

Instructions for use

## **ESBL - ELITe Positive Control**

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plasmid DNA control for qualitative assay



**REF** CTR201ING

**UDI** 08033891486211



**CHANGE HISTORY**

Rev.	Notice of change	Date (dd/mm/yy)
02	Extended Use of the product in association with ELITe BeGenius®.	27/05/25
01	Formal corrections	02/02/18
00	new product development	30/01/17

**NOTE**

The revision of this IFU is also compatible with the previous versions of the kit

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## 1 INTENDED USE

The product **ESBL - ELITE Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as DNA positive control in nucleic acids Real-Time PCR assay for the detection of the DNA of Extended Spectrum Beta-Lactamase genes (ESBL) **CTX-M-1**, **CTX-M-9**, **CTX-M-14** and **CTX-M-15** of *Enterobacteriaceae* with **ESBL ELITE MGB® Kit** and **ELITE InGenius®** and **ELITE BeGenius®** instruments.

## 2 PRODUCT DESCRIPTION

The product supplies the **ESBL Positive Control**, plasmid DNA at known titre in a stabilizing solution based on Tris-HCl and EDTA, aliquoted into **three ready-to-use test tubes**.

The plasmid DNA contains a region of the Extended Spectrum Beta-Lactamase (ESBL) CTX-M-15. The detection of target DNA, using **ESBL ELITE MGB Kit** product in association with **ELITE InGenius** and **ELITE BeGenius** instruments, attests the system ability to detect the DNA of the target genes and consequently the verification of the system (product batch and instrument).

### NOTE

The target CTX-M-1, CTX-M-9 and CTX-M-14 are not included in the Positive Control reagent.

The system ability to detect these targets is checked lot by lot during the Quality Control of the product.

The product contains sufficient reagents for **12 separate sessions** on **ELITE InGenius** and **ELITE BeGenius** (4 sessions each tube), with 20 µL used per reaction.

## 3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
<b>ESBL Positive Control</b> ref. CTR201ING	plasmid DNAs solution in tube with black cap	<b>3 x 160 µL</b>	-

## 4 MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (~13,000 RPM).
- Micropipettes and sterile tips with aerosol filter or sterile positive displacement tips (volume range: 0.5-1000 µL).
- 2.0 mL sterile screw capped tubes (Sarstedt, Germany, ref. 72.694.005).
- 0.5 mL sterile screw capped tubes (Sarstedt, Germany, ref. 72.730.005).
- Molecular biology grade water.

## 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
<b>ELITe InGenius</b> (ELITechGroup S.p.A., EG SpA, ref. INT030) <b>ELITe InGeniusSoftware</b> version 1.3.0.19 (or later) <b>ESBL ELITe_PC</b> , Assay Protocol with parameters for Positive Control analysis.	<b>ESBL ELITe MGB Kit</b> product (EG SpA, ref. RTS201ING) <b>ELITe InGenius PCR Cassette</b> (EG SpA, ref. INT035PCR) <b>300 µL Filter Tips Axygen</b> (Corning Life Sciences Inc., ref. TF-350-L-R-S) with ELITe InGenius only <b>1000 µL Filter Tips Tecan</b> (Tecan, Switzerland, ref. 30180118) with ELITe BeGenius only <b>ELITe InGenius Waste Box</b> (EG SpA, ref. F2102-000)
<b>ELITe BeGenius</b> (EG SpA, ref. INT040) <b>ELITe BeGeniusSoftware</b> version 2.2.1 (or later) <b>ESBL ELITe_Be_PC</b> , Assay Protocol with parameters for Positive Control analysis.	

## 6 WARNINGS AND PRECAUTIONS

This product is designed for in vitro use only.

### 6.1 Warnings and general 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 reagents must be handled under a laminar airflow hood. 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, and free from DNA and RNA.
- The PCR Cassette must be handled carefully and never opened to avoid PCR product diffusion into the environment and sample and reagent 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)
<b>ESBL Positive Control</b>	-20°C or below	one month	up to four	up to four separate sessions* of three hours each

\*with intermediate freezing

## 7 PROCEDURE

The product **ESBL - ELITe Positive Control** must be used in association with the **ESBL ELITe MGB Kit**.

The component **ESBL Positive Control** is ready to use: a volume of **20 µL** is directly added to the reaction mixture (**ESBL PCR Mix**, component of **ESBL ELITe MGB Kit**) by the instrument.

Before use, take and thaw the **ESBL Positive Control** tube at room temperature (+16 / +26 ° C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep it on ice or in a cool block.

The complete assay procedure is described in detail in the instructions for use of the product **ESBL 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 **ESBL ELITe MGB Kit**.

### NOTE

The results of Positive Control will be stored by the **ELITe InGenius** and **ELITe BeGenius** instruments and used to set up the Control Charts monitoring the amplification step performances. For each batch of the product **ESBL ELITe MGB Kit** the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

## 8 REFERENCES

Cantón R. et al., Front Microbiol. 2012 Apr 2;3:110

## 9 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.



Unique Device Identification



Contains sufficient for "N" tests.



Consult instructions for use.



Contents.



Manufacturer.



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