To: [Office Name]

Attn: [Provider Name]

[We want to let you know that the patient you referred to our office, [Patient Name], has declined their colonoscopy at this time.] [We want to let you know that the patient you referred to our office, [Patient Name], was not present at their appointment for a colonoscopy.]

[GI Group Name or Individual Provider Name] believes that getting patients screened is a national priority. That is why we are informing you of the patient's screening status. Following up with them may help you to better understand their barriers to colorectal cancer (CRC) screening.

I have identified this patient as average risk for CRC, so I have ordered a Cologuard® test on the patient’s behalf. Please contact our offices at the number below if you have any concerns or questions regarding this process.

Cologuard is a noninvasive screening option for your patients 45 years of age or older who are at average risk for CRC and due for screening. A positive result does not necessarily mean the patient has colorectal cancer; it means that Cologuard detected elevated levels of altered DNA and/or hemoglobin in the patient’s stool. Patients with a positive result should have a diagnostic colonoscopy as soon as possible, which may involve a cost share. Under normal circumstances, follow-up colonoscopy within 3 months of a positive stool test has been recommended.1

If the Cologuard result is negative, the patient should continue participating in a screening program at an interval and a method appropriate for the individual patient. American Cancer Society guidelines recommend rescreening in 3 years.2

Please feel free to contact me if you have any questions.

[GI contact information]

[Sign off]

**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 cancerm(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.

**References: 1.** Doubeni CA, Gabler NB, Wheeler CM, et al. Timely follow-up of positive cancer screening results: A systematic review and recommendations from the PROSPR Consortium. CA Cancer J Clin. 2018;68(3):199-216. **2.** Wolf A, Fontham E, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA Cancer J Clin. 2018;68:250-281.

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