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EMPOWERING IVD

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NOTICE of CHANGE dated 23/04/2024

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

« Macrolide-R/MG - ELITe Positive Control»
Ref. CTR401ING

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

- *Addition of UDI information*

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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Macrolide-R/MG – ELITe Positive Control

plasmid DNA control for qualitative assay

REF CTR401ING

CE IVD

-20°C

UDI 08033891486464

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INTENDED USE

The product **Macrolide-R/MG - ELITe Positive Control** is an in vitro diagnostic medical device intended to be used by healthcare professionals as a DNA positive control in nucleic acids Real Time PCR assays for the detection of the genomic DNA of *Mycoplasma genitalium* with **Macrolide-R/MG ELITe MGB® Kit** and the **ELITe InGenius®** and **ELITe BeGenius®** instruments.

PRODUCT DESCRIPTION

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

The plasmid DNA contains region of the **23S rRNA** gene for ***M. genitalium***. The detection of target DNA using **Macrolide-R/MG ELITe MGB Kit** product in association with **ELITe InGenius and ELITe BeGenius** instruments, attests the system ability to detect the DNA of the target gene and consequently the verification of the system (product batch and instrument).

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.

Note: The plasmid DNA concentration in copies / mL was determined through absorbance measurement by spectrophotometer. There are no WHO approved standards for the target genomic DNA.

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
R/MG Positive Control ref.CTR401ING	plasmid DNA solution, in tube with 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 (~13,000 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 assay, the following products are required:

Instrument and software	Product and reagents
ELITe InGenius (ELITechGroup S.p.A., EG SpA, ref. INT030) **ELITe InGenius Software** version 1.3.0.17 (or later) **R_MG_ELITe_PC**, Assay Protocol with parameters for Positive Control analysis.	**Macrolide-R/MG ELITe MGB Kit** product (EG SpA, ref. RTS401ING-48) **ELITe InGenius PCR Cassette** (EG SpA, ref. INT035PCR) **300 µL Filter Tips Axygen** (Corning Life Sciences Inc., ref. TF-350-L-R-S) with ELITe InGenius only **1000 µL Filter Tips Tecan** (Tecan, Switzerland, ref. 30180118) with ELITe BeGenius only **ELITe InGenius Waste Box** (EG SpA, ref. F2102-000)
ELITe BeGenius (EG SpA, ref. INT040) **ELITe BeGenius Software** version 2.1.0 (or later) **R_MG_ELITe_Be_PC**, Assay Protocol with parameters for Positive Control analysis.	

WARNINGS AND PRECAUTIONS

This product is designed for *in vitro* use only.

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.

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.

Warnings and precautions specific for the components

Component	Storage temperature	Use from first opening	Freeze / thaw cycles	On board stability (ELITe InGenius and ELITe BeGenius)
R/MG Positive Control	-20°C or below	one month	up to four	up to four separate sessions* of three hours each

* with intermediate freezing

PROCEDURE

The product **Macrolide-R/MG - ELITe Positive Control** product must be used in association with the product **Macrolide-R/MG ELITe MGB Kit**.

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

Before use, take and thaw the **R/MG 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 **Macrolide-R/MG 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 **Macrolide-R/MG 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 **Macrolide-R/MG ELITe MGB Kit** the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

Macrolide-R/MG - ELITe Positive Control
plasmid DNA control for qualitative assay

REF **CTR401ING**

REFERENCES

Twin J. et al. (2012) PLoS ONE Vol. 7, Issue 4
Nijhuis R.H.T. et al J. Antimicrob. Chemother.(2015), 70: 2515-2518
E. A. Lukhtanov et al. (2007) *Nucleic Acids Res*. 35: e30

SYMBOLS

REF	Catalogue Number.
	Upper limit of temperature.
LOT	Batch code.
	Use by (last day of month).
IVD	*in vitro* diagnostic medical device
CE	Fulfilling the requirements of the European Directive 98\79\EC for *in vitro* diagnostic medical device.
UDI	Unique Device Identification
	Contains sufficient for "N" tests.
	Caution, consult instructions for use.
CONT	Contents.
	Manufacturer.