



cologuard plus™

PATIENT GUIDE

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.

To report any adverse effects from using this kit, or if you need assistance, please call our Customer Care Center at 1-844-870-8870. We are available 24 hours a day, 7 days a week to answer your questions.



**EXACT
SCIENCES**
www.CologuardPlus.com
Rx Only



Exact Sciences
Madison, WI USA

LBL-11106_PT Guide Rev. 4, 12/2024

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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 colorectal cancer:
 - 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 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 CRC or APL. A false negative result occurs when the Cologuard Plus test does not detect an APL or CRC 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 the 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-

WARNINGS AND PRECAUTIONS (CONTINUED)

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 prescriber 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.

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

HOW THE COLOGUARD PLUS COLLECTION KIT WORKS

Your healthcare provider has ordered the Cologuard Plus test to screen for colorectal cancer and precancer.

The Cologuard Plus test 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. The Cologuard Plus test is designed to detect the DNA and hemoglobin (blood) released from these abnormal cells in your stool.

The Cologuard Plus Collection Kit is used to collect your stool sample. After you collect your stool sample following the instructions, the collection kit will be delivered to a lab. The lab will test your stool sample and send the results to the healthcare provider who ordered your test. Your results will be shared with you.

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

HOW DO I STORE THE COLOGUARD PLUS 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 PLUS TEST RESULT MEAN?

Your healthcare provider 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 possible signs of precancer or colorectal cancer from your stool sample.
- The test can also have a Positive result that is incorrect (false positive). This means that the test is Positive, but no cancer or precancer is actually present.
- Talk to your healthcare provider about your test result. Any Positive result should be followed by a colonoscopy.
- A colonoscopy is recommended to determine if cancer or precancer is present (true positive) or absent (false positive).

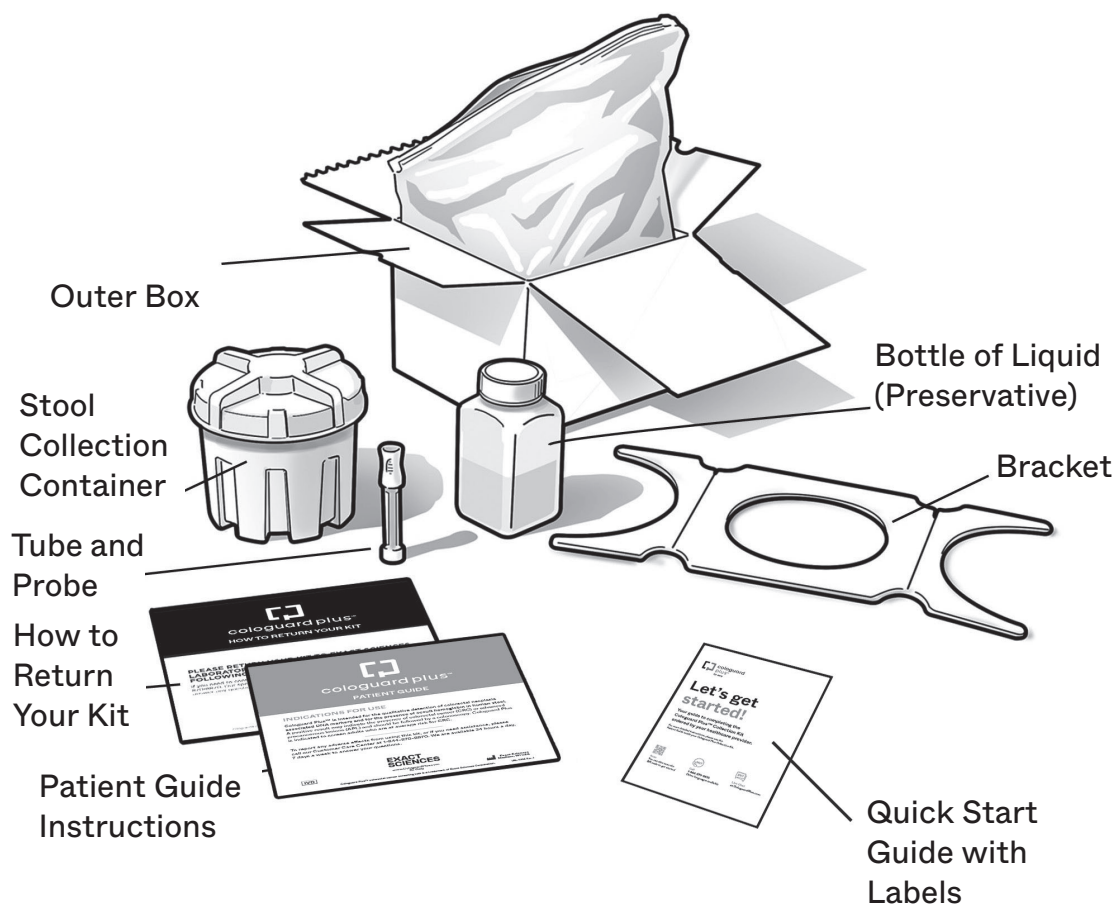
WHAT DOES A NEGATIVE RESULT MEAN?

- 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.
- Talk to your healthcare provider about your test result. A provider 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 healthcare provider 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 PLUS COLLECTION KIT?



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

WHO SHOULD USE THE COLOGUARD PLUS TEST?

