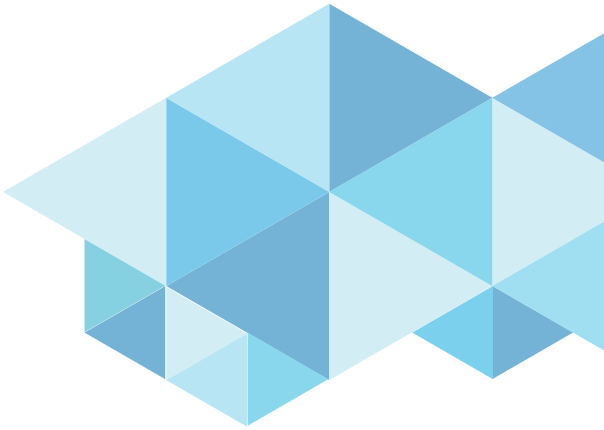

GenomeMe
CANADA

Providing diagnostic
solutions for labs.

HHC
Helvetica Health Care

Healthcare at the speed of life

What is HPV?

The Human Papillomavirus, also known as HPV, is the most common sexually transmitted infection affecting millions worldwide. In fact, at least 4 out of 5 women will have been infected with the HPV virus by age 50 (1).

There are over 120 known types of HPV; approximately 40 of these types infect the epithelial lining of the anogenital tract, mouth, and throat (2). In the majority of individuals (about 90%), HPV infections are asymptomatic and usually clear up within 2 years without the need for any medical intervention (3). However, a small proportion of infections from any of the 14 High Risk HPV Subtypes can persist and progress into cervical cancer. These 14 High Risk Subtypes alone account for nearly all cervical cancer cases and therefore early detection of HPV infection is critical in order to prevent cervical cancer.

HPV and Cervical Carcinoma

After breast cancer, cervical cancer is the second most common cancer in women. In 2012, it was estimated that there were 528,000 new cases of cervical cancer worldwide, which resulted in the deaths of 266,000 women (3).

Unlike all other types of cancers, cervical carcinoma has a clearly defined causation – persistent infection with one of 14 high-risk HPV subtypes. In fact, over 99.7% of cervical cancer arises from persistent HPV infection, with HPV 16 and 18 alone accounting for over 70% of cervical cancer cases (4, 5).

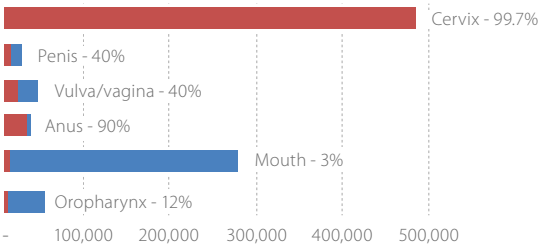

fig. 1 Annual number of cancer cases worldwide, displayed as both the total number of cases as well as the fraction of each type induced by HPV. HPV is responsible for 99.7% of Cervical cancer, 40% of Penile cancer, 40% of Vulva/Vaginal cancer, 90% of Anal cancer, 3% of Oral cancer, and 12% of Oropharyngeal cancer (4).

GenomeMe® GeneNav™ HPV Detection Kits

GeneNav™ HPV One qPCR Kit

Is my patient infected with one of the 14 high-risk HPV genotypes?

Screen your patients for HPV 16, HPV 18, and a pool of 12 other high risk HPV subtypes.

GeneNav™ HPV Genotyping qPCR Kit

Which of the 14 high-risk HPV genotypes is my patient infected with?

Specifically detect and simultaneously genotype each of the 14 high-risk HPV subtypes individually.

For more information on GeneNav™, see page 4.

Cervical cancer is preventable and treatable if identified in earlier stages.

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Benefits of HPV Testing

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 cancer in the developed world. The Pap smear (a microscopic examination of cells by a cytotechnician or pathologist), is one such method that has become a valuable part of women's health since its introduction in 1940. However, though specific, the Pap smear produces false negative results about 50% of the time, due to its low sensitivity (6).

More recently, the development of direct HPV DNA testing and genotyping has lead to more effective screenings for HPV and cervical carcinoma. As a result, medical guidelines in many countries around the world now include HPV DNA testing as part of regular screenings with the aim of preventing cervical cancer.

