Instructions for use

# ADENOVIRUS ELITe Standard

plasmid DNA standard for quantitative assay

ELITechGroup
A BRUKER COMPANY

REF STD078PLD

UDI 08033891483739

CE 0123

IVD

## CHANGE HISTORY

| Rev. | Notice of change | Date (dd/ mm/yy) |
|---|---|---|
| 14–R | Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements .<br>Update of the Intended use:<br>• Validation of the products in association with ELITe InGenius (REF INT030) and ELITe BeGenius (REF INT040) instruments<br>Composition of the product remains unchanged<br>New graphics and content setting of the IFU. | 06/05/26 |
| 13 | Update of the paragraph “Symbols” with the symbol “Consult instructions for use”. | 13/10/25 |
| 12 | Extension of the use of the product in association with «ELITe BeGenius®» instrument (REF INT040). | 20/05/22 |
| 00–11 | New product development and succeeding 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 |
|---|---|---|
| STD078PLD | U0226-008 | 31/07/2027 |
| STD078PLD | U0925-036 | 31/07/2027 |
| STD078PLD | U0425-037 | 31/12/2026 |

# TABLE OF CONTENT

# 1 INTENDED USE

The product **ADENOVIRUS 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 Adenovirus (ADV) in association with Adenovirus ELITe ELITe MGB® Kit and **ELITe InGenius®** and **ELITe BeGenius®** instruments.

# 2 PRODUCT DESCRIPTION

The product supplies the **ADV 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 **Hexon** protein of ADV. The detection and quantification of target DNA using the **ADENOVIRUS ELITe MGB Kit** product in association with **ELITe InGenius** and **ELITe BeGenius** instruments, allows to calculate the Calibration Curve for ADV DNA quantification.

The product contains sufficient reagents for **8 separate sessions** on **ELITe InGenius** and **ELITe BeGenius**, with 20 µL used per reaction.

| NOTE |
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| Standard DNA concentration was determined by spectrophotometer by absorbance measurement of the plasmid DNA preparation. A conversion factor (Fc) allows to express the results of the quantitative analysis in International Units (IU) of Adenovirus, in accordance with the “1st WHO International Standard for human adenovirus DNA for nucleic acid amplification techniques (NIBSC code: 16/324, United Kingdom)”. |

# 3 MATERIALS PROVIDED IN THE PRODUCT

**Table 1**

| Components | Description | Quantity | Classification of Hazards |
|---|---|---|---|
| **ADV Q - PCR Standard $10^5$ ref. STD078PLD-5** | plasmid DNA solution in tube with **RED cap** | **2 x 200 µL** | - |
| **ADV Q - PCR Standard $10^4$ ref. STD078PLD-4** | plasmid DNA solution in tube with **BLUE cap** | **2 x 200 µL** | - |
| **ADV Q – PCR Standard $10^3$ ref. STD078PLD-3** | plasmid DNA solution in tube with **GREEN cap** | **2 x 200 µL** | - |
| **ADV Q - PCR Standard $10^2$ ref. STD078PLD-2** | plasmid DNA solution in tube with **YELLOW cap** | **2 x 200 µL** | - |

| NOTE |
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| |

# 4 MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (~13,000 RPM).

# 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)<br>**ELITe InGenius Software** version 1.4.0 (or later)<br>**ADV ELITe_STD**, Assay Protocol with parameters for Calibrators analysis. | **ADV ELITe MGB Kit** (EG SpA, ref. RTS078PLD)<br>**ELITe InGenius** and **ELITe BeGenius** Consumables (see ELITe InGenius and ELITe BeGenius Instruction for use) |
| **ELITe BeGenius** (EG SpA, ref. INT040)<br>**ELITe BeGenius Software** version 2.3.0 (or later)<br>**ADV 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) |
|---|---|---|---|---|
| **ADV 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 **ADENOVIRUS ELITe Standard** must be used in association with the product **ADENOVIRUS ELITe MGB Kit**.

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

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

**NOTE**

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

# 8 REFERENCES

Saitoh - Inagawa W. et al. (1996) J. Clin. Microbiol. 34: 2113 - 2116

Wong S. et al. (2008) J. Med. Virol. 80: 856 - 865

E. A. Lukhtanov et al. (2007) *Nucleic Acids Res.* 35: e30

# 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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