# QuantideX®

## qPCR BCR-ABL minor Kit*

## Ultra-sensitive Detection of the *BCR-ABL1* minor Transcript

*BCR-ABL1* major fusions (e13a2, e14a2) are very well characterized in Chronic Myeloid Leukemia (CML) development, but for some patients, the rare, minor breakpoint variant (e1a2) appears to be the disease driver. Understanding the role of the minor breakpoint in CML severity and progression requires research tools that enable highly sensitive, accurate and reproducible measurement of this transcript.

Building on the simple workflow and best-in-class sensitivity established with the FDA-cleared QuantideX® qPCR BCR-ABL IS Kit, the QuantideX® qPCR BCR-ABL minor Kit (RUO) allows researchers to explore the predictive and prognostic significance of this distinct leukemic variant with unprecedented ease.


**Figure 1:** Kit components

### REDUCED COMPLEXITY

- Leverages the QuantideX qPCR BCR-ABL IS Kit workflow concept for streamlined implementation
- Software automates *BCR-ABL1:ABL1* %ratio calculation eliminating risk and time associated with manual calculations

### OPTIMIZED WORKFLOW

- Multiplexed design amplifies and detects fusion and control gene in the same reaction
- All-inclusive reagents sourced and quality controlled together from a single vendor
- Ready-to-use reagents significantly reduce assay preparation steps

### QUALITY PERFORMANCE

- Ultra-sensitive Limit of Detection (LOD): Log Reduction of 4.61 (0.0025% ratio)
- Unique Limit of Blank (LOB) approach used to minimize miscalling of non-leukemic low positives
- Armored RNA®-based standards provide true RNA quantification

Asuragen®

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## Analytical Performance of the QuantideX® qPCR BCR-ABL minor Kit*

**Reproducible:** Proven sensitivity based on rigorous testing criterion

| | Replicates tested | Log Reduction | Median 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 | Std Dev |
|---|---|---|
| 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.

**Streamlined:** Multiplexed design yields workflow and cost efficiencies

(a) (b)

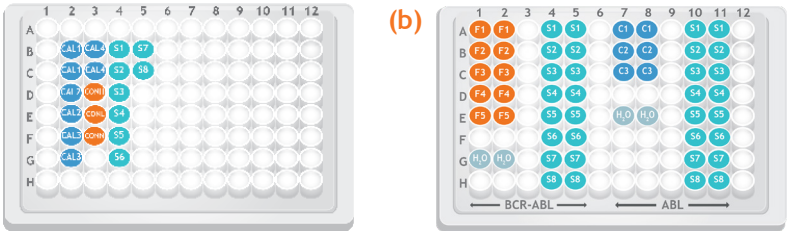


**Figure 2:** Comparison of plate layout for an 8 sample run between the (a) Asuragen assay, which features a multiplexed design and samples run in singlicate, resulting in only 19 reactions; and (b) a competitor assay, which features a singleplex design and samples run in duplicate, resulting in 52 reactions.

| KIT ORDERING INFORMATION | |
|---|---|
| QuantideX® qPCR BCR-ABL minor Kit* | [P/N 49637] 60 Reactions |

*For Research Use Only. Not for use in diagnostic procedures.

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