Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 09/22/2023 11:44 Received: 09/22/2023 11:44

Test Name	Result	Flag	Ref-Ranges	Units	Site

LeukoStrat CDx FLT3 Mutation Assay

Specimen Type	Peripheral Blood	QDRL
Final Diagnosis Overall:	Not Detected	QDRL

FLT3 Mutation was NOT detected above the clinical cut-off of a signal ratio of 0.05.
Midostaurin is not indicated for this patient.
Gilteritinib is not indicated for this patient.

ITD	Not Detected	QDRL
TKD	Not Detected	QDRL
ITD Signal Ratio	.	QDRL
TKD Signal Ratio	.	QDRL
Interpretation:	SEE BELOW	QDRL

The Leukostrat(R) CDx FLT3 Mutation Assay is the only FDA approved predictive test for the efficacy of midostaurin therapy in all acute myeloid leukemia (AML) patients, regardless of cytogenetics. AML Patients without a detectable FLT3 mutaiton above the clinical cut-off are NOT indicated for midostaurin therapy.

The Leukostrat(R) CDx FLT3 Mutation Assay is the only FDA approved predictive test for the efficacy of gilteritinib therapy in relapsed or refractory acute myeloid leukemia (AML) patients. Relapsed or refractory AML Patients without a detectable FLT3 mutation above the clinical cut-off are not indicated for gilteritinib therapy.

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

The Laboratory for Personalized Molecular Medicine(TM) is CLIA certified and CAP accredited to perform high complexity testing. This test was developed and its performance characteristics determined by Invivoscribe, Inc. It has been approved by the U.S. Food and Drug Administration for use in the aid of prescribing midostaurin or gilteritinib (PMA# P160040). The Laboratory for Personalized Molecular Medicine performs the assay in accordance with the instructions for use provided by Invivoscribe, Inc.

Assay Description
The Leukostrat(R) CDx FLT3 Mutation Assay is a PCR based test designed to detect internal tandem duplications

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(ITD) and tyrosine kinase (TKD) mutations 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 or 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.

References:
FLT3-ITD: S P Whitman et al., 2010 Blood 116: 3622-3626
FLT3-TKD: U Bacher et al., 2008 Blood 111: 2527-2537

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

TEST PERFORMED AT:
LABORATORY FOR PERSONALIZED MOLECULAR MEDICINE
10222 BARNES CANYON ROAD SAN DIEGO, CA 92121
VEENA SINGH,MD,FCAP,FACMG

Performing Site:
QDRL: QUEST DIAGNOSTICS REFERENCE LAB VALENCIA 27027 Tourney Road Valencia CA 91355

Reported Date: 2023.09.22 11:45 LUFL3