The Cologuard Plus test is intended for adults who are 45 years or older at average risk for colorectal cancer.

IS THE COLOGUARD PLUS TEST RIGHT FOR YOU?

The Cologuard Plus test is NOT indicated if any of the following apply to you:

- 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 colorectal cancer:
 - 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.

CAUTION



CAUTION

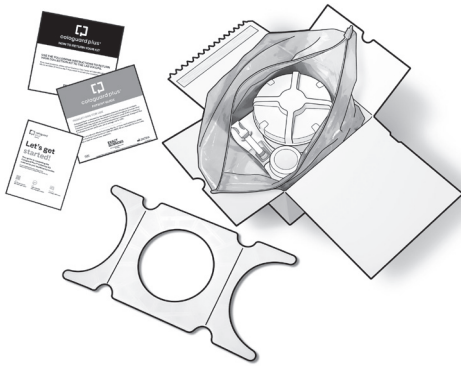
- Do not drink the bottle of preservative liquid.
- Do not let the liquid touch your skin or eyes.
- If the liquid touches your skin or eyes, wash the area with water.

RISKS

The risks related to using the Cologuard Plus Collection Kit are low. No serious adverse events were reported among 18,911 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 PLUS COLLECTION KIT?



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

- **Leave the plastic bag inside the box – do not remove.** The box, zippered bag, and white tray inside the bag will be used to return your sample.
- Use the collection kit before the expiration date printed on the side of the box.
- **Your stool sample should be no larger than the bottle of liquid included in the box.**
- Avoid getting urine in the container when collecting your stool sample.
 - Empty your bladder as much as possible, before collecting your stool sample.
- Avoid getting toilet paper or other materials in the container when collecting your stool sample.

WHAT SHOULD I KNOW BEFORE USING THE COLOGUARD PLUS COLLECTION KIT? (CONTINUED)

- **Plan to collect your sample when you can get it back to UPS that same day or the next day.**
- **Add a reminder to your calendar or phone on the day you will collect your sample. Make sure a Sunday or holiday will not delay your sample return.**
- Refer to the separate return instructions for detailed information on How to Return Your Kit.
- You are not required to change your diet or medications to use this screening test.

When you're ready to collect your sample with the Cologuard Plus Collection Kit, our video will help you through each step. Go to the following website for more information: <https://www.CologuardPlus.com/use>

WHEN SHOULD I NOT USE THE COLOGUARD PLUS COLLECTION KIT?

Certain conditions may cause an incorrect test result or no result.

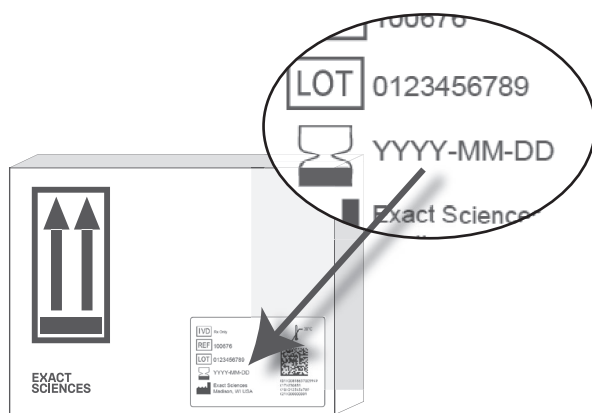
Do **not** use this kit to collect a stool sample if you have:

- Bleeding hemorrhoids
- Bleeding cuts or wounds on your hands
- Rectal bleeding
- Menstrual bleeding
- Diarrhea (abnormal bowel or stool consistency)

HOW TO USE THE COLOGUARD PLUS COLLECTION KIT

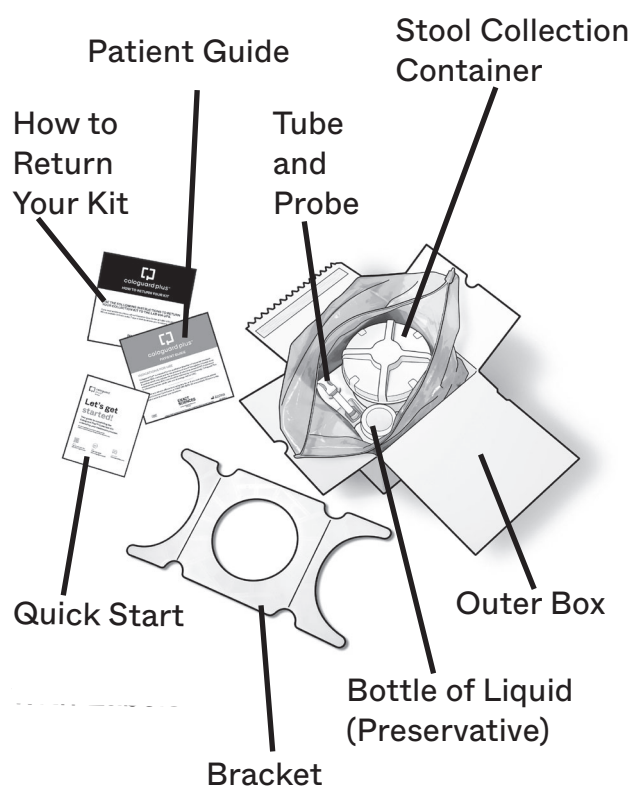
STEP 1: CHECK THE EXPIRATION DATE AND THE KIT

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



- Locate the expiration date on the outside of the box.
- Use the kit before the expiration date printed on the outside of the box.
 - If the date has passed, do **not** collect your sample. Refer to the contact information provided in this guide to request a new kit.

