

QuantideX[®]

qPCR BCR-ABL IS Kit



FOR MEASURING DEEP MOLECULAR RESPONSE



Figure 1: Kit components

HIGH SENSITIVITY

Highly sensitive assay allowing detection of complete molecular response (CMR): Sensitivity of 0.002% IS (MR4.7) with clinical samples.

SIMPLE WORKFLOW

Multiplexed assay design leads to operational and cost efficiencies. All inclusive Kit: No additional reagents required.

ARMORED RNA[®] BASED CALIBRATORS

Robust and reliable assay based on Armored RNA[®] technology for standard curve: RNA based calibrators for quantifying RNA.

ANCHORED TO THE INTERNATIONAL SCALE (IS)

Use of WHO traceable IS reference material as standard curve allows direct IS reporting.

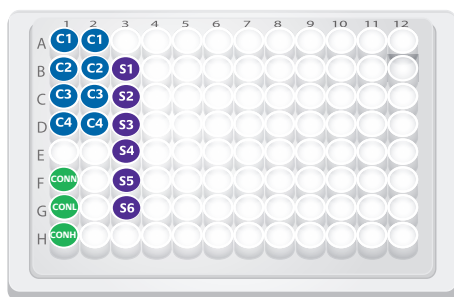


Figure 2: Plate layout with a 6 sample run

The QuantideX[®] qPCR BCR-ABL IS Kit* is a quantitative real time PCR based assay with an intended use of monitoring the BCR-ABL fusion gene levels of patients with Chronic Myelogenous Leukemia (CML). The QuantideX assay provides labs with a robust and reliable method for monitoring Leukemia patients by offering a product that is sensitive, multiplexed and anchored directly to the IS. It is the product that allows diagnostic labs to keep pace with the advances in TKI therapy.

LOD OF MR4.7 (0.002% IS) AFTER RIGOROUS TESTING WITH CLINICAL SAMPLES

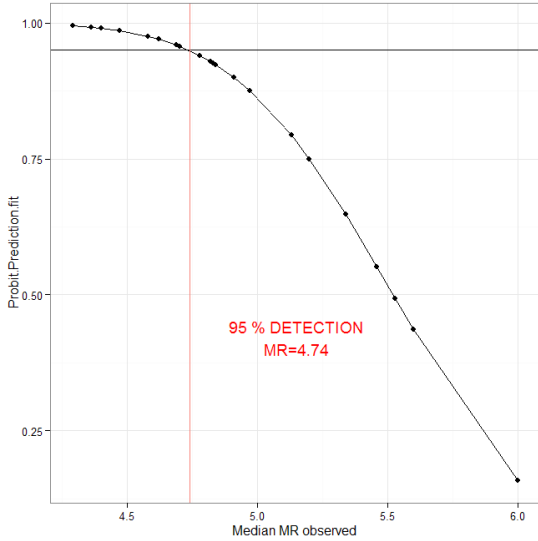


Figure 3: A probit analysis of 1260 data points: (3 dilution series, 7 point dilution in each series, 60 replicates of each point over 6 runs and 2 different lots of product) indicates an LOD of MR4.7. At or below MR4.7, the assay is able to detect positive samples at a 95% detection rate.

MINIMAL VARIABILITY ACROSS THE ENTIRE DYNAMIC RANGE OF %IS VALUES INDICATES A ROBUST ASSAY PERFORMANCE

MEAN % IS	STANDARD DEVIATION	%CV
20.384	3.4	16.67
2.359	0.38	16.11
0.224	0.039	17.41
0.067	0.014	20.90
0.022	0.006	27.27

Table 1: Precision was evaluated by using 5 different levels of positive specimen, tested by 3 operators, consisting of 3 lots of reagents over 20 runs. Each level was tested 40 times to obtain an SD value.

KIT ORDERING INFORMATION

QuantideX[®] qPCR BCR-ABL IS KIT*

[P/N 86003] 60 REACTIONS

*CE-IVD. For US export only.