

Fecal Immunochemical Tests (FIT) Information and Options

<http://www.insuretest.com/index.php>



To help improve colorectal cancer screening compliance, physicians should consider the InSure® FIT™ screening test, which offers high sensitivity and ease of use:

- Patient-friendly, water-based collection method, and patented brush sampling replaces unpleasant fecal collection or smearing
- No dietary or medication restrictions
- The InSure® FIT™ test had a 66% increase in patient compliance versus a guaiac-based fecal occult blood test (gFOBT) in one study.²

InSure® FIT™ is a CLIA waived test available for laboratory services and in-office / point of care (POC) testing. For laboratory services contact your Clinical Genomics sales representative. For in-office / point of care (POC) testing contact one of our distributor partners or Enterix Inc. at 1-800-531-3681.



Status iFOBT is a rapid immunoassay for the qualitative detection of Immunochemical Fecal Occult Blood to detect human hemoglobin in human fecal specimens as an aid in the diagnosis of gastrointestinal disorders. It is a 30-test kit ideal for the physician's office to conduct routine patient screening. The patient's specimen sample can be collected in-office or at home with the inclusion of the user friendly instructions, sample collection tubes, and return mailing envelopes. Its superior sensitivity and specificity reduces the rate of false positive results often associated with traditional guaiac test methods. There are also no dietary or drug restrictions. With a quick and easy-to-perform test procedure, results are available in 5 to 10 minutes, and no other invasive methods are required. Visit <http://www.statusifobt.com>

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The Accutest® iFOBT Dual-Sample Test System is Jant Pharmecal Corporation's newest point-of-care product for colorectal cancer screening. This immunological qualitative test detects human hemoglobin in feces and allows two samples to be tested-economically-on the same test device. Since polyps bleed intermittently, testing more than one sample from different bowel movements improves accuracy and is recommended by the American Cancer Society. The Dual-Sample Test System is CLIA waived, easy to use, requires no dietary restrictions and provides rapid results in less than five minutes. Convenient home collection materials include a unique buffer solution, which allows 18-day stability of sample at room temperature. A single iFOBT test system is also available. Visit www.accutest.net



Hemocult ICT immunochemical fecal occult blood test -(iFOBT) can detect bleeding associated with more cancers and polyps than traditional guaiac-based FOBTs used for colorectal cancer screening. It provides high specificity to reduce the number of false positive test results. It is non-invasive and very patient friendly, as there are no diet or drug restrictions for patients. It provides 14-day on slide sample stability and is available in both two-day and three-day patient collection kits and in boxes of 100 individual collection cards. Separate collection cards and test devices minimize the financial risk of patients not returning collection cards. Beckman Coulter offers comprehensive patient educational support to accompany the Hemocult ICT-helping to increase patient compliance. Visit www.beckmancoulter.com

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The CLIA-waived Hemasure® Immunochemical Fecal Occult Blood Test (iFOBT) offers a notable consideration in that there are no drug or diet restrictions. It is a rapid, convenient, and odorless test for the determination of human hemoglobin in feces, typically used for colorectal cancer screening. The one-step immunological fecal occult blood test is a qualitative, sandwich dye conjugate immunoassay and employs a unique combination of monoclonal and polyclonal antibodies to selectively identify hemoglobin in test samples with a high degree of sensitivity. In less than five minutes, elevated levels of human hemoglobin as low as 50 ng hHB/ mL can be detected and positive results for high levels of hemoglobin can be seen in the test as early as one or two minutes. Visit www.hemosure.com

Alere/Inverness Medical Clearview ULTRA FOB



<http://www.claflinquip.com>

Note: This product can be sold to medical facilities and physicians only.

Clearview ULTRA FOB is a rapid, two-step immunochemical test that patented innovative technology provides highly accurate for the detection of fecal occult blood, with positive result in as soon as 1 minute. It has no dietary restrictions and can aid in the diagnosis of gastrointestinal disorders, which may lead to colorectal cancer if not treated. Early diagnosis and treatment can lead to significant reduction in mortality from colorectal cancer.

Features:

- CLIA waived
- Rapid response
- Two easy steps, positive results as quickly as 1 minute
- Simplicity - easy-to-use test requires no training
- Reliability - Built-in control ensures accuracy
- Flexibility - No dietary restrictions, faster results while the patient waits
- Aid in the diagnosis of gastrointestinal disorders, which may lead the detection of fecal to colorectal cancer if not treated
- Early diagnosis and treatment can lead to significant reduction in mortality from colorectal cancer
- Higher reimbursement with immunoassay test
- Better patient compliance due to easier collection method and no dietary restrictions
- Room temperature storage
- 18 Month shelf life
- Includes 50 test strips and 50 vials per kit

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<http://www.polymedco.com>

The sample is collected and closed by the patient and never reopened. The instrument measures the closed sample collection devices. The laboratory technician never comes in contact with the sample.

Product features:

- Fully automated
- 80 samples per hour
- Runs up to 10 samples per rack
- Results available in eight minutes
- Easy calibration and automatic serial dilution
- Start mode
- 999 sample memory
- 3" L x 1" wide LCD display
- Closed sampling bottle

Product benefits:

- Easy implementation in lab
- Half day installation
- Never come in contact with the sample
- Eliminates subjectivity of read
- Patient results are automatically updated into their records, eliminating transcription errors
- Compact design (57 lbs., 12.5" x 21" x 16.5") is ideal for a small workstation
- New immunoassay CPT code
- National Medicare limit: \$23.22

- Eliminates Exposure to Bio-hazardous material
- Optimizes Test Sensitivity and Specificity
- Samples can be bar coded
- Ability to interface to an LIS
 - RS232 Port
 - Written to HL7