

Abnormal Cervical Cancer Screening Test Results

- What is cervical cancer screening?

Cervical cancer screening is performed to detect abnormal changes in the cervix's cells that may lead to cancer. The Pap test, testing for the virus human papillomavirus (HPV), or both could be included in screening.

- What causes abnormal cervical cancer screening test results?

Cervical cancer is caused mostly by HPV infection. Cancers of the cervix, vulva, vagina, anus, and penis have all been associated to some type of HPV. Some can also lead to head and neck cancer. These HPV types are described as "high-risk" strains.

Only two high-risk forms of HPV, type 16 and type 18, are responsible for the majority of cervical cancer cases. Under a microscope, HPV-infected cells seem different from normal cells. Symptoms of abnormal changes might range from minor to severe. If not addressed, the more significant changes can lead to cancer.

- How are HPV test results described?

The results of an HPV test will reveal whether you have a high-risk type of HPV infection. A negative HPV test indicates that you do not have a significant amount of cancer-causing HPV type virus. A positive HPV test indicates that you have an HPV infection. This does not indicate you have cancer right now, but it could be a warning that you will develop cancer in the future. It's possible that you'll require additional testing.

- How are abnormal Pap test results described?

- ASC-US—This is the most common abnormal Pap test result and indicates the discovery of changes in cervical cells. Almost always, the changes are a symptom of an HPV infection. ASC-US is an acronym for atypical squamous cells with unknown significance. The type of cells that make up the tissue that covers the cervix is referred to as "squamous."

- LSIL—This indicates that the cervical cells have mildly abnormal changes. LSIL is commonly caused by an HPV infection that cures on its own. LSIL is an acronym for low-grade squamous intraepithelial lesion.
 - HSIL—This indicates that the cervix has experienced more serious changes than LSIL. It is more likely to be connected to precancer and cancer than LSIL. HSIL is an abbreviation for high-grade squamous intraepithelial lesion.
 - ASC-H— indicates that changes in cervical cells have been observed that raise suspicion of HSIL infection. HSIL cannot be excluded by ASC-H, which stands for atypical squamous cells.
 - AGC—This indicates that changes in glandular cells have been discovered, raising concerns about the presence of precancer or cancer. Glandular cells are another type of cell found in the tissue that lines the cervix's inner canal and can also be found within the uterus. AGC is an abbreviation for atypical glandular cells.
- What follow-up testing may be needed?

You may need additional testing if you get a positive HPV test or an abnormal Pap test result. Depending on your risk for cervical cancer, the following tests may be performed. Testing is dependent on your age, the results of your initial screening test, and the results of any previous tests. The following are examples of follow-up testing:

- **Reflex testing**—If you have an HPV test, a Pap test could be performed on the same cells and vice-versa. This is referred to as reflex testing.
- **HPV typing**—Another type of HPV test searches for HPV type 16 and type 18 precisely. Cervical cancer is commonly caused by these two categories.
- **Repeat testing**—A repeat Pap test can be done in 6 months or a year for patients under the age of 25. As a follow-up to any abnormal test findings, repeat HPV testing or co-testing (having the HPV test and Pap test done at the same time) is indicated for adults 25 and older. Depending on your initial test result, age, and previous test results, you may need to repeat HPV testing or co-testing in 1 year or 3 years.
- **Colposcopy, biopsy, and endocervical sampling**— A colposcopy is a magnified examination of the cervix. A cervical biopsy may be required if

an area of abnormal cells is discovered. A biopsy involves removing a small sample of tissue and sending it to a lab for testing. The severity of the cell changes can be determined through laboratory testing.

Endocervical sampling is another option. A tiny brush or other instrument is used to collect a tissue sample from the cervical canal in this method.

- **Endometrial sampling**—a sample of the endometrium (uterine lining) is taken for research. This follow-up test is required for certain women who have had an AGC result.

If you have a very high chance of developing cervical cancer based on your initial test findings, you may choose to pursue treatment without further testing. If your obstetrician–gynecologist (ob-gyn) advises this procedure, you should discuss the risks and advantages with him or her.

- What does CIN mean on a biopsy report?

Cervical intraepithelial neoplasia (CIN) is used to report cervical biopsy results. CIN describes the actual changes in cervical cells. CIN 1 is used for mild (low-grade) changes in the cells that usually go away on their own without treatment; CIN 2 is used for moderate changes and CIN 3 is used for more severe (high-grade) modification.

Moderate and high-grade changes can progress to cancer.

