Instructions for use

ENTEROVIRUS— ELITe Positive Control

plasmid DNA control for quantitative assay

ELITechGroup
A BRUKER COMPANY

REF CTR076PLD

UDI 08033891485009

CE 0123

IVD

CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yyyy)
05	Update of the paragraph “Other product required”. Update of the paragraph “Notice to the users”. Update of the paragraph “Warnings and precautions”. Update of the paragraph “Symbols” with the symbol “Consult instructions for use”	09/09/2025
04	Number of tubes of Positive Control from 1 to 2 tubes Extension of the use of the product in association with ELITe BeGenius® instrument (REF INT040). Compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements. **NOTE** Composition of the product remain unchanged New graphics and content setting of the IFU	18/10/2024
03	The number of the analytical sessions to be carried out in association with the "ELITe InGenius" system or in association with other validated systems has been specified.	26/02/2020
00 — 02	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
CTR076PLD	U0224-006	28/02/2026
CTR076PLD	U0723-106	31/07/2025
CTR076PLD	U0423-047	31/01/2025

TABLE OF CONTENT

1 INTENDED USE

The product **ENTEROVIRUS— ELITe Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as a known quantity DNA positive control in nucleic acids reverse transcription and Real-Time PCR assays for the detection and quantification of the RNA of the Human Enterovirus (EV) in association with **ENTEROVIRUS ELITe MGB® Kit** and the **ELITe InGenius®** and **ELITe BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **EV Positive Control**, 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 a **5'-UTR** cDNA region of Enterovirus. The detection and quantification of target DNA, using **ENTEROVIRUS 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 (product batch and instrument).

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius** and **ELITe BeGenius**, (4 sessions each tube), 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.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
EV Positive Control ref. CTR076PLD	plasmid DNA solution in tube with **black 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 (volume range: 0.5-1000 µL).

5 OTHER PRODUCTS REQUIRED

The reagents for the reverse transcription and 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) **EV ELITe_PC**, Assay Protocol with parameters for Positive Control analysis.	**ENTEROVIRUS ELITe MGB Kit** (EG SpA, ref. RTS076PLD) **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) **EV ELITe_Be _PC**, Assay Protocol with parameters for Positive Control analysis.	

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.
- Laboratory coats, gloves and tools dedicated to work session setup are needed.
- 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)
EV Positive Control	-20°C or below	one month	up to four	up to four separate sessions* of three hours each

* with intermediate freezing.

7 PROCEDURE

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

The component **EV Positive Control** is ready to use: a volume of **10 µL** is directly added to the complete reaction mixture (**EV PCR Mix** and **RT-EnzymeMix**, components of **ENTEROVIRUS ELITe MGB Kit**) by the instrument.

Before use, take and thaw the **EV 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 **ENTEROVIRUS 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 **ENTEROVIRUS ELITe MGB Kit**.

NOTE

The results of 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 batch of the product **ENTEROVIRUS 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

W. A. Verstrepen et al. (2001) *J Clin Microbiology* 39: 4093 - 4096

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

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

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. To inform ELITechGroup S. p. A., manufacturer of this device, please use the following mail address: egspa.vigilance@elitechgroup.com..

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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