



PD-L1

INDICATIONS:

1. What: Aurora Diagnostics offers FDA-approved, indication specific PD-L1 stains for melanoma, bladder, lung, breast, gastro-esophageal, cervical, and head & neck cancers.
2. How: Qualitative immunohistochemistry assessment of PD-L1 protein in FFPE tumor tissue. Stains are manually scored by pathologists trained by the vendor. The percentage of tumor and immune cell staining is reported following the FDA- approved protocol.
3. Cost: The CPT charge code is 88360. a. LMC will intercompany bill back to the referring ADX practice.
4. Orders: An ADX requisition will be provided to submit the orders. Select the appropriate PD-L1 order for the tumor type. Contact Customer Service for a requisition.
5. Submit: Either send unstained, charged slides (4 total) or send a tumor block. Blocks will be returned. See "PD-L1 specimen requirements" (separate document) for specific cutting instructions.
6. Stains are performed on an invasive tumor, either primary or metastatic. An H&E stained slide is reviewed by a pathologist to confirm the target area containing tumor. The duration of fixation, using 10% neutral-buffered formalin, is presumed to be no less than 6 hours and no more the 72 hours. Minimum 50 tumor cells recommended.
7. Time: The TAT is usually 72 hrs.
8. Results: Pathology report will be available to the referring ADX facility based on their usual reporting preference.
9. Where: Aurora Diagnostics - LMC Pathology Services
Attn: Send Out Dept.
7455 W. Washington Ave. Suite 301
Las Vegas, NV 89128
Email: lmcsendoutest@lmclabs.com
Tel: 702-732-3441
Fax: 702-732-2310

SPECIMEN:

Formalin-fixed, paraffin-embedded (FFPE) tissue block or slides

VOLUME:

At least two unstained slides sectioned at 4 microns, less than 60 days since sectioning and if stored at 15°C to 30°C. Four slides are ideal.



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MINIMUM VOLUME:

Two unstained slides at 4 microns less than two months since sectioning if stored at 15°C to 30°C.

CONTAINER:

Paraffin block or unstained positively-charged slides

COLLECTION:

Paraffin block or unstained slides sectioned if stored at 15°C to 30°C for two months

STORAGE INSTRUCTIONS:

Refrigerate

CAUSES FOR REJECTION:

Slides sectioned greater than two months prior to test request and not stored at 15°C to 30°C

USE:

The PD-L1 is a qualitative assay intended for use in the detection of PD-L1 in formalin- fixed, paraffin- embedded (FFPE) cancer samples.

METHODOLOGY:

Immunohistochemistry (IHC), Ventana BenchMark Ultra platform or Agilent/Dako Autostainer.