

PD-L1 22C3

Effective Date: July 11, 2017

Synonyms	PD-L1, PD-L1 IHC 22C3 pharmDx, Lung cancer, Lung Adenocarcinoma, pembrolizumab, non-small cell lung cancer (NSCLC)
Instructions	Submit formalin fixed, paraffin embedded tumor tissue block with corresponding H&E slide.
Specimen Collection Criteria	Maintain paraffin-embedded tissue at room temperature (20-25°C or 68-77°F). DO NOT REFRIGERATE OR FREEZE TISSUE BLOCKS
Specimen Preparation for Courier Transport	Transport tissue blocks at room temperature (20-25°C or 68-77°F).
Rejection Criteria	<ul style="list-style-type: none"> Tissue in fixatives other than 10% neutral buffered formalin. (Decalcified FFPE tissue and cytology cell blocks are not FDA approved for testing) Improper labeling, inadequate information
Performed	Twice a week. Results available in 7 business days.
Reference Range	<p>The Tumor Proportion Score (TPS) is the percentage of viable tumor cells showing partial or complete membrane staining ($\geq 1+$) relative to all viable tumor cells present in the sample (positive and negative).</p> <p>PD-L1 expression will be reported as a percentage from 0% to 100%. If there are insufficient tumor cells for evaluation, this will be stated, and a percentage will not be reported. Though the manufacturer's interpretation manual¹ provides the below "Expression Level" categories based on the Tumor Proportion Score (TPS), only the TPS will be reported. "Expression Level" categories will not be reported, because the cutoffs for positive versus negative or treatment versus no treatment depend on the individual patient's clinical history as well as other features which are not known to the interpreting pathologist.</p>
Test Methodology	Immunoperoxidase staining and detection of PD-L1 is performed in formalin-fixed, paraffin embedded tissue sections using a polymer based detection system. 4 micron tissue sections are deparaffinized, subjected to heat-induced antigen retrieval and then sequentially incubated with anti-PD-L1 monoclonal antibody and followed by a polymer detection reagent. Sections are subsequently treated with chromogen diaminobenzidine and the substrate hydrogen peroxide to produce a brown membranous staining in cells expressing PD-L1. Sections are lightly counterstained in Hematoxylin.
Interpretation	Stained slides are examined by a pathologist who will provide a Tumor Proportion Score (TPS) in the interpretive report. Results are reported based on the interpretation guidelines in the FDA approved PD-L1 IHC 22C3 Test
Test Code	MPDLG
CPT Code	88360

If you have questions, please contact Client Services (1-800-551-0488, option 5).

Laboratory Test Directory: <http://beaumontlaboratory.com/test-lab-directory>.

Date submitted: June 14, 2017

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Beaumont Laboratory

Customer Service

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