

AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB)

For research use only

MBTC024-R: Four common microorganisms involved in Sexually transmitted diseases (STDs) pooled that have been inactivated to render them non-infectious and formulated in transport medium. Table 1 lists type of microorganism and culture method used to grow each microorganism included in this control. This kit is intended to validate and control sample processing, amplification and detection in nucleic acid assays based on the molecular identification of microorganisms related to STDs, using the product as an external run control.

CHARACTERISTICS:

The content is lyophilized. It is necessary to reconstitute it before use (refer to "Preparation of the reagents"). Total Controls 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.

Product description:

Microorganisms were grown in the laboratory (see Table 1 for culture method used in each case), inactivated and diluted in a transport medium containing cells obtained from epithelial human cell lines.

MICROORGANISM	STRAIN	GROWTH MEDIUM
<i>Chlamydia trachomatis</i>	Lymphogranuloma venereum (LGV II) strain 434	Elementary bodies purified from supernatants of McCoy cells by differential centrifugation.
<i>Neisseria gonorrhoeae</i>	Type strain	Grown in chocolate agar culture medium
<i>Trichomonas vaginalis</i>	Clinical isolate	Grown in modified LVI broth medium
<i>Mycoplasma genitalium</i>	Type strain	Grown in modified HayFlick culture broth

Table 1.

KIT CONTENTS:

1 VIRCELL TOTAL CT/NG/TV/MGE CONTROL (SWAB): 10 vials with lyophilized CT, NG, TV and MGE simulating a clinical sample. Each microorganism is in a concentration that ranges from 20000-50000 copies/vial. Batch concentration is provided in Certificate of Analysis.

Quantification validation was performed by real-time PCR.

Materials required but not supplied:

Molecular Biology grade water
Additional extraction and detection kit.

STORAGE REQUIREMENTS:

Special transport conditions not required. Store the lyophilized vial at 2-8°C. After reconstitution, suspension should be used on the same day. Unused product should be discarded.

STABILITY AND HANDLING OF REAGENTS:

Handle reagents in aseptic conditions to avoid microbial contaminations.

Use only the amount of reagent required for the test.

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 research 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 TOTAL CONTROL could include genetic material or substances of animal and/or human origin. VIRCELL TOTAL CONTROL contains inactivated microorganism, nevertheless, it should be considered potentially infectious and handled with care. Inactivation was verified by the absence of growth under same culture conditions used for each microorganism. 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 waste disposal.

PREPARATION OF THE REAGENTS:

1. Add 1000 µl of Molecular Biology grade water to vial **1** and mix until completely reconstituted. The concentration will be approximately 35000 copies/ml once reconstituted.
2. Shake with vortex for 30 seconds to dissolve and homogenize completely.
3. Follow research kit instructions treating TOTAL CONTROL in an identical manner to a specimen using recommended amount for extraction and detection.

INTERNAL QUALITY CONTROL:










Each batch is subjected to internal quality control testing before releasing. Quality control analysis is performed using a sample preparation kit and real-time PCR for quantification. Final quality control results for each particular lot are available.

INTERPRETATION OF RESULTS AND VALIDATION PROTOCOL FOR USERS:

Refer to indications of additional extraction and detection kit.



SYMBOLS USED IN LABELS:

	For research use only
	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

For any question please contact:

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