Instructions for use

HSV2 — ELITe Positive Control

plasmid DNA control for quantitative assay

ELITechGroup
A BRUKER COMPANY

REF CTR032PLD

UDI 08033891483494

CE 0123

IVD

CHANGE HISTORY

Rev.	Notice of change	Date (dd/ mm/yyyy)
19–R	Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements . Update of the Intended use: • Validation of the products in association with ELITe InGenius (REF INT030) and ELITe BeGenius (REF INT040) instruments • Validation of the products in association with ABI 7500 Fast Dx Real-Time PCR Instrument. **NOTE** Composition of the product remains unchanged New graphics and content setting of the IFU.	19/05/25
18	Update for the use of the product in association with «ELITe BeGenius®» instrument (REF INT040).	28/01/22
17	Extended Use of the product with the platform Roche cobas z 480 analyzer.	15/06/20
16	The number of tubes and the volume of Positive Control has been modified: from 4 x 65 µL to 2 x 160 µL. All the changes introduced are detailed in the Instruction Manual for Use (IFU). Composition, use and performance of the product remain unchanged.	28/07/17
00–15	New product development and succeeding changes.	-

NOTE

The product batches identified by the following LOT numbers are still placed on the market as per IVDD till to their expiration dates, according to Article 110 of IVDR. If you have those product batches, please contact ELITechGroup staff to request the related previous revision of IFUs.

Those batches of Positive Control are technically compatible with the new IVDR version of the amplification kit and can be used, until exhausted, in association with the new IVDR version of the amplification kit and in accordance with its intended use.

PRODUCT REF.	Lot Number	Expiry date
CTR032PLD	U1124-030	30/06/2026
CTR032PLD	U0524-004	31/05/2026
CTR032PLD	U0823-031	31/08/2025

TABLE OF CONTENT

1 INTENDED USE

The product **HSV2 — ELITe Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as known quantity DNA positive control in nucleic acids Real-Time PCR assays for the detection and quantification of the genomic DNA of **Herpes Simplex human virus type 2 (HSV2)** in association with **HSV2 ELITe MGB® Kit** and **ELITe InGenius®** , **ELITe BeGenius®** and **7500 Fast Dx Real-Time PCR** Instruments.

2 PRODUCT DESCRIPTION

The product supplies the **HSV2 — Positive Control**, a plasmid DNA at known titre* in a stabilizing solution based on Tris-HCl and EDTA, aliquoted into **two ready- to use test tubes**.

The plasmid DNA contains the amplified region of the gene codifying the **glycoprotein G (gpG)** of HSV2. The detection and quantification of target DNA, using **HSV2 ELITe MGB Kit** product, in association with ELITe InGenius and ELITe BeGenius instruments, attests the system ability to detect the DNA of the target gene and consequently the verification of the system. The detection of target DNA using **HSV2 ELITe MGB Kit** product in association with **7500 Fast Dx Real-Time PCR** instrument attests the system ability to detect the DNA of the target gene and consequently the verification of the session.

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius** and **ELITe BeGenius**, **12 separate sessions** on the other systems, with 20 µL used per reaction.

NOTE

Standard DNA concentration was determined by spectrophotometer by absorbance measurement of the plasmid DNA preparation This standard DNA was related to the "1st WHO International Standard for HSV2 DNA"(-NIBSC ref.17/122, United kingdom) with a conversion factor to International Unit as reported in instruction for use of the **HSV2 ELITe MGB Kit** product.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
HSV2 — Positive Control ref. CTR032PLD	plasmid DNA solution in tube with **NATURAL cap**	**2 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 (0.5-10 µL, 2-20 µL, 5-50 µL, 50-200 µL, 200-1000 µL).

5 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:

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) **HSV2 ELITe_PC**, Assay Protocol with parameters for Positive Control analysis.	**HSV2 ELITe MGB Kit** (EG SpA, ref. RTS032PLD) **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 2.2.1 (or later) **HSV2 ELITe_Be _PC**, Assay Protocol with parameters for Positive Control analysis.	
7500 Fast Dx Real-Time PCR Instrument (ThermoFisher Scientific, ref. 4406985) **ELITe GALAXY** (EG SpA, ref. INT020)	**HSV2 ELITe MGB Kit** (EG SpA, ref. RTS032PLD) **MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL** (Life Technologies, ref. 4346906), microplates with 0.1 mL wells and adhesive sealing sheets for real time amplification.

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 the amplification session has to be performed with the 7500 Fast Dx Real-Time PCR Instrument, 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, and free from DNA and RNA.

After the amplification session, the Reaction Plate and the PCR Cassette must be handled carefully and never opened to avoid PCR product diffusion into the environment and sample and reagent 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)
HSV2 — Positive Control	-20°C or below	one month	up to eight	up to four separate sessions* of three hours each

* with intermediate freezing.

7 PROCEDURE

The product **HSV2 — ELITe Positive Control** must be used in association with the product **HSV2 ELITe MGB Kit**.

The component **HSV2 — Positive Control** is ready for use: a volume of **20 µL** is directly added to the reaction mixture (**HSV2 PCR Mix**, component of **HSV2 ELITe MGB Kit**) by the instrument.

Before use, take and thaw the **HSV2 — 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 **HSV2 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 **HSV2 ELITe MGB Kit**.

NOTE

The results of the **HSV2 — ELITe Positive Control** will be stored by the ELITe InGenius and ELITe BeGenius instruments and used to set up the Control Charts monitoring the amplification step performances. For each lot of the product **HSV2 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

E. T. E. Fenner et al. (1991) J Clin Microbiology 29: 2621 - 2622

F. E. A. Lukhtanov et al. (2007) Nucleic Acids Res. 35: e30

9 SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	*in vitro* diagnostic medical device.
CE 0123	Fulfilling the requirements of the IVDR Regulation 2017/746/EC for *in vitro* diagnostic medical device. Certification released by TÜV SÜD Product Service GmbH, Germany.
UDI	Unique Device Identification
	Contains sufficient for "N" tests.
	Consult instructions for use.
CONT	Contents.
	Manufacturer.

10 NOTICE TO THE USERS

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and /or the patient is established. At the moment of the current revision of the IFU, no serious incident or recall with impact on product performance and safety of the device has occurred.

A “Summary of Safety and Performance” will be made available to the public via the European database on medical devices (Eudamed) when this informatic system will be functional. Before the notice of full functionality of Eudamed has been published, the “Summary of Safety and Performance” will be made available to the public upon request by email at emd.support@elitechgroup.com, without undue delay.

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