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

Physician: Doctor, Example

Patient: Patient, Example

DOB	11/26/1933
Sex:	Male
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	01/01/2017 12:34

BCR-ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by Next Generation Sequencing

ARUP test code 2008420

BCR-ABL1 Mutation by NGS Source	Bone Marrow
BCR-ABL1 Mutation by NGS Result	Not Amplified

No BCR-ABL1 transcripts were detectable. A result of "Not Amplified" does not rule out the presence of BCR-ABL1 transcripts at very low levels. Charges have been adjusted to reflect the partial testing that has been performed.

This result has been reviewed and approved by [redacted]

BACKGROUND INFORMATION: BCR-ABL1 Mutation Analysis for Tyrosine Kinase Inhibitor Resistance by Next Generation Sequencing
CHARACTERISTICS: This test is designed to detect mutations in the SH2, SH3 and tyrosine kinase domain of BCR-ABL1 fusions with the major or minor breakpoint that may impart resistance to tyrosine kinase inhibitor (TKI) therapy. The test spans ABL1 codons 46 - 542 and detects essentially all clinically actionable BCR-ABL1 kinase domain mutations, including T315I.

METHODOLOGY: Patient RNA was isolated, reverse transcribed into cDNA, and amplified across the BCR-ABL1 breakpoint using primers specific for the BCR and ABL1 genes. A sequencing library was then constructed from the resulting amplicons and sequencing performed on the Illumina NextSeq sequencing platform. Detected mutations were reported with their frequency.

LIMITATIONS: The next-generation sequencing technology utilized in this test allows for the detection of substitution mutations present at frequencies as low as 5 percent of the sequenced fusions. The sensitivity of this assay may be limited, and sequencing may not be possible in patient samples containing low tumor burden (ie, low levels of BCR-ABL1 fusion transcript by IS percent or NCN). This assay is not intended to be used for detection or quantification of BCR-ABL1 fusion transcripts. Results of this test must always be interpreted within the patient's clinical context and in conjunction with other relevant data. Results 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.

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
BCR-ABL1 Mutation by NGS Source	22-054-400147	2/21/2022 10:35:00 AM	2/23/2022 7:16:38 AM	2/28/2022 10:07:00 PM
BCR-ABL1 Mutation by NGS Result	22-054-400147	2/21/2022 10:35:00 AM	2/23/2022 7:16:38 AM	2/28/2022 10:07:00 PM

END OF CHART

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