

ANCORA *BCR::ABL1* ASSAY

Deep, standardized *BCR::ABL1* monitoring for CML and Ph+ALL using single-molecule counting

The New Standard in Molecular Testing

BCR::ABL1 monitoring often requires separate, labor-intensive workflows for baseline transcript identification and deep MRD. PCR and fragment analysis are typically single-plex methods and rely on per-run standard curves and laboratory specific calibrations that can introduce run-to-run and site-to-site variability.

Powered by Countable PCR single-molecule counting, the Ancora *BCR::ABL1* Assay identifies and directly quantifies p210, p190, and p230, and *ABL1* in a single tube. Its high-color multiplex design assigns each transcript a unique optical signature, enabling sensitivity beyond MR5.0 at high input without per-run standard curves. Automated reporting delivers p210 results on the International Scale and p190/p230 as *BCR::ABL1/ABL1* % ratio. Together, these capabilities support highly sensitive, reproducible monitoring across CML and Ph+ALL in a seamless, software driven workflow.

Key Highlights

Beyond MR5.0 Sensitivity (at high input): Reaches 0.0007% IS at $\geq 1M$ *ABL1* copies for deep molecular response and trial endpoints evaluation.

High-Color Multiplex Detection: Unique optical signatures simultaneously quantify *e14a2*, *e13a2* (p210), *e1a2* (p190), *e19a2* (p230) and *ABL1* in one reaction.

Uncompromising Reproducibility: Direct single-molecule counting delivers <1% CV across days, operators, and sites.

Standardized Reporting: Reports p210 on the International Scale using a validated lot-specific conversion factor; p190/p230 as *BCR::ABL1/ABL1* % ratio, without per-run standard curves or drifting laboratory calibrations.

Maximized Sample Utility: A direct-from-RNA, single-tube workflow eliminates cDNA-transfer, preventing sample loss and preserving sensitivity.



Figure 1. End-to-end workflow of the Ancora *BCR::ABL1* Assay. The workflow consolidates reverse transcription, amplification, and quantification into a closed, single-tube system.

Uncompromised performance in one tube

Isoform	Transcript	Assay Optical Signature
p210	<i>e14a2</i>	
	<i>e13a2</i>	
p190	<i>e1a2</i>	
p230	<i>e19a2</i>	
<i>ABL1</i> reference		

Figure 2. Countable PCR multiplex detection strategy. Each *BCR::ABL1* transcript is assigned a unique optical signature for sensitive specific detection.

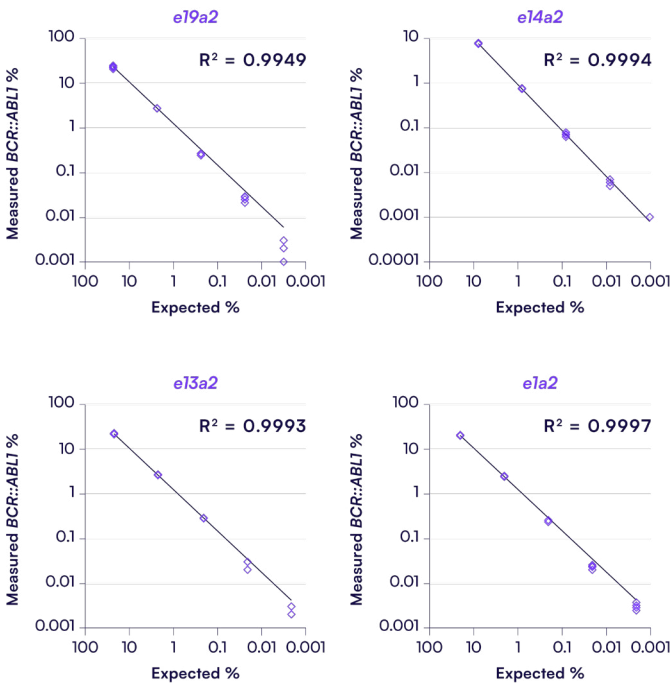


Figure 3. Linearity across *e19a2*, *e14a2*, *e13a2*, and *e1a2* demonstrating high concordance between measured and expected ratios ($R^2 > 0.99$). Optimized for the specific needs of clinical research laboratories, these specifications define the performance limits of the assay. By leveraging the Countable PCR system, the assay maintains linearity and reproducibility across the full spectrum of *BCR::ABL1* transcript levels.

Performance

The high dynamic range of the Countable PCR system enables the Ancora *BCR::ABL1* assay to achieve ultra-deep sensitivity against a background of high *ABL1* expression in the sample.

Sample requirements and input specifications for the Ancora *BCR::ABL1* Assay:

- Sample type:** Extracted Total RNA (from EDTA whole blood)
- Minimum input:** > 20 ng RNA (for transcript/isoform determination)
- High sensitivity input:** > 100 ng to 1µg RNA (depending of sample availability and desired sensitivity level)

Table 1. Dynamic input flexibility enables limits of detection (LoD) down to 0.0007% at 1M *ABL1* copies.

<i>ABL1</i> Expression Counts	Limit of Detection (LoD %)*
100,000	0.007%
500,000	0.0016%
1,000,000	0.0007%

* MR5.0 = 0.001% IS

Ordering

SKU	Kit	Contents
BK005- Ancora <i>BCR::ABL1</i> Assay Bundle	KT0012 Countable Matrix Consumables Kit	Matrix reagents, column strips, and tube strips for 48 reactions
	KT0013 Ancora <i>BCR::ABL1</i> Assay Kit	Enzymes, primer mixes, imaging control, and PCR reagents for 48 reactions

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