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 (SP263) - IHC Test Report

Patient Name	MRS.A.M.M.S.A. Munawwara	Order ID	1042104
Age / Gender	51 Years / Female	Sample ID	8690104
Physician	Dr. Senaka Kandegedara	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	04-09-2024 03:30 PM
Report Date	11-09-2024 05:40 PM	Report Status	Final

Lab/Biopsy No : MBI-4572-24

Clinical Details : Lung mass biopsy - Squamous cell carcinoma

Specimen received : Three blocks and slides

Gross Examination : Three blocks and slides labelled as SWH-1257-A, B & C. Test done on SWH-1257-B block

Test interpretation/Result:

IHC Markers	Tumor cell proportion score (TPS)	Result
PD-L1 IHC	1 %	1 % of tumor cells show membranous staining of weak intensity

Note:

A sample from this individual was referred to our laboratory for "Combo Test" (Two different tests were performed & two different reports shall be sent). Results of these two reports have to be interpreted while making a clinical decision.
Report 1 of 2 (Report 2 of 2 is due for release).

Comments:

1. PD-L1 testing done by ventana PD-L1 (SP263) assay using rabbit anti-human PD-L1/CD274 monoclonal antibody (clone SP 263) on Ventana benchmark autostainer with optiview DAB IHC detection kit.

2. PD-L1 staining / expression is defined as complete or partial circumferential linear plasma membrane staining at any intensity that can be differentiated from background and diffuse cytoplasmic staining. Only cytoplasmic staining is not considered significant.

3. Roche's Ventana PD-L1 (SP263) assay is CE (European Conformity) labelled to inform treatment decisions in lung cancer patients being considered for keytruda (pembrolizumab) immunotherapy as a first line of treatment for high PD-L1 expressors.

4. Recommended positive cut off for PD-L1 (clone SP 263) in lung cancer(NSCLC) : > or = 50% of tumor cells. Studies showed superior progression free survival and overall survival in first-line treatment of mNSCLC with PD-L1 expression > or = 50% of tumor cells. There is also high degree of concordance between SP 263 (CE marked) and 22c3 assays (FDA approved) if a 50 % cut off point is applied in both cases.

5. Recommended positive cut off of PD-L1 (clone SP 263) for metastatic urothelial carcinoma is > or = 25% of tumor cells.

6. Clinical utility of this PD-L1 clone SP 263 assay needs to be verified in clinical studies for tumors other than NSCLC and urothelial carcinoma.

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Note:

System level Controls (internal & or external) run with the test are satisfactory. Reagents used are the complimentary diagnostic assay consisting of primary antibody PD-L1 clone SP 263 and Optiview DAB detection on a Ventana Benchmark autostainer. 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.

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. Ratcliffe et al. Agreement between Programmed Cell Death Ligand-1 Diagnostic Assays across Multiple Protein Expression Cutoffs in Non–Small Cell Lung Cancer. Clin Cancer Res July 15 2017 (23) (14) 35853591; DOI: 10.1158/1078-0432.

Enclosed : Three blocks and slides

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*****

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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