STEP 1 (CONTINUED)



Leave the plastic bag and white tray inside the box.

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

- Patient Guide
- Stool Collection Container
- How to Return Your Kit
- Tube and Probe
- Quick Start Guide with Labels
- Bracket
- Bottle of Liquid (Preservative)
- Outer Box

If any items are missing from your kit, do **not** use the kit.

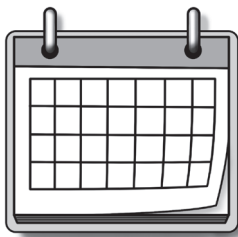
Use the contact information provided in this guide to request a new kit.

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 THE STOOL SAMPLE

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



TIMING YOUR COLLECTION

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 return it promptly.
 - Refer to **How to Return Your Kit** for instructions.
- Do **not** collect a stool sample if you have:
 - Bleeding hemorrhoids
 - Bleeding cuts or wounds on your hands
 - Rectal bleeding
 - Menstrual bleeding
 - Diarrhea

STEP 2 (CONTINUED)



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 collection container out of the box and place on a hard, flat surface.

g.

g. Turn the container lid and unscrew it.

- If the lid sticks, try pushing down or holding the container between your knees to secure it, while turning the lid.

i.

h. Set the container lid aside.

i. Place the stool collection 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 stool collection container.
 - **Your stool sample should be no larger than the bottle of liquid included in the box.**
 - **Try to keep urine from going into the container.**
 - **Do not put toilet paper or other items into the container.**

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

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



Leave
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.

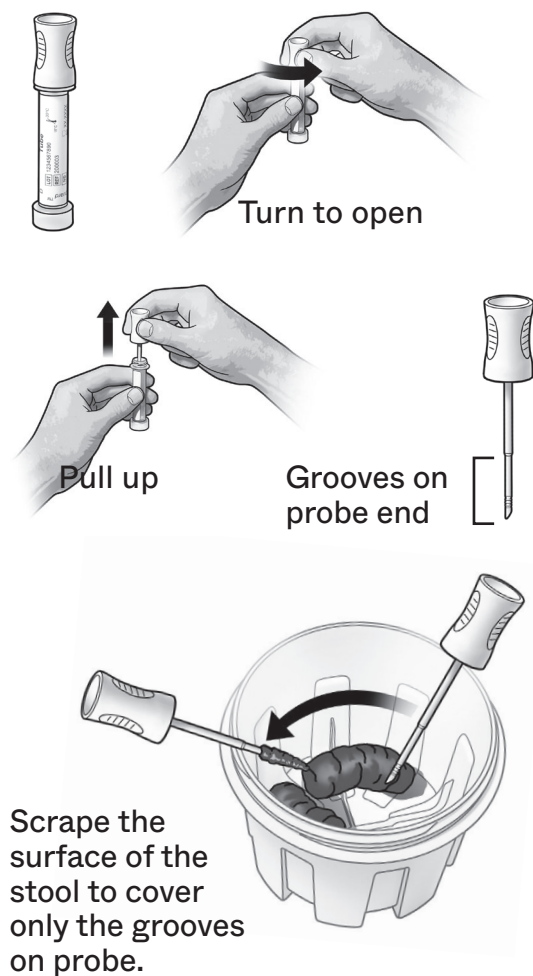
- Follow the rest of the steps in this guide **immediately** after collecting your stool sample.

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

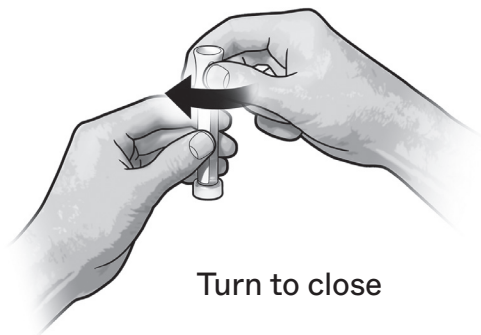
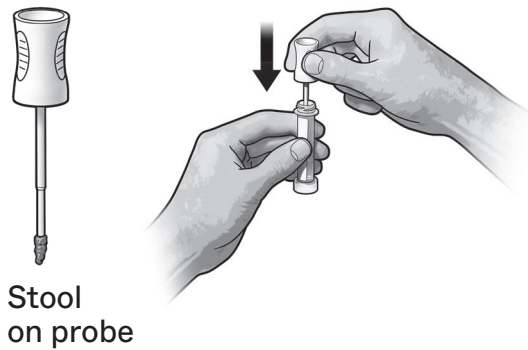
NEXT PAGE

STEP 4: SCRAPE THE STOOL SAMPLE

You must scrape the stool sample with the probe from the tube to get another small sample for the Cologuard Plus 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.
 - You only need to cover the grooves on the probe with stool. **DO NOT FILL TUBE WITH STOOL.**



e.

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

f.

