cologuard™

PATIENT GUIDE

Indication 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 diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 50 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.

exact sciences

IVD

For questions or help call **Exact Sciences at 1-844-870-8878**
www.cologuardtest.com
Rx Only

Exact Sciences
Madison WI USA

LBL-0207rev3

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Contra-Indications

Cologuard is intended for use with patients, age 50 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.

Cologuard 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.
- 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.

Cologuard Warnings and Precautions

- 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 72 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.

How the Cologuard Collection Kit Works

Your doctor has ordered Cologuard to screen for colorectal cancer and precancer.

Cologuard is a screening test that uses a stool sample (your bowel movement) to detect colorectal cancer and precancer. Every day, your colon sheds cells that line the colon. As part of this process, normal cells along with abnormal cells from precancer or cancers are shed into the colon. Your stool picks up those cells as it passes through your colon. Cologuard is designed to detect the DNA and hemoglobin released from these abnormal cells in your stool.

The Cologuard collection kit is used to collect your stool sample. After you collect your stool sample following the instructions in this Patient Guide, the collection kit will be delivered to a lab. The lab will test your stool sample and send the results to your doctor. Your doctor will contact you with the test results.

Note: You are not required to change your diet or medications to use this screening test.

How Do I Store the *Cologuard* Collection Kit When It Arrives?

You can store your kit until you are ready to use it.

- Store at room temperature.
- Keep away from heat and direct sunlight.
- Keep out of the reach of children.

What Does the Cologuard Test Result Mean?

Your doctor will talk with you about your results. The test result can be **Positive**, **Negative** or **No result obtained**.

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.
- 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.
- Any Positive result should be followed by a colonoscopy.
- Talk about your test result with your doctor to find out if additional testing is needed.

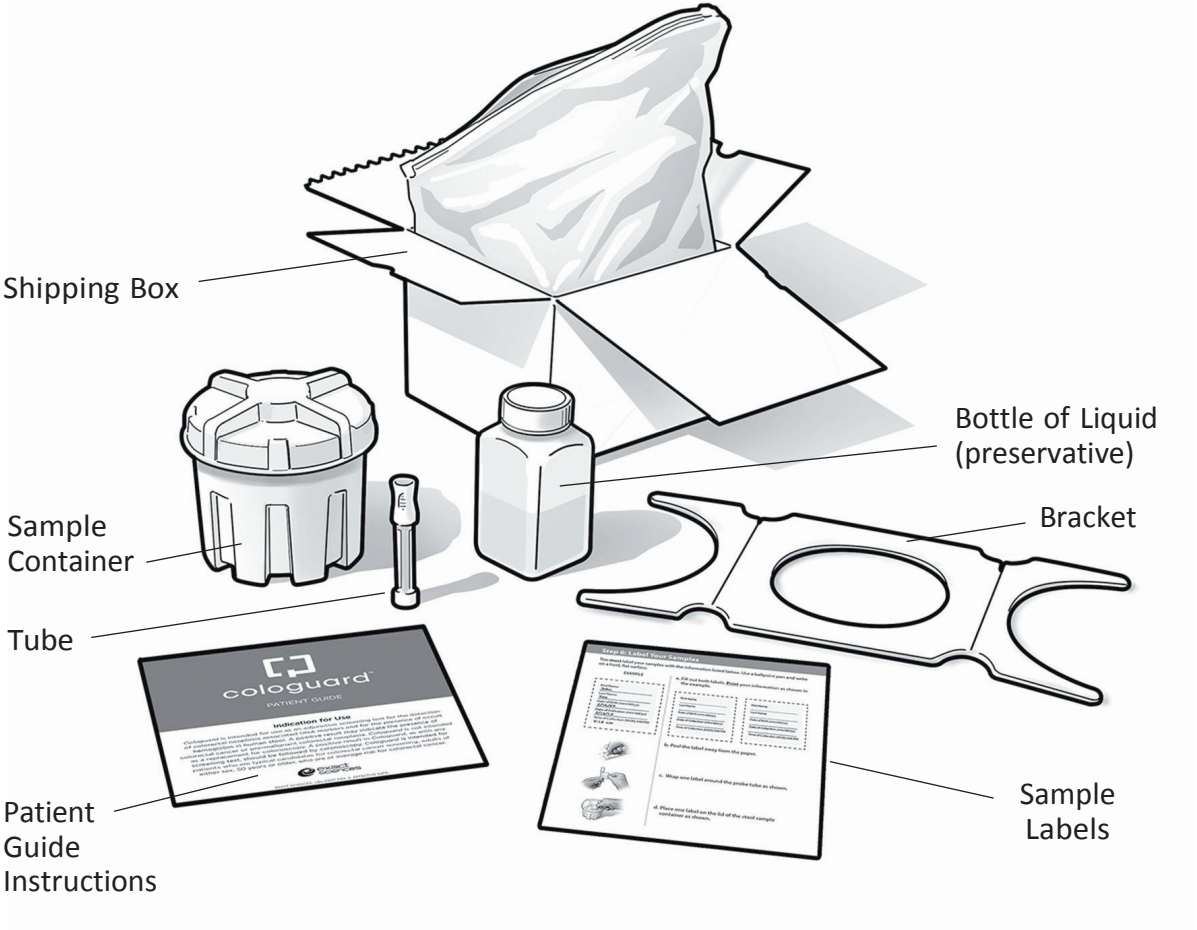
What Does a Negative Result Mean?

