

Assay Summary

Fecal Globin, Immunochemistry (InSure™)

Clinical Use

Screen for lower gastrointestinal bleeding associated with colorectal cancer, adenomas, polyps, and other lower gastrointestinal conditions.

Test Code

11290 Diagnostic
11293 Medicare Scr.

Clinical Background

Colorectal cancer is the third most common form of cancer and the third leading cause of cancer death in the United States, in men as well as women. According to American Cancer Society (ACS) estimates, 147,500 new cases of colorectal cancer will be diagnosed and more than 57,000 people will die of this disease in 2003, accounting for 10% to 11% of cancer deaths in each sex.¹ The most common risk factor is age: >90% of colorectal cancers are diagnosed in people >50 years of age.¹ Screening and early detection are crucial, as survival rates decrease dramatically with increasing cancer stage: 5-year survival ranges from >90% for Dukes stage A to <5% for Dukes stage D. Moreover, detection and removal of precancerous polyps can reduce the incidence of colorectal cancer 76% to 90%.² Although routine screening is recommended for average risk individuals ≥ 50 years of age³⁻⁵, fewer than half of age-eligible adults receive appropriate screening.^{6,7}

Because cancerous and precancerous colorectal lesions tend to cause low-level bleeding, assays for occult blood in feces have become an important screening tool. Annual screening with a fecal occult blood test (FOBT) can decrease colorectal cancer mortality by up to 33%.⁸ Thus, ACS guidelines indicate that the preferred screening method for average-risk individuals ≥ 50 years of age is an annual FOBT, with flexible sigmoidoscopy every 5 years.³

One drawback to the most common currently used FOBTs is that they are guaiac based; they detect heme peroxidase activity and are not specific for human hemoglobin. Thus, hemoglobin from red meat, peroxidase from fruits and vegetables, and certain medications can cause false-positive reactions and need to be avoided for several days before the test. While these FOBTs are non-invasive and specimens can be collected at home, strict dietary and medication restrictions may decrease adherence.^{7,9} Newer immunochemical assays such as InSure do not react with non-human hemoglobin or peroxidase, so food restrictions are not necessary.

Immunochemical FOBTs are also more specific for lower gastrointestinal bleeding because they target the globin portion of hemoglobin, which does not survive passage through the upper gastrointestinal tract. Based on these features and published performance characteristics of immunochemical FOBTs, ACS guidelines suggest that immunochemical FOBTs such as InSure “are more patient-friendly, and likely to be equal or better in sensitivity and specificity” relative to guaiac-based tests.^{3,10}

Individuals Suitable for Testing

Individuals undergoing routine screening for colorectal lesions or other sources of bleeding in the lower gastrointestinal tract.

● Specimen Requirements

One room temperature specimen card containing toilet-water samples from two successive bowel movements. Toilet water is collected by gently disturbing the surface of the stool with the supplied brush and then dabbing the water onto the specimen card. After drying, the specimen card is placed into the supplied envelope and sent to the testing laboratory.

Samples should not be collected 1) during, or 3 days before or after, a menstrual period; 2) if bleeding hemorrhoids are present; 3) if there is visible blood in the urine or toilet bowl; or 4) if there are bleeding cuts on the hands; or 5) if the toilet contains rust or saltwater. Toilet freshener should be removed and the toilet flushed prior to sample collection. Dietary roughage may increase test sensitivity, but no dietary changes or restrictions are required.

● Method

- Immunochemistry
 - Monoclonal, mouse anti-human hemoglobin-coated chromatography test strip
 - Colorimetric detection
- Analytical sensitivity: 50 ug Hb/g feces¹¹
- Analytical specificity: specific for colorectal bleeding; does not detect blood from upper gastrointestinal tract¹¹
- Aliases: fecal immunochemical test; FIT; fecal occult blood test; FOBT; InSure®
- CPT code*: 82274

● Reference Range

Not Detected

● Interpretive Information

Positive results indicate occult blood in the feces and should be followed up with physician consultation and possible endoscopic evaluation. Negative results indicate the absence of fecal blood; however, false-negatives can occur because of uneven distribution of blood in the feces or intermittent bleeding.

References:

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* The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.