

PD-L1 IHC Testing

Available alongside Strata Select™ testing

Quantification of PD-L1 expression in tumor tissue using immunohistochemistry (IHC) assays is currently the most widely validated, used, and accepted biomarker to guide the selection of patients to receive immune checkpoint inhibitor (i.e., anti-PD-1 or anti-PD-L1) therapies.

Strata Oncology offers PD-L1 IHC testing alongside Strata Select testing. A single test requisition form and sample submission will provide you with comprehensive genomic profiling results and PD-L1 expression to help inform targeted therapy and immunotherapy decisions.

Benefits of Ordering PD-L1 IHC Testing with Strata Select

- Save time: no need to wait for block return from PD-L1 testing to submit for Strata Select testing. PD-L1 IHC results available in less than 7 days from receipt of sample at Strata Oncology
- Conserve tissue: tissue is wasted during block preparation each time new slides are cut. A single block preparation for slides to support molecular analysis and IHC spares tissue
- Better treatment: have a full picture of your patient's tumor characteristics before deciding on therapy

Ordering

PD-L1 IHC testing cannot be ordered as a stand alone test. It may be ordered alongside Strata Select testing, but it is not required.

PD-L1 IHC testing, which will be billed separately, can be added to a Strata Select order by choosing the appropriate clone in either the portal or on the paper requisition form.

There are no special or additional specimen requirements for adding PD-L1 IHC testing to a Strata Select order if a block is being sent. If slides are being sent, then three (3) additional slides must be sent.

When ordering, the desired clone should be specified (see table).

If there is not enough tissue to perform both Strata Select and PD-L1 IHC testing, Strata will reach out to you and request more tissue. If this isn't possible only Strata Select will be performed.

The Strata Oncology Financial Assistance Program is available to help commercial insurance patients, Medicaid patients and patients with no insurance with out of pocket costs.

Questions?

The Strata Oncology Financial Assistance Program is available to help commercial insurance patients, Medicaid patients and patients with no insurance with out of pocket costs such as coinsurance and copays.

Contact the Strata Customer Success Team at
client.services@strataoncology.com or 833.523.0585.

PD-L1 IHC Clone Information

The following table lists tumor types for which there is an FDA-approved PD-L1 IHC companion diagnostic available.

Some tumor types have more than one clone available. The ordering physician should order the clone associated with the therapy they are considering for their patient.

If an approved companion diagnostic is not available for the patient's tumor type, it is the physician's choice which clone to order. Clone 22C3 is generally considered the default choice in these situations.

Tumor Type	Tx Setting	Clone	Scoring Method(s)	Threshold	FDA-approved therapy(ies)
Non-small cell lung cancer (NSCLC)	1L, 2L	22C3	TPS	TPS $\geq$ 1%	Keytruda® (pembrolizumab)
	1L	22C3	TPS	TPS $\geq$ 50%	Libtayo® (cemiplimab-rwlc)
	1L	28-8	TC	TC $\geq$ 1%	Opdivo® (nivolumab) in combination with Yervoy® (ipilimumab)
	1L	SP142	TC and IC	TC $\geq$ 50% or IC $\geq$ 10%	Tecentriq® (atezolizumab)
	Adjuvant	SP263	TC	TC $\geq$ 1%	Tecentriq® (atezolizumab)
Cervical cancer	1L, 2L	22C3	CPS	CPS $\geq$ 1	Keytruda® (pembrolizumab)
Urothelial cancer (URC)	1L	SP142	IC	IC $\geq$ 5%	Tecentriq® (atezolizumab)
Head & neck squamous cell carcinoma (HNSCC)	1L	22C3	CPS	CPS $\geq$ 1	Keytruda® (pembrolizumab)
Esophageal squamous cell carcinoma (ESCC)	$\geq$ 2L	22C3	CPS	CPS $\geq$ 10	Keytruda® (pembrolizumab)
Triple negative breast cancer (TNBC)	1L	22C3	CPS	CPS $\geq$ 10	Keytruda® (pembrolizumab)

Abbreviations: TPS = Tumor Proportion Score, TC = Tumor Cell Score, IC = Tumor-Infiltrating Immune Cell Score, CPS = Combined Positive Score