- A Negative test result means the test did not detect abnormal DNA and/or blood in the 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.
- Talk to your doctor about your test result. Your doctor will recommend a screening schedule that is best for you.

What Does No Result Obtained Mean?

- A "No Result Obtained" means the test was not able to provide a result.
- If this happens, your doctor will talk with you about the next steps. For example, you may be asked to provide another stool sample to test.

What Is Inside the Cologuard Collection Kit



- The bottle of liquid contains a preservative (less than 10% EDTA in Tris buffered solution).
- The tube contains a 10% albumin in Tris buffered detergent solution with an antimicrobial agent.

Who Should Use Cologuard?

Cologuard is intended for people who are typical candidates for colorectal cancer screening, which include:

- Men and women 50 years or older
- At average risk for colorectal cancer

Is Cologuard Right for You?

Talk with your doctor about using Cologuard if any of the following apply to you:

- A history of colorectal cancer, adenomas, or other related cancers.
- Had a positive result from another colorectal cancer screening method within the last 6 months.
- 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
- 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, Familial Hyperplastic Polyposis.

Caution

Caution

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

Risks

The risks related to using the Cologuard collection kit are low. No serious adverse events were reported among 10,023 people in a 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 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.

What Should I Know Before Using the Cologuard Collection Kit?

Only remove the items you need to collect your sample following the steps in this guide.

- **Leave the plastic bag inside the box.** The box, zippered bag and cardboard tray inside the bag will be used to send your sample to the lab.
- Use the kit before the expiration date printed on the side of the box.
- Avoid getting urine in the container when collecting your stool sample.
- Avoid getting toilet paper or other materials in the container when collecting your stool sample.
- **The lab must receive samples within 3 days.**
  - Collect a sample when you can ship your sample within a day of collection.
  - Make sure a holiday will not delay your shipment.
  - Review **Step 8: Ship Your Sample Using UPS** in this guide for detailed shipping information.
- You are not required to change your diet or medications to use this screening test.

When Should I Not Use the Cologuard Collection Kit?

Certain conditions may cause an incorrect test result or no result. Do **not** use this kit to collect a stool sample if you have:

- Bleeding hemorrhoids
- Bleeding cuts or wounds on your hands
- Rectal bleeding
- Menstrual period
- Diarrhea

