



HEV - ELITE Positive Control

plasmid DNA control for qualitative assay

REF CTR130ING



TABLE OF CONTENTS

INTENDED USE
PRODUCT DESCRIPTION
MATERIALS PROVIDED IN THE PRODUCT
MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT
OTHER PRODUCTS REQUIRED
WARNINGS AND PRECAUTIONS
PROCEDURE
REFERENCES
SYMBOLS

page 1
page 1
page 2
page 2
page 2
page 2
page 3
page 4
page 4

INTENDED USE

The product «HEV - ELITE Positive Control» is intended for use as a positive control in qualitative nucleic acids amplification assays for the detection of the genomic RNA of Hepatitis E (HEV) by «HEV ELITE MGB® Kit» product in association with «ELITE InGenius®» instrument (ELITechGroup S.p.A.).

PRODUCT DESCRIPTION

The product supplies the **Positive Control**, a stabilized solution of plasmid DNA, aliquoted into **three ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for 4 sessions.

The plasmid DNA contains a portion of the region **ORF-2** of HEV. The detection of target DNA as result of the analysis with «HEV ELITE MGB® Kit» product in association with «ELITE InGenius» instrument, attests the system ability to detect the HEV cDNA.

The product is sufficient for **12 separate analytic sessions**, by using 10 µL for reaction.

HEV - ELITE Positive Control
plasmid DNA control for qualitative assay

REF CTR130ING

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
HEV - Positive Control	plasmid solution	3 x 160 µL	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (2-20 µL, 5-50 µL, 50-200 µL).
- Molecular biology grade water.

OTHER PRODUCTS REQUIRED

The reagents for the reverse transcription and real-time amplification and the consumables are **not** included in this product.

To perform these analytical steps, the use of the product «HEV ELITE MGB® Kit» (ELITechGroup S.p.A., ref. RTS130ING) is required. The product provides the reaction mixtures for reverse transcription of RNA and real-time amplification of cDNA by one-step method.

For automatic sample analysis, the «ELITE InGenius» instrument (ELITechGroup S.p.A., ref. INT030) is required together with the specific Assay Protocol «HEV ELITE_PC» (ELITechGroup S.p.A.), parameters for the amplification of positive control.

The automatic sample analysis with the instrument «ELITE InGenius» also requires the following generic products:

- amplification cartridges «ELITE InGenius® PCR Cassette» (ELITechGroup S.p.A., ref. INT035PCR),
- tips «300 µL Filter Tips Axygen» (Axygen BioScience Inc., CA, USA, ref. TF-350-L-R-S),
- boxes «ELITE InGenius® Waste Box» (ELITechGroup S.p.A., ref. F2102-000).

WARNINGS AND PRECAUTIONS

This product is exclusively for *in vitro* use.

Warnings and general precautions

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be handled and disposed of in compliance with adequate safety standards. Disposable combustible material must be incinerated. Liquid waste containing acids or bases must be neutralised before disposal.

HEV - ELITe Positive Control
plasmid DNA control for qualitative assay

REF CTR130ING

Wear suitable protective clothes and gloves and protect eyes and face.
Never pipette solutions by mouth.
Do not eat, drink, smoke or apply cosmetic products in the work areas.
Carefully wash hands after handling samples and reagents.
Dispose of leftover reagents and waste in compliance with the regulations in force.
Carefully read all the instructions provided in the product before running the assay.
While running the assay, follow the instructions provided in the product.
Do not use the product after the indicated expiry date.
Only use the reagents provided in the product and those recommended by the manufacturer.
Do not use reagents from different batches.
Do not use reagents from other manufacturers.

Warnings and precautions for molecular biology

Molecular biology procedures require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

Lab coats, gloves and tools dedicated to work session setup are needed.

The samples must be suitable and, if possible, dedicated for this type of analysis. Samples must be handled under a laminar airflow hood. Pipettes used to handle samples must be exclusively used for this specific purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips used must be sterile, free from DNases and RNases, free from DNA and RNA.

The PCR Cassettes must be handled in such a way to reduce as much as possible amplification product diffusion into the environment in order to avoid sample and reagent contamination.

Warnings and precautions specific for the components

The **Positive Control** must be stored at -20 °C.

The **Positive Control** can be frozen and thawed for no more than **four times**: further freezing / thawing cycles may cause a loss of product performance.

The **Positive Control** can be used up to **four work sessions of three hours each** ("Extract + PCR" run mode).

PROCEDURE

The «**HEV - ELITe Positive Control**» product must be used with the complete reaction mixture of the «**HEV ELITe MGB® Kit**» product.

Before use, thaw at room temperature (+18 / 25 °C) for 30 minutes the **HEV Positive Control** tubes. Mix gently, spin down the contents for 5 seconds and keep them on ice.

The **HEV Positive Control** is ready to use: a volume of **10 µL** is directly added to the complete reaction mixture by the instrument.

The complete procedure involves setup and carrying out of a real-time amplification reaction and is described in detail in the instructions for use of the «**HEV ELITe MGB® Kit**» product.

The performance characteristics and procedure limitations of the complete assay for the detection of the RNA of the Hepatitis E virus are described in detail in the instructions for use of the «**HEV ELITe MGB® Kit**» product.

Note: The results of the Positive Control amplification will be stored by the instrument «**ELITe InGenius**» and used to create a control chart. For each batch of product «**HEV ELITe MGB® Kit**» the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

Note: The **HEV Positive Control** can be frozen and thawed for no more than **four times**. The **HEV Positive Control** can be used up to **four work sessions of three hours each** ("Extract + PCR" run mode).

HEV - ELITe Positive Control
plasmid DNA control for qualitative assay

REF CTR130ING

REFERENCES

J. J. Germer et al. (2017) *J Clin Microbiology* **55** (5): 1478 - 1487

SYMBOLS

REF

Catalogue Number.



Upper limit of temperature.

LOT

Batch code.



Use by (last day of month).



Fulfilling the requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical.



Contains sufficient for "N" tests.



Attention, consult instructions for use.

CONT

Contents.



Manufacturer.

ELITe MGB®, the ELITe MGB® logo and ELITe InGenius® are registered as trademarks within the European Union.