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ANCORA *KMT2A*-r ASSAY

Highly sensitive detection of complex *KMT2A* rearrangements with a single PCR assay

One multiplex assay, six most common partners

Identifying a *KMT2A* rearrangement and then tracking its levels over time usually requires two different assays. Every new testing method or assay added to a lab makes results harder to compare data from previous time points. Labs need a single, consistent workflow that combines broad fusion coverage with sensitive quantification.

The Ancora *KMT2A*-r Assay is a multiplex RNA reaction that detects 18 fusion transcripts across the six most common *KMT2A* partners. A fusion is called only when the *KMT2A* sequence and partner sequence appear on the same molecule, delivering near-zero false positives at a sensitivity of 0.001%. With no dead volume and a flexible input range, the assay makes the most of every samples, particularly important for precious pediatric research samples, in relation to research associated with diagnosis through MRD monitoring.

Key Highlights

Broad fusion coverage: One assay detects 18 fusion transcripts across the six most common *KMT2A* partners.

Track the same fusion marker: The same assay can identify the fusion at diagnosis and can track the same marker through MRD, in research studies.

Same molecule fusion detection: A fusion is called only when both *KMT2A* and fusion partner appear on the same molecule, delivering near-zero false positives designed for 10^{-5} sensitivity.

Flexible RNA input: From 20 ng to 1 µg, for quantitation in diagnostic research specimens as well as MRD research specimens.

Preserve precious specimen: No dead volume and high volume input (35 µL) maximizes target recovery, especially relevant for pediatric research specimens.

Table 1. *KMT2A* rearrangement prevalence and assay coverage. Reported percentages of cases with *KMT2A* rearrangements within each leukemia type and age group.

Percent *KMT2A* rearrangement cases covered by current panel			
	Infant	Pediatric	Adult
AML	75%	83%	82%
ALL	94%	86%	96%

Source: Meyer C, et al. Leukemia. 2023;37:988—1005

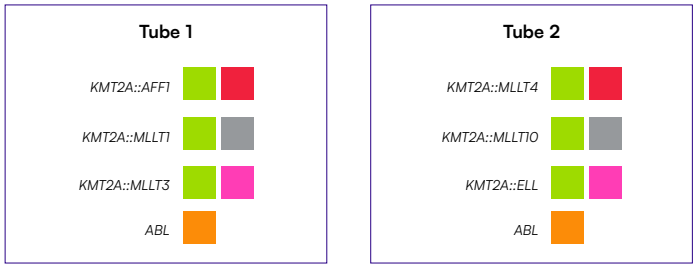


Figure 1. Countable PCR multiplex detection strategy. Each *KMT2A* fusion partner is assigned a unique optical signature, enabling specific identification and direct quantification of 18 fusion transcripts across the six most common partners, alongside the *ABL1* reference.

