

EGFR-T790M 1% AF cfDNA (SID-000013) – Instructions for use

For Research Use Only

SensID Bringing Precision to Molecular Diagnostics

Every diagnostic test as well as R&D needs references and controls. SensID GmbH manufactures High Quality Reference Materials / Controls for Molecular Diagnostics.








Our mission is to provide certified standards ready for your needs in the highest quality to ease your processes.

For more information visit www.sens-id.com

Content

Product	Catalog No.
EGFR-T790M 1% AF cfDNA	SID-000013

Symbols

	Catalog number
	Lot number
	Use by
	Legal manufacturer
	Not for reuse
	Temperature limitations
	GHS07: Harmful

Storage

EGFR-T790M 1% AF cfDNA should be stored at 2°C to 8°C upon arrival. DO NOT FREEZE. EGFR-T790M 1% AF cfDNA is stable until the expiration date when stored under these conditions.

Intended Use

EGFR-T790M 1% AF cfDNA contains a precisely defined allelic frequency of EGFR-T790M 1% AF cfDNA.

Intended application is:

1. As comparative probe for validation of processes for the verification of the EGFR-T790M mutation
2. Control in workflow validation
3. Validation and development of targeted sequencing protocols (Amplicon Sequencing) and PCR protocols
4. Analyze the performance of your NGS pipeline by comparing to freely available datasets

Protocol: EGFR-T790M 1% AF cfDNA in Plasma

Important point before starting:

- *It is recommended to centrifuge SID-000013 briefly to avoid liquid holding back in the lid of the vial!*
- *Mix by pipetting up and down 10 times to obtain a homogeneous suspension. Do not vortex!*
- *To avoid contaminations in the vial work in clean environment (e.g. laminar flow hood)*
- *DNA purified from a reference cell line, GM24385*
- *The purified DNA is present in cfDNA (human) at a fragment size of 167 bp ±10%*

- *While the presence and frequency of each mutation and/or amplification in this product is evaluated during manufacture using ddPCR assay, there may be differences in observed allele frequencies due to specific assay characteristics.*

Technical Assistance

Our Technical Service Assistance is staffed by experienced scientists with extensive practical and theoretical expertise with our products. If you have any questions or experience any difficulties regarding the EGFR-T790M 1% AF cfDNA or SensID GmbH products in general, please do not hesitate to contact us.

SensID GmbH customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at SensID GmbH. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance and more information, please see our Website www.sens-id.com or call one of the SensID GmbH Technical Service Assistance.

Product Use limitations

Attention should be paid to expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components. Check primary packaging before first opening. Do not use products from damaged primary packaging.

Quality Control

In accordance with SensID's Quality Management System, each lot of EGFR-T790M 1% AF cfDNA is tested against predetermined specifications to ensure consistent product quality.

EGFR-T790M 1% AF cfDNA should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

Warnings and precautions

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at www.sens-id.com/shop/plasma-human-tech-cfdna-ctdna/sid-000013 where you can find, view, and print the SDS for each SensID GmbH products, kit component and other products.

Avoid contamination of the product when opening and closing the vial.

CAUTION: Handle as though it is capable of transmitting infectious agents. This product is formulated using the cell line GM24385, which is a B-lymphocytic, male cell line from the Personal Genome Project offered by the NIGMS Human Genetic Cell Repository (<https://catalog.coriell.org/1/NIGMS>).

Equipment and Reagents to Be Supplied by User

- Pipets (adjustable)¹
- Sterile pipet tips with filters

¹ Ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.



Table 1 General information about EGFR

Official Symbol	EGFR
Official Full Name	epidermal growth factor receptor
Organism	Homo sapiens
Also known as	ERBB; HER1; mENA; ERBB1; PIG61; NISBD2
Summary	The protein encoded by this gene is a transmembrane glycoprotein that is a member of the protein kinase superfamily. This protein is a receptor for members of the epidermal growth factor family. EGFR is a cell surface protein that binds to epidermal growth factor. Binding of the protein to a ligand induces receptor dimerization and tyrosine autophosphorylation and leads to cell proliferation. Mutations in this gene are associated with lung cancer. ²

Table 2 Mutations present in the SensID EGFR-T790M Reference materials. HGVS = Human Genome Variation Society; * = GRCh38 · COSMIC v88

Gene	COSMIC ID	Type of mutation	HGVS Nomenclature	Localisation in Genome (GRCh38)	Amino acid change
EGFR	COSM6240*	Substitution (missense)	c.2369C>T	7:55181378..55181378 Exon 20	p.T790M

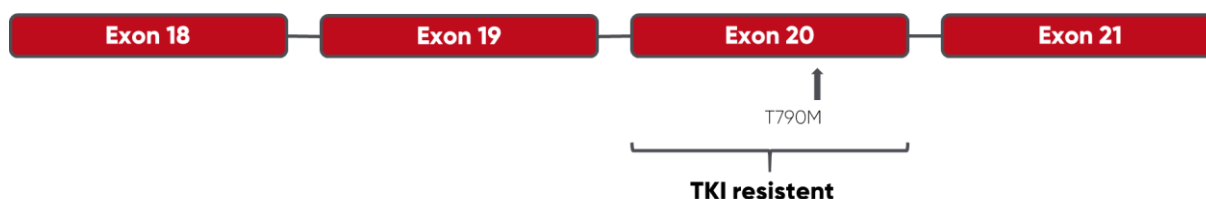


Figure 1 Schematic overview of EGFR mutations in different Exons of EGFR gene included in the product. Mutations above the scheme are associated with sensitivity to EGFR TKIs (TKIs = Tyrosine Kinase Inhibitors). Mutations listed below the scheme are associated with EGFR TKI resistance.

² <https://www.ncbi.nlm.nih.gov/gene/1956>