

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 4/19/1963
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 01/01/2017 12:34

BCR-ABL1, Major (p210), Quantitative

ARUP test code 2005017

BCR-ABL1, t(9;22) Source Not Specified

BCR-ABL1, Major (p210) Result

Not Detected

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

INTERPRETATION

This assay quantified 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 or MMR), results reported use the international scale (IS; see Muller MC et al, Leukemia 2009;23:1957-1963).

METHODS

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).

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 and does not detect the minor breakpoint (p190). 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.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement D: aruplab.com/CS

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Tracy I. George, MD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 19-277-102178
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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4848

BCR-ABL1, International Scale (Percent) 1.0000 %

EER BCR-ABL1, Major (p210) EERUnavailable

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
BCR-ABL1, t(9;22) Source	19-277-102178	10/4/2019 10:22:00 AM	10/4/2019 8:46:23 AM	10/4/2019 8:47:00 AM
BCR-ABL1, Major (p210) Result	19-277-102178	10/4/2019 10:22:00 AM	10/4/2019 8:46:23 AM	10/4/2019 8:47:00 AM
BCR-ABL1, International Scale (Percent)	19-277-102178	10/4/2019 10:22:00 AM	10/4/2019 8:46:23 AM	10/4/2019 8:47:00 AM
EER BCR-ABL1, Major (p210)	19-277-102178	10/4/2019 10:22:00 AM	10/4/2019 8:46:23 AM	10/4/2019 8:47:00 AM

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

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