

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

Physician: Doctor, Example

Patient: Patient, Example

| DOB | Unknown |
|-------------------------|-------------------------|
| Gender: | Female |
| Patient Identifiers: | 01234567890ABCD, 012345 |
| Visit Number (FIN): | 01234567890ABCD |
| Collection Date: | 00/00/0000 00:00 |

ROS1 with Interpretation by Immunohistochemistry with Reflex to FISH if Equivocal or Positive

ARUP test code 2008414

ROS1 by IHC Result

Negative

This result has been reviewed and approved by M.D. Controls performed as expected.

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



INTERPRETIVE INFORMATION: ROS1 by IHC Result

Test Information:

An absence of cytoplasmic or membranous staining is defined as negative for ROS1 by Immunohistochemistry. Positive staining demonstrates strong and diffuse, both membranous and cytoplasmic staining and may predict patient response to tyrosine kinase inhibitor therapy. An equivocal result is defined by any degree of cytoplasmic staining only or by weak and/or focal membranous and cytoplasmic staining. Equivocal and positive results by immunohistochemistry will be confirmed by fluorescent in-situ hybridization (FISH).

Controls were run and performed as expected.

This assay is performed on formalin fixed paraffin embedded tissue, using the ROS1 D4D6 clone and a proprietary multimer based detection system.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

References

1. Lindeman NI., Cagle PT., Aisner DL., et al. Updated Molecular Testing Guideline for the Selection of Lung Cancer Patients for Treatment With Targeted Tyrosine Kinase Inhibitors. Guideline From the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. J Mol Diagn 2018;20:129-59. 2. Yoshida A., Tsuda K., Wakai S., et al. Immunohistochemical detection of ROS1 is useful for identifying ROS1 rearrangements in lung cancers. Mod Pathol 2014;27:711-20. 3. Selinger CI., Li BT., Pavlakis N., et al. Screening for ROS1 gene rearrangements in non-small cell lung cancers using immunohistochemistry with FISH confirmation is an effective method to identify this rare target. Histopathol 2017;70:402-11. 4. Yang J., Pyo J-S., Kang G. Clinicopathological significance and diagnostic approach of ROS1 rearrangement in non-small cell lung cancer: a meta-analysis: ROS1 in non-small cell lung cancer. Int J Biol Markers 2018;33:520-7. 5. Rogers T-M., Russel PA., Wright G., et al. Comparison of Methods in the Detection of ALK and ROS1 Rearrangements in Lung Cancer. J Thorac Oncol 2015;10:611-8.

ROS1 Tissue Source

Lung

ROS1 Client Block ID

A13

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

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| VERIFIED/REPORTED DATES | | | | |
|-------------------------|---------------|------------------|------------------|-------------------|
| Procedure | Accession | Collected | Received | Verified/Reported |
| ROS1 by IHC Result | 23-207-114479 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| ROS1 Tissue Source | 23-207-114479 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| ROS1 Client Block ID | 23-207-114479 | 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

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