ELITechGroup
EMPOWERING IVD

ELITechGroup S.p.A.
C.so Svizzera, 185
10149 Torino ITALIA
Uffici: Tel. +39-011 976 191 Fax +39-011 936 76 11
E-mail: emd.support@elitechgroup.com
Sito internet: www.elitechgroup.com

NOTICE of CHANGE dated 22/02/2024

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«MDR/MTB - ELITe Positive Control»
Ref. CTR120ING

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

- *Extension of the use in association with «ELITe BeGenius®» instrument (REF INT040) and the product MTB EXTRA (REF RTS121ING)*

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
	DIESE FASSUNG DER GEBRAUCHSANLEITUNG IST KOMPATIBEL MIT DER VORHERIGEN VERSION DES TESTKITS

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MDR/MTB - ELITe Positive Control

plasmid DNA control for qualitative assay

REF CTR120ING

CE IVD

-20°C

UDI 08033891486365

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INTENDED USE

The product **MDR/MTB - 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 *Mycobacterium tuberculosis* complex (*M. tuberculosis*, *M. africanum*, *M. bovis*, *M. canettii*, *M. microti, M. caprae*) in association with **MTB EXTRA ELITe MGB® Kit** and with the **ELITe InGenius®** and the **ELITe BeGenius®** instruments, and for the detection of the genomic DNA of *Mycobacterium tuberculosis* complex and for identification of *Mycobacteria* resistant to Rifampicin and/or Isoniazid in association with **MDR/MTB ELITe MGB® Kit**, and with the **ELITe InGenius®** instrument.

PRODUCT DESCRIPTION

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

The plasmid DNAs contain regions of IS6110, rpoB, katG and inhA genes.
The detection of target DNAs using the product **MTB EXTRA ELITe MGB Kit** in association with **ELITe InGenius** and **ELITe BeGenius** instruments, or the product **MDR/MTB ELITe MGB Kit** in association with **ELITe InGenius** instrument, attests the system ability to detect the DNA of the target genes and consequently the verification of the system (product batch and instrument).

The product contains sufficient reagents for **6 separate sessions** on **ELITe InGenius** and **ELITe BeGenius**, (2 sessions each tube) with 20 µL used per reaction.

Note: The plasmid DNAs concentration in copies / mL was determined through absorbance measurement by spectrophotometer.

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazards
TB Positive Control ref. CTR120ING	plasmid DNAs 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:

Instruments and softwares	Products and reagents
ELITe InGenius (ELITechGroup S.p.A., EG SpA, ref. INT030) **ELITe InGenius Software** version 1.3.0.17 (or later) **MDR/MTB_ELITe_PC**, Assay Protocol with parameters for Positive Control analysis (for the purpose of detecting tuberculosis and identifying genotypic resistance) **MTB EXTRA_ELITe_PC**, Assay Protocol with parameters for Positive Control analysis (for the purpose of detecting tuberculosis from MTB complex)	**MDR/MTB ELITe MGB Kit** product (EG SpA, ref. RTS120ING) **MTB EXTRA ELITe MGB Kit** product (EG SpA, ref. RTS121ING) **ELITe InGenius PCR Cassette** (EG SpA, ref. INT035PCR) **300 µL Filter Tips Axygen** (Corning Life Sciences Inc., ref. TF-350-L-R-S) **ELITe InGenius Waste Box** (EG SpA, ref. F2102-000)
ELITe BeGenius (EG SpA, ref. INT040) **ELITe BeGenius Software** version 2.1.0 (or later) **MTB EXTRA_ELITe_Be_PC**, Assay Protocol with parameters for Positive Control analysis (for the purpose of detecting tuberculosis from MTB complex)	**MTB EXTRA ELITe MGB Kit** product (EG SpA, ref. RTS121ING) **ELITe InGenius PCR Cassette** (EG SpA, ref. INT035PCR) **1000 µL Filter Tips Tecan** (Tecan, Switzerland, ref. 30180118) **ELITe InGenius Waste Box** (EG SpA, ref. F2102-000)

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)
TB Positive Control	-20°C or below	one month	up to two	up to two separate sessions* of three hours each

* with intermediate freezing

PROCEDURE

The **MDR/MTB - ELITe Positive Control** must be used in association with the product **MDR/MTB ELITe MGB Kit** or with the product **MTB EXTRA ELITe MGB Kit**.

The component **TB Positive Control** is ready to use: a volume of **20 µL** is directly added to the reaction mixture (TB1 PCR Mix and TB2 PCR Mix, components of **MDR/MTB ELITe MGB Kit** or MTB EXTRA PCR Mix, component of **MTB EXTRA ELITe MGB Kit**) by the instrument.

Before use, take and thaw the **TB 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 **MDR/MTB ELITe MGB Kit** or **MTB EXTRA ELITe MGB Kit**.

The performance characteristics and procedure limitations of the complete assay for the detection of the DNA of *Mycobacterium tuberculosis* complex and for identification of *Mycobacteria* resistant to Rifampicin and/or Isoniazid, are described in detail in the instructions for use of the product **MDR/MTB ELITe MGB Kit**.

MDR/MTB - ELITe Positive Control
plasmid DNA control for qualitative assay

REF **CTR120ING**

The performance characteristics and procedure limitations of the complete assay for the detection of the DNA of *Mycobacterium tuberculosis* complex are described in detail in the instructions for use of the product **MTB EXTRA ELITe MGB Kit**.

Note: The results of Positive Control will be stored by the **ELITe InGenius** and **ELITe BeGenius** instruments and used to setup the Control Charts monitoring the amplification step performances. For each batch of the products **MDR/MTB ELITe MGB Kit** and **MTB EXTRA ELITe MGB Kit** the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

REFERENCES

Thierry D. et al. Nucleic Acids Res, 1990. 18: 188
Heep M. et al., JCM.39.1, 2001 Jan; p. 107–110
Seifert M et al., PLOS ONE, 2015 March 23;10.1371

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.