Warde Medical Laboratory

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: 09/07/2023 14:59 Received: 09/07/2023 14:59

Test Name	Result	Flag	Ref-Ranges	Units	Site
PM-RARA t(15;17), Quantitative RT-PCR					
Specimen Source	Blood				QCRL
Sample ID	N/A				QCRL
PML-RARA transcript level	1216.091			NCN	QCRL
Interpretation	SEE NOTE				QCRL

This data was reviewed and interpreted by

The PML-RARA variant fusion transcript associated with t(15;17) (q22;q21) is detected by quantitative RT-PCR.

Methodology and Interpretation

PML-RARA transcripts are associated with the t(15;17) chromosomal translocation seen in acute promyelocytic leukemia (APL). Quantitative RT-PCR is performed to detect the PML-RARA fusion transcript based on standardized protocols developed by BIOMED-1 Concerted Action and Europe Against Cancer (EAC) Program (Gabert et al, Leukemia 2003, 17:2318-2357). This assay detects the short form (bcr3), long form (bcr1) and the variant exon 6 (bcr2) PML-RARA transcripts. PML-RARA transcript levels are expressed as normalized copy number (NCN) of PML-RARA using ABL1 as internal control.

Two or more positive PML-RARA PCR tests (NCN >= 1) after therapy are a strong predictor of subsequent hematologic relapse in APL. Repeatedly negative PCR results, defined as NCN <1, are associated with long-term survival in the majority of patients.

The method of transcript quantitation in this assay has changed as of 9/18/2014. A PML-RARA NCN of 10 in the current assay corresponds approximately to a PML-RARA/ABL1 ratio of 0.001 in the old assay.

The lower limit of PML-RARA+ leukemia detection in this assay is dependent on the quality of RNA obtained and the cellularity of the sample. Analytic assay sensitivity is determined at 1:100,000.

This assay is a PCR-based test. Since genetic variation and other problems can affect the accuracy of PCR based 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

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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

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

Reported Date: 2023.09.12 14:59 PMPCR