PaxView® HPV16/18/Others MPCR-ULFA Kit CE IVD

[Intended Use]

PaxView® HPV16/18/Others MPCR-ULFA Kit is an in vitro diagnostic kit for the qualitative detection of HPV type 16 and 18, and other HPV types in human vaginal/cervical swab specimens. The kit utilizes multiplex PCR (MPCR) and universal lateral flow assay (ULFA) to detect HPV. This test is for professional use and is intended to aid in the diagnosis of HPV infection.

[Introduction]

Currently, there are over 100 known Human Papillomavirus (HPV) genotypes associated with a number of diseases, particularly cervical cancer. HPV types are often referred to as high-risk and low-risk, based on whether they put a person at risk for cancer. Two major HPV types (16 and 18) cause over 70% of cervical cancer and pre-cancerous cervical lesions. Therefore, sensitive and specific detection of HPV in cervical samples is a useful tool for the early diagnosis of epithelial neoplasia and urogenital lesions.

PaxView® HPV16/18/Others MPCR-ULFA Kit is designed for the simultaneous detection of two high-risk types (16, 18) and common positives of HPV using multiplex PCR and the proprietary universal lateral flow assay (ULFA) which is based on DNA-DNA hybridization on nitrocellulose membranes.

[Principles of the Procedure]

PaxView® HPV16/18/Others MPCR-ULFA Kit uses MPCR-ULFA (Multiplex PCR - Universal Lateral Flow Assay) technology for the detection of the HPV types 16 and 18, and qualitative detection of other HPV types. The kit is comprised of the MPCR kit for the multiplex PCR amplification of HPV DNA and the ULFA kit for the detection of amplified PCR products.

The MPCR kit includes 2X PCR PREMIX and PRIMER MIX for specific amplification of HPV 16, 18, and other HPV types. Forward primers for the amplification include the nucleotide sequence complementary to the universal DNA probes immobilized on the nitrocellulose membrane of the ULFA device. Reverse primers are biotinylated for binding to streptavidin-conjugated gold particles for visualization. When amplified DNA is hybridized to the probe, positive lines will appear on the membrane if HPV is present.

[Kit Components]

Cat. No. V0301F(48T/kit)		
Component 1. MPCR Kit	2X PCR PREMIX	240 μL/ tube X 2
	PRIMER MIX	120 μL/ tube X 2
	POSITIVE CONTROL	30 μL/ tube X 1
Component 2. ULFA Kit	ULFA DEVICE	8 T/ Pouch X 6
	RUNNING BUFFER	2.0 ml / tube X 2
	WASHING BUFFER	2.0 ML / tube X 2

[Sample Preparation]

1. We recommend DNA extracted from the cervical swab.
2. Samples can be stored 2~8°C for up to a week.
3. Samples should be transported in a shatterproof transport container to prevent contamination.
4. Ensure that the sample is kept in proper conditions until the test is carried out and to obtain accurate results.
5. Storing the samples for long periods or repeated freezing/thawing may reduce the sensitivity of the test.

[Methods]

1. Thaw the reagents of the MPCR Kit at room temperature or on ice for 10~15 minutes.
2. Mix the tube briefly and spin down for 3~5 seconds.
3. Prepare a master mixture of 2X PCR PREMIX and PRIMER MIX in a sterilized 1.5 ml microtube. Consider the total amount, including extracted DNA and controls.

Components	Volume/test
2X PCR PREMIX	10 μl
PRIMER MIX	5 μl
Total volume	15 μl

4. Put 15 μl of the prepared master mixture into the PCR tube and add 5 μl of the extracted DNA sample, positive control or negative control. (* Negative control is not provided. Use distilled water or TE buffer as a negative control.)
5. Mix the tube briefly and spin down for 3~5 seconds.
6. Place the tube into the thermal cycler and start PCR amplification with cycling conditions, as shown in the table below.

