

biotechne®

Asuragen®

Excellent Performance & Scalable Workflow for 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). Your lab is empowered to provide reliable results easily with direct reporting on the International Scale and 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

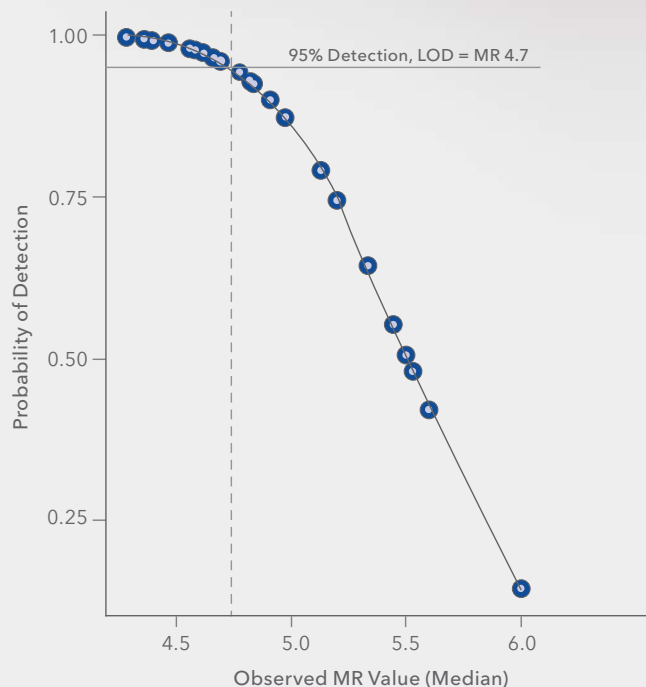
- Multiplex design detects BCR-ABL and ABL in the same reaction, with ability to run up to 49 samples per plate
- Simplified reporting with included QuantideX® Reporter software

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.†

Table 1. Highly reproducible results

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

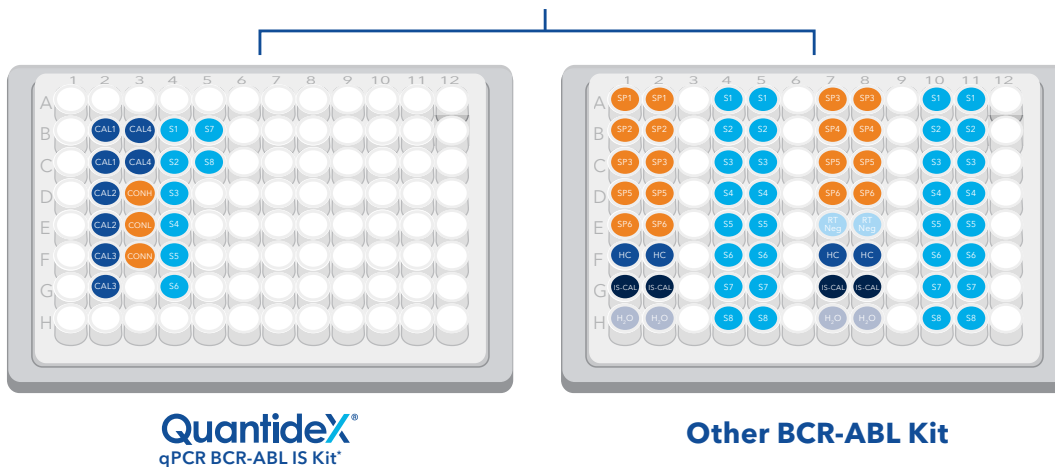
Target MR	Mean MR	SD
Multi-Site Precision		
1	0.74	0.06
2	1.69	0.07
3	2.70	0.09
3.5	3.22	0.13
4	3.72	0.13

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



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