

# Let's get started!

A quick guide on how to use your **Cologuard**<sup>®</sup> collection kit ordered by your healthcare provider

Your kit is on the way. For more detailed instructions, please see the **Patient Guide** inside your Cologuard kit when it arrives



Watch  
How To Use video at  
[Cologuard.com/use](https://Cologuard.com/use)



Call  
1-844-870-8870



Live Chat  
at [Cologuard.com](https://Cologuard.com)

## What the kit includes



Shipping box



Patient Guide



How to return your kit



Labels



Liquid preservative



Tube and probe



Collection container



Bracket

### Indications for Use

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

### Contraindications

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

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

### Warnings and Precautions

- The performance of Cologuard has been established in a cross-sectional study (i.e., single point in time). Programmatic performance of Cologuard (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with Cologuard. Non-inferiority or superiority of Cologuard programmatic sensitivity as compared to other recommended screening methods for CRC and AA has not been established.
- The clinical validation study was conducted in patients 50 years of age and older. ACS Guidelines recommend screening begin at age 45. Cologuard

performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.

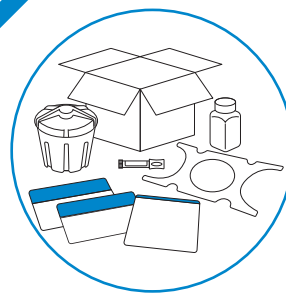
- CRC screening guideline recommendations vary for persons over the age of 75. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with a healthcare provider. Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program with another recommended screening method. The screening interval for this follow-up has not been established.
- Cologuard may produce false negative or false positive results. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps. A false negative result occurs when Cologuard does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.
- Patients should not provide a sample for Cologuard if they have diarrhea or if they have blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation).
- To ensure the integrity of the sample, the laboratory must receive the patient specimens within 96 hours of collection. Patients should send stool samples to the laboratory according to the instructions stated in the Cologuard Patient Guide.
- Patients should be advised of the caution listed in the Cologuard Patient Guide. Patients should NOT drink the preservative liquid.
- The risks related to using the Cologuard Collection Kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain. Rx only.

## Set up your collection kit

## Collect your stool sample

## Ship your collection kit

### 1

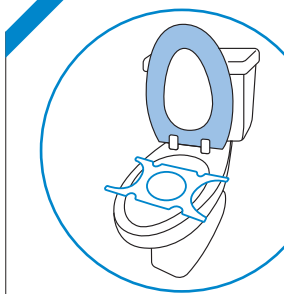


- Check out the previous page, where the kit components are pictured. Unpack all components except plastic bag and white tray at the bottom of the kit

**Tip:**  
Wait to collect your stool sample until you have no diarrhea from illness and have no blood in your urine or stool (such as from hemorrhoids or menstruation)

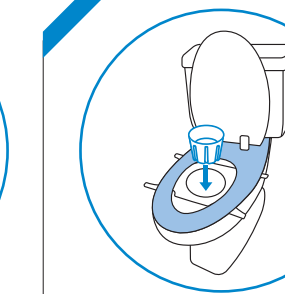
Contact your healthcare provider if you have unexpected bleeding

### 2



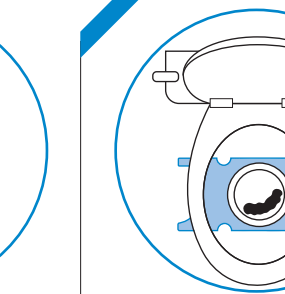
- Empty your bladder before setting up the bracket
- Place the bracket under the seat on the toilet bowl

### 3



- Lower the toilet seat
- Unscrew the collection container lid by pushing it down and turning counterclockwise
- Once open, place the container in the bracket

### 4



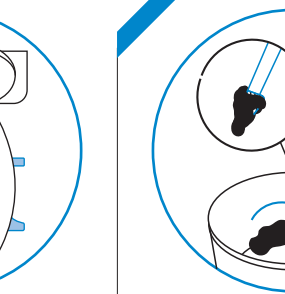
- Sit on the toilet and have a bowel movement into the container

**Tips:**  
Your stool sample doesn't have to be perfect, but should reflect whatever is normal for you

Your stool sample should not be larger than the liquid preservative bottle

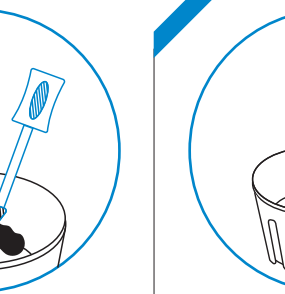
Don't worry if a bit of urine gets in the container

### 5



- Unscrew the probe from the tube. Use the probe to scrape 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

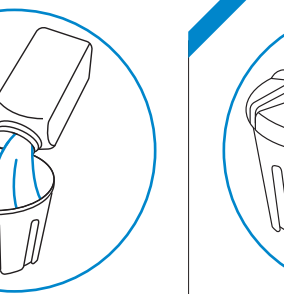
### 6



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

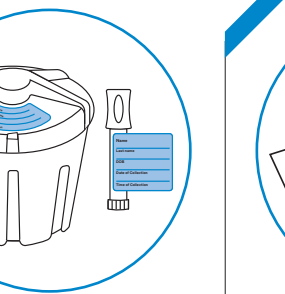
**Tip:**  
It's OK if the stool sample isn't completely covered

### 7



- Fill out both labels
- Place one on the container lid and one around the tube

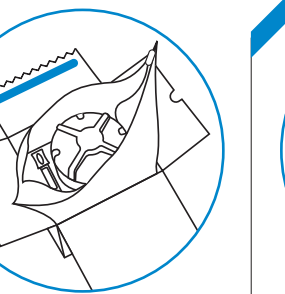
### 8



- Place the container and tube back into the white tray in the original shipping box, and dispose of all other items
- Close the zipper across the top of the bag to close
- Seal the box with the attached adhesive strip on the box flap
- Remove the top shipping label to expose the prepaid return shipping label

Nicely done. You're all set to ship!

### 9



- Ship your kit back to UPS<sup>®</sup> the same day or next day after collection

**Return options:**

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

- Sign up to view your result online at Cologuard.com/result. Results are sent to your healthcare provider within 2 weeks.