SIMPLY HPV™

Molecular Testing for Sexually Transmitted Infections

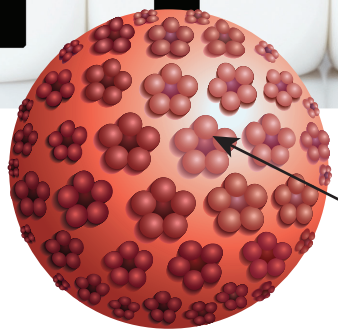
WHY TEST?

Consider these burden of disease facts. Worldwide, in 2018, the 4th most common cause of new cancer cases in women, as well as the 4th most common cause of cancer death for women is tied to HPV.[1,2]

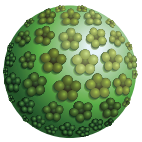
In 2020, According to the American Cancer Society Journal (ACSJ), again, cervical cancer is the fourth most frequently diagnosed cancer and the fourth leading cause of cancer death in women. An estimated 604,000 women were diagnosed with cervical cancer worldwide and about 342,000 women died from the disease in 2020. In addition, cervical cancer is the most commonly diagnosed cancer in 23 countries.[3]

Within the United States, cervical cancer death rates are 2-fold higher among women residing in high-poverty versus low-poverty areas.[3]

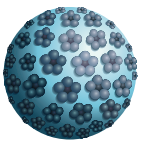
- Almost all sexually active individuals will acquire human papillomavirus (HPV) at some point in their sexual history usually soon after onset of sexual activity.[4]
- 40% are infected within 2 years of first sexual encounter.[4]
- In the United States, there are approximately 79 million infections and 14 million new infections each year.[4]
- HPV infections are usually transient & asymptomatic.[4]
- 90% of infections clear within 2 years where cofactors are not inhibiting the process.[4]
- Cancer is a rare outcome of HPV infection.[4]
- Twelve HPV types have been identified as tumor causing and classified as group 1 carcinogens.[3]
- Cancer requires persistent infection with high risk HPV types. Persistent infection with HPV is a risk factor for the development of cancer of the cervix, vulva, and vagina.[4]
- Cofactors include some sexually transmittable infections (HIV and Chlamydia trachomatis), smoking, a higher number of childbirths, and the long-term use of oral contraceptives.[3]
- Identifying those with persistent infection and contributing cofactors before the onset of dysplasia is key to reducing the incidence of HPV related cancer.[4]
- CDC estimates that about 80 million people are currently infected with HPV in the United States and about 14 million people in the US get a new HPV infection every year.
- **Cervical Cancer is Considered Nearly Completely Preventable.**[7,8,9]



Major Capsid Protein (L1)

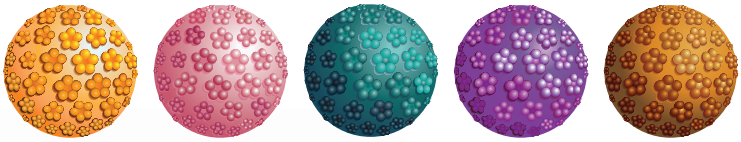


HPV 6



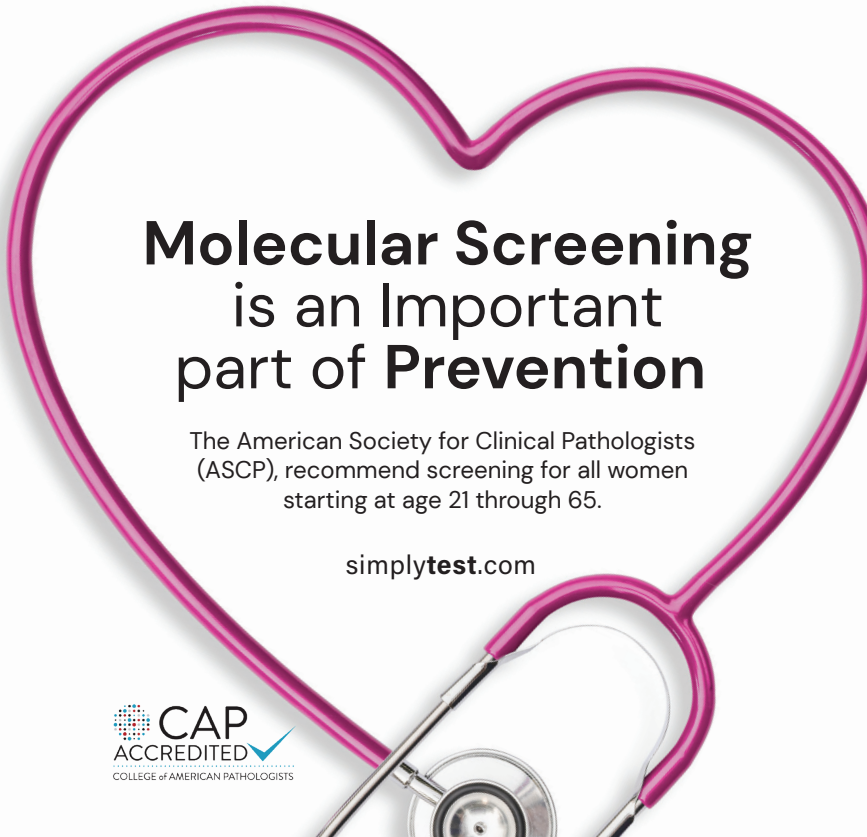
HPV 11

Are the cause of benign lesions of the skin (warts), mucous membrane of the genital and anal areas (warts) or extragenital (papillomas of the mouth) or of the respiratory (recurrent respiratory papillomatosis)



HPV 16 **HPV 18** **HPV 45** **HPV 31** **HPV 33**

Are the five most frequent and aggressive HPV high-risk types involved in the development of precancerous lesions and cancers of various organs first and formost cervical cancer.



