

3 Tips for Cologuard® collection kit completion



1 Discuss with your patients the importance of early screening

- Explain how early screening is important because when detected in early stages, colorectal cancer (CRC) is more treatable^{1*}

2 Ensure your patients understand the process

- Let them know that they should expect a welcome call from the Customer Care Center
- Recommend that they store the Cologuard collection kit on the back of their toilet
- Clarify with them what is considered an acceptable stool sample
 - It should not be larger than the bottle of liquid in the kit and should not be provided if there is diarrhea or blood in the stool

3 Provide tips and set expectations for collection kit completion

- Provide a 2-week time frame for them to return the Cologuard collection kit
- Explain how the sample should be shipped back within one day of collection and be mindful of weekends/holidays to prevent shipping delays

Patients should not provide a sample to Cologuard if they have diarrhea or if they have blood in their urine or stool (eg, from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation). 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 lid to avoid the risk of hand strain.²



See frequently asked questions about Cologuard

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Indication and Important Risk Information

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, 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.

Cologuard is not for high-risk individuals, including patients with a personal history of colorectal cancer and adenomas; have had a positive result from another colorectal cancer screening method within the last 6 months; have been diagnosed with a condition associated with high risk for colorectal cancer such as IBD, chronic ulcerative colitis, Crohn's disease; or have a family history of colorectal cancer, or certain hereditary syndromes.

Positive Cologuard results should be referred to diagnostic colonoscopy. A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient.

False positives and false negatives do occur. In a clinical study, 13% of patients without colorectal cancer or advanced adenomas received a positive result (false positive) and 8% of patients with cancer received a negative result (false negative). The clinical validation study was conducted in patients 50 years of age and older. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.

Cologuard performance when used for repeat testing has not been evaluated or established. Rx only.

*Based on 5-year survival.

References: 1. National Cancer Institute. Cancer stat facts: Colorectal cancer. <https://seer.cancer.gov/statfacts/html/colorect.html>. Accessed April 22, 2020. 2. Cologuard® Physician Brochure. Madison, WI: Exact Sciences Corporation.