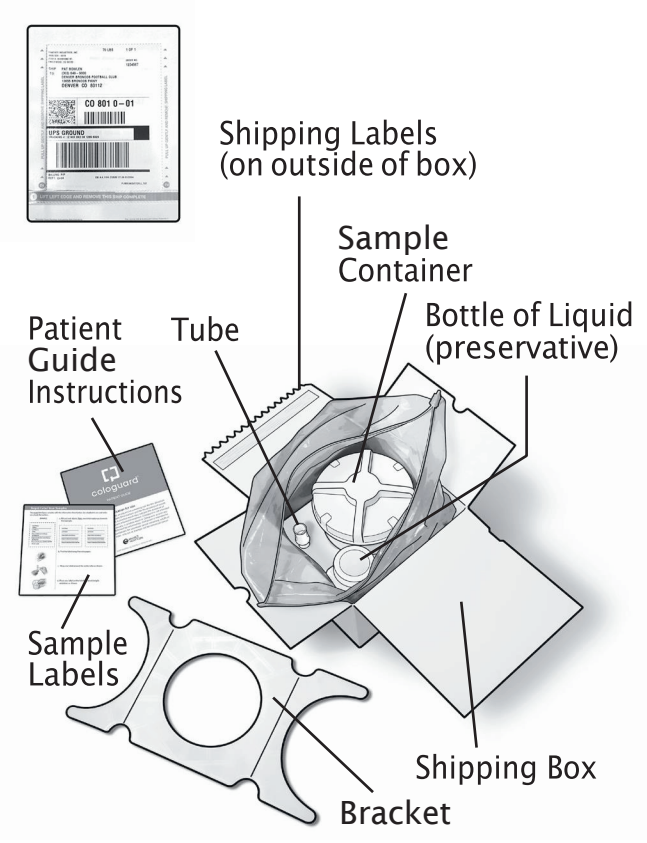
Step 1: Check the Expiration Date and the Kit

Check your kit to make sure the kit has not expired and you have all the parts of the kit.

a. Check the expiration date on the outside of the box.

b. Use the kit before the expiration date printed on the side of the box.

- If the date has passed, do **not** use the kit. Close the box and contact Exact Sciences at 1-844-870-8878 for a new kit.



Leave the plastic bag and gray cardboard insert inside the box.

c. Check the items in your box and make sure you have the following:

- Bracket
- Sample container
- Tube
- Bottle of liquid (preservative)
- Shipping labels (attached to top of box)
- Sample labels

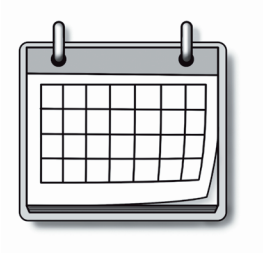
If any items are missing from your kit, do **not** use the kit. Contact Exact Sciences at 1-844-870-8878 for a new kit.

d. If all items are included in your kit, your kit is ready to use.

Follow the next steps when you feel ready to have a bowel movement.

Step 2: Prepare to Collect Stool Sample

Follow these steps in your bathroom to set up the bracket and stool sample container.



Timing Your Collection

- ✓ **Ready to have a bowel movement**
- ✓ **Can ship sample <u>within a day</u>**
- ✓ **Use shipping schedule in Step 8**

a. Decide the best time to collect a stool sample.

- Follow these steps when you feel ready to have a bowel movement.
- Collect your sample on a day when you can ship your sample to arrive at the lab within 3 days.
  - o **Ship your sample <u>within a day</u> of collection.**
  - o See **Step 8: Ship Your Sample Using UPS** for a shipping schedule.
- Do **<u>not</u>** collect a stool sample if you have:
  - o Bleeding hemorrhoids
  - o Bleeding cuts or wounds on your hands
  - o Rectal bleeding
  - o Menstrual period
  - o Diarrhea

b.

b. Remove the bracket from the box and unfold the sides of the bracket

c.

c. Raise the toilet lid **and** seat.

d.

d. Place the bracket on the toilet as shown.

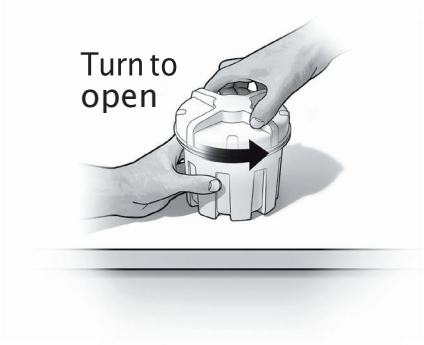
- Place the bracket toward the back of the toilet.

e.

e. Lower the toilet seat onto the bracket.

