Clarity™ Major and Minor BCR-ABL Mutation Quantification Kits

(96 reactions)

Chronic myeloid leukaemia (CML) and acute lymphoblastic leukemia (ALL) are characterized by the generation of Philadelphia (Ph) chromosome which arises from translocation between chromosomes 9 (region q34: ABL) and 22 (region q11: BCR). This translocation results in the formation of BCR-ABL fusion gene whereby majority of the breakpoints occurs in two regions; after the 13th exon resulting in a b2a2 (e13a2) fusion or after the 14th exon resulting in a b3a2 (e14a2) fusion. These fusions are mostly detected in CML patients and are translated into the constitutively active tyrosine kinase of 210kDa (P210). In Ph-positive ALL patients, the breakpoint typically occurs in the region after the 1st exon, resulting in the formation e1a2 fusion. This e1a2 fusion mRNAs are translated into the P190 constitutively active tyrosine kinase. Molecular detection and quantification of the BCR-ABL fusions are essential for disease diagnosis, monitoring of therapeutic responses and minimal residual disease detection.

The Clarity™ Major BCR-ABL Mutation Quantitation Kit and Clarity™ Minor BCR-ABL Mutation Quantitation Kit provide reagents optimized for the quantitative detection of b2a2 and/or b3a2 mutant cDNA* and e1a2 mutant cDNA* respectively in human whole blood samples using the Clarity™ digital PCR instrument (Cat. No. 10001).

Features

REPRODUCIBILITY

Precise quantification of b2a2, b3a2 or e1a2 mutation abundance

HIGH SENSITIVITY

Detect as low as 0.1% of b2a2, b3a2 or e1a2 mutant cDNA

EASE OF USE

Low hands-on-time, compatible with most conventional thermal cyclers

HIGH THROUGHPUT ANALYSIS

Analyze up to 96 reactions under 4 hours

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**Reagents for reverse transcription step is not included in Clarity™ BCR-ABL Quantification Kits*

Product Performance

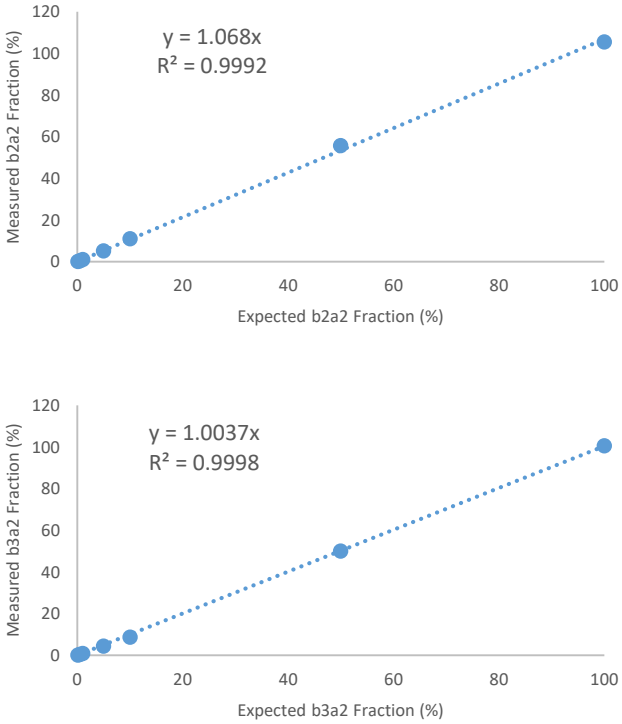

Figure 1. Plot of measured b2a2 or b3a2 mutant fraction against its expected mutant fraction using Clarity™ Major BCR-ABL Mutation Quantification Kit.

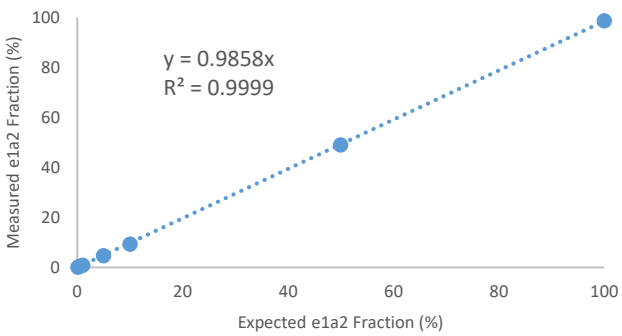

Figure 2. Plot of measured e1a2 mutant fraction against its expected mutant fraction using Clarity™ Minor BCR-ABL Mutation Quantification Kit.

The Clarity™ Major BCR-ABL and Minor BCR-ABL Mutation Quantification Kit detected at least 0.1% mutant cDNA against a high background of more than 35,000 copies of total ABL cDNA. In addition, excellent linearity is achieved (R^2 >0.999) from 100% down to 0.1% for the respective mutant fractions (Figures 1 &2).

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Product Specification	
Technology	Digital PCR
Target Sequence	b2a2, b3a2 or e1a2 and ABL cDNA
Sensitivity (LOD)	0.1% mutation
Time to Result	< 4 h
Specimen Type	Whole Blood
Reporting Format	Ratio of mutant (b2a2, b3a2 or e1a2) versus total ABL expression
Instrument Required	Clarity™ digital PCR system (Cat. No. 10001)
Additional Materials Required	Clarity™ consumables package (Cat. No. 10011)
Detection Channels	FAM (b2a2, b3a2 or e1a2 cDNA), HEX (ABL cDNA)
Kit Storage	-20°C, avoid repeated freezing and thawing of kit contents

Ordering Information		
Product Name	**Description**	**Catalogue Number**
Clarity™ Major BCR-ABL Quantification Kit	96 Reactions	10022
Clarity™ Minor BCR-ABL Quantification Kit	96 Reactions	10023

(주) 바이오디
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