



Doctors Laboratory, Inc.
2906 Julia Drive
Valdosta, GA 31602
Phone: 229-244-4468
www.doctorslabinc.com

IMPORTANT ANNOUNCEMENT: Based upon many inquiries received by our Microbiology Laboratory about immunochemical Fecal Occult Blood Test, we are pleased to announce that effective NOVEMBER 1, 2006; all specimens submitted for fecal occult blood will be tested by immunological technique. For your convenience, test ordering code and specimen submitting instructions will remain same, and are summarized on the next page. Only CPT code will change.

A Better Approach to Colorectal Cancer Screening at Doctors Laboratory, Inc.

Excluding deaths from lung cancer, colorectal cancer is the most common cause of cancer death for men and women combined. The American Cancer Society and Centers for Disease Control and Prevention recommend Fecal Occult Blood Test (FOBT) annually after age 50 to aid in the early detection of colorectal cancer or the precursors of it, e.g polyps, diverticulitis and Crohn's disease.

Until recently Guaiac Test (commonly known as Hemoccult or gFOBT) has been most widely used for colorectal cancer screening. The availability of an immunochemical Fecal Occult Blood Test (iFOBT) has made it possible to avoid several limitations of gFOBT. The following paragraphs compare the two methods and summarize what respectable authorities recommend at this time.

The Guaiac Test (gFOBT): gFOBT is based upon testing a series of THREE fecal specimens collected over a period of three days. Guaiac is a naturally occurring phenolic compound that can be oxidized to quinone by hydrogen peroxidase with a detectable color change. Any food that contains dietary peroxidase, e.g., meat, uncooked fruits and vegetables, certain common medications and supplements, may cause false positive results from gFOBT. As a result, the procedure requires that patients avoid these products for 2 days before the first specimen is collected, and continue to abstain for two more days until a series of three specimens is collected. Compliance to these diet restrictions is inconvenient but important.

The smallest amount of detectable hemoglobin with gFOBT is 90 mcg/ml. sensitivity of only 50%, or significant chance of false-negativity. The specificity, as described above, is poor as well, as it can be affected by a variety of substances to give false positive results. The accuracy of the test is <86%.

The Immunochemical FOB Test (iFOBT): iFOBT is based upon testing a single or two fecal specimens collected over a period of one or two days. iFOBT's use monoclonal or polyclonal antibodies to detect human hemoglobin's intact globin protein. Labeled antibody attaches to the intact globin antigen and results in a positive result. Since the globin protein does not remain intact after passage through the upper gastrointestinal tract, a positive iFOBT is specific for bleeding in the lower gastrointestinal tract. Due to its specificity to globin protein, there are no dietary restrictions to control peroxidase activity, thus consumption of meat, fruit and vegetables, medicines or supplements do not produce false-positive results. Overall specificity of iFOBT is >96% for human hemoglobin. iFOBT can also detect as small amount of hemoglobin as 0.05 mcg/ml. – better than 87% sensitive over gFOBT. The accuracy of this test is over 94%.

Following are excerpts from *Gastroenterology* 2005;129:422-428,745-747

“..... the sensitivity of one-time immunochemical FOB Test for detecting advanced neoplasia and invasive cancer was 27.1% and 65.8%, respectively. Repeated screening may increase the sensitivity of the test, the investigators say.

.... Dr. James E. Allison of the University of California, San Francisco notes in a related editorial, that a sensitivity of 66% for cancer is a "marked improvement" over the 13%-39% sensitivity reported for the most commonly used guaiac test, Hemoccult II.

"If, as it appears, the fecal immunochemical test has better performance characteristics than the guaiac test, that is compelling evidence for recommending its use as the FOBT of choice in colon cancer screening programs," Dr. Allison writes.

He feels, based on the collective evidence to date, that screening programs involving new immunochemical FOBTs "deserve serious consideration as part of our armamentarium of tests for CRC screening."

The specimen collection requirements for typical iFOBT test are quite simple –

- 1) No diet restrictions, thus potential of better compliance by the patient.
- 2) No handling of fecal specimens or test cards by patient. In fact, frequent mishandling of cards or incorrect sampling on the cards by patients was the primary reason that Doctors Laboratory started to recommend submitting direct specimen in containers.
- 3) Due to iFOBT's higher sensitivity and sampling from at least five different sites at the laboratory, a single specimen is adequate, but a series of two is recommended, compared to a series of three in case of gFOBT.

Studies have shown that due to iFOBT's simplicity, there can be 30% increase in specimen submission compliance by patients. In fact, The American Cancer Society (ACS) recently reviewed several iFOBT assays and determined that "in comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity."

Effective November 1, 2006 Doctors Laboratory will perform immunochemical FOBT on all specimens submitted for fecal occult blood testing. Current Guaiac test will continue to be available until December 31, 2006 in case when (a) pre-inoculated cards collected by patient were received, or (b) Guaiac test was specified on request form.

Specimen collection and test ordering procedures WILL NOT CHANGE, and are summarized below:

Test to Order	Specimen(s) to submit	CPT Code	Comments
Test Code: 124 OCCULT BLOOD TEST (Fecal)	Stool specimen(s) collected directly into sterile, secure, screw-capped container(s). One specimen required. Maximum two specimens collected over two days are recommended. No dietary or medicine restrictions needed.	82274	(1) Non-standard containers, e.g. pill bottle, food jar or yogurt cup can introduce contaminants and are not acceptable. (2) Test can not be performed on conventional Occult Blood cards (Hemoccult).

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