LeukoStrat®

CDx *FLT3* Mutation Assay

CE 2797 IVD

COMPANION DIAGNOSTIC

In Vitro Diagnostic Kit
Cat. No. K4120431

The only IVDR/CE 2797 IVD approved assay for selection of acute myeloid leukemia (AML) patients eligible for treatment with XOSPATA®

National Institute for Health and Care Excellence now recommends the use of therapeutics 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 gilteritinib fumarate clinical cut-offs
- Complete technical support
- CE 2797 IVD approved 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 patient management decisions.

Ordering Information

Catalog #	Products	Quantity
K-412-0431	LeukoStrat® CDx *FLT3* Mutation Assay	33 Reactions
K-412-0441	LeukoStrat® CDx *FLT3* Software	(1) CD with purchase

CE 2797 IVD

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

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

invivoscribe®
Improving Lives with Precision Diagnostics®

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Intended Use

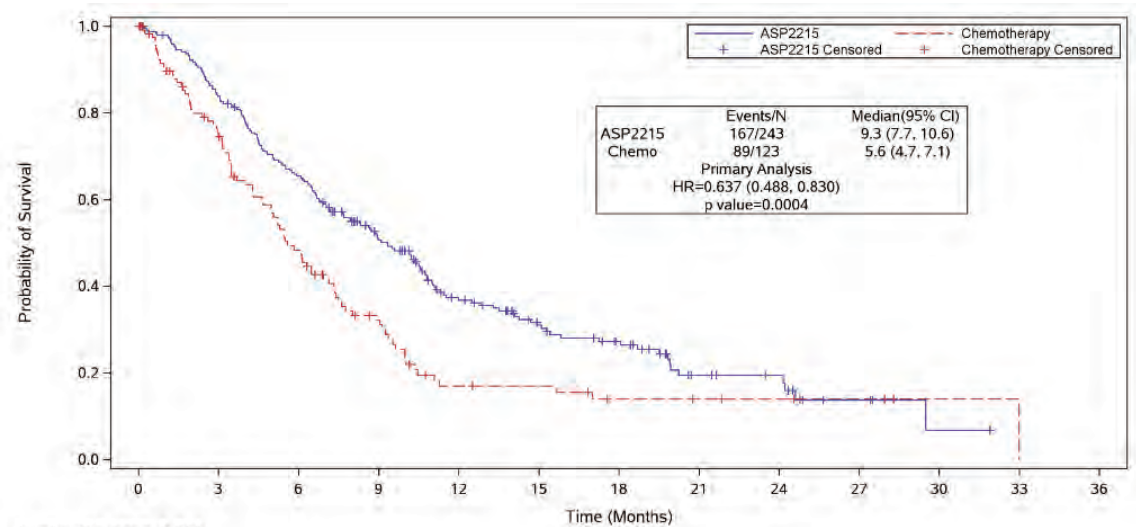
The LeukoStrat CDx *FLT3* Mutation Assay is a PCR-based in vitro diagnostic test designed to detect internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the *FLT3* gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow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

In regions where XOSPATA® (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.

The qualitative, non-automated test is for use on the 3500xL or 3500xL Dx Genetic Analyzers.

Gilteritinib Drug Efficacy - Assay Clinical Performance Evaluation

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.

For more information regarding LabPMM services including the LeukoStrat® CDx *FLT3* Mutation Assay and *FLT3* MRD testing, please contact us at info@labpmm.de

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