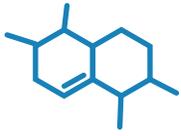




HPV

DNA & RNA Detection Kits

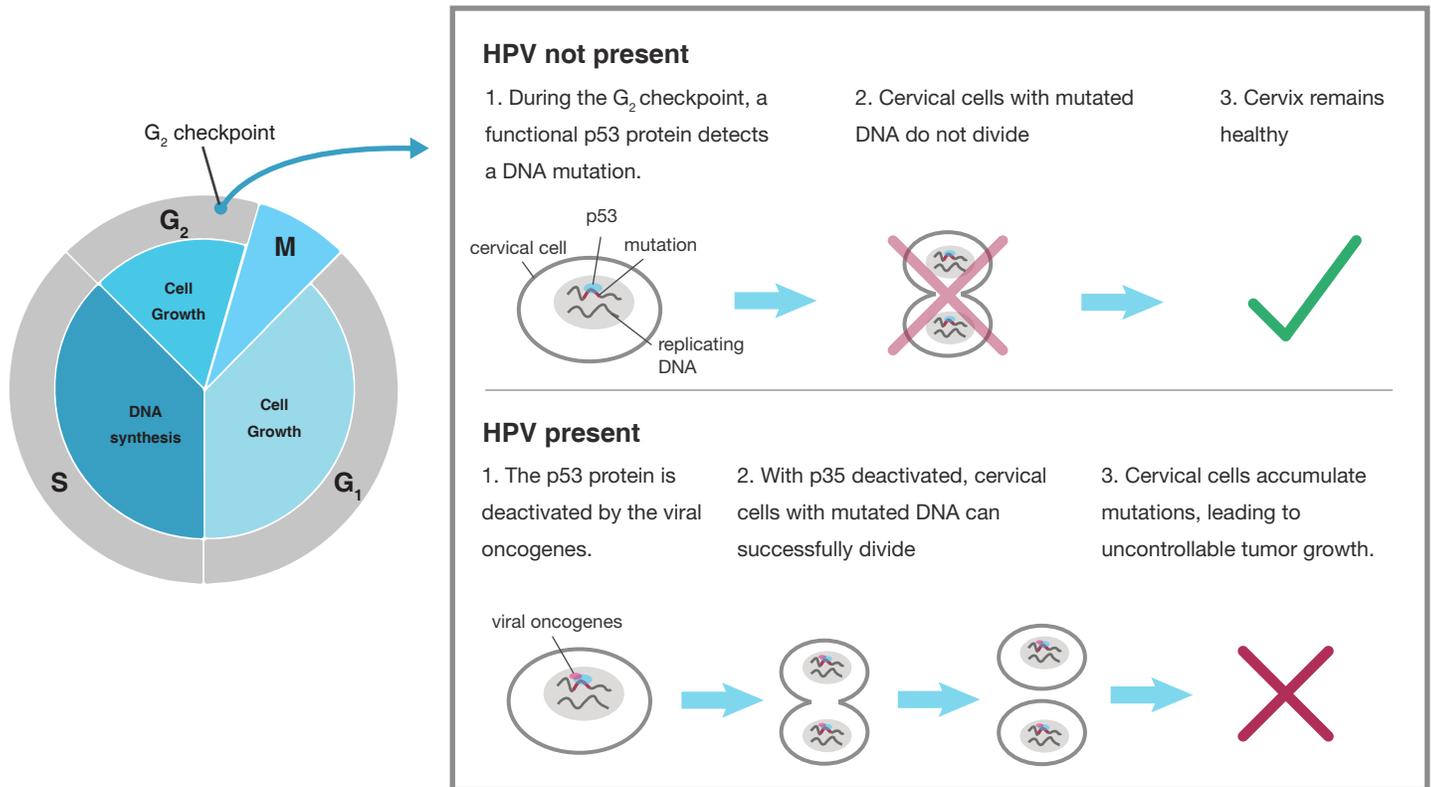




What is HPV?

Human papillomavirus (HPV) is a DNA virus capable of infecting humans. There are over 100 known types of HPV, with infection in humans causing a variety of clinical ailments such as benign papillomas (such as warts [verrucae] or squamous cell papilloma), and cancers of the cervix, vulva, vagina, penis, oropharynx, and anus. Types of HPV that cause warts and squamous cell papilloma are often classified as low-risk types.

Other types of HPV, like HPV 16 and 18 whose persistent infection can cause cancer, are classified as high-risk types. High-risk HPV infections are the cause of nearly all cases (>99%) of cervical cancer, with HPV 16 and 18 subtypes alone accounting for more than 70% of cervical carcinoma.



