gb ONCO EGFR

Clinical implications

The gb ONCO EGFR diagnostic kit enables the detection of EGFR mutations in exons 18, 19, 20 and 21 in cancer patients.

Receptor for epidermal growth factor (EGFR) belongs to the family of tyrosine kinase receptors. Mutations in the gene for EGFR can be activating; carriers of these types of mutations react positively to a therapy with tyrosine kinase inhibitors (TKI). Resistant mutations are a second type of mutations. Carriers of these mutations are resistant to TKIs.

The Epidermal Growth Factor Receptor (EGFR) is expressed on the cell surface and has tyrosine kinase activity. EGFR regulates the cell cycle via the MAPK/ERK and PI3K/AKT/mTOR pathways. Activating mutations of EGFR leads to induction of its kinase activity, which results to uncontrolled cell proliferation. This is used in the cancer treatment by so-called tyrosine kinase inhibitors (TKIs), which bind to the ATP receptor binding site and inhibit EGFR activity. Anti-EGFR TKIs are particularly useful in the treatment of lung tumors, especially non-small cell lung cancer. However, resistance to TKI develops very quickly (median 9–13 months).

Therefore, identifying of the EGFR mutation type will enable more precise and personalized approach to cancer treatment.

CE IVD

Principle of detection

The test is based on real-time PCR methodology with the use of fluorescently labeled probes, allele-specific primers and PCR blockers.
The kit contains 3 specific assays and MasterMix for detection of 7 EGFR mutation groups and 40 single mutations, respectively.

Validity of analysis is checked via WT and MUT standard and IPC (intern positive control). The kit contains all components necessary to perform the test.
EGFR mutation groups detectable via kit (according to fluorescence channels):

	ASSAY qPCR EGFR 1		ASSAY qPCR EGFR 2		ASSAY qPCR EGFR 3	
	Mutation	Exon	Mutation	Exon	Mutation	Exon
FAM	G719X	18	L858R	21	E19del	19
HEX	T790M	20	E20ins	20	S768I	20
ROX	IPC		IPC		IPC	
Cy5	L861Q/R	21	-		CTRL	

IPC - intern positive control for analysis validity check
CTRL - control signal in Cy5 channel for DNA load evaluation

Available products

Cat. No.	Product	rxn
3282-024	gb ONCO EGFR	24

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

Parameters of the diagnostic kit

- ***in vitro* diagnostics**
- **CE IVD marked**
- **sample concentration 8-20 ng/µl**
- **positive and negative controls are included**
- **FAM, HEX, ROX, Cy5 channel detection**

Content and description of kit components

*	Component [1]	Volume	QTY	Conc.
	Assay qPCR EGFR1	0.1 ml [2]	1	1.25× [3]
	Assay qPCR EGFR2	0.1 ml [2]	1	1.25× [3]
	Assay qPCR EGFR3	0.1 ml [2]	1	1.25× [3]
	Master Mix EGFR	1.2 ml [2]	1	1.57×
	Standard WT	0.2 ml	1	10^4 cop/µl
	Standard MUT	0.2 ml	1	10^3 cop/µl
	Calibration Assay	0.2 ml	1	1×
	Deionized water	1.0 ml	1	



1) Tube lid colour corresponds with reagent type.
2) Volume equates to 24 PCR reactions of 25 µl of volume.
4) Concentration after adding Master Mix EGFR.

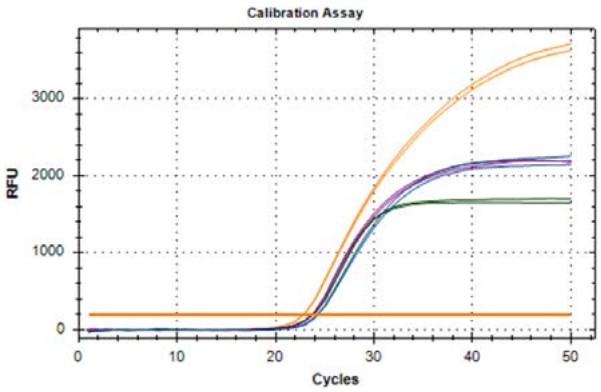


Fig. 1 – Calibration Assay; FAM channel (blue); HEX channel (green); ROX channel (orange); Cy5 channel (violet)

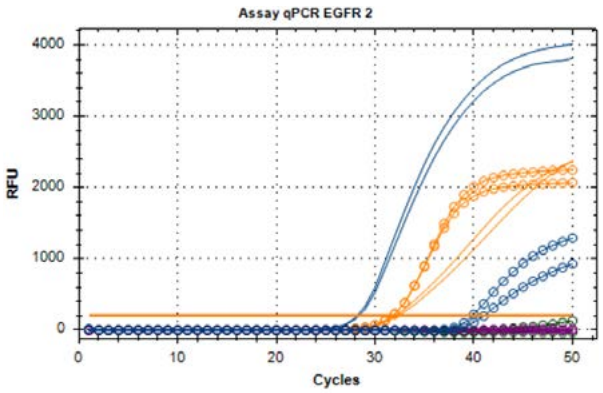


Fig. 3 - Assay qPCR EGFR 2 – Standard WT (FAM channel (blue); ROX channel (orange)), Standard MUT (FAM channel (blue); ROX channel (orange))

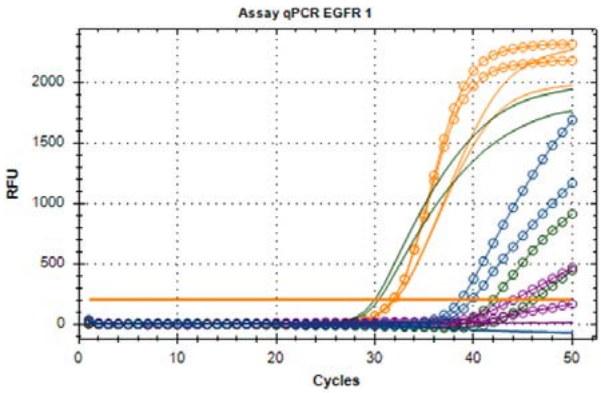


Fig. 2 - Assay qPCR EGFR 1 – Standard WT (HEX channel (green); ROX channel (orange)), Standard MUT (FAM channel (blue circle); HEX channel (green circle); ROX channel (orange circle); Cy5 channel (violet circle))

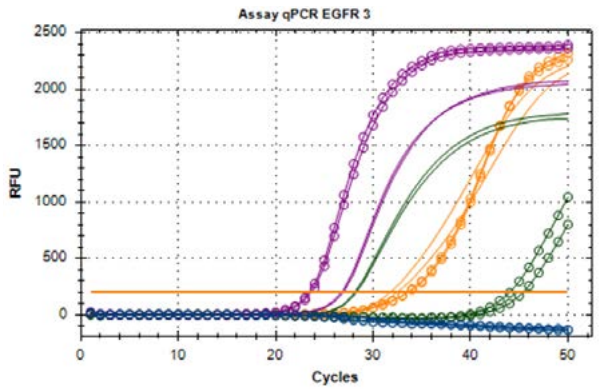


Fig. 4 - Assay qPCR EGFR 3 – Standard WT (HEX channel (green); ROX channel (orange), Cy5 channel (violet)), Standard MUT (HEX channel (green circle); ROX channel (orange circle); Cy5 channel (violet circle))

Validated for cyclers

- CFX96/96Touch (Bio-Rad)
- CFX Opus 96 (Bio-Rad)
- Light Cycler 480/Cobas z480 (Roche Diagnostics)
- QuantStudio 5 (Applied Biosystems)
- RG 3000 (Corbett Research)