VIASURE by certest

"Ready & Easy-to-use" kits.
Lyophilised product

Transport and storage at room temperature.
Shelf-life: 24 months

Validated according to **ISO 13485** and **CE marked**

Macrolide resistance-associated mutations (23S rRNA)

Mycoplasma genitalium (MG) is a common cause of non-gonococcal urethritis (NGU) and non-chlamydial urethritis in men and cervicitis in women, and is reported to be associated with pelvic inflammatory disease, infertility, and preterm birth. *M. genitalium* is a flask-shaped organism with a slightly curved terminal organelle, capable of cause inflammation in the urogenital tract by adhesion to host epithelial cells, eliciting acute inflammatory signals via highly expressed innated immune sensors.

Macrolides are a class of drugs used in the management and treatment of various bacterial infections, such as pneumonia, sinusitis, pharyngitis, tonsillitis, uncomplicated skin infections and otitis media or *Helicobacter pylori* infection, but are also commonly used to treat sexually transmitted infections such as gonococcal and chlamydial infections. The mechanism of action consists of binding to the bacterial 50S ribosomal subunit (close to the peptidyl transferase site (V region)) or to the A2058 and A2059 (*Escherichia coli* numbering) residues of 23S rRNA, causing the cessation of bacterial protein synthesis.

Mycoplasma genitalium is a fastidious organism to culture, requiring weeks to months to grow and conventional methods of susceptibility testing are not possible. Susceptibility testing using *M. genitalium* strains grown in Vero cell culture with dilutions of antibiotics looking for growth inhibition has been shown to be similar to conventional broth dilution. **However, this methodology is not practical for primary diagnostic or most reference laboratories.**

Simultaneous testing for genotypic resistance is recommended to inform treatment given the high rate of antimicrobial resistance.

VIASURE Macrolide resistance-associated mutations (23S rRNA) Real Time PCR Detection Kit is designed for the qualitative detection and differentiation of specific point mutations (conferred by base substitutions in 23S rRNA) implicated in macrolide resistance of *Mycoplasma genitalium*, from genital swab samples of individuals with confirmed *Mycoplasma genitalium* infection with molecular assays. After DNA isolation, the identification of *M. genitalium* resistant/sensitive to macrolides is performed by the amplification of a conserved region of the 23S rRNA gene where specific point mutations related to resistance to macrolides can occurred, using specific primers and a fluorescent–labelled probes.

VIASURE
by certest

Macrolide resistance-associated mutations (23S rRNA)

VIASURE *Macrolide resistance-associated mutations (23S rRNA)* Real Time PCR Detection Kit is a real time PCR assay designed for the qualitative detection and differentiation of specific point mutations (conferred by base substitutions in 23S rRNA) implicated in macrolide resistance of Mycoplasma genitalium, from genital swab samples of individuals with confirmed Mycoplasma genitalium infection with molecular assays.

This test is intended for use as an aid in the diagnosis of potential resistance to macrolides, in combination with clinical and epidemiological risk factors.

Analytical sensitivity

VIASURE *Macrolide resistance-associated mutations (23S rRNA)* Real Time PCR Detection Kit has a detection limit of 8 DNA copies/µL for *M. genitalium* resistant to macrolides, and 0.2 CFU/µL for *M. genitalium* sensitive to macrolides, with a positive rate of ≥95%, on vaginal swab samples. (Figures 1, 2, 3, 4, 5 and 6)

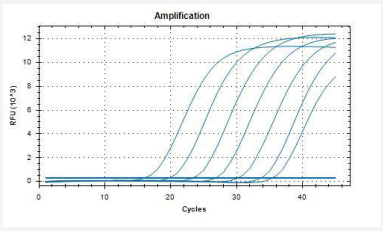

Figure 1.
Dilution series of *M. genitalium* macrolide resistance target sequence (point mutation 1) (10^7-10^1 copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel FAM).

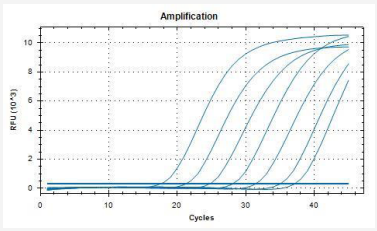

Figure 2.
Dilution series of *M. genitalium* macrolide resistance target sequence (point mutation 2) (10^7-10^1 copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel FAM).

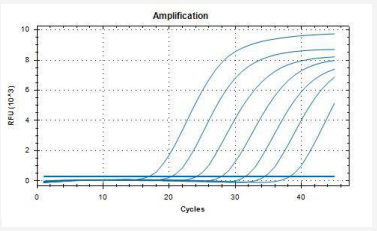

Figure 3.
Dilution series of *M. genitalium* macrolide resistance target sequence (point mutation 3) (10^7-10^1 copies/rxn) template run on the CFX96™ Real-Time PCR Detection System (Bio-Rad) (channel FAM).

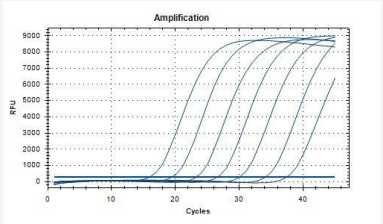

Figure 4.
Dilution series of *M. genitalium* macrolide resistance target sequence (point mutation 4) (10^7-10^1 copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel FAM).

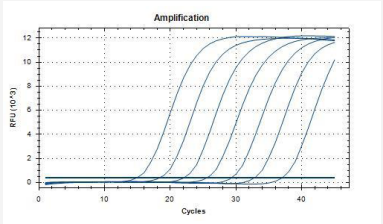

Figure 5.
Dilution series of *M. genitalium* macrolide resistance target sequence (point mutation 5) (10^7-10^1 copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel FAM).

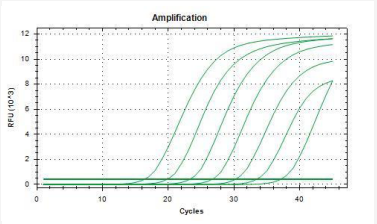

Figure 6.
Dilution series of *M. genitalium* macrolide sensitivity target sequence (10^7-10^1 copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel HEX).

References - VIASURE *Macrolide resistance-associated mutations (23S rRNA)* Real Time PCR Detection Kit

1 x 8-well strips, low profile	VS-MGR101L
6 x 8-well strips, low profile	VS-MGR106L
12 x 8-well strips, low profile	VS-MGR112L
96-well plate, low profile	VS-MGR113L
4 tubes x 24 reactions	VS-MGR196T
2 x 4-well strips, Rotor-Gene®	VS-MGR101
1 x 8-well strips, high profile	VS-MGR101H
6 x 8-well strips, high profile	VS-MGR106
12 x 8-well strips, high profile	VS-MGR112H
96-well plate, high profile	VS-MGR113H
9 x 4-well strips, Rotor-Gene®	VS-MGR136
18 x 4-well strips, Rotor-Gene®	VS-MGR172

certest

For more information and use procedure, read the instructions for use included in this product.

Certest Biotec, S.L. Pol. Industrial Río Gállego II · Calle J, N°1 50840, San Mateo de Gállego, Zaragoza (Spain)
Tel. (+34) 976 520 354 | viasure@certest.es | **www.certest.es**