

Instructions for use

Parvovirus B19 — ELITe Positive Control

plasmid DNA control for quantitative assay



REF CTR070PLD

UDI 08033891483524

CE **IVD**
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CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
14-R	Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements . Update of the Intended use: Validation of the products in association with ELITe InGenius (REF INT030) and ELITe BeGenius (REF INT040) instruments NOTE Composition of the product remains unchanged New graphics and content setting of the IFU.	30/01/26
13	Addition of UDI information	03/06/24
12	Update for the use of the product in association with «ELITe BeGenius®» instrument (REF INT040).	28/01/22
11	The volume of positive control passed from 4 x 65 µL to 2 x 160 µL	13/07/17
00-10	new product development	-

NOTE

The product batches identified by the following LOT numbers are still placed on the market as per IVDD till to their expiration dates, according to Article 110 of IVDR. If you have those product batches, please contact ELITechGroup staff to request the related previous revision of IFUs.

Those batches of Positive Control are technically compatible with the new IVDR version of the amplification kit and can be used, until exhausted, in association with the new IVDR version of the amplification kit and in accordance with its intended use.

<u>PRODUCT REF.</u>	<u>Lot Number</u>	<u>Expiry date</u>
CTR070PLD	U0624-004	30/06/26
CTR070PLD	U0225-022	28/02/27
CTR070PLD	U0925-039	30/09/27

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1 INTENDED USE

The product **Parvovirus B19 — ELITe Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as 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.

2 PRODUCT DESCRIPTION

The product supplies the **PVB19 Positive Control**, a 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 the amplified region of the gene codifying 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** instruments, attests the system ability to detect the DNA of the target gene and consequently the verification of the system.

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius** and **ELITe BeGenius** with 20 µL used per reaction.

NOTE

*The titre was determined by spectrophotometer by absorbance measurement of the plasmid DNA preparation. A conversion factor allows to calculate quantitative results in PVB19 International Units of "3rd WHO International Standard for Parvovirus B19 DNA for Nucleic Acid Amplification (NAT) Assay" (NIBSC, code 12/208, United Kingdom).

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Components	Description	Quantity	Classification of Hazards
PVB19 — Positive Control ref. CTR070PLD	plasmid DNA solution in tube with natural 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 2-200 µL).
- Molecular biology grade water.

5 OTHER PRODUCTS REQUIRED

The reagents for Real-Time amplification reaction 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) PVB19 ELITe_PC , Assay Protocol with parameters for Positive Control analysis.	Parvovirus B19 ELITe MGB Kit (EG SpA, ref. RTS070PLD) 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) PVB19 ELITe_Be_PC , Assay Protocol with parameters for Positive Control 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 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)
PVB19 — Positive Control	-20°C or below	one month	up to four	up to four separate sessions* of three hours each

* with intermediate freezing.

7 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 to use: a volume of **20 µL** is directly added to the reaction mixture (**PVB19 Q — PCR Mix**, component of the **Parvovirus B19 ELITE MGB Kit**) by the instrument.

Before use, take and thaw the **PVB19 — Positive Control** 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 **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 the **Parvovirus B19 — ELITE 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**

8 REFERENCES

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

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

9 SYMBOLS



Catalogue Number.



Upper limit of temperature.



Batch code.



Use by (last day of month).



in vitro diagnostic medical device.



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.



Unique Device Identification



Contains sufficient for "N" tests.



Consult instructions for use.



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.



ELITechGroup S.p.A.
C.so Svizzera, 185, 10149 Torino ITALY
Tel. +39-011 976 191
Fax +39-011 936 76 11
E. mail: emd.support@elitechgroup.com
WEB site: www.elitechgroup.com