ARUP LABORATORIES
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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	6/5/1958
Gender:	Male
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	Negative

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., 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.
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	RUL wedge
ALK(D5F3) by IHC Reference Number	SS23-1195 B1

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
ALK(D5F3) by IHC Result	23-017-160810	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK Tissue Source	23-017-160810	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ALK(D5F3) by IHC Reference Number	23-017-160810	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