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NOTICE of CHANGE dated 04/04/2025

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«BKV ELITe Standard»
Ref. STD175PLD

The BKV ELITe Standard (Ref. STD175PLD) product batches still placed on the market as per IVDD (identified by the LOT numbers reported in this Standard IFU) are technically compatible with the new IVDR version of the amplification kit BKV ELITe MGB® Kit (Ref. RTS175PLD) and can be used, until exhausted, in association with the new IVDR version of the amplification kit and in accordance with its intended use.

Instructions for use

BKV ELITe Standard

plasmid DNA standard for quantitative assay

ELITechGroup
A BRUKER COMPANY

REF STD175PLD

UDI 08033891483746

CE 0123

IVD

CHANGE HISTORY

<table>
<tr><th>Rev.</th><th>Notice of change</th><th>Date (dd/ mm/yy)</th></tr>
<tr><td>15–R</td><td>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
• Validation of the products in association with the ABI 7500 Fast Dx Real-Time PCR Instrument.
NOTE
Composition of the product remains unchanged
NOTE
The following product batches are still placed on the market as per IVDD till to their expiration dates, according to Article 110 of IVDR. If you have these product batches, please contact ELITechGroup staff to request the related previous version of IFUs
<table><tr><th>PRODUCT REF.</th><th>Lot Number</th><th>Expiry date</th></tr><tr><td>STD175PLD</td><td>U0124-057</td><td>31/12/2025</td></tr></table>New graphics and content setting of the IFU.</td><td>26/09/24</td></tr>
<tr><td>14</td><td>Extended Use of the product in association with «ELITe BeGenius®» instrument REF INT040).</td><td>22/10/21</td></tr>
<tr><td>13</td><td>Extended Use of the product with the platform Roche cobas z 480 analyzer</td><td>25/01/21</td></tr>
<tr><td>12</td><td>The number of analytical sessions that could be performed in association with “ELITe InGenius“ system or in association with the other validated systems has been specified.</td><td>19/07/19</td></tr>
<tr><td>00–11</td><td>New product development and succeeding changes</td><td>-</td></tr>
</table>

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1 INTENDED USE

The product **BKV 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 assays for the detection and quantification of the DNA of human Polyomavirus BK (BKV) in association with **BKV ELITe MGB® Kit** and **ELITe InGenius®** , **ELITe BeGenius®** and **7500 Fast Dx Real-Time PCR** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **BKV Q - PCR Standard**, four levels of Tris-HCl and EDTA stabilized solutions of plasmid DNA at known titre, each aliquoted into a **two ready- to use test tubes**.

The plasmid DNA contains the amplified region of the gene codifying the **Large T antigen** of BKV. The detection and quantification of target DNA using the **BKV ELITe MGB Kit** product in association with **ELITe InGenius** and **ELITe BeGenius instruments,** and **with the 7500 Fast Dx Real-Time PCR** instrument, allows to calculate the Calibration Curve for BKV DNA quantification.

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius** and **ELITe BeGenius** and **16 separate sessions** on the other systems, 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 EBV International Units of "1st WHO International Standard for BK Virus DNA" (NIBSC, code 14/212, United Kingdom).

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Components	Description	Quantity	Classification of Hazards
BKV Q - PCR Standard 10^5 ref. STD175PLD-5	plasmid DNA solution in tube with **RED cap**	**2 x 200 µL**	-
BKV Q - PCR Standard 10^4 ref. STD175PLD-4	plasmid DNA solution in tube with **BLUE cap**	**2 x 200 µL**	-
BKV Q – PCR Standard 10^3 ref. STD175PLD-3	plasmid DNA solution in tube with **GREEN cap**	**2 x 200 µL**	-
BKV Q - PCR Standard 10^2 ref. STD175PLD-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 (2-20 µL, 5-50 µL, 50-200 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) **BKV ELITe_STD**, Assay Protocol with parameters for Calibrators analysis.	**BKV ELITe MGB Kit** (EG SpA, ref. RTS175PLD) **ELITe InGenius PCR Cassette** (EG SpA, ref. INT035PCR) **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 InGenius Waste Box** (EG SpA, ref. F2102-000)
ELITe BeGenius (EG SpA, ref. INT040) **ELITe BeGenius Software** version 2.2.1 (or later) **BKV ELITe_Be_STD**, Assay Protocol with parameters for Calibrators analysis.	
7500 Fast Dx Real-Time PCR Instrument (ThermoFisher Scientific, ref. 4406985) **ELITe GALAXY** (EG SpA, ref. INT020)	**BKV ELITe MGB Kit** (EG SpA, ref. RTS175PLD) **MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL** (Life Technologies, ref. 4346906), microplates with 0.1 mL wells and adhesive sealing sheets for real time amplification.

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.

When the amplification session has to be performed with the 7500 Fast Dx Real-Time PCR Instrument, 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, and free from DNA and RNA.

After the amplification session, the Reaction Plate and 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)
BKV Q — PCR Standard	-20°C or below	one month	up to eight	up to four separate sessions* of two hours each

* with intermediate freezing.

7 PROCEDURE

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

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

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

NOTE

The results of the **BKV ELITe Standard** will be stored by the ELITe InGenius and ELITe BeGenius instruments and used to calculate the calibration curve. For each lot of **BKV 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.

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