ARUP LABORATORIES
800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Chief Medical Officer

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

Physician: Doctor, Example

Patient: Patient, Example

DOB	8/30/1950
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

ALK Gene Rearrangements by FISH, Lung

ARUP test code 3001302

ALK FISH Result	Negative This result has been reviewed and approved by [redacted] [redacted]Controls performed as expected.
Total Cell Count	100
Scoring Method	Manual
ALK FISH Reference Number	C23-226 A4
ALK FISH Source	L Pleural Fluid

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

INTERPRETIVE INFORMATION: ALK FISH, Lung

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 ALK gene (Agilent Dako SureFISH). 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 ALK 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 ALK rearrangements in patients with ALK-rearranged carcinomas, except for rare instances of cryptic rearrangements. Assay range and limit of detection were generated using normal and known positive cases respectively. ALK rearrangements occur in approximately 4-6 percent of lung adenocarcinomas. Detection of an ALK 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
ALK FISH Result	23-048-122180	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	23-048-122180	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	23-048-122180	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK FISH Reference Number	23-048-122180	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK FISH Source	23-048-122180	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