Molecular Screening is an Important part of **Prevention**

The American Society for Clinical Pathologists (ASCP), recommend screening for all women starting at age 21 through 65.

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SPECTRUM SIMPLYTEST ™

WHO TO TEST?

High-quality screening programs are important to prevent cervical cancer among unvaccinated women and for oncogenic subtypes not covered by the vaccine. In the absence of effective screening, there have been rapid increases in premature cervical cancer mortality in recent generations.[3]

Using an HPV DNA NAAT as the primary screening test prevents more cervical cancers and saves more lives than using visual inspection with acetic acid (VIA) or cytology (conventional Pap smear and liquid-based cytology) as the primary screening test.[5]

Accumulated evidence supports the use of HPV-based tests for the detection of precancerous lesions as a preferred test for primary screening[3] which can also offer opportunities of self-sampling to women who live in remote areas or who are reluctant to undergo gynecologic examination.[3]

Studies suggested that self-sampled HPV testing can be cost effective, either as an addition to existing screening programs or as a primary screening strategy. According to the World Health Organization (WHO) continuing screening is crucial and existing programs with quality-assured cytology or VIA as primary screening tests should be continued **until access to HPV NAATs screening, like the SimplyHPV test, are able to replace them.** In addition, the transition to use of HPV NAATs should be done rapidly because of the inherent challenges with performance and quality assurance of other screening approaches, especially VIA.[5]

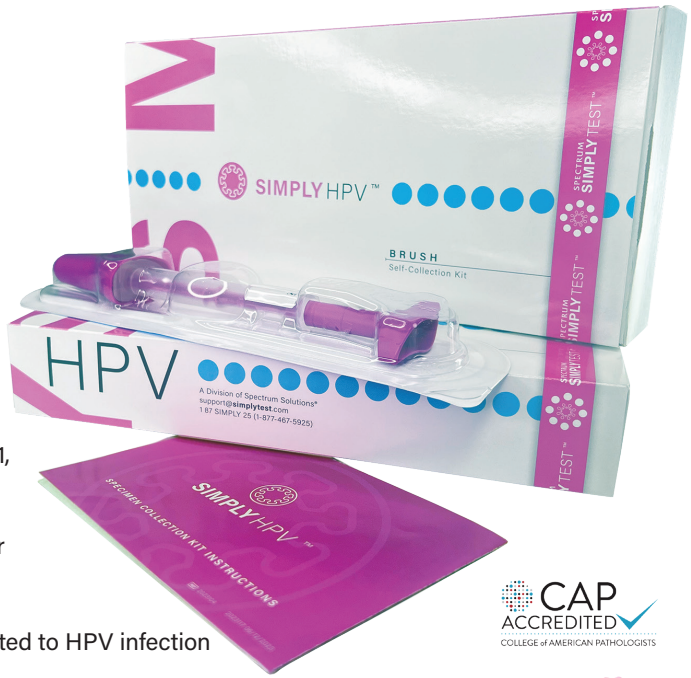
Guidelines	(2020) American Cancer Society	(2018) US Preventive Services Task Force
Age 21-24	▪ No Screening	▪ Pap test every 3 years
Age 25-29	▪ HPV test every 5 years (preferred) ▪ HPV/Pap cotest every 5 years (acceptable) ▪ Pap test every 3 years (acceptable)	▪ Pap test every 3 years
Age 30-65	▪ HPV test every 5 years (preferred) ▪ HPV/Pap cotest every 5 years (acceptable) ▪ Pap test every 3 years (acceptable)	▪ Pap test every 3 years ▪ HPV test every 5 years ▪ (or) HPV/Pap cotest every 5 years
Age 65 and older	No screening if a series of prior tests were normal	No screening if a series of prior tests were normal and not at high risk for cervical cancer

HOW TO TEST?

Nearly all sexually active people are infected with HPV within months to a few years of becoming sexually active. Around half of these infections are with a high-risk type. Cervical cancer screening includes testing for HPV infection and when present, detect pre-cancerous and cancerous changes.[10]

WHO recommends using HPV DNA molecular detection as the primary screening test using samples taken by a health-care provider or self-collected, rather than VIA or cytology in screening and treatment approaches among both the general population of women and women living with HIV.[6]

1. SimplyHPV™ is a test for the qualitative and simultaneous molecular detection of 14 high-risk HPV types in a single test. The test specifically identifies HPV 16 & HPV 18 while concurrently detecting (31, 33, 35, 39, 45, 51, 56, 58, 59, 66, and 68)
2. HPV Testing, HPV/Pap Cotesting, Pap Testing [10]
   - All three test find cervical cancer precursors before they become cancer
   - HPV tests are more accurate than Pap alone
   - The specificity of HPV is superior so the testing interval is longer
   - Pap detects a range of abnormal cell changes some of which are unrelated to HPV infection



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