

HPV high-risk screening  
easy, fast and accurate

IVD

*Simultaneous genotyping of  
14 high-risk HPV types in a single tube*

## WizDx™ CrystalMix HPV-HR



WizDx™ CrystalMix HPV-HR Kit is an in vitro diagnostic multiplex real-time PCR kit that simultaneously detects 14 high-risk human papillomavirus (HPV) types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 in a single tube using a patient's vaginal swab or urine specimen. This kit contains all reagents required for lyophilized high-risk HPV real-time PCR in 8-strip qPCR tubes.

16

18

31

33

35

39

45

51

52

56

58

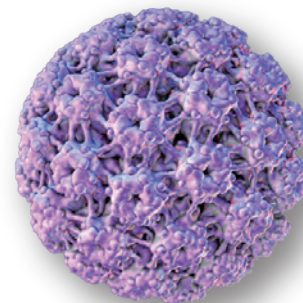
59

66

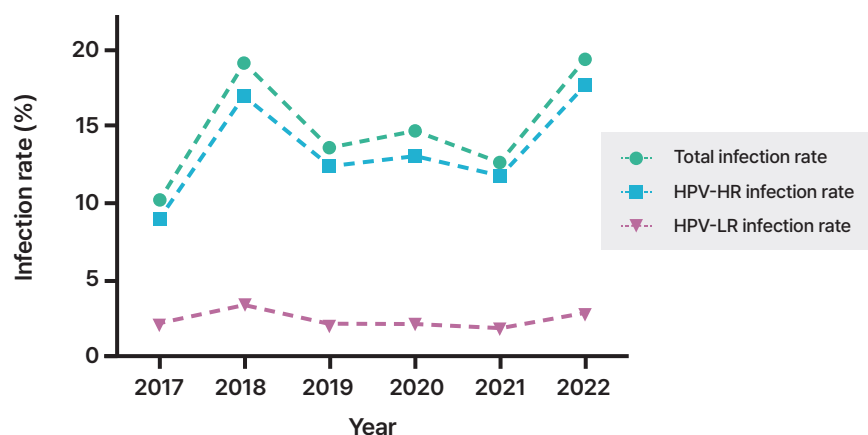
68

# What is HPV ?

When a high-risk type of HPV infects cells, it changes how they communicate with one another. It also causes the cells to multiply. Usually, the immune system becomes aware of these cells and regulates them. However, if these abnormal cells remain, they can continue to change and become precancerous.



The Human papillomavirus infection (HPV) is caused by a DNA virus from the Papillomaviridae family. Many HPV infections cause no symptoms and 90% resolve spontaneously within two years. In some cases, an HPV infection persists and results in either warts or precancerous lesions. These lesions, depending on the site affected, increase the risk of cancer of the cervix, vulva, vagina, penis, anus, mouth, tonsils, or throat. Nearly all cervical cancer is due to HPV, and two strains – HPV16 and HPV18 – account for 70% of all cases. HPV16 is responsible for almost 90% of HPV-positive oropharyngeal cancers. Between 60% and 90% of the other cancers listed above are also linked to HPV.



Trends in the overall prevalence of HPV infection, high-risk HPV (HPV-HR) infection, and low-risk HPV (HPV-LR) infection from 2017 to 2022

## 13 million

Human papillomavirus (HPV) is the most common sexually transmitted virus, with doctors diagnosing roughly 13 million new cases every year.

## 10%

Worldwide HPV prevalence in healthy women

## 600,000

Annual number of cervical cancer cases worldwide ('20)

## Key Features

- Tests for 14 types of high-risk HPV simultaneously in one tube, enabling fast and accurate testing.
- Uracil-DNA glycosylase (UDG) technology prevents carryover contamination.
- Hot-start PCR technology minimizes non-specific PCR reactions and increases specificity.
- Ready-to-use freeze-dried PCR mix allows convenient storage and minimal test procedure
- Internal cellular control helps prevent false negatives.
- Positive results are clinically meaningful because it does not cross-react with low-risk HPV genotypes