- The entire opening of the bracket should be visible.

f. Lift the stool sample container out of the box and place on a hard, flat surface.



g.

g. Turn the container lid and unscrew it.

h. Set the container lid down.

i.

i. Place the container into the top of the bracket.

Step 3: Collect the Stool Sample

- Make sure you have help if you have trouble sitting and standing when using the toilet.

a.

a. Sit on the toilet and have a bowel movement in the container.
   - **Try to keep urine from going into the container.**
   - **Do <u>not</u> put toilet paper or other items into the container.**

b. When your bowel movement is complete, stand up.

c.

c. Lift the stool sample container from the bracket and set the container on a flat, stable surface.
   - **Leave the container open.**

d.

d. Remove the bracket from the toilet.

- The bracket can be recycled or thrown in the trash.

e.

e. Finish using the bathroom if needed.

- Follow the rest of the steps in this guide **immediately** after collecting your stool sample.

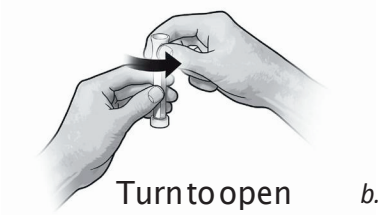
IMPORTANT: Complete the next step **before** you close the container.

Next Page

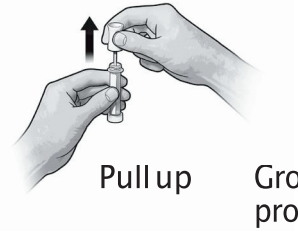
Step 4: Scrape the Stool Sample

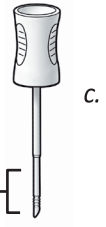
You must scrape the stool sample with the probe to get another small sample for the Cologuard test.

a. Lift the tube out of the box.



b. Turn the white tube cap and unscrew it.



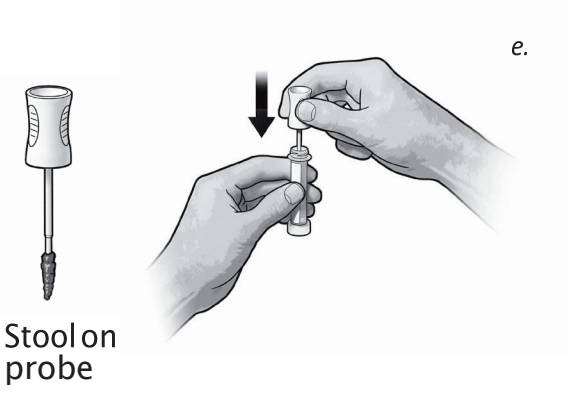


c. Pull the probe from the tube.

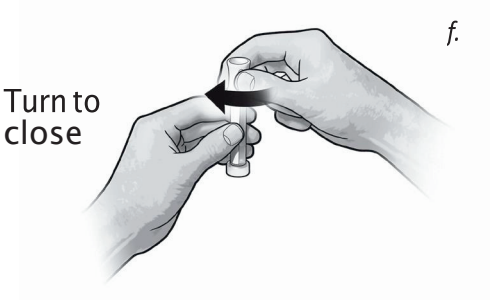
- You may have to pull hard.

d. Scrape the surface of your stool sample until the end of the probe has stool on it.

- Your stool sample may look different from the stool sample pictured.



e. Place the probe back into the open end of the tube.

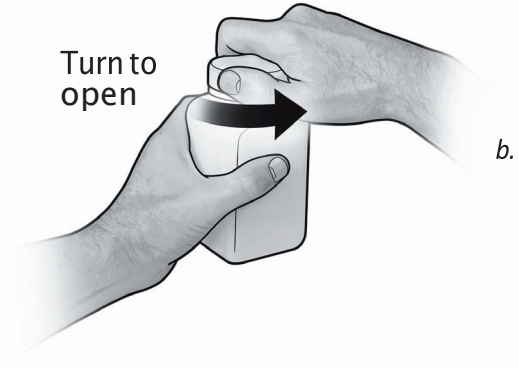


f. Turn the cap to close.

g. Set the tube down.

Step 5: Prepare Stool Sample Container for Shipping

The stool sample must have a preservative poured onto it to make sure the lab can test it. Then, the container must be closed tightly for shipping.



