

Dear

We healthcare providers know that colorectal cancer (CRC) screening is a national priority, as together, we strive to achieve the National Colorectal Cancer Roundtable's screening goal of 80% in every community.<sup>1</sup> However, due to limited health care visits during this uncertain time, we believe that a large part of the population is going unscreened or not being screened on time for CRC.

I support and endorse an informed decision-making approach between you and your patients that offers choices, including guideline recommended non-invasive 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, optical colonoscopy is the recommended screening option. And for patients at average risk for CRC, the non-invasive screening option I recommend most often is Cologuard<sup>®</sup>. It is significantly more sensitive than fecal occult blood testing (OC FIT-CHECK, Polymedco Inc.) for early stages 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.<sup>2</sup> In addition to being highly sensitive, Cologuard is a non-invasive screening option for your patients 45 years of age or older who are at average risk for CRC and due for screening. Cologuard 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 is easily returned to Exact Sciences Laboratories by scheduling an at-home pick up by UPS<sup>®</sup>.

Cologuard is not for patients at increased CRC risk, due to a family history of colorectal cancer, a personal history of colorectal cancer or adenoma, IBD, and certain hereditary syndromes. Cologuard is also not a replacement for diagnostic or surveillance colonoscopy.<sup>3</sup> With Cologuard, there is a chance for false positives and false negatives.

When you prescribe Cologuard and your patient completes the test, you will receive a "positive" or "negative" result. Positive tests may reflect the presence of CRC or advanced adenoma.<sup>2</sup> 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.<sup>6</sup> During the COVID-19 pandemic, the major GI societies (AASLD, ACG, AGA, ASGE) have advised that, for most asymptomatic patients with either a positive Cologuard or FIT test, "colonoscopy should be considered non-urgent and can be delayed by at least 4-6 weeks and reassessed."<sup>4</sup>

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. Guidelines recommend re-screening with Cologuard again in three years.<sup>5</sup>

I am committed to screening patients for CRC by offering them choice especially during these uncertain times.

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

  
  
  
  
  

References:

1. National Colorectal Cancer Roundtable. 80% In Every Community. <https://nccrt.org/80-in-every-community/>. Accessed May 19, 2020.
2. Imperiale TF, Randssohoff OF, Itzkowitz SH, et Al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med*. 2014; 370(14):1287-1297.
3. Exact Sciences Corporation. Cologuard<sup>®</sup> Physician Brochure. Madison, WI.
4. ACG. COVID-19 and GI. Gastroenterology Professional Society guidance on endoscopic procedures during the COVID-19 pandemic. <https://gi.org/media/covid-19-and-gi/>. Updated March 31, 2020. Accessed May 19, 2020.
5. 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.
6. Doubeni CA, Gabler NB, Wheeler CM, et al. Timely follow-up of positive cancer screening results: A systematic review and recommendations from PROSPR Consortium. *CA Cancer J Clin*. 2018;68(3):199-216.