LeukoStrat®

CDx *FLT3* Mutation Assay

The only FDA Approved assay for assessment of acute myeloid leukemia (AML) patients eligible for treatment with midostaurin or gilteritinib fumarate.

NCCN, ELN and CAP Guidelines recommend *FLT3* testing to inform patient treatment decisions.

Guide treatment decisions at AML diagnosis or AML relapse.

Assay Overview

- Ready-to-use *FLT3* ITD & TKD master mixes and run controls
- Short turnaround protocol (1-2 business days)
  ELN guidance is <=3 day TAT in patients eligible for intensive chemotherapy
- Software included
  Analysis with Interpretation of results plus Signal Ratio report
- Mutant:wild type ratio results
  Automatically evaluated against the midostaurin & gilteritinib fumarate clinical cut-offs
- Complete technical support
- IVD labeled including software developed under ISO 13485

Proven & Consistent Quality

The LeukoStrat® CDx *FLT3* Mutation Assay enables laboratories and physicians to support patients with local access to high-quality, diagnostic tests that improve treatment.

Ordering Information

Catalog #	Products	Quantity
K-412-0361	LeukoStrat® CDx *FLT3* Mutation Assay	33 Reactions
K-412-0371	LeukoStrat® CDx *FLT3* Software	(1) CD with purchase
K-412-0401	LeukoStrat® CDx Assay Installer	(1) USB with purchase

IVD These IVD products are intended for *in vitro* diagnostic use, and are available for sale or use within the United States only.

Accelerate AML Treatment Decisions: Bring CDx Testing In-House for Rapid Patient Results

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Improving Lives with Precision Diagnostics®

041 Rev A June 2020

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CDx *FLT3* Mutation Assay

Each year ~20,000 patients in the United States are diagnosed with AML. Of those diagnosed with AML, ~1 out of 3 are *FLT3*mut+

Intended Use

The LeukoStrat® CDx *FLT3* Mutation Assay is a PCR-based in vitro diagnostic test designed to detect internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the *FLT3* gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia (AML).

The LeukoStrat® CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom RYDAPT® (midostaurin) treatment is being considered.

The LeukoStrat® CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA® (gilteritinib) treatment is being considered.

The test is for use on the 3500xL Dx Genetic Analyzer.

Assay Clinical Performance Evaluation - Midostaurin Drug Efficacy

Adult patients, newly diagnosed AML

The safety and efficacy of the LeukoStrat® CDx *FLT3* Mutation Assay was assessed during a bridging study, corresponding to the Phase 3 RATIFY clinical study of midostaurin in newly diagnosed AML patients with *FLT3* mutations.

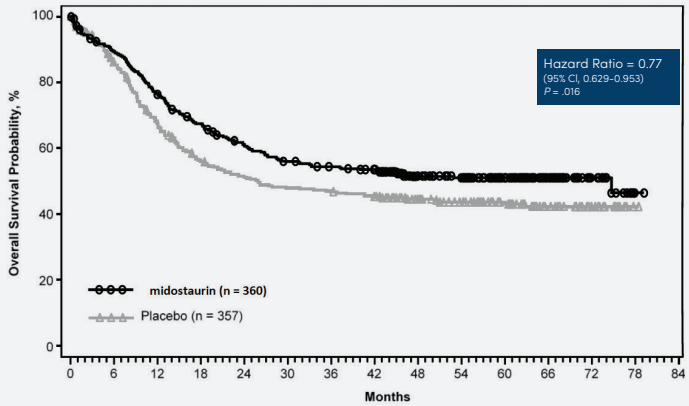

Figure 1: Kaplan-Meier for overall survival in the RATIFY trial in the CTA+ population.

Assay Clinical Performance Evaluation - Gilteritinib Drug Efficacy

Adult patients, relapsed or refractory AML

FDA approval of gilteritinib is based on Phase 3 ADMIRAL trial results which investigated gilteritinib versus salvage chemotherapy in patients with relapsed or refractory *FLT3*mut+ AML. The ADMIRAL trial is designed to demonstrate device & drug efficacy when AML patients are selected for treatment with the LeukoStrat® CDx Test & treated with the drug compound. Interim results demonstrated that the median duration of response in subjects with response of CR/CRh was 4.6 months.

Refer to Assay labeling for complete clinical performance summary.

The LeukoStrat® CDx *FLT3* Mutation Assay is the Companion Diagnostic to All Approved Tyrosine Kinase Inhibitor Therapies in AML.

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