ARUP LABORATORIES
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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	11/27/1970
Gender:	Unknown
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

PD-L1 22C3 IHC with Combined Positive Score (CPS) Interpretation, pembrolizumab (KEYTRUDA)

ARUP test code 3000197

PDL1 22C3 IHC Result	Expression

This result has been reviewed and approved by [redacted]
M.D., Ph.D. Controls stained appropriately.
2000 Circle of Hope, RM 3100
Salt Lake City, UT 84112

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

INTERPRETIVE INFORMATION: PDL1 22C3 Combined Positive Score

PD-L1 protein expression in cervical carcinomas (squamous cell carcinomas and adenocarcinomas), esophageal squamous cell carcinoma, head and neck squamous cell carcinomas, and triple-negative breast cancer (ER-negative, PR-negative, Her2-negative) is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells showing partial or complete linear membrane staining equal to or greater than 1+ plus lymphocytes and macrophages within tumor nests and adjacent supporting stroma, as determined by assay manufacturer, showing partial or complete linear and/or cytoplasmic staining equal or greater than 1+) divided by the total number of viable tumor cells, multiplied by 100. For cervical carcinomas and head and neck squamous cell carcinomas, the specimen will be reported to show No PD-L1 Expression if the CPS is less than 1. The specimen will be reported to show PD-L1 Expression if the CPS is greater than or equal to 1. For esophageal squamous cell carcinomas and triple-negative breast cancer, the specimen will be reported to show No PD-L1 Expression if the CPS is less than 10. The specimen will be reported to show PD-L1 Expression if the CPS is greater than or equal to 10.

PD-L1 22C3 by IHC with Interpretation is an immunohistochemical assay using monoclonal mouse anti-PD-L1, clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) in cervical cancer, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma specimens, and triple-negative breast cancer, using EnVision FLEX visualization system on Autostainer Link 48.

The specimen submitted for testing must contain at least 100 viable, invasive tumor cells to be considered adequate for evaluation. This assay is indicated as an aid in identifying cervical cancer, esophageal squamous cell carcinomas, head and neck squamous cell carcinomas, and triple-negative breast cancer in patients considered for treatment with pembrolizumab (KEYTRUDA).
This assay is validated and FDA approved for cervical cancer, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, and triple-negative breast cancer specimens only. Submission of slides that have been oven baked is not recommended as staining may be affected by overbaking or prolonged time between baking and staining. The use of this assay on decalcified tissues has not been validated and is not recommended.
Testing on specimens fixed in any fixative other than 10 percent neutral buffered formalin is not recommended.

Controls were run and performed as expected.

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

Combined Positive Score	11-20
Adequacy of Specimen	Adequate
PD-L1 Client Block ID	S23-4883 1

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

PDL1 Tissue Source	Esophagus

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
PDL1 22C3 IHC Result	23-345-401727	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Combined Positive Score	23-345-401727	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Adequacy of Specimen	23-345-401727	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PD-L1 Client Block ID	23-345-401727	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PDL1 Tissue Source	23-345-401727	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

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