gb ONCO BRAF (V600E)

Clinical implications

Single nucleotide mutation of the BRAF V600E gene leads to increased activation of the MAP kinase cascade, resulting in proliferation and dedifferentiation. However, the BRAF gene mutation alone is not sufficient to induce a malignant transformation, its role lies more in the progression of the disease than in the initiation. The occurrence of the BRAF V600E mutation was observed, for example, in melanoma, Langerhans' ischemia of the pancreas, or ovarian and colon cancers. BRAF gene mutations are also associated with a number of tumors (malignant melanoma, non-Hodgkin's lymphoma, thyroid papillary carcinoma, non-small cell lung carcinoma and lung adenocarcinoma). Prior to initiating treatment with vemurafenib or dabrafenib, patients should be confirmed with the validated test of the V600 mutation of the BRAF gene. Vemurafenib is not suitable for patients with malignant melanoma and a wild type variant of the BRAF gene.

Principle of detection

The kit is used to detect and quantify the BRAF V600E, E2, D somatic mutation in human genomic DNA. The detection principle is based on **real-time polymerase chain reaction (qPCR) using fluorescently labeled probes and allele specific primers**.

CE IVD

Available products

Cat. No.	Product	rxn
3241-024	gb ONCO BRAF (V600E)	24
3241-048	gb ONCO BRAF (V600E)	48

1 kit contains reagents to provide 24 or 48 PCR reactions (25 µl volume of each reaction).

Parameters of the diagnostic kit

- ***in vitro* diagnostics**
- **CE IVD marked**
- **ready-to-use assay**
- **LOD 0.05% mutated BRAF on WT background at 100,000 copies in reaction**
- **sample concentration 10-80 ng/µl**
- **positive and negative controls included**
- **FAM channel detection**
- **identical amplification profile as gb HEMO, gb GENETIC, gb PHARM kits**

Content of the diagnostic kit

1)	Component 1)	Volume	Qty 2)	Conc.
	Assay qPCR BRAF Control V600E	0.2 ml 3)	1 | 2	3,125×
	Assay qPCR BRAF MUT V600E	0.2 ml 3)	1 | 2	3,125×
	Master Mix BRAF V600E	0.6 ml	1 | 2	2,083×
	Standard WT BRAF V600E	0.2 ml	1	10^4 kopií/µl
	Standard MUT 1% BRAF V600E	0.2 ml	1	10^4 kopií/µl
	Deionized Water	1.0 ml	1	

1) tube lid color
2) number indicated for 24 and 48 reaction package
3) 0,2 ml equates to 24 PCR reactions of 25 µl



Validated for cyclers

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

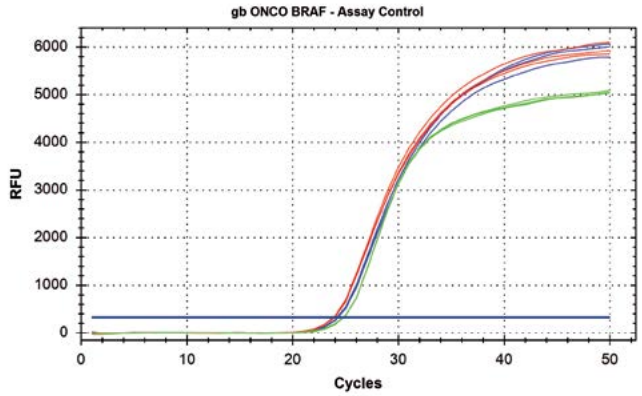


Fig. 1 – Detection of assay Control on CFX96 device; red line – MUT; green line – 1% MUT; blue line – WT

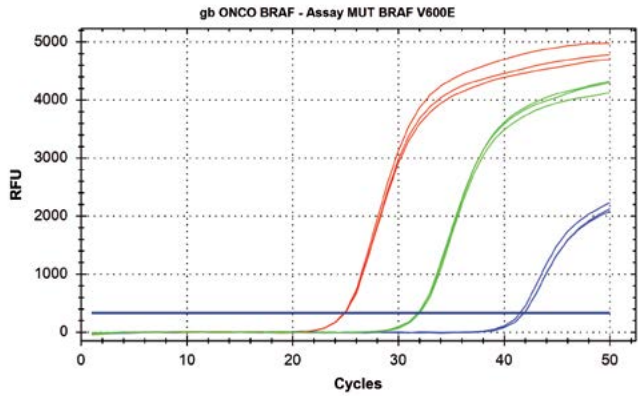


Fig. 2 – Detection of assay Control on CFX96 device; red line – MUT; green line – 1% MUT; blue line – WT