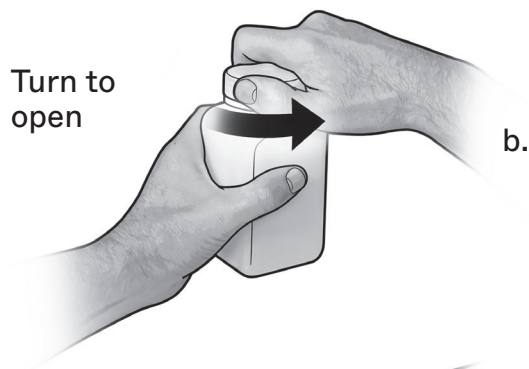
f. Turn the cap to close.

g. Set the tube aside.

Note: Do not place the tube into the stool collection container.

STEP 5: PREPARE STOOL COLLECTION CONTAINER FOR RETURN

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



b.

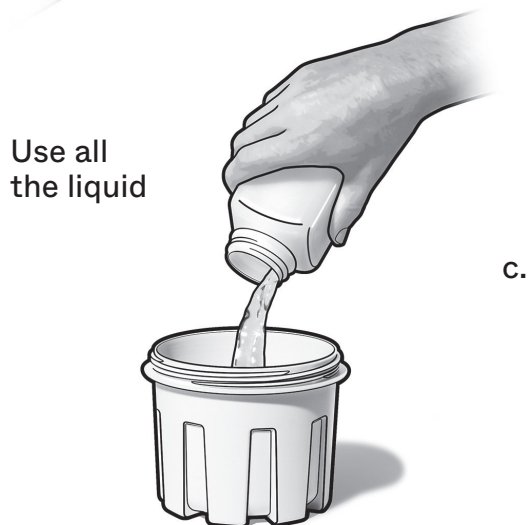
a. Lift the bottle of liquid preservative out of the box.

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.

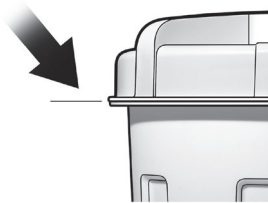
c. Pour **ALL** the liquid in the bottle into the container with the stool.

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

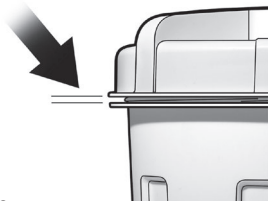
Turn to
close tight



Tight seal
Correct!



Lid with gap
**Wrong:
loosen and
tighten again**



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

e. Place the lid on top of the container.

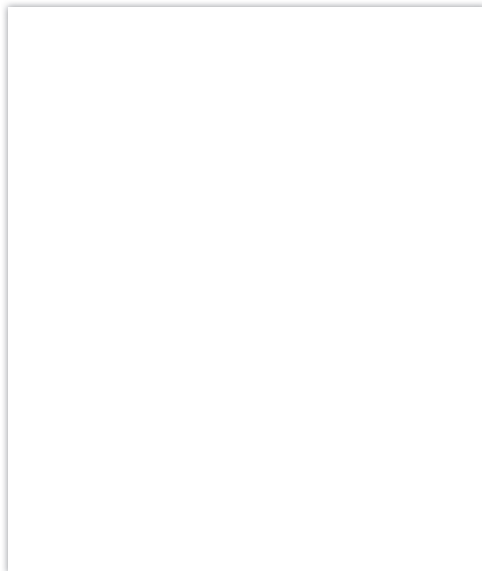
- Make sure the lid is straight so
it will close tightly.

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

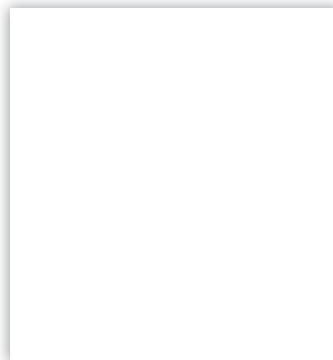
- **Note:** If the lid is not on
correctly, liquid could leak out
of the container.

STEP 6: LABEL YOUR SAMPLES

You **must** label your samples so the lab can identify them. For best results fill out the labels, as indicated below, before you apply them to the containers. Use a ballpoint pen and write on top of a hard, flat surface.



Example
(enlarged for
easier reading)



a.

a. Find the sample labels on the Quick Start Guide included in the kit.

b.

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

- Your first name (as it appears on the shipping label)
- 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; you must also fill in the AM or PM circle



c. c. Peel the label away from the paper.



d. d. Wrap one label around the tube.
• **The label can cover the existing label.**



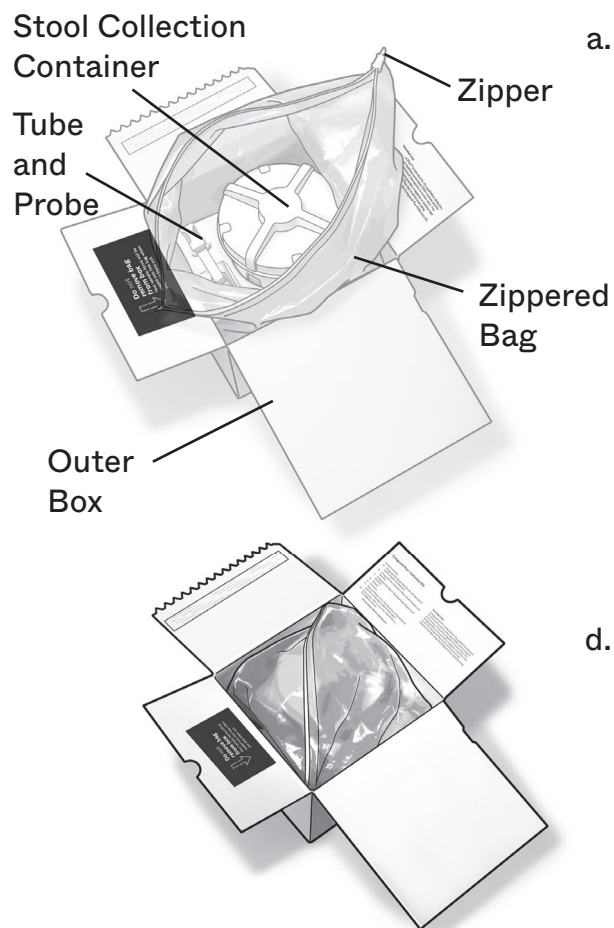
e. e. Place one label on the lid of the stool collection container.

