



# GeneProof

## GeneProof CT/NG/MG Multiplex PCR Kit



### MORE INFORMATION WITH LESS SAMPLES

- PCR Kit detects the most important STI pathogens in a single reaction tube:
- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Mycoplasma genitalium*

### DETECTS *porA* MUTANT OF *N. GONORRHOEAE*

- Dual target detection of 16S rRNA gene and *porA* pseudogene

### SWEDISH VARIANT OF *C. TRACHOMATIS*

- Dual target detection of 16S rRNA gene and cryptic plasmid

### HIGH SENSITIVITY

- Secured by targeting the multicopy sequence of 16S rRNA for all three detected pathogens

### CONTAMINATION ELIMINATION

- Ready-to-Use Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating contamination with amplification products



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



# GeneProof CT/NG/MG Multiplex PCR Kit

- + CT/NG/MG Multiplex PCR Kit
- + Mycoplasma genitalium/hominis PCR Kit
- + Herpes Simplex Virus 1 (HSV-1) PCR Kit
- + Chlamydia trachomatis PCR Kit
- + Human Papillomavirus (HPV) PCR Kit
- + Herpes Simplex Virus 2 (HSV-2) PCR Kit
- + Neisseria gonorrhoeae PCR Kit
- + Ureaplasma PCR Kit
- + Herpes Simplex Virus (HSV-1/2) PCR Kit

<b>TECHNOLOGY</b>	real-time PCR
<b>TYPE OF ANALYSIS</b>	qualitative
<b>TARGET SEQUENCE</b>	the cryptic plasmid sequence and the 16S rRNA gene for <i>Chlamydia trachomatis</i> the 16S rRNA gene and porA pseudogene for <i>Neisseria gonorrhoeae</i> the 16S rRNA gene for <i>Mycoplasma genitalium</i>
<b>ANALYTICAL SPECIFICITY</b>	<i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> and <i>Mycoplasma genitalium</i> , 100 %
<b>ANALYTICAL SENSITIVITY (LOD)</b>	reaches up to 0.177 cp/μl with the probability of 95 % (on Amplirun® <i>Chlamydia trachomatis</i> DNA control, Vircell) reaches up to 0.22 cp/μl with the probability of 95 % (on Amplirun® <i>Neisseria gonorrhoeae</i> DNA control, Vircell) reaches up to 1.129 cp/μl with the probability of 95 % (on Amplirun® <i>Mycoplasma genitalium</i> DNA control, Vircell)
<b>DIAGNOSTIC SPECIFICITY</b>	96.89 % (CI <sub>95 %</sub> : 93.04 % - 98.73 %)
<b>DIAGNOSTIC SENSITIVITY</b>	97.67 % (CI <sub>95 %</sub> : 86.20 % - 99.88 %)
<b>EXTRACTION/INHIBITION CONTROL</b>	PCR inhibition control (ISIN version) PCR inhibition and DNA extraction efficiency control (ISEX version)
<b>VALIDATED SPECIMEN</b>	swab, urine
<b>STORAGE</b>	-20 ± 5 °C
<b>VALIDATED EXTRACTION METHODS</b>	croBEE NA16 Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation Kit
<b>INSTRUMENTS</b>	croBEE Real-Time PCR System* Applied Biosystems 7500 Real-Time PCR System CFX96™/ Dx Real-Time PCR Detection System Mic qPCR Cycller QuantStudio™ 5 Real-Time PCR System Rotor-Gene 3000 / Q
<b>REQUIRED DETECTION CHANNELS</b>	FAM, HEX, Cy5, Texas Red
<b>EXTERNAL QUALITY ASSESSMENT</b>	regularly tested by QCMD and Instand e.V. External Quality Assessment Panels - results at <a href="http://www.geneproof.com">www.geneproof.com</a>
<b>REGULATORY STATUS</b>	CE <sub>1023</sub> IVD

\* Validated instruments

PRODUCT NAME	TECHNOLOGY	ORDER NO.		
		25 REACTIONS	50 REACTIONS	100 REACTIONS
GeneProof CT/NG/MG Multiplex PCR Kit	real-time PCR	CNMX/ISEX/025	CNMX/ISEX/050	CNMX/ISEX/100