ARUP LABORATORIES | aruplab.com
500 Chipeta Way, Salt Lake City, Utah 84108-1221
phone: 801-583-2787, toll free: 800-522-2787
Jonathan R. Genzen, MD, PhD, Chief Medical Officer

PATIENT REPORT

Patient Age/Sex: Female

Specimen Collected: 15-Sep-22 12:16

X-BCR-ABL1, Minor, Quant (Internal only) | **Received: 15-Sep-22 12:29** | **Report/Verified: 16-Sep-22 10:13**

Procedure	Result	Units	Reference Interval
BCR-ABL1,t(9;22) Source	Whole Blood		
BCR-ABL1,Minor (p190) Result	**Detected** * f1 i1		
BCR-ABL1/ABL1,Minor (p190) Quant Ratio	1.00000		
EER BCR-ABL1,Minor (p190)	See Note f2		

X-Diagnostic Qual BCR-ABL1 Assay w/ Reflex | **Received: 15-Sep-22 12:16** | **Report/Verified: 16-Sep-22 10:14**

Procedure	Result	Units	Reference Interval
Diagnostic Qual BCR-ABL1 Assay, Source	Whole Blood		
Diagnostic Qual BCR-ABL1 Assay, Result	**Positive Minor** * f3 i2		

Result Footnote

f1: BCR-ABL1, Minor (p190) Result

BCR-ABL1 fusion transcripts (p190 form) were detected by RT-qPCR.

This result has been reviewed and approved by

f2: EER BCR-ABL1, Minor (p190)
Authorized individuals can access the ARUP Enhanced Report using the following link:

f3: Diagnostic Qual BCR-ABL1 Assay, Result

There is evidence of minor (p190, e1a2) BCR-ABL1 fusion transcripts by RT-PCR analysis.

BCR-ABL1 quantitative testing will be performed. Additional charges will apply.

This result has been reviewed and approved by

Test Information

i1: BCR-ABL1, Minor (p190) Result

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

*=Abnormal, #=Corrected, C=Critical, f=Result Footnote, H-High, i-Test Information, L-Low, t-Interpretive Text, @=Performing lab

Test Information

i1: BCR-ABL1, Minor (p190) Result

Total RNA is isolated and converted to cDNA and BCR-ABL1 fusions are quantitated by real-time PCR amplification. The primers are 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 normalized copy number (NCN) is calculated (# BCR-ABL1 cDNA molecules/# ABL1 cDNA molecules).

LIMITATIONS
The limit of detection of this assay is 1 BCR-ABL1 positive cell in 125,000 normal cells. 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 US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

i2: Diagnostic Qual BCR-ABL1 Assay, Result

INTERPRETIVE INFORMATION: Diagnostic Qualitative BCR-ABL1
Assay with Reflex to p190 or p210
Quantitative Assays

This assay is designed to detect the presence of BCR-ABL1 translocations with breakpoints in the major breakpoint cluster region (p210 fusion), minor breakpoint cluster region (p190 fusion), or the micro breakpoint cluster region (p230 fusion) for screening purpose at the time of an initial diagnosis.

METHODOLOGY:
RNA is isolated from whole blood or bone marrow and reverse transcribed. The resulting cDNA is subjected to multiplex PCR amplification with primers designed to amplify p190, p210, or p230 BCR-ABL1 fusion transcripts involving ABL1 exon 2. The ABL1 reference gene is also amplified for specimen quality control and to ensure the integrity of RNA. The PCR products are resolved by capillary electrophoresis and evaluated for the presence of amplicons that indicate a positive result. A positive common p210 or p190 result will trigger either quantitative p210 or p190 testing to provide a quantitative level as the diagnostic baseline to monitor treatment response. The p210 transcript level is reported as the percent International Scale (%IS). The p190 transcript level is reported as the normalized copy numbers (NCN). These quantitative results are integrated into the final report. If the initial qualitative testing is negative, or a rare p230 from is detected, then no reflex testing will be performed.

ANALYTICAL SENSITIVITY:

Test Information

i2: Diagnostic Qual BCR-ABL1 Assay, Result

Fusion Transcripts	Analytical Sensitivity
Minor (e1a2)	NCN = 0.00004
Major (e13a2)	%IS = 0.0040
Major (e14a2)	%IS = 0.0047
Micro (e19a2)	1 x 10-5 RNA molecules

CLINICAL SENSITIVITY:
Estimated to be greater than 99 percent for chronic myelogenous leukemia (CML).

LIMITATIONS:
Rare BCR-ABL1 fusions with alternative breakpoints (e.g., any fusion transcripts involving ABL1 other than exon 2) are not detected by this test. This qualitative test is designed as a screening test for initial diagnosis of chronic myeloid leukemia (CML) or acute lymphoblastic leukemia/lymphoma (ALL). This test is not intended to monitor therapeutic response or to detect minimal residual disease (MRD). Low-level fusion transcripts indicating MRD might not be detected by inappropriate use of this test. 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 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.