Clinical implication

The BCR-ABL1 MAJOR fusion gene is found in 99 % of patients with chronic myeloid leukemia. This chromosomal abberation leads to dysregulation of tyrosine kinase cascade resulting in the manifestation of leukemia. Patient response to treatment as well as minimal residual disease is monitored on a standardized basis through quantification of the BCR-ABL1 MAJOR b2a2 (e13a2) and b3a2 (e14a2) transcripts relative to the number of control gene ABL1 transcripts. STANDARD MMR BCR-ABL MAJOR (Cat.No 3280), verified by the National Reference Laboratory for DNA Diagnostics (Institute of Hematology and Blood Transfusion, Prague, Czech Republic), enables conversion to the international scale of treatment response (IS).

Principle of detection

Real-time PCR diagnostic kit enables quantitative determination of the copy number ratio of the b2a2 and b3a2 transcript of the BCR-ABL1 fusion gene to the copy number of the ABL1 reference gene transcript. The examination is based **on one-step RT-qPCR using fluorescently labeled probes**. Quantification of both fusion and reference transcripts is processed in one tube.

CE IVD

Available products

Cat. No.	Product	rxn
3243-048	gb ONCO BCR-ABL MAJOR/ABL	48
3243-096	gb ONCO BCR-ABL MAJOR/ABL	96

1 kit contains reagents to provide 48 or 96 PCR reactions (25 µl volume of each reaction).

Parameters of the diagnostic kit

- ***in vitro* diagnostics**
- **CE IVD marked**
- **detection in the FAM (BCR-ABL1) channel and HEX (ABL1) channel**
- **panel of standards and no template control included**

Content of the diagnostic kit

*	Component	Conc.	Purpose
●	Assay BCR-ABL MAJOR / ABL	3.13×	Detection assay
●	Master Mix BCR-ABL	2.08×	Master Mix
●	Standard 6 BCR-ABL MAJOR	4×10^{5} cop/µl	Standard
●	Standard 5 BCR-ABL MAJOR	4×10^{4} cop/µl	Standard
●	Standard 4 BCR-ABL MAJOR	4×10^{3} cop/µl	Standard
●	Standard 3 BCR-ABL MAJOR	4×10^{2} cop/µl	Standard
●	Standard 2 BCR-ABL MAJOR	4×10^{1} cop/µl	Standard
●	Standard 1 BCR-ABL MAJOR	4×10^{0} cop/µl	Standard
●	Deionized Water		Negative control



** Lid colour*

Validated for cyclers

- **Rotor-Gene 3000 (Corbett Research)**
- **CFX96/CFX96 Touch (Bio-Rad)**
- **Light Cycler 480/Cobas z480 (Roche Diagnostics)**
- **QuantStudio 5 (Applied Biosystems)**

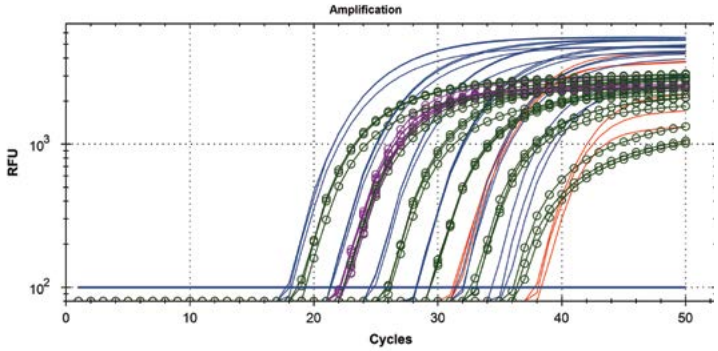


Fig. 1 – A representative result of BCR-ABL1/ABL1 quantification using gb ONCO BCR-ABL MAJOR / ABL kit. simple curves: FAM channel (BCR-ABL1); curves with circles: HEX channel (ABL1 detection); blue curves: standards for BCR-ABL1 quantification; green curves: standards for ABL1 quantification; red curves: 2 independent RNA samples analyzed in FAM channel; purple curves: the same samples in HEX channel.

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