

Immunochemical Colorectal Cancer Screening An Improved Fecal Occult Blood Test

Colorectal cancer (CRC) is the third most frequently diagnosed cancer among men and women in the US. Excluding deaths from lung cancer, CRC is the most common cause of cancer deaths for men and women combined. According to current estimates, CRC will develop in about 5.9% of the population during their lifetime.¹

CRC is a type of cancer for which screening is particularly effective. Screening can detect adenomatous polyps, precursors to cancer that can be successfully removed thereby preventing the cancer from occurring. Screening can also detect early-stage CRC when it is amenable to treatment, as evidenced by the fact that 90% of patients diagnosed with localized disease are alive five years after diagnosis. Currently, however, only about 37% of colorectal cancers are diagnosed at this stage, reflecting low rates of awareness about the disease.¹

There are two recent sets of guidelines regarding colorectal cancer screening and prevention, one from the US Preventive Services Task Force (USPSTF) and a second one from the American College of Gastroenterology.

The guidelines from the US Preventive Services Task Force (USPSTF) recommend that adults 50 to 75 years of age be screened either with an annual high-sensitivity FOBT or with sigmoidoscopy every five years and with high-sensitivity FOBT between sigmoidoscopic examinations or colonoscopy every 10 years. Clinicians should be aware that the FOBT recommendations are for the new high-sensitivity tests.⁵

The guidelines from the American College of Gastroenterology recommend that screening begin at age 50 in asymptomatic, average-risk adults with the exception of African Americans with whom the updated guidelines recommend that screening begin at age 45. The ACG guidelines also group colorectal cancer screening tests into two categories: (1) cancer prevention tests (those that better detect both polyps and cancer, ie, imaging tests: colonoscopy, flexible sigmoidoscopy, CT colonography) and (2) cancer detection tests that demonstrate less sensitivity for polyps. The preferred cancer prevention test is colonoscopy every 10 years. The preferred cancer detection test is the annual fecal immunochemical test for blood. An alternative cancer detection test may be a stool DNA test (every three years). **The American College of Gastroenterology supports the joint guideline recommendations that older guaiac-based fecal occult blood testing be abandoned as a method for CRC screening.**⁶

Advantages of Screening With the FOBT

Conventional stool testing for colorectal cancer has many positive aspects:

- It is noninvasive.
- Samples can be collected in the privacy of a person's home.
- It detects lesions throughout the length of the large bowel.
- It requires no bowel preparation.
- It is inexpensive.

- Clinical trials have shown that mortality rates from colorectal cancer can be reduced by as much as 33% with annual iFOBT screening.⁴
- The presence of fecal occult blood in the stool is associated with other gastrointestinal disorders such as diverticulitis, polyps, and Crohn's disease, which may lead to colorectal cancer if not treated.⁵

Tests that examine stool for the presence of blood currently rely on two main methods: guaiac and immunochemical. In the US the majority of FOBTs performed use the guaiac-based method. These tests can yield false-positive results if certain foods, vitamins, or drugs (including meat, some raw fruits and vegetables, vitamin C, or aspirin) are ingested in the days before collecting the specimen.²

Advantages of iFOBT vs Guaiac-based FOBT

Recent evidence has revealed an unacceptably wide range of sensitivity among some traditional guaiac-based FOBT strategies, with some practices and tests performing so poorly that the large majority of prevalent cancers are missed at the time of screening.²

Annual screening with iFOBT, on the other hand, has been shown in peer-reviewed literature to detect a majority of prevalent CRC in an asymptomatic population at the time of testing and is an acceptable option for CRC screening in average-risk adults who are 50 years old and older.²

The advantages of iFOBT include the following:

- The assay has superior specificity and sensitivity. One study, using the samples from normal subjects, shows the positivity rate obtained from the guaiac method to be 17.6%; however, the same set of samples shows the positivity rate obtained from the iFOBT method to be only 4.1%. This same study also included patients with colorectal cancer. iFOBT correctly identified 91% of the patients as positive; however, guaiac was able to detect only 57% of the positive cases.⁶
- iFOBT uses antibodies specific for human globin and are, unlike guaiac tests, specific for colorectal bleeding and not affected by diet or medications.⁴
- iFOBT is processed by automated developers and readers. This innovation allows for management of large numbers of tests in a standardized manner with excellent quality assurance.⁴
- There is evidence that iFOBT use improves patient participation in screening for colorectal cancer.⁴
- iFOBT technology allows for quantitation of fecal hemoglobin. This innovation enables sensitivity, specificity, and positivity rates to be adjusted in screening for colorectal neoplasia.⁴
- The developing instrument for the iFOBT has the ability to read a bar code on the test, a feature that ensures accurate identification of the person screened.⁴

