

MEMORANDUM

TO: Regional Medical Laboratory Clients

FROM: Gerald C. Miller, PhD, Chief of Immunology & Microbiology
Brenda Ghavami MT (ASCP), Executive Director

DATE: November 17, 2014

SUBJECT: Cologuard - New DNA test for Colorectal Cancer (CRC) Screening

On August 11, 2014, the Food and Drug Administration (FDA) approved Cologuard, a noninvasive fecal DNA test for the qualitative detection of colorectal neoplasia associated DNA markers and the presence of occult hemoglobin in stool.

A large study having 10,023 patients compared Cologuard to the fecal immunochemical test (FIT), a commonly used stool test for screening colorectal cancers. Cologuard detected 92% of colorectal cancers and 42% of advanced precancerous polyps, compared to the FIT screening test, which detected 74% of cancers and 24% of advanced polyps. Cologuard appears to have good potential at detecting cancer but misses more pre-cancers. It has been demonstrated to rule out colon cancer only 87% of the time versus 95% for the FIT test. Thus, the Cologuard test directs 13% of the patients to have follow-up colonoscopies which were not needed, since the patient did not have cancer. Another point of view would be that if the goal is to screen everyone prior to going to a colonoscopy, the Cologuard would direct 87% of patients to avoid colonoscopy.

However, it must be recognized that “Colonoscopy is the gold standard.” Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in people at high risk for CRC, although it is being marketed as an alternative. Patients with a positive Cologuard test result should be referred right away for diagnostic colonoscopy. A clinician must prescribe the new test, but patients collect their stool samples at home and ship the specimens to a specified laboratory via prepaid mailer. The company making the test has decided to work with physicians and patients directly. At this time, they will not involve any other laboratories that could facilitate the performance of the test by them. The patient must work directly with the company via their website.

Cologuard is now covered for all Medicare patients. The out-of-pocket cost for Cologuard varies depending on patient insurance company. A \$50 nonrefundable prepayment and a signed Assignment of Benefits will be required before testing can be performed. The cost of Cologuard test for self-pay patients is \$599 versus about \$25 for the current stool blood tests.

Only about 60% of people recommended for colonoscopy screening actually get screened. Thus, if a larger percent of patients is willing to participate in colorectal screening using the Cologuard test, then it becomes a viable screening test. The take-home message is that the sensitivity of the test is 92% and its specificity is 87% in an average risk population. Even though Cologuard has promise, it has yet to prove itself in more in-depth studies. The present concern with the test is the false positive rate.

For more information on how to order the test, collect the specimen or billing questions, visit their website at: www.cologuardtest.com/hcp.

If you have any questions or concerns, please feel free to Dr Gerald Miller 918-744-2555, ext 15543 or email at gmliller@sjmc.org.