

Instructions for use

# GI Viral PLUS - ELITe Positive Control

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plasmid DNA control for qualitative assay



**REF** CTR501ING

**UDI** 08033891487522

**CE** **IVD**  
0123

**CHANGE HISTORY**

<b>Rev.</b>	<b>Notice of change</b>	<b>Date (dd/mm/yy)</b>
01	Update of the paragraphs: "Other product required", "Materials required but not provided", "Warning for molecular biology", "Symbols" and "Notice to the users" New graphics and content setting of the IFU.	28/10/25
00	new product development	15/03/24

**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 **GI Viral PLUS - ELITE Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as DNA positive control in nucleic acids reverse transcription and Real-Time PCR assay for the detection and identification of the genomic DNA of Adenovirus, and the genomic RNA of Norovirus, Rotavirus, Astrovirus and Sapovirus, in association with **GI Viral PLUS ELITE MGB® Kit** and the **ELITE InGenius®** and **ELITE BeGenius®** instruments.

## 2 PRODUCT DESCRIPTION

The product supplies the **GI-V Positive Control**, plasmid DNAs at known titre in a stabilizing solution based on Tris-HCl and EDTA, aliquoted into **three ready-to-use test tubes**

The plasmid DNAs contain the following genes: Hexon for Adenovirus Serotype F40, polyprotein for **Norovirus Genogroup GII**, **NSP3** for **Rotavirus**, **capsid protein** for **Astrovirus** and **polyprotein** for **Sapovirus GI/GII/GIV**. The detection of target DNAs, using **GI Viral PLUS ELITE MGB Kit** product in association with **ELITE InGenius** and **ELITE BeGenius** instruments, attests the system ability to detect the DNA and RNA of the target genes and consequently the verification of the system (product batch and instrument).

The product contains sufficient reagents for 12 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
<b>GI-V Positive Control</b> ref. CTR501ING	plasmid DNAs solution in tube with black cap	<b>3 x 160 µL</b>	-

## 4 MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (~13,000 RPM).

## 5 OTHER PRODUCTS REQUIRED

The reagents for the reverse transcription and Real-Time PCR and the consumables are not included in this product.

To perform the assay the following products are required:

**Table 2**

Instruments and software	Products and reagents
<b>ELITe InGenius</b> (ELITechGroup S.p.A., EG SpA, ref. INT030) <b>ELITe InGenius Software</b> version 1.3.0.19 (or later) <b>GI Viral PLUS ELITe_PC</b> , Assay Protocol with parameters for Positive Control analysis.	<b>GI Viral PLUS ELITe MGB Kit</b> product (EG SpA, ref. RTS501ING) <b>ELITe InGenius</b> and <b>ELITe BeGenius Consumables</b> (see ELITe InGenius and ELITe BeGenius Instruction for Use)
<b>ELITe BeGenius</b> (EG SpA, ref. INT040) <b>ELITe BeGenius Software</b> version 2.3.0 (or later) <b>GI Viral PLUS ELITe_Be_PC</b> , Assay Protocol with parameters for Positive Control analysis.	

## 6 WARNINGS AND PRECAUTIONS

This product is designed for in vitro use only.

### 6.1 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 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)
<b>GI-V Positive Control</b>	-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 **GI Viral PLUS - ELITE Positive Control** must be used in association with the product **GI Viral PLUS ELITE MGB Kit**.

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

Before use, take and thaw the **GI-V 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 **GI Viral PLUS 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 **GI Viral PLUS 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 **GI Viral PLUS 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

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Y. Liu et al. (2012) *J. Clin. Microbiol.* 50: 2384 - 2389

: F. Jakab et al. (2019) *J. Med. Virol.* 74: 71 - 7

S. Q. Zeng et al. (2008) *J. Virol. Methods* 153: 238 - 240

M. Diez-Valcarce et al. (2018) *J. Clin Virol.* 104: 65 - 72

E. Lukhtanov et al. (2007) *Nucleic Acids Res.* 35: e 30

P. Chhabra et al. (2019) *J. Gen. Virol.* 100: 1393 - 1406

K. Kumthip et al. (2019) *Ann Res Hosp* 3: 1 - 3

B. Lopman et al. (2015) *CDC Review*: 1-44

## 9 SYMBOLS



Catalogue Number.



Upper limit of temperature.



Batch code.



Use by (last day of month).



*in vitro* diagnostic medical device.



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.



Unique Device Identification



Contains sufficient for "N" tests.



Consult instructions for use.



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](mailto:egspa.vigilance@elitechgroup.com).

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