KMT2A MRD Assay

Defining Residual Disease to Inform Treatment Strategy

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Clinical Information

KMT2A gene rearrangements (*KMT2Ar*) are known driver mutations in both Acute lymphoblastic leukemia (ALL) and Acute myeloid leukemia (AML), and are associated with chemotherapy resistance, high rates of relapse, and poor clinical outcomes.[1] *KMT2Ar* are present in over 80% of new ALL infant diagnoses and 15% of adult and up to 10% of AML cases. However, with advances in assessment technology, therapeutics, understanding of the disease biology, and development of risk stratification guidelines such as the NCCN Guidelines®[2,3] and ELN[4,5] the paradigm has shifted for patients with ALL or AML.[6-8]

The *KMT2A* MRD Assay provides a standardized, highly sensitive solution for the detection and monitoring of clinically relevant *KMT2A* rearrangements*: *MLLT3* (AF9), *MLLT10* (AF10), *ELL*, and *MLLT4/AFDN* (AF6). Designed for both disease characterization and MRD testing, it delivers the sensitivity, reliability, and rapid turnaround laboratories need to support confident clinical decision-making, translational research and drug development.

MRD Insights for Pharma and Clinical Care

- Highly sensitive dPCR detects low-level disease and enables early identification of relapse
- Distinguishes true responders, improves patient stratification, and clinical trial efficacy assessment
- Enables longitudinal monitoring to track depth and durability of response
- Informs treatment escalation or transplant planning

References

1. Guarnera et al. 2024. *Int. J. Mol. Sci.* DOI: 10.3390/ijms25169023
2. NCCN Guidelines Version 1.2026 Pediatric Acute Lymphoblastic Leukemia.
3. NCCN Guidelines Version 1.2025 Acute Myeloid Leukemia.
4. Cloos et al. 2026. *Blood.* DOI: 10.1182/blood.2025031480
5. Gökbuget et al. 2024. *Blood.* DOI: 10.1182/blood.2023023568
6. Jani et al. 2023. *JCO Glob Oncol.* DOI: 10.1200/GO.23.00229
7. Sekeres et al. 2025. *Blood Advances.* DOI: 10.1182/bloodadvances.2025017934
8. Shimony et al. 2025. *Am J Hematol.* DOI: 10.1002/ajh.27625

*Not all breakpoints are detected.

Indications for Testing

- Disease characterization
- Stratify risk for disease recurrence
- Post-treatment monitoring
- Inform continuation, escalation, and transplant decisions

Interpretation

- If detected, the report provides the percent *KMT2Ar /ABL1* for each rearrangement.

Turnaround Time

- 7 to 10 business days

Specimen Requirements

- 1-3 mL of peripheral blood in EDTA
- 0.25-1 mL of bone marrow in EDTA
- 7.5 µg of previously isolated RNA

Specimen Stability

- 2-8 °C up to 3 days prior to testing

Shipping Conditions

- Ambient or Cool; do not freeze (peripheral blood or bone marrow)
- Frozen on dry ice (isolated RNA)

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