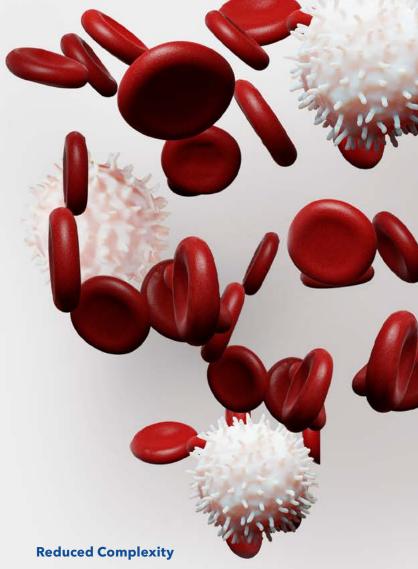


Ultra-sensitive Detection of the BCR-ABL1 minor Transcript

While BCR-ABL1 Major fusions (e13a2, e14a2) are well characterized in Chronic Myeloid Leukemia (CML), the rare, minor breakpoint variant (e1a2) can act as a disease driver in certain patients. Interpreting the role of this minor breakpoint in CML severity and progression demands a toolkit that offers unparalleled sensitivity, accuracy, and reproducibility. The QuantideX® qPCR BCR-ABL minor Kit (RUO) builds upon the proven performance and scalability of the FDA-cleared QuantideX qPCR BCR-ABL IS Kit. With a streamlined workflow, unparalleled sensitivity, and the ability to run on the same plate as the BCR-ABL IS assay, this kit empowers researchers to delve into the prognostic significance of the e1a2 breakpoint with unprecedented ease.





- Leverages the excellent performance and scalable workflow of the QuantideX qPCR BCR-ABL IS Kit for seamless integration into your oncology assay portfolio
- Automated BCR-ABL1: ABL1 % ratio calculation eliminates manual calculation errors with time-saving software module

Optimized Workflow

- Utilizes multiplexed design for simultaneous amplification and detection of fusion and control genes in a single reaction
- Ready-to-use quality-controlled reagents significantly reduce assay preparation steps and increase scalability

Quality Results

- Ultra-sensitive Limit of Detection (LOD): 0.0025% ratio (log reduction value of 4.61)
- Optional CLSI-compliant Limit of Blank (LOB) approach used to minimize miscalling of non-leukemic low positives
- Armored RNA*-based standards provide true RNA quantification

Analytical Performance of the QuantideX qPCR BCR-ABL minor Kit

Sensitive: Proven accuracy based on rigorous testing criteria

	Replicates Tested	LOD (LR)	LOD (% ratio)
Human RNA	90	LR4.61	0.0025%
Cell Lines	80	LR5.31	0.0005%

Table 1: LOD as determined by CLSI EP17-A2 guidelines by testing human RNA and cell line dilutions spanning lots, batch runs, days, operators and instruments

Precise: Minimal variability across the entire dynamic range

Target LR	Mean LR	SD
1	0.98	0.12
2	1.95	0.17
3	2.96	0.12
4	3.98	0.17

Table 2: Assay precision determined by testing 4 different log reduction (LR) levels in human RNA, using 2 operators and 8 runs for a total of 192 data points.

Figure 1. Streamlined: Multiplexed design reduces consumables and hands-on time

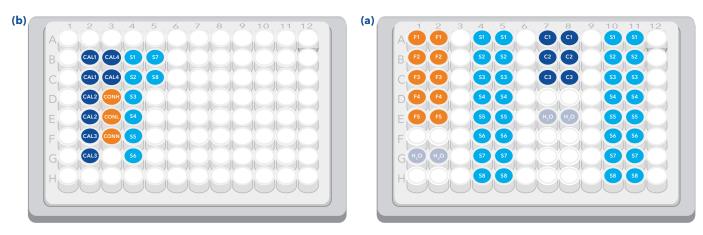


Figure 1: Comparison of plate layout for an 8 sample run between the (a) Asuragen assay, which features a multiplexed design and samples run in singleton, resulting in only 19 reactions; and (b) a competitor assay, which features a simplex design and samples run in duplicate, resulting in 52 reactions.

Ordering Information

Part Number	Product Description	Number of Reactions
49637	QuantideX® qPCR BCR-ABL minor Kit (RUO)	60