Diagnostic & Development Tools for Detecting *FLT3* Mutated AML

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

Invivoscribe international products and services include kits, reagents, and testing services specific to detecting both ITD and TKD mutation of the *FLT3* gene. *FLT3* ITD MRD testing at sensitivities as low as 10^{-5} is further available as a service offering.

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, (*FLT3*mut+).

Clinical Testing Services

Minimal Residual Disease Testing

FLT3 ITD MRD Assay by NGS (International)

To track and identify previously detected ITD mutations in post treatment follow up samples, a multiplex master mix targeting in & 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 $5x10^{-5}$.

Companion Diagnostic

In Vitro Diagnostic Kit

NEW!
Now FDA Approved Distributable Kit

LeukoStrat CDx FLT3 Mutation Assay (USA, PN: K4120361)

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.

Currently Under Validation or Regulatory Review

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

invivoscribe
Improving Lives with Precision Diagnostics™

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Clincal Testing Services

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

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The LeukoStrat CDx *FLT3* Mutation Assay is to be performed only at Laboratory for Personalized Molecular Medicine (LabPMM) LLC, a single laboratory site, located at 10222 Barnes Canyon Rd., Bldg. 1, San Diego, CA 92121.

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

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

In Vitro Diagnostic Kits

LeukoStrat CDx *FLT3* Mutation Assay (Japan, PN: K4120331)

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 (AUS, PN: K4120381)

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 selection of patients with AML for whom midostaurin treatment is being considered.

LeukoStrat CDx *FLT3* Mutation Assay (CE-marked, PN: K4120281)

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.

LabPMM®
an invivoscribe company

*Clinical testing services are provided through LabPMM laboratories.