PreGen-Plus™
Non-Invasive Colorectal Cancer Screening

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PreGen-Plus™ Fact Sheet

What is PreGen-Plus™?

PreGen-Plus™ is a breakthrough colorectal cancer screening option for the asymptomatic, average-risk population, aged 50 and older. According to the American Cancer Society, everyone aged 50 and over should be screened regularly for colorectal cancer. Developed by EXACT Sciences Corporation, PreGen-Plus is the only non-invasive, DNA-based test available for the detection of colorectal cancer. Unlike other screening tests for colorectal cancer, PreGen-Plus provides a sensitive, non-invasive and easy-to-use option for the early detection of colorectal cancer, the second leading cause of cancer-related deaths in the U.S.

How does PreGen-Plus work?

PreGen-Plus is a non-invasive test that isolates and analyzes DNA extracted from a patient's stool sample for alterations associated with the presence of colorectal cancer.

After a physician writes an order for the test, the patient receives a collection kit at the physician's office, at a LabCorp® Service Center or at his/her own home. The patient then collects a single, whole stool sample, and sends the sample to Laboratory Corporation of America® (LabCorp®) using pre-paid packaging. At the laboratory, the human DNA, coming from cells shed from the colon each day into stool, is extracted and then examined for alterations. PreGen-Plus consists of a panel of 23 individual tests each looking for the presence of DNA alterations in human DNA isolated from stool. The test analyzes the DNA for 21 specific point alterations in the APC, K-ras and p53 genes, a marker for microsatellite instability known as BAT-26, and a novel marker known as DNA Integrity Assay (DIA®), all of which have been associated with the presence of cancer.

After analysis, test results are returned to the patient's physician within approximately two to three weeks. Patients who receive a positive test result indicating the likely presence of colorectal cancer would be referred on for additional testing as medically appropriate, including colonoscopy. With a negative test result, it is recommended patients continue their regular screening program.

How is PreGen-Plus different from other available screening methods?

According to the American Cancer Society, survival rates for colorectal cancer are greater than 90 percent if the disease is detected early. However, nearly 60,000 people die each year from colorectal cancer despite the availability of screening and diagnostic tests for more than 20 years. PreGen-Plus is a sensitive, completely non-invasive test that holds promise as a colorectal cancer screening option from which people will not shy away.

PreGen-Plus has the potential to significantly increase the number of people accurately screened for colorectal cancer. PreGen-Plus removes many of the common barriers associated with current screening methods, including invasiveness, discomfort, and inconvenience. An increase in compliance with screening programs could potentially lower mortality rates from colorectal cancer. PreGen-Plus is:

- *Sensitive.* PreGen-Plus analyzes DNA extracted from stool for alterations associated with the presence of colorectal cancer. Based on published studies to date, PreGen-Plus is comparable to other cancer screening tests such as the Pap smear for cervical cancer. Additionally, in data presented at the American College of Gastroenterology 2003 Annual Conference, PreGen-Plus was four times more sensitive than the fecal occult blood test, currently the only other non-invasive screening method for colorectal cancer.

- *Non-invasive.* Compared to current screening methods like colonoscopy and flexible sigmoidoscopy, PreGen-Plus only requires a stool sample for testing, and requires no handling or sampling of fecal matter.

- *Simple, Convenient.* Patients can collect a single, whole stool sample in the privacy of their home. PreGen-Plus does not require any special bowel preparation, stool handling or alteration in diet or medications prior to testing.

How sensitive is PreGen-Plus?

In published studies to date, PreGen-Plus has demonstrated a sensitivity of approximately 65 percent and a specificity of approximately 95 percent. This point sensitivity is significantly greater than that of fecal occult blood testing and comparable to other cancer screening tests such as the Pap smear for cervical cancer.

How can I get PreGen-Plus?

PreGen-Plus must be ordered by a physician or other healthcare professional. Laboratory Corporation of America (LabCorp®) has licensed the PreGen-Plus technology from EXACT Sciences and is currently the designated exclusive source for all patient testing within the U.S. Patients should ask their physicians to contact LabCorp for more information or to order PreGen-Plus.

Physicians can obtain additional product and ordering information at www.pregenplus.com or www.exactsciences.com.

How can I learn more about PreGen-Plus and colorectal cancer?

Visit the following Web sites:

- PreGen-Plus: www.pregenplus.com
- EXACT Sciences: www.exactsciences.com
- American Cancer Society: www.cancer.org
- American Digestive Health Foundation: www.gastro.org/adhf
- National Cancer Institute: www.cancer.gov
- Cancer Research and Prevention Foundation: www.preventcancer.org

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