

# AMPLIRUN® MYCOBACTERIUM TUBERCULOSIS DNA CONTROL



MBC034



For *in vitro* diagnostic use

## INTENDED PURPOSE

Purified DNA of *Mycobacterium tuberculosis* to be used to control techniques based in nucleic acids amplification.  
The device is an assayed control.

## INTRODUCTION

*Mycobacterium tuberculosis* is an strictly aerobic, nonchromogenic, slowly-growing, acid fast bacillary bacterium. Humans are the only reservoir of *M. tuberculosis*, an obligate pathogen that is transmitted by airborne particles and may remain latent for years before causing an active tuberculosis.

## 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 Middlebrook 7H9 Broth.  
Extract preparation: Commercial genomic DNA extraction method.

## MATERIALS PROVIDED

- [1] VIRCELL MTU DNA CONTROL: 1 vial with lyophilized DNA of *Mycobacterium tuberculosis*, (H37Rv (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.

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

1. For *in vitro* diagnostic use only. For professional 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.
16. 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

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.

## 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

1. The device is not intended to detect antibodies from lymphocyte secretions immunoassay intended for the detection of active *Mycobacterium tuberculosis* infection.
2. This reagent is intended to be used with methods for human diagnostics. Other methods have not been verified.
3. This external run control does not substitute the internal controls of the diagnostic kit.
4. 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.
5. 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.
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. 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	0.2	0.6	0.2	0.5

CV: Coefficient of variation

## IDENTITY TEST

PCR analysis was performed using an oligonucleotide pair specific for the identification of *Mycobacterium tuberculosis*, 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 10000-20000 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

1. Bustin, S. A. 2000. Absolute quantification of mRNA using real-time reverse transcription polymerase chain reaction assays. *J Mol Endocrinol*, 25(2), 169-93.
2. Bustin, S. A. 2002. Quantification of mRNA using real-time reverse transcription PCR (RT-PCR): trends and problems. *J Mol Endocrinol*, 29(1), 23-39.
3. Freeman, W. M. et al. 1999. Quantitative RTPCR: pitfalls and potential. *Biotechniques*, 26(1), 112-122, 124-125.
4. Larionov, A. et al. 2005. A standard curve based method for relative real time PCR data processing. *BMC Bioinformatics*, 6, 62.
5. Xiong, L. et al. 2006. Use of PCR and reverse line blot hybridization microarray based on 16S-23S rRNA gene internal transcribed spacer sequences for rapid identification of 34 *Mycobacterium* species. *J Clin Microbiol*, 44, 3544-3550.

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