

AMPLIRUN® TOTAL CT/NG CONTROL (URINE)

REF

MBTC003

CE 0318

For *in vitro* diagnostic use

INTENDED PURPOSE

Inactivated *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) cells formulated to mimic human urine specimen and intended to validate and control sample processing, analysis and detection in nucleic acid assays using the product as an external run control.

INTRODUCTION

Chlamydiae are nonmotile, obligate intracellular bacteria with a unique life cycle that includes two phases: reticulate and elementary bodies. *Chlamydia trachomatis* is comprised of two human biovars: the lymphogranuloma venereum, remarkable for its tropism for lymphoid cells and its ability to cause systemic disease, and the trachoma biovar, limited primarily to epithelial cells of mucous membranes and able to cause trachoma, sexually transmitted disease, and neonatal inclusion conjunctivitis and pneumonia.

Neisseria gonorrhoeae or gonococcus is a Gram-negative, oxidase-positive, aerobic, nutritionally fastidious, coccal bacterium that appears microscopically under diplococcal arrangement. Humans are the only natural hosts for gonococcus, which is transmitted by sexual intercourse. Infections are generally limited to mucous surfaces that are lined with columnar epithelium cells, involving the urethra, cervix, rectum, pharynx, and conjunctiva.

KIT FEATURES

VIRCELL TOTAL CONTROL are lyophilized. It is necessary to reconstitute them before use (see "Preparatory treatment of the device" section).

VIRCELL TOTAL CONTROL are designed for single use, excess material should be discarded.

Nucleic acid detection requires an extraction step that releases DNA/RNA for amplification and detection.

MATERIALS PROVIDED

[1] VIRCELL TOTAL CT/NG CONTROL (URINE): 10 vials with lyophilized cells of *Chlamydia trachomatis* (20000-50000 copies/vial) and *Neisseria gonorrhoeae* (20000-50000 copies/vial). Batch concentration is provided in Certificate of Analysis.

Quantification validation was performed by real-time PCR.

Special materials required but not provided:

- Molecular Biology grade water
- Additional extraction and detection kit.

STORAGE AND HANDLING CONDITIONS

Store at 2-8°C. Do not use the kit reagents beyond the expiration date. This will be valid only if reagents are stored closed and at 2-8°C.

IN-USE STABILITY

VIRCELL TOTAL CONTROL reconstituted: use it in the same day, keep it refrigerated for a maximum of 12 hours. Unused product should be discarded.

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. The product should be limited to personnel who have been trained in the technique.
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. Dispose of unused reagents and waste in accordance with all applicable regulations.

13. Reagents in this kit contains inactivated microorganism and could include genetic material or substances of animal and/or human origin. Although the material is not infectious, it should be handled as potentially infectious. All material should be handled and disposed as potentially infectious. Observe the local regulations for waste disposal.

14. The glass elements contained in kits could cause physical damage in the event of break. Handle with care.

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

1. Add 1000 µl of Molecular Biology grade water to each vial [1] and mix until completely reconstituted. The cellular concentration will be approximately 35000 copies/ml once reconstituted.

2. Shake with vortex for 30 seconds to dissolve and homogenize completely.

ASSAY PROCEDURE

Follow diagnostic kit instructions treating TOTAL CONTROL in an identical manner to a clinical specimen using recommended amount for extraction and detection.

INTERNAL QUALITY CONTROL

Each batch is subjected to internal quality control (Q.C.) testing before batch release. Final Q.C. results for each particular lot are available.

VALIDATION PROTOCOL FOR USERS

Refer to indications of additional extraction and detection kit.

INTERPRETATION OF RESULTS

Refer to indications of additional extraction and detection kit.

LIMITATIONS OF USE

1. This reagent is intended to be used with methods of human diagnostics. Other methods have not been verified.
2. This external run control does not substitute internal diagnostic kit controls.
3. Quantification conclusions cannot be drawn from a single point sample of known concentration. Precise clinical sample quantification could only be achieved by the standard curve method using a calibrator as MBC075 AMPLIRUN® NEISSERIA GONORRHOEAE DNA CONTROL or MBC012 AMPLIRUN® CHLAMYDIA TRACHOMATIS DNA CONTROL.
4. AMPLIRUN® TOTAL has not been designed to be used with a particular diagnostic kit coming from a certain manufacturer. It is used to validate and control sample processing, analysis and detection of a diagnostic laboratory functioning procedure.

PERFORMANCE CHARACTERISTICS

PRECISION

Real-time PCR analysis including 2 replicates of each vial, two runs per day (with different operators and different thermocyclers) for 20 days. The CV% of within-run precision, between-run precision, between-day precision and between-laboratory precision were analysed.

The results were as follows:

Chlamydia trachomatis

Sample	Within-run precision %CV	Between-run precision %CV	Between-day precision %CV	Between-laboratory precision %CV
Vircell Total Control	2.1	0.8	0.6	2.3

CV: Coefficient of variation

Neisseria gonorrhoeae

Sample	Within-run precision %CV	Between-run precision %CV	Between-day precision %CV	Between-laboratory precision %CV
Vircell Total Control	1.5	0.9	1.1	2.1

CV: Coefficient of variation

IDENTITY TEST

Chlamydia trachomatis

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

Neisseria gonorrhoeae

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

QUANTIFICATION TEST

Quantification is based on Real-Time qPCR using the standard curve method. Real-time PCR analysis of 3 replicates of each vial. The concentration (Log copies/vial) is determined by interpolating the Ct value obtained for each replicate on the previously obtained standard curve performed with the corresponding quantification standard.

The results were as follows:

Chlamydia trachomatis

% Coefficient of variation: 1.5

Neisseria gonorrhoeae

% Coefficient of variation: 1.1

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> µl



Shipment temperature



Storage temperature



Manufacturer

BIBLIOGRAPHY

1. Boel, C. H. et al. 2005. Evaluation of conventional and real-time PCR assays using two targets for confirmation of results of the COBAS AMPLICOR Chlamydia trachomatis/Neisseria gonorrhoeae test for detection of Neisseria gonorrhoeae in clinical samples. J Clin Microbiol, 43(5), 2231-5.
2. Hjeltnes, S. O. et al. 2006. A fast real-time polymerase chain reaction method for sensitive and specific detection of the Neisseria gonorrhoeae porA pseudogene. J Mol Diagn, 8(5), 574-581.
3. Jaton, K. et al. 2006. A novel real-time PCR to detect Chlamydia trachomatis in first-void urine or genital swabs. J Med Microbiol, 55(12), 1667-1674.

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Updates: Modification of the composition and concentrations of the products - see "Update in section"

Update in section: MATERIALS PROVIDED