

Intended Use and Indications for Use

The Cologuard Plus™ 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 Plus test is performed on samples collected using the Cologuard Plus Collection Kit. A positive result may indicate the presence of colorectal cancer (CRC) or advanced precancerous lesions (APL) and should be followed by colonoscopy. The Cologuard Plus test is indicated to screen adults 45 years or older, who are at average risk for CRC. The Cologuard Plus test is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

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

Contraindications

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

- A personal history of colorectal cancer or advanced precancerous lesions.
- A positive result from another colorectal cancer 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, Cronkhite-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 healthcare 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 healthcare provider. Cologuard Plus test results should be interpreted

with caution in older patients as the rate of false positive results increases with age.

- The Cologuard Plus test may produce false negative or false positive results. A false positive result occurs when the Cologuard Plus test produces a positive result, even though a colonoscopy will not find cancer or advanced precancerous lesions. A false negative result occurs when the Cologuard Plus test does not detect an advanced precancerous lesion or colorectal cancer even when a colonoscopy identifies either of these findings.
 - Out of 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 Plus test result does not guarantee absence of cancer or advanced precancerous lesions. Patients with a negative Cologuard Plus test result should continue participating in colorectal cancer screening programs, at the appropriate guideline recommended intervals.
- 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 Cologuard Plus Collection Kit back to UPS the same day they collect or the next day.** Patients should refer to the shipping instructions included in the Cologuard Plus Collection Kit, or ask their prescribers for more information.

- Patients should be advised of the caution listed in the Cologuard Plus Collection Kit instructions. Patients should NOT drink the preservative liquid.

- The risks related to using the Cologuard Plus 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.

Please call our Customer Care Center at 1-844-870-8870 with any questions.

Rx only.

What the kit includes

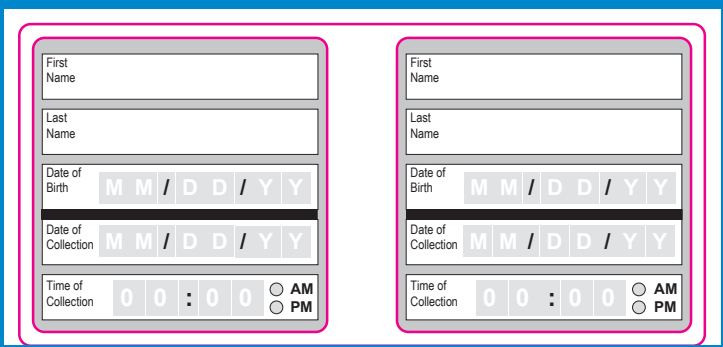


Shipping Box Quick Start Guide Patient Guide How to Return Your Kit Bracket Collection Container Tube and Probe Liquid Preservative

Label your samples

You **must** label your samples with the information listed below. Use a ballpoint pen and write on a hard, flat surface.

A. Fill out both labels. Print your information as shown in the example.



B. Peel the label away from the paper.



C. Wrap one label around the Tube as shown.



D. Place one label on the lid of the Container as shown.



Let's get started!

A quick guide on how to use your Cologuard Plus™ Collection Kit ordered by your healthcare provider.

For more detailed instructions, please see the instructions inside your Cologuard Plus Collection Kit.



Scan
You can also scan the QR code to get started



Call
1-844-870-8870
Other languages available



Live Chat
at CologuardPlus.com



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Before you start, make sure you collect the sample when it can be returned the same day or the next day.

Set up your Collection Kit

Collect your stool sample

Ship your Collection Kit

Label your samples

You **must** label your samples with the information listed below. Use a ballpoint pen and write on a hard, flat surface.

Example

(Enlarged for easier reading)

First Name	John
Last Name	Doe
Date of Birth	0 8 / 2 6 / 6 1
Date of Collection	0 5 / 1 9 / 2 5
Time of Collection	0 8 : 1 5 <input checked="" type="radio"/> AM <input type="radio"/> PM

A. Peel the label away from the paper.



B. Wrap one label around the Tube as shown.



C. Place one label on the lid of the Container as shown.



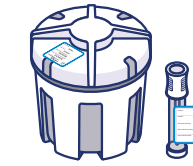
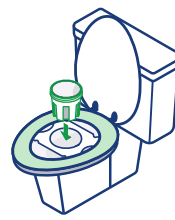
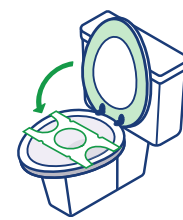
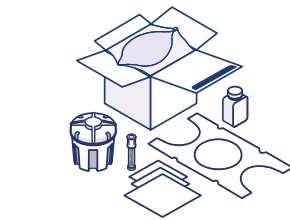
Your labels are included on the back of this guide.

IVD

Exact Sciences
Madison, WI USA

LBL-11093_QSG Rev 4, 12/2024

Rx only



1

- Look at the section of this guide titled “What the kit includes.” It shows all the items included in your kit. Unpack all items **except** plastic bag and white tray at the bottom of the kit.

Tip: Wait to collect your stool sample until you have no diarrhea and have no blood in your urine or stool (such as from hemorrhoids or menstrual bleeding). Contact your healthcare provider if you have unexpected bleeding.

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.

4

- Sit on the toilet. Have a bowel movement into the container.

Tip: Your stool sample doesn't have to be perfect. Your stool sample should not be larger than the liquid preservative bottle. Don't worry if a bit of urine gets in the container.

5

- Unscrew the probe from the tube. Use the probe to scrape the surface of your stool sample.
- Completely cover the grooves on the **tip** of the probe with stool.
- Place the probe in the tube and screw the cap closed.

6

- Pour the bottle of liquid preservative into the container.
- Screw the lid back onto the container until tight.

Tip: It's OK if the stool sample isn't completely covered.

7

- Fill out both sample labels attached to the back of this guide.
- Place one on the container lid and one around the tube.

Tip: Use a ballpoint pen on a flat surface when filling out the label card.

8

- Place the container and tube back into the white tray in the original shipping box. Dispose of all other items.
- 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.

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

Nicely done. You're all set to ship!

9

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

Return options:

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

- Sign up to view your results online at: **CologuardPlus.com/results**. Results are sent to the healthcare provider who prescribed your test within 2 weeks.