

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 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

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

