



Sexually
Transmitted
Infections

GeneProof[®]

GeneProof Neisseria gonorrhoeae PCR Kit



DUAL TARGET DETECTION

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

HIGH SENSITIVITY

- Secured by targeting the multicopy sequence of the 16S rRNA gene

RELIABLE DETECTION OF *porA* MUTANT

- Elimination of false-negative results caused by a sequence variation in the *porA* pseudogene

CONTAMINATION PREVENTION

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

ORDER INFORMATION

REF	PACKAGE
NG/GP/025	25 reactions
NG/GP/100	100 reactions



COMPATIBLE WITH A WIDE
RANGE OF REAL-TIME PCR
DEVICES



CERTIFIED
DIAGNOSTIC TEST

www.geneproof.com

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



GeneProof *Neisseria gonorrhoeae* 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 IVD
INTENDED USER	For professional use in laboratories with trained staff
TECHNOLOGY	Real-time PCR
TYPE OF ANALYSIS	Qualitative
TARGET SEQUENCE	A multi-copy sequence of the gene encoding 16S rRNA and <i>porA</i> pseudogene specific for <i>N. gonorrhoeae</i>
ANALYTICAL SPECIFICITY	<i>N. gonorrhoeae</i> , including mutants in <i>porA</i> pseudogene, 100%
ANALYTICAL SENSITIVITY (LoD with 95% probability)	0.109 cp/μl (on Amplirun® <i>Neisseria gonorrhoeae</i> DNA control, Vircell)
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 System GeneProof PathogenFree DNA Isolation Kit
INSTRUMENTS	croBEE Real-Time PCR System Applied Biosystems 7300 / 7500 Real-Time PCR System AriaMx Real-Time PCR System CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System LightCycler® 2.0 / 480 LineGene 9600 / 9600 Plus Mic qPCR Cyclers Rotor-Gene 3000 / 6000 / Q SLAN® Real-Time PCR System StepOne™ / StepOnePlus™ Real-Time PCR System QuantStudio™ 3 / 5 Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com