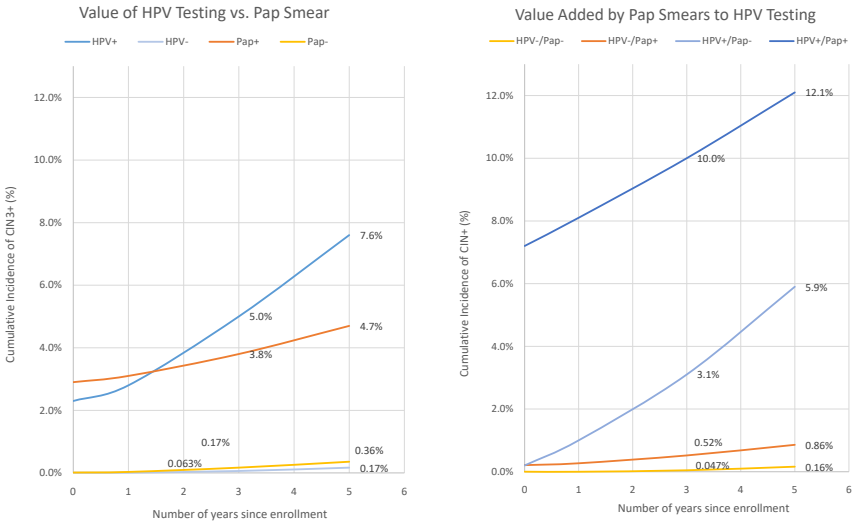

fig. 2 Analysis of a five-year cumulative incidence of cervical cancer and cervical intraepithelial neoplasia grade 3 or worse (CIN3+) for over 300,000 women aged 30 and older (7). **Left** – 4.7% of women who were found to be Pap-positive vs. 7.6% of women who were found to be HPV-positive developed cervical cancer. 0.36% of women who were found to be pap negative vs. 0.17% of women who were found to be HPV-negative developed cervical cancer. **Right** – 12.1% of women who were both HPV and Pap-positive, 5.9% of women who were HPV-positive but Pap-negative, 0.86% of women who were HPV-negative but Pap-positive, and 0.16% of women who were HPV and Pap-negative developed cervical cancer (7).

Pap smear and HPV co-testing is the best line of defense against cervical cancer.
Pap smears alone are not enough!

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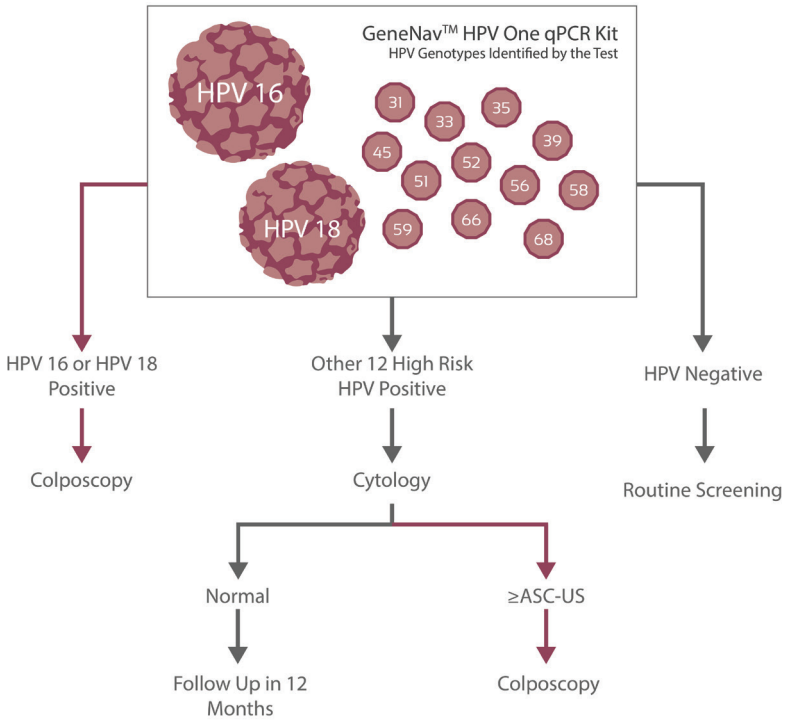
Clinical Guidelines

Based on the World Health Organization (WHO) guidelines, all women over the age of 30 are advised to undergo routine testings for HPV, often at the same time as their regular Pap smear (3). The 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, therefore HPV testing is critical to allow for early detection. The earlier HPV is detected, the more time doctors and patients have to monitor, test, and prevent the eventual development of cervical carcinoma.

