# Test Definition: 22C3

PD-L1 (22C3) SemiQuant IHC, Manual

## Overview

### Useful For

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

### 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

**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.

### Reject Due To

| | |
|---|---|
| Tissue/Slides | Wet/frozen tissue Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides |

### 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, gastric and gastroesophageal junction, 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 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 fresh.

### 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 August 1;3(8):1051-1058 doi: 10.1001

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

3. Sunshine JC, Nguyen PL, Kaunitz GJ, et al: PD-L1 expression in melanoma: A quantitative immunohistochemical antibody comparison. Clin Can Res 2017 Aug 15;23(16):4938-4944

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

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

## Performance

### Method Description

Immunohistochemistry on sections of paraffin-embedded tissue using Dako PD-L1 clone 22C3.(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 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 U.S. 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 |

| Result ID | Test Result Name | Result LOINC Value |
|---|---|---|
| 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 |