

### LABORATORY REPORT

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

## **EXAMPLE, REPORT**

WX0000003481 F 12/08/1988 34 Y

Referral Testing

Collected: 10/01/2021 11:14 Received: 10/01/2021 11:14

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

# Acute Myeloid Leukemia Prognostic Panel (Normal Karyotype)

Specimen SourceBloodQCRLSample ID123456QCRLCEBPA MutationNOT DETECTEDQCRL

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

NPM Mutation, Cell-based NOT DETECTED QCRL

Reference Range:
NOT DETECTED

A mutation at exon 12 of the NPM gene is a predictor of favorable prognosis in acute myeloid leukemia (AML) cases with a normal karyotype; it is also an indication of good response to induction chemotherapy.

This assay can detect 5% of mutant cells in the background of wildtype cells. The PCR amplification was performed using NPM intron 11 forward primer and 6-fam-labeled NPM exon 12 reverse primer. The wildtype displayed a 212bp peak, while the NPM mutant displayed a 216bp peak in addition to the NPM wildtype peak. The % of mutant to total (peak height) will be reported.

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

San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

FLT3 ITD NOT DETECTED QCRL

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

D001000007 WX0000003481 Printed D&T: 11/30/23 09:19 Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 3



### LABORATORY REPORT

QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT** 

WX0000003481 F 12/08/1988 34 Y

Referral Testing

Collected: 10/01/2021 11:14 Received: 10/01/2021 11:14

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Reference Range:

NOT DETECTED

FLT3 TKD NOT DETECTED QCRL

Reference Range:

NOT DETECTED

FLT3 ITD Size NOT DETECTED QCRL

UNITS OF MEASURE: Base pairs (bp)

FLT3 ITD Allelic Ratio 4.08
FLT3 TKD Allelic Ratio 0.10

QCRL
QCRL

FLT3 mutations have been described in approximately 30% of acute myeloid leukemia cases. Both ITD and TKD mutations activate FLT3 kinase activity and promote malignancy. FLT3-ITD mutations are associated with a poor prognosis, high relapse rates, and reduced overall survival.

For additional information, please refer to https://education.questdiagnostics.com/faq/FAQ221 (This link is being provided for informational/educational purposes only.)

Genomic DNA was extracted from the patient sample and tested for the presence of FLT3 gene ITD (Internal Tandem Duplication) and TKD (Tyrosine Kinase Domain) mutations. The TKD test detects mutations in codons 835 and 836, but cannot distinguish between them. Genomic regions of interest were amplified by fluorescence-labelled primers. The TKD product was further digested with the EcoRV restriction enzyme. The ITD PCR product and the enzyme digested TKD product were analyzed by fragment analysis. The assay can detect 5 mutation containing cells in the background of 100 total cells or 0.05 allelic ratio.

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

D001000007 WX0000003481 Printed D&T: 11/30/23 09:19 Ordered By: CLIENT CLIENT WX00000000000002063

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 3



## LABORATORY REPORT

QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT** 

WX0000003481 F 12/08/1988 34 Y

**Referral Testing** 

Collected: 10/01/2021 11:14 Received: 10/01/2021 11:14

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

**Reported Date:** 10/01/2021 11:21 ACMYL

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

D001000007 WX0000003481 Printed D&T: 11/30/23 09:19 Ordered By: CLIENT CLIENT WX0000000000000003

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 3 OF 3