



HPV_{TEST}

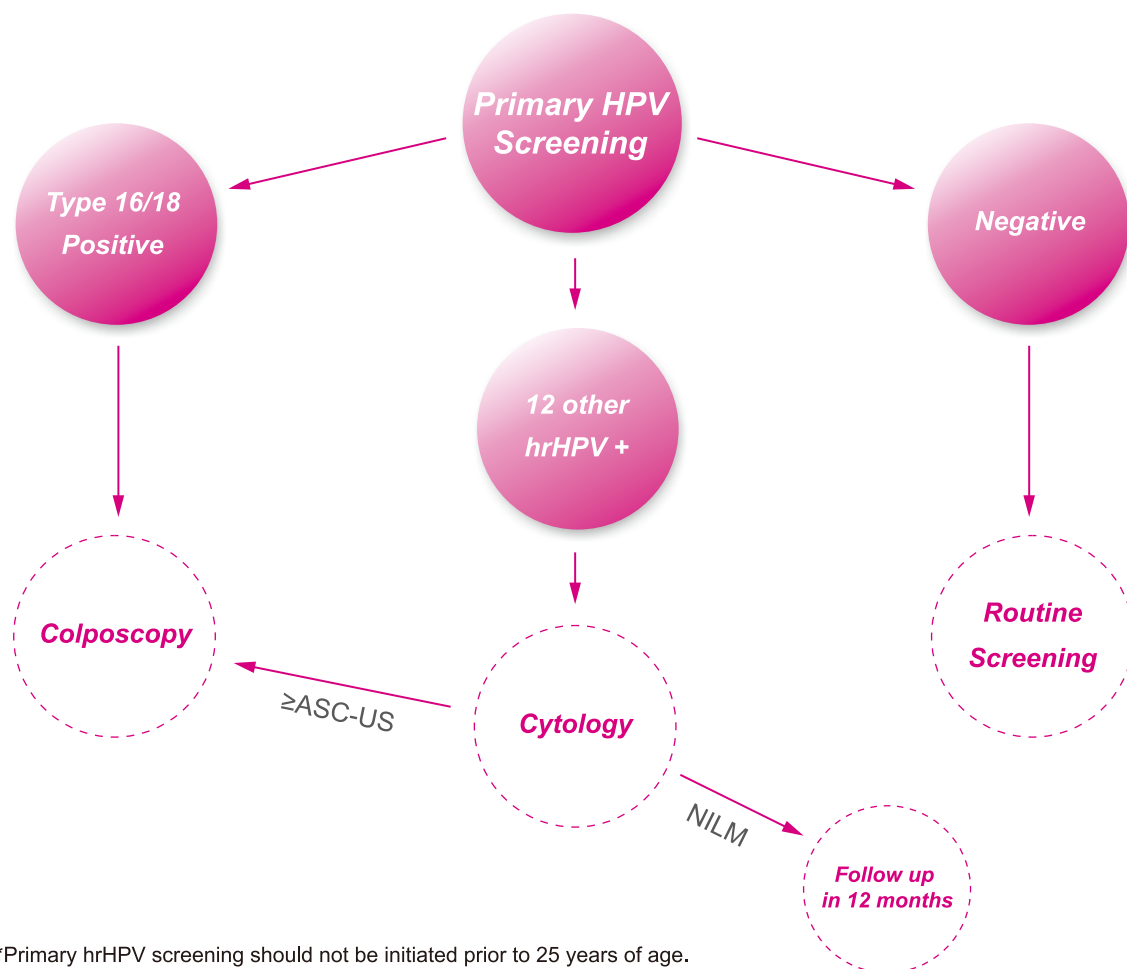
We care about women's health

The Comprehensive Solution for HPV
Nucleic Acid Detection



We care about women's health

Clinical Commentary



*Primary hrHPV screening should not be initiated prior to 25 years of age.
Gynecologic Oncology 136 (2015) 178–182

Tellgen's three HPV products have participated and passed **WHO** HPV LabNet proficiency Study.

◇ Product List

Catalogue No.	Product	Packing Size	Storage
LGA1002P1	Tellgenplex® HPV27 genotyping Assay	48 tests/kit	Liquid(-20 °C)
PGA1004P1	HPV5+9(16, 18, 33, 52, 58 genotyping)	48 tests/kit	Liquid (-20 °C) Lyophilized reagents (Room temperature)
PGA1003P1	HPV2+12(16, 18 genotyping)	48 tests/kit	Liquid (-20 °C) Lyophilized reagents (Room temperature)

Tellgenplex® HPV 27 genotyping Assay



Tellgenplex® HPV 27 genotyping assay is an in vitro diagnostic test for the identification and differentiation of 17 high-risk HPV types (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 82) and 10 low-risk HPV types (6, 11, 40, 42, 43, 44, 55, 61, 81, 83).

