Instructions for use

CMV RNA ELITe Standard

plasmid DNA standard for quantitative assay



REF STD115ING

UDI 08033891487331

CE 0123

IVD

CHANGE HISTORY

<table>
<tr><th>Rev.</th><th>Notice of change</th><th>Date (dd/mm/yy)</th></tr>
<tr><td>05</td><td>Update of the paragraph: “Other products required”
Update of the paragraph: “Notice to the users”
Update of the paragraph: “References”</td><td>04/09/25</td></tr>
<tr><td>04</td><td>Extension of product use for a period of 60 days after first opening.</td><td>03/06/25</td></tr>
<tr><td>03</td><td>Expansion of use with ELITe BeGenius
New graphics and content setting of the IFU.</td><td>29/11/24</td></tr>
<tr><td>02</td><td>Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements.
NOTE
The lot number shown in the table below, and still on the market as Research Use Only (RUO), will not be recalled. This product can be used as per its expiration date below indicated. If you have this lot, please, use it according to the intended use described in the RUO IFU and only in association with related RTS115ING product (in RUO format as well). Please, contact ELITechGroup staff to obtain RUO IFU.
<table>
<tr><th>PRODUCT REF.</th><th>Lot Number</th><th>Expiry date</th></tr>
<tr><td>STD115ING</td><td>U0524-036</td><td>30/04/2026</td></tr>
</table>
Do not use the new STD115ING product commercialized as CE-IVDR in association with related RTS115ING product still in RUO format.
The use of the new STD115ING product commercialized as CE-IVDR requires the use of the related CE-IVD Assay Protocols. Please, contact ELITechGroup staff for any additional information needed.</td><td>03/06/24</td></tr>
<tr><td>00–01</td><td>new product development and subsequent changes</td><td>-</td></tr>
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1 INTENDED USE

The product **CMV RNA ELITe Standard** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as a known quantity DNA standard in nucleic acids reverse transcription and Real-Time PCR assay 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®** and **ELITe BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **CMV RNA Q - PCR Standard**, four levels of Tris-HCl and EDTA stabilized solutions of plasmid DNA at known titre, each aliquoted into **two ready-to use test tubes**.

The plasmid DNA contains the spliced region of **UL21.5 CMV mRNA**. The detection and quantification of the CMV RNA using **CMV RNA ELITe MGB Kit** product in association with **ELITe InGenius** and **ELITe BeGenius** instruments, allows to calculate the Calibration Curve of the system (product batch and instrument) for CMV RNA quantification.

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius and ELITe BeGenius**, (4 sessions each tube), with 20 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 virion mRNA of CMV.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Components	Description	Quantity	Classification of Hazards
CMV RNA Q - PCR Standard 10^5 ref. STD115ING-5	plasmid DNA solution in tube with **RED cap**	**2 x 160 µL**	-
CMV RNA Q - PCR Standard 10^4 ref. STD115ING-4	plasmid DNA solution in tube with **BLUE cap**	**2 x 160 µL**	-
CMV RNA Q – PCR Standard 10^3 ref. STD115ING-3	plasmid DNA solution in tube with **GREEN cap**	**2 x 160 µL**	-
CMV RNA Q - PCR Standard 10^2 ref. STD115ING-2	plasmid DNA solution in tube with **YELLOW 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) **CMVRNA ELITe_STD**, Assay Protocol with parameters for Calibrators analysis.	**CMV RNA ELITe MGB Kit** (EG SpA, ref. RTS115ING) **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) **CMVRNA ELITe_Be _STD**, Assay Protocol with parameters for Calibrators 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 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 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)
CMV RNA Q — PCR Standard	-20°C or below	60 days	up to four	up to four separate sessions* of two hours each

* with intermediate freezing.

7 PROCEDURE

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

The components **CMV RNA Q - PCR Standard** are ready to use: a volume of **20 µL each** is directly added to the complete reaction mixture (**CMV RNA PCR Mix** and **RT-EnzymeMix**, components of **CMV RNA ELITe MGB Kit**) by the instrument.

Before use, take and thaw the **CMV RNA Q - PCR Standard** tubes at room temperature (+16 / +26 °C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep them on ice or in a cool block.

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

NOTE

The results of the **CMV RNA Q - PCR Standard** will be stored by the ELITe InGenius and ELITe BeGenius instruments and used to calculate the calibration curve. For each lot of **CMV RNA ELITe MGB Kit**, the calibration curve is required. The stored results of the Q - PCR Standard amplification will expire after **60 days**.

8 REFERENCES

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

G. Gerna et al. (2019) *Expert Opinion on Pharmacotherapy* 20: 1429 - 1438

I. Cassaniti et al. (2021) *Am. J. Transplantat.* 21: 1622 - 1628

C. N. Kotton et al. (2025) *Transplantation* 1; 109(7):1066-1110

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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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