



PATIENT BROCHURE

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Intended Use and Indications for Use

The Cologuard® test is a qualitative in vitro diagnostic test intended for the detection of colorectal neoplasia-associated DNA markers and for the presence of occult hemoglobin in human stool. The Cologuard test is performed on samples collected using the whole stool collection kit provided by Exact Sciences. A positive result may indicate the presence of colorectal cancer (CRC) or advanced precancerous lesions (APL) and should be followed by a colonoscopy. The Cologuard test is indicated to screen adults 45 years or older who are at average risk for CRC. The Cologuard test is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

The Cologuard test is performed at Exact Sciences Laboratories, Madison, WI.

Contraindications

The Cologuard test is not indicated for use in patients who have the following:

- A personal history of CRC or APL.
- A positive result from another CRC screening method within the last 6 months, or:
 - 12 months for a fecal occult blood test (FOBT) or a fecal immunochemical test (FIT)
 - 36 months for a FIT-DNA test
- A family history of CRC, defined as having a first-degree relative (parent, sibling, or child) with a CRC diagnosis at any age.
- Personal history of any of the following high-risk conditions for CRC:
 - A diagnosis of Inflammatory Bowel Disease (Chronic Ulcerative Colitis, Crohn's Disease).
 - A diagnosis of a relevant familial (hereditary) cancer syndrome or other polyposis syndrome, including but not limited to: Familial adenomatous polyposis (FAP or Gardner's), Hereditary non-polyposis colorectal cancer syndrome (HNPCC or Lynch), Peutz-Jeghers, MYH-Associated Polyposis (MAP), Turcot's (or Crail's), Cowden's, Juvenile Polyposis, Cronkhite-Canada, Neurofibromatosis, or Serrated Polyposis.

Warnings and Precautions

- Patients should not provide a sample for the Cologuard test if they have diarrhea or if they have blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation). Unexpected bleeding should be discussed with your health care provider.
- Reference national guidelines for the recommended screening ages for CRC. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with your health care provider. The Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- The Cologuard test may produce false negative or false positive results. A false positive result occurs when the Cologuard test produces a positive result, even though a colonoscopy will not find CRC or APL. A false negative result occurs when the Cologuard test does not detect an APL or CRC even when a colonoscopy identifies either of these findings.
- A negative Cologuard test result does not guarantee absence of CRC or APL. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program at the appropriate guideline recommended intervals.
- The initial performance of the Cologuard test has been established in a cross-sectional study (i.e., single point in time). Programmatic performance of the Cologuard test (i.e., benefits and risks with repeated testing over an established period of time) was assessed in a longitudinal study over a three-year period. Non-inferiority or superiority of the Cologuard test's programmatic sensitivity as compared to other recommended screening methods for CRC and APL has not been established.
- The clinical validation study was conducted in patients 50 years of age and older. The Cologuard test performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.
- **Patients should collect their sample when they can get it back to UPS on the same day or the next day.** Patients should refer to the instructions provided with the collection kit, or ask their health care provider for more information. Patients should send stool samples to the laboratory according to the instructions provided with the collection kit.
- Patients should be advised of the caution listed in the instructions provided with the collection kit. Patients should NOT drink the preservative liquid.
- The risks related to using the collection kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain.

What is cancer screening?

Some types of cancer can be found before symptoms are present or when the disease is in an early stage of development. Checking for cancer (or for conditions that may lead to cancer) in people who have no symptoms is called **screening**. Screening can help doctors find and treat some types of cancer early. Generally, the earlier colorectal cancer is detected, the easier it is to treat.

Being screened for colorectal cancer is the first and most important step in finding and preventing colorectal cancer for all adults 45 years of age and older.

Important facts about colorectal cancer

Colorectal cancer is one of the most preventable, yet least prevented, cancers in the US today.¹ It is the third most diagnosed cancer, and the second leading cause of cancer deaths in both men and women 50 years of age and older.² Despite these facts, colorectal cancer is one of the most treatable cancers if it is found early through screening.¹ Yet, approximately two in five adults 45 years of age and older are still not getting screened as recommended.³

Colorectal cancer can be detected early, if you are looking for it.¹ Colorectal cancer grows slowly, generally starting from small, noncancerous polyps in the colon or rectum.¹ A polyp is simply an abnormal growth in the inner wall of your colon or rectum and is relatively common in people over 50 years of age.¹ Polyps are found at similar rates in adults younger than 50 years of age as in adults 50-59 years of age.⁴ While polyps are common and typically don't cause symptoms, some are dangerous and can turn into cancer over time.⁵ If polyps are found and removed early, the chance of developing colorectal cancer can be reduced dramatically.⁶ If colorectal cancer is detected in its early stages through screening, treatment is most likely to be successful.⁶

Why should I get screened for colorectal cancer?

