

Patient Cologuard[®] Rescreen Letter From GI

Entities using this material are responsible for, and should pay close attention to, the accuracy of the information about the specific circumstances in which they distribute these materials. This template is provided to any appropriately requesting entity, regardless of the manner in which they recommend or participate in the ordering of Cologuard, and is not intended to interfere with the individualized care decision made between the provider and patient.

Dear [Patient Name]:

Use if patient last screened with Cologuard:

Our records here at [provider/network office name] indicate that the last time you screened for colon cancer, you used a Cologuard[®] Collection Kit. According to the American Cancer Society, the recommended screening interval for colon cancer using Cologuard as a screening method is once every three years.¹ If you are still at average risk for colon cancer,* then using Cologuard again may be appropriate.

Use if patient last screened with a method other than Cologuard:

Our records here at [provider/network office name] indicate that you are due for a colon cancer screening. The last time you screened for colon cancer, you [had; used] a [screening method]. This year, if you are still at average risk for colon cancer,* Cologuard[®] may be an appropriate alternative screening method.

Cologuard is a noninvasive and easy-to-use test. No special preparation, diet, or change in medication is needed, and no time off is required. You collect a single stool sample in the privacy of your own home using this kit, then send it to Exact Sciences Laboratories via prepaid UPS[®] pickup without ever leaving your house.²

For your convenience, Cologuard has a patient navigation program backed by an expert customer care team that offers you support at every step of the screening process.

As you may know, colon cancer is the second leading cause of cancer deaths in the United States, taking the lives of approximately 53,000 Americans this year alone.³ Fortunately, there is much we can do because, with regular screening, it can be caught in the early stages, when it is highly treatable.^{4-6†}

For these reasons, I encourage you to continuously undergo regular screening for colon cancer. Please call our office to determine if Cologuard is right for you. If you have any questions or want to learn more about Cologuard, feel free to visit www.cologuard.com.

[Sign off]

[GI contact information]

*Average risk: no history of colon cancer or adenoma, no family history of colon cancer, no inflammatory bowel disease, and no hereditary syndromes associated with a high risk of colon cancer, including familial adenomatous polyposis and hereditary nonpolyposis colon cancer (commonly known as Lynch syndrome).²

†Based on 5-year survival.⁵

Indications and Important Risk Information

Cologuard is intended to screen adults 45 years of age and older who are at average risk for colorectal cancer by detecting certain DNA markers and blood in the stool. Do not use if you have had adenomas, have inflammatory bowel disease and certain hereditary syndromes, or a personal or family history of colorectal cancer. Cologuard is not a replacement for colonoscopy in high risk patients. Cologuard performance in adults ages 45-49 is estimated based on a large clinical study of patients 50 and older. Cologuard performance in repeat testing has not been evaluated.

The Cologuard test result should be interpreted with caution. A positive test result does not confirm the presence of cancer. Patients with a positive test result should be referred for colonoscopy. A negative test result does not confirm the absence of cancer. Patients with a negative test result should discuss with their doctor when they need to be tested again. False positives and false negative results can occur. In a clinical study, 13% of people without cancer received a positive result (false positive) and 8% of people with cancer received a negative result (false negative). Rx only.

References: 1. Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin.* 2018;68(4):250-281. 2. Cologuard[®] Clinician Brochure. Madison, WI: Exact Sciences Corporation. 3. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. *CA Cancer J Clin.* 2022;72(1):7-33. 4. Davidson KW, Barry MJ, Mangione CM, et al. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. *JAMA.* 2021;325(19):1965-1977. 5. American Cancer Society survival rates for colorectal cancer. Accessed August 17, 2022. <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html>. 6. American Cancer Society. *Cancer Facts & Figures.* Atlanta, GA: American Cancer Society; 2022.

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