

## Declined Colonoscopy Letter From GI

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To: [Office Name]

Attn: [Provider Name]

[I want to let you know that the patient you referred to our office, [Patient Name – (DOB xx/xx/xxxx)], has declined their colonoscopy at this time.] [I want to let you know that the patient you referred to our office, [Patient Name – (DOB xx/xx/xxxx)], was not present at their appointment for a colonoscopy.]

Stressing the importance of screening for colorectal cancer (CRC) to patients is important to us. That is why I am informing you of [Patient Name]'s screening status.

I encourage having a discussion with [Patient Name] and applying a shared decision-making approach because it is crucial that patients understand the importance of regular screening and are offered choices to help them complete their screening. In one study, when participants were offered more than one choice for screening, adherence rates almost doubled.<sup>1</sup>

I have identified this patient as average risk for CRC, so I recommend offering alternatives to colonoscopy such as Cologuard®, an easy-to-use, noninvasive screening test.<sup>2</sup> Please contact our office at the number below if you have any concerns or questions regarding this process.

Thank you for all you do to help improve CRC screening rates. I am eager to see how far we can take this initiative with your commitment to a shared decision-making approach. Together, we can improve outcomes for patients in a truly meaningful way. Please feel free to contact me if you have any questions.

[Sign off]

[GI contact information]

## Indications 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 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 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.

**References:** 1. Inadomi JM, Vijan S, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med.* 2012;172(7):575-582. 2. Cologuard® Clinician Brochure. Madison, WI: Exact Sciences Corporation.

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