- The iFOBT provides sensitive detection of metachronous and recurrent cancer in postoperative surveillance.⁷
- Studies show that detection rates for advanced adenomas and cancer were significantly higher for iFOBT. The guaiac test significantly underestimates the prevalence of advanced adenomas and cancer in the screening population compared with iFOBT.⁸
- By eliminating dietary and medicinal restrictions and by requiring only a single sample collection, patients are able to perform the collection with ease and no disruption to their daily routine. The result is a significant increase in patient compliance.⁹

According to the most recent guidelines, physicians and institutions should select stool blood tests that have been shown in the scientific literature to detect the majority of prevalent CRC in an asymptomatic population. If there is no evidence that an available test has met that benchmark, it should not be offered to patients for CRC screening.²

The fecal occult blood immunoassay test has been established as a more precise marker for colorectal cancer than traditional guaiac-based FOBT.¹⁰ The iFOBT is recommended for use in (1) routine physical examinations, (2) monitoring for gastrointestinal bleeding in patients, and (3) screening for colorectal cancer or gastrointestinal bleeding.

References

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Occult Blood, Fecal, Immunoassay* 182949

Related Information Occult Blood, Stool, Guaiac

Synonyms FIT; iFOBT

Specimen Stool in Polymedco OC-Auto Sampling Bottle

Volume One Polymedco OC-Auto Sampling Bottle with stool

Container Polymedco OC-Auto Sampling Bottle

Collection Enter patient identification and date of collection on sampling bottle label. Place collection paper inside toilet bowl on top of water. Deposit fecal sample on top of collection paper. Do not allow fecal sample to contact toilet water until after specimen has been collected. Open the green cap on the sampling bottle by twisting and pulling upwards. Scrape the surface of the fecal sample with the sampling probe. Cover the grooved portion of the sampling probe completely with the fecal sample. Close the sampling bottle by inserting the sampling probe and snap the green cap on tight. Do not reopen. Flush remaining stool and used collection paper. Return the sampling bottle to the physician or laboratory. Only one stool specimen collected from one bowel movement is required.

Storage Instructions Specimen in sampling bottle can be stored for up to eight days at room temperature or for up to 14 days if refrigerated (2°C to 8°C).

Patient Preparation No special drug or dietary restrictions are required. Results of this test are not affected by dietary peroxidases, animal blood, or vitamin C.

Causes for Rejection Collection tube or sampling device other than the Polymedco OC-Auto Sampling Bottle; specimens with obvious blood, which may be due to menstrual bleeding, bleeding hemorrhoids, constipation bleeding, or urinary bleeding; raw stool submitted in a container; unlabeled specimen or name discrepancy between specimen and request label; specimen received after prolonged delay (more than eight days at room temperature since collection); expired sampling bottle; leaking sampling bottle or sampling bottle without adequate liquid.

Use Qualitative detection of fecal occult blood

Limitations This test is intended only for the detection of human hemoglobin in fecal specimens. It is not for use in testing urine, gastric specimens, or other bodily fluids. Results cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. This test is designed for preliminary screening. A positive result should be followed up with additional diagnostic procedures, such as colonoscopy or sigmoidoscopy, to determine the exact cause and source of the occult blood in the feces. A negative result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of disease. False-negative results may occur when occult blood is not uniformly distributed throughout the stool. Repeat testing is recommended if a pathological condition is suspected. Urine and excessive dilution of specimens with water from the toilet bowl may cause erroneous results. For best results, use the collection paper in the collection kit.

Patients with menstrual bleeding, bleeding hemorrhoids, constipation bleeding, and urinary bleeding should not be considered for testing as these conditions may interfere with test results. These patients may be considered for testing after such bleeding ceases.

Alcohol and certain medications, such as aspirin, indomethacin, reserpine, phenylbutazone, corticosteroids, and nonsteroidal anti-inflammatory drugs, may cause gastrointestinal irritation and subsequent bleeding in some patients.

Methodology Immunoassay (IA)

*For the most current information regarding test options, including specimen requirements and CPT codes, please consult the online Test Menu at www.LabCorp.com.



www.LabCorp.com