STEP 7: PREPARE YOUR STOOL SAMPLES FOR RETURN

For best results, prepare your box on a hard, flat surface.

When you start, the zippered bag should be inside the box.

The white tray for holding the container and tube should be inside the bag.



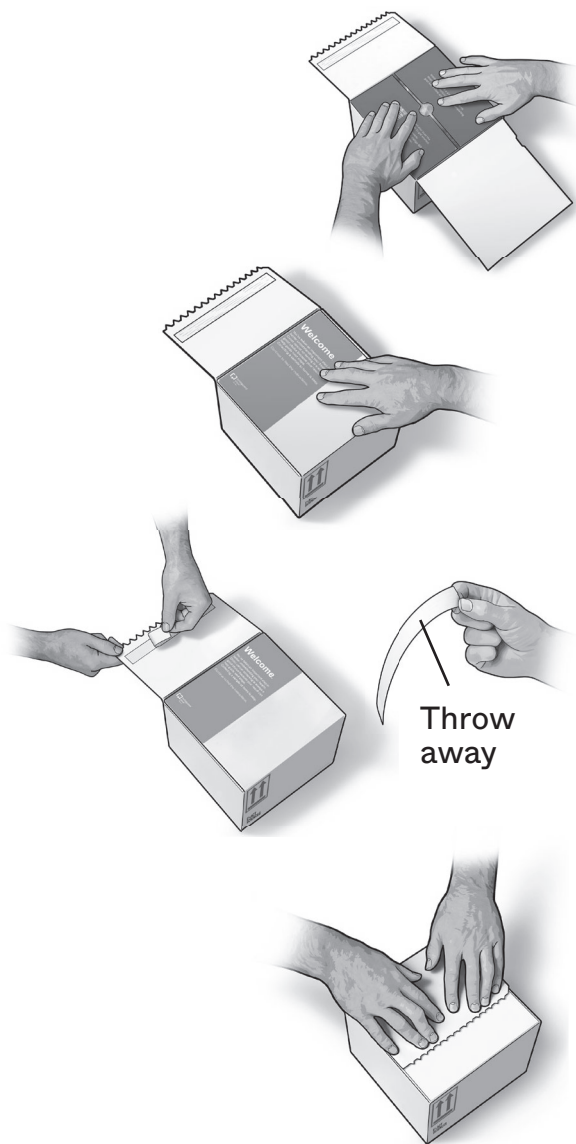
a. Place the tube and stool collection container into the tray inside the box.

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. Fold the bag until it fits inside the box.



- e. e. Fold the smaller flaps over the top of the box.
- f. f. Fold the long flap over the two smaller flaps.
- This is the blue flap with the white writing on it.
- g. g. Peel the paper backing off the tape on the box lid.
- Discard paper backing in garbage.
- h. h. Fold the box top over the other flaps and press down firmly to seal the box.
- i. i. Return your samples. Refer to the instructions in How to Return Your Kit.

GLOSSARY

ADVANCED PRECANCEROUS LESIONS (APL):

A collection of advanced polyps which have the highest likelihood of progressing into cancer based on the size of the lesion and/or what it looks like under a microscope.

COLON:

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

COLORECTAL CANCER (CRC) OR COLON 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 healthcare provider if there is cancer or a possibility of cancer.

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.

SYMBOLS USED ON THE COLOGUARD PLUS COLLECTION KIT

Harmonized and self-defined symbols used on labeling for the kit.



Lot Number



Storage
Temperature



Catalog
Number



Part Number



Expiration
Date



Manufacturer



Contains
Sufficient for
(n) Tests



In Vitro
Diagnostic Use



Caution

CLINICAL STUDY RESULTS

The Cologuard Plus test was studied in a large clinical trial to determine the effectiveness of the test. The trial included more than 18,000 patients at 186 sites in the U.S. The study analysis included adults ages 45 and older. Each person in the study completed the Cologuard Plus test before having a standard colonoscopy. The main purpose of the study was to find out the performance of the Cologuard Plus test for finding cancer and precancer compared to a colonoscopy.

In the clinical study, the Cologuard Plus test correctly detected 95% of colorectal cancers and 43% of advanced precancerous lesions in the study population that had disease. The Cologuard Plus test correctly gave a negative screening result for 91% of the study subjects that did not have colorectal cancer or advanced precancerous lesions. In other words, 9% of people without cancer or precancerous lesions tested positive.





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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

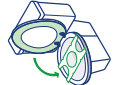
Ship your Collection Kit



1

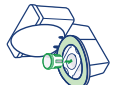
- Look at the section of this guide titled "What the kit includes." The items included in your kit: Unpack all items except plastic bag and white tray at the bottom of the kit.

