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t(15;17) - Positive Control

plasmidic cDNA control for qualitative assay

REF CTRG12

CE

-20°C

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INTENDED USE

The product **«t(15;17) - Positive Control»** is intended for use as a positive control in amplification reactions for the **detection of the cDNA of the PML-RARA translocation, t(15;17), variant bcr1 (bcr1), variant bcr2 (bcr2) and variant bcr3 (bcr3)** with **«t(15;17) oligomix Alert kit»** and **«DNA pol. 2U / µL»** by ELITechGroup S.p.A.

PRODUCT DESCRIPTION

The product provides the **Positive Control**, two stabilized solutions of plasmid containing the required sequences, **each divided into two ready-to-use test tube aliquots**. Each test tube contains 65 µL of solution, sufficient for 12 sessions.

The procedure involves the use of the bcr1 positive control in the amplification reaction specific for the PML-RARA translocation, variants bcr1 and bcr3, of the bcr3 positive control in the amplification reaction specific for the PML-RARA translocation, variant bcr3 and the RARA positive control in the amplification reaction specific for the RARA control gene. The presence of the specific product in the amplification reaction confirms its ability to highlight the presence of the cDNA of the PML-RARA translocation and the RARA control gene.

The product provides **25 amplification reactions** using 5 µL per reaction.

MATERIALS PROVIDED IN THE PRODUCT

Reagent	Description	Quantity	Composition	Labelling
bcr1 - Positive Control	Plasmid solution	**2 x 65 µL**	Plasmid, TRIS base, TRIS hydrochloride, EDTA, total yeast RNA	
bcr3 - Positive Control	Plasmid solution	**2 x 65 µL**	Plasmid, TRIS base, TRIS hydrochloride, EDTA, total yeast RNA	
RARA - Positive Control	Plasmid solution	**2 x 65 µL**	Plasmid, TRIS base, TRIS hydrochloride, EDTA, total yeast RNA	

MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT

- Laminar airflow hood.
- Disposable latex powder-free gloves or similar material.
- 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).
- Sterile bidistilled water.
- Programmable heater (thermal cycler).

OTHER PRODUCTS REQUIRED

The reagents for DNA amplification and detection are **not** included with this product. To perform these analytical steps the following products, manufactured by ELITechGroup S.p.A., are recommended:

«t(15;17) oligomix Alert kit» (code BANG12-02), nested amplification kit for the cDNA of the PML-RARA rearrangement from the product of the reverse transcription reaction of RNA extracted from cell samples; the kit provides 25 reactions.

«DNA pol. 2U / µL» (code ER40 and ER140), thermostable DNA polymerase enzyme for amplification of nucleic acids; the products provide 125 reactions.

«ELECTROPHORESIS 3» (code EPH03), detection of amplified DNA for electrophoresis on agarose gel; the product provides 120 detections.

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 of transmitting 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 capable of transmitting infective agents. 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 and 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.
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' products.

Warnings and precautions for molecular biology

Molecular biology procedures, such as extraction, reverse transcription, amplification and detection of nucleic acids, require qualified 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.

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.

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. Test 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. 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 to reagents

The test tubes containing **Positive Control** can be frozen and thawed a maximum of **twelve times**. Further cycles of freezing and thawing could cause a reduction in titre.

The **Positive Control bcr1, Positive Control bcr3** and **Positive Control RARA** reagents have the following safety phrases (S):

S 23-25. Do not breathe gas/fumes/vapour/spray. Avoid contact with eyes.

PROCEDURE

The **«t(15;17) - Positive Control»** product must be used with **«t(15;17) oligomix Alert kit»** and **«DNA pol. 2U / µL»** products.

Positive Control is ready for use, hence must be used by adding **5 µL** directly to the reaction mixture.

The complete procedure involves preparation and execution of an amplification reaction with a programmable heater (thermal cycler) and is described in detail in the instruction manual enclosed with the **«t(15;17) oligomix Alert kit»** kit.

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The performance characteristics and procedure limitations of the complete assay for detection of the cDNA of the PML-RARA rearrangement, t(15;17) translocation, variants bcr1, bcr2 and bcr3, are described in detail in the instruction manual enclosed with the **«t(15;17) oligomix Alert kit»** kit.

N.B.: The **Positive Control** can be frozen and thawed a maximum of **twelve times**.

REFERENCES

J.J.M. van Dongen et al. (1999) *Leukemia* 13: 1901 – 1928

SYMBOLS

REF	Catalogue number.
	Upper temperature limit.
LOT	Batch code.
	Use by (last day of month).
IVD	*In vitro* diagnostic medical device.
CE	In keeping with the requirements of European Directive 98\79\EC for *in vitro* diagnostic medical devices.
	Contents sufficient for "N" tests.
CONT	Contents.
	Please refer to the instructions for use.
	Manufacturer.