# LeukoStrat®

CDx *FLT3* Mutation Assay

## The only FDA Approved assay for assessment of acute myeloid leukemia (AML) patients eligible for treatment with midostaurin, gilteritinib, or quizartinib.

NCCN, ELN and CAP Guidelines recommend *FLT3* testing to inform patient treatment decisions.


## Guide Treatment Decisions at AML Diagnosis or AML Relapse.

### Assay Overview

- **Ready-to-use *FLT3* ITD and TKD master mixes and run controls**
- **Short turnaround protocol (1-2 business days)** - ELN guidance is <=3 day TAT in patients eligible for intensive chemotherapy
- **Software included** - Analysis with Interpretation of results plus Signal Ratio report
- **Mutant:wild type ratio results** - Automatically evaluated against the midostaurin, gilteritinib, and quizartinib clinical cut-offs
- **Complete technical support**
- **IVD labeled 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 assist with AML patient management.

### Accelerate AML Treatment Decisions: Bring CDx Testing In-House for Rapid Patient Results.

## Ordering Information

| Catalog # | Products | Quantity |
|---|---|---|
| K-412-0361 | LeukoStrat® CDx *FLT3* Mutation Assay | 33 Reactions |
| K-412-0371 | LeukoStrat® CDx *FLT3* Software | (1) CD with purchase |
| K-412-0401 | LeukoStrat® CDx Assay Installer | (1) USB with purchase |

IVD These IVD products are intended for *in vitro* diagnostic use, and are available for sale or use within the United States only.



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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 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.

**Each year ~ 20,000 patients in the United States are diagnosed with AML. Of those diagnosed with AML, ~1 out of 3 are *FLT3*mut+**

## Assay Clinical Performance Evaluation - Midostaurin Drug Efficacy

### Adult patients, newly diagnosed AML

The safety and efficacy of the LeukoStrat® CDx *FLT3* Mutation Assay was assessed during a bridging study, corresponding to the Phase 3 RATIFY clinical study of midostaurin in newly diagnosed AML patients with *FLT3* mutations.

## Assay Clinical Performance Evaluation - Gilteritinib Drug Efficacy

### Adult patients, relapsed or refractory AML

FDA 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.

## Assay Clinical Performance Evaluation - Quizartinib Drug Efficacy

### Adult patients, newly diagnosed AML

The safety and efficacy of the LeukoStrat® CDx *FLT3* Mutation Assay was assessed during a bridging study, corresponding to the Phase III AC220-A-U302 clinical trial of quizartinib in newly diagnosed AML patients with *FLT3*-ITD mutations (QuANTUM-First).


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