gb ONCO BCR-ABL DETECT

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 e13a3
Assay BCR-ABL DETECT 2	e1a2 e1a3	e19a2 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

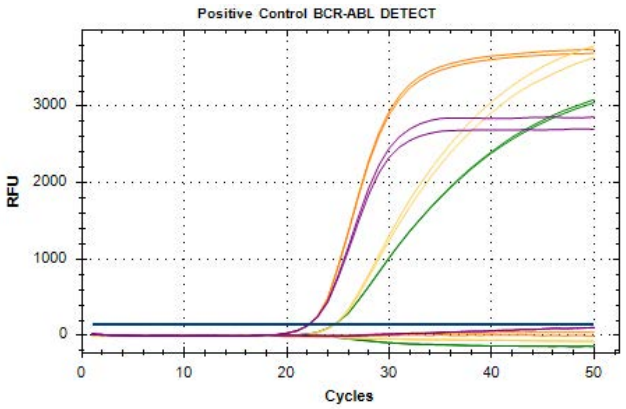


Fig. 1 – FAM channel (green); HEX channel (yellow); ROX channel (orange); Cy5 channel (violet)

Validated for cyclers

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

CE IVD