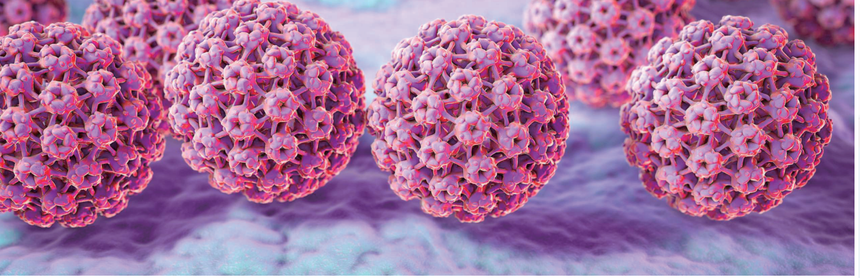

HPV Nucleic Acid Detection and 16/18 Genotyping Kit (Fluorescent PCR)

15 High-risk HPV genotypes : 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, and 68

CE-IVD

Human Papillomavirus (HPV) is a non-enveloped double-stranded circular DNA virus with a preference for epithelial tissues. The genome is approximately 8000 base pairs long and consists of three functional regions: the early transcriptional region (E region), the late transcriptional region (L region), and the non-transcriptional region (long control region, LCR). Based on their pathogenicity or carcinogenic risk, HPV is classified into high-risk and low-risk types. According to research by the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) and other international organizations, HPV types such as 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68 are classified as high-risk, while types like 26, 53, 66, 73, and 82 are considered intermediate risk, with HPV53 and HPV66 being suspected high-risk types.

It is now established that persistent infection with high-risk HPV is a key factor in the development of cervical cancer and precancerous lesions. In recent years, the incidence and mortality of cervical cancer have been on the rise globally, with approximately 500,000 women diagnosed with cervical cancer and around 300,000 women succumbing to cervical cancer annually. Therefore, rapid and accurate screening is crucial for the prevention and early detection of cervical cancer. The growing population, favorable government policies worldwide, and increased awareness of women's health further contribute to the growth of the HPV testing market.

This assay kit targets the conserved L region and E region of high-risk HPV, employing specific primers and TaqMan probes. The probe is labeled with a fluorescent reporter group at the 5' end and a quenching group at the 3' end. During PCR amplification, both primers and probes can specifically bind to the target sequence. At this stage, the fluorescence of the reporter group is quenched by the quenching group without emitting fluorescence. As the extension proceeds, the hot-activated Taq DNA polymerase initiates polymerization and exhibits 5' → 3' exonuclease activity, leading to the hydrolysis of the fluorescent probe. This separation results in the emission of fluorescence from the free fluorescent reporter group. The fluorescence PCR instrument plots a fluorescence curve based on the detected signals and determines the test results. The detection system includes dUTP-UDG enzyme contamination control measures to thoroughly degrade potential product contamination, avoiding false-positive results. Additionally, an internal standard, a highly conserved region on the human genome, monitors the entire process of specimen collection, transportation, nucleic acid extraction, and PCR amplification, preventing false-negative results and ensuring the effectiveness of the entire process. When combined with Bioer Technology 's self-produced fully automatic nucleic acid extractor and real-time fluorescence quantitative PCR analyzers FQD-96A, FQD-96C, and FQD-A1600, the kit demonstrates features such as fast detection speed, excellent specificity, and high sensitivity.

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Hangzhou Bioer Technology Co., Ltd.

Add: 1192 Bin An Rd., Hi-tech (Binjiang) District, Hangzhou, 310053, P.R.China

Tel: +86-571-87774575 **E-mail:** overseas@bioer.com.cn

Fax: +86-571-87774553 **Http:** //www.bioer.com

After-sales service: +86-571-87774558

BioFlux

BIOER

HPV Nucleic Acid Detection and 16/18 Genotyping Kit (Fluorescent PCR)

