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*****Example Report*****

Patient Age/Gender: Unknown Male
Printed: 18-Mar-19 14:13:27

Procedure	Result	Units	Ref Interval	Accession	Collected	Received	Reported/ Verified
BCR-ABL1, t(9;22) Source	Whole Blood			19-077-900234	18-Mar-19 13:52:00	18-Mar-19 13:53:00	18-Mar-19 14:08:18
BCR-ABL1, Major (p210) Result	**Detected *f**			19-077-900234	18-Mar-19 13:52:00	18-Mar-19 13:53:00	18-Mar-19 14:08:18
BCR-ABL1, International Scale (Percent)	0.3060	%		19-077-900234	18-Mar-19 13:52:00	18-Mar-19 13:53:00	18-Mar-19 14:08:18
EER BCR-ABL1, Major (p210)	See Note			19-077-900234	18-Mar-19 13:52:00	18-Mar-19 13:53:00	18-Mar-19 14:08:18

18-Mar-19 13:52:00 BCR-ABL1, Major (p210) Result:

BCR-ABL1 fusion transcripts (p210 forms) were detected by RT-qPCR.

This result has been reviewed and approved by Jay Patel, M.D.

18-Mar-19 13:52:00 BCR-ABL1, Major (p210) Result:
INTERPRETIVE INFORMATION: BCR-ABL1, Major (p210), Quantitative

INTERPRETATION
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.

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