# Clinical implications

The gb ONCO BCR-ABL DETECT diagnostic kit enables the identification or detection of the BCR-ABL1 fusion gene breakpoints variants in patients with a hemato-oncological disease.
The aim of BCR-ABL1 breakpoint variant determination is the confirmation of a diagnosis, the determination of a prognosis and the setting up of a treatment plan for patients with e.g. chronic myeloid leukaemia (CML), acute lymphoblastic leukaemia (ALL) and for patients after bone marrow transplantation.

## Principle of detection

The test is based on one-step RT-qPCR using fluorescently labelled probes. The kit enables detection of the following BCR-ABL1 fusion variants:

| | FAM/SYBR | HEX/JOE/VIC | ROX | Cy5 |
|---|---|---|---|---|
| Assay BCR-ABL DETECT 1 | e14a2 | e13a2 | reference GUSB | e14a3<br>e13a3 |
| Assay BCR-ABL DETECT 2 | e1a2<br>e1a3 | e19a2<br>e19a3 | e6a2 | reference GUSB |

The validity of the samples analysis is evaluated according to the level of the reference GUSB gene transcript and the homogeneity of its analysis by both of the assays.

## Available products

| Cat. No. | Product | rxn |
|---|---|---|
| 3246-048 | gb ONCO BCR-ABL DETECT | 48 |

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

# Parameters of the diagnostic kit

- ***in-vitro*** **diagnostics**
- **CE IVD marked**
- **detection in the following channels: FAM, HEX, ROX and Cy5**

## Content of the diagnostic kit

| * | Component [1] | Volume | Qty [2] | Conc. |
|---|---|---|---|---|
| | Assay BCR-ABL DETECT 1 | 0.2 ml [2] | 2 | 1.25× [3] |
| | Assay BCR-ABL DETECT 2 | 0.2 ml [2] | 2 | 1.25× [3] |
| | Master Mix BCR-ABL DETECT | 0.6 ml [2] | 2 | |
| | Positive Control DETECT | 0.1 ml | 4 | 5x |
| | Calibration Assay | 0.2 ml | 2 | 1x (8 rxn) |
| | Deionized Water | 1.0 ml | 1 | |


*1) tube lid colour corresponds to reagent type*
*2) volume equates to 24 PCR reactions of 25 µl volume*
*3) Concentration after adding the Master Mix BCR-ABL DETECT*

## Validated for cyclers

- **Rotor-Gene 6000/Q (Corbett Research, Qiagen)**
- **CFX96/CFX96 Touch (Bio-Rad)**
- **Light Cycler 480/Cobas z480 (Roche Diagnostics)**