The earlier colorectal cancer is detected, the easier it is to treat. Regular colorectal cancer screening for all adults 45 years of age and older is worth doing because it has the potential to save lives. Choosing among colorectal cancer screening tests isn't always an easy decision. That is why it is important to talk to your health care provider about when to begin screening for colorectal cancer and how to choose among the different colorectal cancer screening methods and procedures available today. There are many colorectal cancer screening methods, both invasive and noninvasive, with newer noninvasive methods that are available to everyone considered at "normal risk" for colorectal cancer.

Choosing the best colorectal cancer screening test for you

Be certain to consult your health care provider about your colorectal cancer screening options when choosing a colorectal cancer screening test that's right for you— you have multiple choices. Factors to discuss include:

- Your age, medical history, family history, general health
- The ability of the test to find both precancer and cancer
- How the test is performed
- If sedation is necessary
- The preparation and amount of time required to take the test
- The convenience of the test
- The potential harms of the test
- Follow-up care after the test

What is the Cologuard test? Why is it different?

The Cologuard test is an accurate noninvasive colorectal cancer screening test for men and women, 45 years of age and older, who are at average risk for colorectal cancer. The Cologuard test is the only colorectal screening test that uses advanced stool DNA technology and is effective in finding both precancer and cancer.

What is stool DNA technology?

Every day your colon sheds cells that line the inside of the colon. As part of this process, if precancer or cancer is present, abnormal cells will shed into the colon, along with normal cells. When you have a bowel movement, your stool picks up the shedding cells as it passes through your colon. The Cologuard test utilizes advanced stool DNA technology to detect the DNA and hemoglobin (red blood cells) released from abnormal cells, if present. Stool DNA technology looks for specific markers from abnormal cells and does not require analysis of your personal genetic information. Unlike other noninvasive colorectal cancer screening tests, the Cologuard test can detect both precancer and cancer.

The Cologuard test is easy to use:

- The Cologuard test allows you to easily collect a stool sample for testing in the privacy of your own bathroom.
- The test does not require you to follow a special diet or change your medications

Is the Cologuard test accurate and effective in finding precancer and cancer?

The Cologuard test is an effective noninvasive colorectal cancer screening test.

- The Cologuard test finds 92% of colon cancers.
- The Cologuard test is effective because it finds both advanced precancerous lesions (precancer) and cancer
- In a large clinical study, the Cologuard test found more cancers and precancers than an ordinary fecal blood test (e.g. FIT).

The Cologuard test does produce some false positive results, so any positive should be discussed with your health care provider and followed by a colonoscopy. In a large clinical study, the Cologuard test detected 92% of colorectal cancers and 42% of precancers while an ordinary fecal blood test (e.g., FIT) detected 74% of cancers and 24% of precancers. The Cologuard test correctly gave a negative screening result for 87% of the study subjects without disease, while the FIT provided accurate negative screening results for 95% of the study population without disease.

How was the effectiveness of the Cologuard test determined?

The Cologuard test was studied in a large clinical trial to determine the effectiveness of the test. The trial included more than 10,000 patients at 90 sites in the US and Canada. The study included adults ages 50-84. Individuals in the study completed the Cologuard test and a fecal immunochemical test before having a standard colonoscopy. The main purpose of the study was to find out how well the Cologuard test detects cancer and precancer compared to a colonoscopy. The performance of the Cologuard test in adults ages 45-49 is estimated based on this large study.

I want to be screened for colorectal cancer. How do I get the Cologuard test?

The Cologuard test is prescribed through your health care provider and cannot be purchased over the counter. Once your health care provider prescribes the Cologuard test, Exact Sciences Laboratories makes it easy to complete the Cologuard sample collection process:

- A collection kit is sent directly to your preferred mailing address. You can store your kit until you are ready to use it - just store at room temperature in a cool, dry place. Keep away from heat and direct sunlight and out of reach of children.
- When you are ready, the sample collection can be done at home. Caution, do not collect your sample if you are experiencing any of the following:
 - Bleeding hemorrhoids
 - Bleeding cuts or wounds on your hands
 - Rectal bleeding

- Menstrual period
- Diarrhea
- After you have completed your stool sample collection, you drop off the collection kit at any UPS store or call to schedule a pick-up where it will be sent directly back to Exact Sciences Laboratories. All postage is pre-paid.
- Exact Sciences Laboratories will test your stool sample and send the results back to the health care provider who prescribed your test. **Your test results will be shared with you.**



If you have any questions or concerns, call Customer Care at 844-870-8870. You can also find helpful information www.cologuard.com.

