

# VIASURE MULTIPLEX

## Papilloma Virus 16 + 18 Real Time PCR Detection Kit

### Pathogen and product description

**H**uman papillomavirus (HPV) is the most common viral infection of the reproductive tract. Most sexually active women and men will be infected at some point in their lives and some may be repeatedly infected.

Human papillomaviruses (HPV) are small double stranded DNA viruses classified in the *Papillomaviridae* family. These viruses infect skin or mucosal epithelial cells, therefore, viral DNA can be detected from skin, oral and anogenital samples from all human populations.

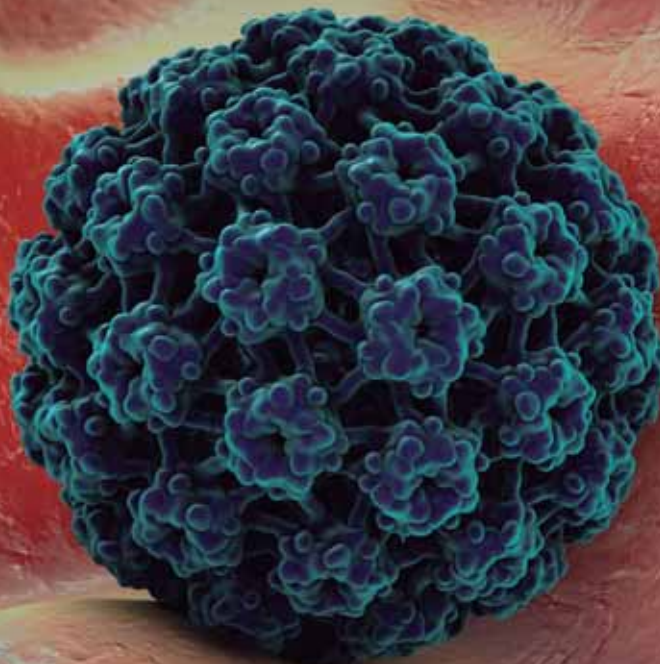
HPV is transmitted through intimate skin-to-skin contact. Nearly all men and women get it at some point in their lives due to this virus can be passed even when an infected person has no signs or symptoms. In fact, you can develop symptoms years after being infected, making it hard to know when you first became infected. The majority of HPV infections do not cause symptoms or disease and resolve spontaneously. But when HPV does not go away, it can cause health problems like genital warts, respiratory papillomatosis and cervical, anogenital and oropharyngeal cancer.

Cervical cancer is the fourth most common cancer among women worldwide and is of particular importance in developing countries based on the lack of proper cervical cancer screening programs.

In particular, specific types of HPV (16 and 18) are the most frequently may lead to precancerous lesions. Men and women can get cancer of mouth/ throat, and anus/rectum caused by HPV infections. Men can also develop penile cancer. In women, HPV infection might cause cervical, vaginal, and vulvar cancers. Currently, there are vaccines that could prevent infection with the types of HPV that most commonly cause cancer.

A variety of diagnostic methods of differing sensitivity and specificity have been developed to detect HPV in skin, oral and anogenital samples (mostly, cervical scrapings and biopsy material). Since HPV cannot be cultured efficiently and the clinical performance of serological assays is poor, the diagnosis of HPV infection is almost entirely based on molecular tools. Currently, Real Time PCR offers a high sensitivity and can be performed in different types of samples.

VIASURE *Papilloma Virus 16 + 18* Real Time PCR Detection Kit is designed for the diagnosis of Human papillomavirus 16 and Human papillomavirus 18 in clinical samples. After DNA isolation, the identification of Human papillomavirus 16 and/or Human papillomavirus 18 is performed by the amplification of a conserved region of the *L2* gene for Human papillomavirus 16 and *L1* gene for Human papillomavirus 18, using specific primers and a fluorescent-labelled probe.



### Analytical sensitivity

VIASURE Papilloma Virus 16 + 18 Real Time PCR Detection Kit has a detection limit of  $\geq 10$  DNA copies per reaction for Human papillomavirus 16 and Human papillomavirus 18 (Figure 1 and 2).