## 1-tube, 14-types

HPV 16



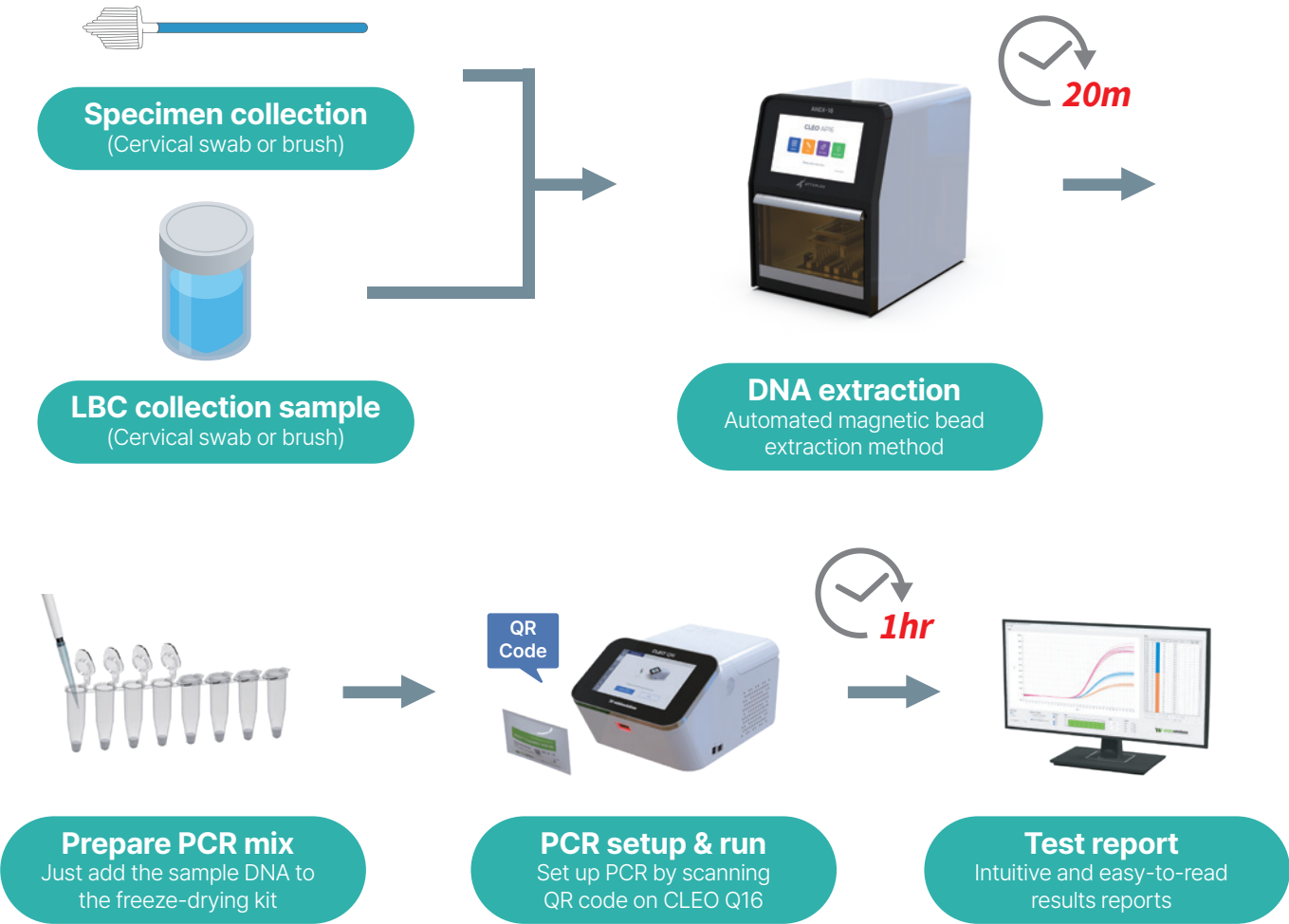
HPV 18



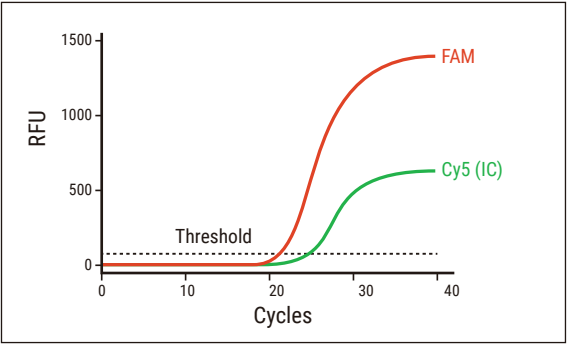
12 pooled high-risk HPV



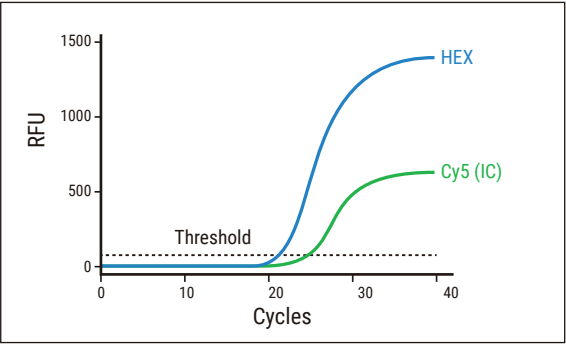
# HPV-HR PCR test workflow



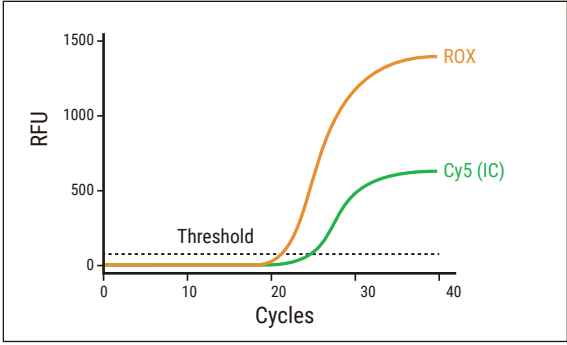
HPV 16



HPV 18



12 pooled high-risk HPV



# WizDx™ CrystalMix HPV-HR kit



WizDx™ CrystalMix HPV-HR kit is an in vitro diagnostic multiplex real-time PCR test for single or simultaneous diagnosis of Human Papillomavirus (HPV) type 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 for the qualitative detection using vaginal swab or urine specimens from patients. WizDx™ CrystalMix HPV-HR kit combines all reagents necessary for successful Real-time PCR in a convenient individual aliquot and lyophilized in an 8-strip qPCR tube. Real-time PCR technology utilizes polymerase chain reaction (PCR) for the amplification of specific target sequences to detect the L1 gene of Human papillomavirus genotype 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. The probes are labeled with a fluorescent reporter and quencher dyes.

## ○ Principle of test

Multiplex real-time PCR

## ○ Limit of detection (LoD)

5 ag/μL

## ○ Specimens

Vaginal swab or urine specimens

