

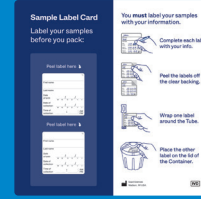
What the kit includes



Shipping Box



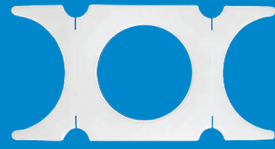
Collection Container



Sample Label Card



Tube and Probe



Bracket



Preservative Bottle

Visit Cologuard.com/result to create an account. There, you can find info about the test you received and access your result when it is available. Results are sent to the health care provider who prescribed your test in 8 to 10 days of receiving your sample.

Intended Use and Indications for Use

The Cologuard® and Cologuard Plus™ tests are qualitative in vitro diagnostic tests intended for the detection of colorectal neoplasia-associated DNA markers and for the presence of occult hemoglobin in human stool. The Cologuard and Cologuard Plus tests are 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 and Cologuard Plus tests are indicated to screen adults 45 years or older who are at average risk for CRC. The Cologuard and Cologuard Plus tests are not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

The Cologuard and Cologuard Plus tests are performed at Exact Sciences Laboratories, Madison, WI.

Contraindications

The Cologuard and Cologuard Plus tests are not indicated for use in patients who have the following:

- A personal history of CRC or APLs.
- 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 with 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, Cronkhitte-Canada, Neurofibromatosis, or Serrated Polyposis.

Warnings and Precautions

- Patients should not provide a sample if they are experiencing diarrhea or have known blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstrual bleeding). Unexpected bleeding should be discussed with your health care provider.
- Reference national guidelines for the recommended screening ages for colorectal cancer. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with your health care provider. Cologuard and Cologuard Plus test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- The Cologuard and Cologuard Plus tests may produce false negative or false positive results. A false positive result occurs when the Cologuard or Cologuard Plus test produces a positive result, even though a colonoscopy will not find CRC or APLs. A false negative result occurs when the Cologuard or Cologuard Plus test does not detect an APL or CRC even when a colonoscopy identifies either of these findings.



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Testing for Cologuard Plus showed:

- Out of every 100 patients testing positive, approximately 3 patients will have CRC, 34 patients will have APL, 33 will have a non-advanced adenoma, and 30 will have no neoplastic findings.
- Out of every 10,000 patients testing negative, approximately 2 will be falsely reassured that they do not have CRC. Out of every 100 patients testing negative, approximately 7 patients will be falsely reassured that they do not have APL.

• A negative Cologuard or Cologuard Plus test result does not guarantee the absence of CRC or APL. Patients with a negative Cologuard or Cologuard Plus test result should continue participating in colorectal cancer screening programs, 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 performance of the Cologuard Plus test has been established in a cross-sectional study (i.e., single point in time). Programmatic performance of the Cologuard Plus test (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Non-inferiority or superiority of the Cologuard Plus test's programmatic sensitivity as compared to other recommended screening methods for CRC and APL has not been established.

• **Patients should initiate the return process when they can get the collection kit back to UPS the same day they collect or the next day.**

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

• 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.

Note: Patients are not required to change their diet or medications to use this screening test.

Storing your collection kit

Keep the box upright, at room temperature, away from direct sunlight, and out of the reach of children.

Questions about your test?

To learn more about your test, log in to your Exact Sciences account at patient.exactsciences.com, or contact us at 1-844-870-8870. If you don't have an account, you can create one in four simple steps.

Rx only.



Let's get started!

Make yourself a priority. Collect your sample today.



Scan

You can also scan the QR code to get started



Call

1-844-870-8870

Other languages available



Chat

at Cologuard.com

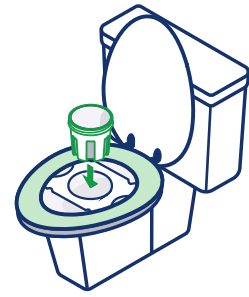
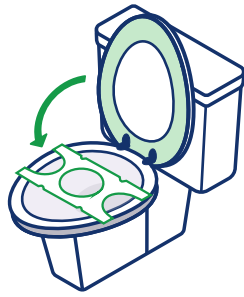
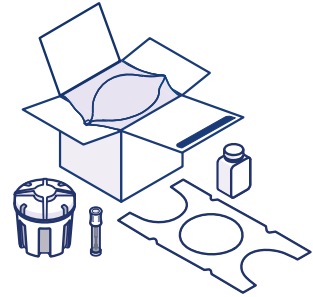
EXACT SCIENCES CORPORATION
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1-844-870-8870



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Set up your collection kit



1

- Unpack all the items shown above. Do not pull the plastic bag or white tray out of your kit.

