

# Cologuard Information for Patients

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## COLOGUARD INFORMATION

Cologuard® is an easy-to-use, noninvasive colon cancer (also referred to as colorectal cancer) screening test based on the latest advances in stool DNA science. It is for adults 45 years of age or older who are at average risk for colorectal cancer, and it is available by prescription only.

Cologuard finds biomarkers associated with cancer and precancer. According to guidelines from the American Cancer Society (ACS), the recommended screening interval with Cologuard is every 3 years.<sup>1</sup>

### How does Cologuard work?

DNA is continuously shed from cells in the lining of the colon, where it is passed into the stool. If cancer or precancer is present, abnormal cells will shed into the colon and stool along with normal cells.

Cologuard is not a genetic test, but it uses advanced stool DNA technology to identify altered DNA and/or blood in stool; these biomarkers are associated with colon cancer and precancer.

### How is a sample collected?

The Cologuard Collection Kit is easy to use, and it's shipped directly to your home. There is no special preparation, diet, or change in medication needed and no time off is required. You collect a single stool sample in the privacy of your own home using this kit, then send it to Exact Sciences Laboratories (ESL), which remains fully operational at this time, via prepaid UPS pickup, no need to leave your home. ESL provides the result back to your healthcare provider after a few weeks.

### Is Cologuard right for you?

Cologuard is indicated to screen men and women, 45 years or older, who are at average risk for colorectal cancer. Cologuard is not for everyone. It is not a replacement for diagnostic or surveillance colonoscopy in high-risk individuals. Cologuard is not for you if:

- You have a history of colorectal cancer, adenomas, or other related cancers
- You have a family history of colorectal cancer
- You have had a positive result from another colorectal cancer screening method within the last 6 months
- You have been diagnosed with a condition that is associated with high risk for colorectal cancer
- You have been diagnosed with a relevant familial (hereditary) cancer syndrome

### How do I receive the results of my Cologuard test?

- Your results will be provided to your healthcare provider
  - Following a positive result, schedule a diagnostic colonoscopy with your healthcare provider

- Recognizing it may be challenging to schedule a follow-up colonoscopy immediately during the COVID-19 pandemic, Exact Sciences is actively engaged in finding options to assist patients in connecting with gastroenterologists in their area.
- Following a negative result, you should continue participating in a screening program at an interval and with a method agreed upon with your healthcare provider.

## What should I consider when interpreting the results of my Cologuard test?

- Cologuard may produce false-positive or false-negative results
  - A false positive occurs when Cologuard produces a positive result, even though a subsequent diagnostic colonoscopy does not find cancer, precancer, or polyps. Results should be interpreted with caution for individuals over age 75, as the rate of false positives increases with age. Any positive result should be followed by diagnostic colonoscopy
  - A false-negative result occurs when Cologuard does not detect the presence of colon cancer or precancer

## Important Information

Cologuard is intended to screen adults 45 years of age and older who are at average risk for colorectal cancer by detecting certain DNA markers and blood in the stool. Do not use if you have had adenomas, have inflammatory bowel disease and certain hereditary syndromes, or a personal or family history of colorectal cancer. Cologuard is not a replacement for colonoscopy in high risk patients. Cologuard performance in adults ages 45-49 is estimated based on a large clinical study of patients 50 and older. Cologuard performance in repeat testing has not been evaluated.

The Cologuard test result should be interpreted with caution. A positive test result does not confirm the presence of cancer. Patients with a positive test result should be referred for diagnostic colonoscopy. A negative test result does not confirm the absence of cancer. Patients with a negative test result should discuss with their doctor when they need to be tested again. False positives and false negative results can occur. In a clinical study, 13% of people without cancer received a positive result (false positive) and 8% of people with cancer received a negative result (false negative). Rx only.

**Additional frequently asked questions can be found at**

<http://www.cologuardtest.com/what-is-cologuard/faq>.

**Reference:** 1. American Cancer Society. American Cancer Society Guideline for Colorectal Cancer Screening.

<https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>. Revised May 30, 2018. Accessed March 25, 2020.

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