

## NOTICE of CHANGE dated 23/01/2024

### IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:







<h2>«HHV7 - ELITe Positive Control»</h2> <h3>Ref. CTR037PLD</h3>
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This new revision of the Instruction for Use (IFU) contains the following changes:

- *Extension of the use of the product in association with «ELITe BeGenius®» instrument (REF INT040).*

Composition, use and performance of the product remain unchanged.

### PLEASE NOTE

	LA REVISIONE DI QUESTO IFU E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT
	THE REVIEW OF THIS IFU IS ALSO COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT
	CET IFU MIS A JOUR ANNULE ET REMPLACE ET EST PARFAITEMENT COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT
	LA REVISIÓN DE ESTE IFU ES COMPATIBLE TAMBIÉN CON LA VERSIÓN ANTERIOR DEL KIT
	A REVISÃO DO ESTE IFU ÉTAMBÉM COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT
	DIESE FASSUNG DER GEBRAUCHSANLEITUNG IST KOMPATIBEL MIT DER VORHERIGEN VERSION DES TESTKITS



## HHV7 - ELITe Positive Control

plasmid DNA control for quantitative assay

REF CTR037PLD



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### 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<sup>®</sup> Kit** and the **ELITe InGenius<sup>®</sup>**, **ELITe BeGenius<sup>®</sup>**, **7300 Real-Time PCR System** and **7500 Real-Time PCR System** instruments.

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

**HHV7 - ELITe Positive Control**  
plasmid DNA control for quantitative assay

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### MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazards
HHV7 Positive Control ref. CTR037PLD	plasmid DNA solution in tube with black cap	1 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 (~13,000 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.
- Programmable thermostat with optical fluorescence detection system 7300 Real Time PCR System or 7500 Fast Dx Real-Time PCR Instrument calibrated following manufacturer's instructions.

### OTHER PRODUCTS REQUIRED

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

To perform the assay the following products are required:

Instruments and softwares	Products and reagents
<b>ELITe InGenius</b> (ELITechGroup S.p.A., EG SpA, ref. INT030)	<b>HHV7 ELITe MGB Kit</b> product (EG SpA, ref. RTS037PLD)
<b>ELITe InGenius Software</b> version 1.3.0.17 (or later)	<b>ELITe InGenius PCR Cassette</b> (EG SpA, ref. INT035PCR)
<b>HHV7 ELITe_PC</b> , Assay Protocol with parameters for Positive Control analysis.	<b>300 µL Filter Tips Axygen</b> (Corning Life Sciences Inc., ref. TF-350-L-R-S) with ELITe InGenius only
<b>ELITe BeGenius</b> (EG SpA, ref. INT040)	<b>1000 µL Filter Tips Tecan</b> (Tecan, Switzerland, ref. 30180118) with ELITe BeGenius only
<b>ELITe BeGenius Software</b> version 2.1.0 (or later)	<b>ELITe InGenius Waste Box</b> (EG SpA, ref. F2102-000)
<b>HHV7 ELITe_Be_PC</b> , Assay Protocol with parameters for Positive Control analysis.	
7300 Real-Time PCR System (ThermoFisher Scientific, ref. 4351101)	<b>HHV7 PLUS ELITe MGB Kit</b> (EG SpA, cod. RTS037PLD)
	<b>MicroAmp<sup>™</sup> Optical 96-Well Reaction Plate</b> (Life Technologies, ref. N8010560)
7500 Fast Dx Real-Time PCR Instrument (ThermoFisher Scientific, ref. 4406985)	<b>HHV7 PLUS ELITe MGB Kit</b> (EG SpA, cod. RTS037PLD)
	<b>MicroAmp<sup>™</sup> Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL</b> (Life Technologies, ref. 4346906)

### WARNINGS AND PRECAUTIONS

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

#### Warnings and general 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.

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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 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.

### 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.

When amplification session is manually setup it is necessary to have available lab coats, gloves and tools which are exclusively used for the extraction / preparation of the amplification reactions and for the amplification / detection of amplification products. Never transfer lab coats, gloves or tools from the area designated for the amplification / detection of amplification products to the area designated for the extraction / preparation of the amplification reactions.

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, and free from DNA and RNA.

The PCR Cassette must be handled carefully and never opened to avoid PCR product diffusion into the environment and sample and reagent contamination.

### Warnings and precautions specific for the components

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 three hours each

\* with intermediate freezing

## 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**.

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**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**.

## REFERENCES

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

## SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	<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.
	Contains sufficient for "N" tests.
	Caution, consult instructions for use.
CONT	Contents.
	Manufacturer.

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