



TECH-ONLY SERVICES

ALK FISH For NSCLC

FDA-Approved

A Rapid, Comprehensive Test for Therapy Selection

NeoGenomics offers FDA-approved FISH testing for ALK gene rearrangements in non-small cell lung cancer (NSCLC). This test:

- Identifies patients eligible for treatment with XALKORI® (crizotinib)**

Approximately 3-5% of non-small cell lung carcinomas (NSCLC) have a rearrangement of the ALK gene, resulting in fusion between ALK and another gene, ALK activation, impaired apoptosis, and abnormal cell proliferation. Patients with such tumors have been shown to respond to the ALK kinase inhibitor XALKORI® (crizotinib).¹ NeoGenomics uses the FDA-approved companion diagnostic, the Vysis ALK Break Apart FISH Probe Kit, to identify patients for this therapy.²

- Fulfills NCCN Guidelines**

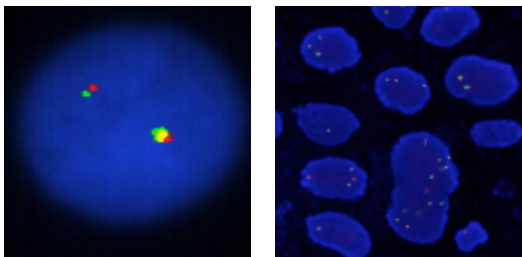
ALK rearrangement testing by FISH and EGFR molecular testing are recommended for recurrent or metastatic cases with histological subtypes of adenocarcinoma, large cell carcinoma, or NSCLC NOS (not otherwise specified).³

- Is more comprehensive than other test methods**

The ALK gene has more than 20 known rearrangement partner genes.⁴ In lung cancer, the most common partner is EML4, and 15 molecular variants of the EML4-ALK fusion have been described to date. Molecular testing methods such as PCR currently target only one potential ALK rearrangement (EML4-ALK), and may not detect all of its variants. FISH targets all potential ALK fusion rearrangements.⁵ Commercially-available antibodies for IHC do not have satisfactory sensitivity and specificity for ALK detection in lung tissues.^{3,5}

Result: Negative for ALK Rearrangement

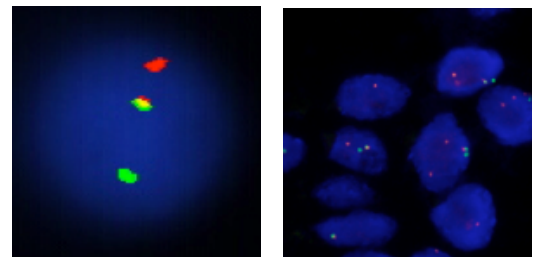
Polysomy or gene amplification ($\geq 3F$) is common and present in this sample, but it is not an indication for XALKORI®.



Signal Pattern	2F	1R1G1F	1R1F	2R1G1F	2R2G	1F	$\geq 3F$
Signal Interp	Neg	Pos	Pos	Pos	Pos	Neg	Neg
# of Nuclei (Total 50)	24	0	0	0	0	4	22

Result: Positive for ALK Rearrangement

Result is associated with response to XALKORI®.



Signal Pattern	2F	1R1G1F	1R1F	2R1G1F	2R2G	1F	$\geq 3F$
Signal Interp	Neg	Pos	Pos	Pos	Pos	Neg	Neg
# of Nuclei (Total 50)	15	10	3	22	0	0	0

INTENDED USE: The Vysis ALK Break Apart FISH Probe Kit is a qualitative test to detect rearrangements involving the ALK gene via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens to aid in identifying those patients eligible for treatment with XALKORI® (crizotinib).¹

SPECIMEN REQUIREMENTS: Paraffin block with 10% neutral buffered formalin-fixed paraffin-embedded (FFPE) lung tissue plus one H&E slide (invasive area circled) cut at 4-5 microns.

If ordering additional tests such as EGFR and/or KRAS, please note preferred testing sequence if limited tumor is present.

