

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

Physician: Doctor, Example

Patient: Patient, Example

DOB 1/14/1952
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 01/01/2017 12:34

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

ARUP test code 3000197

PDL1 22C3 IHC Result

No Expression

This result has been reviewed and approved by Joshua F. Coleman, M.D. Controls performed as expected.

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

Unless otherwise indicated, testing performed at:

INTERPRETIVE INFORMATION: PDL1 22C3 Combined Positive Score

PD-L1 protein expression in gastric and gastroesophageal junction (GEJ) adenocarcinoma (not esophageal squamous cell carcinoma), urothelial carcinoma, cervical carcinomas (squamous cell carcinomas and adenocarcinomas) and head and neck squamous cell carcinomas 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 gastric/GEJ adenocarcinomas, 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 urothelial carcinomas, 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) gastric and GEJ adenocarcinoma, urothelial carcinoma, cervical cancer and head and neck squamous cell carcinoma specimens, 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 gastric/GEJ adenocarcinoma, urothelial carcinoma, cervical cancer and head and neck squamous cell carcinomas in patients considered for treatment with pembrolizumab (KEYTRUDA).

This assay is validated and FDA-approved for gastric/GEJ adenocarcinomas, urothelial, cervical cancer and head and neck squamous cell carcinoma specimens only. For all other specimen types, results should be interpreted with caution and within the appropriate clinical context. The use of this assay on decalcified tissues has not been validated and 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_nojva.va.asp#site.

Combined Positive Score	< 1
Adequacy of Specimen	Adequate
PD-L1 Client Block ID	SP20-01470 B1
PDL1 Tissue Source	STOMACH BIOPSY

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Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Tracy I. George, MD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 20-036-112844
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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4848

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
PDL1 22C3 IHC Result	20-036-112844	2/5/2020 1:27:00 PM	2/5/2020 1:27:18 PM	2/5/2020 3:24:00 PM
Combined Positive Score	20-036-112844	2/5/2020 1:27:00 PM	2/5/2020 1:27:18 PM	2/5/2020 3:24:00 PM
Adequacy of Specimen	20-036-112844	2/5/2020 1:27:00 PM	2/5/2020 1:27:18 PM	2/5/2020 3:24:00 PM
PD-L1 Client Block ID	20-036-112844	2/5/2020 1:27:00 PM	2/5/2020 1:27:18 PM	2/5/2020 3:24:00 PM
PDL1 Tissue Source	20-036-112844	2/5/2020 1:27:00 PM	2/5/2020 1:27:18 PM	2/5/2020 3:24:00 PM

END OF CHART

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