

# 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 both highly prognostic and 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, which portend a worse prognosis (*FLT3*mut+).

## *FLT3* Reagents

* GPR Product Description	Catalogue #	Available Regions
<i>FLT3</i> ITD Positive DNA - GPR	R0880230	USA
<i>FLT3</i> TKD Positive DNA - GPR	R0880240	USA
<i>FLT3</i> Extraction Control - GPR	R0880250	USA
<i>FLT3</i> No Template Control - GPR	R0930070	USA

\*For Laboratory Use

* ASR Product Description	Catalogue #	Available Regions
<i>FLT3</i> ITD MM - 6FAM & HEX- ASR	A4120071	USA
<i>FLT3</i> TKD MM -6FAM - ASR	A4120081	USA

\*Analyte Specific Reagent. Analytical and performance characteristics are not established.

## Products Currently Under Validation or Regulatory Review

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

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## 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 two levels of sensitivity.

The assay requires a sample taken at diagnosis as well as the post treatment follow up samples. However, in the event of a diagnostic sample not being available, we are still able to detect ITDs.

Two levels of sensitivity are offered:

- The standard assay reliably detects sequences present at  $10^{-4}$ .
- The sensitive assay reliably detects sequences present at  $10^{-5}$ .

#### Companion Diagnostic

##### 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 selection 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 selection of patients with AML for whom XOSPATA® (gilteritinib) treatment is being considered.

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 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.

##### 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 selection of patients with AML

for whom midostaurin 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 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.

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

\*Clinical testing services are provided through LabPMM laboratories