

Instructions for use

BCR-ABL P190 - ELITe Positive Control

plasmid DNA control for quantitative assay



REF CTRG07PLD190

UDI 08033891486877



CHANGE HISTORY

Rev.	Notice of change	Date (dd/mm/yy)
01	Update of the paragraph "Symbols" with the symbol "Consult instructions for use" New graphics and content setting of the IFU.	03/07/26
00	new product development	23/05/22

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1 INTENDED USE

The product **BCR-ABL P190 - ELITe Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as a positive control in qualitative nucleic acids amplification assays for **detection of the cDNA of BCR-ABL rearrangement, t(9;22) translocation, Philadelphia chromosome, P190 variant (P190) and the cDNA of the gene encoding Abelson protein kinase (ABL)** by «**BCR-ABL P190 ELITe MGB® Kit**» product in association with «**ELITe InGenius®**» instrument (ELITechGroup S.p.A.).

2 PRODUCT DESCRIPTION

The product supplies the **P190-ABL - Positive Control**, plasmid DNA at known titre in a stabilizing solution based on Tris-HCl and EDTA, aliquoted into **three ready-to-use test tubes**.

The plasmid DNA contains a region of the cDNA which originates from the **BCR-ABL rearrangement (variant P190 e1a2)**, amplified by the **P190** reaction and by the **ABL** control reaction.

The detection and quantification of target DNA using the **BCR-ABL P190 ELITe MGB®Kit** attests the system ability to detect the DNA of the target gene and consequently the verification of the system (product batch and instrument).

The product contains sufficient reagent for **6 separate analytic sessions** on **ELITe InGenius** with 10 µL used per reaction.

NOTE

The plasmid DNA concentration in copies / mL was determined through absorbance measurement by spectrophotometer and verified with European reference material "BCR-ABL pDNA Calibrant" (ERM® - AD623, IRMM, Belgium).

3 MATERIALS PROVIDED IN THE PRODUCT

Table 1

Component	Description	Quantity	Classification of Hazards
P190-ABL - Positive Control	Plasmid DNA 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 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 InGenius Software version 1.4.0 (or later) BCR-ABL P190 ELITe_PC Assay Protocol with parameters for Positive Control analysis	BCR-ABL P190 ELITe MGB Kit (EG SpA, ref. RTSG07PLD190) ELITe InGenius Consumables (see ELITe InGenius Instructions for Use)

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.

When amplification session is manually setup, it is necessary to have available separate areas for the extraction / preparation of amplification reactions and for the amplification / detection of amplification products. Never introduce an amplification product in the area designated for extraction / preparation of amplification reactions.

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, free from DNA and RNA.

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	Freeze / thaw cycles	On board stability (ELITe InGenius)
P190-ABL - Positive Control	-20°C or below	up to four	up to two separate sessions* of three hours each

*with intermediate freezing

7 PROCEDURE

The product **BCR-ABL P190 — ELITe Positive Control** must be used in association with the product **BCR-ABL P190 ELITe MGB Kit**.

The component **P190-ABL Positive Control** is ready to use: a volume of **10 µL** is directly added to the complete reaction mixture "P190" (**P190 PreMix**, **PCR Master Mix** and **RT EnzymeMix**, components of the BCR-ABL P190 ELITe MGB Kit) twice by the ELITe InGenius, and a volume of **10 µL** is directly added to the complete reaction mixture "ABL" (**ABL PreMix**, **PCR Master Mix** and **RT EnzymeMix**, components of the BCR-ABL P190 ELITe MGB Kit) twice by the ELITe InGenius.

Before use, take and thaw the **P190-ABL - 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 cool block.

The complete assay procedure, that involves preparation and execution of two reverse transcription and real time amplification reactions in duplicates (2 reactions for "P190" and 2 reactions for "ABL") is described in detail in the instructions for use of the product **BCR-ABL P190 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 P190 ELITe MGB Kit**.

NOTE

The results of Positive Control will be stored by the **ELITe InGenius** instrument and used to set up the Control Charts monitoring the amplification step performances. For each batch of the product **BCR-ABL P190 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

J. Gabert et al. (2003) *Leukemia* 17: 2318 - 2357

E. Beillard et al. (2003) *Leukemia* 17: 2474 - 2486

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 European Directive 98/79/EC for *in vitro* diagnostic medical device.



Unique Device Identification



Contains sufficient for "N" tests.



Consult instructions for use.



Contents.



Manufacturer.



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