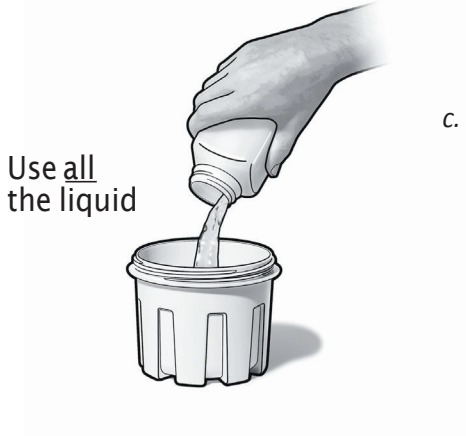
b.

a. Lift the bottle of liquid preservative out of the box.

b. Hold the bottle and turn the cap to unscrew it.

Caution

- Do **not** drink the liquid.
- If the liquid from the bottle touches your skin or eyes, wash with water.



c.

c. Pour **all** the liquid in the bottle into the container with the stool.

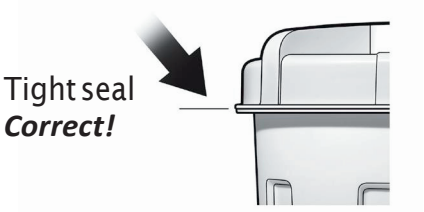
- The empty bottle and cap can be recycled or thrown in the trash.

e.

d. Hold the stool sample container on a hard, flat surface.

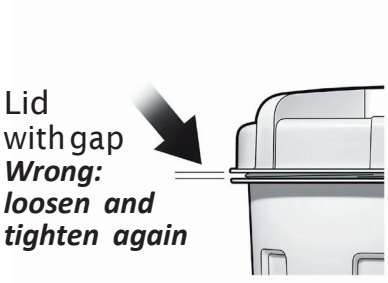
e. Place the lid on top of the container.

- Make sure the lid is straight so it will close tightly.



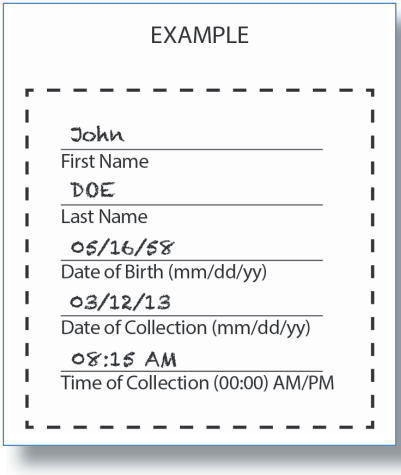
f.

f. Turn the lid to tighten until it does not tighten anymore.



Step 6: Label Your Samples

You **must** label your samples to identify them. For best results, use a ballpoint pen and write the labels on a hard, flat surface.



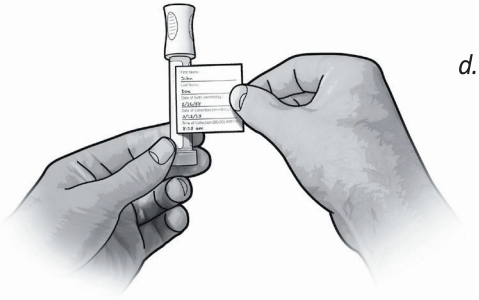
a. a. Find the page **Label Your Samples** that is included with this guide.

b. b. Fill out **both** labels. **Print** the information in this order:

- Your first name
- Your last name
- Your birthdate (MM/DD/YY)
- The date you collected your stool sample (MM/DD/YY)
- The time you collected your stool sample including AM/PM

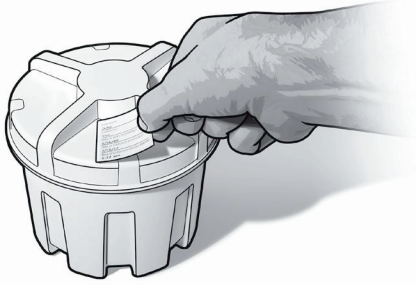
c.

c. Peel the label away from the paper.



d.

d. Wrap one label around the tube.

