

BCR-ABL Monitoring for Patients with CML, with Results Aligned to the International Scale

Confidently deliver results with the first Class C-certified IVDR BCR-ABL translocation monitoring assay in chronic myeloid leukemia (CML) for BCR-ABL Major breakpoints (e13a2, e14a2). With direct reporting to the International Scale (IS) and deep clinical sensitivity of 0.002% IS (MR4.7), diagnostic laboratories can assess the deepest molecular response with unprecedented ease and deliver results physicians and patients can rely on. The QuantideX® multiplex assay design and included analysis software enable reporting of accurate BCR-ABL monitoring results in less than 4 hours.

Reduced Complexity

- Direct reporting on the IS with four RNA calibrators traceable to WHO primary standards
- Ready-to-use kit with included calibrators, controls, and software module

Optimized Workflow

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

Quality Results

- Limit of Detection (LOD) of MR4.7 (0.002% IS confirmed with human blood samples, not cell lines)
- Trusted, reproducible results with Class C IVDR certification

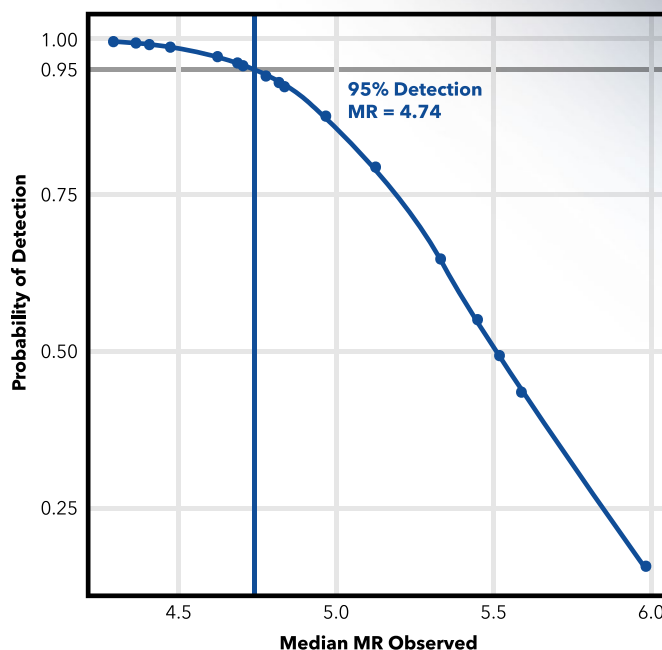


FIGURE 1. MR4.7 with 95% detection was determined from 1,678 valid data points from clinical samples, from 40 test runs by four operators over two kit lots, 15 days, and four instruments

FIGURE 2. Streamlined and Scalable Workflow

Only 19 reactions are required for eight clinical samples tested with the QuantideX® qPCR BCR-ABL IS assay, compared to 64 reactions for an assay with a non-multiplex design and samples run in duplicate. The QuantideX multiplex workflow allows BCR-ABL quantification of up to 49 patient samples, with each sample analyzed in a single well compared to other non-multiplex design assays. This enables streamlined and high-throughput BCR-ABL testing.

