Instructions for use

Pneumocystis ELITe Standard

plasmid DNA standard for quantitative assay

REF STD150ING

UDI 08033891486747

CE 0123

IVD

CHANGE HISTORY

Revision	Notice of change	Date (dd/mm/yyyy)
04–R	Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements . Update of the Intended use.	09/03/2026
03	Update of the paragraph “Other product required”. Update of the paragraph “Notice to the users”. Update of the paragraph “Warnings and precautions”. Update of the paragraph “Symbols” with the symbol “Consult instructions for use”	09/09/2025
02	New graphics and content setting of the IFU	25/07/2024
01	Update for the use of the product in association with «ELITe BeGenius®» instrument (REF INT040)	15/05/2023
00	New product development	09/11//2019

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 Standard 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.

PRODUCT REF.	Lot Number	Expiry date
STD150ING	U0425–107	30/04/2027
STD150ING	U0725–064	31/07/2027
STD150ING	U1125–073	31/07/2027

TABLE OF CONTENT

1 INTENDED USE

The product **Pneumocystis 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 Real-Time PCR assays for the detection and quantification of the genomic DNA of **Pneumocystis *jirovecii* (PJ)**, in association with **Pneumocystis ELITe MGB® Kit** product and **ELITe InGenius®** and **ELITe BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **PJ 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 region of **mtLSU** gene of PJ. The detection and quantification of target DNA, using **Pneumocystis ELITe MGB Kit** product in association with the **ELITe InGenius** and the **ELITe BeGenius** instruments, allows to calculate the Calibration Curve of the system (product batch and instrument) for PJ DNA 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 DNA concentration in copies/mL was determined through absorbance measurement by spectro-photometer. There are no WHO approved standards for the target genomic DNAs.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Components	Description	Quantity	Classification of Hazards
PJ Q - PCR Standard 10^5 ref. STD150ING-5	plasmid DNA solution in tube with **RED cap**	**2 x 200 µL**	-
PJ Q - PCR Standard 10^4 ref. STD150ING-4	plasmid DNA solution in tube with **BLUE cap**	**2 x 200 µL**	-
PJ Q – PCR Standard 10^3 ref. STD150ING-3	plasmid DNA solution in tube with **GREEN cap**	**2 x 200 µL**	-
PJ Q - PCR Standard 10^2 ref. STD150ING-2	plasmid DNA solution in tube with **YELLOW cap**	**2 x 200 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 Real-Time PCR 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) **PJ ELITe_STD**, Assay Protocol with parameters for Calibrators analysis.	**Pneumocystis ELITe MGB Kit** (EG SpA, ref. RTS150ING) **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) **PJ 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 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)
PJ Q — PCR Standard	-20°C or below	one month	up to four	up to four separate sessions* of two hours each

* with intermediate freezing.

7 PROCEDURE

The product **Pneumocystis ELITe Standard** must be used in association with the product **Pneumocystis ELITe MGB Kit**.

The components **PJ Q — PCR Standard** are ready to use: a volume of **20 µL each** is directly added to the reaction mixture (**PJ PCR Mix**, component of **Pneumocystis ELITe MGB Kit**) by the instrument ELITe InGenius or ELITe BeGenius.

Before use, take and thaw the **PJ 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 **Pneumocystis 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 **Pneumocystis ELITe MGB Kit**.

NOTE

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

8 REFERENCES

C. Valero et al. (2016) *Front. Microbiol*. 7:1413

M. Maillet et al. (2014) *Eur J Clin Microbiol Infect Dis*.33(3):331-6

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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