To: [Office Name]

 Attn: [Provider Name]

Colorectal cancer (CRC) screening is a national priority. However, [due to limited health care visits in this uncertain time,] we believe a large part of the population is going unscreened, or not being screened on time, for CRC. We also believe that, together, we can achieve the National Colorectal Cancer Roundtable’s screening goal of 80% in every community.1

This is why I support and endorse an informed decision-making approach between you and your patients that offers choices, including guideline-recommended, noninvasive screening modalities alongside colonoscopy to help improve CRC screening rates in our local community.

To be clear: for all of your patients at high risk for CRC, colonoscopy is the recommended screening option, but for patients at average risk for CRC, the U.S. Preventive Services Task Force guidelines include multiple screening modalities for CRC screening, including other noninvasive tests.2 In the past, if a patient fits the approved criteria below, I have discussed Cologuard® with them, and here is why I recommend it.

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. [It can be used at home, allowing for CRC screening to continue even while social distancing practices are in place.] After Cologuard is prescribed, the Cologuard Collection Kit will be sent directly to the patient’s home, and the patient can easily return it to Exact Sciences Laboratories by scheduling an at-home pick up by UPS®.

Additionally, Cologuard is significantly more sensitive than fecal occult blood testing (OC FIT-CHEK, Polymedco Inc.) for early and all stages of CRC, as well as precancerous polyp detection, as shown in a prospective, head-to-head, 10,000-patient study of individuals 50-84 years of age at average risk for CRC.3

Cologuard is not for patients at increased CRC risk due to a family history of colorectal cancer or a personal history of colorectal cancer or adenoma, irritable bowel disease, and certain hereditary syndromes. Cologuard is also not a replacement for diagnostic or surveillance colonoscopy.4 With Cologuard, there is a chance for false positives and false negatives.

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. This may involve a cost share. Under normal circumstances, follow-up colonoscopy within 3 months of a positive stool test has been recommended.5

If the Cologuard result is negative, the patient should continue participating in a screening program at an interval and method appropriate for the individual patient. American Cander Society guidelines recommend rescreening in 3 years.6 [I am committed to screening patients for CRC by offering them choices, especially during these uncertain times.]

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

[Sign off]

[GI contact information]

**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 diagnostic 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.** National Colorectal Cancer Roundtable. 80% in Every Community. https://nccrt.org/80-in-every-community/. Accessed November 3, 2020. **2.** Bibbins-Domingo K, Grossman DC, U. S. Preventive Services Task Force, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA. 2016;315(23):2564-2575. **3.** Imperiale TF, Ransohoff OF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. N Engl J Med. 2014;370(14):1287-1297. **4.** Exact Sciences Corporation. Cologuard® Physician Brochure. Madison, WI. **5.** 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. **6.** 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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