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EMPOWERING IVD

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NOTICE of CHANGE dated 08/06/22

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«CMV ELITe Standard»
Ref. STD015PLD

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

- *Extension of the use of the product in association with «ELITe BeGenius®» instrument (REF INT040).*

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
	DIESE FASSUNG DER GEBRAUCHSANLEITUNG IST KOMPATIBEL MIT DER VORHERIGEN VERSION DES TESTKITS

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CMV ELITe Standard

plasmid DNA control for quantitative assay

REF STD015PLD

CE 0344 IVD

-20°C

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INTENDED USE

The **«CMV ELITe Standard»** product is intended for use as positive control and as a known quantity DNA standard in quantitative nucleic acids amplification assays for the **detection and quantification of the DNA of human Cytomegalovirus (CMV)** with **«CMV ELITe MGB® Kit»** product manufactured by ELITechGroup S.p.A.

PRODUCT DESCRIPTION

The product supplies the **Q - PCR Standard**, four stabilized solutions of plasmid at **known titre***, each aliquoted into a **ready to use test tube**. Each tube contains 200 µL of solution, sufficient for **4 sessions** (PCR only) in association with the systems **«ELITe InGenius®»** and **«ELITe BeGenius®»** and **8 sessions** in association with the other systems validated.

The plasmid contains the amplified region of **exon 4 of the MIEA gene** of CMV. Detection of target DNA in the real time amplification reaction attests the product ability to detect the CMV DNA and allows to calculate the standard curve.

The product is sufficient for **4 separate analytic sessions** in association with the **«ELITe InGenius®»** and **«ELITe BeGenius®»** and **8 separate analytic sessions** in association with the other systems, by using 20 µL for reaction.

* The Q - PCR Standard titre was determined by using calibrated reference materials (QCMD 2009 *Human Cytomegalovirus* DNA EQA Panel, Qnostics Ltd, Scotland, United Kingdom and OptiQuant CMV DNA, AcroMetrix Europe B.V., the Netherlands). A conversion factor allows to calculate quantitative results in CMV International Units of "1st WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification (NAT) Techniques" (NIBSC code 09/162, United Kingdom).

MATERIALS PROVIDED IN THE PRODUCT

Components	Description	Quantity	Classification and Labelling
CMV Q - PCR Standard 10^5	plasmid solution in tube with **RED cap**	1 x 200 µL	-
CMV Q - PCR Standard 10^4	plasmid solution in tube with **BLUE cap**	1 x 200 µL	-
CMV Q - PCR Standard 10^3	plasmid solution in tube with **GREEN cap**	1 x 200 µL	-
CMV Q - PCR Standard 10^2	plasmid solution in tube with **YELLOW cap**	1 x 200 µL	-

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless gloves in nitrile or similar material.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (0.5-10 µL, 2-20 µL, 5-50 µL, 50-200 µL, 200-1000 µL).
- Molecular biology grade water.
- Programmable thermostat with optical fluorescence detection system 7300 Real Time PCR System or 7500 Fast Dx Real Time PCR Instruments, calibrated following manufacturer's instructions.
- Programmable thermostat with optical fluorescence detection system cobas z 480 analyzer, calibrated following manufacturer's instructions.

OTHER PRODUCTS REQUIRED

The reagents for the amplification reaction and the consumable **are not** included in this product.

To perform these analytical steps, the product **«CMV ELITe MGB® Kit»** (ELITechGroup S.p.A., ref. RTK015PLD), it is required. This is a complete and ready to use reaction mixture for real time amplification in a stabilising solution.

In association with «**ELITe InGenius®**» (ELITechGroup S.p.A, ref. INT030) and «**ELITe BeGenius®**» (ELITechGroup S.p.A, ref. INT040), it is required the use of generic product «**ELITe InGenius® PCR Cassette**» (ELITechGroup S.p.A, ref. INT035PCR). These are dedicated consumables for Real Time PCR reactions.

When a 7300 Real-Time PCR System is used, it is recommended the use of generic product **«Q - PCR Microplates»** (ELITechGroup S.p.A., ref. RTSACC01), microplates with 0.2 mL wells and adhesive sealing sheets for real time amplification.

When a 7500 Fast Dx Real-Time PCR Instrument is used, it is recommended the use of generic product: **«Q - PCR Microplates Fast»** (ELITechGroup S.p.A., ref. RTSACC02), microplates with 0.1 mL wells and adhesive sealing sheets for real time amplification.

When a cobas z 480 analyzer is used, it is required the use of generic product **«AD-plate 0.3ml»** (Roche, ref. 05232724001), microplates with 0.3 mL wells and adhesive sealing sheets for real time amplification.

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 able to transmit infective agents. 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 or autoclaved for one hour at 121°C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. 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 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, such as nucleic acids extraction, amplification and detection, require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

When amplification session is manually setup, it is necessary to have available separate areas for the extraction / preparation of amplification reactions and for the amplification / detection of amplification products. Never introduce an amplification product in the area designated for extraction / preparation of amplification reactions.

When amplification session is manually setup, it is necessary to have available lab coats, gloves and tools which are exclusively used for the extraction / preparation of the amplification reactions and for the amplification / detection of amplification products. Never transfer lab coats, gloves or tools from the area designated for the amplification / detection of amplification products to the area designated for the extraction / preparation of the amplification reactions.

The samples must be exclusively used for this type of analysis. Samples must be handled under a laminar airflow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively used for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips used must be sterile, free from DNases and RNases, free from DNA and RNA.

The reagents must be handled under a laminar airflow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. 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, free from DNA and RNA.

Amplification products must be handled in such a way as to reduce as much as possible dispersion into the environment in order to avoid the possibility of contamination. The pipettes used to handle amplification products must be exclusively used for this purpose.

Warnings and precautions specific for the components

The **CMV Q - PCR Standard** is designed to be frozen and thawed for no more than **eight times**. Further freezing / thawing cycles may cause a loss in titre.

The **CMV Q - PCR Standard** can be kept on board on «**ELITe InGenius®**» and «**ELITe BeGenius®**» up to **four work sessions of two hours each** (“PCR Only” run mode).

CMV ELITe Standard
plasmid DNA control for quantitative assay

REF **STD015PLD**

PROCEDURE

The **«CMV ELITe Standard»** product must be used with the complete reaction mixture of the **«CMV ELITe MGB® Kit»** product.

Before use, take and thaw the **CMV Q - PCR Standard** tubes. Mix gently, spin down the contents for 5 seconds and keep them on ice.

The **CMV Q - PCR Standard** is ready to use: **20 µL** must be directly added to the reaction mixture.

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

Note: In association to **«ELITe InGenius®»** and «**ELITe BeGenius®**», the calibration curve is stored by the instrument. For each batch of product **«CMV ELITe MGB® Kit»** is required calibration curve that will expire after **60 days**.

Note: The **CMV Q - PCR Standard** can be frozen and thawed for no more than **eight times.** The **CMV Q - PCR Standard** can be kept on board on «**ELITe InGenius®»** and «**ELITe BeGenius®**», up to **four work sessions of two hours each** (“PCR Only” run mode).

REFERENCES

T. E. Fenner et al. (1991) *J Clin Microbiology* 29: 2621 - 2622

SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	*in vitro* diagnostic medical device.
CE 0344	Fulfilling the requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device. Certification released by DEKRA Certification B.V., the Netherland.
	Contains sufficient for "N" tests.
	Attention, consult instructions for use.
CONT	Contents.
	Manufacturer.