



GeneProof[®]

GeneProof *Trichomonas vaginalis* PCR Kit



HIGH SPECIFICITY

- Secured by multicopy sequence of beta-tubulin gene
- Ensures excellent sensitivity reaches up to 0.25 cp/μl

RELIABLE DETECTION

- Simple sensitive detection compared to wet mount microscopy and culture

EASY-TO-USE CONCEPT

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

CONTAMINATION PREVENTION

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

SIMPLE LABORATORY WORKFLOW

- Easily combinable with other GeneProof PCR kits in one workflow

ORDER INFORMATION

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



COMPATIBLE WITH A WIDE
RANGE OF REAL-TIME PCR
DEVICES



CERTIFIED
DIAGNOSTIC TEST



GeneProof Trichomonas vaginalis 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 polymerase chain reaction (PCR) - amplification of the specific Target Sequence and detection using TaqMan probes with fluorophore-based detection
TYPE OF ANALYSIS	Qualitative
TARGET SEQUENCE	Beta-tubulin gene
ANALYTICAL SPECIFICITY	<i>Trichomonas vaginalis</i> (TV), 100 %
ANALYTICAL SENSITIVITY (LoD with 95% probability)	0.25 cp/μl (on AmpliRun [®] Trichomonas vaginalis DNA control, Vircell)
DIAGNOSTIC SPECIFICITY	98.21 % (CI _{95%} : 89.19 % - 99.91 %)
DIAGNOSTIC SENSITIVITY	100.00 % (CI _{95%} : 87.68 % - 100.00 %)
POSITIVE PREDICTIVE VALUE	97.22 % (CI _{95%} : 83.80 % - 99.85 %)
NEGATIVE PREDICTIVE VALUE	100.00 % (CI _{95%} : 91.87 % - 100.00 %)
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control (IC)
VALIDATED SPECIMEN	Swab (transport medium: UTM [®] Viral Transport, eNATTM, both from COPAN Diagnostics Inc.), 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 7300 / 7500 Real-Time PCR System BioQuant-96 Real-Time PCR System CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System LightCycler [®] 480 LineGene 9600 Plus Mic qPCR Cyclers QuantStudio™ 3 / 5 Real-Time PCR System Rotor-Gene 3000 / 6000 / Q SLAN [®] Real-Time PCR System StepOne™ / StepOne Plus™ Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM (TV), HEX/JOE/VIC (IC)
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels - results at www.geneproof.com