HPV and Cervical Carcinoma

In 2012, it was estimated that there were 528,000 cases of cervical cancer, resulting in 266,000 deaths worldwide. After breast cancer, cervical cancer is the second most common cause of female specific cancer, accounting for around 8% of total cancer cases and total cancer deaths in women. Approximately 80% of cervical cancer cases occur in developing countries as the

prevalence of HPV infection is higher in regions where hygiene is poor.

Unlike all other types of cancers, cervical carcinoma has a clearly identified causation—persistent high-risk HPV infection. The disease is therefore preventable and treatable if identified in earlier stages.

GenomeMe™

In the past 30 years, many different methods have been developed for cervical carcinoma screening and detection that have proven to be effective in the prevention of cervical carcinomas in the developed world. These methods include the Pap smear, which produces false negatives 50% of the time due to its low sensitivity, and liquid-based cytology, a method developed to improve on the accuracy of the Pap test (reducing the number of inadequate smears from 9% to 1%). More recently,

the development of direct HPV DNA testing and typing has led to more effective screenings for HPV and cervical carcinoma. This is a sensitive and fast assay that allows accurate HPV typing of high-risk groups like HPV 16 and 18. qPCR-based HPV screening and testing offers a high throughput method that is extremely applicable in developing countries where rates of HPV infection and cervical carcinoma are high.



Testing for HPV

HPV is detected by examining a sample of cervical cells for the presence of the human papillomavirus genome or viral particle. There are several different methods available for HPV testing including Polymerase Chain Reaction (PCR), Enzyme-Linked Immuno Assay (ELISA), probe hybridization, and quantitative Polymerase Chain Reaction (qPCR). qPCR based HPV detection methods outperform other techniques due to their 1) ease of operation, 2) sensitivity, and 3) accuracy in HPV typing. In addition, their closed reaction setup completely eliminates contamination problems. When combined with a classic cytological examination (Pap test), qPCR detection makes it much easier to identify patients with a risk of developing cervical carcinoma.

Based on the World Health Organization (WHO) guidelines, all women over the age of 30 years are advised to be routinely tested for HPV, often at the same time as their regular Pap test. Changes in the cervix that could lead to cervical cancer may take several years (up to 10 years or more) to develop before becoming detectable by conventional cytology and pathological examination. The earlier HPV is detected, the more time doctors and patients have to monitor, test, and prevent the eventual development of cervical carcinoma.



qPCR technique
for sensitive and
specific detection



Interpreting Test Results

The HPV test is a reliable test for cervical carcinoma prevention and treatment. Even if your HPV test does not detect any high-risk strains of HPV, regular HPV screenings and testings are recommended every 6 months as part of your routine check-up. Should your results return as HPV positive, there is no need for immediate panic. A positive result does NOT mean you

have cancer; it simply means that you are in the high-risk category for developing pre-cancerous changes. Your doctor will further advise you on the required steps, steps which might include repeating the HPV test as well as conducting a colposcopy, a cervical biopsy, or other tests.

HPV DNA & RNA Detection Kits





GenomeMe™'s HPV Test

GenomeMe™ has a modern facility of over 8000 sqf that is accredited by USCAP for any genetic testing, including HPV qPCR testing and typing. Our facility offers the most comprehensive HPV testing and evaluation of likelihood for cervical carcinoma development in the world. Our services include:

1. HPV infection screening test for 23 genotypes: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 67, 68, 70, 73, 82, 6, 11, and 81.
2. Testing of HPV E6/E7 mRNA for possibilities of early onset of precancerous lesions if the sample is found to be HPV positive.

3. IL-12A and IL-12B SNP detection test: As most women with HPV infection (even high-risk types) do not develop cervical carcinoma, other factors from a genetic or immunological background may also play a role in the development of the disease. Current research has suggested that women with IL-12A and IL-12B mutant SNP forms are more likely to develop cervical carcinoma when infected with HPV. Medical practitioners will likely suggest an IL-12A and IL-12B SNP test for patients with a positive high-risk of HPV infection as part of the health management plan.



Collaborate with us

1. Diagnostic technology transfer (our technologies include qPCR-based HPV detection and typing; HPV E6/E7 mRNA expression detection; IL-12A and IL-12B SNP detection; and cancer panels based on NGS platforms).
2. Joint ventures in China, Brazil, Mexico, Middle East, or India to obtain government regulation for local HPV marketing.

3. Contract diagnostic development of genetic and immunological assays that are affordable and have a quick turn-around time. Take advantage of our team of professional scientists and get unrestricted access to clinical samples.
4. Clinical trials for diagnostic kit development based on your specific requirements.