- How are abnormal cervical cells treated?

In general, there are two ways to treat abnormal cervical cells:

- **Excisional treatment**—Tissue is removed from the cervix and sent to a laboratory to be analyzed. Results can tell whether CIN is present and, if so, how severe it is.
- **Ablative treatment**—Abnormal cervical tissue is destroyed, and there is no tissue to send to a laboratory for study.

- What are the types of excisional treatments?

Excisional treatments include the following:

- Loop electrosurgical excision procedure (LEEP)—A thin wire loop that carries an electric current is used to remove abnormal areas of the cervix.

- Conization—A cone-shaped piece of the cervix that contains the abnormal cells is removed.
- What are the types of ablative treatments?

Ablative treatments include the following:

- Cryotherapy—An instrument is used to freeze abnormal cervical tissue, which then sloughs off.
 - Laser therapy—A focused beam of light is used to destroy abnormal cervical tissue.
- Will I need more cervical cancer screening after treatment?

Yes, you should continue to get your cervical cancer checked on a regular basis. Depending on the type of atypical cell changes you had, more regular screening may be required. Consult your ob-gyn about the tests you'll require.

Glossary

Anus: The opening of the digestive tract through which bowel movements leave the body.

Biopsy: A minor surgical procedure to remove a small piece of tissue. This tissue is examined under a microscope in a laboratory.

Cells: The smallest unit of a structure in the body. Cells are the building blocks for all parts of the body.

Cervical Biopsy: A minor surgical procedure to remove a small piece of cervical tissue. This tissue is examined under a microscope in a laboratory.

Cervical Intraepithelial Neoplasia (CIN): Abnormal changes in the cells of the cervix that are caused by infection with human papillomavirus (HPV). CIN is graded as 1 (low grade), 2 (moderate), or 3 (high grade).

Cervix: The lower, narrow end of the uterus at the top of the vagina.

Colposcopy: Viewing of the cervix, vulva, or vagina under magnification with an instrument called a colposcope.

Conization: A procedure that removes a cone-shaped wedge of tissue from the cervix.

Cryotherapy: A freezing technique used to destroy diseased tissue.

Human Papillomavirus (HPV): The name for a group of related viruses, some of which cause genital warts and some of which are linked to cancer of the cervix, vulva, vagina, penis, anus, mouth, and throat.

Loop Electrosurgical Excision Procedure (LEEP): A procedure that removes abnormal tissue from the cervix using a thin wire loop and electric energy.

Obstetrician–Gynecologist (Ob-Gyn): A doctor with special training and education in women’s health.

Pap Test: A test in which cells are taken from the cervix (or vagina) to look for signs of cancer.

Penis: The male sex organ.

Squamous Intraepithelial Lesion (SIL): A term used to describe abnormal cervical cells detected by the Pap test.

Uterus: A muscular organ in the female pelvis. During pregnancy, this organ holds and nourishes the fetus. Also called the womb.

Vagina: A tube-like structure surrounded by muscles. The vagina leads from the uterus to the outside of the body.

Vulva: The external female genital area.

SOURCE: [Abnormal Cervical Cancer Screening Test Results | ACOG](#)

Colposcopy

- What is colposcopy?

Colposcopy is a procedure that involves using a special magnifying equipment called a colposcope to examine the cervix. It shoots a beam of light into the vaginal canal and onto the cervix. The normal view can be substantially magnified with a colposcope. An obstetrician–gynecologist (ob-gyn) can use this exam to detect issues that aren't visible to the naked eye.

- Why is colposcopy done?

Colposcopy is done when results of cervical cancer screening tests show atypical changes in the cells of the cervix to provide more information. Colposcopy might need to be done more than once, can be used to check the results of a treatment, and also can also be done to further assess other problems, like

- genital warts on the cervix
- cervicitis (an inflamed cervix)
- benign (not cancer) growths, such as polyps
- pain
- bleeding

- How is the procedure performed?

Colposcopy is normally done in your ob-gyn's office and it is better when a woman is not on her period. This gives the ob-gyn a better view of the cervix. For at least 24 hours before the test, you should not

- douche
- use tampons
- use vaginal medications
- have sex

You will lie on your back with your feet lifted and supported by foot rests, just as you would for a pelvic exam. The vaginal walls will be held apart with a speculum so that the inside of the vagina and the cervix can be seen, like a pap smear. The colposcope is positioned outside the vaginal entrance.

A cotton swab or cotton ball will be used to apply a mild solution to your cervix and vagina. This liquid makes abnormal cervix areas more visible. There may be a mild burning sensation.

