

For Measuring Deep Molecular Responses in CML Patients

Advances in TKI therapy have driven 5-year survival rates in CML patients to nearly 90%¹ and are making treatment-free remission a reality². To accurately assess treatment response and determine eligibility for cessation, a rapid, accurate and highly sensitive assay for measurement of disease burden is required.

The QuantideX[®] qPCR BCR-ABL IS Kit is the only FDA-cleared assay for ultra-sensitive detection and precise monitoring of *BCR-ABL1* transcripts resulting from the Major breakpoints (e13a2, e14a2). With its simple workflow, direct reporting on the IS, and best-in-class clinical sensitivity - 0.002% IS (MR4.7), *any* molecular laboratory can now assess the deepest molecular responses with unprecedented ease.



Figure 1: Kit components

REDUCED COMPLEXITY

- Multi-point standard curve reduces variability and removes need for costly, complex sample exchange
- QuantideX[®] Reporter software automates calculation and reporting of %IS, reducing burden of manual calculations

OPTIMIZED WORKFLOW

- Multiplexed design amplifies and detects fusion and endogenous control genes in the same reaction
- All-inclusive reagent kits sourced and quality controlled together from a single vendor

QUALITY PERFORMANCE

- Limit of Detection (LOD) of MR4.7 (0.002% IS) confirmed in clinical human RNA specimens, not cell lines
- Armored RNA[®]-based, IS-calibrated standards provide true RNA quantification

Proven Sensitivity Based on Rigorous Testing Criterion to Assess Complete Molecular Response

Target MR	Total Tested	Tested Positive	% Undetected	Median %IS
e13a2	179	172	3.9	0.002
e14a2	420	400	4.8	0.002

Table 1: LOD as determined by CLSI EP17-A2 guidelines by testing Human RNA dilutions ranging from MR4.4 to MR6.0 - 60 replicates at each dilution for a total of 1680 data points. 10 of the 28 specimens near LOD that maintained <5% undetected results were used to determine LOD.

Minimal Variability Across the Entire Dynamic Range of MR Values Demonstrates the Robustness of the Assay

Target MR	Mean MR	Std Dev
1	0.697	0.08
2	1.634	0.08
3	2.658	0.08
3.5	3.185	0.10
4	3.675	0.13

Table 2: Precision was evaluated by using 5 different MR levels composed of 5 unique positive specimens each. Testing spanned 3 lots, 3 operators, 20 runs, and 3 qPCR instruments. To see full precision data, please refer to Table 4 of the Instructions for Use.

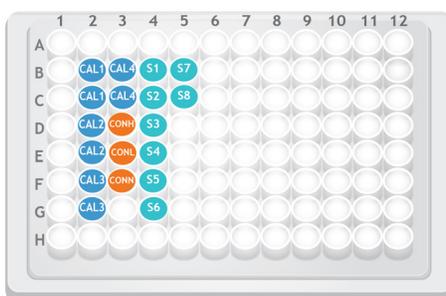


Figure 2: Plate layout with an 8 sample run

ORDERING INFORMATION		
QuantideX [®] qPCR BCR-ABL IS Kit	60 REACTIONS	49574