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® (gilteritinib fumarate) and/or VANFLYTA® (quizartinib hydrochloride).

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 & quizartinib hydrochloride 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
K4120431	LeukoStrat® CDx *FLT3* Mutation Assay	33 Reactions
K4120441	LeukoStrat® CDx *FLT3* Software	CD complementary 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

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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:

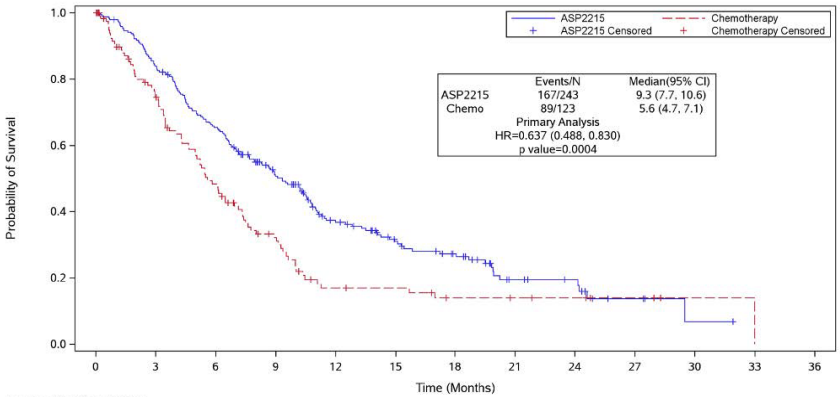
In regions where XOSPATA® (gilteritinib fumarate) is available, the LeukoStrat CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA (gilteritinib fumarate) treatment is being considered.

In regions where VANFLYTA® (quizartinib hydrochloride) is available, the LeukoStrat CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with *FLT3*-ITD+ AML for whom VANFLYTA® (quizartinib hydrochloride) treatment is being considered.

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

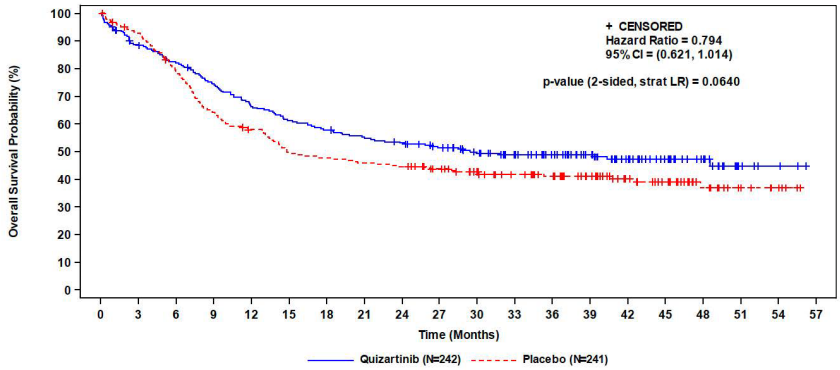
Presence of a *FLT3* mutation in patients with AML is both highly prognostic and clinically actionable.

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.

Quizartinib Hydrochloride Efficacy - Assay Clinical Performance Evaluation



The Assay clinical utility as a CDx for quizartinib hydrochloride is based on the bridging study of the LeukoStrat CDx *FLT3* Mutation Assay in samples from AML subjects screened in theQuANTUM-First trial results which investigated quizartinib hydrochloride + standard chemotherapy versus placebo in patients with de novo *FLT3*-ITD AML. The bridging study demonstrated in the (CTA(+), CDx(+)) population, quizartinib treatment in combination with standard chemotherapy resulted in a clinically relevant improvement in OS compared to placebo. The median OS in the quizartinib arm was 29.4 months (19.1, NE) compared to 14.8 months (13.1, 26.2) for placebo resulting in 14.6 months prolongation of median OS (2-sided, stratified log rank p-value= 0.0640). The results were comparable to those observed in the QuANTUM-First (AC220-A-U302) study.

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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