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EMPOWERING IVD

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NOTICE of CHANGE dated 23/01/2024

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«HHV7 ELITe Standard»
Ref. STD037PLD

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

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HHV7 ELITe Standard

plasmid DNA standard for quantitative assay

REF STD037PLD

IVD

-20°C

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INTENDED USE

The **HHV7 ELITe Standard** product is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as known quantity DNA standard in quantitative nucleic acids Real-Time PCR assay for **detection and quantification of the DNA of Herpes human virus 7 (HHV7),** with **HHV7 ELITe MGB® Kit** product and the **ELITe InGenius®**, **ELITe BeGenius®**, **7300 Real-Time PCR System and 7500 Real-Time PCR System** instruments.

PRODUCT DESCRIPTION

The product supplies the **HHV7 Q - PCR Standard**, four levels of Tris-HCl and EDTA stabilized solutions of plasmid DNA at known titre , each aliquoted into **two ready-to use test tubes**.

The plasmid DNA contains the region of a gene codifying the **capsid protein (U57)** of HHV7**.** The detection and quantification of target DNA, using **HHV7 ELITe MGB Kit** product in association with **ELITe InGenius and ELITe BeGenius** instruments, allows to calculate the Calibration Curve of the system (product batch and instrument) for HHV7 DNA quantification.

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius and ELITe BeGenius**, (4 sessions each tube), and **16 separate sessions** (8 sessions each tube) in association with the other systems, with 10 µL for 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.

MATERIALS PROVIDED IN THE PRODUCT

Components	Description	Quantity	Classification of Hazards
HHV7 Q - PCR Standard 10^5 ref. STD037PLD	plasmid DNA solution in tube with **RED cap**	**2 x 160 µL**	-
HHV7 Q - PCR Standard 10^4 ref. STD037PLD	plasmid DNA solution in tube with **BLUE cap**	**2 x 160 µL**	-
HHV7 Q - PCR Standard 10^3 ref. STD037PLD	plasmid DNA solution in tube with **GREEN cap**	**2 x 160 µL**	-
HHV7 Q - PCR Standard 10^2 ref. STD037PLD	plasmid DNA solution in tube with **YELLOW cap**	**2 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 reaction and the consumable **are not** included in this product.

To perform the assay the following products are required:

Instruments and softwares	Products and reagents
ELITe InGenius (ELITechGroup S.p.A., EG SpA, ref. INT030) **ELITe InGenius Software** version 1.3.0.17 (or later) **HHV7 ELITe_STD**, Assay Protocol with parameters for Calibrators analysis.	**HHV7 ELITe MGB Kit** product (EG SpA, ref. RTS076PLD) **ELITe InGenius PCR Cassette** (EG SpA, ref. INT035PCR) **300 µL Filter Tips Axygen** (Corning Life Sciences Inc., ref. TF-350-L-R-S) with ELITe InGenius only **1000 µL Filter Tips Tecan** (Tecan, Switzerland, ref. 30180118) with ELITe BeGenius only **ELITe InGenius Waste Box** (EG SpA, ref. F2102-000)
ELITe BeGenius (EG SpA, ref. INT040) **ELITe BeGenius Software** version 2.1.0 (or later) **HHV7 ELITe_Be_STD**, Assay Protocol with parameters for Calibrators analysis.	
7300 Real-Time PCR System (ThermoFisher Scientific, ref. 4351101)	**HHV7 ELITe MGB Kit** product (EG SpA, ref. RTS076PLD) **MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL** (Life Technologies, ref. 4346906)
7500 Fast Dx Real-Time PCR Instrument (ThermoFisher Scientific, ref. 4406985)	**HHV7 ELITe MGB Kit** product (EG SpA, ref. RTS076PLD) **MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL** (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.

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 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 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 Q – PCR Standard	-20°C or below	one month	up to eight	up to four separate sessions* of two hours each

* with intermediate freezing

PROCEDURE

The product **HHV7 ELITe Standard** must be used in association with the product **HHV7 ELITe MGB Kit**.

The components **HHV7 Q - PCR Standard** are ready to use: a volume of **10 µL each** 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.

HHV7 ELITe Standard
plasmid DNA standard for quantitative assay

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Before use, take and thaw the **HHV7 Q - PCR Standard** tubes at room temperature (+16 / +26 °C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep them 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 the HHV7 Q - PCR Standard will be stored by the **ELITe InGenius and ELITe BeGenius** instruments and used to calculate the calibration curve. For each lot of **HHV7 ELITe MGB Kit**, the calibration curve is required. The stored results of the Q-PCR Standard amplification will expire after **60 days**.

REFERENCES

F. Drago et al. (1997) *Lancet* 349: 1367 - 1368 (annex n° 1, 2 pages);
C. N. Kotton et al. (2018) *Transplantation* 02: 900 - 931

SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	*in vitro* diagnostic medical device.
	Fulfilling the requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device.
	Contains sufficient for "N" tests.
	Caution, consult instructions for use.
CONT	Contents.
	Manufacturer.