gb ONCO BRAF (V600)

Clinical implications

Single nucleotide mutation of the BRAF V600 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 cancer. BRAF gene mutations are also associated with several tumors (malignant melanoma, non-Hodgkin's lymphoma, thyroid papillary carcinoma, non-small cell lung carcinoma and lung adenocarcinoma). Before 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, K, R, M somatic mutation in human genomic DNA. The principle of detection is based on real-time PCR methodology with the use of fluorescently labeled probes and allele-specific primers. The kit contains all components necessary to perform the analysis.

Detected mutations in the BRAF gene

Change of AMK	Change of nucleotide	Cosmic ID
p.V600E	c.1799T>A	476
p.V600E	c.1799_1800 TG>AA	475
p.V600D	c.1799_1800 TG>AT	477
p.V600D	c.1799_1800 TG>AC	308550
p.V600K	c.1798_1799 GT>AA	473
p.V600R	c.1798_1799 GT>AG	474
p.V600R	c.1798G>A	1130

Available products

Cat. No.	Product	rxn
3281-024	gb ONCO BRAF (V600)	24
3281-048	gb ONCO BRAF (V600)	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**
- **qPCR assay + Master Mix**
- **LOD 0.27% mutated BRAF on WT background at 100,000 copies in reaction**
- **sample concentration 10-80 ng/µl**
- **positive and negative controls are included**
- **FAM channel detection**
- **identical amplification profile as gb HEMO, gb GENETIC, gb PHARM kits**

Content of the diagnostic kit

	Component [1]	Volume	Qty [2]	Conc.
●	Assay qPCR BRAF Control V600	0.2 ml [3]	1 | 2	3,125×
●	Assay qPCR BRAF MUT V600	0.2 ml [3]	1 | 2	3,125×
●	Master Mix BRAF V600	0.6 ml	1 | 2	2,083×
●	Standard WT BRAF V600E	0.2 ml	1	10^4 cop/µl
●	Standard MUT 1% BRAF V600E	0.2 ml	1	10^4 cop/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



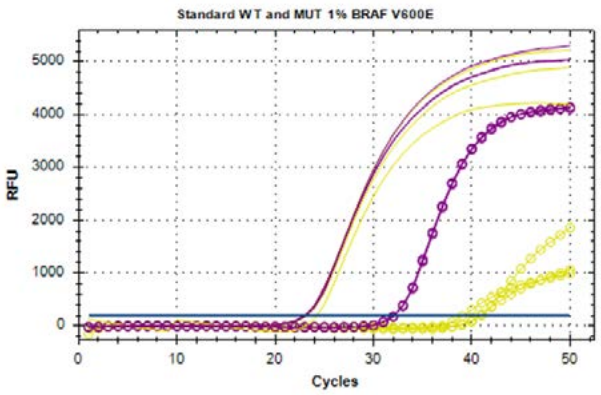


Fig. 1 – Assay control: Standard WT BRAF V600E (yellow), Standard MUT 1% BRAF V600E (violet); Assay MUT: Standard WT BRAF V600E (yellow circles), Standard MUT 1% BRAF V600E (violet circles)

Validated for cyclers

- CFX96/96Touch (Bio-Rad)
- Light Cycler 480/Cobas z480 (Roche Diagnostics)
- QuantStudio 5 (Applied Biosystems)

IVD