If you are experiencing diarrhea, menstrual bleeding, or bleeding from hemorrhoids, do not collect a sample. If you notice unexpected blood, please contact your health care provider.

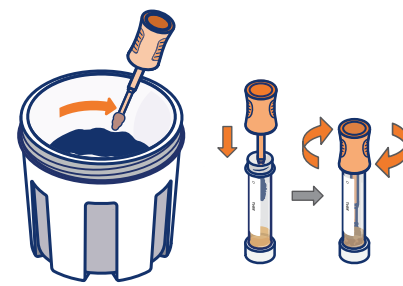
2

- Empty your bladder before setting up the Bracket.
- Place the Bracket under the seat on the toilet bowl.
- Lower the toilet seat.

3

- Take the Collection Container lid off by unscrewing it.
- Once open, place the Container in the Bracket.

Collect your stool sample



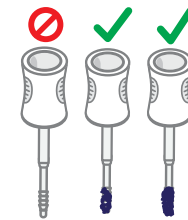
4

- Sit on the toilet. Have a bowel movement into the Container.
- Your stool sample doesn't have to be perfect. Look at the Preservative bottle in your kit. Your stool sample should be bigger than the bottle's cap but not bigger than the bottle itself.

Try not to get urine in the Container. It's OK if a small amount gets in. Make sure objects like toilet paper do not get in the Container.

5

- Unscrew the Probe from the Tube. Use the Probe to scrape the surface of your stool sample.

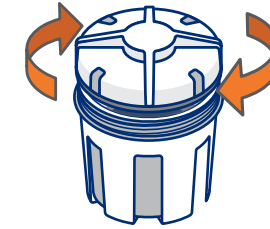


- Completely cover the tip of the Probe before returning it to the Tube.
- Place the Probe in the Tube and screw the cap closed.

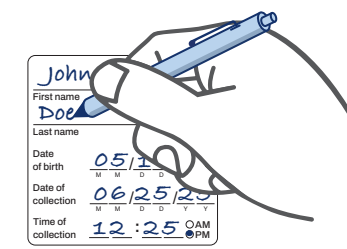
Do not fill the Tube with stool. Do not place the Tube into the Collection Container.

6

- Empty the entire Preservative bottle into the Container. It's OK if the stool sample isn't completely covered.
- Remove the Container from the Bracket. Screw the lid back onto the Container until it is sealed completely.

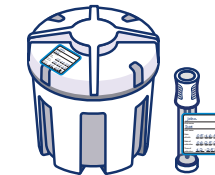


Ship your collection kit

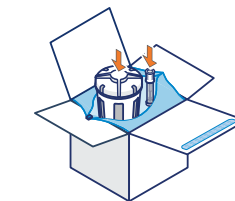


7

- Fill out both labels included on the Sample Label Card. Place one on the Container lid and one around the Tube.



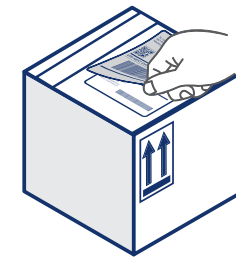
- Place the Container and Tube back into the white tray in the original Shipping Box.



Dispose of all other items.

8

- Close the zipper across the top of the bag to seal the bag.
- Seal the box with the attached adhesive strip on the box flap
- Remove the top shipping label to expose the prepaid return shipping label.



9

- Send your kit back the same day or next day after collection in one of two ways.

Prepaid return options:

1. Drop it off at UPS.
2. Schedule a UPS pickup:
 - Schedule online at **Cologuard.com/UPS**
 - or
 - Call **1-844-870-8870** for help.

View your results at:
Cologuard.com/results