## ○ Reagent type

Lyophilized (Freeze-dried) in PCR tube

## ○ Precision

Respectively detect the reference specimen of high and low concentrations in different time ranges-10 times, and the precision values of intra-assay and inter-assay Ct values were all <5%.

## ○ Specificity

- Analytical specificity : 100 %
- Clinical Sensitivity : #16 (92.37%), #18 (95.00%), #HR (91.63%)
- Clinical Specificity : #16 (99.48%), #18 (99.70%), #HR (96.59%)

## ○ Features

- Accurate genotyping of HPV type 16, 18 and toher high risk HPV in a single reaction
- Multiplex real-time PCR with high sensitivity and specificity
- Utilization of the UDG system to prevent carry-over contamination
- Improved reproducibility and accuracy of results with an all-in-one kit
- Convenient data interpretation through Q16 automated analysis program

## Ordering Information

Product	Cat No.	Package	
WizDx™ CrystalMix HPV-HR	DX1240	96 test	
CLEO™ Q16 Real-time PCR	CL0016	1 set	
CLEO™ AP16 Nucleic acid extractor	CL2016	1 set	
CLEO™ AP48 Nucleic acid extractor	CL2048	1 set	
WizMag™ Viral DNA/RNA	W7020	64 prep	16 prpe/run
	W7021	192 prep	
	W7022	32 prep	1~8 prep/run
	W72023	96 prep	



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