LeukoStrat®

CDx *FLT3* Mutation Assay

The only CE-IVD marked assay for selection of acute myeloid leukemia (AML) patients eligible for treatment with midostaurin or gilteritinib fumarate.

NICE now recommends the use of Midostaurin in *FLT3*+ myeloid leukemia patients.

Assay Overview

- Ready-to-use *FLT3* ITD & TKD master mixes and run controls
- Short turnaround protocol (1-2 business days)
- Software included
  From run planning to analysis with local interpretation
- Mutant:wild type ratio results
  Automatically evaluated against the midostaurin & gilteritinib fumarate clinical cut-offs
- Complete technical support
- CE-IVD marked 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-412-0291	LeukoStrat® CDx *FLT3* Mutation Assay	33 Reactions
K-412-0281	LeukoStrat® CDx *FLT3* Mutation Assay Software	(1) CD with purchase

CE IVD These are *in vitro* diagnostic products, and are not available for sale or use within North America.
LeukoStrat® is a registered trademark of Invivoscribe Technologies, Inc.

For more information regarding products, please contact us at sales-EU@invivoscribe.com

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Intended Use

The LeukoStrat® CDx *FLT3* Mutation Assay is a PCR-based in vitro diagnostic test designed to detect internal tandem duplications (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 aspiratesof patients diagnosed with acute myelogenous leukemia (AML).

In regions where midostaurin is available, 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.

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

Assay Clinical Performance Evaluation - Midostaurin Drug Efficacy

The safety and efficacy of the LeukoStrat® CDx *FLT3* Mutation Assay was assessed during a bridging study, corresponding to the Phase III CPKC412A2301 (RATIFY) clinical study of midostaurin in newly diagnosed AML patients with *FLT3* mutations.

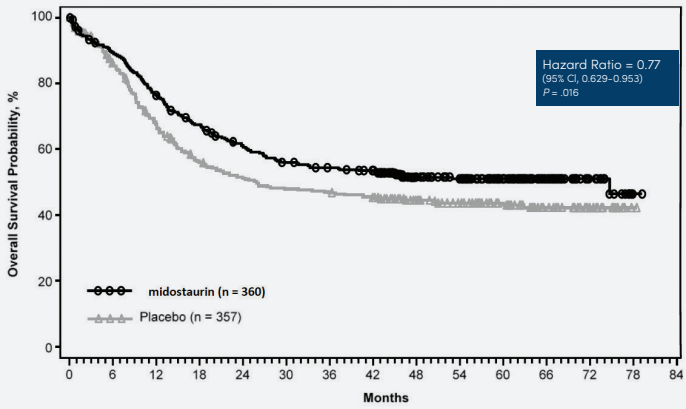

Figure 1: Kaplan-Meier for overall survival in the RATIFY trial in the CTA+ population.

Assay Clinical Performance Evaluation - Gilteritinib Drug Efficacy

European Commission 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 study demonstrated that gilteritinib resulted in a statistically significant improvement in median overall survival (9.3 months) compared to salvage chemotherapy (5.6 months) when patients were selected with the LeukoStrat CDx *FLT3* Mutation Assay.

Presence of a *FLT3* mutation in patients with AML is both highly prognostic and clinically actionable.

The LeukoStrat® CDx *FLT3* Mutation Assay is intended to assist physicians in making treatment decisions for their AML patients with *FLT3* Mutations.

The LeukoStrat® CDx *FLT3* Mutation Assay is also offered as ISO 15189 accredited service through an Invivoscribe, fully-owned subsidiary, Laboratories for Personalized Molecular Medicine (LabPMM). LabPMM GmBH is DAkkS accredited and follows RiliBAK guidelines.

For more information regarding LabPMM services, please contact us at info@labpmm.de

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