ELITechGroup
EMPOWERING IVD

ELITechGroup S.p.A.
C.so Svizzera, 185
10149 Torino ITALY
Offices: Tel. +39-011 976 191 Fax +39-011 936 76 11
E. mail: emd.support@elitechgroup.com
WEB site: www.elitechgroup.com

SARS-CoV-2 Variants - ELITe Positive Control

plasmid DNA control for qualitative assay

REF **CTR171ING** **CE** **IVD** -20°C

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INTENDED USE

The product **«SARS-CoV-2 Variants - ELITe Positive Control»** is intended for use as a positive control in qualitative multiplex nucleic acids amplification assay for the detection and discrimination of the mutations E484K, E484Q and N501Y of the S gene of Severe Acute Respiratory Syndrome Coronavirus 2 (**SARS-CoV-2**) with **«SARS-CoV-2 Variants ELITe MGB® Kit»** product (ELITechGroup S.p.A.).

PRODUCT DESCRIPTION

The product supplies the **CoV-2 Wild Type Positive Control** and the **CoV-2 Mutant Positive Control,** stabilized solutions of plasmids, aliquoted each into **two ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for 4 sessions.

Plasmids contain the regions of **S gene** of SARS-CoV-2 carrying the 484E and 501N codons (Wild Type) or the E484K and N501Y codons (Mutant). The detection and typing of target DNAs as a result of the analysis by **«SARS-CoV-2 Variants ELITe MGB® Kit»** product, attests the system ability to detect and type the cDNA of the target gene.

The product is sufficient for **8 separate analytic sessions,** using 10 µL for reaction.

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
CoV-2 Wild Type Positive Control	plasmid DNA solution, **BLACK** cap	**2 x 160 µL**	**-**
CoV-2 Mutant Positive Control	plasmid DNA solution, **RED** cap	**2 x 160 µL**	**-**

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless nitrile 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.

OTHER PRODUCTS REQUIRED

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

To perform the real time amplification, the product **«SARS-CoV-2 Variants ELITe MGB® Kit»** (ELITechGroup S.p.A, ref. RTS171ING) is required. The product provides the reaction mixtures for reverse transcription of RNA and real-time amplification of cDNA by one-step method.

For the real-time amplification and the result interpretation, the **«ELITe InGenius®»** instrument (ELITechGroup S.p.A., ref. INT030) is required together with the specific Assay Protocol **«SARS-CoV-2 VAR ELITe_PC»** (ELITechGroup S.p.A.), parameters for the amplification and the result interpretation of Positive Control.

With the instrument **«ELITe InGenius®»** the following generic products are required:
- amplification cassettes **«ELITe InGenius® PCR Cassette»** (ELITechGroup S.p.A, ref. INT035PCR),
- tips **«300 µL Filter tips Axygen »** (Axygen BioScience Inc., CA, ref. TF-350-L-R-S),
- boxes **«ELITe InGenius® Waste Box»** (ELITechGroup S.p.A, ref. F2102-000).

WARNINGS AND PRECAUTIONS

This product is intended for *in vitro* use.

Warnings and general precautions

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 neutralised 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 with the product before running the assay.
While running the assay, follow the instructions provided with the product.
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.

Warnings and precautions for molecular biology

Molecular biology procedures 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.

Laboratory coats, gloves and tools dedicated to work session setup are needed.

The reagents must be handled under a laminar airflow hood. The reagents required for reverse transcription and amplification must be prepared for a maximum of three consecutive sessions in association with ELITe InGenius. 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.

The positive control reagent 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 PCR Cassettes must be handled in such a way to reduce as much as possible amplification product diffusion into the environment in order to avoid sample and reagent contamination.

Warnings and precautions specific for the components

The **Positive Control** must be stored at temperature lower than -20 °C.
The **Positive Control** can be frozen and thawed for no more than **four times**: further freezing / thawing cycles may cause a loss of product performance.
The **Positive Control** can be used on the **«ELITe InGenius»** instrument up to **four work sessions of three hours each** (“Extract + PCR” run mode).

PROCEDURE

The **«SARS-CoV-2 Variants - ELITe Positive Control»** product must be used with the complete reaction mixture of the **«SARS-CoV-2 Variants ELITe MGB® Kit»** product.

Before use, take and thaw the **CoV-2 Wild Type Positive Control** tube and the **CoV-2 Mutant Positive Control** tube at room temperature (~+25 °C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep both on ice.

The **CoV-2 Wild Type Positive Control** and the **CoV-2 Mutant Positive Control** are ready to use: a volume of **10 µL** is directly added to the complete reaction mixture.

The complete procedure involves setup and carrying out of a real time amplification reaction and it is described in detail in the instructions for use of the **«SARS-CoV-2 Variants ELITe MGB® Kit»** product.

The performance characteristics and procedure limitations of the complete assay for the detection and discrimination of the mutations E484K, E484Q and N501Y of the S gene are described in detail in the instructions for use of the **«SARS-CoV-2 Variants ELITe MGB® Kit»** product.

Note: The results of the Positive Control amplification will be stored by the instrument **«ELITe InGenius»** and used to create a control chart. For each batch of product **«SARS-CoV-2 Variants ELITe MGB® Kit»** the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

Note: The **CoV-2 Wild Type Positive Control** and the **CoV-2 Mutant Positive Control** can be frozen and thawed for a maximum of **four times**. The **CoV-2 Wild Type Positive Control** and the **CoV-2 Mutant Positive Control** can be used on the **«ELITe InGenius»** instrument up to **four work sessions of three hours each** (“Extract + PCR” run mode).

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C. W. Ku et al. (2021) *Int J Infect Dis* 104: 255 - 261.

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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.