invivoscribe

Diagnostic and Development Tools to Detect *FLT3* Mutated AML

Invivoscribe Leads the Way Providing Innovative *FLT3* Kits and Services Worldwide.

Invivoscribe's international products and services include kits, and testing services for the detection of both ITD and TKD mutations of the *FLT3* gene. *FLT3* ITD measurable residual disease (MRD) testing at sensitivities as low as 10^{-5} is also available as a kit and service.

Clinical Significance of *FLT3* Mutation Status

Since *FLT3*mut+ AML is clinically actionable, stratification of AML patients by testing for *FLT3* mutation status has become a standard of care.

Each year approximately 21,000 patients in the United States are diagnosed with acute myeloid leukemia (AML). Of those diagnosed with AML, ~1 out of 3 are expected to have presence of FLT3 mutations, (FLT3mut+).

Measurable Residual Disease Testing **Clinical Testing Service**

FLT3 ITD MRD Assay by NGS

To track and identify previously detected ITD mutations in post treatment follow up samples, a multiplex master mix targeting in and around the juxtamembrane domain of the *FLT3* gene is used to amplify DNA extracted from a patient sample.

Next-generation sequencing of the PCR products is used to identify DNA sequences specific to previously identified mutations detected at diagnosis. Bioinformatics tools facilitate the detection of these specific sequences present at an allelic sensitivity of $5x10^{-5}$.

Currently Under Validation or Regulatory Review

Distributable Kit, LeukoStrat CDx *FLT3* Mutation Assay (China)

Companion Diagnostic *In Vitro* Diagnostic Kit

LeukoStrat CDx *FLT3* Mutation Assay (USA) Catalog # K-412-0361

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

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

M-0124 Rev01 July 2023

email: sales@invivoscribe.com visit: www.invivoscribe.com
San Diego, CA | Munich, Germany | Kawasaki, Japan | Shanghai, China

LabPMM®
an invivoscribe company

Companion Diagnostic
Clinical Testing Services

LeukoStrat CDx *FLT3* Mutation Assay (USA, Call 858.224.6650)

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

LeukoStrat CDx *FLT3* Mutation Assay (Japan, Call +81 44.281.1500)

The LeukoStrat CDx *FLT3* Mutation Assay is a PCR-based, *in vitro* diagnostic test designed to detect internal tandem duplication (ITD) mutations 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.

The LeukoStrat CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom Gilteritinib Fumarate treatment is being considered.

The LeukoStrat CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom Quizartinib Hydrochloride treatment is being considered.

LeukoStrat CDx *FLT3* Mutation Assay (CE-Marked, Call +49 89 899480780)

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 aspirates of 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.

In Vitro Diagnostic Kits

LeukoStrat CDx *FLT3* Mutation Assay (Japan, PN: K-412-0331)

The LeukoStrat CDx *FLT3* Mutation Assay is a PCR-based, *in vitro* diagnostic test designed to detect internal tandem duplication (ITD) mutations 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.

The LeukoStrat CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom Gilteritinib Fumarate treatment is being considered.

The LeukoStrat CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom Quizartinib Hydrochloride treatment is being considered.

LeukoStrat CDx *FLT3* Mutation Assay (CE 2797 IVD, PN: K-412-0431)

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.

*Clinical testing services are provided through LabPMMM laboratories.

LabPMM®
an invivoscribe company