

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

Positive

This result has been reviewed and approved by Joshua F. Coleman, M.D. Controls performed as expected.

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

**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 R Lung

ROS1 Client Block ID A-12

**ROS1 by FISH**  
ARUP test code 3001308

ROS1 FISH Result Positive

This result has been reviewed and approved by Joshua F. Coleman, M.D. Controls performed as expected.

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

Total Cell Count 100

Scoring Method Manual

ROS1 FISH Reference Number A-12

ROS1 FISH Source R Lung

**INTERPRETIVE INFORMATION: ROS1, FISH**

Fluorescence in situ hybridization (FISH) analysis was performed on a section from a paraffin-embedded tissue block using differentially labeled fluorescent probes targeting the upstream (5') and downstream (3') flanking regions of the ROS1 gene (Agilent Technologies). Cells were evaluated from regions of tumor identified on histopathologic review of a matching hematoxylin- and eosin-stained section. Controls performed appropriately.

This test is designed to detect rearrangements involving the ROS1 gene, but it does not identify a specific partner gene. An abnormal signal pattern seen in 15 percent or more of the evaluated tumor cells is considered a positive result. Based on the assay performance during test validation, the test is expected to detect 100 percent of ROS1 rearrangements in patients with ROS1-rearranged carcinomas, except for rare instances of cryptic rearrangements. Assay range and limit of detection were generated using normal and known positive cases respectively.

ROS1 rearrangement occurs in approximately 1 percent of non-small cell lung carcinomas. Detection of a ROS1 rearrangement is useful for predicting tumor response to targeted therapy.

**Reference:**

Takeuchi K et al. RET, ROS1 and ALK fusions in lung cancer. Nat Med. 18(3): 378-381, 2012.

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

VERIFIED/REPORTED DATES				
Procedure	Accession	Collected	Received	Verified/Reported
ROS1 by IHC Result	23-227-116279	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ROS1 Tissue Source	23-227-116279	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ROS1 Client Block ID	23-227-116279	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ROS1 FISH Result	23-227-116279	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	23-227-116279	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	23-227-116279	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ROS1 FISH Reference Number	23-227-116279	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ROS1 FISH Source	23-227-116279	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

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

Patient: Patient, Example  
ARUP Accession: 23-227-116279  
Patient Identifiers: 01234567890ABCD, 012345  
Visit Number (FIN): 01234567890ABCD  
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