



## PATIENT BROCHURE

LBL-0259rev3

## Indications for Use

Cologuard® is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by a colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.

## Contraindications

Cologuard is intended for use with patients, age 45 years and older, at average risk who are typical candidates for CRC screening. Cologuard was not clinically evaluated for the following types of patients:

- Patients with a history of colorectal cancer, adenomas, or other related cancers.
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.
- Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
  - Inflammatory Bowel Disease (IBD)
  - Chronic ulcerative colitis (CUC)
  - Crohn's disease
  - Familial adenomatous polyposis (FAP)
  - Family history of colorectal cancer
- Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis.

## Warnings and Precautions

- The performance of Cologuard has been established in a cross sectional study (i.e., single point in time). Programmatic performance of Cologuard (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with Cologuard. Non-inferiority or superiority of Cologuard programmatic sensitivity as compared to other recommended screening methods for CRC and AA has not been established.
- The clinical validation study was conducted in patients 50 years of age and older. ACS Guidelines recommend screening begin at age 45. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.
- CRC screening guideline recommendations vary for persons over the age of 75. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with a healthcare provider. Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program with another recommended screening method. The screening interval for this follow-up has not been established.
- Cologuard may produce false negative or false positive results. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps. A false negative result occurs when Cologuard does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.
- Patients should not provide a sample for Cologuard 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).
- To ensure the integrity of the sample, the laboratory must receive the patient specimens within 96 hours of collection. Patients should send stool samples to the laboratory according to the instructions stated in the Cologuard Patient Guide.
- Patients should be advised of the caution listed in the Cologuard Patient Guide. Patients should NOT drink the preservative liquid.
- The risks related to using the Cologuard 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.**<sup>1</sup> 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.<sup>2</sup> Despite these facts, colorectal cancer is one of the most treatable cancers if it is found early through screening.<sup>1</sup> Yet, one in 3 adults 50 years of age or older are still not getting screened as recommended.<sup>3</sup>

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

## 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 healthcare 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 Cologuard? Why is it different?

Cologuard 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. Cologuard 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. Cologuard 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, Cologuard can detect both precancer and cancer.

## Cologuard is easy to use:

- Cologuard 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 Cologuard accurate and effective in finding precancer and cancer?

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

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

Cologuard does produce some false positive results, so any positive should be discussed with your doctor and followed by a colonoscopy. In the clinical study of Cologuard, Cologuard 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 Cologuard determined?

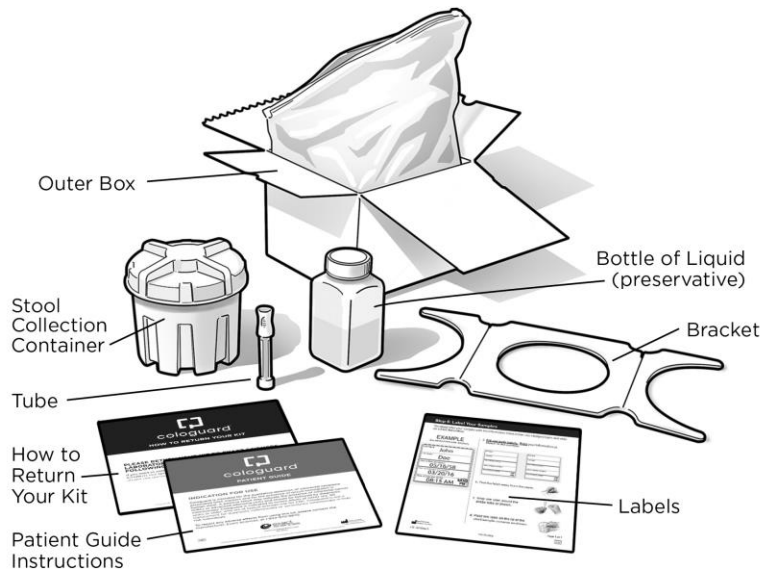
Cologuard was studied in a large clinical trial to determine the effectiveness of the test. The trial included more than 10,000 patients at 90 sites in the US and Canada. The study included adults ages 50-84. Individuals in the study completed Cologuard and a fecal immunochemical test before having a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

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

**Cologuard is prescribed through your health care provider** and cannot be purchased over the counter. Once a health care provider prescribes Cologuard, 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, a 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 within 3 days of your sample collection. All postage is pre-paid.
- Exact Sciences Laboratories will test your stool sample and send the results directly back to your doctor. **Your doctor will contact you with your test results.**



Should you have any questions or concerns, Exact Sciences Laboratories offers a dedicated Customer Support Center that will be happy to assist you. You can call, toll free, and speak with a representative at 844-870-8870. More resources are also available online at [www.cologuard.com](http://www.cologuard.com) or at your healthcare provider's office.

## Understanding your results

Your doctor 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 abnormal DNA and/or blood that could be caused by precancer or cancer in the colon.
- 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 doctor to find out if additional testing is needed.

What does a **NEGATIVE** result mean?

- A Negative result means the test did not detect abnormal DNA and/or blood that could be caused by precancer or cancer in the colon.
- 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 doctor may recommend an alternative screening method.
- Talk to your doctor about your test result. Your doctor will recommend a screening schedule that is best for you.

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

### **Cologuard may not be for everyone**

**Talk with your doctor** if any of the following apply to you:

- A history of colorectal cancer, adenomas, or other related cancers.
- 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 (IBD), Chronic ulcerative colitis (CUC), Crohn's disease, Familial adenomatous polyposis (FAP), Family history of colorectal cancer.
- Been diagnosed with a relevant cancer syndrome passed on from your family (hereditary), such as Hereditary non-polyposis colorectal cancer syndrome (HNPCCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, Familial Hyperplastic Polyposis.

### **What are the risks associated with using Cologuard?**

The risks related to using the Cologuard 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.

## Cologuard 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?

If you have questions, please call Exact Sciences Laboratories Customer Support Center. You may also find helpful resources online.

Contact Center: 1-844-870-8870

Hours of Operations: 24 hours a day, 7 days a week

[www.cologuard.com](http://www.cologuard.com)

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  6. Zauber AG et al. N Engl J Med. 2012;366(8):687-696;

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

U.S. and International Contact Information:

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**RX Only**

[www.exactsciences.com](http://www.exactsciences.com)

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