



# GeneProof<sup>®</sup>

## GeneProof Gardnerella vaginalis PCR Kit



### COMPLETE SOLUTION FOR STI

- As a part of STI Panel enables a comprehensive solution for symptomatic STI diagnostics
- Suitable especial for differential diagnostics of non-candidal vulvovaginitis

### 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

### CONTAMINATION PREVENTION

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

#### ORDER INFORMATION

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



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



# GeneProof *Gardnerella 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 PCR
TYPE OF ANALYSIS	Qualitative
TARGET SEQUENCE	tuf gene for transcription elongation factor
ANALYTICAL SPECIFICITY	<i>Gardnerella vaginalis</i> , 100 %
ANALYTICAL SENSITIVITY (LoD with 95% probability)	0.82 cp/μl (performed on AmpliRun® GVA DNA control, Vircell)
DIAGNOSTIC SPECIFICITY	93.33 % (CI <sub>95%</sub> : 86.28 % - 97.05 %)
DIAGNOSTIC SENSITIVITY	100.00 % (CI <sub>95%</sub> : 91.73 % - 100.00 %)
POSITIVE PREDICTIVE VALUE	88.52 % (CI <sub>95%</sub> : 77.17% - 94.88 %)
NEGATIVE PREDICTIVE VALUE	100.00 % (CI <sub>95%</sub> : 95.30 % - 100.00 %)
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control by Internal Control
VALIDATED SPECIMEN	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 Applied Biosystems 7300 / 7500 Real-Time PCR System AMPLilab Real-Time PCR System AriaMx Real-Time PCR System BioQuant-96 real-time PCR detection system CFX Connect™ / CFX96™ / Dx Real-Time PCR Detection System Gentier 96E/96R Real-Time PCR System LightCycler® 480 Line Gene 9600 Plus Rotor-Gene 3000 / 6000 / Q
REQUIRED DETECTION CHANNELS	FAM, HEX/JOE
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>