8 Clinical Samples

Including necessary calibrators and controls

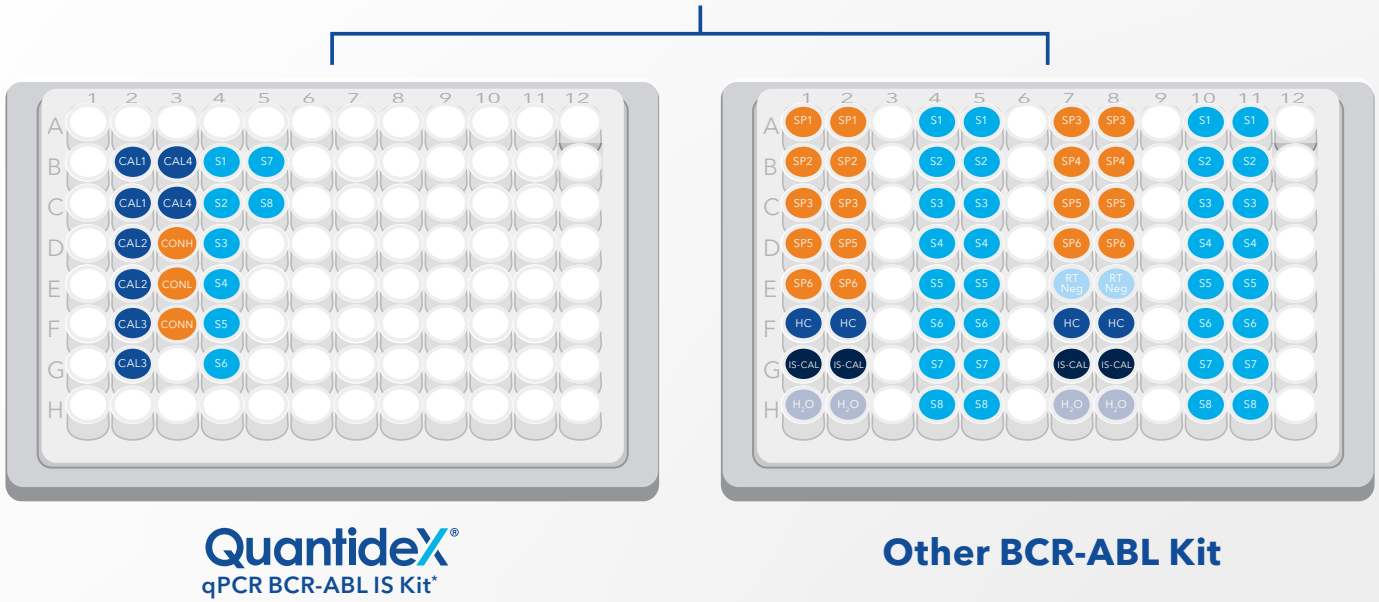
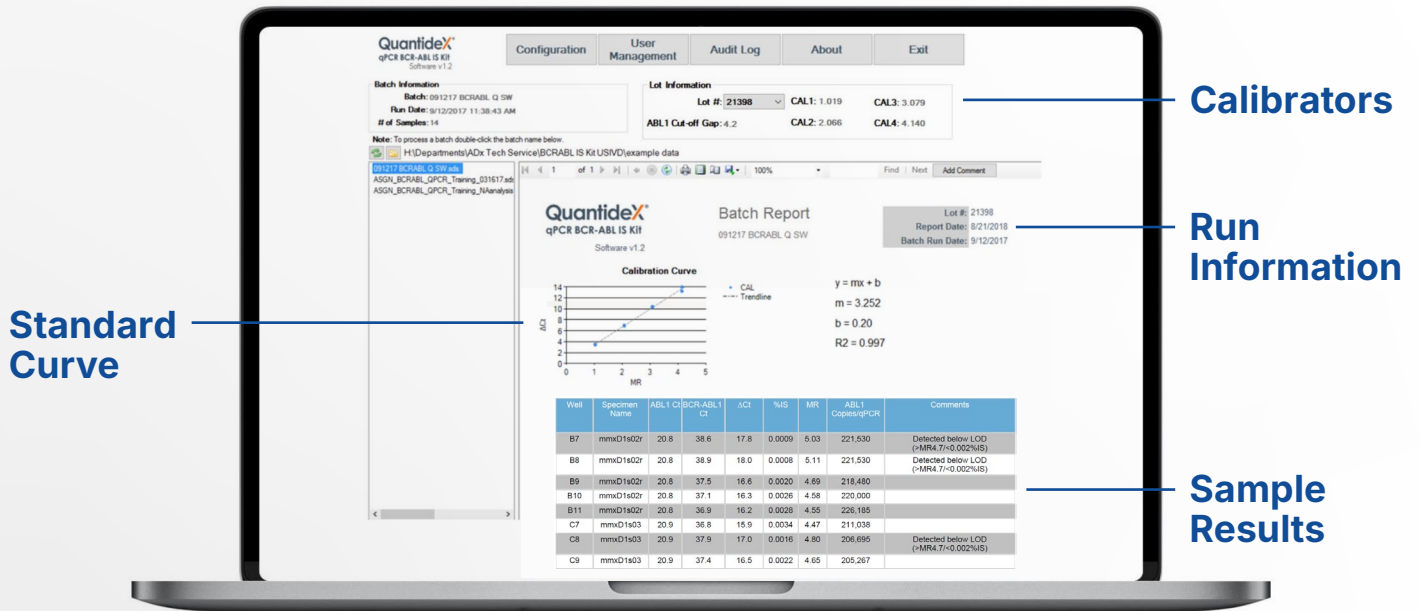


FIGURE 3.

The QuantideX Reporter automates reporting of results for the qPCR BCR-ABL IS assay. The software performs all calculations, automatically generating a batch report containing the Standard Curve, MR values and %IS for controls and each patient sample. The Standard Curve is also included in the run report. Reports are generated in PDF and formats, such as XML and CSV file types, compatible with LIMS system.



Ordering Information

Part Number	Product Description	Number of Reactions
86003	QuantideX qPCR BCR-ABL IS Kit	60

Contact Us



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