

# VIASURE MULTIPLEX

## Sexually transmitted diseases Real Time PCR Detection Kit

### Pathogen and product description

**S**exually transmitted infections (STIs) represent a group of diseases that affect the sexual and reproductive health of millions of people, being a public problem of interest. Etiological agents responsible for STIs include fungi, bacteria, parasites and viruses. Some of these microorganisms are eliminated after a period of time, while others are recurrent and some remain in the body asymptotically, allowing the progress of the disease and generating consequences such as inflammations of the genito-urinary tract, infertility and even the development of cancer.

*Trichomonas vaginalis* infection is one of the most common sexually transmitted diseases (STDs) in the world. In women it can be found in the vagina and in the urethra, while in men it can be found in the urethra, the prostate and the epididymis. *Trichomonas vaginalis* infection has been associated with vaginitis, cervicitis and urethritis, premature rupture of membranes and premature delivery in pregnant women. *Trichomonas vaginalis* infection has also been associated with an increased risk of HIV acquisition and transmission in women.

*Mycoplasma hominis* colonizes the lower urogenital tract and is associated with urogenital infections, particularly bacterial vaginosis and non-gonococcal urethritis. It is also involved in extra genital infections, such as postpartum or post-abortion fever, in post-caesarean wound infections or after a hysterectomy. It is considered a bacterium present in the normal micro flora in 20% of the male population and in 40% of the female population.

*Mycoplasma genitalium* is a facultative anaerobic organism and a recognized cause of nongonococcal urethritis in men. In women, *M. genitalium* has been associated with cervicitis, endometritis, pelvic inflammatory disease (PID), infertility, susceptibility to human immunodeficiency virus (HIV), and adverse birth outcomes, indicating a consistent relationship with female genital tract pathology.

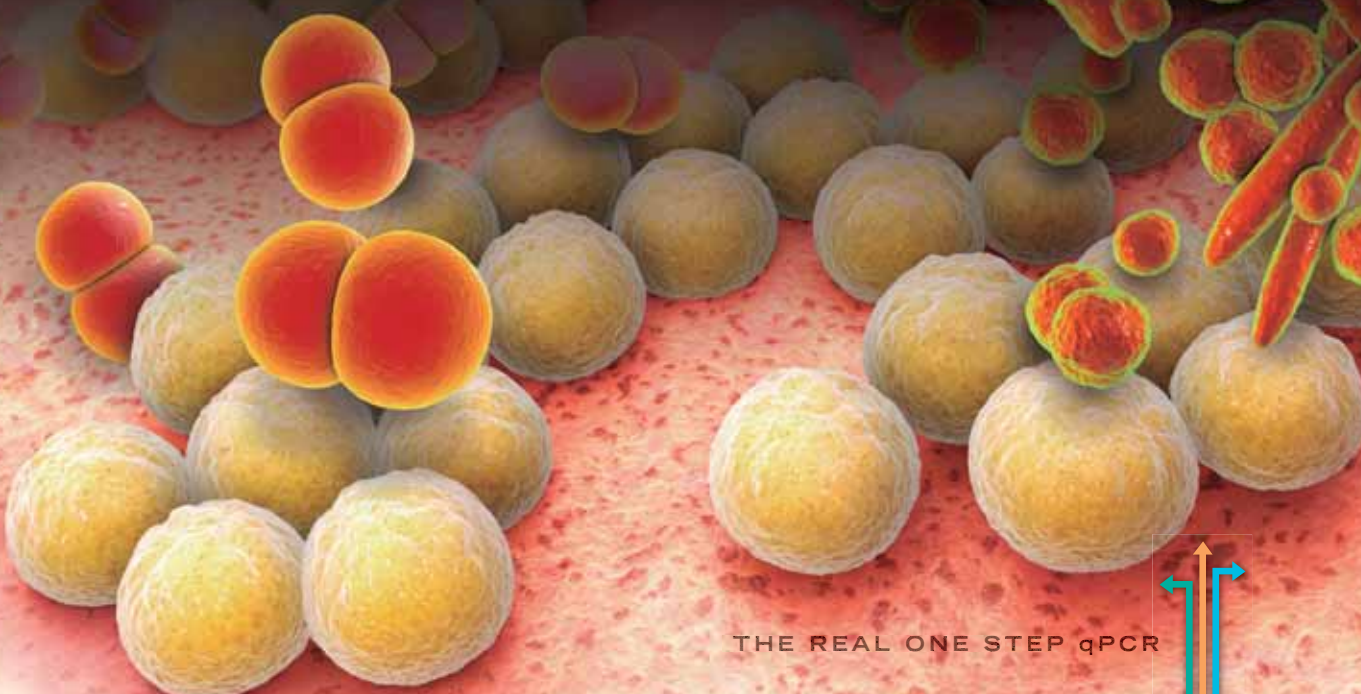
*Ureaplasma spp.* are often isolated from human genital

mucosa of individuals with a lack of symptoms. In humans, two major species, namely *Ureaplasma parvum* and *Ureaplasma urealyticum* (family *Mycoplasmataceae*, genus *Ureaplasma*) are part of the genital flora of men and women and are present in almost 70% of sexually active population. These bacteria cause inflammation and lead to chorioamnionitis, preterm deliveries, and premature rupture of membranes.

