

Instructions for use

BCR-ABL Dx - ELITe Positive Control

plasmid DNA control for qualitative assay



REF CTRG07ING

UDI 08033891487492

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CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
03	extension of validity of the product after opening update of the paragraph "Notice to the Users"	27/08/25
02	update of the paragraph "Symbols" with the symbol "Consult instructions for use"	30/01/25
01	New product development	26/07/24

NOTE

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

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1 INTENDED USE

The product **BCR-ABL Dx - ELITe Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as DNA positive control in nucleic acids reverse transcription and Real-Time PCR assay for the detection of the mRNA of *BCR::ABL* (BCR-ABL) rearrangement, and the discrimination of the main variants in association with **BCR-ABL Dx ELITe MGB® Kit** and the **ELITe InGenius®** and **ELITe BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the following components:

- **BCR-ABL a2 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 part of mRNA of BCR-ABL genes **p190 e1a2, p195 e6a2, p200 e8a2, p210 e13a2, p230 e19a2**.
- **BCR-ABL a3 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 part of mRNA of BCR-ABL genes **p190 e1a3, p195 e6a3, p200 e8a3, p210 e13a3, p230 e19a3**.

The detection of BCR-ABL as a result of analysis with **BCR-ABL Dx ELITe MGB Kit** product, in association with **ELITe InGenius** and **ELITe BeGenius** instruments, attests the system ability to detect the RNA 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 10 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
BCR-ABL a2 Positive Control ref. CTRG07INGA2	plasmid DNAs solution in tube with BLACK cap	3 x 160 µL	-
BCR-ABL a3 Positive Control ref. CTRG07INGA3	plasmid DNAs solution in tube with RED 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).
- Molecular biology grade water

5 OTHER PRODUCTS REQUIRED

The reagents for the reverse transcription and 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 InGeniusSoftware version 1.3.0.19 (or later) BCR-ABL a2 ELITe_PC BCR-ABL a3 ELITe_PC Assay Protocols with parameters for Positive Controls analysis.	BCR-ABL Dx ELITe MGB Kit product (EG SpA, ref. RTSG07ING) ELITe InGenius and ELITe BeGenius Consumables (see ELITe InGenius and ELITe BeGenius Instruction for Use)
ELITe BeGenius (EG SpA, ref. INT040) ELITe BeGeniusSoftware version 2.2.1 (or later) BCR-ABL a2 ELITe_Be_PC BCR-ABL a3 ELITe_Be_PC Assay Protocols with parameters for Positive Controls 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)
BCR-ABL a2 Positive Control	-20°C or below	60 days	up to four	up to four separate sessions* of three hours each
BCR-ABL a3 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 **BCR-ABL Dx - ELITe Positive Control** must be used in association with the product **BCR-ABL Dx ELITe MGB Kit**.

The components **BCR-ABL a2 Positive Control** and **BCR-ABL a3 Positive Control** are ready to use: a volume of **10 µL** is directly added to the complete reaction mixtures (**BCR-ABL a2 PCR Mix** plus **RT-EnzymeMix**, and **BCR-ABL a3 PCR Mix** plus **RT-EnzymeMix**, components of the **BCR-ABL Dx ELITe MGB Kit**) by the instrument.

Before use, take and thaw the **BCR-ABL a2 Positive Control** and **BCR-ABL a3 Positive Control** tubes 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 **BCR-ABL Dx 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 **BCR-ABL Dx 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 **BCR-ABL Dx 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

- N. C. P. Cross et al. (2023) Leukemia 37: 2150 - 2167
- M. Baccarani et al. (2019) Leukemia 33: 1173 - 1183.
- J. Gabert et al. (2003) Leukemia. 17: 2318 – 2357
- J. J. M. van Dongen et al. (1999) Leukemia. 13: 1901 – 1928
- 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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