



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 09/27/2023 15:38 Received: 09/27/2023 15:38

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: EML4-ALK Gene Fusion, PCR, NOT DETECTED, QCRL

Reference Range:
NOT DETECTED

Inhibitors of anaplastic lymphoma kinase (ALK) may be beneficial in treating patients harboring gene fusions between echinoderm microtubule-associated protein-like 4 (EML4) and ALK. These fusions result from a paracentric inversion on chromosome 2 [inv(2)(p21;p23)] and have been identified in 3-7% of all non-small cell lung cancer (NSCLC) cases. To date, 11 variants have been published involving 8 different EML4 exons (exon 2, 6, 13, 14, 15, 17, 18, and 20) and invariably involving exon 20 of ALK.

This assay is a reverse transcription PCR-based exon scanning approach to detect fusion variants spanning nearly the entire EML4 gene. This assay detects all of the previously reported EML4-ALK translocations to date (1, 2, 3a, 3b, 4, "V4," 5a 5b, "V5," 6, 7, 8a, 8b, E20;ins18A20, and E17; ins68A20). In addition, novel EML4-ALK fusion variants can potentially be detected in this assay given that the product size is within amplifiable range.

This test does not detect the presence of other translocations. The sensitivity of our assay is 1% tumor cells in the background of normal cells. Since genetic variation and other problems can affect the accuracy of direct translocation testing, the results should always be interpreted in light of clinical data.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

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



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Test Name Result Flag Ref-Ranges Units Site
San Juan Capistrano, CA 92675-2042 J M Nakamoto MD, PhD

Reported Date: 09/27/2023 15:38 EML4P

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

F327000050
WX0000003826
Printed D&T: 11/20/23 15:44

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

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