BCR-ABL1, Major (p210), Quantitative

Patient: [redacted]
DOB: [redacted] Age: 71 Gender: M
Patient Identifiers: [redacted]
Visit Number [redacted]

Client: [redacted]
Physician: [redacted]

ARUP Test Code: 2005017

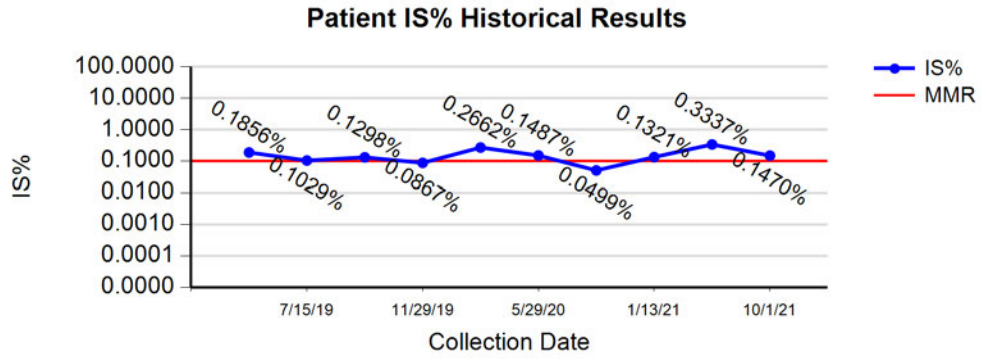
Collection Date: 10/01/2021
Received in lab: 10/02/2021
Completion Date: 10/07/2021

Patient Result Summary

Result: Detected

***BCR-ABL1* IS: 0.1470%**

BCR-ABL1 fusion transcripts (p210 forms) were detected by RT-qPCR. This result has been reviewed and approved by [redacted]



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

LOQ (limit of quantification):
0.0069% IS

Patient Historical Result Summary

Collected	Result	IS%	Source
10/01/2021	Detected	0.1470	Whole Blood
04/08/2021	Detected	0.3337	Whole Blood
01/13/2021	Detected	0.1321	Whole Blood
10/28/2020	Detected	0.0499	Whole Blood
05/29/2020	Detected	0.1487	Whole Blood
03/02/2020	Detected	0.2662	Whole Blood
11/29/2019	Detected	0.0867	Whole Blood
10/16/2019	Detected	0.1298	Whole Blood
07/15/2019	Detected	0.1029	Whole Blood
04/08/2019	Detected	0.1856	Whole Blood

-Weak positive results represent an IS value which is less than 0.0069%.
-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.

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Tracy I. George, MD, Chief Medical Officer

Chart continues on following page(s)

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

Test Information

Background
This assay quantifies BCR-ABL1 transcripts (e13a2 and e14a2) for diagnosis and ongoing therapeutic monitoring. 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 (ALL). To facilitate the interlaboratory comparison of findings and the assessment of molecular milestones (major molecular response; MMR), results are reported using the international scale (IS; see Muller MC et al, Leukemia 2009;23:1957-1963).

Methods
Total RNA is isolated and converted to cDNA; BCR-ABL1 fusions are quantitated by real-time PCR amplification. The primers are 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. From this, a normalized copy number (NCN) is calculated and reported for each sample (#BCR-ABL1 cDNA molecules/#ABL1 cDNA molecules). The NCN is further 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 has been 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).

Limitations
The limit of detection of this assay is 1 BCR-ABL1 positive cell in 125,000 normal cells. The limit of quantification is 0.0069 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. The results of this test must always be interpreted in the context of morphologic and other relevant data and should not be used alone for a diagnosis of malignancy.

Compliance
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.