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Product Data Sheet
BCR-ABL International Scale Standards

Cat. #: BA-IS1, BA-IS2, BA-IS3, BA-IS4

BCR-ABL Clinical Relevance:

The BCR-ABL fusion results in constitutive ABL tyrosine kinase activity contributing to unregulated cell division. The BCR-ABL fusion is found in 95% of chronic myelogenous leukemia (CML), 25–30% adult acute lymphoblastic leukemia (ALL), and 2–10% child ALL. Researchers have identified the utility of measuring BCR-ABL transcripts to aid in the assessment of minimal residual disease (MRD) and the response to treatment. An international consortium has developed "International Standards" allowing the comparison of BCR-ABL levels measured by different quantitative PCR assays.[1,2,3]

CytoGenes offers primer mixes, standards, and controls allowing laboratories to detect the three most common BCR-ABL fusions by quantitative PCR (b2a2, b3a2, and e1a2). A set of standards normalized to the International Scale allows results to be reported on the International Scale.

Product Description:

International Scale Standards can be utilized such that results measured by any quantitative PCR assay can be compared quantitatively regardless of testing laboratory or assay utilized. Each control contains total RNA isolated from cell lines generating RNA specific for each of the indicated targets at the indicated nominal values (% BCR-ABL / ABL) (See Product Specifications). Researchers are advised to utilize the International Scale Standards to generate a normalization factor to utilize in subsequent assay runs and verify the acceptability of the normalization factor periodically.

International Scale Standards are designed to yield positive results for the b2a2 and b3a2 BCR-ABL fusions as well as the endogenous ABL gene for normalization purposes.

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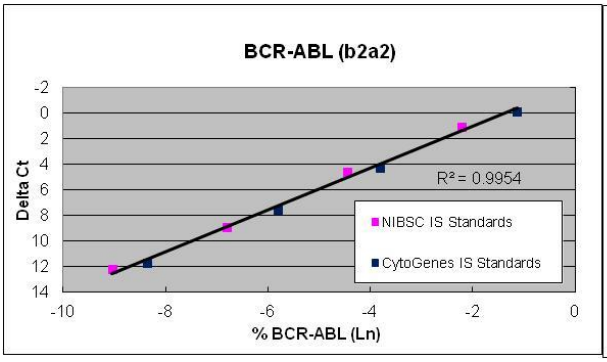
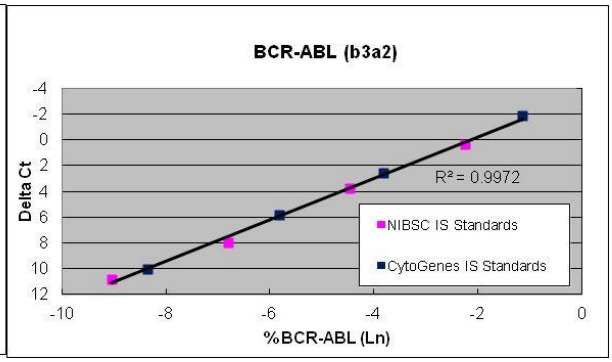
Calibration to NIBSC International Scale:

CytoGenes International Scale Standards were calibrated against NIBSC International Scale Standards according to NIBSC guidelines. The graphs below demonstrate the high degree of correlation between the NIBSC and CytoGenes International Scale Standards for both the b2a2 and b3a2 BCR-ABL fusion products.





Product Specifications:

The table below indicates the assay targets and concentrations for each of the International Scale Standards. Absolute values are lot dependent.

Cat #	Item	Assay Targets Included	Concentration
BA-IS1	BCR-ABL-IS1	ABL, BCR-ABL (b2a2, b3a2)	~20% BCR-ABL / ABL
BA-IS2	BCR-ABL-IS2	ABL, BCR-ABL (b2a2, b3a2)	~2% BCR-ABL / ABL
BA-IS3	BCR-ABL-IS3	ABL, BCR-ABL (b2a2, b3a2)	~0.2% BCR-ABL / ABL
BA-IS4	BCR-ABL-IS4	ABL, BCR-ABL (b2a2, b3a2)	~0.02% BCR-ABL / ABL

Volume: 20µl
Reactions: 9 (2µl/ reaction)

Procedure:

Researchers are advised to optimize the use of these standards in any application. RNA controls should be tested utilizing the same conditions as utilized for test samples. The volume of RNA controls used in a PCR reaction should be the same as all other test samples. Guidelines for generating a conversion factor to the international scale are available from NIBSC (see reference below).

Storage:

Store at -20°C. Once open store at 4°C. Repeated freezing/thaw cycles should be avoided.

References:

1. White HE, Matejtschuk P, Rigsby P, Gabert J, Lin F, Lynn Wang Y, Branford S, Müller MC, Beaufils N, Beillard E, Colomer D, Dvorakova D, Ehrencrona H, Goh HG, El Housni H, Jones D, Kairisto V, Kamel-Reid S, Kim DW, Langabeer S, Ma ES, Press RD, Romeo G, Wang L, Zoi K, Hughes T, Saglio G, Hochhaus A, Goldman JM, Metcalfe P, Cross NC. Establishment of the first World Health Organization International Genetic Reference Panel for quantitation of BCR-ABL mRNA. Blood. 2010 Nov 25;116(22):e111-7. Epub 2010 Aug 18.

2. WHO International Standard. 1st WHO International Genetic Reference Panel for quantitation of BCR-ABL translocation by RQ-PCR.

3. Hughes T, et al. Monitoring CML patients responding to treatment with tyrosine kinase inhibitors: Review and recommendations for harmonizing current methodology for detecting BCR-ABL transcripts and kinase domain mutations and for expressing results. Blood. 2006;108:28-37.