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## NOTICE of CHANGE dated 13/01/2026

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

# «Respiratory Viral PLUS – ELITE Positive Control» Ref. CTR160ING

This new revision of the Instruction for Use (IFU) contains the following changes:

- *Update of the paragraph “Symbols” with the symbol “Consult instructions for use”*

Composition and use of the product remain unchanged.

### PLEASE NOTE



LA REVISIONE DI QUESTO IFU E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT



THE REVIEW OF THIS IFU IS ALSO COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT



CET IFU MIS A JOUR ANNULE ET REMPLACE ET EST PARFAITEMENT COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT



LA REVISIÓN DE ESTE IFU ES COMPATIBLE TAMBIÉN CON LA VERSIÓN ANTERIOR DEL KIT



A REVISÃO DO ESTE IFU ÉTAMBÉM COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT



DIESE FASSUNG DER GEBRAUCHSANLEITUNG IST KOMPATIBEL MIT DER VORHERIGEN VERSION DES TESTKITS



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# Respiratory Viral PLUS - ELITE Positive Control

plasmid DNA control for qualitative assay

REF CTR160ING



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## INTENDED USE

The product «**Respiratory Viral PLUS - ELITE Positive Control**» is intended for use as a positive control in qualitative multiplex nucleic acids reverse transcription and amplification assay for the detection of the RNA of Influenza A Virus (FluA), Influenza B Virus (FluB), Respiratory Syncytial Virus (RSV) and human Metapneumovirus (hMPV) in association with «**Respiratory Viral PLUS ELITE MGB® Kit**» product and with «**ELITE InGenius®**» instrument (ELITechGroup S.p.A.).

## PRODUCT DESCRIPTION

The product supplies the **Positive Control**, a stabilized solution of plasmids, aliquoted into **three ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for 4 sessions.

Plasmids contain regions of the following genes: **Matrix protein gene for FluA**, **Matrix protein gene for FluB**, **Matrix protein gene for RSV** and **Fusion protein gene for hMPV**. The detection of target DNAs as a result of the analysis with «**Respiratory Viral PLUS ELITE MGB® Kit**» product in association with «**ELITE InGenius**» instrument, attests the system ability to detect the cDNA of the target genes.

The product is sufficient for **12 separate analytic sessions**, using 10 µL for reaction.

**Respiratory Viral PLUS - ELITE Positive Control**  
plasmid DNA control for qualitative assay

REF CTR160ING

**MATERIALS PROVIDED IN THE PRODUCT**

Component	Description	Quantity	Classification of Hazard
RV PLUS Positive Control	plasmid DNA solution, BLACK cap	3 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 reverse transcription and the real time amplification, the product «**Respiratory Viral PLUS ELITE MGB® Kit**» (ELITechGroup S.p.A, code RTS160ING) 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 reverse transcription and the real-time amplification and the result interpretation, the «**ELITE InGenius**» instrument (ELITechGroup S.p.A., code INT030) is required together with the specific Assay Protocol «**RV PLUS 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 samples must be suitable and, if possible, dedicated for this type of analysis. Samples must be handled under a laminar airflow hood. Pipettes used to handle samples must be exclusively used for this specific 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 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 -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 up to **four work sessions of three hours each** ("Extract + PCR" run mode).

## PROCEDURE

The «**Respiratory Viral PLUS - ELITE Positive Control**» product must be used with the complete reaction mixture of the «**Respiratory Viral PLUS ELITE MGB® Kit**» product.

Before use, take and thaw the **RV PLUS Positive Control** tube at room temperature (+18 / 25°C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep it on ice.

The **RV PLUS Positive Control** is ready to use: a volume of **10 µL** is directly added to the complete reaction mixture by the instrument.

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 «**Respiratory Viral PLUS ELITE MGB® Kit**» product.

The performance characteristics and procedure limitations of the complete assay for the detection of the RNA of FluA, FluB, RSV and hMPV are described in details in the instructions for use of the «**Respiratory Viral PLUS 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 «**Respiratory Viral PLUS 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 **RV PLUS Positive Control** can be frozen and thawed for a maximum of **four times**. The **RV PLUS Positive Control** can be used up to **four work sessions of three hours each** ("Extract + PCR" run mode).

## REFERENCES

- W. Zhang et al. (1991) *J. Virol. Methods* 33: 165 – 189  
J. Stockton et al. (1998) *J. Clin. Microbiol.* 36: 2990- 2995  
E. J. Kuypers et al. (2005) *J. Clin. Virology* 33: 299-305  
E. A. Lukhtanov et al. (2007) *Nucleic Acids Res.* 35: e30

## SYMBOLS



Catalogue Number.



Upper limit of temperature.



Batch code.



Use by (last day of month).



*In vitro* diagnostic medical device.



Fulfilling the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical device.



Contains sufficient for "N" tests.



Consult instructions for use.



Contents.



Manufacturer.