

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

Physician: Doctor, Example

Patient: Patient, Example

DOB: 8/17/1971
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

PD-L1 22C3 by Immunohistochemistry, with Interpretation

ARUP test code 3017615

Adequacy of Specimen	Adequate
PD-L1 Client Block ID	CLMS24-9941 2
PDL1 Tissue Source	Liver
PDL1 TEST	TPS

PD-L1 22C3 by IHC With Tumor Proportion Score (TPS) Interpretation, Pembrolizumab (KEYTRUDA) and Cemiplimab-rwlc (LIBTAYO)

ARUP test code 3017680

Tumor Proportion Score	<1%
PDL1 22C3 by IHC Result	Off-Label

The predictive value of PD-L1 22C3 biomarker testing (with tumor proportion score (TPS), as provided in this report) in tumors other than non-small cell lung cancer is uncertain and represents an off-label use of this assay.

Controls were run and performed as expected. This result has been reviewed and approved by [REDACTED]
2000 Circle of Hope, RM 3100
Salt Lake City, UT 84112

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

Unless otherwise indicated, testing performed at:

INTERPRETIVE INFORMATION: PD-L1 22C3 IHC with Tumor Proportion Score (TPS)

PDL1 22C3 by IHC with Tumor Proportion Score Interpretation is an FDA-approved 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) tissue using the EnVision FLEX visualization system on Autostainer Link 48 in non-small cell lung cancer (NSCLC).

PD-L1 protein expression in NSCLC is determined using the tumor proportion score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity.

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 NSCLC patients for treatment with pembrolizumab (KEYTRUDA) and cemiplimab (LIBTAYO). For all other specimen types, results should be interpreted with caution and within the appropriate clinical context. The table below summarizes how TPS is used to assess PD-L1 expression. Please refer to the full prescribing information for tumor-specific indications and PD-L1 expression level cutoff.

For NSCLC Patients:

TPS <1%: No PD-L1 expression

TPS >=1%: PD-L1 expression

TPS >=50%: High PD-L1 expression

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 has not been validated and is not recommended.

Submission of slides that have been oven baked, or specimens that are decalcified and/or fixed in any fixative other than 10 percent neutral buffered formalin are not validated and should be interpreted with caution.

Controls were run and performed as expected.

Adequacy of Specimen

Adequate

PD-L1 Client Block ID

CLMS24-9941 2

PDL1 Tissue Source

Liver

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Tumor Proportion Score	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PDL1 22C3 by IHC Result	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Adequacy of Specimen	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Adequacy of Specimen	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PD-L1 Client Block ID	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PD-L1 Client Block ID	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PDL1 Tissue Source	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PDL1 Tissue Source	24-134-159396	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PDL1 TEST	24-134-159396	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

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 24-134-159396
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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