Tellgenplex® HPV 27 genotyping assay uses multiplexed bead flow fluorescence technology, which supports simultaneous detection of 27 HPV subtypes in a single assay on Luminex® 200.

◇ High sensitivity, high specificity*

Flow cytometry double laser detection system, the results were taken from median of detection of 100 independent microspheres, with high precision, accuracy and reproducibility(CV≤5%),the limit of detection (LOD)is less than 100 copies/test.

Comparing with sequencing method for HPV L1 specific primer in detecting 1020 samples:

- Kappa value:0.84
- Sensitivity:100%
- Coincidence rate:96.8%

◇ High-throughput

Test up to 96 samples per run.

◇ Digital Result

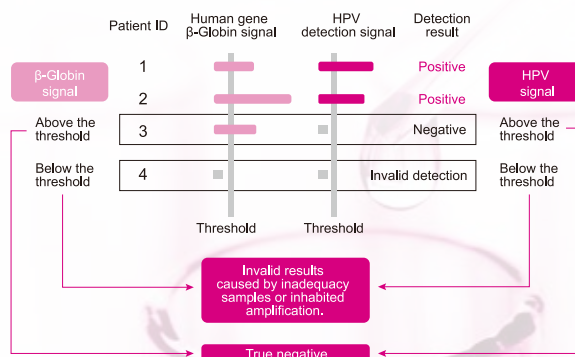
Reading by two lasers, results automatically given by software with interpretation. Supports LIS connection for easy data transfer.

◇ Easy Operation

Highly automated with automatic hybridization and detection. Less than 0.5h manual operation. No washing needed.

◇ Internal Control(β-globin)in the whole procedure

Readily identify the false negative result caused by sample inadequacy, inhibited amplification, etc.



* Please refer to Tellgenplex® HPV 27 genotyping Assay package insert for details.

◇ Result Review

Sample ID\HPV Type	Globin	HPV6	HPV11	HPV16	HPV18	HPV26	HPV31	HPV33	HPV35	HPV39	HPV40	HPV42
A1(HPV16 positive)	2321	22	21	2320	21	22	40	24	22	37	24	29
A2(HPV18 positive)	3101	25	26	35	2230	31	30	39	18	32	120	45
A3(HPV52 positive)	2982	40	20	24	39	29	41	20	40	44	37	36
A4(HPV58 positive)	2436	28	32	37	25	21	35	22	35	19	41	47
A5(HPV16,33 positive)	2620	9	36	2051	110	25	27	894	31	31	21	32
A6(HPV18,45 positive)	3242	28	24	33	963	19	49	29	26	21	32	27
A7(HPV6, 55 positive)	2913	1235	46	252	26	27	30	26	38	5	14	29
A8(HPV31,68 positive)	2438	23	23	25	28	37	652	31	31	38	19	5
B1(HPV negative)	2955	35	26	43	32	41	39	33	31	47	26	26
B2(Invalid)	46	19	33	31	22	30	29	42	18	23	37	33

◇ 27 HPV types

Detect HPV 27(17hr + 10lr)types and β -Globin in a single test.

High Risk

Detect and identify high risk HPV types

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

Low Risk

Detect and identify low risk HPV types

6、11、40、42、43、44、55、61、81、83

◇ Clinical Significance

1/ Cervical Cancer Screening

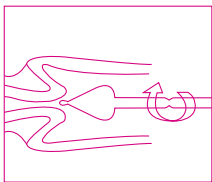
- Early detection of cervical lesions and stratify high risk women
- Discover women with persistent HPV infection but with normal cytology result

2/ ASCUS triage and management

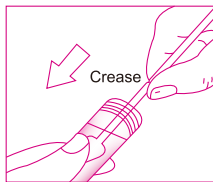
- Effectively differentiates the risk level of cervical cancer, provide a informed suggestion for use of colposcopy
- High negative predictive value provides reassurance for periodic follow-up screening, protecting women from overdiagnosis and overtreatment

◇ Operation Procedure

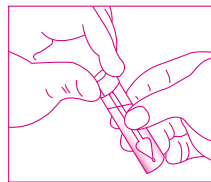
Sample Collection



Sampling by Endocervical brush*



Cell Preservation Solution*



3/ Used in follow-up and management after surgery of cervical lesions

Comparing the infected HPV types before and after surgery.

- Indicate whether the lesion was cleared.
- Distinguish whether persistent type-specific HPV infection, get the possibility of recurrence.
- Indicate whether infected with a new type of HPV.

