

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

Physician: Doctor, Example

**Patient: Patient, Example**

**DOB** 12/31/2000  
**Gender:** Unknown  
**Patient Identifiers:** 01234567890ABCD, 012345  
**Visit Number (FIN):** 01234567890ABCD  
**Collection Date:** 00/00/0000 00:00

**ALK (D5F3) by Immunohistochemistry with Reflex to ALK Gene Rearrangements by FISH**  
ARUP test code 2011431

ALK(D5F3) by IHC Result

Positive

Controls were run and performed as expected.  
This result has been reviewed and approved by [REDACTED]  
M.D.

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

INTERPRETIVE INFORMATION: ALK(D5F3) by IHC Result

A result of negative is defined by absence of cytoplasmic staining in tumor cells. A positive result is defined as the presence of strong and diffuse, cytoplasmic staining in tumor cells. An equivocal result is defined by weak and/or focal cytoplasmic staining. ALK Gene Rearrangements by FISH may be useful for resolving an equivocal IHC result. Positive IHC results may predict response to ALK inhibitors.

Controls were run and performed as expected.

This assay is performed on formalin fixed paraffin embedded tissue, using the ALK D5F3 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. Rogers T-M., Russell 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.
3. Wynes MW., Sholl LM., Dietel M., et al. An International Interpretation Study Using the ALK IHC Antibody D5F3 and a Sensitive Detection Kit Demonstrates High Concordance between ALK IHC and ALK FISH and between Evaluators. *J Thorac Oncol* 2014;9:631-8.
4. von Laffert M., Warth A., Penzel R., et al. Multicenter Immunohistochemical ALK-Testing of Non-Small-Cell Lung Cancer Shows High Concordance after Harmonization of Techniques and Interpretation Criteria. *J Thorac Oncol* 2014;9:1685-92.
5. Thorne-Nuzzo T., Williams C., Catallini A., et al. A Sensitive ALK Immunohistochemistry Companion Diagnostic Test Identifies Patients Eligible for Treatment with Crizotinib. *J Thorac Oncol* 2017;12:804-13.

ALK Tissue Source	Lung
ALK(D5F3) by IHC Reference Number	A-55

**ALK Gene Rearrangements by FISH, Lung**

ARUP test code 3001302

ALK FISH Result	Positive
	Controls were run and performed as expected. This result has been reviewed and approved by [REDACTED] M.D.

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

Total Cell Count 100

Scoring Method Manual

ALK FISH Reference Number A-55

ALK FISH Source

Lung

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.

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

VERIFIED/REPORTED DATES				
Procedure	Accession	Collected	Received	Verified/Reported
ALK(D5F3) by IHC Result	23-060-110907	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK Tissue Source	23-060-110907	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK(D5F3) by IHC Reference Number	23-060-110907	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK FISH Result	23-060-110907	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	23-060-110907	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	23-060-110907	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK FISH Reference Number	23-060-110907	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK FISH Source	23-060-110907	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: 23-060-110907  
Patient Identifiers: 01234567890ABCD, 012345  
Visit Number (FIN): 01234567890ABCD  
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