

Instructions for use

Bordetella - ELITE Positive Control

plasmid DNA control for qualitative assay



REF CTR140ING

UDI 08033891486792

CE **IVD**
0123

CHANGE HISTORY

| Rev. | Notice of change | Date (dd/mm/yy) |
|------|--|-----------------|
| 04-R | Update of the paragraph "Other product required" Update of the paragraph "Notice to the users" | 08/09/25 |
| 03-R | Update of the paragraph "Symbols" with the symbol "Consult instructions for use" | 24/03/25 |
| 02-R | Expanded use on the automated and integrated instrument ELITe BeGenius New graphics and content setting of the IFU. | 31/10/24 |
| 01-R | Update for compliance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) requirements. | 19/01/23 |
| 00 | new product development | — |

NOTE

The product batches identified by the following LOT numbers are still placed on the market as per IVDD till to their expiration dates, according to Article 110 of IVDR. If you have those product batches, please contact ELITechGroup staff to request the related previous revision of IFUs

Those batches of Positive Control are technically compatible with the new IVDR version of the amplification kit and can be used, until exhausted, in association with the new IVDR version of the amplification kit and in accordance with its intended use.

| <u>PRODUCT REF.</u> | <u>Lot Number</u> | <u>Expiry date</u> |
|---------------------|-------------------|--------------------|
| CTR140ING | U1223-043 | 31/12/2025 |
| CTR140ING | U0524-105 | 31/05/2026 |

TABLE OF CONTENT

| | |
|--|----------|
| 1 INTENDED USE | 4 |
| 2 PRODUCT DESCRIPTION | 4 |
| 3 MATERIALS PROVIDED IN THE PRODUCT | 4 |
| 4 MATERIALS REQUIRED BUT NOT PROVIDED IN THE PRODUCT..... | 4 |
| 5 OTHER PRODUCTS REQUIRED..... | 4 |
| 6 WARNINGS AND PRECAUTIONS | 5 |
| 7 PROCEDURE..... | 6 |
| 8 REFERENCES..... | 6 |
| 9 SYMBOLS | 7 |
| 10 NOTICE TO THE USERS..... | 7 |

1 INTENDED USE

The product **Bordetella - ELITE Positive Control** is an *in vitro* diagnostic medical device intended to be used by healthcare professionals as DNA positive control in nucleic acids Real-Time PCR assay for the detection and identification of the genomic DNA of ***Bordetella pertussis* (BP)**, ***Bordetella parapertussis* (BPP)** and ***Bordetella holmesii* (BH)**, in association with **Bordetella ELITE MGB® Kit** and the **ELITE InGenius®** and **ELITE BeGenius®** instruments.

2 PRODUCT DESCRIPTION

The product supplies the **BORD 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 regions of the following genes: **IS481** for ***Bordetella pertussis*** and ***Bordetella holmesii***, **ptxA** promoter for ***Bordetella pertussis***, **recA** for ***Bordetella holmesii*** and **IS1001** for ***Bordetella parapertussis***. The detection of target DNAs using **Bordetella ELITE MGB Kit** product in association with **ELITE InGenius** and **ELITE BeGenius** instruments, attests the system ability to detect the DNA 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 20 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 |
|---|--|-------------------|---------------------------|
| BORD Positive Control Ref. CTR140ING | plasmid DNAs 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 Real Time amplification and the consumables are not included in this product.

To perform the assay the following products are required:

Table 2

| Instrument and software | Product and reagents |
|--|---|
| ELITe InGenius (ELITechGroup S.p.A., EG SpA, ref. INT030) ELITe InGenius Software version 1.3.0.19 (or later) BORD ELITe_PC , Assay Protocol with parameters for Positive Control analysis. | Bordetella ELITe MGB Kit product (EG SpA, ref. RTS140ING) ELITe InGenius and ELITe BeGenius Consumables (see ELITe InGenius and ELITe BeGenius Instruction for Use) |
| ELITe BeGenius (EG SpA, ref. INT040) ELITe BeGenius Software version 2.3.0 (or later) BORD ELITe_Be_PC , Assay Protocol with parameters for Positive Control 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 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 | Use from first opening | Freeze / thaw cycles | On board stability (ELITe InGenius and ELITe BeGenius) |
|------------------------------|---------------------|------------------------|----------------------|--|
| BORD Positive Control | -20°C or below | one month | up to four | up to four separate sessions* of three hours each |

*with intermediate freezing

7 PROCEDURE

The product **Bordetella - ELITE Positive Control** must be used in association with the product **Bordetella ELITE MGB Kit**.

The component **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.

Before use, take and thaw the **BORD Positive Control** tube 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 **Bordetella 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 **Bordetella 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 **Bordetella 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

U. Reischl et al. (2001) *J Clin Microbiol.* 39: 1963–1966.

N. K. Fry et al. (2009) *J Med Microbiol.* 58: 1023-9.

A. Van der Zee (1993) *J Bacteriol.* 175: 141-7.

J. L. Guthrie et al. (2010) *J Clin Microbiol.* 48: 1435-7

E. A. Lukhtanov et al. (2007) *Nucleic Acids Res.* 35: e30

<https://www.mayocliniclabs.com/> - BPRPV

<https://www.questdiagnostics.com/healthcare-professionals/test-directory>

Laboratory Manual for the diagnosis of Whooping Cough caused by *Bordetella pertussis*/

Bordetella parapertussis Update 2014 – ISBN WHO_IVB_14.03_eng

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.

ELITechGroup S.p.A.
C.so Svizzera, 185, 10149 Torino ITALY
Tel. +39-011 976 191
Fax +39-011 936 76 11
E. mail: emd.support@elitechgroup.com
WEB site: www.elitechgroup.com

