

AMPLIRUN® TOTAL

MYCOPLASMA GENITALIUM and macrolide resistance markers

Take control now, Molecular Control

AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB)

EXTRACTION & AMPLIFICATION CONTROLS FOR NUCLEIC ACID TESTS

- The first third-party control panel including wildtype MGE and the two most common macrolide resistance markers.
- Inactivated whole pathogen - Contains the entire genome and is compatible with any analysis.
- Total control in a matrix that mimics a human genital specimen - For monitoring the entire process: extraction, amplification, and detection.
- Quantified, Low Positive - Prepared to produce results at a significant clinical concentration.
- Monodose format and lyophilized presentation - It guarantees stability and avoids handling and additional transport costs.
- Non-infectious material with inactivation certificate.
- Multiple platform compatibility.



RUO

vircell
MICROBIOLOGISTS

AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB)

Ref. MBTC029-R

Inactivated *Mycoplasma genitalium* (MGE) cells formulated in viral transport medium, intended to validate and control nucleic acid assays as an external run control.

The use of AmpliRun® Total Controls will help your lab to:

- Enhance the quality of the whole testing process: extraction, amplification and detection.
- Monitor the instrument performance in the long term obtaining comparable results.
- Validate and verify new assays.
- Follow variations in laboratory procedures, including batches of assay reagents.
- Comply with lab accreditation requirements.

➤ **Verify MGE resistance detection with AmpliRun® Total Control Panel including wildtype MGE and the two most common macrolide resistance markers.**

This product has been successfully validated for its use with the Speedx **ResistancePlus**® MG Flexible, a sample-to-answer solution for Cepheid GeneXpert® System.



KIT CONTENTS

- 4 vials with lyophilized cells of *M. genitalium* sensitive type strain.
- 3 vials with lyophilized cells of *M. genitalium* harboring the A2059G mutation in 23S rRNA gene.
- 3 vials with lyophilized cells of *M. genitalium* harboring the A2058G mutation in 23S rRNA gene.
- Each vial contains 20,000-50,000 copies. Precise batch concentration is provided in the certificate of analysis.
- The quantification is performed by real-time PCR.
- Reconstitution volume: 1 mL.

ORIGIN

Mycoplasma was in vitro cultivated, once purified, cells were inactivated rendering them non-infectious and diluted in a transport medium containing cells obtained from epithelial human cell lines to mimic a clinical sample.

STORAGE REQUIREMENTS AND SHELF LIFE

No special transport conditions are required. The vials are to be kept lyophilized at 2-8°C. After reconstitution, suspension should be used on the same day. Unused product should be discarded.

AmpliRun® Total Controls have a shelf life of 30 months from the date of manufacture.

INFORMATION AND RELATED PRODUCTS

| Description | Cat. No. | Content |
|---|------------------|-------------------------|
| AMPLIRUN® TOTAL MACROLIDE RESISTANT MGE CONTROL PANEL (SWAB) NEW | MBTC029-R | 10 vials |
| AMPLIRUN® TOTAL CT/NG/TV/MGE CONTROL (SWAB) | MBTC024-R | 10 vials |
| AMPLIRUN® MYCOPLASMA GENITALIUM DNA CONTROL | MBC085 | 10,000-20,000 copies/µl |

