



# GeneProof<sup>®</sup>

## GeneProof *Treponema pallidum* PCR Kit



### HIGHLY SPECIFIC DETECTION

- Secured by highly conservative *poIA* gene for DNA polymerase I

### 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
TP/GP/025	25 reactions
TP/GP/100	100 reactions



COMPATIBLE WITH A WIDE  
RANGE OF REAL-TIME PCR  
DEVICES



CERTIFIED  
DIAGNOSTIC TEST



# GeneProof *Treponema pallidum* 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	Gene <i>poA</i> encoding DNA polymerase I
ANALYTICAL SPECIFICITY	<i>Treponema pallidum</i> , 100 %
ANALYTICAL SENSITIVITY (LoD with 95% probability)	0.61 cp/µl (on synthetic DNA ultramer Control <i>Treponema pallidum</i> )
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control
VALIDATED SPECIMEN	<b>Swab from genital ulcer, urine, transport medium:</b> UTM <sup>®</sup> Viral Transport <sup>®</sup> (COPAN Diagnostics Inc.)
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 AMPLilab Real-Time PCR System CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System Gentier 96E/96R Real-Time PCR System LightCycler <sup>®</sup> 480 LineGene 9600 Plus Mic qPCR Cyclers Rotor-Gene 3000 / Q SLAN <sup>®</sup> Real-Time PCR System StepOne™ / StepOne Plus™ 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 <a href="http://www.geneproof.com">www.geneproof.com</a>

\* UTM<sup>®</sup> Viral Transport is validated only in combination with croBEE 201A Nucleic Acid Extraction System