

Instructions for use

HHV7 — ELITe Positive Control

plasmid DNA control for quantitative assay



REF CTR037PLD

UDI 08033891484583

CE **IVD**

CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
06	Update of the paragraphs: "Other product required", "Materials required but not provided", "Symbols". New graphics and content setting of the IFU.	31/10/25
05	Extension of the use of the product in association with «ELITe BeGenius®» instrument (REF INT040).	23/01/24
04	The number of analytical sessions that could be performed in association with "ELITe InGenius" system or in association with the other validated systems has been specified.	01/08/19
00 — 03	new product development and subsequent changes	-

NOTE

The revision of this IFU is also compatible with the previous version of the kit

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1 INTENDED USE

The product **HHV7 — ELITE Positive Control** is an in vitro diagnostic medical device intended to be used by healthcare professionals as a DNA positive control in nucleic acids Real Time PCR assays for the **detection of the DNA of Herpes human virus 7 (HHV7)** with **HHV7 ELITE MGB® Kit** and the **ELITE InGenius®, ELITE BeGenius®, 7300 Real-Time PCR System and 7500 Real-Time PCR System** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **HHV7 Positive Control**, plasmid DNA at known titre in a stabilizing solution based on Tris-HCl and EDTA, aliquoted into **one ready to use test tube**.

The plasmid DNA contains region of a **capsid protein gene (U57) of HHV7**. The detection and quantification of target DNA, using **HHV7 ELITE MGB Kit** product in association with the **ELITE InGenius** and **ELITE BeGenius** instruments, attests the system ability to detect the DNA of the target genes and consequently the verification of the system (product batch and instrument).

The product contains sufficient reagents for **4 separate sessions** on **ELITE InGenius** and **ELITE BeGenius**, and **12 separate sessions** in association with the other systems, with 10 µL used per reaction.

NOTE

The plasmid DNA concentration in copies/mL was determined through absorbance measurement by spectrophotometer. There are no WHO approved standards for the target genomic DNAs.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
HHV7 Positive Control ref. CTR037PLD	plasmid DNA solution in tube with black cap	1 x 160 µL	-

4 MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (~13,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (volume range: 0.5-1000 µL).
- Molecular biology grade water

5 OTHER PRODUCTS REQUIRED

The reagents for Real-Time amplification reaction and the consumable **are not** included in this product.

To perform the assay the following products are required:

Table 2

Instruments and softwares	Products and reagents
ELITe InGenius (ELITechGroup S.p.A., EG SpA, ref. INT030) ELITe InGenius Software version 1.3.0.19 (or later) HBV ELITe_PC , Assay Protocol with parameters for Positive Control analysis.	HHV7 ELITe MGB Kit product (EG SpA, ref. RTS037PLD) ELITe InGenius and ELITe BeGenius Consumables (see ELITe InGenius and ELITe BeGenius Instruction for Use)
ELITe BeGenius (EG SpA, ref. INT040) ELITe BeGenius Software version 2.3.0 (or later) HHV7 ELITe_Be_PC , Assay Protocol with parameters for Positive Control analysis.	
7300 Real-Time PCR System (ThermoFisher Scientific, ref. 4351101)	HHV7 ELITe MGB Kit (EG SpA, ref. RTS037PLD) MicroAmp™ Optical 96-Well Reaction Plate , (Life Technologies, ref. N8010560)
7500 Fast Dx Real-Time PCR Instrument (ThermoFisher Scientific, ref. 4406985)	HHV7 ELITe MGB Kit (EG SpA, ref. RTS037PLD) MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL (Life Technologies, ref. 4346906)

6 WARNINGS AND PRECAUTIONS

This product is designed for *in-vitro* use only.

6.1 General warnings and precautions

- Handle and dispose of all reagents and all materials used to carry out the assay as if they were infectious. 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 neutralized before disposal.
- 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 before running the assay.
- While running the assay, follow the product instructions provided.
- Do not use the product after the indicated expiry date.
- Only use the reagents provided with the product and those recommended by the manufacturer.
- Do not use reagents from different batches.
- Do not use reagents from other manufacturers.

6.2 Warnings and precautions for molecular biology

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

When amplification session is manually setup, it is necessary to have available separate areas for the extraction / preparation of amplification reactions and for the amplification / detection of amplification products. Never introduce an amplification product in the area designated for extraction / preparation of amplification reactions.

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

The reagents must be handled under a laminar airflow hood. The pipettes used to handle the reagents must be exclusively used for this 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 Cassette must be handled carefully and never opened to prevent PCR product diffusion and carryover contamination.

6.3 Warnings and precautions specific for the components

Table 3

Component	Storage temperature	Use from first opening	Freeze / thaw cycles	On board stability (ELITe InGenius and ELITe BeGenius)
HHV7 Positive Control	-20°C or below	one month	up to twelve	up to four separate sessions* of two hours each

* with intermediate freezing.

7 PROCEDURE

The product **HHV7 — ELITe Positive Control** must be used in association with the product **HHV7 ELITe MGB Kit**.

The component **HHV7 Positive Control** is ready to use: a volume of **10 µL** is directly added to the reaction mixture (**HHV7 PCR Mix**, component of **HHV7 ELITe MGB Kit**) by the instrument ELITE InGenius or ELITE BeGenius, or manually when other instruments are used.

Before use, take and thaw the **HHV7 Positive Control** tube at room temperature (+16 / +26 °C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep it on ice or in a cool block.

The complete assay procedure is described in detail in the instructions for use of the product **HHV7 ELITe MGB Kit**.

The performance characteristics and procedure limitations of the complete assay are described in detail in the instructions for use of the product **HHV7 ELITe MGB Kit**.

NOTE












The results of Positive Control will be stored by the **ELITe InGenius** and **ELITe BeGenius** instruments and used to setup the Control Charts monitoring the amplification step performances. For each batch of the product **HHV7 ELITe MGB Kit** the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

8 REFERENCES

F. Drago et al. (1997) Lancet 349: 1367 - 1368 (annex n° 1, 2 pages);

C. N. Kotton et al. (2024) Transplantation 00: 00 - 00

9 SYMBOLS

	Catalogue Number.
	Upper limit of temperature.
	Batch code.
	Use by (last day of month).
	<i>in vitro</i> diagnostic medical device.
	Fulfilling the requirements of the European Directive 98/79/EC for <i>in vitro</i> diagnostic medical device.
	Unique Device Identification
	Contains sufficient for "N" tests.
	Consult instructions for use.
	Contents.
	Manufacturer.

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