

CE-IVD

TaqPath Menu GeneProof Human Papillomavirus (HPV) Screening PCR Kit

Molecular diagnostic for sexually transmitted infections

Broad range of reliable and simple PCR-based testing to help diagnosis

Prompt and early diagnosis of sexually transmitted infections (STIs) is important to enable appropriate treatment and help prevent further transmission. Clinical testing labs require STI testing solutions that help provide confidence, fast turnaround

time, and accurate results. The CE-marked Applied Biosystems™ TaqPath™ Menu | GeneProof™ STI portfolio supports sexual health testing and delivers reliable results with excellent sensitivity and specificity. This helps give confidence in screening, diagnostic, and treatment decisions, and helps stop the spread of disease.

Applied Biosystems™ TaqPath™ Menu | GeneProof™ Human Papillomavirus (HPV) Screening PCR Kit features:



Self-sampling option

- Validation of self-sampling devices Evalyn® Brush and FLOQSwab®
- Supports widespread HPV screening through simple and comfortable sampling
- Housekeeping GAPDH for correct sampling control



Detection and differentiation of high-risk types 16, 18, and 45

- Responsible for cervical cancer cases and precancerous cervical lesions
- Enables specific management of patient monitoring and therapy



Compliance with guidelines for HPV screening

- German S3-guidelines "Prevention of cervical cancer"*
- Clinical and reproducibility criteria of the International Guidelines for HPV tests for use in cervical cancer screening



Contamination reduction

- Ready-to-use Master Mix contains uracil-DNA glycosylase (UNG) and dUTPs reducing possible carryover contamination



High specificity

- Unique detection of 24 high-risk HPV types



Compatible with a wide range of real-time PCR devices

* (S3-Leitlinie Prävention des Zervixkarzinoms Langversion 1.0 – Dezember 2017)

Product details for the TaqPath Menu | GeneProof Human Papillomavirus (HPV) Screening PCR Kit

Technology	Qualitative real-time PCR
Target sequence	E1/E2 genes
Sample type	Swab (cervical, vaginal, and penile), LBC medium NOVAPREP (Novacyte), SurePath (BD), Self-sampling device FLOQSwab (COPAN), Evalyn Brush (Rovers Medical Devices)
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, and 97 with differentiation of 16, 18, and 45 types
Analytical sensitivity (LoD)	0.745 IU/μL (on 1st WHO International Standard for Human Papillomavirus Type 16 DNA) 1.561 IU/μL (on 1st WHO International Standard for Human Papillomavirus Type 18 DNA)
Diagnostic specificity	99% (CI _{95%} : 93.6%–99.9%)
Diagnostic sensitivity	100% (CI _{95%} : 87.7%–100%)
Extraction/inhibition control	PCR inhibition and DNA extraction efficiency control
Instruments	<ul style="list-style-type: none"> Applied Biosystems™ 7500 Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18) Applied Biosystems™ QuantStudio™ 3 Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 18) Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System (detection of high-risk HPV with differentiation of HPV 16 and HPV 18) croBEE Real-Time PCR System 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 Rotor-Gene Q (detection of high-risk HPV and presence of HPV18, 16, and 45 but it does not distinguish coinfection of types 16, 18, and 45 with 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)
Validated extraction methods	Refer to the instructions for use (IFU)
Detection channel	FAM, HEX, Cy5, Texas Red, Cy5.5
External quality assessment	Regularly tested in QCMD and Instand e.V. External Quality Assessment Panels

Ordering information

Description	Quantity	Cat. No.
TaqPath Menu GeneProof Human Papillomavirus Screening PCR Kit	100 reactions	A58120

Rely on a comprehensive portfolio of Applied Biosystems™ TaqPath™ Menu | GeneProof™ Kits to help meet your lab's clinical testing needs

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



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