

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

Physician: Doctor, Example

Patient: Patient, Example

DOB: 7/8/1942
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

ROS1 by FISH
ARUP test code 3001308

ROS1 FISH Result **Negative**

Controls were run and performed as expected.
This result has been reviewed and approved by [REDACTED],
M.D.
2000 Circle of Hope, RM 3100
Salt Lake City, UT 84112

Total Cell Count **100**

Scoring Method **Manual**

ROS1 FISH Reference Number **HS23-27 1B**

ROS1 FISH Source **R Bronchus**

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

Unless otherwise indicated, testing performed at:

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.

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.

VERIFIED/REPORTED DATES

| Procedure | Accession | Collected | Received | Verified/Reported |
|----------------------------|---------------|------------------|------------------|-------------------|
| ROS1 FISH Result | 23-009-158630 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Total Cell Count | 23-009-158630 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Scoring Method | 23-009-158630 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| ROS1 FISH Reference Number | 23-009-158630 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| ROS1 FISH Source | 23-009-158630 | 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: