



Scalable Workflow for High-Sensitivity BCR-ABL Monitoring in CML Patients

Confidently deliver results with the first FDA-cleared chronic myeloid leukemia monitoring assay for BCR-ABL Major breakpoints (e13a2, e14a2). The QuantideX qPCR BCR-ABL Kit delivers reliable results quickly, with direct reporting on the International Scale and a deep clinical sensitivity of 0.002% IS (MR4.7). Scalable, high-throughput testing is enabled by QuantideX® multiplex assay design and included analysis software.

Reduced Complexity

- Direct reporting on the IS with four calibrators traceable to the WHO primary standards
- All-in-one kit and software from a single vendor

Optimized Workflow

- Multiplex design detects BCR-ABL and ABL in the same reaction, with ability to run up to 49 samples per plate
- Simplified reporting with included QuantideX® Reporter software

Quality Results

- Limit of Detection of MR4.7 (0.002% IS) was confirmed in clinical human blood samples, not cell lines
- Rigorous validation with FDA-clearance, single- and multi-site reproducibility studies, and seven years in clinical market use

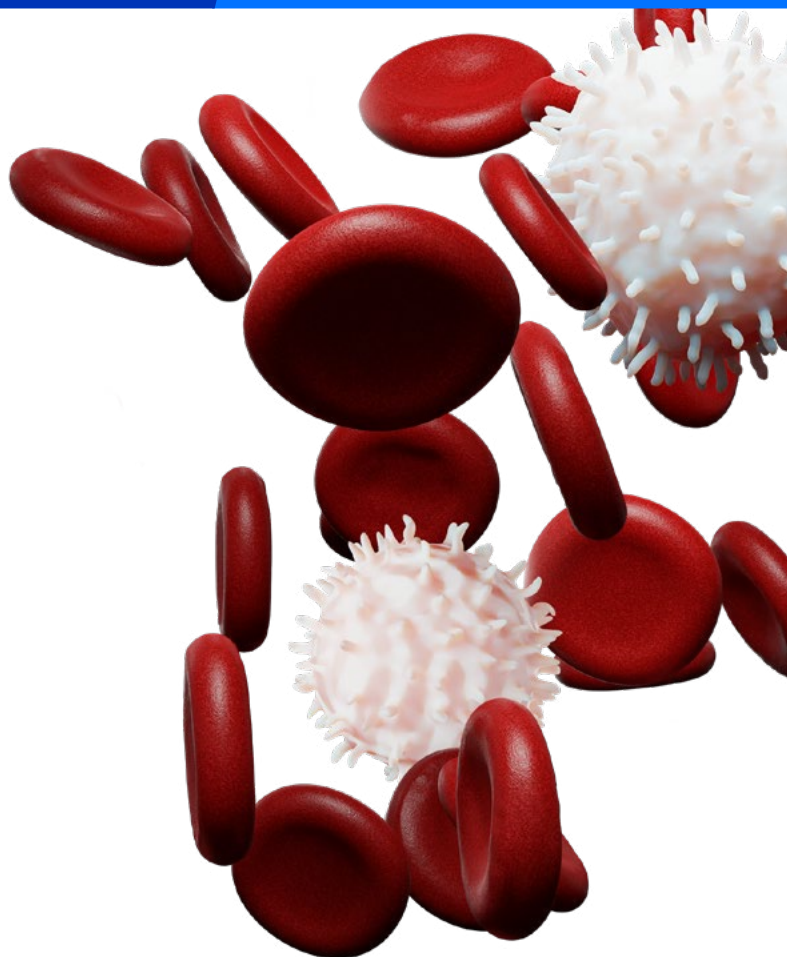
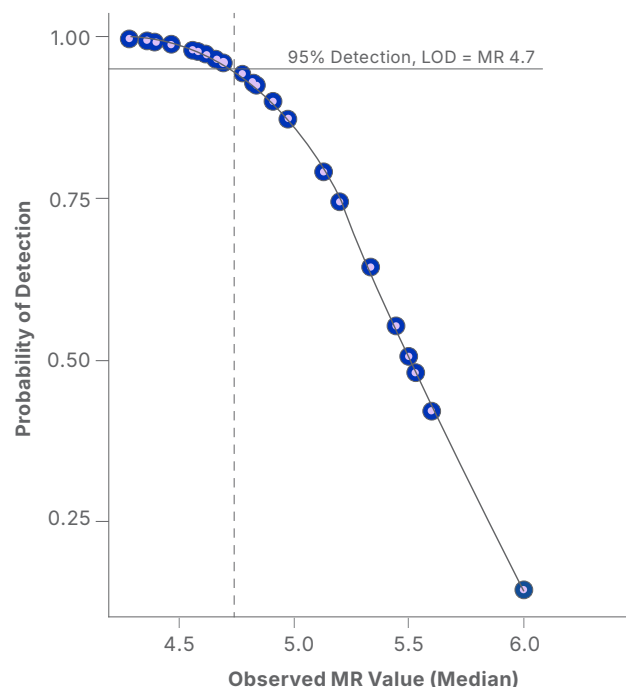


FIGURE 1.

Highly sensitive results



LOD of 95% detection at MR4.7 was determined from 1,678 valid data points from human RNA, from 40 test runs by four operators over two kit lots, 15 days, and four instruments.*

*US-IVD *Brown JT, et al. J Mol Diagn. 2019 Jul;21(4):718-733.

TABLE 1.

Highly reproducible results

Target MR	Mean MR	SD	Target MR	Mean MR	SD
Single-Site Precision			Multi-Site Precision		
1	0.70	0.08	1	0.70	0.08
2	1.63	0.08	2	1.63	0.08
3	2.66	0.08	3	2.66	0.08
3.5	3.18	0.10	3.5	3.18	0.10
4	3.68	0.13	4	3.68	0.13

Single- and multi-site reproducibility studies* demonstrated minimal variation across the assay dynamic range, with a maximum standard deviation of 0.13 MR units.

Scalable Workflow

8 Samples
Including necessary calibrators and controls

QuantideX®qPCR BCR-ABL IS Kit

Other BCR-ABL Kit

Only 19 reactions are required for eight samples tested with the QuantideX assay, compared to 64 reactions for an assay with a simplex design and samples run in duplicate.

The QuantideX multiplex workflow allows up to 49 samples in singleton per plate, enabling efficient, high-throughput testing.

Ordering Information

Part Number	Product Description	Number of Reactions
49574	QuantideX qPCR BCR-ABL IS Kit	60



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