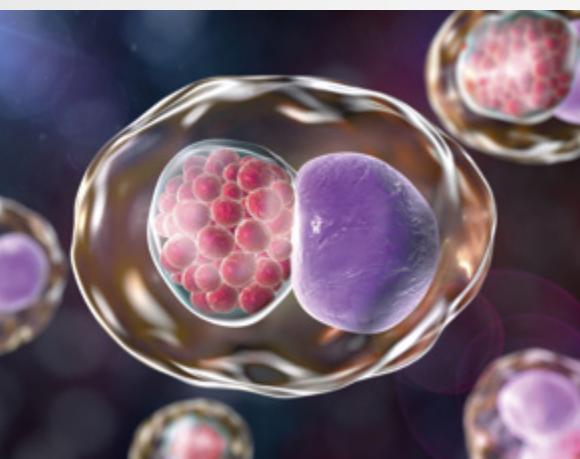




Sexually
Transmitted
Infections

GeneProof®

GeneProof CT/NG/MG Multiplex PCR Kit



MORE INFORMATION FROM ONE REACTION

- PCR Kit detects and distinguishes the most important STI pathogens in a single reaction tube:

Chlamydia trachomatis

Neisseria gonorrhoeae

Mycoplasma genitalium

SIMPLE LABORATORY WORKFLOW

- Easily combinable with other PCR kits from the STI Panel in one workflow

EASY-TO-USE CONCEPT

- Single tube Ready-to-Use Master Mix contains all components for PCR amplification
- No additional PCR reagents pipetting necessary



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

HIGH SENSITIVITY

- Detects porA mutant of *Neisseria gonorrhoeae* and Swedish variant of *Chlamydia trachomatis*
- Secured by targeting the multicopy sequence of 16S rRNA for all three detected pathogens

CONTAMINATION PREVENTION

- Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating carryover contamination

ORDER INFORMATION

REF	PACKAGE
CNMX/ISEX/025	25 reactions
CNMX/ISEX/100	100 reactions



CERTIFIED
DIAGNOSTIC TEST

www.geneproof.com

ISO 13485

GUARANTEED CONTROL OVER
THE COMPLETE PROCESS OF DEVELOPMENT,
MANUFACTURING AND DISTRIBUTION OF ALL
THE OFFERED GENEPROOF PRODUCTS



GeneProof CT/NG/MG Multiplex PCR Kit

- + GeneProof Chlamydia trachomatis PCR Kit
- + GeneProof Neisseria gonorrhoeae PCR Kit
- + GeneProof CT/NG/MG Multiplex PCR Kit
- + GeneProof Gardnerella vaginalis PCR Kit

- + GeneProof MH/UU/UP Multiplex PCR Kit
- + GeneProof Mycoplasma genitalium/hominis PCR Kit
- + GeneProof Ureaplasma PCR Kit
- + GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit

- + GeneProof Trichomonas vaginalis PCR Kit
- + GeneProof Treponema pallidum PCR Kit
- FOR SCREENING PURPOSES**
- + GeneProof Human Papillomavirus (HPV) Screening PCR Kit

INDICATION	<i>in vitro</i> diagnostic medical device
REGULATORY STATUS	CE ₁₀₂₃ IVD
INTENDED USER	For professional use in laboratories with trained staff
TECHNOLOGY	Real-time PCR
TYPE OF ANALYSIS	Qualitative
TARGET SEQUENCE	The cryptic plasmid sequence and the 16S rRNA gene for <i>Chlamydia trachomatis</i> The 16S rRNA gene and <i>porA</i> pseudogene for <i>Neisseria gonorrhoeae</i> The 16S rRNA gene for <i>Mycoplasma genitalium</i>
ANALYTICAL SPECIFICITY	<i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> and <i>Mycoplasma genitalium</i> , 100 %
ANALYTICAL SENSITIVITY (LoD with 95% probability)	0.177 cp/μl (on Amplirun® Chlamydia trachomatis DNA control, Vircell) 0.22 cp/μl (on Amplirun® Neisseria gonorrhoeae DNA control, Vircell) 1.129 cp/μl (on Amplirun® Mycoplasma genitalium DNA control, Vircell)
DIAGNOSTIC SPECIFICITY	96.89 % (CI _{95%} : 93.04 % – 98.73 %)
DIAGNOSTIC SENSITIVITY	97.67 % (CI _{95%} : 86.20 % – 99.88 %)
VALIDATED SPECIMEN	Swab, urine
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation Kit
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Real-Time PCR System Applied Biosystems 7500 Real-Time PCR System CFX96™/ Dx Real-Time PCR Detection System Mic qPCR Cyclor QuantStudio™ 5 Real-Time PCR System AriaMx Real-Time PCR System LineGene 9600 Plus Rotor-Gene 3000 / Q
DETECTION CHANNELS	FAM, HEX, Cy5, Texas Red
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels – results at www.geneproof.com