CE-IVD

15 High-risk HPV genotypes :
16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, and 68

Product Specification

Specification	Description
Intended Purpose	This assay kit is intended for the auxiliary diagnosis of high-risk Human Papillomavirus (HPV) infections, specifically targeting 15 high-risk types including HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, and 68. It also allows for the subtyping detection of HPV16 and HPV18. Since this assay kit has not undergone relevant clinical trials, it is solely intended for clinical auxiliary diagnosis and cannot be used for ASC-US population triage or cervical cancer screening purposes.
Sample Type	Cervical Swab
Sensitivity	The sensitivity for HPV16 and HPV18 is 500 copies/mL, The sensitivity for other genotypes is 1000 copies/mL.
Precision	The coefficients of variation for inter-batch, intra-batch, inter-day, and intra-day precision are all less than 5%.
Accuracy	The positive conformity rate and negative conformity rate for the detection of the national reference samples for HPV are both 100%.
Specificity	This assay kit detects 15 HPV types within its designated range, as confirmed by testing against the national reference samples for HPV. There is no cross-reactivity observed among the 15 HPV types within the detection range. Additionally, there is no cross-reactivity with HPV types outside the detection range, including HPV6, 11, 26, 40, 42, 44, 54, 61, 67, 69, 70, 71, 72, 81, and 83. Furthermore, the assay kit demonstrates no cross-reactivity with common pathogenic microorganisms found in the human urogenital and reproductive tracts, as well as other sexually transmitted pathogens, those causing similar clinical symptoms, such as Ureaplasma urealyticum, Chlamydia trachomatis, Herpes Simplex Virus II, Human Cytomegalovirus, Treponema pallidum (syphilis spirochete), Human Mycoplasma, Neisseriagonorrhoeae, Candida albicans, Trichomonas vaginalis, Escherichia coli, and others.
Compatible Platform	LineGene9600 Plus (FQD-96A), QuantGene 9600 (FQD-96C), Automated Nucleic Acid Purification and Real Time PCR System (FQD-A1600 and FQD-A9600)
Detection Time	60 min
Storage Conditions	-20 ± 5°C

Product Features

Short Turnaround Time for Reporting

Completion of the entire process, from sample processing to result reporting, within 90 minutes.

Simple Operation

Paired with the Bioer fully automatic nucleic acid extractor, extraction for 96 samples takes only 15 minutes, effectively enhancing laboratory workflow efficiency.

Sample Collection Monitoring

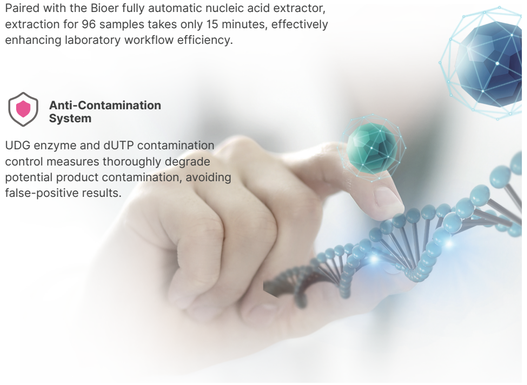
The non-competitive human β-Globin internal reference can be used to assess sample quality and PCR inhibition factors, while preventing false-negative results.

Anti-Contamination System

UDG enzyme and dUTP contamination control measures thoroughly degrade potential product contamination, avoiding false-positive results.

Four-Channel Fluorescence Detection

FAM, HEX, ROX, CY5



Application Cases

Case 1: Specificity

The assay kit has been tested with the national reference samples for HPV, demonstrating no cross-reactivity among the 15 high-risk HPV types within the detection range. Additionally, there is no cross-reactivity observed with HPV types outside the detection range, including HPV6, 11, 26, 40, 42, 44, 54, 61, 67, 69, 70, 71, 72, 81, and 83.

Furthermore, the assay exhibits no cross-reactivity with common pathogenic microorganisms representing human urogenital and reproductive parasitic agents, as well as other pathogenic microorganisms. It also shows no cross-reactivity with other sexually transmitted pathogens, those capable of sexual transmission, and other pathogens that may cause similar or identical clinical symptoms. These pathogens include Ureaplasma urealyticum, Chlamydia trachomatis, Herpes Simplex Virus II, Human Cytomegalovirus, Treponema pallidum (syphilis spirochete), Human Mycoplasma, Neisseria gonorrhoeae, Candida albicans, Trichomonas vaginalis, Escherichia coli, and others.

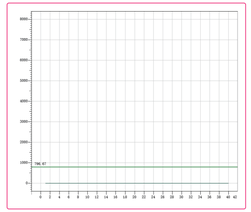


Figure 1 Specificity Testing

Result: The results indicate that there is no cross-reactivity with other types of human papillomavirus outside the detection range. Additionally, there is no cross-reactivity observed with representative microorganisms that parasitize the human urogenital and reproductive tracts or other sexually transmitted pathogens.

