



LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1968 57 Y

Referral Testing

Collected: 07/17/2025 08:39 Received: 07/17/2025 08:39

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: EGFR Mut. w/r to NSCLC, ALK 2p23 Rearrangement, FISH. Source: Lung, Block/Specimen ID: 9657, EGFR Mutation Analysis: DETECTED, AB.

Reference Range:
NOT DETECTED

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

FISH, ALK 2p23, Lung Cancer SEE NOTE QCRL

Specimen Type: Paraffin Embedded Tumor Tissue

Clinical Indication: FISH study for oncology

Method : FISH
Total Cells : 50
Images Captured : 2

RESULT :

nuc ish(5'ALKx1-4,3'ALKx2-5)(5'ALK sep
3'ALKx1)(23/50)/(ALKx3)(8/50)

INTERPRETATION :

POSITIVE FISH RESULT FOR REARRANGEMENT OF ALK GENE

This fluorescence in-situ hybridization (FISH) analysis, using break-apart probes specific for ALK gene (2p23; Abbott Molecular), exhibited an abnormal pattern of hybridization consistent with an ALK rearrangement in 46% of interphase cells. In addition, 16% of interphase cells showed 3 copies of ALK region. The rest of the cells showed a normal hybridization pattern.

Overexpression of the ALK kinase, through a rearrangement producing a variety of different fusion proteins, is seen in a variety of

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED



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neoplasms, including anaplastic large cell lymphoma (most commonly NPM1-ALK), non-small cell lung carcinoma (ELM4-ALK), and inflammatory myofibroblastic tumors (partners genes include TPM3, TPM4, and CLTC, among others). While the significance of copy number gain or amplification of the ALK region is not clear.

This result should be considered in combination with other clinical and/or laboratory data. Please expect the result of any other concurrent test in a separate report.

This fluorescence in situ hybridization (FISH) test was performed using a break-apart probe specific for the ALK gene (2p23; Abbott Molecular). According to the manufacturer's directional insert, the cutoff value for ALK rearrangement is 15% of interphase cells in paraffin-embedded specimens.

The analytical performance characteristics of this assay have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano, CA. The modifications have not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Guang Li, PhD, FACMG
Electronic Signature:05/21/2025
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Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Reported Date: 07/17/2025 08:39 EGFR

Performing Site:

QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H517000000 Ordered By: CLIENT CLIENT
WX0000003827 WX00000000002844
Printed D&T: 07/17/25 08:39

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1
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