Tip: Wait to collect your stool sample until you have no diarrhea and have no blood in your urine or stool (which may indicate urinary 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 let the sample touch the sides or bottom of the container.



5

- Unscrew the probe from the tube. Use the probe to scoop a small amount of stool sample.
- Completely cover the groove on the tip of the probe with stool.
- Place the probe in the tube and screw the cap closed.



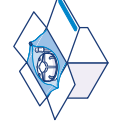
6

- 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 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 adhesive closure strip on the box flap.
 - Remove the top shipping label and attach the prepaid return shipping label.
- Tip:** Keep the box upright, at room temperature, away from moisture 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](https://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/](https://cologuardplus.com/) and receive a text message to the healthcare provider who prescribed your test within 2 weeks.



Scan the QR code to get started

Call 1-844-870-8870
Other languages available



Live Chat at cologuardplus.com

Label your samples

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

Example (Enlarged for easier reading)

First Name	John
Last Name	Doe
Date of Birth	08 / 25 / 61
Date of Collection	05 / 19 / 25
Time of Collection	1:50 PM

- Peel the label away from the paper.
- Wrap one label around the Tube as shown.
- Place one label on the lid of the Container as shown.

Your labels are included on the back of this guide.



Exact Sciences
Madison, WI USA

LBL-10193_QSG Rev 4.12/2024

Rx only



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1 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.

2 Contraindications

The Cologuard Plus test is not indicated for use in patients that 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 colorectal cancer:
 - 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.

3 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 CRC or APL. 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.
- A negative Cologuard Plus test result does not guarantee the absence of cancer or advanced precancerous lesions. Patients with a negative Cologuard Plus test result should continue participating in colorectal screening programs at the appropriate guideline recommended levels.
- 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 provided in with 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.

4 What is cancer screening?

Some types of cancer can be found before warning signs are present. Or they can be found when the disease is in an early stage of growth. Screening checks for cancer (or

for conditions that may lead to cancer) in people who have no warning signs. Screening can help doctors find and treat some types of cancer early. Generally, the earlier colon cancer is detected, the easier it is to treat.

Screening for colorectal cancer (CRC) or colon cancer is the first and most crucial step in finding and preventing colon cancer for adults who are at average risk for colon cancer.

5 Key facts about colon cancer

Many people do not know that colon cancer can be avoided.¹ It is the third most common cancer. It is the second leading cause of cancer deaths in both men and women in the US.² Despite these facts, colon cancer can be treated if it is found early through screening.¹ Yet, about 40% of adults ages 45-75 years are not getting screened.³

Colorectal cancer can be found early, if you are looking for it.¹ Colon cancer grows slowly. It generally starts from small polyps in the colon or rectum.¹ A polyp is a growth on the inside wall of your colon or rectum.¹ Polyps are found in adults younger than 45 and in older adults, too.⁴ While polyps are common and do not usually cause symptoms, some are harmful and can turn into cancer over time.² If polyps are found and removed early, the chances of getting colon cancer can be lowered.⁵ If colon cancer is found early through screening, treatment is most likely to be successful.¹

6 Why should I get screened for colon cancer?

It is easier to treat colon cancer if it is found early. National guidelines recommend that screening starts at age 45.¹ There are different ways of screening for colon cancer. Choosing a colon cancer screening test isn't always an easy decision. It is important to talk to your healthcare provider about when to begin screening for colon cancer and how to choose among the different tests.

7 Choosing the best colon cancer screening test for you

Talk to your healthcare provider. They can help you choose a colon cancer screening test that is right for you. You have options. Here are some of the questions to ask:

- Is the test right for your age, medical history, family history, and general health?

- Can the test find both precancer and cancer?
- How is the test performed?
- Will you need to be sedated?
- How much time will the test take?
- Is the test easy to use?
- Are there any potential harms of the test?
- What care is needed after the test?

8 What is the Cologuard Plus test? Why is it different?

- The Cologuard Plus test is an accurate noninvasive colon cancer screening test.
- It is for patients who are at average risk for colon cancer.
- Patients collect a sample at home.
- The Cologuard Plus test is the colon screening test that uses a stool DNA technology. It is effective in finding both precancer and cancer.

9 What is stool DNA technology?

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. The Cologuard Plus test is designed to detect the DNA and hemoglobin (blood) released from these abnormal cells in your stool.

10 The Cologuard Plus test is easy to use:

Use the Cologuard Plus Collection Kit to collect a stool sample. The kit comes with easy-to-use instructions. You ship your sample back to Exact Sciences Laboratories. The laboratory tests your stool sample and sends the results back to your healthcare provider who prescribed your test. Your results will be shared with you.

You do not need to change your diet or medications to use this screening test.

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

- The Cologuard Plus test finds 95% of colon cancers.
- The Cologuard Plus test is effective because it finds both precancer and cancer.
- In a large clinical study, the Cologuard Plus test found more cancers and precancers than an ordinary fecal blood test (FIT).

The Cologuard Plus test does produce some false positive results. Any positive result should be discussed

with your doctor and followed by a colonoscopy. In the clinical study of the Cologuard Plus test, the Cologuard Plus test detected 95% of colorectal cancers and 43% of precancers. An ordinary fecal blood test (FIT) detected 71% of cancers and 23% of precancers.

