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IMMUNOASSAY SCREENING METHOD FOR COLORECTAL CANCER

Rapid Lateral Flow Occult Blood Detector

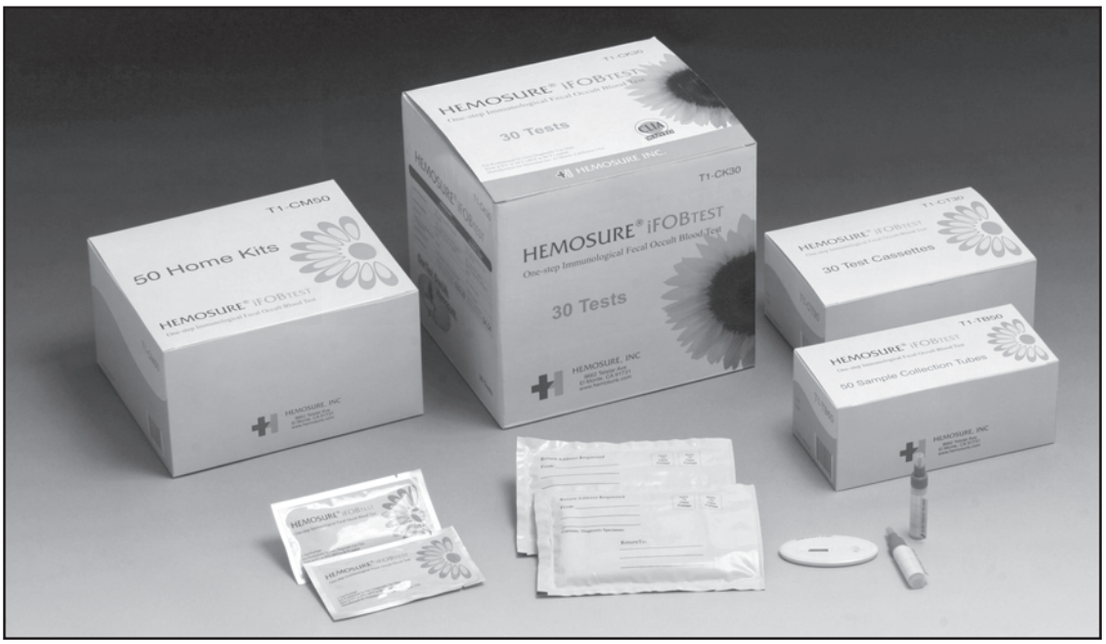
In the United States, colorectal cancer (CRC) is the third most common cancer diagnosed among men and women and the second leading cause of death from cancer with more than 55,000 deaths per year.[1,2] That's a frightening statistic! But it is estimated that CRC can largely be prevented by the detection and removal of adenomatous polyps and survival is significantly better when CRC is diagnosed while still localized.[1] That's the good news!

That's where the **iFOB Test** from **Hemosure (El Monte, CA)** has an important role to play. While a colonoscopy is recommended every five to 10 years for adults over the age of 50, there is a need for screening in the intervening years. The standard chemical-based Guaiac method has several limitations—it can be difficult to interpret, is subject to false positives from food and medicine and detects non-specific hemoglobin.

On the other hand, the iFOB Test is an immunoassay that is highly specific for human hemoglobin, and detects as low as 0.05 µg HB/mL. It is easy to perform—the format is a simple lateral flow device—and it provides clear, accurate reading very similar to a pregnancy test.

Research Studies

So how does it fit in with current expectations for a screening test? In 2008, Levin *et al.*[1] issued a Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer and the American College of Radiology on the screening and surveillance for the early detection of colorectal cancer and adenomatous polyps. They concluded that



The iFOB Test from Hemosure (El Monte, CA) has an important role to play in screening fecal occult blood.

annual screening with the iFOB immunoassay is an acceptable option for colorectal screening in average-risk adults aged 50 years and older.

It is also recommended that two tests are performed because polyps may bleed intermittently and this provides a better chance of discovering their presence. The iFOB Test is affordable enough to make this option cost-beneficial, although it should be noted that the product is offered in a flexible choice of packages to meet needs for either one or two tests per patient.

This claim is supported by an independent, published study. Li, *et al.*[3] compared the iFOB Test directly with the standard Guaiac test in a total of 324 patients recruited from five hospitals in Beijing, China. Comparing a two-sample to a three-sample setting, the Guaiac-based test showed significant loss of sensitivity for the detection of cancer as well as adenoma, whereas the iFOB Test did not change significantly. Overall, the iFOB Test with two-sample testing showed compatible sensitivity and specificity to three-sample testing and had a lower relative cost per cancer detected than three-sample testing. They concluded that the Hemosure iFOB Test with two consecutive stool samples appeared to be the most cost-effective approach for colon cancer screening.

Practical Use

These findings are borne out in practice. Prafull C. Shah, M.Sc., M.S. is Director of the Microbiology Lab at Doctors Laboratory, Valdosta, GA. His lab compared four brands of iFOB Test in three different formats—card, strip, and lateral flow. The selection criteria included sensitivity, specificity, ease of specimen collection and submission, ease-of-use for the operator, easily readable results. Cost-per-test and availability of published data were also factors.

> *"I would encourage any health provider considering iFOBT to give Hemosure a serious try."*
>
> **Prafull Shah, MSc, MS**

While most of the kits they tested met their criteria, they chose the Hemosure iFOB Test because it was found to have better readability, a more streamlined test procedure and a specimen collection kit that was patient friendly. They also appreciated the excellent technical support available from the company. "I would encourage any health provider considering iFOBT to give Hemosure a serious try," says Prafull Shah.

Jianyu Rao, MD, Associate Professor of Pathology and Epidemiology at UCLA, Los Angeles, CA has also evaluated the Hemosure iFOB Test. In addition to being a co-author of the study carried out in Beijing, China,[3] he has carried out other studies with his colleagues at UCLA. One involved 120 Korean Americans in Los Angeles, aged 50 to 70, to study the educational and compliance issues of colorectal cancer. He and his UCLA colleagues found that Hemosure's iFOBT had a significantly higher compliance rate compared with the standard chemical-based FOBT—80 percent versus 40 percent.

Another study in Dr. Rao's laboratory showed that Hemosure's iFOBT was easier to perform and was more sensitive to detect significant lesions compared with the chemical-based fecal occult blood test.

And finally, a large scale population based cohort study in Hangzhou, China involving over 14,000 subjects found that with an overall positive rate of 3.5 percent of Hemosure's iFOBT, there was a relatively high positive predictive value for significant lesions (about 50 percent) for this test. These results were presented at the Annual AACR (American Association for Cancer Research) meeting in Washington, DC, in 2006. "Together, these data support the use of iFOBT as a screening test for colorectal cancer," adds Dr. Rao.

Conclusion

Hemosure's iFOB Test has been tested in a wide range of situations and been found to satisfy a number of important criteria that meet the manufacturer's claims. The test will make a significant contribution to the screening and early detection of a major life-threatening disease. That's more good news!

To Learn More

For more information about the **iFOB Test,** including improved reimbursement information, and references to the published literature, please call 1-888-Hemosure (436-6787), email to sales@hemosure.com, or visit the company's Web site at www.hemosure.com.

HEMOSURE® iFOB TEST
-Immunochemical Fecal Occult Blood Test (FIT)

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1. Levin, B. *et al. CA Cancer J Clin* 2008 58 1-31.
2. American Cancer Society www.cancer.org.
3. Li *et al. Int J Cancer* 2006 118 3078-3083.