PD-L1 28-8 pharmDx by Immunohistochemistry with Interpretation, nivolumab (OPDIVO)
ARUP test code 203684

PD-L1 28-8 by IHC Result

>=10%

This result has been reviewed and approved by Parisa Khalili, M.D. Controls performed as expected.

PD-L1 protein expression, if detected by this assay, may be associated with enhanced survival from OPDIVO (nivolumab) therapy in patients with non-squamous non-small cell cancer (NSCLC). However, testing for PD-L1 expression is not required for patients to qualify for treatment with OPDIVO. To be adequate for evaluation, specimens must contain at least 100 viable tumor cells.

PD-L1 protein expression is defined as the percentage of tumor cells exhibiting positive (partial or complete) membrane staining at any intensity. In non-squamous NSCLC specimens, the FDA defines four categories of PD-L1 expression: less than 1 percent, equal to or greater than 1 percent, equal to or greater than 5 percent, and equal to or greater than 10 percent.

Methodology: PD-L1 IHC 28-8 pharmDx by IHC with Interpretation is a qualitative immunohistochemical assay using Monoclonal Rabbit Anti-PD-L1, Clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-squamous NSCLC, squamous cell carcinoma of the head and neck (SCCHN), urothelial carcinoma (UC), and melanoma tissues using Envision FLEX visualization system on Autostainer Link 48. This assay is FDA-approved for non-squamous NSCLC, SCCHN, UC, and melanoma specimens only. The use of this assay on decalcified tissues has not been validated and is not recommended.

For more information, please refer to practice guidelines published by the National Comprehensive Cancer Network (NCCN) at http://www.nccn.org /professionals/physician_gls/f_guidelines_nojava.aspx#site.

Percent of PD-L1 Positive Tumor Cells

21-30%

Adequacy of Specimen

Adequate

PD-L1 Client Block ID

H=High, L=Low, *=Abnormal, C=Critical
### PD-L1 Tissue Source

LUNG

#### VERIFIED/REPORTED DATES

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**END OF CHART**

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*H=High, L=Low, *=Abnormal, C=Critical*