

AMPLIRUN® CLOSTRIDIUM DIFFICILE DNA CONTROL

For research use only

MBC043-R: Purified DNA of *Clostridium difficile* to be used to control techniques based in nucleic acids amplification.

CHARACTERISTICS:

The lyophilized nucleic acid is included in a thermo-sealed foil pouch containing a silica gel bag. It is necessary to reconstitute it before use (refer to "Preparation of reagents").

Preparation: Grown in Blood agar culture medium.

Extract preparation: Commercial genomic DNA extraction method.

KIT CONTENTS:

1 VIRCELL CDI DNA CONTROL: 1 vial with lyophilized DNA of *Clostridium difficile*, (type strain), (10000-20000 copies/μl once reconstituted (see Table 1)). DNA quantification has been performed by real-time PCR.

2 VIRCELL CONTROL RECONSTITUTION SOLUTION: 500 μl of molecular biology grade water, DNase, RNase free.

Lot number	
Concentration	copies/μl

Table 1.

STORAGE REQUIREMENTS:

Special transport conditions not required. Store the lyophilized vial at 2-8°C inside the foil pouch. Once the pouch is opened, reconstitute the lyophilized vial immediately and store between -5°C and -40°C after reconstitution (temperature indicated on the label).

STABILITY AND HANDLING OF REAGENTS:

Handle reagents in aseptic conditions to avoid microbial contaminations.

Use only the amount of reagent required for the test.

After control resuspension DNA solution should be aliquoted in order to avoid multiple freeze-thaw cycles. The product is stable until the expiry date indicated in the label, if the instructions for use are followed.

VIRCELL, S.L. does not accept responsibility for the mishandling of the reagents included in the kit.

RECOMMENDATIONS AND PRECAUTIONS:

- For research use only. Not for use in diagnostic procedures.
- Sterile tips with aerosol barrier are essential to prevent contamination.
- Specimens should be handled as in the case of infectious samples using research safety laboratory procedures. Thoroughly clean and disinfect all work surfaces with a freshly prepared solution of 0.5% sodium hypochlorite in deionized or distilled water.
- In order to perform the test it is essential to have separate working areas.

5. Dispose of unused reagents and waste in accordance with all applicable regulations.

6. The component VIRCELL DNA CONTROL could include genetic material or substances of animal and/or human origin. VIRCELL DNA CONTROL could contain inactivated antigen. VIRCELL DNA CONTROL contains purified nucleic acids obtained from inactivated microorganism, nevertheless, it should be considered potentially infectious and handled with care. No present method can offer complete assurance that these or other infectious agents are absent. All materials should be handled and disposed as of potentially infectious. Observe the local regulations for waste disposal.

7. Dilutions below 1000 copies/μl should be made immediately before use. Freezing of product dilutions containing less than 1000 copies/μl is not recommended as partial DNA degradation might occur.




PREPARATION OF THE REAGENTS:

- Tear the foil pouch containing VIRCELL DNA CONTROL **1**.
- Centrifuge VIRCELL DNA CONTROL **1** 1 minute at 1000 g.
- Add 100 μl of VIRCELL CONTROL RECONSTITUTION SOLUTION **2** and mix until completely reconstituted. The concentration will be 10000-20000 copies/μl once reconstituted (see Table 1).
- Shake with vortex for 30 seconds to dissolve and homogenize completely.

INTERNAL QUALITY CONTROL:

Each batch is subjected to internal quality control testing before releasing. Quality control analysis is performed by real-time PCR. Final quality control results for each particular lot are available.

SYMBOLS USED IN LABELS:

RUO	For research use only
	Use by (expiration date)
	Store at x-y°C
LOT	Batch code
REF	Catalogue number
	Consult instructions for use
RCNS X μl	Reconstitute in x μl
SHIP	Shipment temperature
STORE	Storage temperature
NO-OP	Do not open until use

For further inquiries please contact:

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