

# AMPLIRUN® TREPONEMA PALLIDUM DNA CONTROL



MBC109



For *in vitro* diagnostic use

## INTENDED PURPOSE

Purified DNA of *Treponema pallidum* to be used to control techniques based in nucleic acids amplification.

The device is an assayed control.

## INTRODUCTION

*Treponema pallidum* is a motile spirochete with a Gram-negative bacterial type cell wall and metabolic requirements consistent with microaerophiles. It is an obligate parasite that cannot be grown in culture. *T. pallidum* is the causal agent of syphilis. Syphilis is transmitted from person to person by direct contact with syphilis sores during sexual intercourse. Congenital syphilis is caused by transplacental transmission of spirochetes. Nonvenereal trepanomatoses (yaws, pinta and bejel) are caused by subspecies of *T. pallidum*, have a more restricted geographical distribution and affect mainly infants.

## 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 rabbit testis.

Extract preparation: Commercial genomic DNA extraction method.

## MATERIALS PROVIDED

[1] VIRCELL TPA DNA CONTROL: 1 vial with lyophilized DNA of *Treponema pallidum*, (Nichols strain), (700-2000 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.

Special materials required but not provided:

Additional diagnosis kit.

## 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

- For *in vitro* diagnostic use only. For professional use only.
- Use of this product should be limited only to personnel trained in molecular techniques.
- 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.
- 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.
- Sterile tips with aerosol barrier are essential to prevent contamination.
- Never pipette by mouth.
- Do not use in the event of damage to the package.
- Do not use the kit after expiration date.
- Do not leave the reagents at temperature different to the recommended longer than absolutely necessary.
- Keep containers for samples and reagents closed while they are not being handled.
- 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. Any serious incident that occurs 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.

## PREPARATORY TREATMENT OF THE DEVICE

- 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 700-2000 copies/μl once reconstituted (batch concentration is provided in Product Datasheet).
- Mix with vortex for 30 seconds to dissolve and homogenize completely.
- It is recommended to prepare VIRCELL DNA CONTROL aliquots.

## ASSAY 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.

## VALIDATION PROTOCOL FOR USERS

Refer to indications of additional diagnosis kit.

## INTERPRETATION OF RESULTS

Refer to indications of additional diagnosis kit.

## LIMITATIONS OF USE

- The device is not intended to be used for the detection of the presence of, or exposure to, a transmissible agent in biological samples, in order to assess their suitability for transfusion, transplantation or cell administration.
- This reagent is intended to be used with methods for human diagnostics. Other methods have not been verified.
- This external run control does not substitute the internal controls of the diagnostic kit.
- AMPLIRUN® has not been designed to be used with a particular diagnostic kit. It is used to control amplification of a diagnostic laboratory functioning procedure.
- 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 different results.
- 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.
- A summary of safety and performance is available on EUDAMED or it can be requested at email address customerservice@vircell.com.

## PERFORMANCE CHARACTERISTICS

### PRECISION

Real-time PCR analysis including 2 replicates of each vial, two runs per day (with different thermocyclers, CFX96 (Bio-Rad)) for 20 days. Within-run precision, between-run precision, between-day precision and within-laboratory precision were determined.

The results were as follows:

Sample	Within-run precision %CV	Between-run precision %CV	Between-day precision %CV	Within-laboratory precision %CV
Vircell Control	0.5	0.8	0.2	0.9

CV: Coefficient of variation

## IDENTITY TEST

PCR analysis was performed using an oligonucleotide pair specific for the identification of *Treponema pallidum*, previously described in literature. The reactions produced a specific amplification.

## QUANTIFICATION TEST

Quantification is based on Real-Time qPCR using the standard curve method. The concentration is determined by interpolating the Ct value obtained on the previously obtained standard curve performed with the corresponding quantification standard.

The results were as follows:

The concentration was within the range 700-2000 copies/ $\mu$ l.

## SYMBOLS USED IN LABELS



In vitro diagnostic medical device



Use-by (expiry date)



Store at x-y °C



Batch code



Catalogue number



Consult instructions for use



Reconstitute in <X>  $\mu$ l



Shipment temperature



Storage temperature



Do not open until use



Manufacturer

## BIBLIOGRAPHY

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3. Freeman, W. M. et al. 1999. Quantitative RTPCR: pitfalls and potential. Biotechniques, 26(1), 112-122, 124-125.
4. Grange, P. A. et al. 2012. Evaluation of a PCR test for detection of *Treponema pallidum* in swabs and blood. J Clin Microbiol, 50(3), 546-52.
5. Larionov, A. et al. 2005. A standard curve based method for relative real time PCR data processing. BMC Bioinformatics, 6, 62.
6. Tipple, C. et al. 2011. Getting the measure of syphilis: qPCR to better understand early infection. Sex Transm Infect, 87(6), 479-85.

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