



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 09/28/2023 13:56 Received: 09/28/2023 13:56

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Epidermal Growth Factor Receptor (EGFR) Mutation Analysis, NOT DETECTED, QCRL

Reference Range:
NOT DETECTED

Based on sequencing analysis, no clinically significant mutations were detected in the EGFR gene exons 2, 3, 6, 7, 8, 9, 15, 17-22, 24.

EGFR kinase domain mutations are found in 10-15% of lung adenocarcinomas, particularly those occurring in younger patients without a smoking history, and identify tumors that may have significant clinical response to EGFR-targeted kinase inhibitors. After a period of initial treatment, secondary somatic mutations in EGFR, particularly T790M in exon 20, may accompany acquired resistance to these inhibitors. Newer FDA-approved agents are available for patients with the T790M mutation.

For fixed tissue samples, microscopic review and marking of the specimen was performed by a pathologist, and genomic DNA was extracted from macro-dissected paraffin-embedded tissue sections. Next-generation sequencing (NGS) was used to assess for mutations in the entire coding regions of exons 2, 3, 6, 7, 8, 9, 15, 17-22, 24 of EGFR. This also includes codon T790 which is commonly mutated in case of secondary resistance to inhibitor treatment. EGFR coding sequence from NM_005228.4 was used as reference sequence. The sensitivity for mutation detection of the assay is 5% mutant allele in a background of normal alleles in the macro-dissected area. Insertions up to 30bp and deletions up to 48bp have been successfully detected by this assay.

This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Laboratory results and submitted clinical information reviewed by

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

Table with 3 columns: Source, TISSUE, QCRL. Row 1: Block/Specimen ID, N/A, QCRL

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



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

Reported Date: 2023.09.28 13:56 EGFR

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

F328000018
WX0000003827

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

Printed D&T: 09/28/23 14:04

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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