Step	Temp.	Time	Cycle
1	50 °C	4 min	1
2	95 °C	10 min	1
3	95 °C	15 sec	25
	72 °C	90 sec	
4	95 °C	15 sec	20
	62 °C	45 sec	
	72 °C	30 sec	

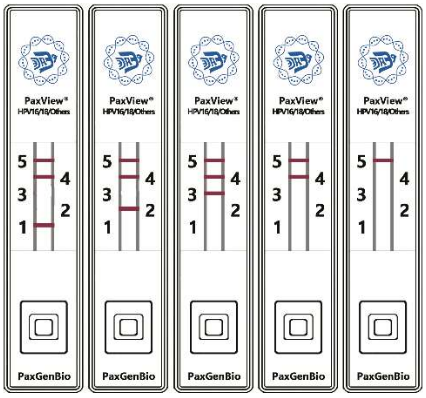
7. After the reaction, take out the tube and spin down for 3~5 seconds.
8. Prepare ULFA DEVICE from the pouch and then BUFFERS.
9. Load 5 μl of the PCR products into the sample loading well on the ULFA device and add 50 μl of running buffer to the well.
10. After 5 minutes, add 50 μl of washing buffer.
11. After 5 minutes, check the results (Do not exceed 10 minutes after the completion of running).

12. Analyze the results using the table below.

Line	Target species
1	HPV 16
2	HPV 18
3	HPV Others
4	Internal control (IC)
5	Hybridization control (HC)

[Analysis of Results]

Result	Detection Line
HPV 16 positive	1, 4, 5
HPV 18 positive	2, 4, 5
HPV Others	3, 4, 5
Negative	4, 5
Invalid	5 or No band



HPV16 Positive **HPV18 Positive** **HPV Others Positive** **HPV Negative** **Invalid PCR**

Note:

*The single positive of HPV-Others at line 3 means being infected with HPV subtypes other than HPV 16 or 18.

*When infected with HPV 16 or 18, a positive result for HPV-Others may show up along with positive results for HPV 16 or 18, because HPV-Others are for DNAs that all HPV subtypes have in common.

*When the amount of HPV PCR products is substantial, a positive result for the control lines (4 and/or 5) may not be observed. Then, if 'positive' results are obtained at lines 1, 2 and/or 3 it may be analyzed as 'positive'.

[Performance Characteristics]

1. Analytical Sensitivity

The Limit of Detection (LoD) (copies/ µl)

Target	HPV16	HPV18	HPV Others
LoD	60	60	140

2. Analytical Specificity

No cross-reactivity was observed for 25 species of bacteria and viruses tested.

3. Clinical performance evaluation

PaxView® HPV16/18/Others MCR-ULFA Kit			
	HPV 16	HPV 18	HPV Others
Sensitivity	98.7%	98.5%	95.2%
Specificity	96.2%		

[Precautions]

1. This kit is intended for in vitro diagnostic use.
2. Do not use kits after their expiration date.
3. For reliable results, appropriate collection, storage, transport and handling should be performed.
4. Quality control materials shall be in accordance with the actual guidelines of each laboratory.
5. Do not pool reagents from different kits or lots.
6. Repeated freezing and thawing of the reagents should be avoided as it may affect the sensitivity of the test.
7. Store the nucleic acid extracts at -20°C and place it on the ice when using.
8. Care should be taken to ensure that reagents are not contaminated by nucleic acid extracts, PCR amplification products, or positive controls.
9. We recommend using sterile disposable filter tips.
10. Be careful of microbial and cross-contamination, spill samples when samples preparation. We recommend using a screw-cap tube during the test.
11. When handling the samples and reagents, wear disposable gloves, gowns and eyeglasses.
12. Gloves must be worn and must be changed between handling specimens and reagents to prevent contamination.
13. Use different pipettes for nucleic acid extraction, reagent mixing, nucleic acid template mixing and PCR amplification product mixing.
14. Avoid skin contact with all reagents. Be sure to wash your hands after handling samples and reagents.

[Package]

V0301F: 48 tests/kit

[Storage]

- Component 1. RT-PCR Kit: -25˚C ~ -15˚C
- Component 2. ULFA Kit: 15˚C ~ 30˚C (ULFA DEVICE must be keep enclosed with the desiccant in Pouch)

[Expiration date]

12 months from the date of manufacturing

⁎ Once opened, components are stable in the period below.

Components		Shelf life after opening
Component 1. MPCR Kit	2X PCR PREMIX	3 Months
	PRIMER MIX	3 Months
	POSITIVE CONTROL	3 Months
Component 2. ULFA Kit	ULFA DEVICE	1 Months With Desiccant
	RUNNING BUFFER	1 Months
	WASHING BUFFER	1 Months

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