



Bordetella - ELITE Positive Control

plasmid DNA control for qualitative assay

REF CTR140ING



TABLE OF CONTENTS

INTENDED USE	page 1
PRODUCT DESCRIPTION	page 1
MATERIALS PROVIDED IN THE PRODUCT	page 2
MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT	page 2
OTHER PRODUCTS REQUIRED	page 2
WARNINGS AND PRECAUTIONS	page 2
PROCEDURE	page 3
REFERENCES	page 4
SYMBOLS	page 4

INTENDED USE

The product «**Bordetella - ELITE Positive Control**» is intended for use as a positive control in qualitative multiplex nucleic acids amplification assays for the detection and identification of the DNA of *Bordetella pertussis*, *Bordetella parapertussis* and *Bordetella holmesii* with «**Bordetella ELITE MGB® Kit**» product in association with «**ELITE InGenius®**» instrument (ELITechGroup S.p.A.).

PRODUCT DESCRIPTION

The product supplies the **Positive Control**, a stabilized solution of plasmids, aliquoted into **three ready-to-use test tubes**. Each test tube contains 160 µL of solution, sufficient for 4 sessions.

The plasmids contain regions of the following genes: **IS481** for *Bordetella pertussis* and *Bordetella holmesii*, **ptxA** for *Bordetella pertussis*, **recA** for *Bordetella holmesii* and **IS1001** for *Bordetella parapertussis*. The detection of target DNAs as a result of the analysis with «**Bordetella ELITE MGB® Kit**» product in association with «**ELITE InGenius**» instrument, attests the system ability to detect the DNA of the target genes.

The product is sufficient for **12 separate analytic sessions**, using 20 µL for reaction.

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REF CTR140ING

MATERIALS PROVIDED IN THE PRODUCT

Component	Description	Quantity	Classification of Hazard
BORD Positive Control	plasmid DNA solution, black cap	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).

OTHER PRODUCTS REQUIRED

The amplification reagents and the consumables are **not** included in this product.

To perform the real time amplification, the product «**Bordetella ELITE MGB® Kit**» (ELITechGroup S.p.A. code RTS140ING) is required. This is a complete and ready for use reaction mixture for real time amplification in a stabilising solution.

For the real-time amplification and the result interpretation, the «**ELITE InGenius**» instrument (ELITechGroup S.p.A., code INT030) is required together with the specific Assay protocol «**BORD ELITE_PC**» (ELITechGroup S.p.A.) parameters for the amplification and the result interpretation of positive control.

With the instrument «**ELITE InGenius**» the following generic products are required:

- amplification cartridges «**ELITE InGenius® PCR Cassette**» (ELITechGroup S.p.A. ref. INT035PCR),
- tips «**300 µL Filter tips Axygen** » (Axygen BioScience Inc., CA, ref. TF-350-L-R-S),
- boxes «**ELITE InGenius® Waste Box**» (ELITechGroup S.p.A. ref. F2102-000).

WARNINGS AND PRECAUTIONS

This product is intended 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.

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REF CTR140ING

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 different batches.
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.

Laboratory coats, gloves and tools dedicated to work session setup are needed. It is necessary to have available separate areas for the molecular biology test and the microbiological culture test. Never handle the liquid or solid culture into the area designated for extraction / amplification reactions.

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 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.

The **Positive Control** can be frozen and thawed for no more than **four times**.

The **Positive Control** can be kept on board in the extraction area up to **four work sessions of three hours each** ("Extract + PCR" run mode).

PROCEDURE

The «**Bordetella - ELiTe Positive Control**» product must be used with the complete reaction mixture of the «**Bordetella ELiTe MGB® Kit**» product.

Before use, take and thaw the **BORD Positive Control** tube at room temperature (+18 / 25°C) for 30 minutes. Mix gently, spin down the content for 5 seconds and keep it on ice.

The **BORD Positive Control** is ready to use: a volume of **20 µL** is directly added to the reaction mixture (BORD PCR Mix, component of «**Bordetella ELiTe MGB® Kit**») by the instrument.

The complete procedure involves setup and carrying out of a real time amplification reaction and it is described in detail in the instructions for use of the «**Bordetella ELiTe MGB® Kit**» product.

The performance characteristics and procedure limitations of the complete assay for the detection of the DNA of *Bordetella pertussis*, *Bordetella parapertussis* and *Bordetella holmesii* are described in detail in the instructions for use of the «**Bordetella ELiTe MGB® Kit**» product.

Note: The results of the Positive Control amplification will be stored by the instrument «**ELiTe InGenius**» and used to create a control chart. For each batch of product «**Bordetella ELiTe MGB® Kit**» the amplification of Positive Control is required. The stored results of the Positive Control amplification will expire **after 15 days**.

Note: The **BORD Positive Control** can be frozen and thawed for a maximum of **four times**. The **BORD Positive Control** can be kept on board in the extraction area up to **four work sessions of three hours each** ("Extract + PCR" run mode).

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REFERENCES

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N. K. Fry et al. (2009) J Med Microbiol. 58: 1023-9.
A. Van der Zee (1993) J Bacteriol. 175: 141-7.
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E. A. Lukhtanov et al. (2007) *Nucleic Acids Res.* 35: e30

SYMBOLS

REF

Catalogue Number.



Upper limit of temperature.

LOT

Batch code.



Use by (last day of month).

IVD

in vitro diagnostics medical device.



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



Contains sufficient for "N" tests.



Attention, consult instructions for use.

CONT

Contents.



Manufacturer.

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