



"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

Neisseria gonorrhoeae ciprofloxacin resistant

- ▶ *N. gonorrhoeae* is a bacterium (gonococcus) mainly known worldwide as the aetiological agent of gonorrhoea. *N. gonorrhoeae* generally causes mucosal infections of the urogenital tract. Such *N. gonorrhoeae* infections most frequently result in urethritis in men and cervicitis in women, but urethritis in women can also be observed. If infections are not detected and/or adequately treated, ascending infections, such as epididymitis and salpingitis, can result in a variety of serious complications and sequelae, particularly in women who bear the major burden of the disease; these complications and sequelae include pelvic inflammatory disease (PID), chronic pelvic pain, ectopic pregnancy, and infertility.

Ciprofloxacin is an oral fluoroquinolone that is used to treat mild-to moderate urinary and respiratory tract infections, but is also used for infectious diarrhoea, typhoid fever, uncomplicated gonorrhoea, treatment of *Neisseria meningitidis* nasal carriage and prophylaxis against anthrax.

N. gonorrhoeae ciprofloxacin resistance is most often conditioned by mutations in the *gyrA* and *parC* genes, coding for topoisomerases II (DNA gyrase) and IV, respectively. Simultaneous combination of changes in both proteins usually determines the resistance. The most frequently described substitutions in the *N. gonorrhoeae* GyrA protein include: S91F for T, A92P, D95N or A or G, I97M and Q102H, while the most common combinations of amino acid substitutions in the GyrA and ParC proteins conditioning resistance to fluoroquinolones are: S91F + D95G/A in GyrA and S87R in ParC. This combination was found in more than 40% of *N. gonorrhoeae* strains resistant to fluoroquinolones.

- ▶ **VIASURE *Neisseria gonorrhoeae* ciprofloxacin resistant Real Time PCR Detection Kit** is designed for the qualitative detection and identification of DNA from *N. gonorrhoeae* and/or a specific point mutation that generates resistance to ciprofloxacin (CIP) in *N. gonorrhoeae*, from isolate strains from clinical samples and clinical samples such as urethral urine, urethral swabs, endocervical swabs and rectal swab samples already characterized as *N. gonorrhoeae* positive (using molecular assays).

Neisseria gonorrhoeae ciprofloxacin

VIASURE Neisseria gonorrhoeae ciprofloxacin Real Time PCR Detection Kit is a real-time PCR assay designed for the qualitative detection and identification of DNA from *N. gonorrhoeae* and/or a specific point mutation (located in the *gyrA* gene, changing the serine in position 91 of the wild type of genotype to phenylalanine) that generates resistance to ciprofloxacin (CIP) in *N. gonorrhoeae*, from isolate strains from clinical samples and clinical samples such as urethral urine, urethral swabs, endocervical swabs and rectal swab samples already characterized as *N. gonorrhoeae* positive (using molecular assays) of individuals suspected of gonorrhoea disease by their healthcare professional (HCP).

This test is intended for use as an aid in the diagnosis of *N. gonorrhoeae* infection and its potential resistance or sensitive to CIP, in combination with clinical and epidemiological risk factors.

DNA is extracted from clinical specimens, amplified using real time PCR, and detected using fluorescent reporter dye probes specific for *N. gonorrhoeae* and for a specific point mutation associated to CIP resistance in *N. gonorrhoeae*.

► Analytical sensitivity

VIASURE Neisseria gonorrhoeae ciprofloxacin Real Time PCR Detection Kit has a detection limit of 4 DNA copies per reaction for *N. gonorrhoeae* ciprofloxacin resistance coding gene, 0.02 CFU per reaction for *N. gonorrhoeae*, and 1.28 CFU per reaction for *N. gonorrhoeae* ciprofloxacin sensitivity coding gene, with a positive rate of $\geq 95\%$, on vaginal swab clinical samples. (Figure 1, 2 and 3)

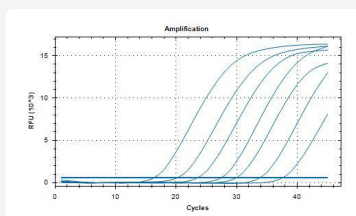


Figure 1.

Dilution series of *N. gonorrhoeae* CIP resistant coding gene (10^7 - 10^1 copies/rxn) template run on the CFX96™ Real-Time PCR Detection System (Bio-Rad) (channel FAM).

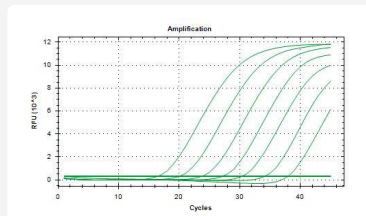


Figure 2.

Dilution series of *N. gonorrhoeae* CIP sensitive coding gene (10^7 - 10^1 copies/rxn) template run on the CFX96™ Real-Time PCR Detection System (Bio-Rad) (channel HEX).

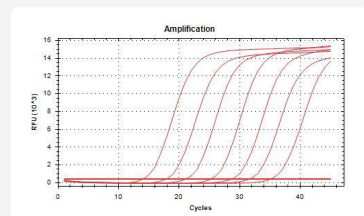


Figure 3.

Dilution series of *N. gonorrhoeae* (*porA* gene) (10^7 - 10^1 copies/rxn) template run on the CFX96™ Real-Time PCR Detection System (Bio-Rad) (channel ROX).

► References - VIASURE Neisseria gonorrhoeae ciprofloxacin Real Time PCR Detection Kit

1 x 8-well strips, low profile..... VS-NCR101L
6 x 8-well strips, low profile..... VS-NCR106L
12 x 8-well strips, low profile VS-NCR112L
96-well plate, low profile..... VS-NCR113L
4 tubes x 24 reactions..... VS-NCR196T
2 x 4-well strips, Rotor-Gene®..... VS-NCR101

1 x 8-well strips, high profile.....VS-NCR101H
6 x 8-well strips, high profile.....VS-NCR106H
12 x 8-well strips, high profileVS-NCR112H
96-well plate, high profile.....VS-NCR113H
9 x 4-well strips, Rotor-Gene®.....VS-NCR136
18 x 4-well strips, Rotor-Gene®.....VS-NCR172

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