

Immunohistochemistry Predictive Screening Test – ROS 1

Patient Name	A.H.M Aruna Rohantha	Order ID	1201686
Age / Gender	58 Years / Male	Sample ID	8970656
Physician	Dr. Mahendra Perera	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	17-02-2025 11:45 AM
Report Date	25-02-2025 06:45 PM	Report Status	Final

Lab/Biopsy No : MBI-575-25

Clinical Details : Pleural biopsy –Metastatic Carcinoma in a Suspected case of Ca Lung

Specimen received : One block

Gross Examination : One block labelled as XL-2095

Immunohistochemistry Microscopy

Tumor cells show no specific cytoplasmic immunoreactivity to ROS1 antibody. H score :- 0.

Viable tumor cell content in section examined is approximately 35%.

Test interpretation/Result:

Negative for ROS 1- D4D6

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

COMMENTS: ROS 1 gene rearrangements are reported in 1-2% lung adenocarcinomas and are associated with response to multitargeted TKI Crizotinib. ROS1 rearrangements are detected by FISH, however ROS1 immunohistochemistry (IHC) is an alternate screening modality.

H Score method :- H score which is the sum of products of multiplying intensity (0, 1,2, and 3) by extent of each staining intensity (%). H-scores range from 0 to 300. The definition of intensity is as follows : 0 for no detectable staining, 1+ for weak reactivity, and 2+ for moderate reactivity and 3+ for strong reactivity.

As per Cha YJ et al : All FISH-positive cases showed an H-score of 100 or more, extent of 75% or more, or the presence of 2+ or 3+ intensity on IHC. These cut off lines showed high specificity maintaining 100% sensitivity. Because gene rearrangements are rare, sensitive IHC screening is reasonable before FISH. FISH studies remain the gold standard to assess ROS1 rearrangements.

Advised to confirm ROS 1 status for equivocal and positive IHC results by FISH test.

NOTE: Positive and negative controls run with the test are satisfactory. This assay has not been validated on decalcified tissue, result should be interpreted with caution. Given the likelihood of false negativity of decalcified specimen, testing on non-decalcified FFPE tissue is recommended. Specimen should be processed by routine tissue processing method. Inappropriate fixation (non formalin) and processing may give erroneous result.

Source of antibody with details of clone:

ROS-1: Clone **D4D6** rabbit mAB from cell signaling technology

Secondary detection: Ventana Optiview DAB detection kit on a Ventana Benchmark GX / XT autostainer.

The performance characteristics of this assay has been determined by MedGenome.

Performance characteristics refer to the analytical performance of the test.

Reference: Cha YJ, Lee JS, Kim HR, Lim SM, Cho BC, et al. (2014 Screening of ROS1 Rearrangements in Lung Adenocarcinoma by Immunohistochemistry and Comparison with ALK Rearrangements. PLoS ONE 9(7): e103333. doi:10.1371/journal.pone.0103333:

Boyle, T., Masago, K., Ellison, K., Yatabe, Y. and Hirsch, F., 2022. ROS1 Immunohistochemistry Among Major Genotypes of Non-Small-Cell Lung Cancer.

Enclosed: One block

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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.
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PD-L1 (SP263) - IHC Test Report

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Specimen received : One block

Gross Examination : One block labelled as XL-2095

Test interpretation/Result:

IHC Markers	Tumor cell proportion score (TPS)	Result
PD-L1 (SP263) IHC	0 %	Negative. No membranous staining evident in tumor cells.

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.

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.

PD-L1 (SP263) - IHC Test Report

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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 : One block



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CMET-Screening Immunohistochemistry Test Report

Patient Name	A.H.M Aruna Rohantha	Order ID	1201686
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Physician	Dr. Mahendra Perera	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	17-02-2025 11:45 AM
Report Date	25-02-2025 06:44 PM	Report Status	Final

Lab/Biopsy No : MBI-575-25

Clinical Details : Pleural biopsy –Metastatic Carcinoma in a Suspected case of Ca Lung

Specimen received : One block

Gross Examination : One block labelled as XL-2095

Immunohistochemistry Microscopy

Tumor cells show no cytoplasmic membranous immunoreactivity to cMET antibody.

Viable tumor cell content on sections examined is approximately 35%.

Test interpretation/Result:

Negative for CMET expression

COMMENTS : H Score method :- H score which is the sum of products of multiplying intensity (0, 1,2, and 3) by extent of each staining intensity (%). H-scores range from 0 to 300. The definition of intensity is as follows: 0 for no detectable staining, 1+ for weak reactivity, 2+ for moderate reactivity and 3+ for strong reactivity.

Moderate to strong cytoplasmic membrane staining intensity of atleast 50% of invasive tumor cells is required to interpret as positive for cMET expression in NSCLC. Confirmation of equivocal and positive cMET gene amplification is recommended by FISH test.

NOTE: Positive and negative controls run with the test are satisfactory.

This assay has not been validated on decalcified tissue result should be interpreted with caution. Given the likelihood of false negativity of decalcified specimen testing on non-decalcified FFPE tissue is recommended. Specimen should be processed by routine tissue processing method. Inappropriate fixation (non formalin) and processing may give erroneous result.

Source of antibody with details of clone:

cMET: SP44 Rabbit Monoclonal Primary Antibody Roche Ventana.

Secondary detection: Ventana UltraView DAB detection kit.

The performance characteristics of this assay has been determined by MedGenome.

Performance characteristics refer to the analytical performance of the test.

Reference: 1) Dziadziuszko, Rafal et al. "Correlation between MET Gene Copy Number by Silver in Situ Hybridization and Protein Expression by Immunohistochemistry in Non-Small-Cell Lung Cancer." Journal of Thoracic Oncology 7.2 (2012): 340–347.

2) Giovanni et al. CMET Signaling pathway in cancer, Scientific overview and clinical trails management. White paper,Quintiles,2015.

Enclosed: One block

CMET-Screening Immunohistochemistry Test Report

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ALK (D5F3) – Immunohistochemistry Test Report

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Physician	Dr. Mahendra Perera	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	17-02-2025 11:45 AM
Report Date	25-02-2025 06:43 PM	Report Status	Final

Lab/Biopsy No : MBI-575-25**Clinical Details** : Pleural biopsy –Metastatic Carcinoma in a Suspected case of Ca Lung**Specimen received** : One block**Gross Examination** : One block labelled as XL-2095**Immunohistochemistry Microscopy :**

Tumor cells show heterogenous weak to moderate cytoplasmic immunoreactivity for ALK antibody.
Viable tumor cell content in section examined is approximately 35%.

Test interpretation/Result:

Equivocal for ALK D5F3

Advice:

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

ADV : Confirmation of ALK status by FISH is suggested and is available on additional request**Note:** Positive and negative controls run with the test are satisfactory. Reagents used are as per the FDA approved companion diagnostic assay consisting of primary antibody ALK clone D5F3 and Optiview DAB with amplification detection on a Ventana Benchmark GX / XT autostainer. It is intended for use in detection of ALK protein in NSCLC.

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.

Participant of CAP PT international external quality assurance programme.**Enclosed:** One block**Verified By**

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**Approved By**

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ALK (D5F3) – Immunohistochemistry Test Report

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