



A new proposal for HPV DNA testing

Convenient and comprehensive

Allplex™ HPV HR Detection
Allplex™ HPV28 Detection



More than **600,000** women diagnosed with HPV annually



Throughout the world, more than 600,000 women are being diagnosed annually with cervical cancer that is caused by human papillomavirus (HPV)¹⁾. However, the risk of cervical cancer can be predicted and prevented if high-risk HPV types are detected in early stages with regular testing.

WHO recommends DNA testing for primary cervical cancer screening¹⁾ and the recent trends show that screening method is shifting from the cytology test to HPV DNA test. Furthermore, the prevalence of HPV type is different across the world due to increasing vaccination and difference in regional characteristics²⁾, making DNA testing more useful in screening HPVs.

Allplex™ HPV HR Detection kit is suitable for HPV screening in all circumstances, meeting diverse region-specific testing needs.

Allplex HPV28 Detection kit is specially designed for HPV genotyping, providing accurate information on infection status and HPV genotype distribution.

It allows more efficient testing with fast test time and fully automated workflow and is designed to provide comprehensive information for precise patient care.

Why is HPV DNA testing better for cervical cancer screening?

For HPV primary screening, DNA-based tests are more efficient compared to cytology tests as they minimize false negative results and human error³⁾. They are also more cost-efficient, making them more accessible across various regions⁴⁾.



Cytology test



DNA test

Explore Seegene's HPV screening and genotyping solution



✓ Fast and automated testing

1.5-hour PCR TAT and workflow automation from extraction to result analysis

✓ Comprehensive information

Individual genotypes and Ct values in a single test

Allplex™ HPV HR Detection

14 high-risk HPV types

16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

Allplex™ HPV28 Detection

19 high-risk HPV types

16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73, 82

9 low-risk HPV types

6, 11, 40, 42, 43, 44, 54, 61, 70

Specimen	<ul style="list-style-type: none"> • Cervical swab • Self-collected vaginal swab • Liquid based cytology (ThinPrep® and Surepath™) 	
Compatible Instrumentation	<p>Automated extraction & PCR setup</p> <ul style="list-style-type: none"> • Seegene STARlet • Seegene STARlet-AIOS • Seegene NIMBUS 	<p>Real-time PCR</p> <ul style="list-style-type: none"> • CFX96™ Dx

Enhancing efficiency for a large-scale HPV DNA testing

Short PCR turn-around time (TAT)

- 1.5 hours of PCR TAT
- Detection of individual HPV types

Fully automated workflow

- Application of Seegene STARlet-AIOS providing one streamlined workflow from nucleic acids extraction to result analysis
- Reduced hands-on time for minimized human error and contamination

Convenient automation workflow

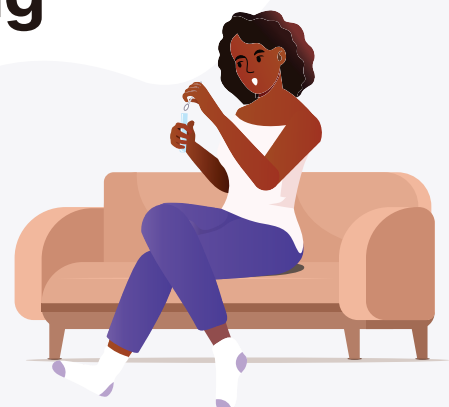


Expanding sampling options for more accessible HPV testing

Self-collected samples

i Self-collection is proposed by WHO and clinicians to encourage participation in cervical cancer screening¹⁾.

Increased accessibility of HPV screening due to alternative sample collection method, enabling early prevention of cervical cancer



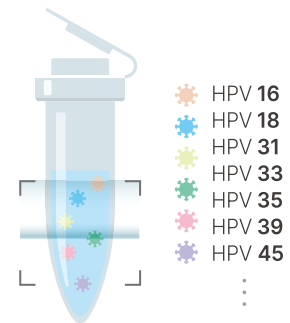
Empowering Clinicians with comprehensive information

Screen Individual HPV genotypes

Prevalent HPV types vary depending on countries due to vaccination. Also, multiple HPV infection increases the duration of infection, which leads to increased risk of cervical cancer⁵.

Therefore, it is important to track and monitor individual HPV types.

