

## REALQUALITY

### REALQUALITY RS-BCR-ABL p190

code RQ-S55

Kit for detection and quantification of  
 translocation t(9;22)(q34;q11)  
 variant p190 by Real-Time PCR



#### INTRODUCTION

The **Philadelphia chromosome** arises from translocation t(9;22)(q34;q11) and is found in more than 95 % of patients with **Chronic Myeloid Leukemia (CML)** as well as in 10 - 25 % of adult and 5 % of underage patients with **Acute Lymphoblastic Leukemia (ALL)**. This translocation links the proto-oncogene **ABL1**, (*c-ABL*, chromosome 9), to a specific region of the **BCR** gene. Approx. 40 % of ALL-patients with the Ph chromosome (Ph+) show the same molecular rearrangement as is found in CML (*BCR-ABL M-bcr*, major breakpoint cluster region). In the remaining Ph+ ALL cases (60 %) the chromosomal breakpoint is located in the **minor breakpoint cluster region (m-bcr)** of the **BCR** gene. This specific translocation links the **BCR** exon e1 to the **ABL** exon a2 (e1-a2 rearrangement) creating the fusion gene **BCR-ABL m-bcr**, which produces a fusion protein of 190 kDa (**BCR-ABL p190**).

Parallel quantification of the **ABL** transcript (housekeeping gene) and the **BCR-ABL p190** transcript allows control of sample integrity and reverse transcription. With standard curves for **BCR-ABL p190** and **ABL** the absolute quantity of **BCR-ABL p190** transcript can be determined and normalized to the number of **ABL** transcripts. Detection of translocation t(9;22)(q34;q11) provides crucial information for diagnosis and prognosis of Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL), and is a valuable tool for monitoring Minimal Residual Disease (MRD).

#### TECHNICAL CHARACTERISTICS

**Number of tests:** 48 or 96

**Stability:** 12 months

**Sample material:** cDNA from reverse transcription using the Rev-T Kit *RQ variant* (see RELATED PRODUCTS)

**Amplified regions:** transcript of fusion gene **BCR-ABL p190** and of gene **ABL**

**Internal Control:** amplification of housekeeping gene **ABL**

**Positive controls:** DNA corresponding to fragments of the **BCR-ABL p190 (m-bcr)** and **ABL** transcripts

**Compatible platforms:** Validated on

- Applied Biosystems 7500 Fast Dx, 7300 and StepOnePlus / StepOne Real-Time PCR System,
- Dx Real-Time System and CFX96 Real-Time PCR Detection System (Bio-Rad)

The kit can be used on instruments that allow a reaction volume of 25 µL and read the FAM fluorescence.

**Analytical specificity:** No non-specific pairing of primers and probes, no cross-reaction

**Analytical sensitivity (detection limit):** 12.5 copies / reaction (96 % samples tested positive)

**Analytical sensitivity (linear range):** 12.5 - 10<sup>6</sup> copies / reaction (**BCR-ABL p190**) and 10 - 10<sup>5</sup> copies / reaction (**ABL**)

**Reproducibility, intra-assay variability:** 0.552 % (**BCR-ABL p190**) and 0.508 % (**ABL**)

**Reproducibility, inter-assay variability:** 0.704 % (**BCR-ABL p190**) and 0.916 % (**ABL**)

**Diagnostic specificity:** 100 %

**Diagnostic sensitivity:** 100 %

**Accuracy:** 100 %

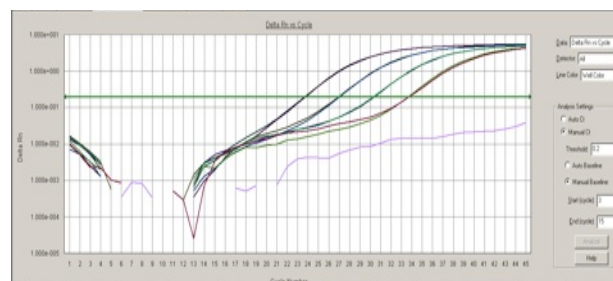


Fig. 1: **BCR-ABL p190** standard curve on the Applied Biosystems 7300 Real Time PCR System using SDS software 1.2.3.

#### ORDERING INFORMATION

Code	Product	PKG
RQ-S55-48/96	REALQUALITY RS-BCR-ABL p190	48/96 test

#### RELATED PRODUCTS

Code	Product	PKG
RQ-56-ST	REALQUALITY RQ-BCR-ABL p190 STANDARD	4 × 60 µL BCR-ABL p190 4 × 60 µL ABL
06-R1-25/50	Rev-T Kit <i>RQ variant</i>	25/50 tests
RQ-S53-48/96	REALQUALITY RS-BCR-ABL p210	48/96 tests
RQ-54-ST	REALQUALITY RQ-BCR-ABL p210 STANDARD	4 × 60 µL BCR-ABL p210 4 × 60 µL ABL

#### REFERENCES

- Baccarani M et al. Blood 15;108(6):1809-20, 2006  
 Melo JV. Leukemia 10, 751-756, 1996.  
 van Dongen JJ et al. Lancet 352, 1731-1738, 1998.  
 Verfaillie CM. Biology and therapy of chronic myelogenous leukaemia vol 12, num 1, 1998.

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