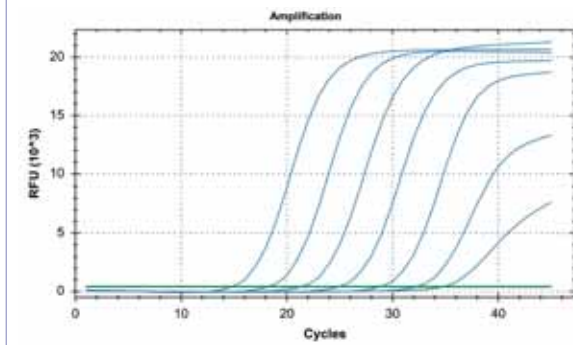


Figure 1. Dilution series of Human papillomavirus 16 ( $10^7$ – $10^1$  copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (channel FAM).

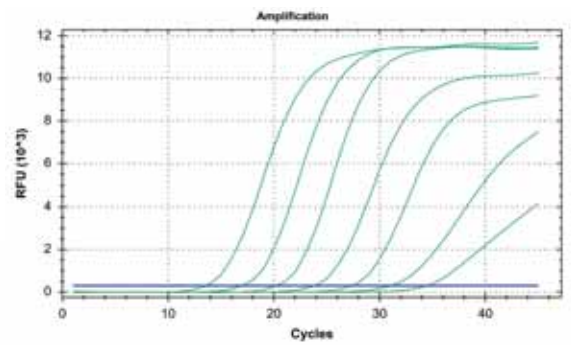


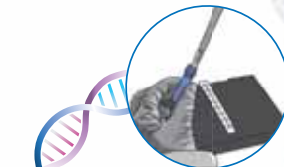
Figure 2. Dilution series of Human papillomavirus 18 ( $10^7$ – $10^1$  copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (channel HEX).

### Components

Reagent/Material	Description	Colour	Quantity
Papilloma Virus 16 + 18 8-well strips	A mix of enzymes, primers-probes, buffer, dNTPs, stabilizers and Internal control in stabilized format	White	6/12 X 8-well strip
Rehydration Buffer	Solution to reconstitute the stabilized product	Blue	1 vial x 1.8 mL
Papilloma Virus 16 + 18 Positive Control	Non-infectious synthetic lyophilized cDNA	Red	1 vial
Negative Control	Non template control	Violet	1 vial x 1 mL
Water RNase/DNase free	Water RNase/DNase free	White	1 vial x 1 mL
Tear-off 8-cap strips	Optical caps for sealing Wells during thermal cycling	Transparent	6/12 x 8-cap strip

### Work Flow

One-step rehydration of wells and add your extracted DNA



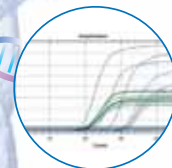
**STEP 1**  
Add 15  $\mu$ l of rehydration buffer into each well



**STEP 2**  
Add 5  $\mu$ l of DNA sample / positive control / negative control



**STEP 3**  
Load the strips into the thermocycler and run the specified protocol



**STEP 4**  
Interpretate results

### Kit References

Reference	Description
VS-HPV106L	VIASURE Papilloma Virus 16 + 18 Real Time PCR Detection Kit 6 x 8-well strips, low profile
VS-HPV106H	VIASURE Papilloma Virus 16 + 18 Real Time PCR Detection Kit 6 x 8-well strips, high profile
VS-HPV112L	VIASURE Papilloma Virus 16 + 18 Real Time PCR Detection Kit 12 x 8-well strips, low profile
VS-HPV112H	VIASURE Papilloma Virus 16 + 18 Real Time PCR Detection Kit 12 x 8-well strips, high profile
VS-HPV113L	VIASURE Papilloma Virus 16 + 18 Real Time PCR Detection Kit 96-well plate, low profile
VS-HPV113H	VIASURE Papilloma Virus 16 + 18 Real Time PCR Detection Kit 96-well plate, high profile