

Take a closer look at the

Revolutionary

Second Generation **FIT**[®]

Colon Cancer Test

Now available with

No Prescription

No Doctors Visit

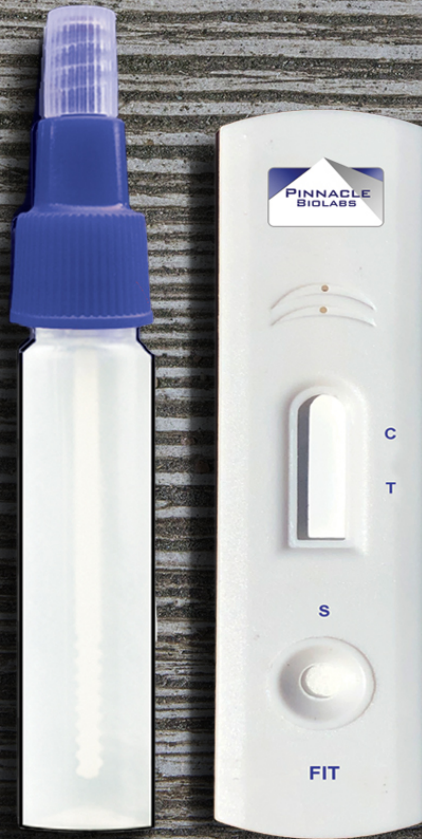
No Bowel Prep

With results in your own home

In about 5 minutes.



This guide was designed to let you make an informed decision about colon cancer screening. The information in this booklet will help you decide if the Second Generation FIT® test is right for you.



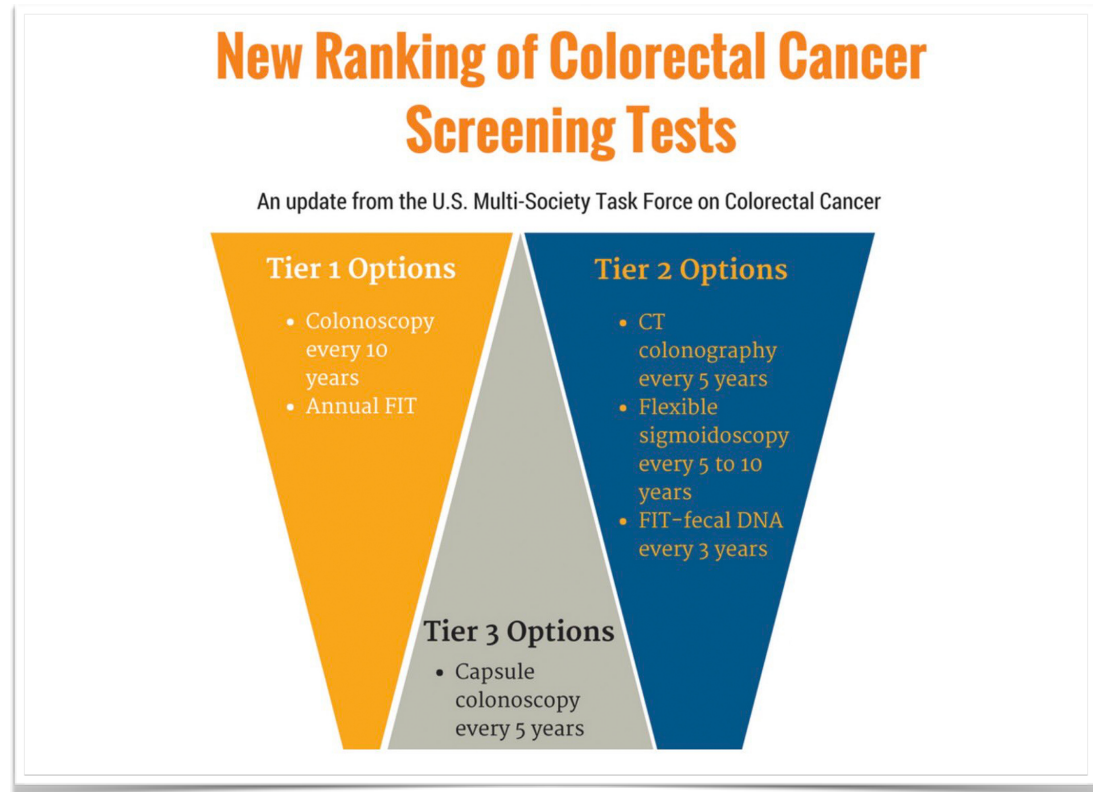
Experts agree that an annual Fecal Immunochemical Test is just as accurate at detecting Colon Cancer as a colonoscopy every 10 years.

