. Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

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 paraffin embedded tissue	Reject
Wet/frozen tissue	Reject
Cytology smears	Reject
Nonformalin fixed tissue including alcohol-formalin-acetic acid (AFA), 95% ethanol, PREFER fixatives or zinc formalin	Reject
Nonparaffin embedded tissue	Reject
Noncharged slides	Reject
ProbeOn slides	Reject
Snowcoat slides	Reject
Broken or cracked unstained slides	Reject

Broken or cracked stained slides that cannot be repaired	Reject

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-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, gastric and gastroesophageal junction, thymus, colon, pancreas, ovary, breast, kidney, and in melanoma and glioblastoma.

Reference Values

An interpretive report will be provided.

Interpretation

The results of the test will be reported in the 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 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 at Mayo Clinic in Rochester, Minnesota. Specimens are recommended to be placed in formalin within 1 hour of acquisition and fixed between 3 and 72 hours. This assay has not been validated on tissue or cellblocks subjected to alternative fixatives or decalcification.

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.

The charge of glass slides can be affected by environmental factors and subsequently may alter slide staining. Sending unsuitable glass slides can result in inconsistent staining due to poor slide surface chemistry.
Best practices for storage of positively charged slides:
-Minimize time slides are stored after being unpackaged
-Limit exposure to high humidity and heat
-Minimize exposure to plastics

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

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 Cancer 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.0000000000000177
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 Dako PD-L1 clone 22C3.(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 using an analyte specific reagent. 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
22C3	PD-L1 (22C3) SemiQuant IHC, Manual	85147-7

Result ID	Test Result Name	Result LOINC® Value
603763	Interpretation	59465-5
603764	Participated in the Interpretation	No LOINC Needed
603765	Report electronically signed by	19139-5
603766	Material Received	81178-6
603767	Disclaimer	62364-5
603768	Case Number	80398-1