Instructions for use

JCV ELITe Standard

plasmid DNA standard for quantitative assay

ELITechGroup
A BRUKER COMPANY

REF STD176PLD

UDI 08033891484491

CE 0123

IVD

CHANGE HISTORY

Revision	Notice of change	Date (dd/mm/yy)
09-R	Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements. Update of the Intended use.	25/03/25
08	New graphics and content setting of the IFU	13/11/24
07	Extended use of the product in association with «ELITe BeGenius®» instrument (REF INT040) .	23/06/22
00–06	New product development and subsequent changes	-

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
STD176PLD	U0723-169	31/07/2025
STD176PLD	U1024-011	31/08/2026
STD176PLD	U0325-101	28/02/2027

TABLE OF CONTENT

1 INTENDED USE

The product **JCV ELITe Standard** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as known quantity DNA standard in quantitative nucleic acids Real-Time PCR assays for the **detection and quantification of the DNA of human Polyomavirus JC (JCV),** in association with **JCV ELITe MGB® Kit** product and the **ELITe InGenius®** and **ELITe BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **JCV Q - PCR Standard**, four stabilized solutions of plasmid at **known titre**, each aliquoted into **two ready to use test tubes**.

The plasmid DNA contains the **Large T antigen region of the JCV gene.**

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius** and **ELITe BeGenius**, (4 sessions each tube), with 10 µL used per reaction.

NOTE

Standard DNA concentration was determined by spectrophotometer by absorbance measurement of the plasmidic DNA preparation. This standard DNA was related to the "1st WHO International Standard for JC Virus DNA" (NIBSC, code 14/114, United Kingdom) with a conversion factor to International Unit as reported in instruction for use of the product JCV ELITe Standard.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Components	Description	Quantity	Classification of Hazards
JCV Q - PCR Standard 10^5 ref. STD176PLD-5	plasmid DNA solution intube with **RED cap**	**2 x 160 µL**	-
JCV Q - PCR Standard 10^4 ref. STD176PLD-4	plasmid DNA solution intube with **BLUE cap**	**2 x 160 µL**	-
JCV Q - PCR Standard 10^3 ref. STD176PLD-3	plasmid DNA solution intube with **GREEN cap**	**2 x 160 µL**	-
JCV Q - PCR Standard 10^2 ref. STD176PLD-2	plasmid DNA solution intube with **YELLOW 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 (0.5-10 µL, 2-20 µL, 5-50 µL, 50-200 µL, 200-1000 µL).
- 2.0 mL sterile screw capped tubes (Sarstedt, Germany, ref. 72.694.005)
- 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) **JCV ELITe_STD**, Assay Protocol with parameters for Calibrators analysis.	**JCV ELITe MGB Kit** (EG SpA, code RTS176PLD) **ELITe InGenius PCR Cassette** (EG SpA, ref. INT035PCR) **ELITe InGenius Waste Box** (EG SpA, ref. F2102-000) **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
ELITe BeGenius (EG SpA, ref. INT040) **ELITe BeGenius Software** version 2.2.1 (or later) **JCV 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 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, and 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.

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)
JCV 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 **JCV ELITe Standard** must be used in association with the product **JCV ELITe MGB Kit**.

The components **JCV Q - PCR Standard** are ready to use: a volume of 10 µL each is directly added to the reaction mixture (**JCV Q PCR Mix**, component of **JCV ELITe MGB Kit**) by the instrument.

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

NOTE

The results of the **JCV 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 **JCV ELITe MGB Kit**, the calibration curve is required. The stored results of the Q-PCR Standard amplification will expire after 60 days.

8 REFERENCES

P. Ferrante et al. (1995) J Med Vir 47: 219 - 225

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. At the moment of the current revision of the IFU, no serious incident or recall with impact on product performance and safety of the device has occurred.

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