



HEV ELITe Standard

plasmid DNA control for quantitative assay

REF STD130ING

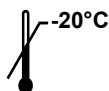


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INTENDED USE

The «HEV ELITe Standard» product is intended for use as known quantity DNA standard in quantitative nucleic acids amplification assays for the detection and quantification of the genomic RNA of Hepatitis E virus (HEV) by «HEV ELITe MGB® Kit» product in association with «ELITe InGenius®» instrument (ELITechGroup S.p.A.).

PRODUCT DESCRIPTION

The product supplies the **Q - PCR Standard**, four stabilized solutions of plasmid DNA at **known titre***, each aliquoted into two **ready to use test tubes**. Each tube contains 160 µL of solution, sufficient for 4 sessions by using 10 µL for reaction.

The plasmid DNA contains a portion of the region **ORF-2** of HEV. The detection of target DNA in the real time amplification reaction attests the product ability to detect the HEV cDNA and allows to calculate the standard curve for HEV quantification in the samples.

The product is sufficient for **8 separate analytic sessions**, using 10 µL for reaction.

* Plasmid DNA concentration was determined through absorbance measurement by spectrophotometer. This plasmid DNA concentration was related to the "1st World Health Organization International Standard for Hepatitis E Virus RNA Nucleic Acid Amplification Techniques (NAT)-Based Assays" (PEI, Germany, code 6329/10) with a conversion factor to International Unit as reported in instruction for use of the «HEV ELITe MGB® Kit» product.

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MATERIALS PROVIDED IN THE PRODUCT

Components	Description	Quantity	Classification and Labelling
HEV Q - PCR Standard 10 ⁵	plasmid solution in tube with RED cap	2 x 160 µL	-
HEV Q - PCR Standard 10 ⁴	plasmid solution in tube with BLUE cap	2 x 160 µL	-
HEV Q - PCR Standard 10 ³	plasmid solution in tube with GREEN cap	2 x 160 µL	-
HEV Q - PCR Standard 10 ²	plasmid solution in tube with YELLOW cap	2 x 160 µL	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless gloves in nitrile 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 amplification reaction and the consumable **are not** included in this product.

- To perform these analytical steps, the use of the product «HEV ELITe MGB® Kit» (ELITechGroup S.p.A., EG SpA, 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 STD» (ELITechGroup S.p.A.), parameters for the amplification of standard DNA and standard curve calculation.

- 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 designed for *in-vitro* use.

General warnings and 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.

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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 **Q - PCR Standard** must be stored at -20 °C.

The **Q - PCR Standard** can be frozen and thawed for no more than **four times**: further freezing / thawing cycles may cause a loss in titre.

The **Q - PCR Standard** can be used up to **four work sessions of two hours each** ("PCR Only" run mode).

PROCEDURE

The «**HEV ELITE Standard**» product must be used with the complete reaction mixture of the «**HEV ELITE MGB® Kit**» product.

Before use, thaw the **HEV Q - PCR Standard** tubes. Mix gently, spin down the contents for 5 seconds and keep them on ice.

The **HEV Q - PCR Standard** is ready to use: a volume of **10 µL** is directly added to the 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 HEV Q - PCR Standard 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 calibration curve is required. The stored results of the Q - PCR Standard amplification will expire **after 60 days**.

Note: The **HEV Q - PCR Standard** can be frozen and thawed for no more than **four times**. The **HEV Q - PCR Standard** can be used up to **four work sessions of two hours each** ("PCR Only" run mode).

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REFERENCES

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

SYMBOLS



Catalogue Number.



Upper limit of temperature.



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.



Contents.



Manufacturer.

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