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PATIENT REPORT

Patient Age/Sex: Female

Specimen Collected: 15-Sep-22 16:36

X-Quant Detection of BCR-ABL1 Major (p210) **|Received: 15-Sep-22 16:36** **Report/Verified: 16-Sep-22 16:25**

Procedure	Result	Units	Reference Interval
Quant BCR-ABL1,Major (p210), Source	See Note		
Quant BCR-ABL1,Major (p210), Result	High Positive [f1] [i1]		
Quant BCR-ABL1,Major (p210),IS Percent	51.0000	%	
Quant BCR-ABL1,Major (p210),EER	EERUnavailable		

Result Footnote

f1: Quant BCR-ABL1, Major (p210), Result

BCR-ABL1 fusion transcripts (p210 forms) were detected by RT-qPCR but were above the higher limit of quantitation for this assay. A BCR-ABL1 International Scale (IS) cannot be calculated. The result on the IS is greater than 50%.

This result has been reviewed and approved by Ganna Shestakova, MD, PhD

Test Information

i1: Quant BCR-ABL1, Major (p210), Result

INTERPRETIVE INFORMATION: Quantitative Detection of BCR-ABL1, Major Form(p210)

This assay quantifies BCR-ABL1 transcripts (e13a2 and e14a2) for ongoing therapeutic monitoring and minimal residual disease detection. BCR-ABL1 translocations with BCR breakpoints in the major breakpoint cluster region result in the p210 fusion protein and are seen in nearly all cases of chronic myelogenous leukemia (CML) and in a few cases of acute lymphoblastic leukemia/lymphoma (ALL). To facilitate the interlaboratory comparison of findings and the assessment of molecular milestones (major molecular response or MMR), results are reported using the international scale (IS; see Muller MC, et al. Leukemia. 2009;23:1957-1963).

METHODOLOGY:
Total RNA was isolated and converted to cDNA; BCR-ABL1 fusions were quantitated by real-time PCR amplification with primers designed to detect the major (p210) BCR-ABL1 breakpoint, including fusions between BCR exon 13 and ABL1 exon 2 (e13a2) and BCR exon 14 and ABL1 exon 2 (e14a2). Each PCR assay includes a standard curve for BCR-ABL1 and the ABL1 control.

The normalized copy number(NCN)is calculated and converted to a value on the international scale (IS) using a validated reference sample (provided by Qiagen, Germantown, MD; see White HE, et al. Blood. 2010;116:111-117) that was calibrated to a standard set of diagnostic specimens defined during the original trial of

Test Information

i1: Quant BCR-ABL1, Major (p210), Result

tyrosine kinase inhibitor therapy in CML patients (Hughes TP, et al. NEJM. 2003;349:1423-1432).

ANALYTICAL SENSITIVITY:
Detection limit percent international scale (IS) at 0.0032.

LIMITATIONS:
The limit of quantification is 0.0032 percent IS. This assay does not detect transcripts resulting from a rare BCR-ABL1 rearrangement with a BCR exon 19 breakpoint that results in the p230 fusion protein,and does not detect the minor breakpoint (p190) or rare major fusion transcripts (p210) involving ABL1 other than exon 2. The results of this test must be interpreted in the context of morphologic and other relevant data, and should not be used alone for a diagnosis of malignancy.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.