

PD-L1 BY IMMUNOHISTOCHEMISTRY: OPTIONS FOR COMPANION AND COMPLEMENTARY DIAGNOSTIC ASSAYS

CLONE MCL TEST CODE	DRUG	TUMOR	SCORING INFORMATION
22C3	Pembrolizumab (Keytruda)	Non-small-cell lung cancer (NSCLC)	Companion diagnostic, scored with tumor proportion score (TPS)
		Urothelial carcinoma	Companion diagnostic, scored with combined positive score (CPS)
		Gastric or gastroesophageal junction adenocarcinoma	
		Cervical cancer	
		Head and Neck Squamous Cell Carcinoma (HNSCC)	
		Esophageal Squamous Cell Carcinoma (ESCC)	
SP263	Nivolumab (Opdivo)	NSCLC	Complementary diagnostic, scored with TPS
	Durvalumab (Imfinzi)	Urothelial carcinoma	Complementary diagnostic scored with tumor cells (TC) or tumor areas with immune cells present (ICP) and tumor infiltrating immune cells (IC)
SP142	Atezolizumab (Tecentriq)	NSCLC	Complementary diagnostic, scored with TPS
		Urothelial cancer	Companion diagnostic scored with IC
	Atezolizumab (Tecentriq) plus nab-paclitaxel (Abraxane)	Breast cancer (triple negative)	Companion diagnostic scored with IC

CLINICAL INFORMATION

PD-L1 immunohistochemistry (IHC) is indicated in patients with specific tumor types in order to predict their responses to treatment with PD-L1 inhibitors. The specific PD-L1 clone, scoring method, and eligibility requirements are dependent on the tumor type, stage of malignancy, previous treatment outcomes, and specific PD-L1 inhibitor being considered.



22C3 | PD-L1 (22C3) SemiQuant IHC, Manual



SP142 | PD-L1 (SP142) SemiQuant IHC, Manual

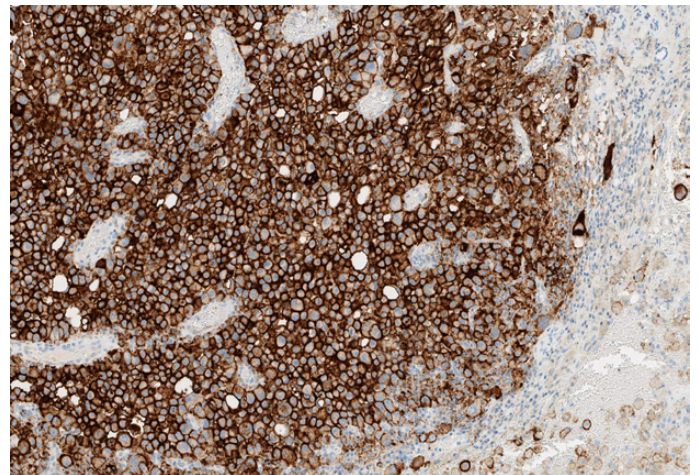


SP263 | PD-L1 (SP263) SemiQuant IHC, Manual

If additional interpretation or analysis is needed, request test [PATHC/Pathology Consultation](#).

SPECIMEN REQUIRED

- Tissue block, formalin-fixed paraffin-embedded; or
- Three unstained slides, four microns thick, formalin-fixed paraffin-embedded tissue



Adenocarcinoma stained with PD-L1 clone 22C3.

FREQUENTLY ASKED QUESTIONS

Q What is PD-L1?

A PD-L1 is expressed on tumor cells and ligates to PD-1, which is expressed on immune cells. This interaction hampers the immune response against tumor cells. Drugs have been developed to block this interaction and boost the immune response.

Q Why does Mayo Clinic Laboratories offer multiple tests for PD-L1?

A We currently offer three clones of the PD-L1 antibody for IHC staining: clone 22C3, clone SP263, and clone SP142. Each clone is associated with a different drug and tumor type and can have a unique staining pattern and interpretation guidelines.

Q Are the three clones all equivalent?

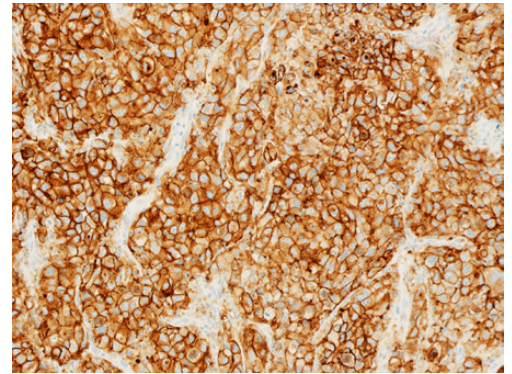
A Generally, clones 22C3 and SP263 have similar staining patterns. Clone SP142 has a lower sensitivity and often stains fewer cells—both tumor cells and immune cells. However, because of the different therapies and tumor types associated with each clone, none of the clones should be used interchangeably. The oncologist should request the appropriate clone for the specific tumor type and therapy under consideration.

Q How are the PD-L1 stains scored and reported?

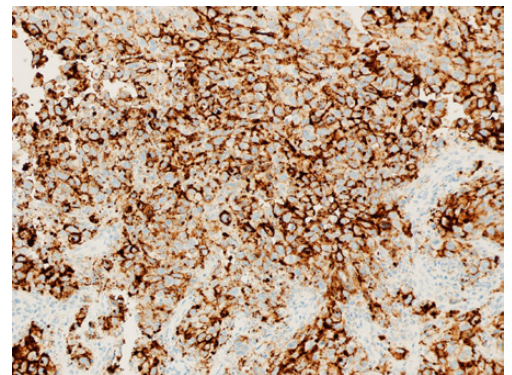
A Interpretation of PD-L1 stains are performed by a Mayo Clinic Laboratories pathologist specializing in that particular tumor type. There are several scoring systems including TPS, CPS, and IC for PD-L1 staining. The scoring system used will depend on the requirements for the specific tumor type, clone, and therapy of interest.

Q What is unique or challenging about the interpretation of PD-L1?

A Both tumor cells and immune cells can express PD-L1. In tumor types that have many macrophages, such as NSCLC, it can be difficult to differentiate between the tumor cells and the immune cells. Also, PD-L1 expression can be very heterogeneous within a tumor, meaning that expression in a single biopsy may not be reflective of the entire tumor. There is also heterogeneity in the expression of PD-L1 between the primary tumor and metastatic tumor, between the primary tumor and recurrent tumor, and among multiple primary tumors.



Adenocarcinoma stained with PD-L1 clone SP263.



Adenocarcinoma stained with PD-L1 clone SP142.