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EMPOWERING IVD

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NOTICE of CHANGE dated 03/06/2024

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«PVB19 - ELITe Positive Control» Ref. CTR070PLD

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

- *Formal corrections.*
- *Addition of UDI information.*

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



Parvovirus B19 - ELITE Positive Control
 plasmidic DNA control for quantitative assay

REF CTR070PLD

*Note: Standard DNA concentration was determined by spectrophotometer by absorbance measurement of the plasmid DNA preparation. This standard DNA was related to the "3rd WHO International Standard for Parvovirus B19 DNA for Nucleic Acid Amplification (NAT) Assay" (NIBSC, code 12/208, United Kingdom). With a conversion factor to International Unit as reported in instruction for use of the **Parvovirus B19 ELITE MGB Kit** product.

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UDI 08033891483524

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INTENDED USE

The product **Parvovirus B19 - ELITE Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as a known quantity DNA positive control in nucleic acids Real-Time PCR assays for the detection and quantification of the DNA of Parvovirus B19 human virus (PVB19) in association with **Parvovirus B19 ELITE MGB® Kit** and the **ELITE InGenius®** and **ELITE BeGenius®** instruments, the **7300 Real-Time PCR System** and the **7500 Real-Time PCR Instrument**.

PRODUCT DESCRIPTION

The product supplies the **PVB19 Positive Control**, plasmid DNA at known titre in a stabilizing solution based on Tris-HCl and EDTA, aliquoted into **two ready-to-use test tubes**.

The plasmid DNA contains a region of the gene coding for the **capsidic protein VP1** of Parvovirus B19. The detection and quantification of target DNA, using **Parvovirus B19 ELITE MGB Kit** product in association with **ELITE InGenius** and **ELITE BeGenius**, the **7300 Real-Time PCR System** and the **7500 Real-Time PCR Instrument**, attests the system ability to detect the DNA of the target gene and consequently the verification of the system (product batch and instrument).

The product contains sufficient reagents for **8 separate sessions** on **ELITE InGenius** and **ELITE BeGenius** (4 sessions each tube), **12 separate sessions** in association with the system **ELITE GALAXY**, and **14 separate sessions** in association with the other systems, with 20 µL used per reaction.

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazards
PVB19 - Positive Control ref.CTR070PLD	plasmid DNA solution in tube with black 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 (~13,000 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.
- Programmable thermostat with optical fluorescence detection system 7300 Real Time PCR System or 7500 Fast Dx Real-Time PCR Instrument calibrated following manufacturer's instructions.

OTHER PRODUCTS REQUIRED

The reagents for Real-Time amplification and the consumables **are not** included in this product. To perform the assay the following products are required:

Instruments and softwares	Products and reagents
ELITE InGenius (ELITechGroup S.p.A., EG SpA ref. INT030)	Parvovirus B19 ELITE MGB Kit (EG SpA, ref. RTS070PLD)
ELITE InGenius Software version 1.3.0.17 (or later)	ELITE InGenius PCR Cassette (EG SpA, ref. INT035PCR).
PVB19 ELITE_PC , Assay Protocol with parameters for Positive Control analysis	ELITE InGenius Waste Box (EG SpA, ref. F2102-000)
ELITE BeGenius (EG SpA ref. INT040)	300 µL Filter Tips Axygen (Corning Life Sciences Inc., ref. TF-350-L-R-S) with ELITE InGenius only
ELITE BeGenius Software version 2.1.0. (or later)	1000 µL Filter Tips Tecan (Tecan, Switzerland, ref. 30180118) with ELITE BeGenius only
PVB19 ELITE_Be_PC , Assay Protocol with parameters for Positive Control analysis	Parvovirus B19 ELITE MGB Kit (EG SpA ref. RTS070PLD)
7300 Real-Time PCR System (ThermoFisher Scientific, ref. 4351101)	MicroAmp™ Optical 96-Well Reaction Plate (Life Technologies, ref. N8010560)
7500 Fast Dx Real-Time PCR Instrument (ThermoFisher Scientific, ref. 4406985)	Parvovirus B19 ELITE MGB Kit (EG SpA ref. RTS070PLD) «MicroAmp™ Fast Optical 96-Well Reaction Plate» with Barcode, 0.1 mL (Life Technologies, ref. 4346906)

WARNINGS AND PRECAUTIONS

This product is designed for *in vitro* use only.

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.

Warnings and precautions for molecular biology

Molecular biology procedures, require qualified and trained staff to avoid the risk of erroneous results, especially due sample nucleic acids degradation or sample contamination by PCR 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.

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, free from DNA and RNA.

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

Warnings and precautions specific for the components

Component	Storage temperature	Use from first opening	Freeze / thaw cycles	On board stability (ELITE InGenius and ELITE BeGenius)
PVB19 Positive Control	-20°C or below	one month	up to seven	up to four separate sessions* of three hours each

* with intermediate freezing

PROCEDURE

The product **Parvovirus B19 - ELITE Positive Control** must be used in association with the product **Parvovirus B19 ELITE MGB Kit**.

The component **PVB19 Positive Control** is ready for use: a volume of **20 µL** is directly added to the reaction mixture (**PVB19 PCR Mix**, component of the **Parvovirus B19 ELITE MGB Kit**) by the instrument **ELITE InGenius** or **ELITE BeGenius**, or manually when other instruments are used.

Before use, take and thaw the **PVB19 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 **Parvovirus B19 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 **Parvovirus B19 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 **Parvovirus B19 ELITE MGB Kit** the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

REFERENCES

F. McOmish et al. (1993) *J. Clin. Microbiol.* 31: 323 - 328

SYMBOLS

-  REF Catalogue Number.
-  Upper limit of temperature.
-  LOT Batch code.
-  Use by (last day of month).
-  IVD *in vitro* diagnostic medical device.
-  CE Fulfilling the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical device.
-  Σ Contains sufficient for "N" tests.
-  UDI Unique Device Identification
-  Caution, consult instructions for use.
-  CONT Contents.
-  Manufacturer.

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