

NOTICE of CHANGE dated 28/11/2023

IMPORTANT COMMUNICATION FOR THE USERS OF PRODUCT:







<h2>«BCR-ABL P210 ELITe Standard»</h2> <h3>Ref. STDG07PLD210</h3>

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

- *Specified the information of calibration curve validity (60 days)*

Composition, use and performance of the product remain unchanged.

PLEASE NOTE

	LA REVISIONE DI QUESTO IFU E' COMPATIBILE ANCHE CON LA VERSIONE PRECEDENTE DEL KIT
	THE REVIEW OF THIS IFU IS ALSO COMPATIBLE WITH THE PREVIOUS VERSION OF THE KIT
	CET IFU MIS A JOUR ANNULE ET REMPLACE ET EST PARFAITEMENT COMPATIBLE AVEC LA VERSION PRECEDENTE DU KIT
	LA REVISIÓN DE ESTE IFU ES COMPATIBLE TAMBIÉN CON LA VERSIÓN ANTERIOR DEL KIT
	A REVISÃO DO ESTE IFU ÉTAMBÉM COMPATÍVEL COM A VERSÃO ANTERIOR DO KIT
	DIESE FASSUNG DER GEBRAUCHSANLEITUNG IST KOMPATIBEL MIT DER VORHERIGEN VERSION DES TESTKITS



BCR-ABL P210 ELITE Standard

plasmid DNA control for quantitative assay

REF STDG07PLD210



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INTENDED USE

The «**BCR-ABL P210 ELITE Standard**» product is intended for use as positive control and as a known-quantity DNA standard to obtain the standard curve in reverse transcription and real time amplification quantitative assays of nucleic acids for **detection of the cDNA of BCR-ABL rearrangement, t(9;22) translocation, Philadelphia chromosome, P210 variant (P210)** and for the **quantification of the cDNA of P210 compared with the cDNA of the gene encoding Abelson protein kinase (ABL)**. The product must be used with the «**BCR-ABL P210 ELITE MGB® Kit**» product, manufactured by ELITechGroup S.p.A.

The results obtained with this product can be aligned to the International Scale (IS) by a conversion factor that can be calculated using the product «**PHILADELPHIA P210 RNA Reference**», manufactured by ELITechGroup S.p.A. and calibrated against the "1st World Health Organization (WHO) International Genetic Reference Panel for quantitation of BCR-ABL translocation by RQ-PCR".

PRODUCT DESCRIPTION

The product supplies the **Q - PCR Standard**, five stabilized plasmid solutions at **known titer**, aliquoted into **two ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for **4 sessions** in association with the system «**ELITE InGenius®**» and 3 sessions in association with the other systems validated.

The plasmid contains a region of the cDNA which originates from the **BCR-ABL rearrangement (variant P210 b3a2)**, which is amplified by the **P210** reaction and by the **ABL** control reaction. Detection of the target DNA during the real time amplification reaction attests the ability of the product to detect the P210 and ABL cDNA and allows calculation of the standard curves.

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The product enables **4 separate analysis sessions** (each session involves one "P210" reactions and one "ABL" reactions with each **Q - PCR Standard**) in association with «**ELITE InGenius**» system, and **6 separate analysis sessions** (each session involves two "P210" reactions and two "ABL" reactions with each **Q - PCR Standard**) in association with other systems, by using 10 µL for the reaction.

The concentration of the standard was determined by measuring the absorbance of the plasmid DNA preparation with a spectrophotometer and verified with European reference material "BCR-ABL pDNA Calibrant" (ERM® - AD623, IRMM, Belgium).

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of hazards
P210-ABL Q-PCR Standard 10 ⁵	Plasmid solution in test tube with RED cap	2 x 160 µL	-
P210-ABL Q-PCR Standard 10 ⁴	Plasmid solution in test tube with BLUE cap	2 x 160 µL	-
P210-ABL Q-PCR Standard 10 ³	Plasmid solution in test tube with GREEN cap	2 x 160 µL	-
P210-ABL Q-PCR Standard 10 ²	Plasmid solution in test tube with YELLOW cap	2 x 160 µL	-
P210-ABL Q-PCR Standard 10 ¹	Plasmid solution in test tube with BROWN cap	2 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).
- Sterile micropipettes and tips with aerosol filter or positive displacement (0.5-10 µL, 2-20 µL, 5-50 µL, 50-200 µL, 200-1000 µL).
- Sterile bidistilled water.
- Programmable heater with optical fluorescence detection system 7300 Real-Time PCR System or 7500 Fast Dx Real-Time PCR Instrument calibrated as required by the manufacturer.

OTHER PRODUCTS REQUIRED

The reagents for amplification reaction and the microplates **are not** included in this product.

To perform these analytical steps, the «**BCR-ABL P210 ELITE MGB® Kit**» (ELITechGroup S.p.A., code RTSG07PLD210) product provides the necessary components for the preparation of the reaction mixtures "P210" and "ABL" for reverse transcription and real time amplification.

In association with «**ELITE InGenius®**» (ELITechGroup S.p.A, ref. INT030) it is required the use of generic product «**ELITE InGenius® PCR Cassette**» (ELITechGroup S.p.A, ref. INT035PCR). These are dedicated consumables for Real Time PCR reactions.

When 7300 Real-Time PCR System is used, it is required the use of generic product: «**MicroAmp™ Optical 96-Well Reaction Plate**» (Life Technologies, ref. N8010560), microplates with 0.2 mL wells and adhesive sealing sheets for real time amplification.

