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.

Three IHC Tests to Evaluate PD-L1 Expression

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

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/Dako 22C3, 28-8/Dako 28-8, or SP142/Ventana SP142). A patient's tumor type and the therapies under consideration may inform your decision. Four additional 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, and has specific therapies associated with it. Some cancer types have multiple options for approved clones. Use the tables below to help determine the appropriate clone for your patient.

NON-SMALL CELL LUNG CANCER (NSCLC)

CLONE OFFERED	SCORING METHOD	FDA-APPROVED THERAPY
Dako 22C3	Tumor Proportion Score (TPS)	Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc)
Dako 28-8	Tumor Cell Expression (%)	Opdivo® (nivolumab) in combination with Yervoy® (ipilimumab)
Ventana SP142	Tumor Cell (TC) and Tumor-Infiltrating Immune Cell (IC) Score	Tecentriq® (atezolizumab)

PD-L1 IHC Clones by Tumor Type Continued on Back

CERVICAL CANCER

CLONE OFFERED	SCORING METHOD	FDA-APPROVED THERAPY
Dako 22C3	Combined Positive Score (CPS)	Keytruda® (pembrolizumab)

UROTHELIAL CARCINOMA (URC)

CLONE OFFERED	SCORING METHOD	FDA-APPROVED THERAPY
Ventana SP142	Tumor-Infiltrating Immune Cell (IC) Score	Tecentriq® (atezolizumab)

HEAD & NECK SQUAMOUS CELL CARCINOMA (HNSCC)

CLONE OFFERED	SCORING METHOD	FDA-APPROVED THERAPY
Dako 22C3	Combined Positive Score (CPS)	Keytruda® (pembrolizumab)

ESOPHAGEAL SQUAMOUS CELL CARCINOMA (ESCC)

CLONE OFFERED	SCORING METHOD	FDA-APPROVED THERAPY
Dako 22C3	Combined Positive Score (CPS)	Keytruda® (pembrolizumab)

TRIPLE NEGATIVE BREAST CANCER (TNBC)

CLONE OFFERED	SCORING METHOD	FDA-APPROVED THERAPY
Dako 22C3	Combined Positive Score (CPS)	Keytruda® (pembrolizumab)

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/ihc.

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

References:

1. Dako PD-L1 IHC 22C3 pharmDx. Package insert. Agilent Technologies, Inc. 2022. https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150013S014C.pdf
2. Dako PD-L1 IHC 28-8 pharmDx. Package insert. Agilent Technologies, Inc. 2020. https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150025S013C.pdf
3. Ventana® PD-L1 SP142. Package insert. Roche Diagnostics GmbH. 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf16/p160002s009c.pdf

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