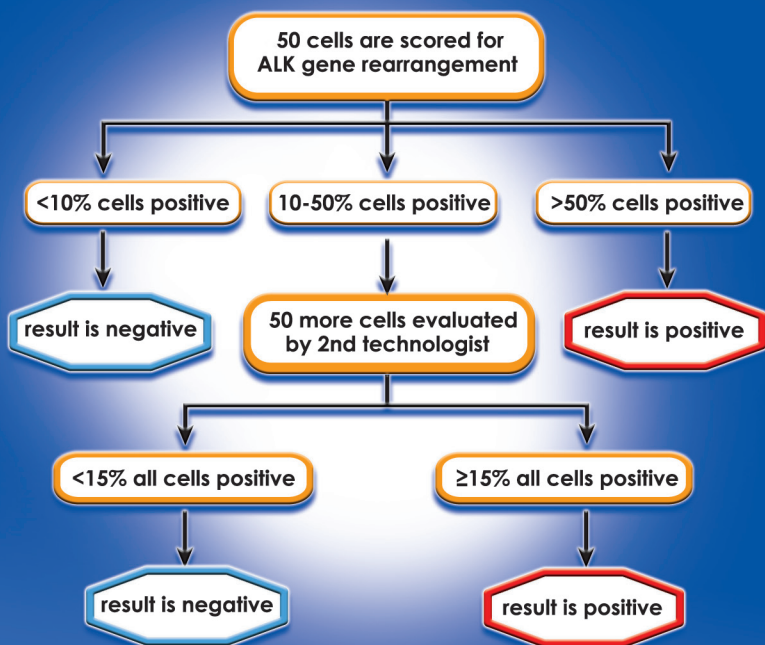
TURNAROUND TIME: 4 days

COMMON PROFESSIONAL BILLING CPT CODES

- 88367(x2) automated
- 88368(x2) manual

Note: The CPT codes provided follow American Medical Association (AMA) guidelines and are intended for informational purposes only. It is the sole responsibility of the client to select the appropriate CPT codes and number of units for their patients at all times.

SCORING ALGORITHM



Specimen ID#: _____ Fixative/Preservative: _____
 Collection Date: ____/____/____ Collection Time: ____ am pm
 Body Site: **LUNG** Primary Mets.
 If Mets., please list Primary: _____

Other: _____

FISH FISH Level of Service (MUST BE MARKED)
 With Interpretation (Global) NeoFISH® (Tech-Only/No Interpretation)
 FISH Panels (Please see back for list of included FISH probes)

HER2 by FISH®: HER2, cen17 Site: _____ Hours Fixed (req): _____
 Bladder Cancer FISH (Bladder Panel)
 MelanoSITE™ (Melanoma Panel)
 With Comprehensive Consultation that may include IHC and/or special stains if deemed medically necessary. Available with Global MelanoSITE only.

AML MDS CLL NHL High Risk MM®
 MM/MGUS®
 Available with Global MM/MGUS panel: Reflex to MM IgH Complex if IgH positive.
 Available with Tech-Only MM/MGUS panel: Add IgH Complex to run concurrently.

Individual Probes (please see back for FISH probes by disease state)

ALK for NSCLC (2p23) FGFR1 (8p11) PDGFRb t(5;12)
 ALK for Lymphoma (2p23) IgH (14q32) PML/RARA t(15;17)
 API2/MALT1 (12p12) IgH (21q21) p53 (17p13.1)

Sample Requisition

PROFESSIONAL COMPONENT FEATURES:

- On-demand and live training is offered regularly.
- No additional equipment required: use high-speed internet connection and current computer hardware.
- Email alert to signal the case is ready for your interpretation.
- Case data and images delivered via our secure web-based portal.
- Create personalized custom reports with client logo, including FlexREPORT: a multi-methodology summary report template.
- Vacation coverage available.

References

1. Kwak EL et al. New Engl J Med. 2010;363(18):1693-1703.
2. Vysis ALK Break Apart FISH Probe Kit package insert. Vysis ALK United States website. http://www.abbottmolecular.com/static/cms_workspace/pdfs/US/Vysis_ALK_FISH_Probe_Kit_PI.pdf. Accessed 12-28-2011.
3. NCCN Guidelines, Non-Small Cell Lung Cancer, version 2.2012. National Comprehensive Cancer Network website. http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed 12-29-2011.
4. ALK page. Atlas of Genetics and Cytogenetics in Oncology and Haematology. <http://atlasgeneticsoncology.org/Genes/ALK.html>. Accessed 12-29-2011; last updated 2-2010.
5. Sasaki T et al. Eur J Cancer. 2010;46:1773-1780.



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Laboratories

Time Matters. Results Count.

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