ELITechGroup
EMPOWERING IVD

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

NOTICE of CHANGE dated 20/08/2024

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:

«Coagulation - ELITe Positive Control»
Ref. CTRD00ING

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

- *Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements and update of the Intended use, accordingly.*

- ***NOTE:** Composition and performance of the product remain unchanged.*

- ***NOTE:** The product lot reported into the table below is still placed on the market as per IVDD (98/79/EC) until expiration date, according to Article 110 of IVDR. If you are using this product lot, the related IFU revision, NOT available anymore on the website, can be requested by contacting ELITechGroup staff.*

PRODUCT REF	Lot Number	Expiry date
CTRD00ING	U0224-039	31/01/2026

PLEASE NOTE

	LA REVISIONE DI QUESTA IFU NON È COMPATIBILE CON LA VERSIONE PRECEDENTE DEL KIT
	THE REVISION OF THIS IFU IS NOT COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT
	LA RÉVISION DE CETTE IFU N'EST PAS COMPATIBLE AVEC LA VERSION PRÉCÉDENTE DU KIT
	LA REVISIÓN DE ESTE IFU NO ES COMPATIBLE CON LA VERSIÓN ANTERIOR DEL KIT
	A REVISÃO DO ESTE IFU NÃO ÉTAMBÉM COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT
	DIESE FASSUNG DER GEBRAUCHSANLEITUNG IST NICHT KOMPATIBEL MIT DER VORHERIGEN VERSION DES TESTKITS

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Coagulation - ELITe Positive Control

plasmid DNA control for qualitative assay

REF CTRD00ING

CE 0123

IVD

-20°C

UDI 08033891486211

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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 **ELITe InGenius®** and **ELITe BeGenius®** instruments.

PRODUCT DESCRIPTION

The product supplies the components **52M Positive Control**, a stabilized solution of seven plasmid DNAs, aliquoted into **three ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for 4 sessions, in association with the **ELITe InGenius** and **ELITe BeGenius.**

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** instrument attests the system ability to determine the presence of the alleles of the genes of interest.

The product is sufficient for **12 separate analytic sessions**, in association with the **ELITe InGenius** and **ELITe BeGenius,** by using 20 µL for reaction.

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
52M Positive Control	Plasmid DNA solution	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 (12,000 - 14,000 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 these analytical steps the product **Coagulation ELITe MGB Kit** (ELITechGroup S.p.A., EG SpA, ref. RTSD00ING), it is required. The product provides the reaction mixture, as complete and ready for use, for real time amplification in a stabilising solution.

For automatic sample analysis with the **ELITe InGenius** (EG SpA, ref. INT030) or **ELITe BeGenius** (EG SpA, ref. INT040) the following generic products are required:

- **ELITe InGenius® Waste Box** (EG SpA, ref. F2102-000),
- **ELITe InGenius® PCR Cassette** (EG SpA, Ref. INT035PCR),
- **300 µL Filter Tips Axygen** (Corning Life Science, ref. TF-350-L-R-S), for **ELITe InGenius**,
- **1000 µL Filter Tips Tecan** (Tecan, ref. 30180118), for **ELITe BeGenius**.

For the Real-Time amplification and result interpretation, the **ELITe InGenius** instrument (EG SpA, ref. INT030) is required together with the specific Assay protocol **52M ELITe_PC** (EG SpA), parameters for the amplification and result interpretation of positive control.

For the Real-Time amplification and result interpretation, the **ELITe BeGenius** instrument (EG SpA, ref. INT040) is required together with the specific Assay protocol **52M ELITe_Be_PC** (EG SpA), parameters for the amplification and result interpretation of positive control.

WARNINGS AND PRECAUTIONS

This product is exclusively for *in vitro* use.

Warnings and general precautions

Handle and dispose of all biological samples as if they were able to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with the biological samples must be treated for at least 30 minutes with 3% sodium hypochlorite or autoclaved for one hour at 121 °C before disposal.

Handle and dispose of all reagents and all materials used to carry out the assay as if they were able to transmit infective agents. 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 neutralised 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 with the product before running the assay.
While running the assay, follow the instructions provided with the product.
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 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 the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

Lab coats, gloves and tools dedicated to work session setup are needed.

The samples must be suitable and, if possible, dedicated for this type of analysis. Samples must be handled under a laminar airflow hood. Pipettes used to handle samples must be exclusively used for this specific 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, free from DNA and RNA.

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 positive control must be handled in such a way as to minimize dispersion into the environment in order to avoid the possibility of contamination. The pipettes used to handle positive control must be exclusively used for this purpose.

The PCR Cassettes must be handled in such a way to reduce as much as possible amplification product diffusion into the environment in order to avoid sample and reagent contamination.

Warnings and precautions specific for the components

The **Positive Control** must be stored at -20 °C or below.
The **Positive Control** must be used within one month from the first opening.
The **Positive Control** can be frozen and thawed for no more than **four times**: further freezing / thawing cycles may cause a loss of product performance.

The **Positive Control** can be used up to **four work sessions of three hours each** (“Extract + PCR” run mode).

PROCEDURE

The **Coagulation - ELITe Positive Control** product must be used with the complete reaction mixture of the **Coagulation ELITe MGB Kit** product.

Before use, take and thaw the **52M Positive Control** tube at room temperature (+21 ±5 °C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep it on ice.

The **52M Positive Control** is ready to use: a volume of **20 µL** is directly added to the reaction mixture by the instrument.

The complete assay procedure is described in detail in the instructions for use of the **Coagulation ELITe MGB Kit** product.

The performance characteristics and procedure limitations of the complete assay are described in detail in the instructions for of the **Coagulation ELITe MGB Kit** product.

Note: The results of the Positive Control amplification will be stored by the instrument **ELITe InGenius** and **ELITe BeGenius** and used to create a Control Chart. For each batch of **Coagulation ELITe MGB Kit** product the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days.**

Note.: The **52M Positive Control** can be frozen and thawed up to **four times. The Positive Control** can be use up to **four work sessions of three hours each** (“Extract + PCR” run mode).

Coagulation - ELITe Positive Control
plasmid DNA control for qualitative assay

REF CTRD00ING

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

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 Regulation IVDR (EU) 2017/746 for *in vitro* diagnostic medical device. Certification released by TÜV SÜD Product Service GmbH, Germany.
UDI	Unique Device Identification
	Contains sufficient for "N" tests.
	Attention, consult instructions for use.
CONT	Contents.
	Manufacturer.

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. At the moment of the current revision of the IFU, no serious incident or recall of the device has occurred.

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 without undue delay.