

Human Papilloma Virus (HPV) Test Kit (Micro-array Chip Method)

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◎ Clinical Background

Cervical cancer is one of the major diseases threatening women's health, and its incidence ranks the second in women malignant tumors. It is shown by survey data of WHO that there are about 500,000 new patients of cervical cancer all over the world every year, causing about 250,000 deaths, and there are approximately 90% of new patients from developing countries. China is the high incidence area of cervical cancer, and there are about 150,000 new patients every year, accounting for 1/3 of the total new cases of cervical cancer all over the world.

Human Papilloma Virus (HPV) can be divided into high-risk type and low-risk type by carcinogenic risk, in which the persistent infection of high-risk HPV is the definite reason for inducing the cervical cancer. Cervical cancer is the only cancer with definite reason and can be prevented in advance and cured currently. Women HPV screening is the most efficient and direct method for preventing in advance, early finding, early diagnosis and early treatment of cervical cancer, and also the best way for decreasing the incidence and mortality of cervical cancer.

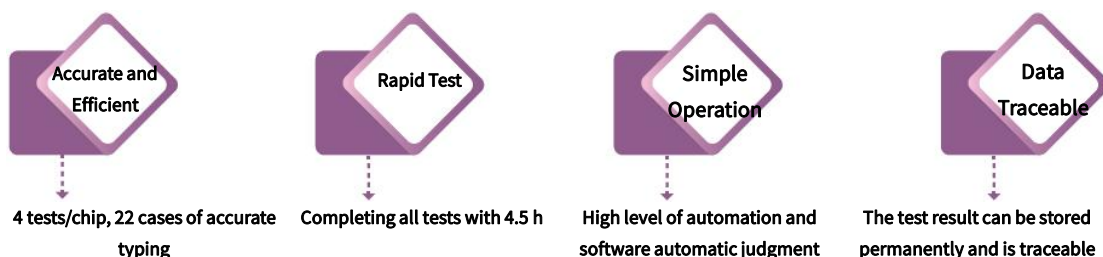
◎ Product Introduction

The technology combining multiple asymmetric PCR with general chip (Tag array) is applied to test and type the common HPV.

◎ Test Content

High-risk Type	Type 16, type 18, type 31, type 33, type 35, type 39, type 45, type 51, type 52, type 56, type 58 and type 59		
Suspected high-risk Type	Type 26, type 53, type 66, type 68, type 70, type 73 and type 82	Low-risk Type	Type 6, type 11 and type 81

◎ Product Characteristics



◎ Applicable Population

- The women who had sexual activity over three years or who had sexual activity with age over 21
- The patient who is suspected or has abnormality in TCT test
- The patient of cervicitis, cervical erosion
- The patient of condyloma acuminata
- The patient who had the unclear sexual experience



◎ Applicable Department



◎ Clinical Verification

The test results of 1925 clinical specimens (from Peking University First Hospital, Shanxi Tumor Hospital and other medical institutes) tested by HPV test kit indicated that: compare the chip test result with DAN sequencing result of HPV infection positive specimens and the percent agreement is above 95%.

Clinical Hospital	Total Specimens	Percent agreement comparing with sequencing result
Peking University First Hospital	609	94.6%
Shanxi Tumor Hospital	502	96.8%
Tongji Hospital of Tongji Medical College of HUST	434	94.9%
The First Affiliated Hospital of Xinjiang Medical University	380	95.3%
Total	1925	95.4%

◎ Clinical Application

Judge the risk of cervical lesions	Assist to cytological examination	Follow up the post-operation condition
• Clinical treatment schemes are different for cases infected by different genotyping HPVs • Judge whether the patient is persistently infected by the same genotype or repeatedly infected by different genotypes	• HPV test can exclude the suspected lesion of atypical squamous epithelial cell • Separate the women with potential risk of cervical cancer from population of low-risk area, decreasing the risk of diagnosis missing	• Predict the risk of post-operation relapse and guide the post-operation tracking • The test result of post-operation HPV typing is negative which shows the effect of nidus excision is good

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