12 How do we know the Cologuard Plus test is effective?

The effectiveness of the Cologuard Plus test was proven in a large clinical study. The trial included more than 18,000 patients at 186 sites in the U.S. Each person completed the Cologuard Plus test before having a standard colonoscopy. The main purpose of the study was to find out the performance of the Cologuard Plus test for finding cancer and precancer compared to a colonoscopy.

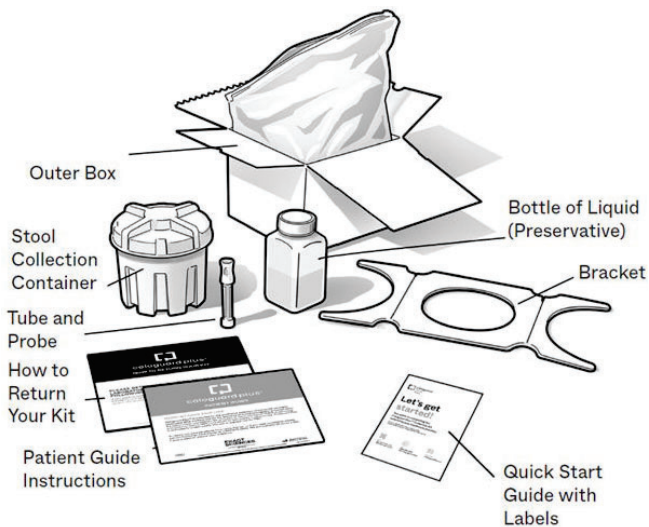
In the study, the Cologuard Plus test:

- Correctly detected 95% of colon cancers and 43% of advanced precancerous lesions in the patients in the study that had disease.
- Correctly gave a negative result for 91% of the study patients that did not have colon cancer or advanced precancer. This means 9% of people without colorectal cancer or advanced precancerous lesions tested positive.

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

The Cologuard Plus test is prescribed by your healthcare provider. It cannot be purchased over the counter. Once your healthcare provider prescribes the Cologuard Plus test, it is easy to collect a sample.

- A collection kit is sent directly to your preferred mailing address. You can store your kit until you are ready to use it. Store it at room temperature in a cool, dry place. Keep away from heat and direct sunlight and out of reach of children.
- Wait to collect your stool sample until you have no diarrhea. Also wait until you have no blood in your urine or stool (such as from hemorrhoids or menstruation). Contact your healthcare provider if you have unexpected bleeding.
- When you are ready, collect a sample in the privacy of your own home.
- After you collect a stool sample, you drop off the collection kit at any UPS store or call to schedule a pickup. Your sample 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 result to the provider who ordered your test.



- If you have any questions or concerns, call the Customer Care Center toll free at 1-844-870-8870. Representatives are available 24/7. Or chat with someone and find help at www.cologuardplus.com.

14 Understanding your results

Your healthcare provider 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 possible signs of precancer or colorectal cancer from your stool sample.
 - Out of 100 patients testing positive, approximately 3 patients will have CRC, 34 will have APL, 33 will have a non-advanced adenoma, and 30 will have no neoplastic findings.
- Talk to your healthcare provider about your test result. Any Positive Result should be followed by a colonoscopy.
- A colonoscopy is recommended to determine if cancer or precancer is present (True Positive) or not (False Positive).
- 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 signs of precancer or colorectal cancer from your stool sample.
 - Out of every 10,000 patients testing negative,

approximately 2 patients 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.

- The test can also have a Negative Result that is incorrect (False Negative). This means the test missed a potential cancer or precancer.
- Talk to your healthcare provider about your test result. They 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, you may be asked to provide another stool sample to test.

15 The Cologuard Plus test may not be for everyone

Talk with your healthcare provider about using the Cologuard Plus test if any of the Contraindications apply to you.

16 What are the risks associated with using the Cologuard Plus test?

The risks related to using the Cologuard Plus Collection Kit are low. No serious adverse events were reported among 18,911 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.

17 Cologuard Plus test Precautions

- **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 the area with water.

18 Who can I call if I have questions?

If you have questions, please call the Exact Sciences Laboratories Customer Care Center. You may also find helpful resources online (<http://www.cologuardplus.com>).

Phone Number: 1-844-870-8870

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

19 References

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20 Trademarks and Copyright

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**Do not
remove bag
from box**
Your sample items will be
sealed into this bag when
you ship them out.

