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

Physician: Doctor, Example

Patient: Patient, Example

DOB: [redacted]
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

BCR-ABL1, Major, Quant
ARUP test code 2005011

BCR-ABL1, t(9;22) Source: Whole Blood

BCR-ABL1, Major (p210) Result: Detected *

BCR-ABL1 fusion transcripts (p210 forms) were detected by RT-qPCR.
This result has been reviewed and approved by Anna Matynia, M.D.
INTERPRETIVE INFORMATION: BCR-ABL1, Major (p210), Quantitative

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

BCR-ABL1, International Scale (Percent) 40.6870 %

EER BCR-ABL1, Major (p210) See Note

Access ARUP Enhanced Report using either link below:
- Direct access: [Link]
- Enter Username, Password: [Password]

BCR-ABL1, Qualitative with Reflex to BCR-ABL1 Quantitative
ARUP test code 2005010

BCR-ABL1 Source Whole Blood

H=High, L=Low, *=Abnormal, C=Critical
BCR-ABL1, t(9;22) Qual by RT-PCR

**Positive Major**  *

This result has been reviewed and approved by Anna Matynia, M.D.

Evidence found of major (p210) BCR-ABL1 fusion transcripts by RT-PCR analysis.

BCR-ABL1 quantitative testing will be performed.

**INTERPRETIVE INFORMATION:** BCR-ABL1, t(9;22) Qual by RT-PCR

This assay is designed to detect the presence of BCR-ABL1 translocations with breakpoints in the major breakpoint cluster region (p210 fusion) or the minor breakpoint cluster region (p190 fusion).

**METHODOLOGY:**

RNA is isolated from whole blood or bone marrow and reverse transcribed. The resulting cDNA is subjected to separate PCR amplifications with primers designed to amplify fusions that give rise to either the p190 or p210 forms of BCR-ABL1. An additional RT-PCR amplification is directed at the ABL1 gene as a control for sample quality. The PCR products are resolved by electrophoresis and evaluated for the presence of amplicons that indicate a positive result.

**LIMITATIONS:**

Rare BCR-ABL1 fusions that give rise to the p230 form are not detected by this test. The limit of detection for this assay is 1 BCR-ABL1 positive cell in 100,000 normal cells. Results of this test must always be interpreted within the clinical context and other relevant data, and should not be used alone for a diagnosis of malignancy. This test is not intended to detect minimal residual disease.

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

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**VERIFIED/REPORTED DATES**

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