

Instructions for use

Macrolide-R/MG- ELITe Positive Control

plasmid DNA control for qualitative assay



REF CTR401ING

UDI 08033891486464

CE IVD
0123

CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
03-R	<p>Compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements.</p> <p>Expansion of the use of the product in association with ELITe BeGenius® instrument, with cervical-vaginal swab matrices.</p> <p>Replacement of the abbreviation MG with MYG</p> <p>Change the name of the component by removing -48</p> <p>Update of the packaging of the PCR Mix tube (paragraph "Materials provided in the product")</p> <p>Update of the paragraph "Materials Required But Not Provided In The Product"</p> <p>Update of the paragraph "Other products required".</p> <p>Update of the paragraph "Warnings and precautions for molecular biology"</p> <p>Update of the paragraph "Symbols" with the symbol "Consult instructions for use"</p>	27/11/25
02	Addition of UDI information	23/04/24
01	Update for the use of the product for Urine matrix in association with ELITe BeGenius□ instrument (REF INT040).	07/12/23
00	new product development	20/03/19

NOTE

The product batches identified by the following LOT numbers are still placed on the market as per IVDD till to their expiration dates, according to Article 110 of IVDR. If you have those product batches, please contact ELITechGroup staff to request the related previous revision of IFUs.

Those batches of Positive Control are technically compatible with the new IVDR version of the amplification kit and can be used, until exhausted, in association with the new IVDR version of the amplification kit and in accordance with its intended use.

PRODUCT REF	Lot number	Expiry date
CTR401ING	U0125-212	28/02/2027

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1 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 DNA positive control in nucleic acids Real-Time PCR assays for the detection of the genomic DNA of *Mycoplasma genitalium* (MYG) and for identification of main Macrolide resistance associated mutations in association with **Macrolide-R/MG ELITE MGB®Kit** and the **ELITE InGenius®** and **ELITE BeGenius®** instruments.

2 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 the region of the **23S rRNA** gene for *M. genitalium*. The detection of target DNAs, 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 DNAs concentration in copies / mL was determined through absorbance measurement by spectrophotometer. There are no WHO approved standards for the target genomic DNAs.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
R/MG Positive Control ref. CTR401ING	plasmid DNA solution in tube with black cap	3 x 160 µL	-

4 MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Disposable powderless nitrile gloves or similar material.
- Vortex mixer.
- Bench microcentrifuge (~13,000 RPM).

5 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:

Table 2

Instrument and software	Product and reagents
ELITE InGenius (ELITechGroup S. p. A., EG SpA, ref. INT030) ELITE InGenius Software version 1.3.0.19 (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 and ELITE BeGenius Consumables (see ELITE InGenius and ELITE BeGenius Instruction for use) eSWAB ® (COPAN Italia S. p. A., ref. 480CE), or an equivalent device, for cervical-vaginal swab specimens
ELITE BeGenius (EG SpA, ref. INT040) ELITE BeGenius Software version 2.3.0 (or later) R_MG_ELITE_Be_PC , , 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 PCR Cassette must be handled carefully and never opened to prevent PCR product diffusion and carryover 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)
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

7 PROCEDURE

The product **Macrolide-R/MG- ELITE Positive Control** 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**.

8 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

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 IVDR Regulation 2017/746/EC for *in vitro* diagnostic medical device. Certification released by TÜV SÜD Product Service GmbH, Germany.



Unique Device Identification



Contains sufficient for "N" tests.



Consult instructions for use.



Contents.



Manufacturer.

10 NOTICE TO THE USERS

Any serious incident that 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. To inform ELITechGroup S. p. A., manufacturer of this device, please use the following mail address: egspa.vigilance@elitechgroup.com.

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. Before the notice of full functionality of Eudamed has been published, the "Summary of Safety and Performance" will be made available to the public upon request by email at emd.support@elitechgroup.com, without undue delay.

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