TEST

# Cologuard

Cologuard is an at-home stool test that screens for signs of colorectal cancer.

**WHAT IT MEASURES**
Stool DNA changes and hidden blood linked to colorectal cancer

**SAMPLE**
Stool

**FASTING NEEDED?**
No

**HOW LONG IT TAKES**
About 10 minutes at home

**RESULTS IN**
Usually one to two weeks; laboratory turnaround differs

**USED FOR**
Colorectal cancer screening

**MAIN LIMITATION**
False results occur, and positive results require colonoscopy

## Overview

Cologuard is a prescription stool test used to screen for colorectal cancer. Colorectal cancer begins in the colon or rectum, which are parts of the large intestine.

The test looks for two types of changes in a bowel movement:

This combination is called a multitarget stool DNA test with a fecal immunochemical test, or stool DNA-FIT.

You collect the sample at home and send it to a laboratory. Cologuard does not require bowel preparation, sedation, dietary restrictions, or a visit to an endoscopy unit.

It is a screening test, not a diagnostic test. A positive result does not prove that you have cancer. A colonoscopy is needed to examine the colon and find the cause. A negative result does not completely rule out cancer or precancerous growths.

- DNA changes that can be shed by cancers or precancerous growths
- Tiny amounts of blood that may not be visible

## Why the test is ordered

Cologuard may be offered as one way to screen for colorectal cancer before symptoms develop. Screening can find some cancers at an earlier stage. It may also detect advanced precancerous growths, although it misses more of these growths than it misses cancers.

Some people choose Cologuard because they prefer an at-home test or want to avoid the preparation and sedation used for colonoscopy. Unlike colonoscopy, however, Cologuard cannot show where an abnormality is or remove a polyp during the test.

The usual screening interval for stool DNA-FIT in US Preventive Services Task Force guidance is every three years. The right screening method and schedule depend on your age, health, previous test results, and colorectal cancer risk.[1]

## Who should have the test

Cologuard is intended for adults age 45 or older who are at average risk of colorectal cancer. "Average risk" generally means that you do not have symptoms or a personal history that makes colorectal cancer substantially more likely.

It is not a substitute for colonoscopy in people at higher risk. This may include people with:

Cologuard is also not designed to investigate symptoms. Rectal bleeding, ongoing changes in bowel habits, unexplained iron-deficiency anemia, persistent abdominal symptoms, or unexplained weight loss may require diagnostic testing instead.

Guidelines commonly recommend routine colorectal cancer screening from ages 45 through 75. From ages 76 through 85, screening decisions are more individual and consider overall health, previous screening, and personal preferences.[1,2]

- A previous colorectal cancer or advanced precancerous polyp
- Inflammatory bowel disease involving the colon
- Certain inherited cancer syndromes
- A strong family history of colorectal cancer or advanced polyps
- A previous positive colorectal cancer screening test

## How to prepare

You do not need to fast or change your usual diet. Coffee, meals, and ordinary daily activity do

not affect the DNA part of the test.

Do not stop prescribed medicines unless the clinician who prescribed them tells you to. Cologuard generally does not require stopping aspirin, anti-inflammatory medicines, or blood thinners like warfarin or apixaban . These medicines can influence bleeding, so make sure the clinician who ordered the test knows what you take.

Read the kit instructions before collecting the sample. Check the expiration date and make sure all parts are present.

Avoid collecting when visible blood could enter the sample from menstruation, active hemorrhoidal bleeding, or blood in the urine. Significant diarrhea may also make proper collection difficult. Contact the testing service if you are unsure whether to collect or wait.

## What happens during the test

The kit includes a collection container, bracket, preservative, labels, and shipping materials. Place the bracket under the toilet seat and fit the container into it. Your bowel movement should go into the container without mixing with urine or toilet water.

You then take a small sample for the separate blood-testing tube and add the preservative to the main container. Close and label everything as directed.

Return the kit promptly using the provided shipping method. Follow the kit's timing instructions because the laboratory must receive the sample within the allowed period. If the sample leaks, is incomplete, or arrives too late, you may need to collect another one.

