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

ARUP LABORATORIES

Patient: [redacted] DOB: [redacted] Age: [redacted] Sex: [redacted] **Patient Identifiers:** [redacted] **Visit Number (FIN):** [redacted]	Client: [redacted] Physician: [redacted]	ARUP Test Code: 3005840 Collection Date: 09/21/2023 Received in lab: 09/22/2023 Completion Date: 09/29/2023

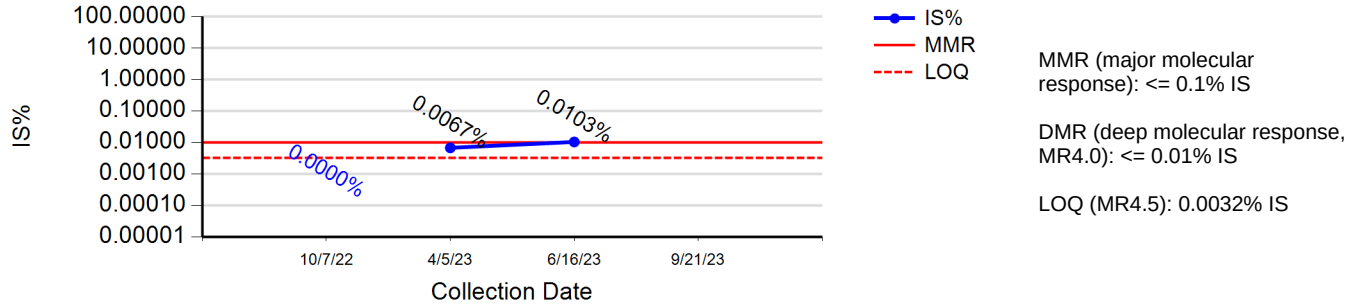
Patient Result Summary

Result: Low Positive

BCR-ABL1 IS: See Note

BCR-ABL1 fusion transcripts (p210 forms) were detected by RT-qPCR but were below the limit of quantitation for this assay. A BCR-ABL1 to ABL1 International Scale (IS) percentage cannot be calculated. The result on the IS is less than 0.0032%. This result has been reviewed and approved by Madhu Menon, M.D., Ph.D.

Patient IS% Historical Results



MMR (major molecular response): <= 0.1% IS

DMR (deep molecular response, MR4.0): <= 0.01% IS

LOQ (MR4.5): 0.0032% IS

Patient Historical Result Summary

Collected	Result	IS%	Source
09/21/2023	Low Positive		Whole Blood
06/16/2023	Detected	0.0103	Whole Blood
04/05/2023	Detected	0.0067	Whole Blood
10/07/2022 *	Not Detected	0.0000	Whole Blood

-Weak positive results represent an IS value which is less than 0.0032%.
-IS% values before May 16, 2011 are calculated by a validated conversion factor.
-See previous individual reports for details on specific test results.
-Consecutive test results are displayed on this chart; however, this result set may be incomplete due to variations in the demographic information submitted for prior tests. If the information shown on this chart appears incomplete, please consult this patient's prior charts.
*-Asterisk * signifies historical results for tests 2005011 and 2005017*

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Chart continues on following page(s)

Patient: [redacted] | **Date of Birth:** [redacted] | **Sex:** [redacted] | **Physician:** [redacted]
Patient Identifiers: [redacted] | **Visit Number (FIN):** [redacted]

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 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.

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