# FDA approves Shield blood test for colorectal cancer screening



**FDA Approves Shield Blood Test for Colorectal Cancer Screening**

**Washington D.C. - October 2023:** The U.S. Food and Drug Administration (FDA) has greenlit a new blood test for colorectal cancer screening, marking a significant advancement in the fight against one of the most deadly forms of cancer in the United States. The test, called Shield, is developed by Guardant Health, a biotechnology company based in Palo Alto, California.

**Key Details of the Approval**
The FDA's approval on Monday paves the way for Shield to be used as a primary screening option for adults aged 45 and older who are at average risk of developing colorectal cancer. This is the first blood test of its kind to receive FDA approval and to meet requirements for Medicare reimbursement. The commercial insurance coverage timeline is still unclear, but most plans are expected to cover it following the FDA endorsement. Shield currently retails for $895.

Dr. Sapna Syngal, Director of Strategic Planning for Prevention and Early Cancer Detection at Dana-Farber Cancer Center in Boston, highlighted the significance of increased screening. "The biggest problem with colon cancer right now is that there’s a significant part of the population that’s not getting screened," she stated. "If this test increases the number of people getting screened, it’s going to have a huge impact."

**Performance and Recommendations**
A clinical study published in the New England Journal of Medicine in March revealed that Shield can detect colorectal cancer with 83% accuracy for later-stage diseases but is less effective for early-stage detection, finding just 13% of early-stage cancers. The test works by identifying cancerous DNA released into the bloodstream by tumors.

Doctors recommend the Shield test to be administered every three years starting at age 45, paralleling the guidelines for colonoscopies. However, it is important to note that a positive Shield test result necessitates a follow-up colonoscopy to confirm the presence of cancerous lesions or tumours. Dr. Robert Smith, Senior Vice President of Early Cancer Detection Science at the American Cancer Society, emphasized this point: "A test like this is not complete if it’s positive and you have not had a colonoscopy."

**Impact on Colorectal Cancer Screening**
The approval of the Shield test arrives amid rising colorectal cancer rates, especially among younger demographics. According to the American Cancer Society, more than 53,000 Americans are expected to die from the disease this year. While the reasons for this increase are still being investigated, diet and lifestyle factors are considered significant contributors.

Dr. William M. Grady, a gastroenterologist at Fred Hutchinson Cancer Center, expressed optimism: "This is a promising step toward making more convenient tools available to detect colorectal cancer early while it is more easily treated."

Existing screening methods include traditional colonoscopies, which are performed every 10 years, virtual colonoscopies every five years, and at-home stool tests, which can be done annually or every three years. Despite these options, around one in three adults aged 50 to 75 are not adequately screened.

Dr. Daniel Chung, a gastroenterologist at Massachusetts General Hospital and Professor of Medicine at Harvard Medical School, remarked on the Shield test's potential to close this screening gap: "The FDA’s approval of the Shield blood test marks a tremendous leap forward, offering a compelling new solution to close this gap. This decision will help make screening tests more broadly accessible."

With an estimated 106,590 new cases of colon cancer projected for 2024, the Shield test could significantly impact public health by encouraging more people to undergo screening.

**Final Thoughts**
While Shield offers a less invasive option compared to traditional colonoscopies and may appeal to those hesitant to undergo current screening methods, it does not replace the need for visual examinations. Colonoscopies remain the gold standard for their ability to locate and remove precancerous polyps, potentially preventing cancer altogether.

Overall, the introduction of the Shield blood test presents a new frontier in colorectal cancer screening, promising to make early detection more accessible and potentially saving lives through increased screening rates.