

## NOTICE of CHANGE dated 23/05/2023

### IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:







# «CMV RNA - ELITe Positive Control» Ref. CTR115ING

This new revision of the Instruction for Use (IFU) contains the following changes:

- *Intended use modification*

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
	DIE REVIEW VON DIESER IFU IST KOMPATIBLE MIT DER VORIGE VERSION VON DEM TEST-KIT



## CMV RNA - ELITE Positive Control

plasmid DNA control for qualitative and quantitative assay

REF CTR115ING

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### INTENDED USE

The product **CMV RNA - ELITE Positive Control** is an *in vitro* reagent intended to be used by healthcare professionals as a known quantity DNA positive control in a quantitative nucleic acids reverse transcription and amplification assays for the detection and quantification of the **human Cytomegalovirus** **virion mRNA (CMV RNA)** in association with **CMV RNA ELITE MGB® Kit** and the **ELITE InGenius®** instrument.

### PRODUCT DESCRIPTION

The product supplies the **CMV RNA Positive Control**, a stabilized solution of plasmid DNA at known titre, aliquoted into **three ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for 4 sessions.

The plasmid DNA contains the spliced region of **UL21.5 CMV mRNA**. The detection and quantification of the CMV RNA, as result of the analysis with **CMV RNA ELITE MGB Kit** product in association with **ELITE InGenius®** instrument, allows to construct the Control Chart for the verification of the system (product batch and instrument).

The product contains sufficient material for **12 sessions on ELITE InGenius®**, using 20 µL for reaction.

**CMV RNA - ELITE Positive Control**  
plasmid DNA control for qualitative and quantitative assay

REF CTR115ING

### MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
CMV RNA Positive Control ref. CTR115ING	plasmid DNA solution, BLACK cap	3 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 (12,000 - 14,000 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.

### 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 **CMV RNA ELITE MGB Kit** product (ELITechGroup S.p.A, EG SpA, ref. RTS115ING) is required. The product provides the reaction mixtures for reverse transcription of RNA and real-time amplification of cDNA by one-step method.

For automatic nucleic acids extraction, reverse transcription, real-time amplification, and result interpretation of samples to be analysed, the **ELITE InGenius®** instrument (EG SpA, ref. INT030) is required together with the specific Assay Protocol **CMV RNA ELITE\_Open\_PC** (EG SpA) parameters for the amplification and the result interpretation of Positive Control.

With the instrument **ELITE InGenius®** the following generic products are required:

- amplification cassettes **ELITE InGenius® PCR Cassette** (EG SpA, ref. INT035PCR),
- tips **300 µL Filter tips Axygen** (Axygen BioScience Inc., CA, ref. TF-350-L-R-S),
- boxes **ELITE InGenius® Waste Box** (EG SpA, ref. F2102-000).

### WARNINGS AND PRECAUTIONS

**This product is intended for *in vitro* use.**

#### Warnings and general precautions

Handle and dispose of all biological samples as if they were infectious. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite (bleach) or autoclaved for one hour at 121 °C before disposal. Do not allow extraction reagents to contact sodium hypochlorite (bleach).

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 neutralised 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 with the product before running the assay.  
While running the assay, follow the instructions provided with the product.  
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.

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.

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

#### Warnings and precautions specific for the components

The **CMV RNA Positive Control** must be stored at temperature of -20 °C or below.

The **CMV RNA Positive Control** must be used within one month from the first opening.

The **CMV RNA Positive Control** can be frozen and thawed up to **four times**: further freeze / thaw cycles may cause a loss of product performances.

The **CMV RNA Positive Control** can be used on the **ELITE InGenius®** instrument up to **four work sessions of three hours each** ("Extract + PCR" run mode).

### PROCEDURE

The **CMV RNA - ELITE Positive Control** product must be used with the complete reaction mixture of the **CMV RNA ELITE MGB Kit** product.

Before use, take and thaw the **CMV RNA Positive Control** tube at room temperature (~+25 °C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep it on ice.

The **CMV RNA Positive Control** is ready to use: a volume of **20 µL** is directly added to the complete reaction mixture.

The complete assay procedure is described in detail in the instructions for use of the **CMV RNA ELITE MGB Kit** product.

The performance characteristics and procedure limitations of the complete assay are described in detail in the instructions for use of the **CMV RNA ELITE MGB® Kit** product.

**Note:** The results of the Positive Control amplification will be stored by the instrument **ELITE InGenius®** and used to create a Control Chart. For each batch of **CMV RNA ELITE MGB Kit** product the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

**Note:** The **CMV RNA Positive Control** can be frozen and thawed up to **four times**. The **CMV RNA Positive Control** can be used on the **ELITE InGenius®** instrument up to **four work sessions of three hours each** ("Extract + PCR" run mode).

### REFERENCES

Rawlinson W. D. et al. (1993) *J. Virology* **67**: 5502 - 5513

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Sarcinella E. et al. (2004) *Virus Research* **104**: 129 - 137

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

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### SYMBOLS



Catalogue Number.



Upper limit of temperature.



Batch code.



Use by (last day of month).



Research Use Only.



Contains sufficient for "N" tests.



Attention, consult instructions for use.



Contents.



Manufacturer.