



## Respiratory Bacterial-ELITE Positive Control

plasmid DNA control for qualitative assay

REF CTR553ING



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### INTENDED USE

The product «**Respiratory Bacterial-ELITE Positive Control**» is intended for use as a positive control in qualitative nucleic acids amplification assays for the detection of the DNA of *Legionella pneumophila*, *Mycoplasma pneumoniae* and *Chlamydia pneumoniae* specific gene with «**Respiratory Bacterial ELITE MGB® Panel**» product in association with «**ELITE InGenius®**» instrument (ELITechGroup S.p.A.).

### PRODUCT DESCRIPTION

The product supplies the **RB Positive Control**, a stabilized solution of plasmids, aliquoted into **two ready-to-use test tubes**. Each test tube contains **120 µL** of solution, sufficient for 6 sessions.

Plasmids contain amplified regions of *Legionella pneumophila*, *Mycoplasma pneumoniae* and *Chlamydia pneumoniae* specific genes. The detection of target DNA as a result of the analysis with «**Respiratory Bacterial ELITE MGB® Panel**» product in association with «**ELITE InGenius®**» instrument, attests the system ability to detect the DNA of the pathogens.

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

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### MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
RB Positive Control	Plasmid DNA solution	2 x 120 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 real time amplification and the consumables are **not** included in this product.

To perform the real time amplification, the product «**Respiratory Bacterial ELITE MGB® Panel**» (ELITechGroup S.p.A, ref. RTS553ING) is required. This is a complete and ready for use reaction mixture for real time amplification in a stabilising solution.

For automatic real time amplification and result interpretation, the «**ELITE InGenius®**» instrument (ELITechGroup S.p.A, ref. INT030) is required together with the specific Assay protocol «**RB ELITE\_PC**» (ELITechGroup S.p.A.) parameters for the amplification positive control.

- The automatic test execution with the instrument «**ELITE InGenius®**» also requires the following generic products:
- amplification cartridges «**ELITE InGenius® PCR Cassette**» (ELITechGroup S.p.A, ref. INT035PCR),
- tips «**300 µL Universal Fit Filter Tips**» (Axygen BioScience Inc., CA, USA, ref. TF-350-L-R-S),
- boxes «**ELITE InGenius® Waste Box**» (ELITechGroup S.p.A, ref. F2102-000).

### WARNINGS AND PRECAUTIONS

**This product is exclusively 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.

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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.  
Refer to the current version of IFU available online.  
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.

Lab 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 **RB Positive Control** can be frozen and thawed for no more than **six times**.

## PROCEDURE

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

Before use, take and thaw the **RB Positive Control** tubes. The positive control needs to be thawed at room temperature for 20-30 minutes and vortexed thoroughly right before use. The **RB Positive Control** is ready to use: **10 µL** is directly added to the reaction mixture by the instrument.

The complete procedure involves setup and carrying out of a real time amplification reaction and is described in detail in the instructions for use enclosed with the «**Respiratory Bacterial ELITE MGB® Panel**» product.

The performance characteristics and procedure limitations of the complete assay for the detection of *Legionella pneumophila*, *Mycoplasma pneumoniae* and *Chlamydia pneumoniae* are described in details in the instructions for use enclosed in the «**Respiratory Bacterial ELITE MGB® Panel**» product.

**N.B.:** 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 Bacterial ELITE MGB® Panel**» the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire after **15 days**.

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## SYMBOLS

REF

Catalogue Number.



Upper limit of temperature.

LOT

Batch code.



Use by (last day of month).

CE  
0344

Fulfilling the requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device. Certification released by DEKRA Certification B.V., the Netherlands.



Contains sufficient for "N" tests.



Attention, consult instructions for use.

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Manufacturer.

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