

NOTICE of CHANGE dated 23/05/2023

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:







«CMV RNA ELITE Standard» Ref. STD115ING
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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 Standard

plasmid DNA standard for quantitative assay

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INTENDED USE

The product **CMV RNA ELITE Standard** is an *in vitro* reagent intended to be used by healthcare professionals as known quantity DNA standard 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 Q - PCR Standard**, four stabilized solutions of plasmid DNA at known titre, each aliquoted into **two 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 calculate the standard curve of the system (product batch and instrument) for CMV RNA quantification.

The product contains sufficient material for **8 sessions on ELITE InGenius**, by using 20 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 CMV virion mRNA.

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MATERIALS PROVIDED IN THE PRODUCT

Components	Description	Quantity	Classification of Hazards
CMV RNA Q - PCR Standard 10 ⁵ ref. STD115ING-5	plasmid DNA solution, RED cap	2 x 160 µL	-
CMV RNA Q - PCR Standard 10 ⁴ ref. STD115ING-4	plasmid DNA solution, BLUE cap	2 x 160 µL	-
CMV RNA Q - PCR Standard 10 ³ ref. STD115ING-3	plasmid DNA solution, GREEN cap	2 x 160 µL	-
CMV RNA Q - PCR Standard 10 ² ref. STD115ING-2	plasmid DNA solution, 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 (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 consumable 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_STD** (EG SpA), parameters for the amplification of standard DNA and standard curve calculation.

With the **ELITE InGenius** instrument 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, USA, ref. TF-350-L-R-S),
- boxes **ELITE InGenius® Waste Box** (EG SpA, ref. F2102-000).

WARNINGS AND PRECAUTIONS

This product is exclusively designed for *in-vitro* use.

General warnings and 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.

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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 in the product before running the assay.
While running the assay, follow the instructions provided in the product.
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.

Lab 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 Q - PCR Standard** must be stored at temperature of -20 °C or below.

The **CMV RNA Q - PCR Standard** must be used within one month from the first opening.

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

The **CMV RNA Q - PCR Standard** can be used on the **ELITE InGenius** instrument up to **four work sessions of two hours each** ("PCR Only" run mode).

PROCEDURE

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

Before use, thaw the **CMV RNA Q - PCR Standard** tubes at room temperature (~+25 °C) for 30 minutes. Mix gently, spin down the contents for 5 seconds and keep them on ice.

The **CMV RNA Q - PCR Standard** 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 CMV RNA Q - PCR Standard amplification will be stored by the **ELITE InGenius** instrument. For each batch of **CMV RNA ELITE MGB Kit** product, the calibration curve is required. The stored results of the Q - PCR Standard amplification will expire **after 60 days**.

Note: The **CMV RNA Q - PCR Standard** can be frozen and thawed up to **four times**. The **CMV RNA Q - PCR Standard** can be used on the **ELITE InGenius** instrument up to **four work sessions of two hours each** ("PCR Only" run mode).






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SYMBOLS

- REF** Catalogue Number.
-  Upper limit of temperature.
- LOT** Batch code.
-  Use by (last day of month).
- RUO** Research Use Only.
-  Contains sufficient for "N" tests.
-  Attention, consult instructions for use.
- CONT** Contents.
-  Manufacturer.

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