Source: New England Journal of Medicine "Colonoscopy vs Fecal Immunochemical Test in Colon Cancer Screening" Quintero et. al.

Left: The Second Generation FIT® collection tube and cassette. Results are ready to view in about five minutes in your home.

Not long ago, the only colon cancer screening test options were guaiac based fecal occult blood tests developed in the 1960's and colonoscopy. A clear preference was given to colonoscopy as a physician could visualize the colon with an endoscope and excise polyps. The fecal occult blood test was a rudimentary test looking for peroxidase activity; a by-product of blood. Unfortunately, peroxidase is found in red meat, green leafy vegetables and Vitamin C. These tests were also rendered ineffective when being performed while a person was on prescription medications or NSAIDs.

In 2014, the Second Generation FIT® test was FDA cleared to aid in the detection of colorectal (colon) cancer, colitis, diverticulitis and other lower GI disease states. There are no diet restrictions, no medicine restrictions and the entire test is performed in the privacy of your own home in about five minutes. Additionally, Second Generation FIT® does not require a prescription or doctor's visit.



FIT & Colonoscopy are the only Tier 1 Colon Cancer Screening Tests.

Second Generation FIT® and other fecal immunochemical tests have been used in clinical settings in large hospitals and teaching institutions with great success. The FIT test has been featured in more than one hundred studies, which has led to the American College of Gastroenterology, the American Gastroenterological Association, the

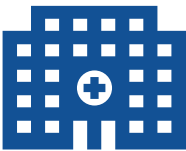
US Joint Preventative Task Force and the American Cancer Society recommending FIT for colon cancer screening, with outcomes similar to screening with colonoscopy. Continue reading to see how the Second Generation FIT® test is changing the landscape of colon cancer screening for all average risk people.

The Younger Face of Colon Cancer

More and more individuals ages 25-35 years olds are being diagnosed with colon cancer...



Colonoscopy is not covered by insurance unless an individual is deemed high risk or until age 50.



There is a general unwillingness to have a colonoscopy due to uncomfortable bowel prep, time away from work, and expense.



Second Generation FIT® is a highly accurate test completed in about five minutes in the privacy of your home with no bowel prep and no diet or medicine restrictions.



The Fecal Immunochemical Test has been proven to find cancer early when it is curable. Even more compelling is its ability to find precancerous adenomas thus preventing colon cancer.