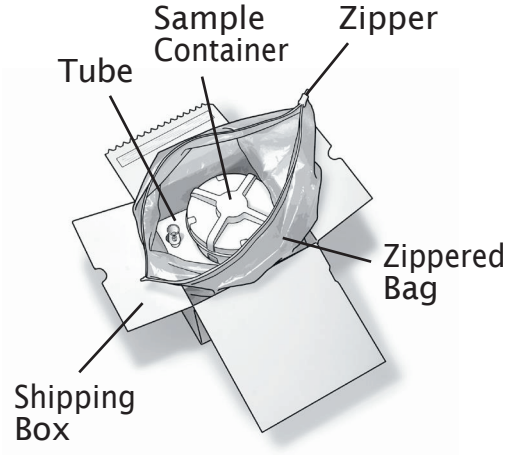


e.

e. Place one label on the lid of the stool sample container.

Step 7: Prepare Your Samples for Shipment

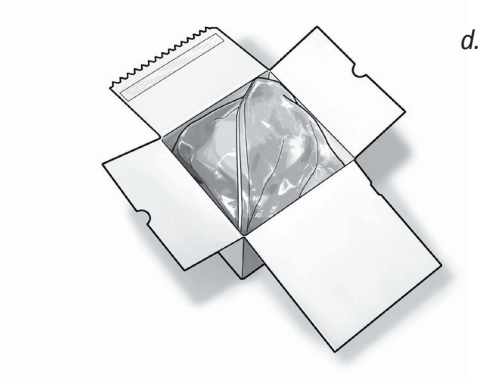
- For best results, prepare your box on a hard, flat surface.
- When you start, you should have the zippered bag inside the box. The tray for holding the container and tube should be inside the bag.



a. Place the tube and container into the box.

b. Fold the bag and push extra air out of the bag.
   - Too much air in the bag will make it hard to close the box.

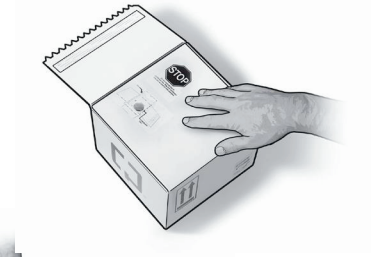
c. Slide the zipper across the top of the bag to close and seal the bag.



d.

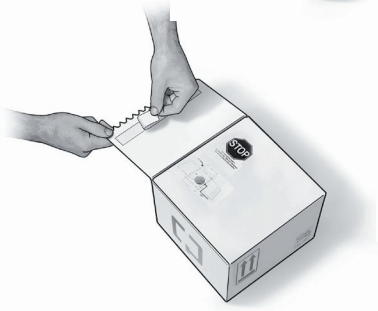
d. Fold the bag until it fits inside the box.

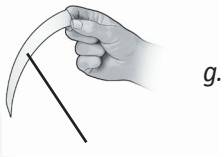
e. Fold the smaller flaps over the top of the box.



f. Fold the long flap over the two smaller flaps.

- This is the flap with the STOP sign printed on it.

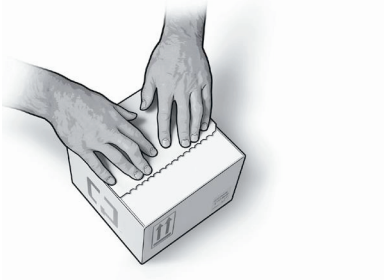




Throw away

g. Peel the paper backing off the tape on the box lid.

- Discard paper backing in garbage.

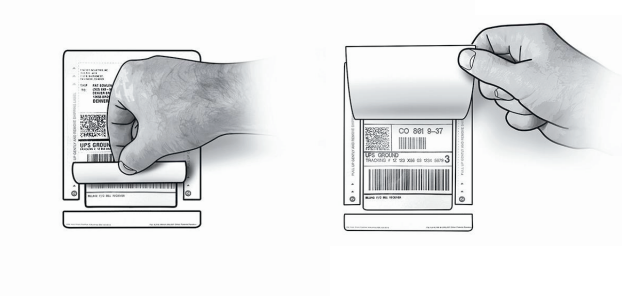


h. Fold the box top over the other flaps and press down firmly to seal the box.

i.

i. Locate the shipping label on top of your box.
   - Shipping labels on the box may differ.

j.



j. If the shipping label has a green tear strip, it must be removed.
   - Lift the left corner of the tear strip and pull it off.
   - Lift the bottom edge of the label and pull up.
   - Tear the top label off the box.
   - A new label now shows.
   - You are ready to ship your box.
   - Continue with the next step.

k. If the shipping label has **no** green tear strip, you are ready to ship your box.

