bio-techne®

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

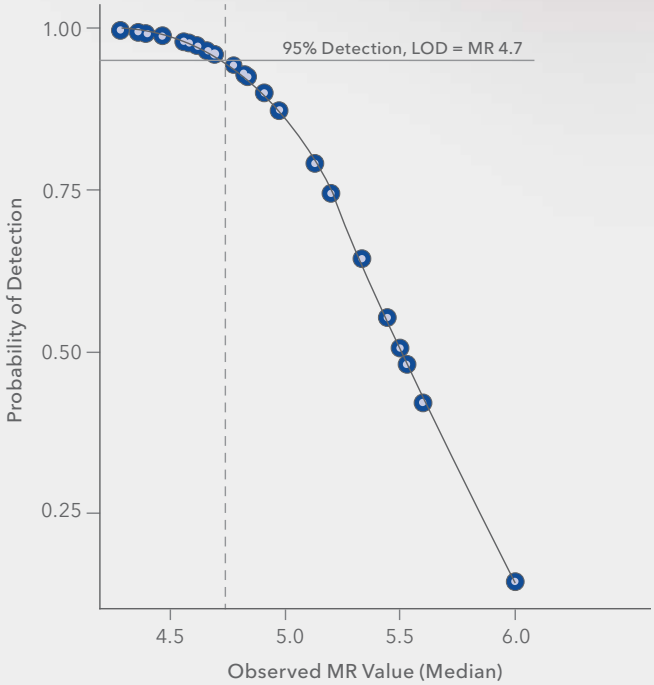
Optimized Workflow

- 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.†