

AMPLIRUN® MYCOPLASMA GENITALIUM DNA CONTROL

For *in vitro* diagnostic use

MBC085: Purified DNA of *Mycoplasma genitalium* to be used to control *in vitro* diagnosis techniques based in nucleic acids amplification.

INTRODUCTION:

Mycoplasma genitalium belongs to the class Mollicutes, that comprises fastidious small bacteria (in dimensions as well as in genome size) lacking a cell wall that grow as colonies of small size. It attaches to the ciliated epithelial cells. The urogenital tract appears to be the primary tissue infected by *M. genitalium*.

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 modified HayFlick culture broth

Extract preparation: Commercial genomic DNA extraction method.

KIT CONTENTS:

1 VIRCELL MGE DNA CONTROL: 1 vial with lyophilized DNA of *Mycoplasma genitalium*, (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.

Materials required but not supplied:

Additional diagnosis kit.

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:

1. This product is for *in vitro* diagnosis use only and for professional qualified staff.
2. Sterile tips with aerosol barrier are essential to prevent contamination.
3. 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.
4. 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 contains *Mycoplasma genitalium* nucleic acids. 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 clinical 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:

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 (see Table 1).
4. Shake 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.

TEST PROCEDURE:

Once nucleic acid is reconstituted, use it according to indications of additional diagnosis kit. Use resuspended VIRCELL CONTROL as an extracted clinical sample adding it directly to amplification reagents.

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.

INTERPRETATION OF RESULTS AND VALIDATION PROTOCOL FOR USERS:

Refer to indications of additional diagnosis kit.

LIMITATIONS OF METHOD:

1. This reagent is intended to be used with methods of human diagnosis. This test has not been verified with other methods.
2. The user of this kit is advised to read carefully and understand the package insert. Strict adherence to the protocol is necessary to obtain reliable test results.



3. Use of this product should be limited only to personnel trained in molecular techniques.

4. The identity test was carried out with some specific primers according to publicly available sequences of the microorganism. Changes in the sequences of the primers of the reaction may produce a range of different sizes or may not display product amplification.

5. This control does not substitute internal diagnostic kit controls.

6. The quantification was carried out by own brand qPCR against a standard used as a calibrator. Results may vary with the amplification conditions of the end user.

7. AMPLIRUN® has not been designed to be used with a particular diagnostic kit coming from a certain manufacturer. It is used to control amplification of a diagnostic laboratory functioning procedure.

PERFORMANCES:

• IDENTITY TEST

PCR analysis of DNA control: PCR analysis was performed with a specific oligonucleotide pair on purified *Mycoplasma genitalium* DNA. The reaction produced a fragment of the expected size.

• QUANTIFICATION TEST

A correlation test was performed between microorganism culture and *Mycoplasma genitalium* extracted DNA. Less than 0.5 log variance was observed between both assays.

• INTRA-ASSAY PRECISION

3 replicas of 5 serial dilutions of 3 different vials of the product were performed by the same operator under identical qPCR conditions.







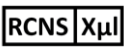



Less than 5% coefficient of variance was observed between all assays.

• INTER-ASSAY PRECISION

3 different replicas of 5 different serial dilutions of 1 vial of the product were individually amplified by 2 different operators on 3 consecutive days.

Less than 5% coefficient of variance was observed between all assays.

SYMBOLS USED IN LABELS:

	In vitro diagnostic medical device
	Use by (expiration date)
	Store at x-y°C
	Batch code
	Catalogue number
	Consult instructions for use
	Reconstitute in x µl
	Shipment temperature
	Storage temperature
	Do not open until use

BIBLIOGRAPHY:

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4. Larionov A, Krause A, Miller W. (2005). A standard curve based method for relative real time PCR data processing. BMC Bioinformatics. 6:62.

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