The following are the guidelines published by The American College of Obstetricians and Gynecologists as well as the American Cancer Society (8, 9):

- The Pap smear alone is recommended for women aged 21-29 every 3 years.
- A Pap smear and an HPV test (co-testing) is recommended for women aged 30-65 every 5 years.
- Women aged 65 and older may not require cervical screening if:
    - They have no history of moderate or severe abnormal cervical cells or cervical cancer.
    - They have had three negative Pap smear results in a row or two negative co-test results in a row within the past 10 years.



GeneNav™ HPV Detection Kits

Her first line of defense against cervical cancer.

With GeneNav™, go from sample collection to results in less than two hours for a smoother, smarter, and faster healthcare experience for your patients.

Rapid and precise analysis · **Quick and easy setup** · **No need for purchasing equipment** · **Quality by design**

Principle behind the GeneNav™ Assay

The GeneNav™ HPV qPCR Kits use probe-based qPCR technology to detect HPV with high specificity and sensitivity. Each sequence-specific probe contains a 5′ fluorophore and a 3′ quencher. On its own, the probe's 3′ quencher effectively absorbs the emission from the nearby 5′ fluorophore so that no net fluorescence is detected. During PCR amplification, the probe binds to its specific target template. While replicating the DNA sample, the PCR *Taq* Polymerase's 5′ to 3′ exonuclease activity also hydrolyzes the probe, releasing a free-floating 5′-fluorophore that is detectable by the qPCR machine and can be translated into an amplification plot.

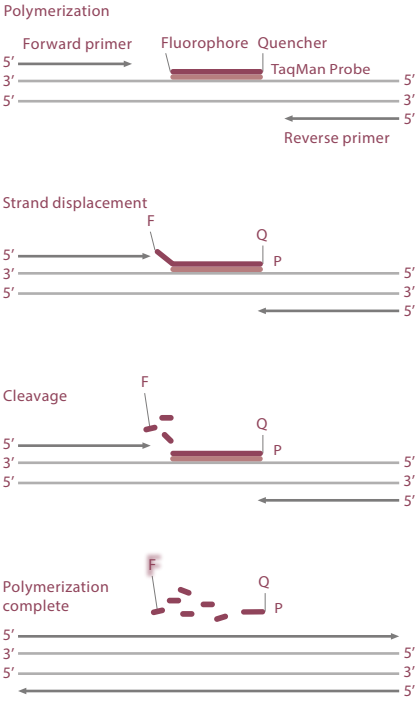


fig. 3 TaqMan-based real-time PCR. 5′ to 3′ exonuclease activity of *Taq* DNA polymerase displaces the fluorophore dye and cleaves the fluorophore from the quencher.

GeneNav™ HPV One qPCR Kit REF E114

"Is my patient infected with one of the 14 high-risk HPV genotypes?"

Registration Status

IVD CE

Health Canada-IVD
Clinical Testing

FDA-IVD
Clinical Testing

Purpose

Quick initial screening to distinguish between individuals who are HPV-positive from those who are HPV-negative, so that physicians may identify those who require continuous monitoring.

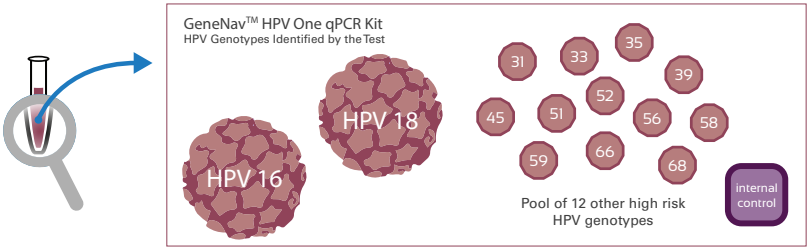


fig. 4 A simple one-tube system for specific detection and discrimination between HPV 16 and HPV 18, and non-specific pooled detection of 12 high-risk HPV subtypes from cervical swab specimens. The beta-actin internal control enables identification of samples with low cellularity, reducing the risk of false negative results.

