

Cologuard® Information for Patients

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COLOGUARD® INFORMATION

Based on advances in stool DNA science, Cologuard is an easy-to-use screening option for colorectal cancer. This simple, noninvasive option is available by prescription only to adults 45 years of age and older who are at average risk of colorectal cancer.

American Cancer Society guidelines recommend that people at average risk of colorectal cancer start screening at age 45.¹ For these individuals who are screening with Cologuard, The American Cancer Society recommends screening again three years after a negative Cologuard result. Talk with your health care provider about the available options for screening.

How Does Cologuard Work?

Cologuard identifies specific biomarkers associated with colorectal cancer and precancer by using advanced stool DNA technology that detects altered DNA and/or blood in the stool. Cologuard finds 92% of colorectal cancers, even in earlier stages.²

How Is a Sample Collected?

The Cologuard collection kit is easy to use and shipped directly to your home. You don't need to take time off or make any changes to diet or medication before using the test; you simply collect a single stool sample in the privacy of your own home. Plan to collect your sample when you can get it back to UPS® that same day or the next day. Send it back to Exact Sciences Laboratories using the no-cost return option that works best for you. You can ask for a contact free pickup by calling 1-844-870-8870 for help or visit Cologuard.com/UPS to schedule it on your own or drop it off at UPS. Exact Sciences Laboratories will send the results to your health care provider in a few weeks.

Is Cologuard Affordable?

Cologuard is covered by Medicare and most major commercial insurance providers.³ Nationwide, about 94% of patients using Cologuard have no out-of-pocket cost for screening.^{3*}

What Should I Know About the Results of My Cologuard Test?

Exact Sciences Laboratories sends your results to your health care provider. If your test result is⁴:

- Negative
 - The test did not detect altered DNA and/or blood that could be caused by a precancerous polyp or colon cancer. A negative result means you have a very low chance of having colorectal cancer or pre-cancer, and you do not need further follow-up at this time. However, false negatives can occur. You should get screened again in the future.
- Positive
 - The test detected altered DNA and/or blood that could be caused by a precancerous polyp or colon cancer. A positive result means you have an increased chance of having colorectal cancer or pre-cancer. You do not necessarily have cancer, because false positives can occur. You should discuss your result with your ordering provider and schedule a colonoscopy as soon as possible.

Indications and Important Risk 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 a diagnostic 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 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.

References: 1. Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin.* 2018;68(4):250-281. 2. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med.* 2014;370(14):1287-1297. doi:10.1056/NEJMoa1311194 3. Internal Data on File. Exact Sciences Corporation. Madison, WI. 4. Cologuard Clinician Brochure. Exact Sciences Corporation. Madison, WI. Accessed June 30, 2022.

*Exact Sciences estimate based on historical patient billing. Rate of coverage varies by state and region. Exceptions for coverage may apply, only your insurer can confirm how Cologuard would be covered.

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