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Jonathan R. Genzen, MD, PhD, Chief Medical Officer

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	Unknown
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

PD-L1 28-8 pharmDx by Immunohistochemistry with Interpretation, nivolumab (OPDIVO)

ARUP test code 2013684

PD-L1 28-8 by IHC Result

Exp >=1%

This result has been reviewed and approved by [redacted] M.D. Controls performed as expected.

INTERPRETIVE INFORMATION: PD-L1 28-8 pharmDx by Immunohistochemistry with Interpretation, nivolumab (OPDIVO)

PD-L1 protein expression, if detected by this assay, is associated with an overall survival benefit from OPDIVO (nivolumab) in combination with YERVOY (ipilimumab) in non-small cell lung cancer (NSCLC). PD-L1 protein expression is defined as the percentage of tumor cells exhibiting positive (partial or complete) membrane staining at any intensity. In NSCLC in the setting of first line combination therapy, the FDA defines two categories of PD-L1 expression: less than 1 percent, and equal to or greater than 1 percent.

PD-L1 protein expression, if detected by this assay, may be associated with enhanced survival from OPDIVO (nivolumab) therapy in patients with previously treated non-squamous non-small cell cancer (nsNSCLC). However, testing for PD-L1 expression is not required for patients to qualify for second line treatment with OPDIVO in this setting.

PD-L1 protein expression, if detected by this assay, may be associated with enhanced survival from OPDIVO (nivolumab) in patients with squamous cell carcinoma of the head and neck (SCCHN). However, testing for PD-L1 expression is not required for patients to qualify for treatment with OPDIVO in this setting. SCCHN specimens are considered PD-L1 positive if the percentage of tumor cells exhibiting PD-L1 staining is equal to or greater than 1 percent.

PD-L1 protein expression, if detected by this assay, may be associated with enhanced response rate from OPDIVO (nivolumab) in patients with urothelial carcinoma (UC). However, testing for PD-L1 expression is not required for patients to qualify for treatment with OPDIVO in this setting. UC specimens are considered PD-L1 positive if the percentage of tumor cells exhibiting PD-L1 staining is equal to or greater than 1 percent.

The predictive value of PD-L1 expression, if detected by this assay, is uncertain in tumors other than non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), and urothelial carcinoma (UC).

No guidelines exist for interpretation of PD-L1 expression in tumors other than NSCLC, SCCHN, and UC.

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

	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. 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-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), and urothelial carcinoma (UC) tissues using EnVision FLEX visualization system on Autostainer Link 48. This assay is FDA-approved for NSCLC, SCCHN, and UC specimens only. The use of this assay on decalcified tissues has not been validated and is not recommended. Submission of slides that have been oven-baked is not recommended, as staining may be affected by over-baking or prolonged time between baking and staining. Submission of specimens fixed in media other than 10% neutral buffered formalin 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.asp#site.
Percent of PD-L1 Positive Tumor Cells	11-20%
Adequacy of Specimen	Adequate
PD-L1 Client Block ID	A-14
PDL1 Tissue Source	Lung

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
PD-L1 28-8 by IHC Result	24-023-102115	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Percent of PD-L1 Positive Tumor Cells	24-023-102115	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Adequacy of Specimen	24-023-102115	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PD-L1 Client Block ID	24-023-102115	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PDL1 Tissue Source	24-023-102115	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

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