

HPV 5+9



The kit is an in vitro diagnostic test for the qualitative detection of DNA from Human Papillomavirus in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV 16, HPV 18, HPV 52, HPV 58, HPV 33 while concurrently detection the rest of the high risk types (31, 35, 39, 45, 51, 56, 59, 66 and 68). Within the hrHPV genotypes, the top 5 HPV types (HPV 16, 18, 58, 52, 33) incur higher risks of per cancer than others in some Asian countries. Therefore, when determining the course of clinical management for women who are NILM hrHPV+, it is important to have a test that provides individual results on the highest-risk HPV genotypes.

One Assay—6 Results



Probe Labelling (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 Labelling (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)

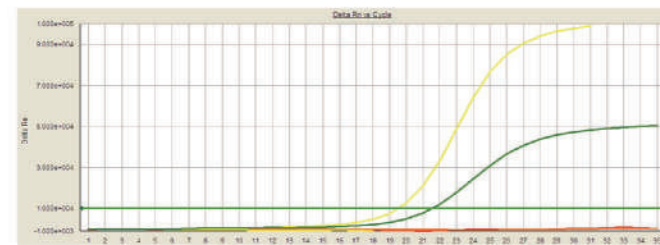
Confidence in Results*

- 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

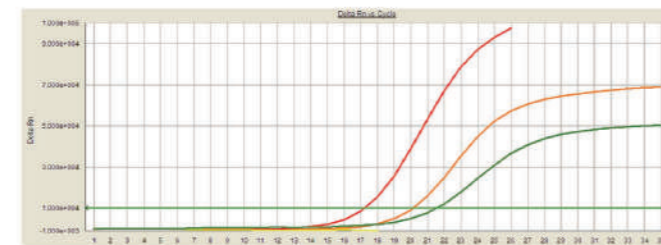
Compatible instruments:

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.



HPV 2+12 HPV 5+9

Lyophilized Kit

1. Transport at room temperature
2. No blue ice
3. No dry ice
4. Save cost

HPV 2+12



The kit is an in vitro diagnostic test for the qualitative detection of DNA from Human Papillomavirus in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV 16 and HPV 18 while concurrently detection the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 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 high risk HPV genotypes. Detection of the 14 high risk HPV genotypes and genotyping of HPV 16 and HPV 18 allow for improved risk assessment and patient management

One Assay—3 Results



Probe Labelling

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)

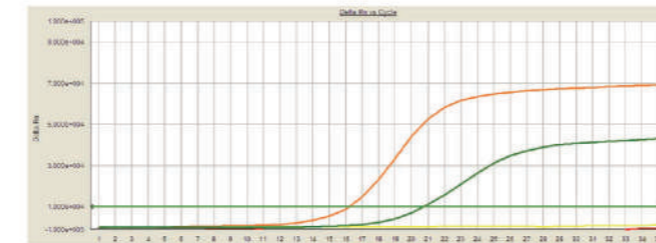
Confidence in Results*

- Limit of Detection (LOD): <100 copies/test
 - Reproducibility: CV ≤ 5%
 - No cross reaction with low risk HPV
- Comparing with sequencing method for HPV L1 specific primer in detecting 1000 samples:**
- Coincidence rate: 98%
 - Sensitivity: 100%
 - Specificity: 91%
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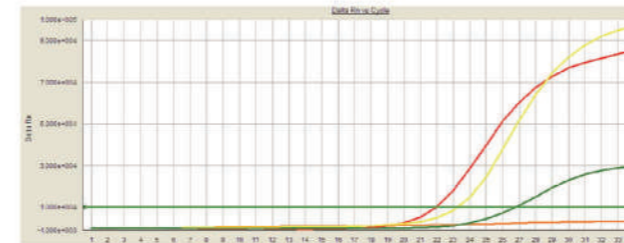
Compatible instruments:

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.

Other Related Products

Catalogue No.	Product	Packing Size	CE Mark
PF04X011	Cell Preservation Solution	48ml X 2	CE
PF03X010	Nucleic Acid Extraction Kit	50tests/kit	CE
FP01005	Endocervical Brush	1pcs/pack	CE
	Tellegen Real Time PCR Machine		CE
	Luminex® 200		CE/FDA

