Medgenome Labs Ltd
Sy No 94/1C and 94/2, Tower-1, Veerasandra Village,
Attibele Hobli, Electronic City, Phase-1, Bangalore,
Karnataka, 560100.

PD-L1 (22C3 Dako PharmDx) - IHC Test Report (REVISED REPORT)

Patient Name	A.S Jayalath Silva	Order ID	1062394
Age / Gender	44 Years / Male	Sample ID	8724928
Physician	Dr. T. Skandarajah	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	25-09-2024 04:15 PM
Report Date	14-10-2024 04:20 PM	Report Status	Final

Lab/Biopsy No : MBI-4810-24 **UID :** AOMG016

Clinical Details : Lung biopsy – Adenocarcinoma

Specimen received : Two blocks

Gross Examination : Two blocks labelled as RD-790/H/24, RD-816/H/24. Test done on both the blocks

Sample Adequacy : Adequate tumor cells (≥ 100 cells) are present : Yes

Test interpretation/Result:

IHC Markers	Microscopy	Tumor Proportion Score (TPS)	Impression
PD-L1 (22C3)	No evidence of membranous staining in tumor cells seen.	0%	No PDL1 Expression

Comments:

1. PD-L1 IHC 22C3 pharmDx is a qualitative 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) non-small cell lung cancer (NSCLC) tissue using EnVision FLEX visualization system on Autostainer Link 48.
2. PD-L1 protein expression is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining.
3. PD-L1 IHC 22C3 pharmDx is a CE- IVD marked and is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (Pembrolizumab).
4. The specimen should be considered PD-L1 positive if TPS ≥ 1% of the viable tumor cells exhibit membrane staining at any intensity and is reported as negative if TPS
5. The Tumor Proportion Score (TPS) determines the PD-L1 expression of the specimen.
   Specimens are interpreted as having:
   1. No PD-L1 Expression (TPS
   2. Low PD-L1 Expression (TPS 1–49%)
   3. High PD-L1 Expression (TPS ≥ 50%)

Note:

System level Controls (internal & or external) run with the test are satisfactory. Reagents used are the companion diagnostic assay consisting of primary antibody PDL 1 clone 22C3 using EnVision FLEX visualization system on Autostainer Link 48. This assay has not been validated on decalcified tissue and result should be interpreted with caution given the likelihood of false negativity of decalcified specimen. Specimen should be processed by routine tissue processing method. Inappropriate fixation (nonformalin) and processing may give erroneous result.
The performance characteristics of this assay has been determined by MedGenome.
Performance characteristics refer to the analytical performance of the test.

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Please correlate the block# given with that of its HPE report.

References:

1. Kerr K. M., Nicolson. M.C.; Non-small cell lung cancer, PDL-1 and the Pathologist. Arch Pathol Lab Med. 2016;140:249-254.
2. Fred . Hirsch , McElhinny A, Dave Stanforth D. PD-L1 Immunohistochemistry Assays for Lung Cancer: Results from Phase 1 of the Blueprint PD-L1 IHC Assay Comparison Project. Journal of Thoracic Oncology. 2017; 12: 208–22.
3. Scholl L.M. et al. 2016. Programmed Death Ligand-1 Immunohistochemistry—A New Challenge for Pathologists. A Perspective From Members of the Pulmonary Pathology Society Arch Pathol Lab Med. 140: 341-344.
4. Lantuejoul S, et al. PD-L1 Testing for Lung Cancer in 2019: Perspective From the IASLC Pathology Committee. J Thorac Oncol. 2020 Apr;15(4):499-519.
5. Scheel AH, Schäfer SC. Current PD-L1 immunohistochemistry for non-small cell lung cancer. J Thorac Dis. 2018 Mar;10(3):1217-1219.
6. Lou S et al : Implementation of PD-L1 22C3 IHC pharmDx in Cell Block Preparations of Lung Cancer: Concordance with Surgical Resections and Technical Validation of CytoLyt® Prefixation. Acta Cytologica 2020;64:577-587.

Enclosed : Two blocks

This report supersedes the previous report. Report amended to change the clinician Name, amended from Dr. Mahendra Perera to Dr. T. Skandarajah as requested by the Aegle Omics on 9/10/2024

Verified By

Dr. Rumana Tasneem
Junior Pathologist, MBBS, MD
KMC Reg No. 96079

Approved By

Dr. Syed Muqlisur Rehman, MD (Path)
Molecular Pathologist
KMC Reg No. - 71468

*****End of Report*****

CONDITIONS OF LABORATORY TESTING AND REPORTING

Medgenome Labs Ltd, Bangalore, Karnataka, India

- Laboratory results should be used with other clinical information to determine a final diagnosis.
- In case of unexpected test results please contact the laboratory. We will investigate and repeat analysis if possible.
- The medical report must be viewed and reproduced as a whole
- This medical report is not intended for medico-legal purposes.
- The medical report is to be interpreted and used by medical personnel only
- Assays are performed and reported in accordance with the stated schedule.
- There may be circumstances beyond our control that delay results, e.g., invalid assay run.
- The results of a laboratory test are dependent on the quality of the sample as well as the assay procedure.
- A requested test may not be carried out if:
- Sample is insufficient or inappropriate
- Sample quality is unsatisfactory
- Request for testing is withdrawn by the ordering doctor or patient
- There is discord between the labelling of the sample container and the name on the test requisition.
- For any query contact customer support : +91(0)8067154932/33
