PD-L1 Immunohistochemistry (IHC) Testing

FOUNDATION MEDICINE®

Foundation Medicine offers IHC testing for PD-L1 as a supplemental test to our portfolio of comprehensive genomic profiling (CGP) tests for clinical customers.

Well-informed Treatment Decisions

The results of PD-L1 IHC testing combined with CGP results, including data on tumor mutational burden (TMB) and microsatellite instability (MSI), may help you make well-informed treatment decisions regarding use of immunotherapies and enrollment in appropriate clinical trials for your patients.

Four IHC Tests to Evaluate PD-L1 Protein Expression

- **Dako® PD-L1 22C3 pharmDx**
  Associated therapies: Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc)
- **Dako® PD-L1 28-8 pharmDx**
  Associated therapies: Opdivo® (nivolumab) in combination with Yervoy® (ipilimumab)
- **Ventana® PD-L1 SP142**
  Associated therapy: Tecentriq® (atezolizumab)
- **Ventana® PD-L1 SP263**
  Associated therapies: Tecentriq® (atezolizumab), Libtayo® (cemiplimab-rwlc)

When ordering PD-L1 through Foundation Medicine, you are asked to select one (or more if appropriate) of these tests by choosing the associated clone (listed as 22C3, 28-8, SP142, and SP263). A patient's tumor type and the therapies under consideration may inform your decision.

Formalin-fixed paraffin embedded (FFPE) blocks are preferred. Alternatively, four additional unstained slides are required per each clone selected (see IHC Specimen Instructions for details). Please note that there may be billing implications if multiple clones are ordered.

Selecting an FDA-Approved PD-L1 IHC Test

Each of the tests above uses its own PD-L1 clone and scoring method with associated therapies. Use the tables on the next page to help determine the appropriate clone for your patient based on their diagnosis and the treatment(s) under consideration.

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NON-SMALL CELL LUNG CANCER (NSCLC)

Therapy	Relevant clone(s) and scoring method
Libtayo® (cemiplimab-rwlc)	Dako PD-L1 22C3 PharmDx assay with Tumor Proportion Score (TPS)
	Ventana PD-L1 (SP263) assay with Tumor Cell (TC) Score (%)
Keytruda® (pembrolizumab)	Dako PD-L1 22C3 PharmDx assay with Tumor Proportion Score (TPS)
Tecentriq® (atezolizumab)	Early disease: Ventana PD-L1 (SP263) assay with Tumor Cell (TC) Score (%)
	Advanced disease: Ventana PD-L1 (SP142) with Tumor Cell (TC) Score (%) and/or Tumor-Infiltrating Immune Cell (IC) Score (%)
Opdivo® (nivolumab) + Yervoy® (ipilimumab)	Dako PD-L1 28-8 pharmDx assay with Tumor Cell Expression Score (%)

OTHER DISEASE TYPES

Therapy	Relevant clone(s)
Keytruda® (pembrolizumab) monotherapy or combination therapy <u>Tumor types with PD-L1 companion diagnostic indications:</u> • Triple-negative breast cancer • Cervical cancer* • Esophageal SCC • HER2-positive gastric/GEJ adenocarcinoma^ • Head and neck SCC	Dako PD-L1 22C3 pharmDx assay with Combined Positive Score (CPS)

*Approved combination regimens include chemotherapy with or without Avastin® (bevacizumab).
^Approved regimen for HER2-positive disease includes Herceptin® (trastuzumab) & fluoropyrimidine- and platinum-based chemotherapy.
GEJ = gastroesophageal junction, SCC = squamous cell carcinoma.

For tumor types that do not have an approved PD-L1 indication, we will use the test indicated on the order. If PD-L1 testing is requested but a clone is not selected, we will default to Dako 22C3 with TPS score in most instances. To learn more about defaults and prioritization of testing, visit foundationmedicine.com/info/detail/ihc-testing

To order a test, go to *www.foundationmedicine.com/info/detail/order-a-test*

References:

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