For Sales, Customer Service and Technical Support

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HPV TEST

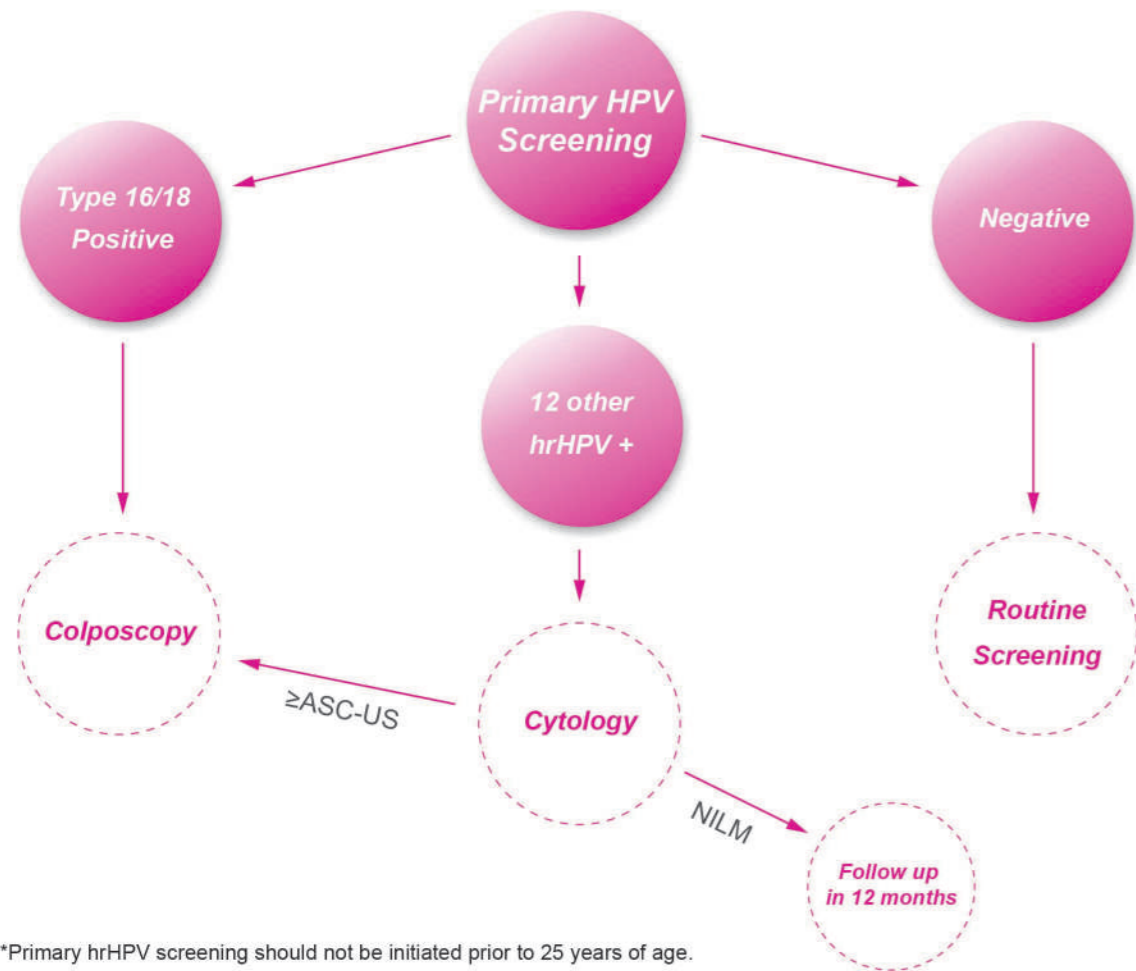
We care about women's health

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
LG01002P1	Tellgenplex® HPV27 genotyping Assay	48 tests/kit	Liquid(-20℃)
PG01004P1	HPV5+9(16、18、33、52、58 genotyping)	48 tests/kit	Liquid (-20℃) and lyophilised(Room temperature) reagents available
PG01003P1	HPV2+12(16、18 genotyping)	48 tests/kit	Liquid (-20℃) and lyophilised(Room temperature) reagents available

Tellgenplex® HPV 27 genotyping Assay



Tellgenplex® HPV 27 genotyping Assay is an in vitro diagnostic test for the simultaneous detection and identification of 17 high-risk Human Papillomavirus(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) by Tellgenplex®.

Tellgenplex® is a multiplex technology using flow cytometry and coding beads, which make it simple to identify 27 specific HPV types 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

Number of samples is flexible with max. load of 96 samples.

Digital Result

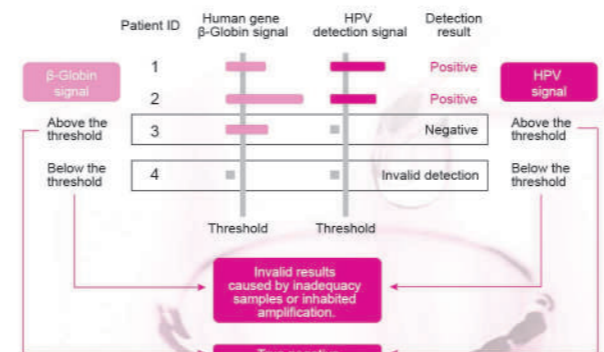
Laser reading, automatic results given by software, unite and objective interpretation. Connect with Lis system, and keep the results for ever.

Easy Operation

High level automation, automatic hybridization and detection. Less than 0.5h for total manual operation time. NO wash step.

