



COLOGUARD® ISSUE OVERVIEW

Colorectal cancer is often considered the most preventable, yet least prevented cancer in the United States¹ and is the second leading cause of cancer-related death in the U.S.² Colon cancer is cancer of the large intestine (colon), the lower part of the digestive system. Rectal cancer is cancer of the last several inches of the colon. Most colorectal cancers develop slowly over several years. Before cancer develops, a polyp—a non-cancerous growth—usually appears on the inner lining of the colon or rectum. The identification and removal of these polyps, through routine screenings, can effectively prevent colorectal cancer. Most polyps and early stage cancers cause no symptoms, so adherence to routine screenings is critical in detecting cancer.

While colorectal cancer is highly treatable when caught early, lack of compliance with screening often leads to late-stage detection. In more than 60% of all cases, colorectal cancer is not detected until its late stages, making treatment difficult and survival rates low.³ The five-year survival rate for colon cancer found at late stage is 12%. For those whose cancer is detected at an earlier stage, the five-year survival rate can be greater than 90%.⁴

American Cancer Society screening guidelines call for men and women at average risk for the disease to begin colorectal screening at age 50, while those with a family history and those in certain racial groups, including African-Americans, should be screened starting at age 45. More than half of colorectal cancer-related deaths could be avoided with regular screenings⁵, yet 23 million Americans age 50 and over do not get screened for CRC as recommended.⁶ Among some groups, including Hispanics, African-Americans, Medicare patients and low income Americans, screening rates are even lower.

When it comes to colorectal cancer screening, new noninvasive screening options are needed to address patient compliance issues. Currently, colonoscopy is the gold standard procedure used to diagnose colorectal cancer. However, low screening rates prove many patients are unwilling to undergo colonoscopy because the procedure is invasive, expensive and usually requires bowel preparation including a clear liquid diet and laxatives. Colonoscopy also requires the patient to be sedated during the procedure, requiring time off from work and transportation needs. Another invasive procedure called sigmoidoscopy takes less time, but still requires fasting and laxatives to prepare for the procedure and sedation. Noninvasive colon cancer screening tests, such as a fecal occult blood test (FOBT) and fecal immunochemical test (FIT), are designed to detect blood not seen by the naked eye in the stool. However, because there are unrelated conditions that can cause blood in the stool, and not all polyps or lesions actively bleed on a regular basis, these test may not be reliable on their own for the detection of cancer.

About Cologuard®

Cologuard® is an FDA approved screening test that detects both altered DNA and blood biomarkers in the stool known to be associated with colorectal cancer and precancer. Every day, cells are shed from the colon wall during the digestion process. As part of this process, normal cells along with altered cells

from precancer or cancers are shed into the colon. The stool picks up those cells as it passes through the colon. Cologuard is designed to detect DNA and blood in the stool.

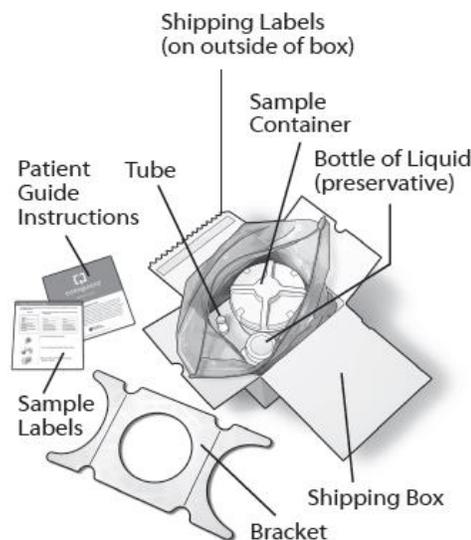
Cologuard does not require medication or dietary restrictions prior to taking the test, and requires no bowel preparation. After testing, the lab provides the patient's physician with the results. A negative test result means that the test did not detect altered DNA and/or blood in the sample. A positive Cologuard test means that the test detected altered DNA and/or blood that could be caused by advanced adenomas or cancer in the colon or rectum. Any positive result should be followed by a diagnostic colonoscopy.

In a prospective, 90-site, 10,000-patient [pivotal study](#), Cologuard detected 92 percent of cancers and 69 percent of the most advanced precancerous polyps in average risk patients.

Cologuard is intended for men and women 50 years or older at average risk for colorectal cancer. Cologuard makes it easy for patients to take the test at their convenience without having to worry about making an appointment, taking time off of work or securing transportation.

How taking Cologuard works:

1. The patient's healthcare provider prescribes Cologuard to the patient.
2. The patient receives the Cologuard kit in the mail, which includes two collection containers—one to collect stool for sDNA testing; the second for blood testing.
3. After collecting a stool sample in the collection container and tube, the patient pours a solution into both to preserve the integrity of the sample as it is transported to the lab.
4. The patient then simply ships the Cologuard kit back to the lab via UPS.
5. At the lab, samples are processed through a series of sophisticated, automated processes to isolate specific DNA targets and to detect the presence of blood.
6. After testing, the patient learns of their results directly from their prescribing healthcare provider. If the test comes back positive, the doctor will refer the patient for a colonoscopy. If the test is negative, the patient should speak with his or her physician to discuss next steps in the screening process and protocol.



To learn more, visit CologuardTest.com or www.exactsciences.com, where you can sign up for the company's eNewsletter or call 1-844-870-8870. Or visit the informational site on colon cancer and the importance of screening and early detection at <http://www.beseengetscreened.com/>.

¹ JNCI J Natl Cancer Inst (2009) 101 (18): 1225-1227. doi: 10.1093/jnci/djp273 First published online: August 21, 2009: <http://jnci.oxfordjournals.org/content/101/18/1225.full.pdf+html>

² American Cancer Society statistics:

<http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics>

³ SEER Cancer Statistics Review, 1975-2009 (Vintage 2009 Populations), National Cancer Institute

⁴ American Cancer Society Colorectal Cancer Facts & Figures 2011-2013:

<http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-028312.pdf>

⁵ Centers for Disease Control and Prevention (CDC): "Colorectal Cancer

Screening Saves Lives" brochure: http://www.cdc.gov/cancer/colorectal/pdf/SFL_brochure.pdf.

⁶ Centers for Disease Control and Prevention (CDC): "Vital Signs: Colorectal Cancer Screening":

<http://www.cdc.gov/vitalsigns/colorectalcancerscreening/>