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

Immunohistochemistry Predictive Screening Test – ROS 1

Patient Name	Nirosha M Karunarathna	Order ID	1158792
Age / Gender	51 Years / Female	Sample ID	8893196
Physician	Dr. Sujeewa Siyambalapitiya	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	04-01-2025 05:55 PM
Report Date	13-01-2025 05:16 PM	Report Status	Final

Lab/Biopsy No : MBI-52-25

Clinical Details : Lung lesion biopsy – Adenocarcinoma

Specimen received : Five blocks and nine slides

Gross Examination : Five blocks and nine slides labelled as 1524/H/24 and 1526/H/24. Test done on 1526/H/24- D block

Immunohistochemistry Microscopy

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

Viable tumor cell content in section examined is approximately 50%.

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: Five blocks and nine slides

MEDGENOME

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Verified By

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*****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