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	HPV43	HPV44	HPV45	HPV51	HPV52	HPV53	HPV55	HPV56	HPV58	HPV59	HPV61	HPV66	HPV68	HPV81	HPV82	HPV83
A1(HPV16 positive)	2321	22	21	2320	21	22	40	24	22	37	24	29	40	37	26	40	52	26	25	37	22	41	31	30	47	21	26	62
A2(HPV18 positive)	3101	25	26	35	2230	31	30	39	18	32	120	45	51	44	51	51	34	50	41	44	20	29	46	52	29	39	50	51
A3(HPV52 positive)	2982	40	20	24	39	29	41	20	40	44	37	36	25	16	26	26	1740	17	39	61	55	47	25	20	28	50	17	33
A4(HPV58 positive)	2436	28	32	37	25	21	35	22	35	19	41	47	26	61	39	30	159	25	52	18	1628	54	37	30	21	5	25	27
A5(HPV16,33 positive)	2620	9	36	2051	110	25	27	894	31	31	21	32	39	42	27	28	40	30	35	42	46	50	26	15	48	25	30	37
A6(HPV18,45 positive)	3242	28	24	33	963	19	49	29	26	21	32	27	30	42	721	30	47	33	33	42	38	31	33	32	37	36	50	26
A7(HPV6, 55 positive)	2913	1235	46	252	26	27	30	26	38	5	14	29	45	28	37	38	21	37	963	28	33	35	45	43	21	31	14	17
A8(HPV31,68 positive)	2438	23	23	25	28	37	652	31	31	38	19	5	23	51	28	17	62	50	21	51	53	47	62	17	521	47	45	19
B1(HPV negative)	2955	35	26	43	32	41	39	33	31	47	26	26	45	37	32	45	75	47	28	53	23	45	51	28	43	22	35	22
B2(Invalid)	46	19	33	31	22	30	29	42	18	23	37	33	37	21	28	31	22	36	36	33	28	12	53	19	32	43	20	27

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

• Stratifies high risk women and carry out monitor, early find the cervical lesions.

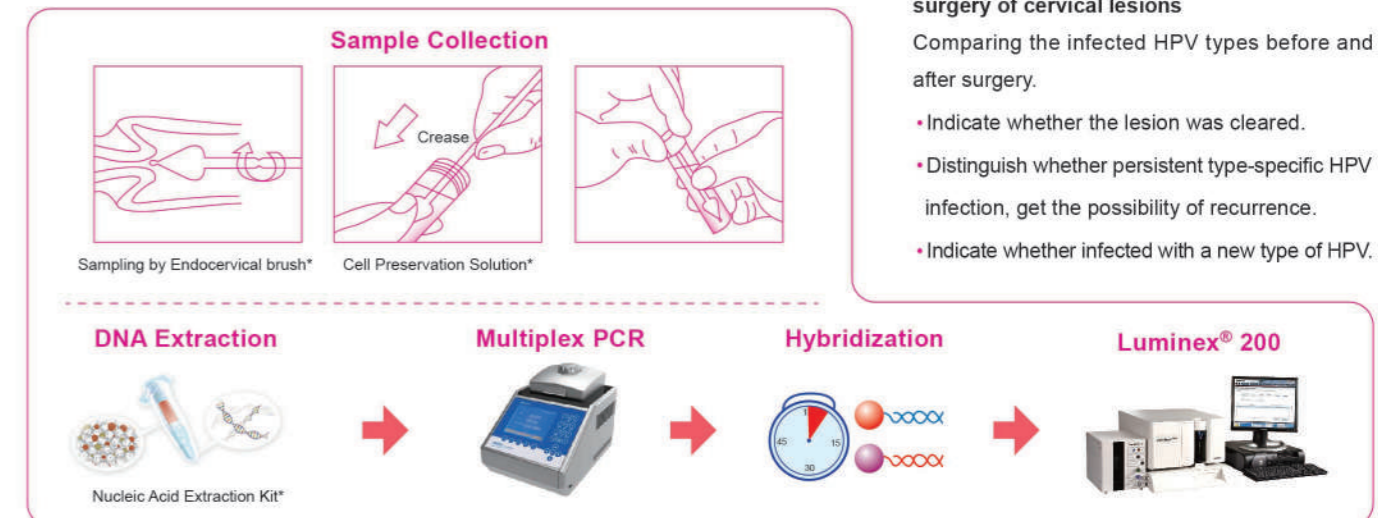
• Discovery of women infected by persistent type specific HPV but normal cytology result.

2/ ASCUS triage and management

• Effectively distinguish the risk level of cervical cancer, provide a reasonable suggestion for use of colposcopy.

• High negative predictive value, identify the women with HPV negative who can safely return to routine screening, protect women from over diagnosis and overtreatment.

Operation Procedure



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.

*please refer to the "Related products" at the last page.