LeukoStrat®
CDx *FLT3* Mutation Assay

CE-IVD Marked Under IVDR | CE 2797 IVD
FDA and PMDA Approved | IVD

Acute myeloid leukemia (AML) is a growing global health challenge, with an estimated 144,646 new incidences in 2021.[1,2] *FLT3*-ITD and -TKD mutations are among the most clinically actionable biomarkers in AML, occurring in approximately 20% and 7% of patients, respectively.[3]

The LeukoStrat® CDx *FLT3* Mutation Assay is a PCR-based in vitro companion diagnostic designed to detect *FLT3* internal tandem duplication (ITD) mutations and tyrosine kinase domain (TKD) mutations, such as the D835 and I836, in patients with AML. The ability to accurately and reliably detect these clinically relevant mutations enables laboratories local access to high-quality diagnostic tests and physicians improved treatment decision making[4,5,6]. Given the clinical actionability of *FLT3*-mutated AML, routine assessment of *FLT3* mutation status has become a standard of care for patient stratification.

The LeukoStrat® CDx *FLT3* Mutation Assay* predicts response to

XOSPATA® (gilteritinib fumurate)

VANFLYTA® (quizartinib hydrochloride)

RYDAPT® (midostaurin)

Operational & Clinical Advantages

Actionable Detection
Two actionable targets for precision therapy

Expanded Detection
Detect ITDs from 3 bp up to 323 bp

Sensitive
Reports signal ratios (SR) down to 0.5%

Rapid Turnaround Time
One-day, end-to-end workflow

Regulatory Ready Solution
Analytically and clinically validated - minimizing compliance burdens

Comprehensive
Turnkey kit with included software

References:

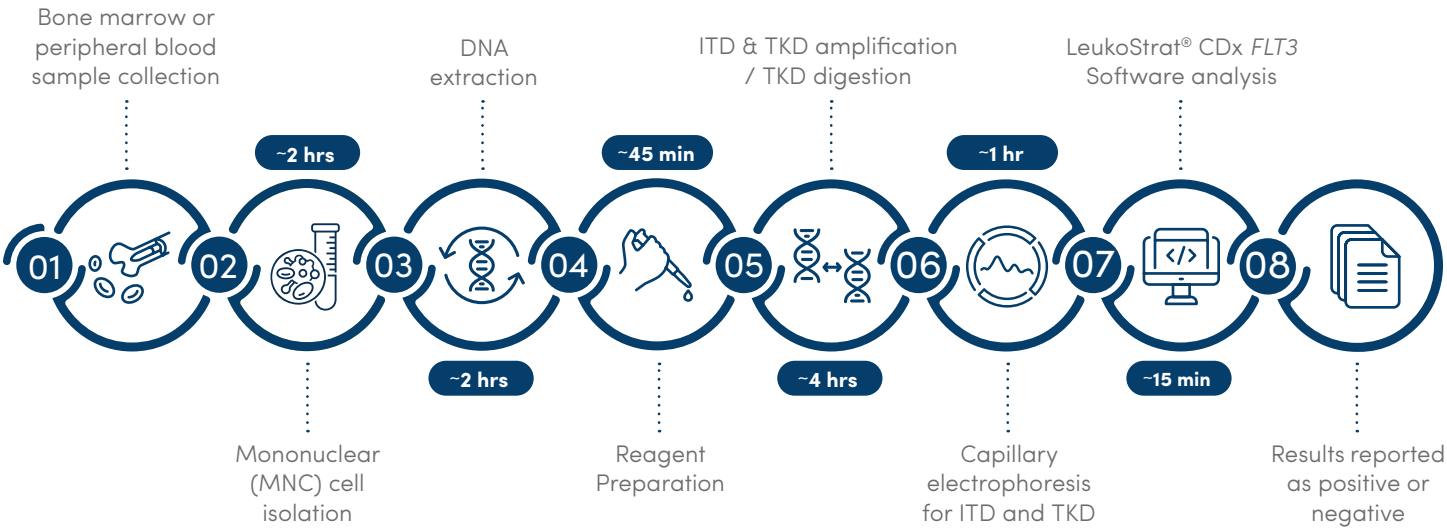
1. Wu et al. *Ann Med.* 2025. doi: 10.1080/07853890.2025.2557507
2. Han et al. *Biomed Eng Online.* 2025. doi: 10.1186/s12938-025-01403-7
3. Sierra et al. *Cancer Med.* 2025. doi: 10.1002/cam4.71205
4. Levis et al. *J Clin Oncol.* 2024. doi: 10.1200/JCO.23.024
5. Levis et al. *Blood.* 2020. doi: 10.1182/blood.2019002180
6. Levis et al. 2026. *Blood* Adv. doi: 10.1182/bloodadvances.2025016444

invivoscribe®
Improving Lives with Precision Diagnostics®

Hands-on Time & Workflow

From MNC Isolation to Results in One Workday

Globally Standardized | Clinically Actionable Diagnostic



The turnkey kit contains all necessary components including an extraction control, both *FLT3*- ITD and -TKD master mixes and positive controls, *FLT3* negative and no template controls, enzymes and buffer.

Catalog No. - Region	Product	Quantity
K4120431 – European Union K4120331 – Japan K4120361 – United States	LeukoStrat® CDx *FLT3* Mutation Assay	33 reactions
S100021 – European Union S100020 – Japan S100019 – United States	LeukoStrat® CDx *FLT3* Software	1 Software Package Download

*The availability of XOSPATA®, VANFLYTA®, and RYDAPT® varies by region and is subject to local regulatory approval. Contact Invivoscribe for details on local regulatory approvals and corresponding catalog numbers.

Learn more about easy-to-implement CDx.
To bring the kit in-house, reach out to inquiry@invivoscribe.com

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