



Sexually  
Transmitted  
Infections

# GeneProof®

## GeneProof MH/UU/UP Multiplex PCR Kit



### MORE INFORMATION FROM ONE REACTION

- PCR Kit detects and distinguishes the important STI pathogens in a single reaction tube:

*Mycoplasma hominis*

*Ureaplasma urealyticum*

*Ureaplasma parvum*

### SIMPLE LABORATORY WORKFLOW

- Easily combinable with other PCR kits from the STI Panel in one workflow

### CONTAMINATION PREVENTION

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

### EASY-TO-USE CONCEPT

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

#### ORDER INFORMATION

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



COMPATIBLE WITH A WIDE  
RANGE OF REAL-TIME PCR  
DEVICES



CERTIFIED  
DIAGNOSTIC TEST

[www.geneproof.com](http://www.geneproof.com)

ISO 13485

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



# GeneProof MH/UU/UP 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	<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	<i>gap</i> gene ( <i>M. hominis</i> ) <i>UreD</i> gene ( <i>U. urealyticum</i> , <i>U. parvum</i> )
ANALYTICAL SPECIFICITY	<i>Mycoplasma hominis</i> , <i>Ureaplasma urealyticum</i> , <i>Ureaplasma parvum</i> , 100 %
ANALYTICAL SENSITIVITY (LoD with 95% probability)	0.84 cp/μl (on Amplirun® <i>Mycoplasma hominis</i> DNA control, Vircell) 1.48 cp/μl (on Amplirun® <i>Ureaplasma urealyticum</i> DNA control, Vircell) 0.73 cp/μl (on synthetic DNA ultramer control <i>Ureaplasma parvum</i> )
DIAGNOSTIC SPECIFICITY	96.00 % (CI <sub>95%</sub> : 87.97 % – 98.96 %) <i>Mycoplasma hominis</i> 98.67 % (CI <sub>95%</sub> : 91.79 % – 99.93 %) <i>Ureaplasma urealyticum</i> 100.00 % (CI <sub>95%</sub> : 92.13 % – 100.00 %) <i>Ureaplasma parvum</i>
DIAGNOSTIC SENSITIVITY	87.50 % (CI <sub>95%</sub> : 60.41 % – 97.80 %) <i>Mycoplasma hominis</i> 93.75 % (CI <sub>95%</sub> : 67.71 % – 99.67 %) <i>Ureaplasma urealyticum</i> 100.00 % (CI <sub>95%</sub> : 87.36 % – 100.00 %) <i>Ureaplasma parvum</i>
POSITIVE PREDICTIVE VALUE	82.35 % (CI <sub>95%</sub> : 55.80 % – 95.33 %) <i>Mycoplasma hominis</i> 93.75 % (CI <sub>95%</sub> : 67.71 % – 99.67 %) <i>Ureaplasma urealyticum</i> 100.00 % (CI <sub>95%</sub> : 87.36 % – 100.00 %) <i>Ureaplasma parvum</i>
NEGATIVE PREDICTIVE VALUE	97.30 % (CI <sub>95%</sub> : 89.69 % – 99.53 %) <i>Mycoplasma hominis</i> 98.67 % (CI <sub>95%</sub> : 91.79 % – 99.93 %) <i>Ureaplasma urealyticum</i> 100.00 % (CI <sub>95%</sub> : 92.13 % – 100.00 %) <i>Ureaplasma parvum</i>
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control
VALIDATED SPECIMEN	Swab, urine, transport medium: UTM® Viral Transport (COPAN Diagnostics Inc.)
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 Real-Time PCR System Applied Biosystems 7500 Real-Time PCR System CFX96™/ Dx Real-Time PCR Detection System Gentier 96E/96R Real-Time PCR System LineGene 9600 Plus Mic qPCR Cyclor QuantStudio™ 5 Real-Time PCR System
REQUIRED DETECTION CHANNELS	FAM, HEX, Cy5, Texas Red
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>