Part Number	Kit Components	Quantity
E-1S	Diagnostic 2X qPCR MasterMix – No Dye	500 µl
E114-A	GeneNav™ HPV One Primers	50 µl
E114-B	GeneNav™ HPV One Probes	50 µl
E10	Sample Prep Solution	10 ml
E0	Nuclease-free Water	1 ml

GeneNav™ HPV Genotyping qPCR Kit REF E115

"Which of the 14 high-risk HPV genotypes is my patient infected with?"

Registration Status

IVD CE

Health Canada-IVD
Clinical Testing

FDA-IVD
Clinical Testing

Purpose

Continuously monitoring the HPV infection status of your patient, to ensure that the infection of one specific genotype does not persist longer than two years; it is the persistence of one HPV genotype, rather than infection itself, that leads to cervical cancer.

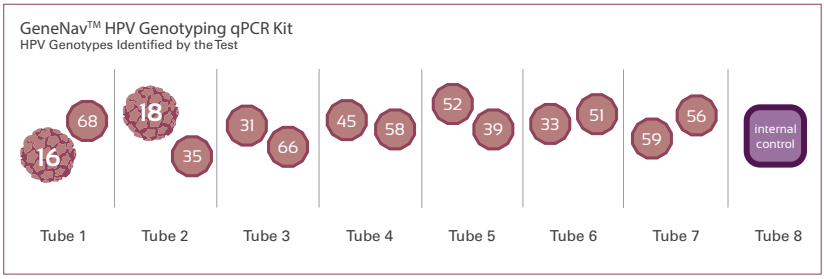


fig. 5 Specifically detect and simultaneously genotype each of the 14 high-risk HPV types individually, all in an eight-tube assay. The beta-actin internal control enables identification of samples with low cellularity, reducing the risk of false negative results.

Part Number	Kit Components	Quantity
E-1G	Diagnostic 2X qPCR MasterMix - No Dye	2 x 1 ml
E115-XA	GeneNav™ HPV Genotyping Primers X	25 µl
E115-XB	GeneNav™ HPV Genotyping Probes X	25 µl
E5	Sample Prep Solution	5 ml
E0	Nuclease-free Water	2 x 1 ml

GeneAb™ Molecular Pathology Antibodies

Precision diagnostics with precision antibodies

Our GeneAb™ recombinant monoclonal antibodies are engineered to deliver consistent, specific, and sensitive stains – so you can make a confident diagnosis every time. Visualize more and gain deeper insights into patient health with our range of ready-to-use antibodies for cancer and stem cell applications, and soon-to-be validated for clinical use.

GeneAb™ p16

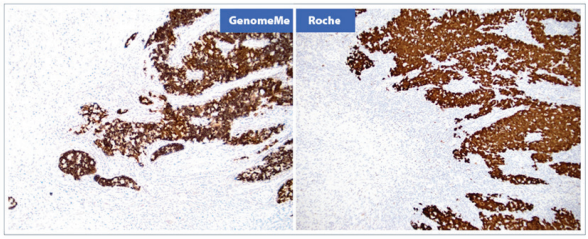


fig. 6 Comparison data showcasing the performance of both GenomeMe® and Roche's p16 monoclonal antibody on the Roche Ventana BenchMark ULTRA fully automated IHC strainer. This study was conducted by the BC Cancer Agency.

Coming soon

A line of over 200 recombinant monoclonal antibodies, including:

p16	PD-1	PD-L1	CTLA-4	CK7	Ki-67	AEG1	ARG1
AKR1B10	BSEP	Clusterin	GCP-3	MUC6	p53	TFE3	MDR3

Who are we?

Precision Medicine is a global phenomenon that is transforming healthcare from a reactive model into a new mode of preventative health management – GenomeMe® is at the forefront of this revolution. By making state-of-the-art diagnostics accessible for use in any clinical lab, GenomeMe® ensures no patient is left behind as technology advances.

Who we are

A team of forward-thinking scientists in medical and human genomics with a vision to better healthcare for humanity, one diagnostic solution at a time.

Our goal

To develop diagnostic kits that enable physicians to peer deep into the unique origins of health and disease within their patients and radically customize the healthcare they can deliver. Our goal is to deliver simple and powerful diagnostic solutions that drive healthcare forward.

Early detection of HPV infection is critical for cervical carcinoma prevention and management. Join us in our movement to diminish the number deaths caused by cervical cancer.

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