Product Name	Number of Reactions	Catalog Number
QuantideX® qPCR BCR-ABL IS Kit†	60	86003
QuantideX® qPCR BCR-ABL minor Kit†	60	49640

† CE-marked for US export only.

Asuragen®

QuantideX®

qPCR BCR-ABL IS Kit & qPCR BCR-ABL minor Kit†

Complete solution for ultra-sensitive quantitation of *BCR-ABL1* fusions for molecular response monitoring in Chronic Myeloid Leukemia

Sensitive | Reliable | Simple

† CE-marked for US export only.

Asuragen®
Oncology

QuantideX®

qPCR BCR-ABL IS Kit & qPCR BCR-ABL minor Kit[†]

Advances in TKI therapy have driven 5-year survival rates in CML patients to nearly 90%[1] and are helping to make treatment-free remission a reality for a significant number of patients[2]. However, to accurately assess response to treatment and determine eligibility for treatment cessation, a rapid, accurate and highly sensitive assay for measurement of disease burden is required.

The QuantideX® BCR-ABL Portfolio offers simple, reliable, ultra-sensitive quantitation of both the Major and minor breakpoints, allowing any molecular laboratory to assess the deepest molecular response with unprecedented ease and deliver the results physicians and patients rely on.

Reduced Complexity

- **Direct reporting on the International Scale (IS)[*]:**
  Multi-point standard curve reduces variability and removes need for costly, complex sample exchange
- **Single method, comprehensive reporting:**
  QuantideX® Reporter Software[†] provides automated calculation of %IS[*], *BCR-ABL1/ABL1* %ratio and *ABL1* copy number[**]

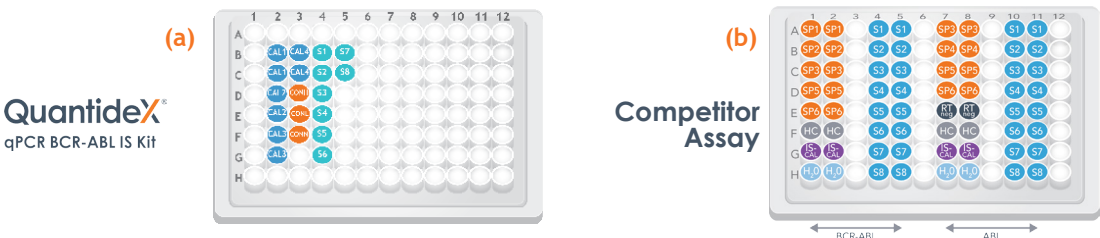**Streamlined:** Multiplexed design yields workflow and cost efficiencies

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 singlicate, resulting in only 19 reactions; and (b) a competitor assay, which features a singleplex design and samples run in duplicate, resulting in 60-64 reactions.

Optimized Workflow

- **Reduced hands-on time:**
  Multiplexed design amplifies and detects both fusion and control genes in the same reaction
- **Simplified inventory & quality management:**
  All necessary RT and qPCR reagents and controls in a single, vendor-sourced kit to reduce QC burden
- **Common workflows:**
  Major & minor kits share common workflows to streamline testing and reduce risk of error
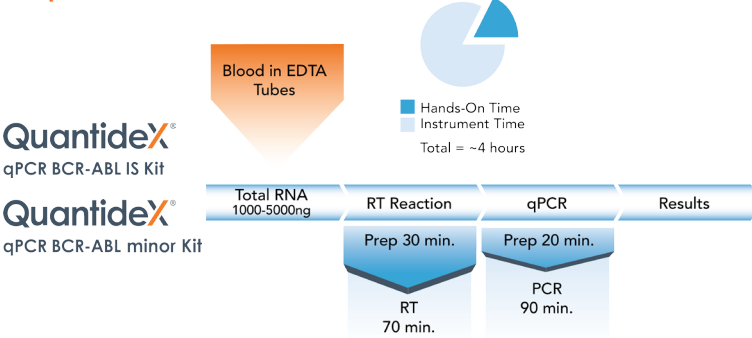
Simple: Two Kits. One Workflow.

Figure 2: Both kits share a common workflow with limited hands-on-time, maximizing laboratory efficiency and sample throughput.

Quality Performance

- **Performance established using human RNA:**
  Limits of Detection (LOD) of MR4.7 (0.002% IS) and LR4.61 (0.0025% ratio) confirmed in human RNA, not cell lines
- **Multi-point Armored RNA®-based standards:**
  Provide reproducible, traceable RNA quantitation values
- **Increased analytical sensitivity without compromising analytical specificity:**
  Unique Limit of Blank (LOB) approach used to minimize miscalling of non-leukemic low positives

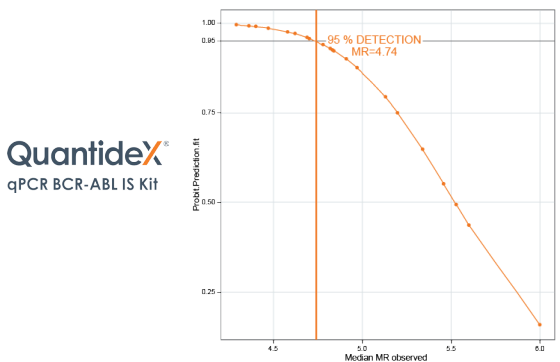**Reproducible: Proven sensitivity based on rigorous testing criterion**

Figure 3: LOD of the QuantideX qPCR BCR-ABL IS Kit as determined by CLSI EP17-A2 guidelines by testing Human RNA dilutions ranging from MR4.4 to MR6: 60 replicates of each dilution for a total of 1680 data points.

	Replicates tested	Log Reduction	Median LOD (%ratio)
Human RNA	90	LR4.61	0.0025%
Cell Lines	80	LR5.31	0.0005%

Table 1: LOD of the QuantideX® qPCR BCR-ABL minor Kit as determined by CLSI EP17-A2 guidelines by testing Human RNA and cell line dilutions spanning multiple lots, batch runs, days, operators, and instruments.

Precise: Minimal variability across the entire dynamic range

Target MR	Mean MR	Std Dev	Limits of Agreement (95%)
1	0.697	0.092	1.53
2	1.634	0.069	1.37
3	2.658	0.053	1.28
3.5	3.185	0.077	1.43
4	3.675	0.092	1.53

Table 2: Precision evaluated using 5 different levels of positive specimens, tested by 3 operators over 20 runs each. Each level was tested 90 times for a total of 450 data points.

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 3: 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.

[1] American Cancer Society   [2] Saußele S, et al. Leukemia (2016) 30, 1638–1647.