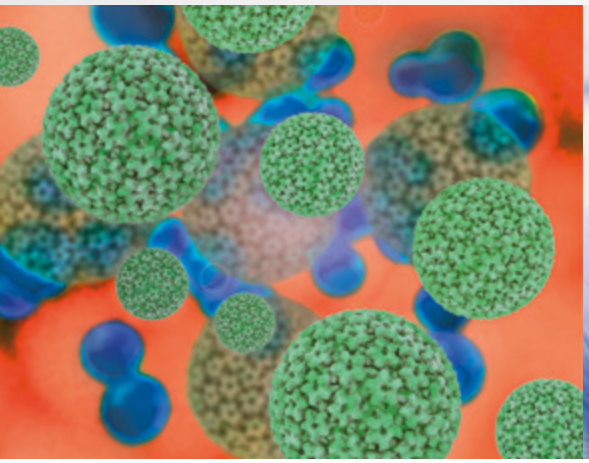
GeneProof®

Sexually Transmitted Infections

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® Brush (Rovers Medical Devices) and FLOQSwab® (COPAN)
- Supports widespreading of HPV screening through simple and comfortable sampling
- Housekeeping *GAPDH* for correct sampling control

CONTAMINATION PREVENTION

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

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 3rd 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 Langverison 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

CE IVD CERTIFIED DIAGNOSTIC TEST

www.geneproof.com

ISO 13485

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

Sexually Transmitted Infections

GeneProof Human Papillomavirus (HPV) Screening 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	*in vitro* 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	*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) (LoD with 95% probability)	**Sample Processing**	**Channel**	**Sensitivity**	**Performed on**
	Without extraction (plasmid)	FAM	745 IU/ml	NIBSC 06/202, HPV 16
	Without extraction (plasmid)	Cy5	766 IU/ml	NIBSC 06/202, HPV 16
	croBEE®max Nucleic Acid Extraction Kit	FAM	4758 IU/ml	NIBSC 06/202, HPV 16
	croBEE®max Nucleic Acid Extraction Kit	Cy5	1558 IU/ml	NIBSC 06/202, HPV 16
	Without extraction (plasmid)	FAM	1561 IU/ml	NIBSC 06/206, HPV 18
	Without extraction (plasmid)	TexRed	2177 IU/ml	NIBSC 06/206, HPV 18
	croBEE®max Nucleic Acid Extraction Kit	FAM	4906 IU/ml	NIBSC 06/206, HPV 18
	croBEE®max Nucleic Acid Extraction Kit	TexRed	3262 IU/ml	NIBSC 06/206, HPV 18
DIAGNOSTIC SPECIFICITY	99 % ($CI_{95\%}$: 93.6 % – 99.9 %)			
DIAGNOSTIC SENSITIVITY	100% ($CI_{95\%}$: 87.7 % – 100 %)			
EXTRACTION/INHIBITION CONTROL	Proper sampling, DNA extraction efficiency and PCR inhibition control by endogenous Internal control (*GAPDH gene*)			
VALIDATED SPECIMEN	Cervical, vaginal and penile swab (transport medium: LBC medium NOVAPREP (Novacyte); SurePath (BD) Self-sampling device FLOQSwab (COPAN); Evalyn® Brush (Rovers medical))			
STORAGE	-20 ± 5 °C			
VALIDATED EXTRACTION METHODS	croBEE 201A Nucleic Acid Extraction Kit GeneProof PathogenFree DNA Isolation Kit croBEE®max Nucleic Acid Extraction Kit			
INSTRUMENTS	croBEE Real-Time PCR System AMPLilab Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18) 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 Gentier 96E/96R Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18) 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)	
DETECTION CHANNELS	FAM (HPV HR), HEX/JOE/VIC (IC), Cy5 (HPV 16), Texas Red/ROX (HPV 18), Cy5.5/Quasar 705 (HPV 45)			
EXTERNAL QUALITY ASSESSMENT	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels – results at www.geneproof.com			

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

GeneProof a.s. / 06-2022

www.geneproof.com

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