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NOTICE of CHANGE dated 19/01/2023

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«COLISTIN-R - ELITe Positive Control»
Ref. CTR202ING

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

- *Update to be in compliance with the Regulation (EU) 2017/746 and the Standard ISO 15223-1:2021 requirements.*
- *Composition, use and performance of the product remain unchanged.*
- *The following lot numbers still on the market have been commercialized as IVDD. According to Article 110 of the IVDR they will not be recalled and they will still be commercialized as per their expiration dates:*

PRODUCT REF	Lot Number	Expiry date
RTS202ING-48	U1222-035	December 2024
CTR202ING	U0123-014	January 2025
CTR202ING	U0821-030	March 2023

PLEASE NOTE

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

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

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

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

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

DIE REVIEW VON DIESER IFU IST _KOMPATIBLE MIT DER VORIGE VERSION VON DEM KIT

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EMPOWERING IVD

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COLISTIN-R - ELITe Positive Control

plasmid DNA control for qualitative assay

REF CTR202ING

CE 0344

IVD

-20°C

UDI 08033891486402

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INTENDED USE

The product **COLISTIN-R - ELITe Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as a positive control in qualitative nucleic acids amplification assays for the detection and identification of the transmissible Colistin-resistance mcr-1 and mcr-2 gene DNA of *Enterobacteriaceae* with **COLISTIN-R ELITe MGB® Kit** and with the **ELITe InGenius®** system (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 **mcr-1** and **mcr-2** genes responsible for transmissible resistance to Colistin. The product contains a stabilising solution based on Tris and EDTA. The detection of target DNA as a result of the analysis with **COLISTIN-R ELITe MGB Kit** product in association with **ELITe InGenius** instrument, attests the system ability to detect the DNA of genes responsible for transmissible resistance to Colistin.

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

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
COL 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 real-time amplification and the consumables are **not** included in this product.

To perform this analytical step, the product **COLISTIN-R ELITe MGB Kit** (ELITechGroup S.p.A, ref. RTS202ING-48) 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 **COLISTIN-R ELITe_PC** (ELITechGroup S.p.A.) including parameters for the amplification positive control.

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 Filter Tips Axygen** (Axygen BioScience Inc., CA, USA, ref. TF-350-L-R-S),
- boxes **ELITe InGenius® Waste Box** (ELITechGroup S.p.A, ref. F2102-000).

Certified Reference Material

The COLISTIN-R – ELITe Positive Control consists of plasmid DNAs containing both, mcr-1 and mcr-2 target sequence, dilution in a stabilizing buffer. The plasmid DNA concentrations are determined by spectrophotometer through absorbance measurement.

WARNINGS AND PRECAUTIONS

This product is intended for *in vitro* Diagnostics 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.

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** 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 kept on board in the extraction area up to **four work sessions of three hours each** ("Extract + PCR" run mode).
The **Positive Control** must be used within **one month** from the first tube opening.

PROCEDURE

The **COLISTIN-R - ELITe Positive Control** product must be used with the complete reaction mixture of the **COLISTIN-R ELITe MGB Kit** product.

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

The **COL Positive Control** is ready to use: **20 µL** are directly added to the reaction mixture by the instrument.

The complete procedure, the performance characteristics and procedure limitations of the complete assay for the detection of the Colistin-resistance **mcr-1** and **mcr-2** genes are described in detail in the instructions for use of the **COLISTIN-R 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 **COLISTIN-R 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 **Positive Control** can be frozen and thawed for a maximum of **four times**. The **Positive Control** can be kept on board in the extraction area up to **four work sessions of three hours each** ("Extract + PCR" run mode).

REFERENCES

Y. Y. Liu et al. (2016) Lancet Infect Dis. 16 (2): 161 – 168
B. B. Xavier et al. (2016) Euro Surveill. 21(27): doi 10.2807/1560-7917
H. Giamarellou (2016) Int. J. Antimicrob. Agents. 48 (6): 614 - 621

COLISTIN - ELITe Positive Control
plasmid DNA control for qualitative assay

REF CTR202ING

SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	*In Vitro* Diagnostic Device
CE 0344	Fulfilling the requirements of the IVDR Regulation 2017/746/EC for *in vitro* diagnostic medical device. Certification released by DEKRA Certification B.V., the Netherland.
UDI	Unique Device Identification
	Contains sufficient for "N" tests.
	Attention, consult instructions for use.
CONT	Contents.
	Manufacturer.

NOTICE TO THE USERS

Any serious incident the has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and /or the patient is established. At the moment of the current revision of the IFU, no serious incident or recall of the device has occurred.

A "Summary of Safety and Performance" will be made available to the public via the European database on medical devices (Eudamed) when this informatic system will be functional.