

INSURE® FECAL IMMUNOCHEMISTRY OCCULT BLOOD TEST SIMPLIFIES COLORECTAL CANCER SCREENING

Colorectal cancer is the second most common cause of death from cancer in the U.S. and yet approximately one-third of the deaths could be avoided if everyone over 50 years of age was screened regularly for the disease.¹ With colorectal cancer, early detection is absolutely crucial to successful treatment, as evidenced by the fact that 90% of patients diagnosed with localized disease are alive 5 years after diagnosis, whereas the 5-year survival rate is only 10% for patients with distant (metastatic) disease.² Clearly patient compliance with screening is crucial to early detection and successful control of this disease.

In 2003, **Quest Diagnostics** entered into an agreement with Enterix Inc., a colorectal cancer screening company, to provide laboratory services for **Enterix's InSure test**, an FDA-approved test for colorectal cancer screening. The InSure test detects human blood that may be from cancers and large adenomatous polyps (precursors of cancer) that have bled into the large intestine. Accurately detecting the presence of this blood is important so that patients with positive results can be followed up by colonoscopy and possible removal of the threatening polyps or cancers that may be found.

InSure FIT is Specific for Lower GI Bleeding

Until recently, colorectal cancer screening programs used fecal occult blood tests (FOBTs), such as Hemoccult®, which are guaiac-based and work by detecting the peroxidase-like activity of the heme portion of hemoglobin. As red meats and some fruits, vegetables and medications may

interfere with these FOBTs, dietary and medicinal restrictions are necessary before and during the testing period. In addition, because the FOBTs detect the stable heme portion of hemoglobin, they do not distinguish between blood from the upper gastro-intestinal (GI) tract (mouth to cecum) versus that from the colon and rectum (large intestine), where colorectal cancer originates.

InSure is a fecal immunochemical test (FIT) that uses a monoclonal antibody against the globin portion of human hemoglobin to detect only blood from the large intestine. Globin derived from upper GI bleeding is degraded by the body's digestive system and the action of bacterial enzymes before reaching the large intestine; therefore InSure has greater specificity for lower GI bleeding and any associated pathology.³



The Difference Is Clear

Researchers conducted clinical sensitivity and specificity

studies to evaluate InSure FIT. In a clinical trial involving 240 participants with a personal or family history of colorectal cancer or adenomas, InSure had 87% sensitivity for colorectal cancer. In another trial of 90 healthy patients over the age of 50, InSure had 98% specificity and thus provided accurate screening with less worry about false positive results.⁴

In a study involving 745 participants, (n=443 patients of average risk, n=158 patients of high risk, n=144 symptomatic patients), that was presented at the Australian Gastroenterology Week conference, researchers compared InSure FIT to Hemoccult II SENSEA® with regard to sensitivity for colorectal cancer and significant neoplasia

(cancer and large adenomas) and found statistically significant differences between the tests. InSure had an 89.9% sensitivity for colorectal cancer versus 50% for Hemocult® II SENSEA® and a 77.1% sensitivity for significant neoplasia versus 42.9% for Hemocult II SENSEA.⁵

InSure Is Simple and Patient-Friendly, Assuring Greater Patient Compliance

The InSure FIT is easier for most patients than guaiac based FOBTs, such as the Hemocult SENSEA, which restrict ingestion of certain drugs and foods, including NSAIDs (non-steroidal anti-inflammatory drugs), vitamin C, fruit juices, and red meats. In contrast, there are no dietary or medication restrictions for InSure, thus leading to greater patient compliance and less risk of false positive results caused by patients not following the dietary and medicinal restrictions required by the Hemocult test.

Fecal handling is eliminated with InSure FIT. The FOBTs, such as the Hemocult test, require the patient to remove feces from the toilet and smear them onto a card with a wooden stick. In contrast, the InSure test involves using a long-handled brush to collect a water sample from around the surface of the stool in the toilet bowl. InSure FIT needs only two water samples, whereas Hemocult requires the patient to collect a total of six stool samples, two stool samples with three different bowel movements.

The simple procedures necessary for InSure help contribute to increased patient compliance. Researchers evaluated patient participation in colorectal cancer screening in a randomized trial involving 1818 participants, of which one group used Hemocult SENSEA and another used InSure. The lack of food and drug restrictions and simplified sampling for InSure® resulted in 66% more participation in the InSure group over that of Hemocult ($p < 0.001$). The researchers concluded, "Because participation in screening is vital to detection, this new technology should contribute to better detection of neoplasia at the population level."⁶

FIT Tests: Supported by the American Cancer Society Colorectal Cancer Advisory Group

The American Cancer Society (ACS) Colorectal Cancer Advisory Group reviewed emerging technologies in colorectal cancer screening, including FIT tests, such as InSure, and tests to detect altered human DNA in stool samples.⁷ Based on the improved specificity of the FIT technology and the elimination of diet and medication restrictions before the test, the ACS amended their guidelines as follows: "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."

InSure is manufactured by Enterix Inc. and laboratory services are provided by Quest Diagnostics.

About Quest Diagnostics

Quest Diagnostics is the nation's leading provider of diagnostic testing, information and services that patients and physicians need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its national network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative new diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at: www.questdiagnostics.com.



References:

1. Centers for Disease Control. http://www.cdc.gov/cancer/screenforlife/fs_detailed.htm, Accessed Sept. 6, 2005).
2. SEER Relative Survival Rates by Stage at Diagnosis, Colon and Rectum Cancer, Both Sexes, SEER 9 Registries for 1988-2001. Available at: <http://seer.cancer.gov>. Accessed Sept. 6, 2005.
3. InSure Product Instructions, No. 85106-001, Rev. B, ©2004 Enterix, Inc.
4. Enterix, Inc., data on file. U.S. Food and Drug Administration (FDA) submission data: 2000
5. Cole SR, Smith A, Bampton P, et al. Colorectal cancer screening: direct comparison of a brush-sampling Faecal immunochemical test for haemoglobin with a guaiac FOBT. Paper presented at: Australian Gastro Week, 2003, Cairns, Australia.
6. Cole SR, Young GP, Esterman A, et al., A randomized trial of the impact of new faecal haemoglobin test technologies on population participation in screening for colorectal cancer. *J Med Screen* 2003; 10:117-22.
7. Smith RA, Cokkinides V, Eyre HJ. American Cancer Society guidelines for the early detection of cancer, 2003. *CA Cancer J Clin* 2003;53:27-43.