Understanding your results

Your health care provider will talk with you about your results. The test result can be **POSITIVE** or **NEGATIVE**.

What does a **POSITIVE** result mean?

- A Positive result means the test detected possible signs of precancer or colorectal cancer from your stool sample.
- Any Positive result should be followed by a colonoscopy.
- The test can also have a Positive result that is incorrect (false positive). This means the test result is Positive, but no cancer or precancer is actually present.
- Talk about your test result with your health care provider to find out if additional testing is needed.

What does a **NEGATIVE** result mean?

- A Negative result means the test did not detect signs of precancer or colorectal cancer from your stool sample.
- The test can also have a Negative result that is incorrect (false negative). This means the test result missed a potential cancer or precancer. For that reason, it is recommended that you schedule regular screenings. Your health care provider may recommend an alternative screening method.
- Talk to your health care provider about your test result. Your health care provider will recommend a screening schedule that is best for you.

Please note that in some cases the Cologuard test may not generate a result. If this happens, you will be contacted and may be asked to provide another stool sample.

The Cologuard test may not be for everyone

Talk with your health care provider if any of the following apply to you:

- A history of colorectal cancer, or advanced precancerous lesions.
- If you had a positive result from another colorectal cancer screening method within the last 6 months.
- If you have been diagnosed with a condition that places you at high risk for colorectal cancer. These include but are not limited to: Inflammatory Bowel Disease (Chronic ulcerative colitis, Crohn's disease).
- Been diagnosed with a relevant cancer syndrome passed on from your family (hereditary), such as Familial adenomatous polyposis (FAP or Gardner's), Hereditary non-polyposis colorectal cancer syndrome (HNPCC or Lynch), Peutz-Jeghers, MYH-Associated Polyposis (MAP), Turcot's (or Crail's), Cowden's, Juvenile Polyposis, Cronkhite-Canada, Neurofibromatosis or Serrated Polyposis.

What are the risks associated with using the Cologuard test?

The risks related to using the collection kit are low. No serious adverse events were reported in the clinical trial.

- Opening or closing the lids of items in the kit may be difficult for some people. Be careful when opening and closing the lids to avoid the risk of hand strain. Close all sample containers tightly.
- Using this kit requires sitting down on the toilet and standing up from the toilet. Have someone who can help you sit down or stand up if needed.
- There is a chance that a stool sample sent to the lab may have no result. If this happens, you will be contacted. You may be asked to provide another sample.

The Cologuard test Precautions

- Do not drink the bottle of preservative liquid & keep away from children. Do not let the liquid touch your skin or eyes. If the liquid touches your skin or eyes, wash the area with water.

Who can I call if I have questions?

Call Customer Care at 1-844-870-8870 if you have any questions. Easy-to-follow guides for collecting and returning your sample are available online at www.cologuard.com. Printed copies of these guides are available upon request.

References

1. American Cancer Society. Can colon cancer be prevented? Available at <https://www.cancer.org/cancer/colon-rectal-cancer/causes-risks-prevention/prevention.html> (accessed April 8, 2019).
2. American Cancer Society. Cancer Facts & Figures 2014. Available at <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf> (accessed April 11, 2019).
3. CDC Vital Signs. Colorectal Cancer Tests Save Lives. Available at <http://www.cdc.gov/vitalsigns/colorectalcancerscreening/index.html> (which references <http://seer.cancer.gov>) (accessed February 19, 2014).
4. Wolf AMD et al. CA Cancer J Clin. 0218;68(4):250-281.
5. Pickhart PJ et al. Clin Gastroenterol Hepatol. 2010;8(7):610-615; Amersi F et al. Clin Colon Rectal Surg. 2005;18(3):133-140; Leggett B, Whitehall V. Gastroenterology. 2010;138(6):2088-2100.
6. Zauber AG et al. N Engl J Med. 2012;366(8):687-696.

Questions? Call toll free and speak with a representative today.

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