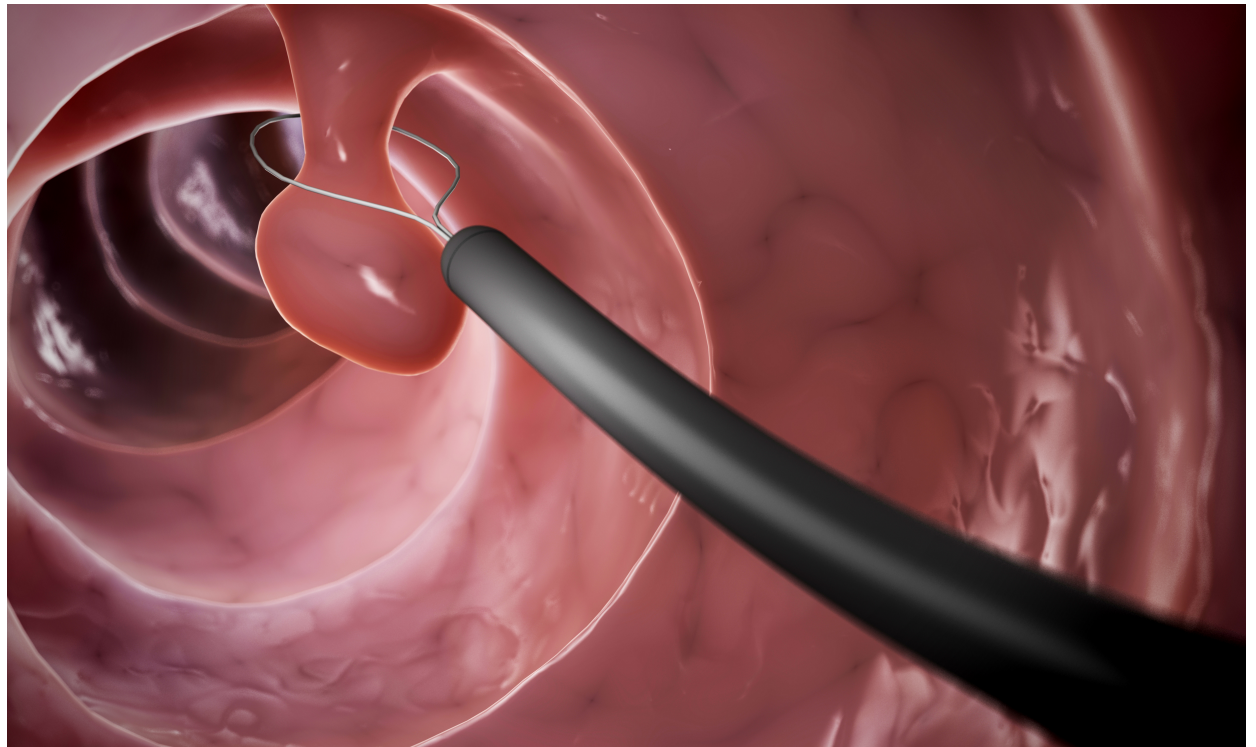


Statistics regarding colon cancer in the United States have remained constant for several years. Each year, roughly 150,000 people will be diagnosed with colon cancer and nearly 50,000 individuals will die from the disease.

Unfortunately, only 58% of the population is current with CRC screening. It is estimated that new CRC cases (actual instances of colon cancer) would drop by 277,000 if 80% of the population would be current, with another 203,000 deaths prevented.

As you would guess, screening rates are dangerously low at only 20% for under-insured persons and 37% for people with no high school diploma. Second Generation FIT® is the only test that breaks down these financial barriers and socio-economic barriers.

The FIT test is designed to look for human globin, part of hemoglobin - the top bio-marker for colon cancer, diverticulitis, colitis, and other lower GI disease states. The Second Generation FIT® test is highly sensitive, designed to illicit a positive result at just 50 nanograms of globin. Studies show that any positive FIT test should be followed up with



A positive Second Generation FIT® should almost always be followed up with a colonoscopy. Consult a physician with your results.

colonoscopy and a good goal is two to three months from the positive FIT.

Remember, only a colonoscopy can prevent or cure colon cancer as a physician can excise polyps during the procedure. The goal of Second Generation FIT® is to get the right people to colonoscopy. If your results are negative, the next step is to simply re-test in 12 months.

The Second Generation FIT® test is over-the-counter cleared for home use, but it is also used by hospitals, laboratories and physician's offices around the country and around the world. Pinnacle BioLabs is an FDA registered manufacturer of in vitro diagnostic tests and the Second Generation FIT® test is designed in Nashville, TN and manufactured entirely in the United States of America.

Which test is right for you?