Case 2: Relationship

The high risk-HPV positive samples were subjected to a 10-fold serial dilution, and each dilution was subsequently tested.

Result: The results indicate that the assay demonstrates a good linear relationship in the amplification of samples for HPV16, HPV18, and other genotypes.

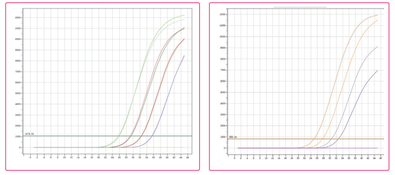


Figure 2 HPV Sample Amplification

Case 3: Precision

HPV16, HPV18, and other high-risk genotypes samples were diluted to concentrations of 10^4 copies/mL and 10^3 copies/mL, respectively. Each dilution was tested in triplicate, repeated 10 times. The coefficient of variation (CV) for the Ct values was calculated, with a requirement that the CV for Ct values should not exceed 5%.

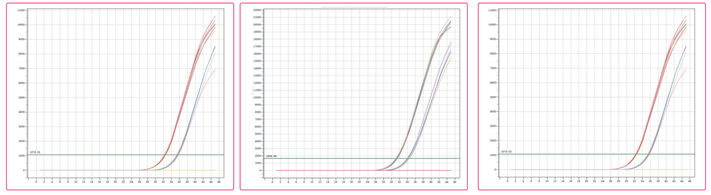


Figure 3 Precision Amplification Curves for Different HPV Genotypes

Result: The results indicate that when HPV16, HPV18, and other high-risk genotypes samples were diluted to concentrations of 10^4 copies/mL and 10^3 copies/mL, and tested repeatedly 10 times, the coefficient of variation (CV) for Ct values was consistently less than 5%. This suggests that the assay kit exhibits good repeatability in detection.

Case 4: Comparative Testing with Similar Products

a.After quantifying the nucleic acid of high-risk Human Papillomavirus (HPV) types 16, 18, 31, 33, 51, 52, 56, 58, and 68 using digital PCR, the samples were diluted to concentrations of 1000 copies/mL and 500 copies/mL. Comparative testing was then performed against well-established and widely recognized assay kits with high market share.

Genotypes	Copies/mL	CT Value of Competitors	CT Value of Bioer
HPV16	1000	34.15	34.34
	500	34.22	35.61
HPV18	1000	36.13	34.37
	500	No call	36.38
HPV31	1000	34.93	34.11
	500	36.79	35.48
HPV33	1000	35.41	32.53
	500	35.80	34.07
HPV51	1000	33.87	35.28
	500	35.01	36.4
HPV52	1000	33.95	34.32
	500	34.23	36.28
HPV56	1000	34.66	34.53
	500	No call	36.96
HPV58	1000	36.48	34.96
	500	36.87	36.34
HPV68	1000	35.95	35.29
	500	36.12	35.89

Conclusion: All positive samples were detected, and the conformity rate between the Bioer assay and the competitors was 100%. The Bioer assay demonstrated higher detection capability than the competitors for certain HPV genotypes.

b.Unknown samples were tested using both the Bioer HPV detection kit and a well-established, widely recognized competitors with high market share.

Copies/mL	CT Value of Competitors	CT Value of Bioer
S1 (other genotypes)	30.72	28.43
S2	Negative	Negative
S3 (HPV16)	29.56	25.49
S4 (HPV16)	32.76	32.19
S5 (other genotypes)	29.95	27.79
S6 (HPV16)	32.12	30.04
S7 (HPV16)	33.69	31.51
S8	Negative	Negative
S9 (HPV16)	29.56	30.08
S10 (other genotypes)	28.04	24.95
S11 (other genotypes)	30.65	26.18
S12 (other genotypes)	28.93	25.77
S13 (other genotypes)	28.63	24.71
S14 (other genotypes)	34.99	26.98

Conclusion: All positive samples were detected, and the conformity rate between the Bioer assay kit and the competitors kit was 100%.

Ordering Information

Product Name	Cat#	Package
HPV Nucleic Acid Detection and 16/18 Genotyping Kit (Fluorescent PCR)	BSJ50M1	48 Tests/kit
HPV Nucleic Acid Detection and 16/18 Genotyping Kit (Fluorescent PCR)	BSJ50L1	96 Tests/kit