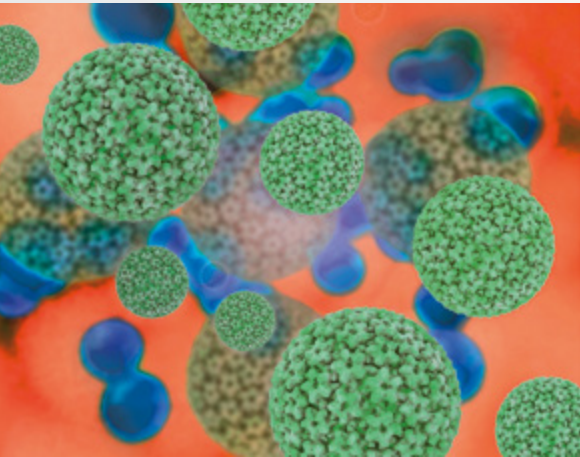




# GeneProof<sup>®</sup>

## GeneProof Human Papillomavirus (HPV) Screening PCR Kit



### HIGH SPECIFICITY

- Unique detection of 24 high-risk HPV types

### SELF-SAMPLING OPTION

- Validation of self-sampling devices Evalyn<sup>®</sup> Brush (Rovers Medical Devices) and FLOQSwab<sup>®</sup> (COPAN)
- Supports widespreading of HPV screening through simple and comfortable sampling

### CONTAMINATION ELIMINATION

- Ready-to-Use Master Mix contains Uracil-DNA glycosylase (UNG) and dUTPs eliminating possible contamination with amplification products

### DIFFERENTIATION OF HIGH-RISK TYPES 16, 18 AND 45

- HPV16 and HPV18 are responsible for 70% of cervical cancer cases and pre-cancerous cervical lesion
- HPV45 is the 3<sup>rd</sup> most prevalent genotype in cases of invasive cervical cancer worldwide (5-6%)
- Enables specific management of patient monitoring and therapy

### COMPLIANCE WITH GUIDELINES FOR HPV SCREENING

- German S3-guidelines “Prevention of cervical cancer” (S3-Leitlinie Prävention des Zervixkarzinoms Langversion 1.0–Dezember 2017)
- The clinical and reproducibility criteria of the International Guidelines for HPV tests for use in cervical cancer screening



COMPATIBLE WITH A WIDE RANGE OF REAL-TIME PCR DEVICES



CERTIFIED DIAGNOSTIC TEST



# GeneProof Human Papillomavirus (HPV) Screening PCR Kit

- + CT/NG/MG Multiplex PCR Kit
- + Mycoplasma genitalium/hominis PCR Kit
- + Chlamydia trachomatis PCR Kit
- + Human Papillomavirus (HPV) Screening PCR Kit
- + Neisseria gonorrhoeae PCR Kit
- + Ureaplasma PCR Kit
- + Herpes Simplex Virus (HSV-1/2) PCR Kit
- + MH/UU/UP Multiplex PCR Kit
- + Treponema pallidum PCR Kit
- + Trichomonas vaginalis PCR Kit

TECHNOLOGY	real-time PCR
TYPE OF ANALYSIS	qualitative
TARGET SEQUENCE	E1/E2 genes
ANALYTICAL SPECIFICITY	Human Papillomavirus high-risk types 16, 18, 26, 30, 31, 33, 34, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 67, 68, 69, 70, 73, 82, 97 with differentiation of 16, 18 and 45 types
ANALYTICAL SENSITIVITY (LOD)	reaches up to <b>0.745 IU/μl</b> with the probability of 95 % (on 1 <sup>st</sup> WHO International standard for Human Papillomavirus Type 16 DNA) reaches up to <b>1.561 IU/μl</b> with the probability of 95 % (on 1 <sup>st</sup> WHO International standard for Human Papillomavirus Type 18 DNA)
DIAGNOSTIC SPECIFICITY	99 % (CI <sub>95%</sub> : 93.6 % - 99.9 %)
DIAGNOSTIC SENSITIVITY	100% (CI <sub>95%</sub> : 87.7 % - 100 %)
EXTRACTION/INHIBITION CONTROL	PCR inhibition and DNA extraction efficiency control
VALIDATED SPECIMEN	Swab (cervical, vaginal and penile), LBC medium NOVAPREP (Novacyte), SurePath (BD), Self-sampling device FLOQSwab® (COPAN), Evalyn® Brush (Rovers Medical Devices)
STORAGE	-20 ± 5 °C
VALIDATED EXTRACTION METHODS	croBEE NA16 Nucleic Acid Extraction System GeneProof PathogenFree DNA Isolation Kit
INSTRUMENTS	<b>croBEE Real-Time PCR System*</b> Applied Biosystems 7500 Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18) AriaMx Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18) CFX Connect™ Real-Time PCR Detection System (detection of high-risk HPV without differentiation) CFX96™/Dx Real-Time PCR Detection System LightCycler® 480 (detection of high-risk HPV without differentiation) LineGene 9600 Plus QuantStudio™ 3 Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 18) QuantStudio™ 5 Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18) Rotor-Gene Q (detection of high-risk HPV and presence HPV18, 16, and 45 but it does not distinguish coinfection of types 16, 18 and 45 respect to the crosstalk between the channels TexRed/Cy5 and Cy5/Cy5.5) SLAN® Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16) Stratagene Mx3005p qPCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18)
REQUIRED DETECTION CHANNELS	FAM, HEX, Cy5, Texas Red, Cy5.5
EXTERNAL QUALITY ASSESSMENT	Regularly tested by QCMD and Instand e.V. External Quality Assessment Panels - results at <a href="http://www.geneproof.com">www.geneproof.com</a>
REGULATORY STATUS	CE IVD

\* Validated instruments

PRODUCT NAME	TECHNOLOGY	ORDER NO.		
		25 REACTIONS	50 REACTIONS	100 REACTIONS
GeneProof Human Papillomavirus (HPV) Screening PCR Kit	real-time PCR	HPVS/GP/025	HPVS/GP/050	HPVS/GP/100