



<u>Procedure</u>	<u>Result</u>	<u>Units</u>	<u>Ref Interval</u>	<u>Accession</u>	<u>Collected</u>	<u>Received</u>	<u>Reported/</u> <u>Verified</u>
FLT3 Source	Whole Blood			18-344-900061	10-Dec-18 10:49:00	10-Dec-18 10:49:00	10-Dec-18 11:39:58
ITD Result	<b>Detected</b> *			18-344-900061	10-Dec-18 10:49:00	10-Dec-18 10:49:00	10-Dec-18 11:39:58
ITD Ratio	5.60			18-344-900061	10-Dec-18 10:49:00	10-Dec-18 10:49:00	10-Dec-18 11:39:58
TKD Result	<b>Detected</b> *			18-344-900061	10-Dec-18 10:49:00	10-Dec-18 10:49:00	10-Dec-18 11:39:58
FLT3 ITD and TKD Mutation Detection	See Note	f		18-344-900061	10-Dec-18 10:49:00	10-Dec-18 10:49:00	10-Dec-18 11:39:58

10-Dec-18 10:49:00 FLT3 ITD and TKD Mutation Detection:

A FLT3 ITD and D835 mutation were detected.

This result has been reviewed and approved by Kristin Karner, M.D.

10-Dec-18 10:49:00 FLT3 ITD and TKD Mutation Detection:

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 because of the prognostic significance of a high or low SR.

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 with 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.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS

\* Abnormal, # = Corrected, C = Critical, f = Footnote, H = High, L = Low, t = Interpretive Text, @ = Reference Lab