DNA Extraction

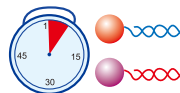


Nucleic Acid Extraction Kit*

Multiplex PCR



Hybridization



Luminex® 200



*please refer to the "Related products"

HPV43	HPV44	HPV45	HPV51	HPV52	HPV53	HPV55	HPV56	HPV58	HPV59	HPV61	HPV66	HPV68	HPV81	HPV82	HPV83
40	37	26	40	52	26	25	37	22	41	31	30	47	21	26	62
51	44	51	51	34	50	41	44	20	29	46	52	29	39	50	51
25	16	26	26	1740	17	39	61	55	47	25	20	28	50	17	33
26	61	39	30	159	25	52	18	1628	54	37	30	21	5	25	27
39	42	27	28	40	30	35	42	46	50	26	15	48	25	30	37
30	42	721	30	47	33	33	42	38	31	33	32	37	36	50	26
45	28	37	38	21	37	963	28	33	35	45	43	21	31	14	17
23	51	28	17	62	50	21	51	53	47	62	17	521	47	45	19
45	37	32	45	75	47	28	53	23	45	51	28	43	22	35	22
37	21	28	31	22	36	36	33	28	12	53	19	32	43	20	27

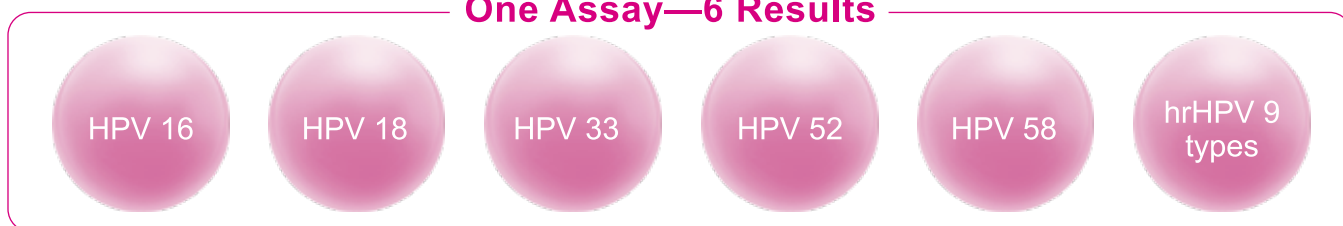
HPV 5+9



This in vitro testing kit can qualitatively detect Human Papillomavirus (HPV) DNA in patient specimens. The kit uses polymerase chain reaction (PCR) to amplify target DNA for the detection of 14 high-risk (hr) HPV types in a single assay. The top 5 hr HPV types, HPV 16, HPV 18, HPV 52, HPV 58, and HPV 33 can be differentially detected by this kit along with non-differential detection of hr HPV types (31, 35, 39, 45, 51, 56, 59, 66, and 68).

Among the hrHPV genotypes, HPV 16, 18, 52, 58, and 33 incur higher risk of precancer than other hrHPV types in some Asian countries. Therefore, when determining the cause of disease in women who are NILM hrHPV+, it is important to have a test that provides individual results on each genotype.

One Assay—6 Results



◇ Probe Label (Tube A)

Dyes	Probe Labels	Type Specific Probes
1	VIC	HPV 16
2	ROX	HPV 18
3	FAM	HPV 52
4	CY5	Internal Control (human beta globin)

◇ Probe Label (Tube B)

Dyes	Probe Labels	Type Specific Probes
1	VIC	HPV 33
2	ROX	HPV 58
3	FAM	HPV 31、35、39、45、51、56、59、66、68
4	CY5	Internal Control (human beta globin)

◇ Confidence in Results*

- Limit of Detection(LOD):<100 copies/test
- Reproducibility:CV≤5%
- No cross reaction with low risk HPV

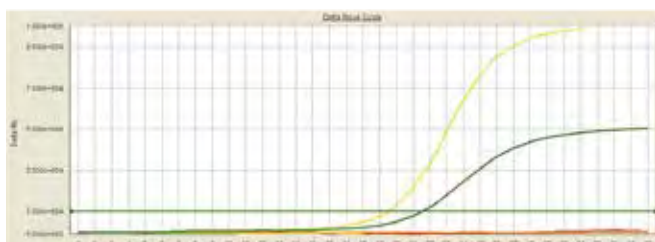
Comparing with sequencing method for HPV L1 specific primer in detecting 1000 samples:

- Coincidence rate:98%
- Sensitivity:100%
- Specificity:91%
- Kappa value:0.94

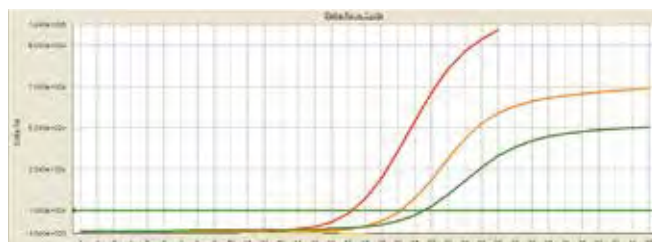
◇ Compatible instruments:

Open real time PCR machine with channels FAM, VIC/HEX, ROX, CY5.

