ARUP LABORATORIES
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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	[redacted]/1962
Gender:	Male
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

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

ARUP test code 3005839

Diagnostic Qual BCR::ABL1 Assay, Source	Whole Blood
Diagnostic Qual BCR::ABL1 Assay, Result	Not Detected

There is no evidence of major (p210, e13a2, or e14a2), minor (p190, e1a2), or micro (e19a2) BCR::ABL1 fusion transcripts by RT-PCR analysis. This result does not entirely exclude the possibility of BCR::ABL1 fusion transcripts other than e1a2, e13a2, e14a2, and e19a2, or transcripts below the limit of detection.

This result has been reviewed and approved by [redacted]

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

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:

Fusion Transcripts	Analytical Sensitivity
Minor (e1a2)	NCN% = 0.004
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.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Diagnostic Qual BCR::ABL1 Assay, Source	25-029-100838	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Diagnostic Qual BCR::ABL1 Assay, Result	25-029-100838	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