

What is cervical cancer?

Cancer that starts in cells of the cervix is called cervical cancer.

Understanding the cervix

The cervix is the lower, narrow part of the uterus. It connects the uterus to the birth canal (vagina), which leads to the outside of the body. It's located between the bladder and the rectum.

Looking for precancer

Precancerous cells on the cervix are the first sign that cervical cancer may develop. These cells can be seen on a Pap test. They are cells that look abnormal, but are not yet cancer. The appearance of these cells may be the first sign of cancer that will grow years later. Treating these precancer cells can prevent cancer from growing. Precancer cells of the cervix often don't cause pain or other symptoms. This is why regular cervical cancer screening is so important.

Types of precancer

Squamous intraepithelial lesions (SIL) is a term that refers to abnormal changes in the cells on the surface of the cervix. These changes can be found with a Pap test and are divided into 2 categories:

Low-grade SIL. This refers to early changes in the size, shape, and number of cells that form the surface of the cervix. They may go away on their own. Or over time, they may grow larger or become more abnormal, forming a high-grade lesion. These changes may also be called mild dysplasia or cervical intraepithelial neoplasia 1 (CIN 1).

High-grade SIL. This means there are a large number of seriously changed cells that are precancer cells. Like low-grade SIL, these changes only happen in cells on the surface of the cervix. The cells often don't become cancer for many months, probably even years. But without treatment, they will become cancer. High-grade lesions may also be called moderate or severe dysplasia, CIN 2 or 3, or carcinoma in situ.

If abnormal cells on the surface of the cervix are not found and treated, over time they can spread deeper into the cervix, or to other tissues or organs. This is then called cervical cancer, or invasive cervical cancer. Cervical cancer occurs most often in women younger than age 50. Most cervical cancer is either squamous cell carcinoma or adenocarcinoma.

The death rates for cervical cancer have dropped sharply as Pap screenings have become more prevalent. Today, most cervical cancer is found in women who have not had regular screenings, and in women who have not had any screenings.

Preventing cervical cancer

Cervical cancer is 1 of the few types of cancer that healthcare providers know how to prevent. There are 2 key ways to prevent cervical cancer:

Get regular Pap tests. These are done to find and treat any precancer cells as soon as possible, before they can change into true cancer.

Prevent precancer cells. You can do this by avoiding contact with the human papilloma virus (HPV), getting an HPV vaccine, and not smoking.

Talk with your healthcare provider

If you have questions about cervical cancer, cervical cancer screening, or how to prevent cervical cancer, talk with your healthcare provider. Your provider can help you understand more about this cancer.

When it starts, cervical cancer might not cause symptoms. As it grows, cervical cancer might cause signs and symptoms, such as:

Vaginal bleeding after intercourse, between periods or after menopause.

Menstrual bleeding that is heavier and lasts longer than usual.

Watery, bloody vaginal discharge that may be heavy and have a foul odor.

Pelvic pain or pain during intercourse.

partners. The greater your number of sexual partners, and the greater your partner's number of sexual partners, the greater your chance of getting HPV.

Early sexual activity. Having sex at an early age increases your risk of HPV.

Other sexually transmitted infections. Having other sexually transmitted infections, also called STIs, increases the risk of HPV, which can lead to cervical cancer. Other STIs that increase the risk include herpes, chlamydia, gonorrhea, syphilis and HIV/AIDS.

A weakened immune system. You may be more likely to develop cervical cancer if your immune system is weakened by another health condition and you have HPV.

Exposure to miscarriage prevention medicine. If your parent took a medicine called diethylstilbestrol, also known as DES, while pregnant, your risk of cervical cancer might be increased. This medicine was used in the 1950s to prevent miscarriage. It's linked to a type of cervical cancer called clear cell adenocarcinoma.

Prevention

To reduce your risk of cervical cancer:

Ask your doctor about the HPV vaccine. Receiving a vaccination to prevent HPV infection may reduce your risk of cervical cancer and other HPV-related cancers. Ask your health care team if an HPV vaccine is right for you.

Have routine Pap tests. Pap tests can detect precancerous conditions of the cervix. These conditions can be monitored or treated in order to prevent cervical cancer. Most medical organizations suggest beginning routine Pap tests at age 21 and repeating them every few years.

Practice safe sex. Reduce your risk of cervical cancer by taking measures to prevent sexually transmitted infections. This may include using a condom every time you have sex and limiting the number of sexual partners you have.