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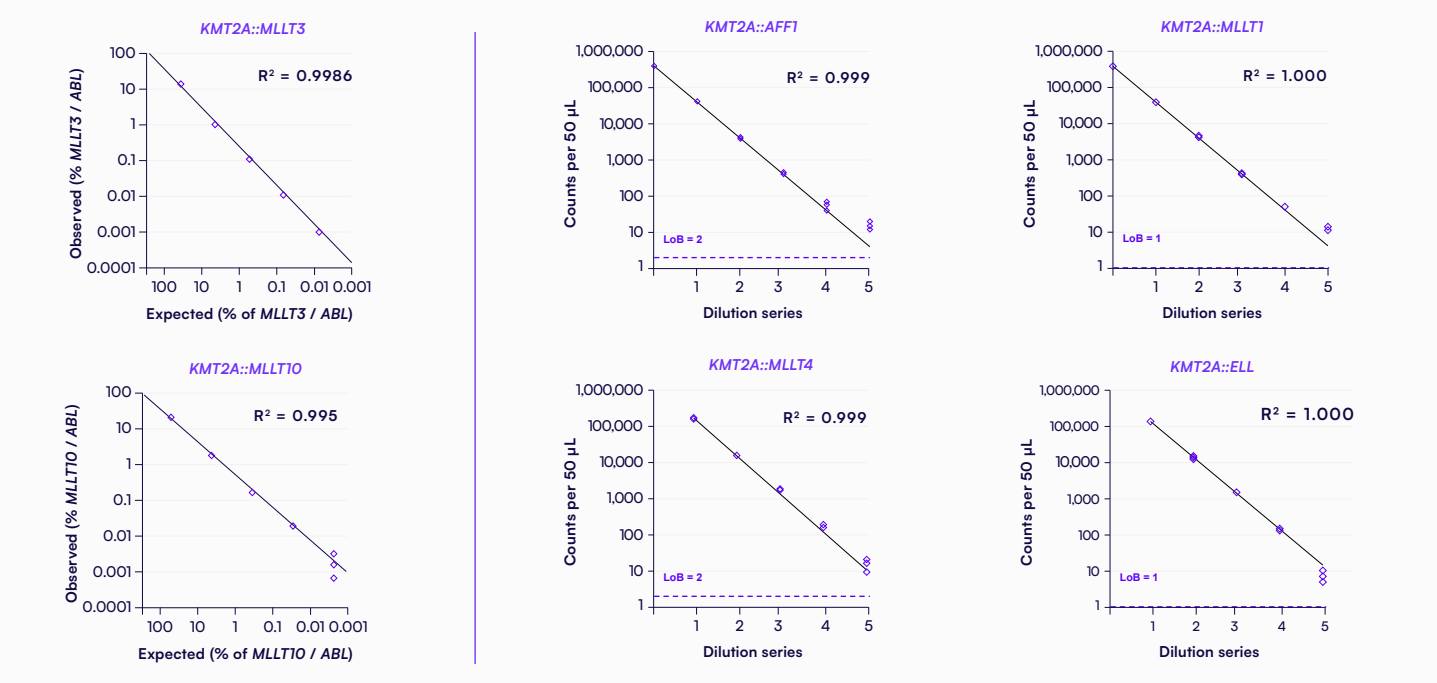


Figure 2. Linearity across *KMT2A* fusion partners demonstrating high concordance between measured and expected ratios (%) ($R^2 > 0.994$) across five orders of magnitude of fusion transcript levels, in relation to research associated with diagnosis through MRD monitoring. Data were generated using synthetic fusion templates spiked into a background of HL-60 cell line RNA.

Performance

The broad dynamic range of the Countable PCR system enables the Ancora *KMT2A*-r Assay to identify a fusion and track the same marker down to very low levels, even against a background of high *ABL1* expression. Because every molecule is counted in its own compartment and a fusion is called only when both sequences appear together, rare fusion transcripts are detected directly rather than inferred, reaching a limit of detection of 0.0007%, at 1,000,000 *ABL1* copies. Direct counting delivers highly reproducible results from high to low burden load without per-run standard curves or patient-specific redesign.

Table 2. LoD % calculated based off of LoB data.

Target	Limit of Detection (LoD%) at 1M *ABL1*
KMT2A::MLLT4	0.001%
KMT2A::ELL	0.0007%
KMT2A::MLLT10	0.0008%
KMT2A::AFF1	0.001%
KMT2A::MLLT3	0.0007%
KMT2A::MLLT1	0.0008%

Sample requirements:

- Sample type: Extracted total RNA (from EDTA whole blood or bone marrow).
- Minimum input: ≥20 ng RNA (for fusion partner identification).
- High sensitivity input: ≥100 ng to 3 µg RNA (depending on sample availability and desired sensitivity level).

Ordering

SKU	Kit Name	Description
BK0006	Ancora *KMT2A*-r Bundle	This complete 48-reaction solution includes two kits and a software module: (1) Two-tube multiplexed 5-color assay that detects 18 fusion transcripts across 6 common partners- *MLLT3, AFF1, MLLT4, ELL, MLLT10*, and *MLLT1* against reference gene *ABL1* in an RNA-input reaction with Imaging Control included; (2) Countable PCR consumables and matrix reagents; and (3) a software module for data collection and reporting.

Required equipment: This assay is designed for use exclusively with the Countable System and its compatible equipment.

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To learn more, visit countablelabs.com or contact support at support@countablelabs.com.

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