*Neisseria gonorrhoeae* is an obligate human pathogen and is the etiological agent of gonorrhoea. Syndromes include cervicitis in women, and urethritis, pharyngitis and proctitis in both sexes. If untreated, women may experience severe sequelae of pelvic inflammatory disease, chronic pelvic pain, ectopic pregnancy and tubal infertility, while men may develop epididymitis, prostatitis and urethral stricture.

*Chlamydia trachomatis* is a small intracellular bacterium that requires living cells to multiply. In males, this can cause epididymitis, which is not thought to be an important cause of long-term sequelae. However, in females, upper tract infection can result in pelvic inflammatory disease (PID), a spectrum of clinical disorders involving infection and inflammation of the uterus, fallopian tubes, ovaries, or adjacent peritoneum.

VIASURE Sexually Transmitted Diseases Real Time PCR Detection Kit is designed for the diagnosis of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, *Trichomonas vaginalis*, *Ureaplasma urealyticum*, *Ureaplasma parvum* and/or *Mycoplasma hominis* in clinical samples. After DNA isolation, the identification of the STDs is performed by the amplification of a conserved region of the *T. vaginalis*-specific 2-kb repeated sequence, (*Trichomonas vaginalis*), *urea* gene (*Ureaplasma urealyticum* and *Ureaplasma parvum*), *gidC* gene (*Mycoplasma hominis*), *porA* and *Opa* genes (*Neisseria gonorrhoeae*), a region within *ORF2* of the chlamydial plasmid (*Chlamydia trachomatis*) and *MgPa adhesin* gene (*Mycoplasma genitalium*), using specific primers and a fluorescent-labelled probe.



## Analytical sensitivity

**VIASURE** Sexually Transmitted Diseases Real Time PCR Detection Kit has a detection limit of  $\geq 10$  DNA copies per reaction (figures 1 to 7).

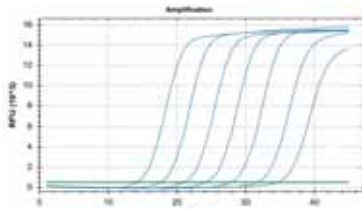


Figure 1. Dilution series of *Trichomonas vaginalis* ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System (Multiplex reaction mix *Trichomonas vaginalis*, *Ureaplasma urealyticum*, *Ureaplasma parvum* & *Mycoplasma hominis*, channel FAM).

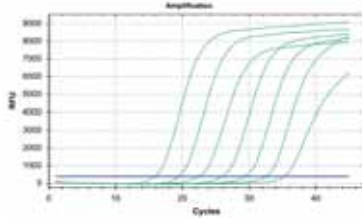


Figure 2. Dilution series of *Ureaplasma urealyticum* ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System (Multiplex reaction mix *Trichomonas vaginalis*, *Ureaplasma urealyticum*, *Ureaplasma parvum* & *Mycoplasma hominis*, channel HEX).

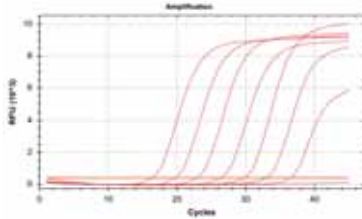


Figure 3. Dilution series of *Ureaplasma parvum* ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System (Multiplex reaction mix *Trichomonas vaginalis*, *Ureaplasma urealyticum*, *Ureaplasma parvum* & *Mycoplasma hominis*, channel ROX).

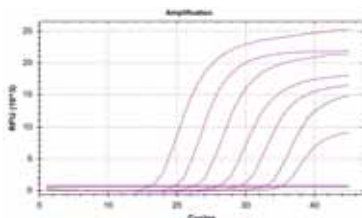


Figure 4. Dilution series of *Mycoplasma hominis* ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System (Multiplex reaction mix *Trichomonas vaginalis*, *Ureaplasma urealyticum*, *Ureaplasma parvum* & *Mycoplasma hominis*, channel Cy5).

