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	9/24/1945
Gender:	Male
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

FLT3 ITD and TKD Mutation Detection

ARUP test code 3001161

FLT3 Source	Whole Blood
ITD Result	Not Detected
ITD Ratio	0.00
TKD Result	See Note
FLT3 ITD and TKD Mutation Detection	See Note

An atypical pattern is detected in the TKD reaction, suggestive of an alternative mutation at or near codon 835. NGS myeloid testing may be helpful in confirmation and in determining the specific mutation.

This result has been reviewed and approved by

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

INTERPRETIVE INFORMATION: FLT3 Mutation Detection by PCR and Fragment Analysis

This test is designed to detect FLT3 mutations in acute myeloid leukemia (AML). FLT3 mutation incidence is 20-30 percent in cytogenetically normal AML and represents an important diagnostic and prognostic marker. Up to 70 percent of FLT3-mutated patients harbor internal tandem duplication (ITD) mutations of the juxtamembrane domain and 30 percent demonstrate tyrosine kinase domain (TKD) D835 mutations in exon 20. This test is designed to detect both ITD and D835 mutations. A signal ratio (SR) is reported in cases with an ITD mutation.

METHODOLOGY: Genomic DNA is isolated from total leukocytes and amplified in multiplex for ITD and D835 variants. PCR products are digested with EcoRV and resolved by capillary electrophoresis. ITDs are reported with an SR, calculated by the peak area of mutated allele divided by the peak area of the wild-type control. D835 variants are reported as Detected or Not Detected.

LIMITATIONS: FLT3 mutations other than ITD and D835 will not be detected by this assay. The limit of detection for this assay is an SR of 0.05 for ITD and 0.05 for D835, based on dilutions of DNA from mutated cell lines and patient specimens. Results of this test must always be interpreted within the patient's clinical context and in conjunction with other relevant data and should not be used alone for a diagnosis of malignancy. A negative result does not definitely exclude the possibility of an FLT3 mutation below the detection limit of this test and does not exclude the possibility of rare forms of FLT3 mutations not detectable by this methodology.

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
FLT3 Source	22-089-125586	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ITD Result	22-089-125586	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ITD Ratio	22-089-125586	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
TKD Result	22-089-125586	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
FLT3 ITD and TKD Mutation Detection	22-089-125586	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