For the average risk person (45 and older) Second Generation FIT® is the smart choice for colon cancer screening. Fast, accurate, inexpensive and easy to perform - Second Generation FIT® is a reliable, potentially life-saving test that can give you the information you need to take action, or the piece of mind to know that you are up to date with screening and no further action is needed for a calendar year. Second Generation FIT® is also evidence-based medicine. This means the test has been studied and proven effective at both finding cancer and reducing mortality and morbidity associated with colorectal cancer.

If you have a family history of colorectal cancer, your physician may recommend colonoscopy ten years prior to the onset of your family member's cancer diagnosis. There are other medical conditions you may have which make this the right choice.

Second Generation FIT® is the affordable, accessible test available without a prescription that is right for most average risk persons. Results are easy to interpret and the test can be performed quickly and intuitively with easy-to-understand instructions. Experts agree that the best colon cancer test is the one that gets done, which is why you can find Second Generation FIT® at CVS stores, RiteAid stores, [walmart.com](https://www.walmart.com), [amazon.com](https://www.amazon.com), and always tax free and with free shipping at www.PBLabs.com.



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Experts say taking the FIT test every year is as accurate at detecting Colon Cancer as getting a colonoscopy every ten years.
”



No bowel prep or missed days of work. No mailing yucky samples. Just results you can rely on.

01 Latest Technology



FIT has been given a grade of 1A for colon cancer screening, the same as colonoscopy.

02 Accurate



The average colonoscopy costs \$3,100. Deductibles range from \$0 to more than \$1,000.

03 Cost



Second Generation FIT® allows you to complete the test and get results in as few as 4 minutes.

04 Minutes

Source: Annals of Internal Medicine: |

American Cancer Society Colon Cancer Screening Statement

The ACS recommends that people at average risk of colorectal cancer start regular screening at age 45. This can be done either with a sensitive test that looks for signs of cancer in a person's stool (a stool-based test), or with an exam that looks at the colon and rectum (a visual exam). These options are listed below.

For screening, people are considered to be at average risk if they do not have:

- A personal history of colorectal cancer or certain types of polyps
- A family history of colorectal cancer
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- A confirmed or suspected hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC)
- A personal history of getting radiation to the abdomen (belly) or pelvic area to treat a prior cancer

Full text at <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>

American Gastroenterological Association Colon Cancer Screening Statement

Advantages of FIT include its noninvasive nature, 1-time sensitivity for cancer of 79% in 1 meta-analysis, fair sensitivity for advanced adenomas (approximately 30%), and low 1-time cost (approximately \$20). FIT is recommended annually in the United States. The MSTF has recently issued detailed recommendations on the technical performance of FIT and considers FIT an essential element of the CRC screening armamentarium for all practitioners. FIT is commonly the test of choice in programmatic screening, an excellent second choice for practitioners using sequential testing who offer colonoscopy first, and should likely always be one of the tests included in a multiple-options approach. Disadvantages of FIT include the need for repeated testing, which can be problematic in the non-programmatic (opportunistic) setting, and poor or no sensitivity for serrated class precursor lesions. However, there is no evidence that cancers arising through serrated class lesions are less likely to bleed than those arising via adenomas.

Full text at <https://www.gastro.org/practice-guidance/gi-patient-center/topic/colorectal-cancer-crc>

American College of Gastroenterology Colon Cancer Screening Statement

The recent joint guideline groups CRC screening tests into cancer prevention and cancer detection tests. Cancer prevention tests have the potential to image both cancer and polyps, whereas cancer detection tests have low sensitivity for polyps and typically lower sensitivity for cancer compared with that in cancer prevention tests (imaging tests). The ACG supports the division of screening tests into cancer prevention and cancer detection tests, but recommends a preferred cancer prevention test—colonoscopy every 10 years (Grade 1 B) and a preferred cancer detection test—annual fecal immunochemical test (FIT) to detect occult bleeding (Grade 1 B).

Full text at <https://gi.org/guidelines/>