Capital TECHNOLOGY

Human Papilloma Virus (HPV) Nucleic Acid Detection Kit

(PCR-Fluorescent Probe Method)

Clinical Background

Cervical cancer is one of the major diseases threatening women's health, ranking second among malignant tumors in women. The World Health Organization (WHO) considers cervical cancer to be the only cancer with a clear cause that can be detected, prevented and treated early. Human papilloma virus (HPV) is the main cause of cervical cancer, and over 99% of cervical cancer patients can be detected for HPV fragments. High-risk HPVs are not only the pathogenic cause of cervical cancer, but also associated with high-grade squamous intraepithelial lesions (HSIL) of the vulva, vagina and cervix. HPV testing is the key to prevent cervical cancer.


CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Product Introduction

The product applies the PCR - fluorescent probe technology to simultaneously detect 18 high-risk HPV types, and offers advantages, such as high efficiency, sensitivity, stability and simplicity. It can be used to assess the risk of cervical cancer, assist cytological testing, and follow-up post-surgery.

Characteristic Advantages

Stable
The freeze-drying technology ensures excellent stability

Specific
The accuracy and specificity are 99% above, and CV is <5.0%

Sensitive
The LOD is 500 copies/ml

Simple
One-tube test provides three results, genotyping for HPV16/18, which is suitable for large-scale cervical cancer initial screening

Quick
It only takes 1.5 hours to complete the whole process

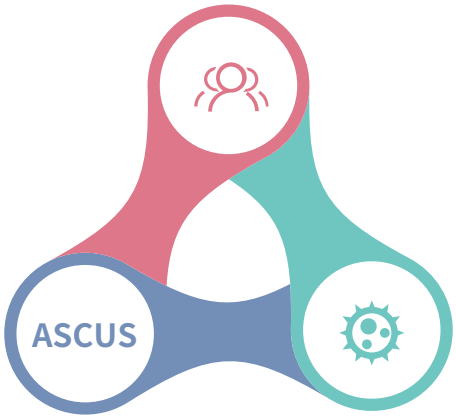
Accurate
Housekeeping gene internal standard control and whole-process monitoring ensure the accuracy

Clinical Application

The product can test 18 high-risk HPVs (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82), and perform the genotyping identification for types 16 and 18. It is used for auxiliary diagnosis of clinical HPV infections.

Clinical Significance

- The screening for cervical lesions and cervical cancer is suitable for large-scale population initial screening;
- Triage management for patients with atypical squamous cells of undetermined significance (ASCUS);
- Monitoring and follow-up after treatment of cervical intraepithelial neoplasia (CIN) and cervical cancer.



Test Process

01 HPV sampling

02 HPV genetic testing

03 data analysis

04 report and interpretation

Applicable Instrument

It is suitable for

1. ABI 7500 Real-time Fluorescent Quantitative PCR Instrument
2. SLAN®-96S Automatic Medical PCR Analyzer

Product Information

Inspection Items	Spec.	Product No.	Storage Condition and Validity Period	Sample Type
Human Papilloma Virus (HPV) Nucleic Acid Detection Kit (PCR - Fluorescent Probe Method)	32 tests / kit	XS0300601	It shall be stored at 2°C -8°C with the valid period of 12 months.	Cervical exfoliated cell

CapitalBiotech

Add: 88 Kechuang 6th Street, Building C, Yizhuang Biomedical Park, Beijing Economic-Technological Development Area, Beijing 101111, China
www.capitalbiotechnology.com Tel: +86-10-69002900 E-Mail: globalsales@capitalbiotech.com