Don't smoke. If you don't smoke, don't start. If you do smoke, talk to a health care professional about ways to help you quite

HPV & Cervical Cancer

In regions where women do not have access to regular check-ups, cervical cancer is a leading cause of death. In many places, the Pap test is used to detect cervical cancer; this outdated method was introduced in the 1940s, and because of its low accuracy it is now often replaced by HPV testing. Nearly all cervical cancers are caused by HPV infection, but only a very small number of women who have HPV will develop cervical cancer. For example, in the US, more than 20% of women have HPV, but less than 0.5% will develop cervical cancer. A positive HPV test alone can therefore lead to unnecessary anxiety, and to unnecessary treatments. Identifying which high-risk HPV infections will lead to cancer has historically been a diagnostic challenge. It is now known that HPV produces two oncoproteins, E6 and E7, without which cancer does not occur.

Detection of HPV DNA or RNA simply identifies infection. Detection of the E6 and/or E7 oncoproteins, however, provides a means of identifying the transition from infection toward cancer. Arbor Vita's OncoE6™ Cervical Test offers a solution to this problem: the OncoE6™ Cervical Test directly detects the cancer-causing E6 oncoprotein molecule, made by those few HPV infections that will cause cervical cancer with a high likelihood.

Arbor Vita's OncoE6™ product line identifies patients that are not only infected with HPV but are also producing E6 oncoproteins, indicating the presence of cervical pre-cancerous or cancerous lesions.

With its dipstick-like format, OncoE6™ is simple, quick, non-invasive, and requires no refrigeration. The test is compatible with specimens collected from either a regular Pap smear or liquid Thinprep© (see OncoE6™ Liquid Specimen Preparation Kit).

OncoE6™ Cervical Test – CE-IVD

The OncoE6™ Cervical Test is a rapid and easy-to-use lateral flow assay based on the detection of E6 oncoproteins. The OncoE6™ Cervical Test is available in the US, as a service through our CLIA-certified laboratory.

PRODUCT AND TECHNICAL DETAILS

Product Description

Arbor Vita Corporation has developed the OncoE6™ Cervical Test, a rapid, easy to use lateral flow assay based on the detection of E6 oncoproteins to assess the likelihood that cervical malignancy is present. The OncoE6™ Cervical test demonstrates outstanding clinical performance with high specificity and high positive predictive value and thus can be used to triage patients with high risk HPV and other abnormal screening results to avoid unnecessary treatment procedures. This qualitative test is used to analyze cells extracted from cervical cytology swab specimens. The assay is based upon the capture and detection of E6 oncoproteins from high risk HPV types 16 and 18 using highly specific monoclonal antibodies (mAbs) in a lateral-flow (LF) assay format. This test detects down to a thousand abnormal cells with a simple line read by eye. The test is room temperature stable and requires no complex equipment.

Advantages

- Easy to use “dipstick” (lateral flow) format
- Predictive cancer biomarker screen with high specificity for cervical cancer and pre-cancerous lesions caused by high risk HPV strains 16 and 18
- Detects strains that account for 70-80% of cervical cancer worldwide (84% in China, 92% in India)
- No complex equipment or refrigeration required
- Minimal laboratory training required
- Low startup and test cost
- Test results available in ~ 2 ½ hours
- Low false positive rate
- Low false negative rate

Kit Components

The OncoE6™ Cervical Test Specimen Collection Kit (part #2001000) contains material for collection and storage of 24 specimens:

- 24 swabs for Specimen Collection – polyester tipped, sterile
- 24 tubes for Specimen Storage

The OncoE6™ Cervical Test Specimen Processing Kit (part #2000000) contains material and reagents for 24 tests:

- 1 bottle of Lysis Solution A
- 1 vial of Conditioning Solution B

- 24 vials of Detector Reagent C
- 1 vial of Wash Solution D
- 1 bottle of Developing Solution E
- 8 Test Units – 3 test strips each
- 1 vial of Positive Control
- 24 tubes for Lysis
- 24 vials for Wash
- 24 tubes for Development
- 1 Instructions For Use

Equipment required but not supplied

- Microcentrifuge, 1.5 to 2.0 mL tubes, >10,000 x g
- Micropipettes
- Tube rotator (end-to-end rotation), 8 RPM
- Timer
- Thermometer.