

**NOTICE of CHANGE dated 05/02/18**

**IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCTS:**







**«ESBL - ELITe Positive Control»**  
**Ref. CTR201ING**

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

- *Formal Correction.*

Composition, use and performance 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
	DIE REVIEW VON DIESER IFU IST KOMPATIBLE MIT DER VORIGE VERSION VON DEM TEST-KIT



## ESBL - ELITe Positive Control

plasmid DNA control for qualitative assay

REF CTR201ING



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### INTENDED USE

The product «**ESBL - ELITe Positive Control**» is intended for use as a positive control in qualitative nucleic acids amplification assays for the detection of the DNA of Extended Spectrum Beta-Lactamase genes (ESBL) **CTX-M-1**, **CTX-M-14**, **CTX-M-15** and **CTX-M-9** of *Enterobacteriaceae* with «**ESBL ELITe MGB® Kit**» product in association with the «**ELITe InGenius®**» instrument (ELITechGroup S.p.A.).

### PRODUCT DESCRIPTION

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

The plasmid DNA contains a region of the Extended Spectrum Beta-Lactamase (ESBL) CTX-M-15 gene. The detection of target DNA as a result of the analysis with «**ESBL ELITe MGB® Kit**» product in association with «**ELITe InGenius**» instrument, attests the system ability to detect the DNA of Extended Spectrum Beta-Lactamase genes.

Please, note that 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 during the Quality Control of the product.

The product is sufficient for **12 separate analytic sessions**, by using 20 µL for reaction.

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### MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
ESBL Positive Control	Plasmid DNA solution	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).
- 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 «**ESBL ELITe MGB® Kit**» (ELITechGroup S.p.A, ref. RTS201ING) is required. This is a complete and ready for use reaction mixture for real time amplification in a stabilising solution.

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 «**ESBL ELITe\_PC**» (ELITechGroup S.p.A.), parameters for the amplification and the result interpretation of positive control.

With the instrument «**ELITe InGenius**» (ELITechGroup S.p.A., ref. INT030) the following generic products are required:

- amplification cartridges «**ELITe InGenius® PCR Cassette**» (ELITechGroup S.p.A, ref. INT035PCR),
- tips «**300 µL Universal Filter Tips**» (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 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.  
Carefully read all the instructions provided in the product before running the assay.  
While running the assay, follow the instructions provided in the product.  
Do not use the product after the indicated expiry date.  
Only use the reagents provided in 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 **Positive Control** can be frozen and thawed for no more than **four times**.

**PROCEDURE**

The «**ESBL - ELiTe Positive Control**» product must be used with the complete reaction mixture of the «**ESBL ELiTe MGB® Kit**» product.

Before use, take and thaw the **ESBL Positive Control** tubes. Mix gently, spin down the contents for 5 seconds and keep them on ice.

The **ESBL Positive Control** is ready to use: **20 µL** is directly added to the reaction mixture.

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 «**ESBL ELiTe MGB® Kit**» product.

The performance characteristics and procedure limitations of the complete assay for the detection of the DNA of the Extended Spectrum Beta-Lactamase genes (ESBL), **CTX-M-1**, **CTX-M-14**, **CTX-M-15** and **CTX-M-9**, are described in details in the instructions for use enclosed in the «**ESBL ELiTe MGB® Kit**» 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 «**ESBL ELiTe MGB® Kit**» the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

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**REFERENCES**

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

**SYMBOLS**



Catalogue Number.



Upper limit of temperature.



Batch code.



Use by (last day of month).



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.



Contents.



Manufacturer.

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