## Understanding your results

A negative result means the test did not detect the DNA patterns or level of blood that would make it positive. This lowers the chance that colorectal cancer was present at the time, but it does not reduce the chance to zero. Continue screening on the schedule recommended for you.

A positive result means blood or DNA changes were detected. It does not show whether the cause is cancer, a precancerous polyp, a noncancerous condition, or another source of bleeding. The appropriate follow-up is a diagnostic colonoscopy, not another Cologuard test.[3]

Occasionally, the result is invalid or cannot be processed. This can happen because of collection, labeling, shipping, or sample-quality problems. A replacement kit may be needed.

Results are interpreted as positive, negative, or unable to process rather than against a universal reference range. Interpretation still depends on age, symptoms, medical history, medicines, and clinical context.

## What affects the results

A result can be misleading even when the laboratory has handled the sample correctly.

Blood from hemorrhoids, menstruation, urinary bleeding, or another noncancerous digestive condition can contribute to a positive blood test. Aspirin, anti-inflammatory medicines, and blood thinners may make bleeding more likely, but you should not stop them on your own.

Cancers and polyps do not always release detectable blood or DNA into every bowel movement. This can lead to a negative result even when an abnormality is present.

Other practical factors include:

Age can also affect how often positive results occur without cancer or an advanced precancerous growth. Pregnancy, fasting, exercise, and time of day are not known to meaningfully affect this stool test.

- Urine or toilet water mixing with the sample
- Too little sample or preservative
- A leaking or incorrectly labeled container
- Delayed shipping or unsuitable storage temperatures
- Collecting during significant diarrhea

## Accuracy and limitations

In a large study of average-risk adults ages 50 to 84, Cologuard detected about 92% of colorectal cancers present at screening. Put another way, it missed about 8%, although the exact performance in an individual cannot be predicted.[4]

It detected about 42% of advanced precancerous growths, meaning it missed more than half. Colonoscopy is better at finding these growths and allows them to be removed during the same procedure.

Among participants who did not have colorectal cancer or an advanced precancerous growth, about 13% had a positive Cologuard result. These false-positive results can lead to colonoscopy even though cancer or an advanced growth is not found.[4]

Study results may not apply equally to every age group or medical situation. Performance is less certain in people at high risk, those with symptoms, and those using the test repeatedly over many screening cycles.

Colonoscopy is the better test after a positive result, when symptoms need investigation, or when a person has a high-risk history. A negative Cologuard result should not delay evaluation of concerning symptoms.

## Risks and complications

Collecting a stool sample does not involve needles, sedation, radiation, or instruments entering the bowel. The physical risks of collection are minimal.

The main harms come from misleading results. A false-negative result may delay further assessment, while a false-positive result can cause worry and lead to a colonoscopy that finds no cancer or advanced growth. Colonoscopy has its own uncommon risks, including bleeding, a tear in the colon, and complications from sedation.

## What happens next

After a negative result, routine screening usually continues at the recommended interval. Do not use the result to dismiss new or ongoing symptoms.

After a positive result, arrange a colonoscopy in a timely way. This is routine follow-up rather than an emergency. Repeating Cologuard does not cancel or explain a positive result.

Contact a healthcare professional promptly if you have ongoing rectal bleeding, a persistent change in bowel habits, or unexplained abdominal symptoms. Seek urgent or emergency care for heavy bleeding, black tar-like stool with weakness or fainting, or severe and persistent abdominal pain.

## Common questions

Can I drink coffee before Cologuard?

Yes. You can eat and drink normally, including coffee. Fasting is not needed.

Does the time of day matter?

No. Collect the sample when you have a bowel movement and can complete the instructions. Return it promptly.

Can I exercise beforehand?

Yes. Exercise is not known to change Cologuard results. Unlike some blood tests, recent strenuous activity is not an important source of error.

Do I need to stop my medicines?

Usually not. Do not stop aspirin, blood thinners, or other prescribed medicines without medical advice. Tell the ordering clinician what you take.

Can I collect the sample during my period?

It is better to wait until menstrual bleeding has stopped so blood does not contaminate the sample.

What if I have hemorrhoids?

Hemorrhoids do not automatically prevent testing. If they are actively bleeding, wait and follow the kit instructions or contact the testing service because visible blood could affect the result.

## Sources

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