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

Physician: Doctor, Example

Patient: Patient, Example

DOB	8/5/1983
Gender:	Male
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

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

ARUP test code 2008420

BCR-ABL1 Mutation by NGS Source	Whole Blood
BCR-ABL1 Mutation by NGS Result	Not Detected No BCR-ABL1 mutations were detected by next-generation sequencing of codons 46-542. This assay is not intended to confirm the presence of the BCR-ABL1 fusion transcripts and these results should only be interpreted in the context of patients with a previously documented BCR-ABL1 positive hematologic malignancy as demonstrated by quantitative real-time PCR testing. This result has been reviewed and approved by [redacted]

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

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.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
BCR-ABL1 Mutation by NGS Source	24-054-122851	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
BCR-ABL1 Mutation by NGS Result	24-054-122851	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