

NOTICE of CHANGE dated 03/06/2024

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:







«PVB19 ELITe Standard» Ref. STD070PLD

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



Parvovirus B19 ELITE Standard

plasmid DNA standard for quantitative assay

REF STD070PLD

IVD 08033891483715



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INTENDED USE

The product **Parvovirus B19 ELITE Standard** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as known quantity DNA standard in nucleic acids Real-Time PCR assay 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 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 a region of the gene coding 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**, allows to calculate the Calibration Curve.

The product contains sufficient reagents for **8 separate sessions** on **ELITE InGenius** and **ELITE BeGenius** (4 sessions each tube), and **16 separate sessions** in association with the other systems, with 20 µL used per reaction.

Parvovirus B19 ELITE Standard plasmid DNA standard for quantitative assay

REF STD070PLD

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.

MATERIALS PROVIDED IN THE PRODUCT

Components	Description	Quantity	Classification of Hazards
PVB19 Q - PCR Standard 10 ⁵ ref. STD070PLD-5	plasmid DNA solution in tube with RED cap	2 x 200 µL	-
PVB19 Q - PCR Standard 10 ⁴ ref. STD070PLD-4	plasmid DNA solution in tube with BLUE cap	2 x 200 µL	-
PVB19 Q - PCR Standard 10 ³ ref. STD070PLD-3	plasmid DNA solution in tube with GREEN cap	2 x 200 µL	-
PVB19 Q - PCR Standard 10 ² ref. STD070PLD-2	plasmid DNA solution in tube with YELLOW cap	2 x 200 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) ELITE InGenius Software version 1.3.0.17 (or later) PVB19 ELITE STD , Assay Protocol with parameters for Calibrators analysis	Parvovirus B19 ELITE MGB Kit (EG SpA, ref. RTS070PLD) ELITE InGenius PCR Cassette (EG SpA, ref. INT035PCR), ELITE InGenius Waste Box (EG SpA, ref. F2102-000)
ELITE BeGenius (EG SpA ref. INT040) ELITE BeGenius Software version 2.1.0. (or later) PVB19 ELITE Be STD , Assay Protocol with parameters for Calibrators analysis	300 µL Filter Tips Axygen (Corning Life Sciences Inc., ref. TF-350-L-R-S) with ELITE InGenius only 1000 µL Filter Tips Tecan (Tecan, Switzerland, ref. 30180118) with ELITE BeGenius only
7300 Real-Time PCR System (ThermoFisher Scientific, ref. 4351101)	Parvovirus B19 ELITE MGB® Kit (EG SpA ref. RTS070PLD) MicroAmp™ Optical 96-Well Reaction Plate (LifeTechnologies, 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 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 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 Q – PCR Standard	-20°C or below	one month	up to eight	up to four separate sessions* of two hours each

* with intermediate freezing

PROCEDURE

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

The components **PVB19 Q - PCR Standard** are ready to use: a volume of **20 µL** is directly added to the reaction mixture (**PVB19 Q PCR Mix**, component of **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 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 **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 **PVB19 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 **Parvovirus B19 ELITE MGB Kit**, the calibration curve is required. The stored results of the Q-PCR Standard amplification will expire **after 60 days**.

REFERENCES

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

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 European Directive 98\79\EC for *in vitro* diagnostic medical device.



Unique Device Identification



Contains sufficient for "N" tests.



Caution, consult instructions for use.



Contents.



Manufacturer.

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