



<u>Procedure</u>	<u>Result</u>	<u>Units</u>	<u>Ref Interval</u>	<u>Accession</u>	<u>Collected</u>	<u>Received</u>	<u>Reported/ Verified</u>
LeukoStrat CDx FLT3 - Specimen Type	Blood @			17-208-106113	27-Jul-17 11:39:00	27-Jul-17 11:39:00	27-Jul-17 11:43:53
LeukoStrat CDx FLT3 Mutation Detection	See Note	f@		17-208-106113	27-Jul-17 11:39:00	27-Jul-17 11:39:00	27-Jul-17 11:43:53

27-Jul-17 11:39:00 LeukoStrat CDx FLT3 Mutation Detection:

Final Diagnosis
 Overall: Positive

ITD: Positive
 TKD: Positive

Interpretation
 Interpretation Description for a Positive result:

This test was performed under the direction of Veena Singh, MD, FCAP, FACMG

The Laboratory for Personalized Molecular Medicine is CLIA certified and CAP accredited to perform high complexity testing.

This test was developed and its performance characteristics determined by Invivoscribe Technologies, Inc. It has been approved by the U.S. Food and Drug Administration for use in the aid of prescribing midostaurin (PMA#P160040). The Laboratory for Personalized Molecular Medicine performs the assay in accordance with the instructions for use provided by Invivoscribe Technologies, Inc.

Assay Description

The Leukostrat CDx FLT3 Mutation Assay is a PCR based test designed to detect internal tandem duplications (ITD) and tyrosine kinase (TKD) mutation in the FLT3 gene.

ITD: The duplication and insertion of a portion of the FLT3 gene that includes the region in and around the juxtamembrane region of the FLT3 gene.

TKD: Nucleotide(s) changes at codon 835 and/or 836 that are detected by inactivation of the EcoRV restriction digestion site within the tyrosine kinase domain for the FLT3 gene.

The polymerase chain reaction is performed on DNA isolated from mononuclear cells obtained from peripheral blood and bone marrow aspirates of patients diagnosed with acute myeloid leukemia. Fluorescently labeled primers are used to amplify the sequences of interest. The TKD PCR product is digested with the EcoRV restriction enzyme. The ITD PCR products and the digested TKD PCR products are run on an ABI 3500xL Genetic Analyzer and their sizes determined.

*FLT3 Mutation Testing is performed pursuant to patents licensed from Takara Bio of Otsu, Japan.

27-Jul-17 11:39:00 LeukoStrat CDx FLT3 Mutation Detection, LeukoStrat CDx FLT3 - Specimen Type:
 Performed at: LabPMM, 6330 Nancy Ridge Drive, San Diego, CA 92121

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