Colguard Plus™ Collection Kit

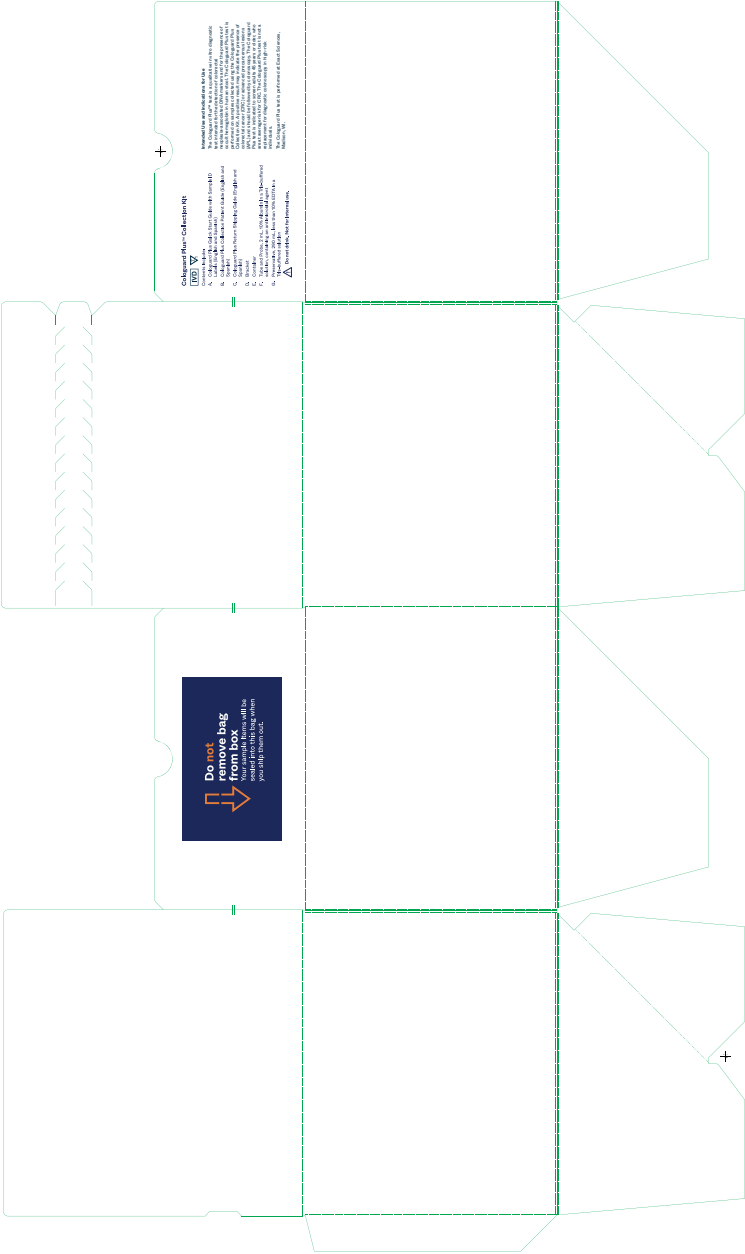
- Contents Include:**
- A. Colguard Plus™ Quick Start Guide with Sample ID Label (English and Spanish)
 - B. Colguard Plus Collection Patient Guide (English and Spanish)
 - C. Colguard Plus Return Shipping Guide (English and Spanish)
 - D. Boxer
 - E. Combiter
 - F. Tube and Probe, 2 mL, 10% Abumin in a Tris-buffered Preservative, 200 mL, less than 10% EDTA in a Tris-buffered solution
 - G. **Do not drink, Not for Internal Use.**

Intended Use and Indications for Use

The Colguard Plus™ test is an in vitro diagnostic test intended for the detection of colorectal cancer (CRC) in stool samples collected at home or about 1000 miles from a hospital. The Colguard Plus test is performed at a laboratory. A sample collected using this Colguard Plus test is not a replacement for diagnostic colonoscopy in high-risk individuals. The Colguard Plus test is performed at Exact Sciences, Madison, WI.

INNER LINER

EXACT SCIENCES5656 Eisenhower LaneMadison, WI 53719 CONFIDENTIAL May not be reproduced or disseminated outside of Exact Sciences without permission.			
Design Description	Printed Part Number	Label Part Number and Revision	File Name
CARTON, COLOGUARD 2.0 COLLECTION KIT – INNER LINER	305037	LBL-11105_INNER CARTON REV 5	LBL-11105_Inner Carton Rev. 5 Colguard 2 Collection KIT.PDF
Material	Size	Color	Effective Date
BLEACHED 32 LB INNER LINER	PMS 2757-C, PMS 7577-C	(SEE CARTON-OUTSIDE INFORMATION)	12-03-2024
Blank Size	Coating	Pre-Add	Sealer & Fill Software Application
34-7/16" W x 20-3/164 H	GLOSS AQUEOUS COATING	(SEE CARTON-OUTSIDE INFORMATION)	ADDBE ILLUSTRATOR (28.7.1, WINDOWS)
Folded Carton Dimensions (SEE FILE FOR OUTSIDE INFORMATION)	Printing (SEE FILE FOR OUTSIDE INFORMATION)	Special Instructions (SEE FILE FOR OUTSIDE INFORMATION)	LAURA CLARK



OUTSIDE VIEW

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Design Name	CARTON, COLOGUARD PLUS COLLECTION KIT - OUTER			Product Part Number	Labels Part Number and Revision		File Name
	CARTON, COLOGUARD PLUS COLLECTION KIT - OUTER			355507	LBL-11105_OUTER CARTON REV.5		LBL-11105_Out Carton Rev.5 Cologuard 2 Collection Kit.Pdf
Material	BLEACHED, 32 LB (ECT) E-FLUTE MEDIUM			1000	PANTONE BLACK C6		Colors
	12 PT SBS C15 OUTER LINER			Coloring	PMS 602-C, PMS 7077-C		Effective Date
Marking Size	34.716" W x 20.3164 H			Gloss	YES		Source File Software Application
	8-3/8" W x 6-3/8" D x 5-5/16" H			Print on Outer & Inner Liner (SEE FILE ON OUTER LINER)	ONE, 3/4" ADHESIVE, 1-1/4" LINER ADHESIVE FINGER LIFT TAPE		Adobe Illustrator (25.7.1, ILLUSTRATIONS)
							Created By
							LAURA CLARK