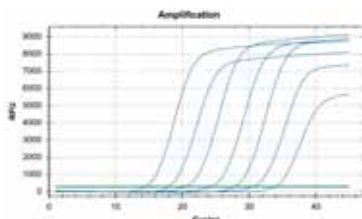


Figure 5. Dilution series of *Chlamydia trachomatis* ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System (Multiplex reaction mix *Neisseria gonorrhoeae*, *Chlamydia trachomatis* & *Mycoplasma genitalium*, channel FAM).

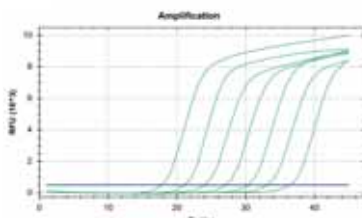


Figure 6. Dilution series of *Mycoplasma genitalium* ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System (Multiplex reaction mix *Neisseria gonorrhoeae*, *Chlamydia trachomatis* & *Mycoplasma genitalium*, channel HEX).

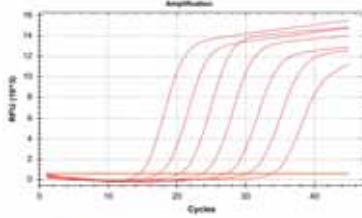


Figure 7. Dilution series of *Neisseria gonorrhoeae* ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96 Touch™ Real-Time PCR Detection System (Multiplex reaction mix *Neisseria gonorrhoeae*, *Chlamydia trachomatis* & *Mycoplasma genitalium*, channel ROX).

## Components

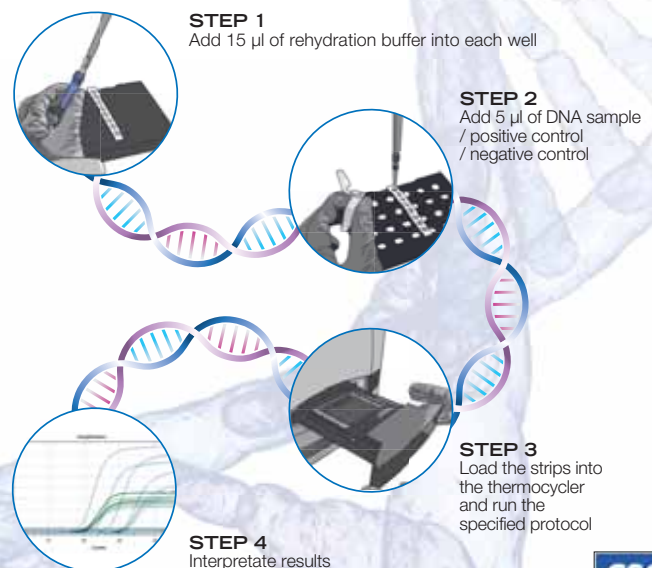
Reagent/Material	Description	Colour	Amount
<i>Neisseria gonorrhoeae</i> , <i>Chlamydia trachomatis</i> & <i>Mycoplasma genitalium</i> 8-well strips	A mix of enzymes, primers-probes, buffer and dNTPs in stabilized format	White	3/6 x 8-well strip
<i>Trichomonas vaginalis</i> , <i>Ureaplasma urealyticum</i> , <i>Ureaplasma parvum</i> & <i>Mycoplasma hominis</i> 8-well strips	A mix of enzymes, primers-probes, buffer and dNTPs in stabilized format	White	3/6 x 8-well strip
Rehydration Buffer	Solution to reconstitute the stabilized product	Blue	1 vial x 1,8 mL
Sexually Transmitted Diseases Positive Control	Non-infectious synthetic lyophilized cDNA	Red	1 vial
Negative Control	Non template control	Violet	1 vial x 1 mL
Water RNase/DNase free	RNase/DNase free water	White	1 vial x 1 mL
Tear-off 8-cap strips	Optical caps for sealing wells during thermal cycling	Transparent	6/12 x 8-cap strip

## Kit References

Reference	Description
VS-STD106L	VIASURE Sexually Transmitted Diseases Real Time PCR Detection Kit 6 x 8-well strips, low profile
VS-STD106H	VIASURE Sexually Transmitted Diseases Real Time PCR Detection Kit 6 x 8-well strips, high profile
VS-STD112L	VIASURE Sexually Transmitted Diseases Real Time PCR Detection Kit 12 x 8-well strips, low profile
VS-STD112H	VIASURE Sexually Transmitted Diseases Real Time PCR Detection Kit 12 x 8-well strips, high profile

## Work Flow

### One-step rehydration of wells and add your extracted DNA



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