When is a biopsy done during colposcopy?

If your ob-gyn sees abnormal areas during colposcopy, a biopsy may be done. During a biopsy, a small piece of tissue is removed from the cervix by a special device. Cells also may be taken from the cervix's canal and a special device is also used to collect the cells. This is known as endocervical curettage.

- What should I expect during recovery?

You should feel fine immediately if you have a colposcopy without a biopsy. You are free to carry on as usual. For a couple of days, you might experience some spotting.

You may experience pain and discomfort for 1 or 2 days after a colposcopy with biopsy. Pain relievers that are available over the counter can help. It's possible that you'll experience vaginal bleeding and for a few days, you may also have a black discharge. This could be a side effect of the medication used to prevent bleeding at the biopsy site. It's possible that you'll need to use a sanitary pad until the discharge stops.

Your ob-gyn may suggest you limit your activity for a short time. While the cervix heals, you will be told not to put anything into your vagina for a short time. Follow these guidelines:

- Do not have sex.
- Do not use tampons.
- Do not douche.

- When should I call my ob-gyn?

Call your ob-gyn right away if you have any of these problems:

- Heavy vaginal bleeding (using more than one sanitary pad per hour)
- Severe lower abdominal pain
- Fever
- Chills

- Glossary

Biopsy: A minor surgical procedure to remove a small piece of tissue. This tissue is examined under a microscope in a laboratory.

Cervical Cancer: A type of cancer that is in the cervix, the opening to the uterus at the top of the vagina.

Cervix: The lower, narrow end of the uterus at the top of the vagina.

Colposcope: A special magnifying instrument used to examine the cervix, vagina, and vulva.

Colposcopy: Viewing of the cervix, vulva, or vagina under magnification with an instrument called a colposcope.

Obstetrician–Gynecologist (Ob-Gyn): A doctor with special training and education in women's health.

Pelvic Exam: A physical examination of a woman's pelvic organs.

Polyps: Abnormal tissue growths that can develop on the inside of an organ.

Speculum: An instrument used to hold open the walls of the vagina.

Vagina: A tube-like structure surrounded by muscles. The vagina leads from the uterus to the outside of the body.

Source: [Colposcopy](#) | [ACOG](#)



Patient Information about GARDASIL®9 (pronounced “gard-Ah-sill nīn”)

(Human Papillomavirus 9-valent Vaccine, Recombinant)

Before purchasing GARDASIL®9, carefully read the following information. Depending on your age, you or your child (the individual receiving GARDASIL 9) will require two or three

doses of the vaccine. Before taking each dose, it's critical to read this information. This information should not be used in place of speaking with your doctor about GARDASIL 9.

What is the meaning of GARDASIL 9?

GARDASIL 9 is a vaccine (injection/shot) that is given to people aged 9 to 45 to help prevent from diseases caused by certain types of Human Papillomavirus (HPV).

What diseases can GARDASIL 9 help protect against?

In girls and women aged 9 to 45, GARDASIL 9 helps protect against:

- Cervical cancer
- Vulvar and vaginal cancers
- Anal cancer
- Certain head and neck cancers, such as throat and back of mouth cancers
- Precancerous cervical, vulvar, vaginal and anal lesions
- Genital warts

In boys and men aged 9 to 45, GARDASIL 9 helps protect against:

- Anal cancer
- Certain head and neck cancers, such as throat and back of mouth cancers
- Precancerous anal lesions
- Genital warts

These diseases may have many causes, including HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 only protects against diseases caused by these nine types of HPV.

People cannot get HPV or any of these diseases from GARDASIL 9.

What important information about GARDASIL 9 should I know?

GARDASIL 9:

- Does not eliminate the necessity for routine cervical cancer screening, as well as screening for vulvar, vaginal, anal, and certain head and neck cancers, such as throat and back of mouth cancers, as advised by a health care provider.
- GARDASIL 9 does not protect the person who receives it from diseases caused by other types of HPV, viruses, or bacteria.
- Doesn't treat an HPV infection.

- Doesn't protect the person who gets GARDASIL 9 against HPV types he or she already has.

GARDASIL 9 may not fully protect each person who gets it.

Who should not get GARDASIL 9?

Anyone with an allergic reaction to:

- A previous dose of GARDASIL 9
- A previous dose of GARDASIL®
- Yeast (severe allergic reaction)
- Amorphous aluminum hydroxyphosphate sulfate
- Polysorbate 80

What should I tell the health care professional before getting GARDASIL 9?

