ARUP LABORATORIES
800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Chief Medical Officer

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

Physician: Doctor, Example

Patient: Patient, Example

DOB	Unknown
Gender:	Unknown
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

Quantitative Detection of BCR-ABL1, Minor Form (p190)

ARUP test code 3016968

Quant BCR-ABL1, Minor (p190), Source	Whole Blood
Quant BCR-ABL1, Minor (p190), Result	Low Positive *

Note: the reporting unit (NCN percent) is updated in this BCR-ABL1 minor quantitative testing and is different from that previously reported (NCN) at ARUP. A conversion factor of 100 is suggested when comparing the results. A BCR-ABL1 minor transcript NCN percent of 10 by the new test corresponds approximately to BCR-ABL1 minor transcript NCN of 0.1 previously reported at ARUP.

BCR-ABL1 fusion transcripts (p190 form) appear detected below the limit of quantitation for this assay (BCR-ABL1/ABL1 ratio less than 0.005 percent) by RT-qPCR; however, false positives cannot be entirely excluded at this low level due to assay limitations.

This result has been reviewed and approved by [redacted]

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

	INTERPRETIVE INFORMATION: BCR-ABL1, Minor (p190), Quantitative INTERPRETATION This assay quantifies BCR-ABL1 transcripts (e1a2) for diagnosis and ongoing therapeutic monitoring. BCR-ABL1 translocations with BCR breakpoints in the minor breakpoint cluster region result in the p190 fusion protein and are predominantly seen in acute lymphoblastic leukemia (ALL) although they may be present in rare cases of chronic myelogenous leukemia (CML). METHODS Total RNA is isolated and converted to cDNA and BCR-ABL1 fusions are quantitated by real-time PCR amplification with primers designed to detect the minor (p190) BCR-ABL1 breakpoint with a fusion between BCR exon 1 and ABL1 exon 2 (e1a2). Each PCR assay includes a standard curve for BCR-ABL1 and the ABL1 control and a BCR-ABL1:ABL1 percent ratio is calculated and reported. ANALYTICAL SENSITIVITY: The limit of quantitation is 5 x 10-5 BCR-ABL1/ABL1 transcripts. Low level p190 (minor) fusion transcripts can occasionally be detected below the limit of quantitation to around 10-20 x 10-6 BCR-ABL1/ABL1 transcripts, and these are reported as detected but below the limit of quantitation in samples meeting quality criteria. LIMITATIONS: This assay is not appropriate for diagnosis or monitoring of BCR-ABL1 major (p210) transcripts, other transcripts resulting from rare rearrangements or minor (p190) transcripts involving beyond ABL1 exon 2. Low-level positivity with this assay may occur when these major p210 transcripts are present at high levels. 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. 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.
Quant BCR-ABL1, Minor (p190), Ratio	See Note %
Quant BCR-ABL1, Minor (p190), EER	See Note

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Quant BCR-ABL1, Minor (p190), Source	24-052-106515	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Quant BCR-ABL1, Minor (p190), Result	24-052-106515	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Quant BCR-ABL1, Minor (p190), Ratio	24-052-106515	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Quant BCR-ABL1, Minor (p190), EER	24-052-106515	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

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