Instructions for use

Meningitis Bacterial- ELITe Positive Control

plasmid DNA control for qualitative assay

ELITechGroup
A BRUKER COMPANY

REF CTR300ING

UDI 08033891486488

CE IVD

CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
02	Update of the paragraph “Other product required”	08/09/25
01	Expansion of use of the product in association with ELITe BeGenius instrument (REF INT040) New graphics and content setting of the IFU.	20/01/25
00	new product development	28/11/18

NOTE
The revision of this IFU is also compatible with the previous version of the kit

TABLE OF CONTENT

1 INTENDED USE

The product **Meningitis Bacterial - 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 assay for the detection and identification of the genomic DNA of *Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae* and *Haemophilus influenzae* type B in association with **Meningitis Bacterial ELITe MGB® Kit** and the **ELITe InGenius®** and **ELITe BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **MB 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 the following genes: **ctrA** for ***Neisseria meningitidis***, **lytA** for ***Streptococcus pneumoniae,*** **fucK** for ***Haemophilus influenzae*** and **bcsB** for ***Haemophilus influenzae*** **type B**. The detection of target DNAs, using **Meningitis Bacterial ELITe MGB Kit** product in association with **ELITe InGenius** and **ELITe BeGenius** instruments, 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 **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.

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
MB Positive Control ref. CTR300ING	plasmid DNAs 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) **MB ELITe_PC**, Assay Protocol with parameters for Positive Control analysis.	**Meningitis Bacterial ELITe MGB Kit** product (EG SpA, ref. RTS300ING) **ELITe InGenius** and **ELITe BeGenius** Consumables (see ELITe InGenius and ELITe BeGenius Instruction for Use)
ELITe BeGenius (EG SpA, ref. INT040) **ELITe BeGenius Software** version 2.3.0 (or later) **MB 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)
MB 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 **Meningitis Bacterial - ELITe Positive Control** must be used in association with the product **Meningitis Bacterial ELITe MGB Kit**.

The component **MB Positive Control** is ready to use: a volume of **20 µL** is directly added to the reaction mixture (**MB PCR Mix**, component of **Meningitis Bacterial ELITe MGB Kit**) by the instrument.

Before use, take and thaw the **MB 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 **Meningitis Bacterial 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 **Meningitis Bacterial 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 **Meningitis Bacterial 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

F. Takenori Higa et al. (2013) Mem. Inst. Oswaldo Cruz 108: 246-247

D. Llull et al. (2006) Journal Of Clinical Microbiology 44: 1250-1256

D. Wroblewski et al. (2013) Molecular and Cellular Probes 27: 86-89

K. L. Meyler et al. (2012) Diagnostic Microbiology and Infectious Disease 74: 356-362

E. A. Lukhtanov et al. (2007) Nucleic Acids Res. 35: e30

9 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.
	Consult instructions for use.
CONT	Contents.
	Manufacturer.

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