Tell the health care provider if you or your child (the person getting GARDASIL 9):

- Are expecting a child or plan to get pregnant
- Have immune system issues, such as HIV or cancer.
- Take anti-immunosuppressive medications.
- Have a temperature higher than 100°F (37.8°C).
- You may have experienced an allergic response to GARDASIL 9 or GARDASIL in the past.
- Take any medications, even over-the-counter ones.

The health care provider will assist you in determining if you or your kid should receive the vaccine.

How is GARDASIL 9 given?

GARDASIL 9 is a shot usually taken in the arm muscle. GARDASIL 9 may be given as 2 or 3 shots.

For persons who are	You will need	Given as
9 through 14 years old	2 or 3-shots**	Dose 1: first shot Dose 2: second shot given between 6 and 12 months after the first shot

		Dose 1: first shot Dose 2: second shot given 2 months after the first shot Dose 3: third shot given 6 months after the first shot
15 through 45 years old	3-shots	Dose 1: first shot Dose 2: second shot given 2 months after the first shot Dose 3: third shot given 6 months after the first shot

*If the second shot is given less than 5 months after the first shot, a third shot must be administered at least 4 months following the second shot.

**Your health care provider will decide whether you need to use a 3-dose schedule instead of a 2-dose schedule.

To ensure that you or your child receives the best protection, make sure to take all of the doses advised by your health care provider. If a person taking GARDASIL 9 misses a dose, inform the health care provider, who will determine when the missed dose should be given. It is critical that you follow their directions regarding follow-up appointments for the follow-up doses.

After receiving an HPV vaccine, you may experience fainting. The health care provider may instruct the individual receiving GARDASIL 9 to sit or lie down for 15 minutes after the vaccine is given. People who pass out can sometimes fall and injure themselves. The health care professional may need to treat the person getting GARDASIL 9.

Can I get GARDASIL 9 if I have already gotten GARDASIL?

Talk to your health care provider to see if GARDASIL 9 is right for you If you have already gotten GARDASIL.

Can I get GARDASIL 9 with other vaccines?

GARDASIL 9 can be given at the same time as:

- Menactra [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid
- Conjugate Vaccine]

- Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed
- (Tdap)]

What are the possible side effects of GARDASIL 9?

The most common side effects seen with GARDASIL 9 are:

- pain, swelling, redness, itching, bruising, bleeding, and a lump where you got the shot
- headache
- nausea
- dizziness
- tiredness
- diarrhea
- abdominal pain
- sore throat

Studies show that there was more swelling where the shot was given when GARDASIL 9 was given at the same time as Menactra and/or Adacel.

If you have any of these symptoms, tell your doctor because they could be evidence of an allergic reaction:

- difficulty breathing
- wheezing (bronchospasm)
- hives
- rash

Additional GARDASIL 9 adverse effects that have been encountered during general use are listed below.

The following are also side effects that have been recorded during the general usage of GARDASIL. Because the vaccines are so similar in composition, GARDASIL side effects may be relevant to GARDASIL 9.

GARDASIL 9

- vomiting
- hives

Additionally, these side effects have been seen with the general use of GARDASIL.

GARDASIL

- swollen glands (neck, armpit, or groin)
- joint pain

- unusual tiredness, weakness, or confusion
- chills
- generally feeling unwell
- leg pain
- shortness of breath
- chest pain
- aching muscles
- muscle weakness
- seizure
- bad stomach ache
- bleeding or bruising more easily than normal
- skin infection

Contact your health care provider immediately if you get any symptoms that bother you.

For a more complete list of side effects, ask your doctor.

Call your health care professional for medical advice about side effects. You may also report any side effects to your doctor or directly to Vaccine Adverse Event Reporting System (VAERS). The VAERS tollfree number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

GARDASIL 9 was not studied in women who knew they were pregnant. A pregnancy registry is available.

You are encouraged to contact the registry as soon as you become aware of your pregnancy by calling 1-800-986-8999, or ask your health care professional to contact the registry for you.

What is in GARDASIL 9?

GARDASIL 9 contains:

- Proteins of HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Amorphous aluminum hydroxyphosphate sulfate
- Yeast protein
- Sodium chloride
- L-histidine
- Polysorbate 80
- Sodium borate
- Water

This document is a summary of information about GARDASIL 9.

To learn more about GARDASIL 9, please talk to the health care professional or visit www.GARDASIL9.com.

For patent information: www.merck.com/product/patent/home.html

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