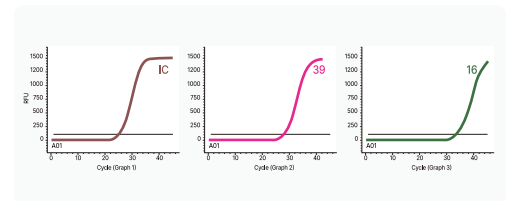
- Detecting and identifying 14/28 individual high-risk HPVs simultaneously with a single test
- Monitoring of clearance and persistence of HPV genotypes and the risk of cervical cancer



Individual Ct values

Viral load is closely related to the severity of cervical lesions^{6,7}.

Seegene 3 Ct PCR technology provides Ct values to infer viral load, helping clinicians to provide personalized patient care with more precise diagnosis



Statistical analysis with SG STATS

Seegene's IT solution providing comprehensive information with analysis and visualization

- Analyzing prevalence of individual genotypes and co-infection patterns and comparing with global HPV trends
- Aggregating and analyzing HPV test results to provide more insightful statistical information

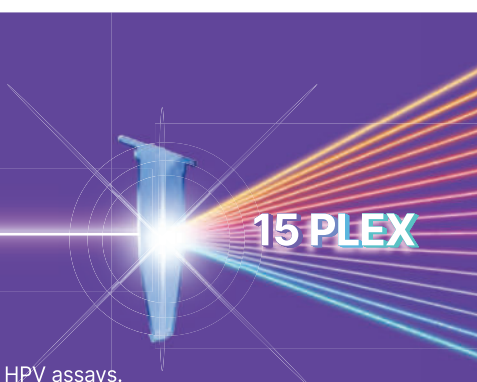


Technology that makes Seegene HPV assays unique

Seegene 3 Ct PCR technology provides individual Ct values of up to 15 targets in a single tube with shortened PCR TAT.

DPO™ + **TOCE™** + **MuDT™** + **More**
Specificity Multiple detection Multiple analysis

Seegene 3 Ct PCR technology is commercialized for the first time in the world through Seegene Allplex™ HPV assays. Starting with HPV, Seegene will expand the application of 3 Ct PCR technology to Respiratory, STI and Gastrointestinal products.



References

- 1) WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention. 2nd ed. Geneva: World Health Organization; 2021.
- 2) Latsuzbaia A et al., Effectiveness of bivalent and quadrivalent human papilloma-virus vaccination in Luxembourg. *Cancer Epidemiol.* 2019 Dec;63:101593.
- 3) Andersen B et al., HrHPV testing vs liquid-based cytology in cervical cancer screening among women aged 50 and older: a prospective study. *Int J Gynecol Cancer.* 2020;30(11):1678-1683.
- 4) WHO. WHO recommends DNA testing as a first-choice screening method for cervical cancer prevention. 2021; Available from <https://www.who.int/europe/news/item/11-09-2021-who-recommends-dna-testing-as-a-first-choice-screening-method-for-cervical-cancer-prevention>.
- 5) Kim M et al., Multiple Human Papilloma Virus (HPV) Infections Are Associated with HSIL and Persistent HPV Infection Status in Korean Patients. *Viruses.* 2021 Jul;13(7):1342.
- 6) HPV World. HPV genotype-specific risk for cervical cancer. 2021; <https://www.hpvworld.com/gynecology/articles/hpv-genotype-specific-risk-for-cervical-cancer>.
- 7) Park NJY et al., Strategic Significance of Low Viral Load of Human Papillomavirus in Uterine Cervical Cytology Specimens. *Diagnostics (Basel).* 2022;12(8):1855.

Ordering information

Product	Size	Cat. No.	Instrument	Cat. No.
Allplex™ HPV HR Detection	25 rxns	HP10371Z	Seegene STARlet	67930-03
	100 rxns	HP10370X	Seegene STARlet-AIOS	SG72100
	100 rxns x 8 kits	HP10376L	Seegene NIMBUS	65415-03
Allplex™ HPV28 Detection	25 rxns	HP10373Z	SEEPREP32™	SG71100
	100 rxns	HP10372X		

Extraction kit	Cat. No.
STARMag 96 X 4 Universal Cartridge Kit	744300.4.UC384
STARMag 96 ProPrep (Plate Type)	EX00009P
STARMag 96 ProPrep (Tube Type)	EX00009T

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