gb ONCO EGFR (T790M)

Clinical implications

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. On the other side, the T790M mutation found in exon 20 leads to the TKI resistance.
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, detection of the T790M mutation is required before the treatment with TKI-group medicinal products.

Principle of detection

gb ONCO EGFR (T790M) kit enables the detection and quantification of the EGFR T790M (2369C>T, rs121434569) somatic mutation in the human genomic DNA.

The detection principle 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.

Available products

Cat. No.	Product	rxn
3245-024	gb ONCO EGFR (T790M)	24
3245-048	gb ONCO EGFR (T790M)	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 0.05% mutated EGFR 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 EGFR Control T790M	0.2 ml [3]	1 | 2	3,125×
●	Assay qPCR EGFR MUT T790M	0.2 ml [3]	1 | 2	3,125×
●	Master Mix EGFR T790M	0.6 ml	1 | 2	2,083×
●	Standard WT EGFR T790M	0.2 ml	1	10^4 cop/µl
●	Standard MUT 1% EGFR T790M	0.2 ml	1	10^4 cop/µl
●	Deionized Water	1.0 ml	1	



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

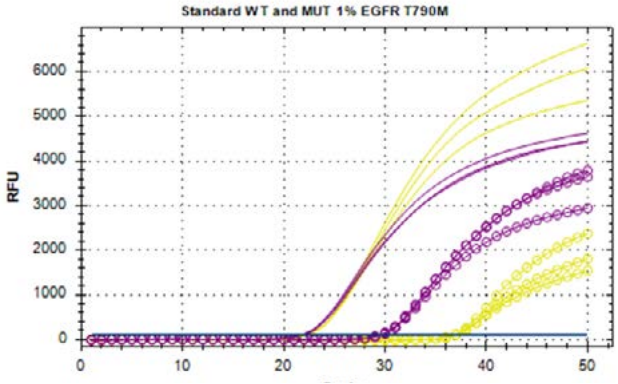


Fig. 1 – Assay control: Standard WT EGFR T790M (yellow), Standard MUT 1% EGFR T790M (violet); Assay MUT: Standard WT EGFR T790M (yellow circles), Standard MUT 1% EGFR T790M (violet circles)

Validated for cyclers

- CFX96/96Touch (Bio-Rad)
- QuantStudio 5 (Applied Biosystems)
- RG 3000 (Corbett Research)

CE IVD