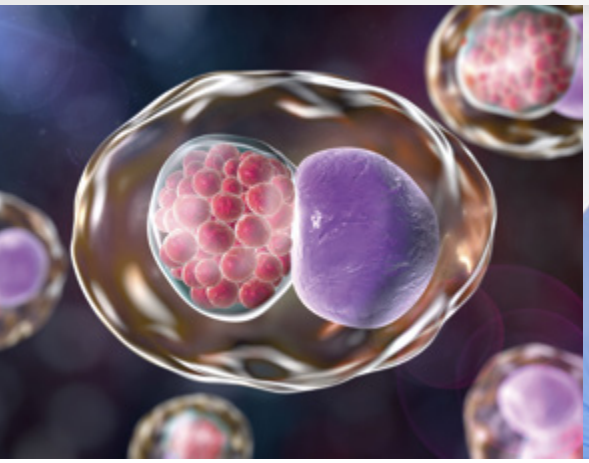
GeneProof®

Sexually Transmitted Infections

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

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

COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES

CE 1023 IVD 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

Sexually Transmitted Infections

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	*in vitro* 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 *Chlamydia trachomatis* The 16S rRNA gene and *porA* pseudogene for *Neisseria gonorrhoeae* The 16S rRNA gene for *Mycoplasma genitalium*
ANALYTICAL SPECIFICITY	*Chlamydia trachomatis, Neisseria gonorrhoeae and Mycoplasma genitalium,* 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 Cycler 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

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