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Turn the page to continue.

Step 8: Ship Your Samples Using UPS

Samples must be shipped to arrive at the lab within 3 days.

- The lab **must** receive samples within 3 days for samples to be tested. The lab will not test samples not received in time.
- UPS will ship your samples to arrive at the lab the next day from the day it shipped.
- Ship your samples **within a day** of collection for quickest delivery to the lab.

Ship your samples within a day of collection and no later than the day listed on the schedule below.

If you collected your samples on:	You must ship your samples by:
Saturday	Monday
Sunday	Tuesday
Monday	Wednesday
Tuesday	Thursday
Wednesday	Friday
Thursday	Friday
Friday	Saturday

Make sure a holiday will not delay your shipment.

If you have questions about when to ship your samples, call Exact Sciences at 1-844-870-8878.

Storing Your Samples Before Shipment

To store the samples while you plan for shipping the box:

- Store your boxed and sealed samples at room temperature.
- Keep the samples away from heat and direct sunlight.
- Keep samples out of the reach of children.
- Keep the box upright.

Ways to Ship the Samples

You have the following options for shipping your samples:

- Drop off at a UPS location. Check **www.ups.com** for UPS drop-off locations.
  - UPS Stores
  - UPS Customer Center
  - UPS Alliance Location (For Example: Staples, Office Depot)
  - UPS Authorized Shipping Outlet
  - Any UPS Driver
- Call UPS at 1-800-742-5877 for pick up or to find a drop off location near you (M-F 7:30am-12:00am, Sa 7:30am-9:00pm Eastern Standard Time).
  - You can also schedule a pick up online at www.ups.com any time.
  - Be sure to provide the tracking number shown on your prepaid return shipping label, which starts with 1Z.

Once you have shipped the samples to the lab, you are finished! Your doctor will contact you with your result.

Glossary

Adjunctive: A test used together with another test.

Colon: A part of the human digestive system sometimes known as the large intestine.

Colorectal Cancer: A disease of abnormal growths in the colon or rectum that, if left untreated, may spread throughout the body. Colon cancer generally develops over a number of years.

Colonoscopy: A medical test where a flexible tube is placed into the colon so the surface of the colon can be seen by a camera. Instruments can be placed through the tube to remove growths found on the colon wall.

DNA: Deoxyribonucleic acid. Changes in the stool DNA (sDNA) can show your doctor if there is cancer or a possibility of cancer present.

Hemoglobin: A compound from blood. Blood or hemoglobin in the stool that cannot be seen by the naked eye is referred to as occult blood or occult hemoglobin.

Neoplasia: A growth that is not normal.

Precancerous Polyp (Adenoma): A growth on the wall of the colon that may become cancer.

Symbols Used on the Cologuard Collection Kit

Collection of harmonized symbols used on labeling for the kit.

Lot Number

Storage Temperature

Catalog Number

Expiration Date

Manufacturer

Contains Sufficient for (n) Tests

In Vitro Diagnostic Use

Caution

Clinical Study Results

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. Each person in the study completed Cologuard and a fecal occult blood test before having a standard colonoscopy. The main purpose of the study was to find out the performance of Cologuard for finding cancer and precancer compared to a colonoscopy.

In the clinical study, Cologuard correctly detected 92% of colorectal cancers and 42% of advanced adenomas in the study population that had disease. The Cologuard test correctly gave a negative screening result for 87% of the study subjects that did not have colorectal cancer or advanced adenomas. In other words, 13% of people without cancer or precancer tested positive.

For questions or help call **Exact Sciences at 1-844-870-8878**
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