

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.^{\dagger}

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	0.74	0.06
2	1.63	0.08	2	1.69	0.07
3	2.66	0.08	3	2.70	0.09
3.5	3.18	0.10	3.5	3.22	0.13
4	3.68	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



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		

Bio-Techne® | R&D Systems[™] Novus Biologicals[™] Tocris Bioscience[™] ProteinSimple[™] ACD[™] ExosomeDx[™] Asuragen[®] ^{*}US-IVD [†]Brown JT, et al. J Mol Diagn. 2019 Jul;21(4):718-733.

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