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NOTICE of CHANGE dated 13/04/2026

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«BKV - ELITe Positive Control RF»
Ref. CTR175PLD-R

For use of the product BKV - ELITe Positive Control RF (Ref. CTR175PLD-R) in association with the Roche instrument cobas z 480 analyzer, please refer to the instructions provided in the Instruction for Use manual of the product BKV ELITe MGB Kit (Ref. RTS175PLD) in its IVDD version (SCH mRTS175PLD_20). This manual, if not available, has to be requested to the ELITechGroup staff.

The product CTR175PLD-R, placed on the market as per IVDD, is compatible with the IVDR version of the amplification kit RTS175PLD, and can be used in accordance with the indications reported in the above-mentioned manual.

ELITechGroup
EMPOWERING IVD

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BKV - ELITe Positive Control RF

plasmid DNA control for qualitative assay

REF CTR175PLD-R CE -20°C

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INTENDED USE

The **«BKV - ELITe Positive Control RF»** product is intended for use as amplification positive control in qualitative nucleic acids amplification assays for the **detection of the DNA of human Polyomavirus BK (BKV)** with the **«BKV ELITe MGB® Kit»** product manufactured by ELITechGroup S.p.A. and the **Roche cobas z 480 analyzer**.

PRODUCT DESCRIPTION

The product supplies the **Positive Control**, a stabilized solution of a plasmid, aliquoted into **one ready to use test tube**. The test tube contains **300 µL** of solution, sufficient for **10 sessions** in association with the **Roche cobas z 480 analyzer** as mentioned in the instruction for use of the **«BKV ELITe MGB® Kit»** product.

The plasmid contains a region of the gene codifying the **Large T antigen** of BKV. Detection of the target DNA in the real time amplification reaction attests the product ability to detect the BKV DNA.

The product is sufficient for **10 separate analytic sessions** in association with the **Roche cobas z 480 analyzer** by using 20 µL per reaction.

BKV - ELITe Positive Control RF
plasmid DNA control for qualitative assay

REF CTR175PLD-R

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification and Labelling
BKV - Positive Control RF	plasmid solution	**1 x 300 µL**	**-**

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable nitrile powder-free gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (12,000 - 14,000 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 cobas z 480 analyzer, calibrated following manufacturer's instructions.

OTHER PRODUCTS REQUIRED

The reagents and consumables for real time amplification **are not** included in this product.

To perform these analytical steps it is required the use of the product **«BKV ELITe MGB® Kit»** (ELITechGroup S.p.A, ref. RTS175PLD), complete and ready for use reaction mixture for real time amplification in a stabilising solution.

When a cobas z 480 analyzer is used, it is required the use of the generic product **«AD-plate 0.3ml»** (Roche, ref. 05232724001), microplates with 0.3 mL wells and adhesive sealing sheets for real time amplification.

WARNINGS AND PRECAUTIONS

This product is exclusively for *in vitro* use.

Warnings and general precautions

This product is not intended to be used in association with the ELITe InGenius® system.

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. 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 the 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 in the product before running the assay.

While running the assay, follow the instructions provided in the product.

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, such as nucleic acids extraction, amplification and detection, require qualified and trained staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

When an 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.

When an amplification session is manually setup, it is necessary to have available lab coats, gloves and tools which are exclusively used for the extraction / preparation of the amplification reactions and for the amplification / detection of amplification products. Never transfer lab coats, gloves or tools from the area designated for the amplification / detection of amplification products to the area designated for the extraction / preparation of the amplification reactions.

The samples must be exclusively used for this type of analysis. Samples must be handled under a laminar airflow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively used for this specific purpose. The pipettes must be of the positive dispensation 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 reagents must be handled under a laminar airflow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. 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.

Amplification products must be handled in such a way as to reduce as much as possible dispersion into the environment in order to avoid the possibility of contamination. The pipettes used to handle amplification products must be exclusively used for this purpose.

Warnings and precautions specific for the components

The **Positive Control** can be frozen and thawed for no more than **10 times**. Further freezing / thawing cycles may cause a loss in titer.

PROCEDURE

The **«BKV - ELITe Positive Control RF»** product must be used with the complete reaction mixture of the **«BKV ELITe MGB® Kit»** product.

Before use, take and thaw the **BKV - Positive Control RF** tube. Mix gently, spin down the content for 5 seconds and keep it on ice.

The **BKV - Positive Control RF** is ready to use: **20 µL** must be directly added to the reaction mixture.

The complete procedure, the performance characteristics and procedure limitations of the complete assay are described in detail in the instructions for use of the **«BKV ELITe MGB® Kit»** product.

REFERENCES

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

SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	*in vitro* diagnostic medical device.
CE	Fulfilling the requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device.
	Contains sufficient for "N" tests.
	Attention, consult instructions for use.
CONT	Contents.
	Manufacturer.