

AMPLIRUN® GARDNERELLA VAGINALIS DNA CONTROL

REF	MBC108-R
RUO	For research use only

INTENDED PURPOSE

Purified DNA of *Gardnerella vaginalis* to be used to control techniques based in nucleic acids amplification.

KIT FEATURES

VIRCELL DNA CONTROL is included in a thermo-sealed foil pouch containing a silica gel bag.

VIRCELL DNA CONTROL is lyophilized. it is necessary to reconstitute it before use (refer to "Preparatory treatment of the device").

Preparation: Grown in gardnerella agar medium.

Extract preparation: Commercial genomic DNA extraction method.

MATERIALS PROVIDED

[1] VIRCELL GVA DNA CONTROL: 1 vial with lyophilized DNA of *Gardnerella vaginalis*, (594 strain (type strain)), (10000-20000 copies/μl once reconstituted (batch concentration is provided in Product Datasheet)). DNA quantification has been performed by real-time PCR.

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

STORAGE AND HANDLING CONDITIONS

Special transport conditions not required.

Store the lyophilized vial at 2-8°C inside the foil pouch.

IN-USE STABILITY

VIRCELL DNA CONTROL reconstituted: store it between -40°C and -5°C and use until expiration date. Avoid more than 3 freeze-thaw cycles during this time period. Store it between 2°C and 8°C and use before 30 minutes.

VIRCELL DNA CONTROL once reconstituted should be aliquoted to avoid repeated freezing and thawing. 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.

WARNINGS AND PRECAUTIONS

1. For research use only.
2. Use of this product should be limited only to personnel trained in molecular techniques.
3. The user of this kit is advised to carefully read and understand the package insert. Strict adherence to the protocol is necessary to obtain reliable test results.
4. Wear personal protective equipment when handling samples and reagents. Wash hands properly after handling the samples and reagents. All procedures must be carried out in accordance with the approved safety standards.
5. Sterile tips with aerosol barrier are essential to prevent contamination.
6. Never pipette by mouth.
7. Do not use in the event of damage to the package.
8. Do not use the kit after expiration date.
9. Do not leave the reagents at temperature different to the recommended longer than absolutely necessary.
10. Keep containers for samples and reagents closed while they are not being handled.
11. Handle in aseptic conditions to avoid microbial contaminations.
12. Reagents in this kit could include nucleic acids. Observe the local regulations for waste disposal.
13. Dispose of unused reagents and waste in accordance with all applicable regulations.
14. Specimens should be handled as in the case of infectious samples using 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.
15. 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.

PREPARATORY TREATMENT OF THE DEVICE

1. Tear the foil pouch containing VIRCELL DNA CONTROL [1].
2. Centrifuge VIRCELL DNA CONTROL [1] 1 minute at 1000 g.
3. Add 100 μl of VIRCELL CONTROL RECONSTITUTION SOLUTION [2] and mix until completely reconstituted. The concentration will be 10000-20000 copies/μl once reconstituted (batch concentration is provided in Product Datasheet).
4. Mix with vortex for 30 seconds to dissolve and homogenize completely.
5. It is recommended to prepare VIRCELL DNA CONTROL aliquots. In case dilutions were to be prepared use VIRCELL CONTROL RECONSTITUTION SOLUTION [2] for this purpose.

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 (expiry date)
	Store at x-y °C
LOT	Batch code
REF	Catalogue number
	Consult instructions for use
RCNS Xμl	Reconstitute in <X> μl
SHIP	Shipment temperature
STORE	Storage temperature
NO-OP	Do not open until use
	Manufacturer

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Updates: General Update