



Seeplex®



HPV

DNA testing by multiplex PCR

Seeplex® HPV4A ACE Screening can simultaneously genotype (HPV 16 and 18) and screen for 16 high-risk types and 2 low-risk types (HPV 6/11).



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HPV DNA Testing

Simultaneous genotyping of HPV 16, HPV 18 and screening (high-risk HPV & HPV 6 / 11)

Seeplex® HPV4A ACE Screening can simultaneously genotype (HPV 16 and 18) and screen for 16 high-risk types and vaccine related 2 low-risk types (HPV 6/11) from patients' cervical brush/swab, or liquid-based cytology specimen (ex. ThinPrep®, specimen transport medium, etc.) in about 3 hr 30 min excluding DNA extraction.

Benefits of HPV DNA Testing

Cervical Cancer

- The third leading cause of cancer death in women worldwide
- **HPV** infection is the primary cause of cervical cancer.

Importance of HPV Screening

- Pap test can only show the transformation of the cervix during the progress into cervical cancer.
- Women, 30 years or older must start HPV DNA testing adjunct to cervical cancer screening¹⁾

The actual CIN* 2/3 rate significantly increases among women in their late 20s and early 30s. Therefore, women in this aged group require to be prepared for risk of cervical cancer by utilizing HPV DNA test.

Importance of HPV Genotyping

- **HPV 16 and HPV 18**
HPV has been identified in 99.7% of the invasive cervical cancer and 70% of them result from HPV 16 and HPV 18.²⁾
- **Prevalence of HPV 16 and HPV 18 by cytology worldwide ²⁾**

Cytology	HPV 16/18 Prevalence	(95% CI)
Normal cytology	3.8 %	(3.7-3.9)
Low-grade lesions	24.3 %	(23.6-25.0)
High-grade lesions	51.1 %	(50.3-51.9)
Cervical cancer	70.9 %	(70.3-71.5)

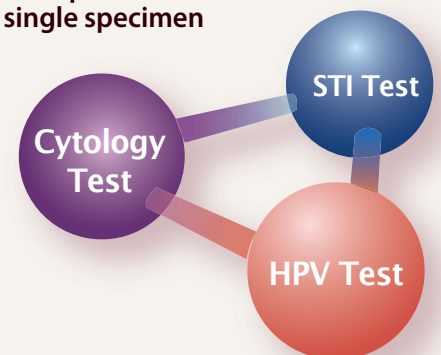
Impact of HPV DNA test for Cervical Cancer

- The sensitivity of cervical cancer screening with cytology alone is 33.8~94.0%. However, when HPV DNA test is combined with cervical cancer screening, the sensitivity significantly increases by 94.2~100%.³⁾
- HPV genotyping is critical in HPV diagnosis because HPV 16 and HPV 18 have significantly higher risk of causing cervical cancer than any others.
- Besides HPV 16 and HPV 18, other high risk HPV types* are also recommended for screening test.

* High risk HPV types : 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82
These have potential to cause cervical cancer, but have low incidence.

Total HPV/STI Care System

Multiple detection with single specimen



Seegene's HPV DNA test is the one-stop solution for all women

- uses of the same specimen collected for the cervical cytology test
- it even detects STI-causative pathogens which can be risk factors for HPV infection.

Available specimens for HPV/STI test

- Liquid-based cytology specimen (ThinPrep®, SurePath™)
- Vaginal or cervical swab
- Genital lesion swab

References

1. Mark S. et al., N. Eng J. Med 2005; Nov 17: 2101-4
2. GM Clifford. et al., British J Cancer 2003; 88: 63-73
3. Thomas C. et al., The American College of Obstetricians and Gynecologists 2004; 103(2). 304-9

Result

Seegene Viewer - LabChip® Dx System

	D01	E01	F01	D02	E02	F02	D03	E03	F03	D04	E04	F04	D05
Sample Name	1	2	3	4	5	6	7	8	9	10	11	PC	NC
Internal control	1919.14	1127.62	1245.09	1779.69	1769.82	1719.50	1449.68	1724.39	963.88	1871.04	1784.62	403.09	1701.14
HPV-16	1316.19		1311.48					1443.87			902.78	1007.46	
HRC			1165.49		1541.91	1313.08	940.18					562.85	
HPV-6/11							963.88				1584.71	860.30	
HPV-18		922.78			941.11					1328.87		1584.61	
Unidentified	0	0	0	0	0	0	0	0	0	0	0	0	0

Amplified PCR products using Seeplex® HPV4A ACE Screening and result analysis. In this result, HPVs were successfully detected in fifteen patient samples (Rapid & easy interpretation using LabChip DX® System).

Analytes

HPV 16
HPV 18
High-risk HPV common¹⁾
HPV 6/11

1) High-risk HPV common (HRC, 16 types) :
26, 31, 33, 35, 39*, 45, 51, 52*, 53, 56, 58, 59, 66,
68*, 73, 82

* High-risk HPV common primers can detect high-risk HPV types
39, 52 and 68 by cross-reactivity.

※ Vaccine related HPV : 6,11,16,18

Specimens

Cervical brush/swab
Liquid-based cytology specimen

Product publications

1. Zivile Gudleviciene, et al., Medicina (Kaunas) 2010;46(9):616-23.
2. Shim et al. BMC Infectious Diseases 2010, 10:284
3. Kyung-Jin Min, et al., J Gynecol oncol 2012; Vol. 23, No.1:5-10

Compatible instruments

Extraction & PCR Setup

Nimbus IVD (Hamilton) - 48 samples/run
STARLET (Hamilton) - 96 samples/run
SEEPREP12™ - 12 samples/run (Extraction only)

PCR instrumentations

GeneAmp® 9700 (Life Technologies)
SEEAMP™*

Auto-electrophoresis instrumentations

ScreenTape® System (Agilent)
MCE®-202 MultiNA (SHIMADZU)
LabChip® Dx (Caliper)*

* The utilization of the Seeplex® Meningitis ACE Detection is not CE approved for use on this instrument.

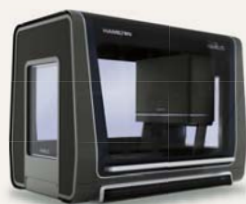
Product

	Cat. No.	Size
HPV4A ACE Screening	HP6401Y	50 rxns

Seeplex® Automatic System



Hamilton
Nimbus IVD CE IVD



Automated Liquid Handling Workstations from NA Extraction to PCR Setup

- A. Wide range of pipetting volume : 0.5 ~ 1,000 µL
- B. Minimized hands-on time
- C. 48 samples processed in 2.5hrs
- D. Built in UV lamp for decontamination of residual DNA/RNA

Cat. No. 65415-02

Caliper LifeSciences
LabChip® Dx CE IVD



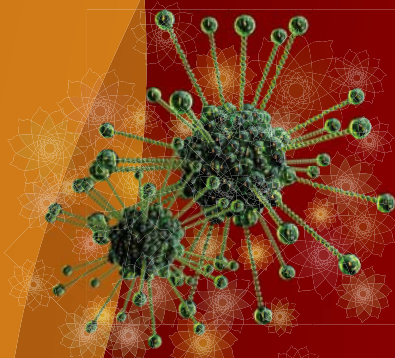
Accelerating throughput on your PCR work

- A. Convenient and no post-PCR contamination
- B. High throughput - Minimum 1hr for 96-well plate
- C. Improvements on time and labor savings (Powerful automated electrophoresis system with barcode reader)

Cat. No. 122000



Seeplex®



Simultaneous Multiple Detection

Molecular Diagnostics
Automatic Detection
DPO™-based Multiplex PCR



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