



GeneProof[®]

GeneProof Chlamydia trachomatis PCR Kit



HIGH SENSITIVITY

- Secured by targeting the multicopy sequence of the 16S rRNA gene
- Dual target detection of the 16S rRNA gene and a cryptic plasmid

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

RELIABLE DETECTION OF SWEDISH VARIANT

- Elimination of false-negative results caused by a sequence variation in the cryptic plasmid

CONTAMINATION PREVENTION

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

ORDER INFORMATION

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



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



GeneProof Chlamydia trachomatis 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 multi-copy sequence and the <i>16S</i> rRNA gene
ANALYTICAL SPECIFICITY	<i>Chlamydia trachomatis</i> , including mutations with deletions in cryptic plasmid (including Swedish variant), 100%
ANALYTICAL SENSITIVITY (LoD)	0.075 cp/μl with the probability of 95 % (on Amplirun [®] Chlamydia trachomatis DNA control, Vircell)
DIAGNOSTIC SPECIFICITY	99.21 % (CI _{95%} : 99.07 % - 99.34 %)
DIAGNOSTIC SENSITIVITY	100.00 % (CI _{95%} : 99.58 % - 100.00 %)
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control
VALIDATED SPECIMEN	sperm, swab, urine
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System DTLite Real-Time PCR System LightCycler [®] 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclers Rotor-Gene 3000 / 6000 / Q SLAN [®] Real-Time PCR System StepOne™ a StepOne™ Plus Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX
EXTERNAL QUALITY ASSESSEMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com