

# gb ONCO BCR-ABL MAJOR/GUSB

## Clinical implication

The BCR-ABL1 MAJOR fusion gene is found in 99 % of patients with chronic myeloid leukemia. This chromosomal aberration leads to dysregulation of tyrosine kinase cascade resulting in the manifestation of leukemia. The patient response to the treatment as well as the minimal residual disease are monitored on a standardized basis through the quantification of the BCR-ABL1 MAJOR b2a2 (e13a2) and b3a2 (e14a2) transcripts relative to the number of GUSB control gene 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 GUSB reference gene transcript. The test is based **on one-step RT-qPCR using fluorescently labeled probes**. Quantification of both fusion and reference transcripts is processed in one tube.

## Available products

Cat. No.	Product	rxn
3249-048	gb ONCO BCR-ABL MAJOR/GUSB	48
3249-096	gb ONCO BCR-ABL MAJOR/GUSB	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 (GUSB) channel
- panel of standards and no template control included

## Content of the diagnostic kit

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

\* Lid colour



## Validated for cyclers

- CFX96/96Touch (Bio-Rad)
- QuantStudio 5 (Applied Biosystems)
- RG 3000 (Corbett Research)

