



<u>Procedure</u>	<u>Result</u>	<u>Units</u>	<u>Ref Interval</u>	<u>Accession</u>	<u>Collected</u>	<u>Received</u>	<u>Reported/Verified</u>
ALK(D5F3) by IHC Result	Positive f			18-348-900116	14-Dec-18 10:50:00	17-Dec-18 10:51:00	17-Dec-18 10:55:19
ALK(D5F3) by IHC Reference Number	S18-123			18-348-900116	14-Dec-18 10:50:00	17-Dec-18 10:51:00	17-Dec-18 10:55:19
ALK FISH Result	Positive f			18-348-900116	14-Dec-18 10:50:00	17-Dec-18 10:51:00	17-Dec-18 10:55:50
ALK FISH Reference Number	S18-123			18-348-900116	14-Dec-18 10:50:00	17-Dec-18 10:51:00	17-Dec-18 10:55:50
ALK FISH Source	Tissue			18-348-900116	14-Dec-18 10:50:00	17-Dec-18 10:51:00	17-Dec-18 10:55:50
Total Cell Count	100			18-348-900116	14-Dec-18 10:50:00	17-Dec-18 10:51:00	17-Dec-18 10:55:50
Scoring Method	Manual			18-348-900116	14-Dec-18 10:50:00	17-Dec-18 10:51:00	17-Dec-18 10:55:50

14-Dec-18 10:50:00 ALK(D5F3) by IHC Result:

This result has been reviewed and approved by Georgios Deftereos, M.D. Controls performed as expected.

14-Dec-18 10:50:00 ALK FISH Result:

Controls were run and performed as expected.

This result has been reviewed and approved by Barbara Chadwick, M.D.

14-Dec-18 10:50:00 ALK(D5F3) by IHC Result:

TEST INFORMATION: ALK (D5F3) with Interpretation by IHC

A result of negative is defined by absence of cytoplasmic staining in tumor cells. A positive result is defined as the presence of cytoplasmic staining in tumor cells. An equivocal result is defined by very weak cytoplasmic staining which is only visible on higher power by microscopy. ALK Gene Rearrangements by FISH may be useful for resolving an equivocal IHC result. Positive IHC results may predict response to ALK inhibitors.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS

14-Dec-18 10:50:00 ALK FISH Result:

METHODOLOGY AND INTERPRETIVE DATA:

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.

* Abnormal, # = Corrected, C = Critical, f = Footnote, H = High, L = Low, t = Interpretive Text, @ = Reference Lab

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. 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.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement A: aruplab.com/CS.