Instructions for use

Coagulation - ELITe Positive Control

plasmid DNA control for qualitative assay

ELITechGroup
A BRUKER COMPANY

REF CTRD00ING

UDI 08033891486211

CE 0123

IVD

CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
05–R	Extension to 60 days of the use from first opening. New graphics and content setting of the IFU.	27/08/25
04–R	Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements . Composition and PERFORMANCE CHARACTERISTICS of the product remain unchanged.	20/08/24
02	Update for the use of the product in association with ELITe BeGenius instrument (REF INT040).	30/03/23
00–01	new product development and succeeding changes	—

NOTE

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

This batch of Positive Control is 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
CTRD00ING	U0224-039	31/01/2026

TABLE OF CONTENT

1 INTENDED USE

The product **Coagulation - ELITe Positive Control** is an in vitro diagnostic medical device intended to be used by healthcare professionals as “all heterozygous” DNA positive control in qualitative nucleic acids Real-Time PCR assay for allelic determination of the loci of coagulation Factor V for single nucleotide polymorphism (SNP) G1691A (Leiden), Factor II for SNP G20210A and 5,10-methylenetetrahydrofolate reductase (MTHFR) for SNP C677T in human genomic DNA in association with **Coagulation ELITe MGB® Kit** product and the **ELITe InGenius®** and **ELITe BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **52M 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 amplicons of the two alleles (wildtype and mutated) of the three genes in analysis: Factor V, Factor II and MTHFR and the amplicon of a region of the human gene encoding beta Globin used as an internal control of suitability of the sample (IC). The product contains a stabilising solution based on Tris and EDTA. The detection of the three genes as a melting temperatures (Tm) result and the threshold cycles (Ct) result of analysis with Coagulation ELITe MGB Kit product in association with **ELITe InGenius** and **ELITe BeGenius** instruments, attests the system ability to determine the presence of the alleles of the genes of interest.

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 DNA

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
52M Positive Control ref. CTRD00ING	plasmid DNAs solution in tube with **black cap**	**3 x 160 µL**	-

4 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 (volume range: 0.5-1000 µL).

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

Instruments and softwares	Products and reagents
ELITe InGenius (ELITechGroup S.p.A., EG SpA, ref. INT030) **ELITe InGenius Software** version 1.3.0.19 (or later) **52M ELITe_PC** , Assay Protocol with parameters for Positive Control analysis.	**Coagulation ELITe MGB Kit** product (EG SpA, ref. RTSD00ING) **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 2.2.1 (or later) **52M 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 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.

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)
52M Positive Control	-20°C or below	60 days	up to four	up to four separate sessions* of three hours each

**with intermediate freezing*

7 PROCEDURE

The product **Coagulation - ELITe Positive Control** must be used in association with the product **Coagulation ELITe MGB Kit**.

The component **52M Positive Control** is ready to use: a volume of **20 µL** is directly added to the complete reaction mixture (**52M PCR Mix**, component of **Coagulation ELITe MGB Kit**) by the instrument.

Before use, thaw the **52M 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 **Coagulation 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 **Coagulation 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 **Coagulation 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

Voorberg, J. et al. (1994) *The Lancet* 343: 1535 - 1536.

Baker, R. et al. (1994) *The Lancet* 344: 1162.

Poort, S. R. et al. (1996) Blood 88: 3698 - 3703.

Kluijtmans L. A. et al. (1996) Am J Hum Genet 58: 35 - 41.

Cattaneo M. et al. (1997) Arterioscler Thromb Vasc Biol. 17: 1662-1666

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 0123	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.
UDI	Unique Device Identification
	Contains sufficient for "N" tests.
	Consult instructions for use.
CONT	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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