When 7500 Fast Dx Real-Time PCR Instrument is used, it is required the use of generic product: «**MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL**» (Life Technologies, ref. 4346906), microplates with 0.1 mL wells and adhesive sealing sheets for real time amplification.

«**PHILADELPHIA P210 RNA Reference**» product (ELITechGroup S.p.A., code SPG07-210), consists of four mixtures of total RNA at known-quantity intended to obtain the conversion factor for and to express the results in the International Scale (IS) calibrated against the "1st World Health Organization (WHO) International Genetic Reference Panel for quantitation of BCR-ABL translocation by RQ-PCR" is recommended.

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 capable to transmit infective agents. Avoid direct contact with the biological samples. Avoid splashing or spraying. The materials that come into contact with biological samples must be treated with 3% sodium hypochlorite for at least 30 minutes or autoclaved at 121°C for one hour before disposal.

Handle and dispose of all reagents and all assay materials as if they were potentially infective. Avoid direct contact with the reagents. Avoid splashing or spraying. Waste must be treated and disposed of in compliance with the appropriate safety standards. Disposable combustible materials must be incinerated. Liquid waste containing acids or bases must be neutralised before disposal.

Wear suitable protective clothing and gloves and protect eyes / face.

Never pipette solutions by mouth.

Do not eat, drink, smoke or apply cosmetic products in the work areas.

Wash hands carefully after handling samples and reagents.

Dispose of leftover reagents and waste in compliance with regulations in force.

Carefully read all the instructions provided with the product before running the assay.

Follow the instructions provided with the product while running the assay.

Do not use the product after the expiry date.

Only use the reagents provided in the product and those recommended by the manufacturer.

Do not mix reagents from different batches.

Do not use reagents from other manufacturers.

Warnings and precautions for molecular biology

Molecular biology procedures, such as extraction, reverse transcription, amplification and detection of nucleic acids, require qualified and trained staff to prevent the risk of erroneous results, especially due to degradation of the nucleic acids contained in the samples or due to sample contamination by amplification products.

When amplification session is manually setup, it is necessary to have 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 designed for extraction/preparation of amplification reactions.

When amplification session is manually setup, it is necessary to have lab coats, gloves and tools which are exclusively employed in the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never transfer lab coats, gloves or tools from the area designed for the amplification/detection of amplification products to the area designed for the extraction/preparation of the amplification reactions.

The samples must be exclusively employed for this type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips employed must be sterile, free from DNases and RNases, free from DNA and RNA.

Reagents must be handled under a laminar flow hood. The reagents required for amplification must be prepared in such a way that they can be used in a single session. The pipettes employed to handle the reagents must be used exclusively for this purpose. The pipettes must be of the positive displacement type or be used with aerosol filter tips. The tips employed must be sterile, free from DNases and RNases, free from DNA and RNA.

Amplification products must be handled in such a way as to reduce dispersion into the environment as much as possible, in order to avoid the possibility of contamination. Pipettes used to handle amplification products must be employed exclusively for this specific purpose.

Warnings and precautions specific for the components

The **Q - PCR Standard** can be frozen and thawed for no more than **eight times**. Further cycles of freezing and thawing could cause a reduction in titre.

The **Q - PCR Standard** can be kept on board on «ELITE InGenius» up to **four work sessions of two hours each** ("PCR Only" run mode).

PROCEDURE

The «**BCR-ABL P210 ELITE Standard**» product must be used with the reaction mixtures "P210" and "ABL" obtained with the product «**BCR-ABL P210 ELITE MGB® Kit**».

Before starting the session, remove and thaw for 30 minutes at room temperature (+18 / 25 °C) the test tubes containing **P210-ABL Q - PCR Standard**. Vortex the tubes for 10 seconds, spin down the content for 5 seconds and keep them on ice.

The **P210-ABL Q - PCR Standard** is ready for use, hence it must be used by adding **10 µL** directly to the "P210" and **10 µL** to the "ABL" reaction mixture.

The complete procedure, the performance characteristics and procedure limitations of the complete assay for detection and quantification of the P210 and ABL cDNA are described in detail in the instruction for use manual enclosed with the «**BCR-ABL P210 ELITE MGB® Kit**» product.

Note: The P210 and ABL Calibration Curves will be stored by the instrument ELITE InGenius in the database (Calibration). For each batch of product BCR-ABL P210 ELITE MGB Kit, the amplification of Calibrator is required. The Calibration curves will expire after 60 days.

Note: The **P210-ABL Q - PCR Standard** can be frozen and thawed a maximum of **eight times**. The **P210-ABL Q - PCR Standard** can be kept on board on «**ELITE InGenius**» up to **four work sessions of two hours each** ("PCR Only" run mode).

REFERENCES

J. Gabert et al. (2003) *Leukemia* 17: 2318 - 2357
E. Beillard et al. (2003) *Leukemia* 17: 2474 - 2486
M. Baccarani et al. (2013) *Blood*: 121: 827 – 884
N. C. Cross et al. (2015) *Leukemia* 29: 999 - 1003

SYMBOLS

REF

Catalogue number.



Upper temperature limit.

LOT

Batch code.



Use by (last day of month).

IVD

In vitro diagnostic medical device.



Fulfilling the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical device.



Contents sufficient for "N" tests.

Please refer to the instructions for use.

CONT

Contents.



Manufacturer.

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