Examples of single and mixed infections



HPV 18 positive



HPV 16+HPV 12 positive

*Products are region specific and may not approved in some countries/regions.

*For sample collection, preservation, and nucleic acid extraction please refer to Tellgenplex® HPV 27 genotyping Assay.

*Please refer to HPV5+9 package insert for details.

For Sales, Customer Service and Technical Support

T: +86-21-50862711

F: +86-21-50270390

E: sales@tellgen.com

W: www.tellgencorp.com



WeChat Program

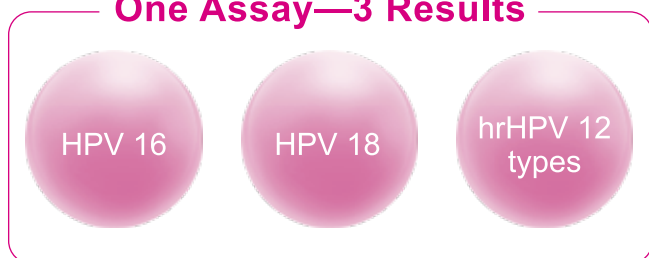


Official Website

This in vitro testing kit can qualitatively detect Human Papillomavirus (HPV) DNA in patient specimens. The kit uses polymerase chain reaction (PCR) to amplify target DNA for the detection of 14 high-risk (hr) HPV types in a single assay. hrHPV types 16 and 18 can be differentially detected along with rest of the hrHPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).

Women infected with HPV 16 and/or HPV 18 have an increased risk of progression to dysplasia and cervical cancer compared to women infected with other hrHPV types. The genotyping of HPV 16 and HPV 18 and detection of the other 14 hrHPV types allows for improved risk assessment and patient management.

One Assay—3 Results



Probe Label

Dyes	Probe Labels	Type Specific Probes
1	VIC	HPV 16
2	ROX	HPV 18
3	FAM	HPV 31,33,35,39,45, 51,52,56,58,59,66,68
4	CY5	Internal Control (human beta globin)

◆ Confidence in Results*

- Limit of Detection (LOD): <100 copies/test
- Reproducibility: CV ≤ 5%
- No cross reaction with low risk HPV

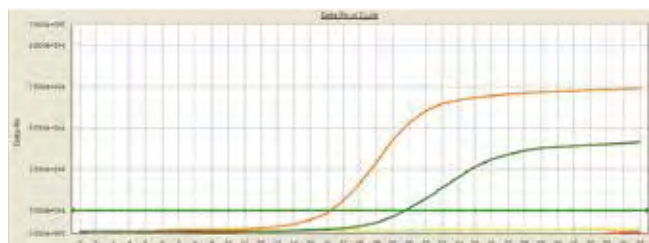
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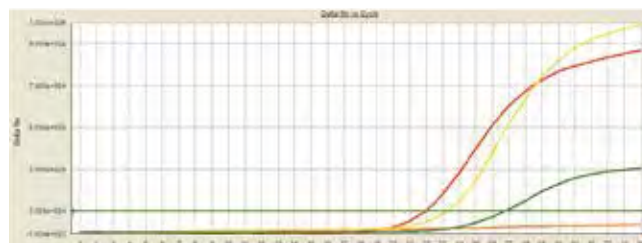
◆ Compatible instruments:

Open real time PCR machine with channels FAM, VIC/HEX, ROX, CY5.

Examples of single and mixed infections



HPV 16 positive



HPV 18+HPV 12 positive

*For sample collection, preservation, and nucleic acid extraction please refer to Tellgenplex® HPV 27 genotyping Assay.

*Please refer to HPV2+12 package insert for details.

HPV 2+12 HPV 5+9

Lyophilized Kit

Save transportation cost by transporting at room temperature

◆ Other Related Products

Catalogue No.	Product	Packing Size	CE Mark
PFA4X012	Cell Preservation Solution	48ml X 2	CE
PFA3X010	Nucleic Acid Extraction Kit	50tests/kit	CE
	Endocervical Brush		CE
	Tellegen Real Time PCR Machine		CE
	Luminex® 200		CE/FDA