Guidelines from the American Cancer Society, the US Preventive Services Task Force, and others recommend Fecal Immunochemical Tests (FIT), High-Sensitivity Fecal Occult Blood Tests (HS-gFOBT) and FIT-DNA testing as options for colorectal cancer (CRC) screening in men and women at average risk for developing colorectal cancer.

This document provides state-of-the-science information about these tests.

American Cancer Society®

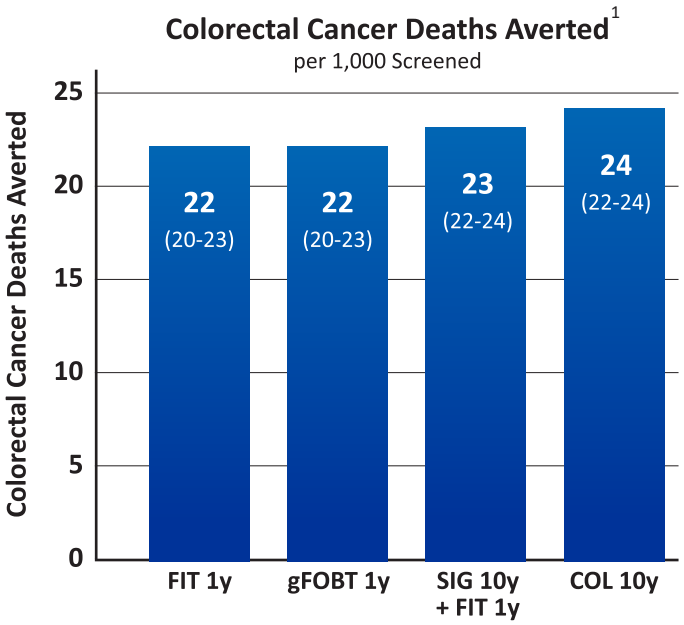
Clinician's Reference
STOOL-BASED TESTS FOR COLORECTAL CANCER SCREENING

80% IN EVERY COMMUNITY

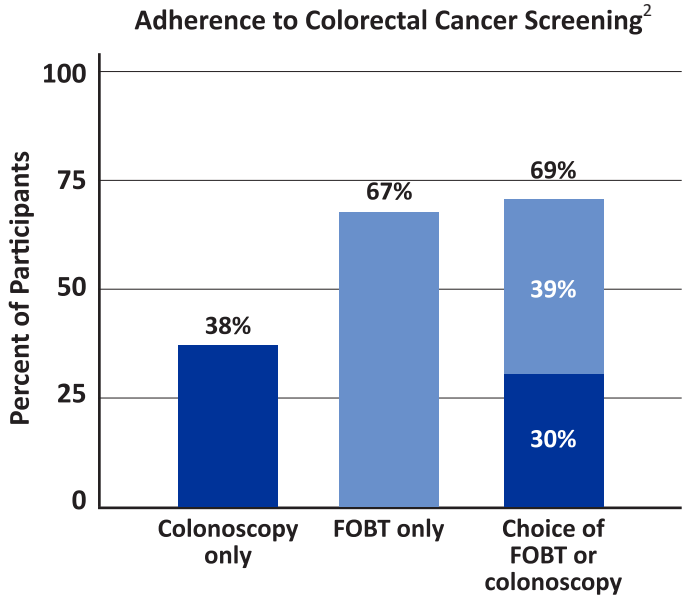
The number of colorectal cancer cases is dropping thanks to screening.
We are helping save lives.
We can save more.

The following factors make stool tests a good option for colorectal cancer screening

- Colorectal cancer screening with guaiac-based FOBT has been shown to decrease both incidence and mortality in randomized controlled trials.
- Modeling studies suggest that lives saved through a high quality stool-based screening program are nearly the same as with a high quality colonoscopy-based screening program when strict adherence to screening and needed follow up occurs at recommended intervals over a lifetime.



- All patients should be aware that stool tests are a recommended screening option, along with invasive exams like colonoscopy. When given a choice, a significant number of patients prefer stool tests. In addition, access to colonoscopy and other invasive tests may be limited or non-existent for many patients.



IMPLEMENTING HIGH QUALITY STOOL-BASED SCREENING PROGRAMS

Use stool tests only for **average risk patients** (no personal or family history of CRC, adenomas, or genetic syndromes). High risk patients should have colonoscopy screening.

Use only high-sensitivity fecal immunochemical (FIT), guaiac-based FOBTs (such as Hemoccult II Sensa), or FIT-DNA tests. Hemoccult II and generic guaiac-based tests are far less sensitive and should not be used for CRC screening.

Stool samples obtained by digital rectal exam (DRE) have low sensitivity for cancer (missing 19 of 21 cancers in one study with guaic-based FOBT) and should never be used for CRC screening.

All patients who have an abnormal stool test must follow up with colonoscopy.

Use reminder and recall systems for health care providers and EHRs to improve the delivery of CRC screening.

High sensitivity gFOBT and FIT should be repeated annually; FIT-DNA tests should be repeated every 3 years based on current screening guidelines.

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Three types of stool tests are available – FIT, guaiac-based FOBT, and FIT-DNA

Fecal Immunochemical Tests (FITs) look for hidden blood in the stool and are specific for human blood while older guaiac-based tests (gFOBTs) are not. Unlike gFOBT, FIT results are not impacted by food or medication. There is evidence that patient adherence with FIT may be higher than with gFOBT possibly because no dietary and medication restrictions are required before collecting samples, or because some brands of FIT require collection of only 1 or 2 specimens for a completed test. It is important to note that not all FITs are equally effective. As of July 2016, there are 26 FDA-cleared FITs available for purchase in the US, however most do not have published data on their performance for detection of cancer. To assist with choosing a FIT for use in your setting, the table below includes FITs that have published data on sensitivity and specificity for cancer.

FIT BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER†,‡	SPECIFICITY FOR CANCER†,‡	NUMBER OF STOOL SAMPLES
Automated (non-CLIA waived) FITs				
OC Auto-FIT*	Polymedco	65%-92.3%[3,4]	87.2%-95.5%[3,4]	1
CLIA-waived FITs				
OC-Light iFOB Test (also called OC Light S FIT)	Polymedco	78.6%-97.0%[3,4]	88.0%-92.8%[3,4]	1
QuickVue iFOB	Quidel	91.9%[5]	74.9%[5]	1
Hemosure One-Step iFOB Test	Hemosure, Inc.	54.5%[3]	90.5%[3]	1 or 2
InSure FIT	Clinical Genomics	75.0%[6]	96.6%[6]	2
Hemoccult-ICT	Beckman Coulter	23.2%-81.8%[3]	95.8%-96.9%[3]	2 or 3

*Used with OC-Sensor DIANA and OC-Auto Micro 80 automated analyzers.

†Detection limits for cancer vary across FIT brand and by study such that direct comparison between FIT brands is not possible.

‡Cited studies should be interpreted in the full context of the published literature given variation in study size and quality.

Guaiac-based FOBTs (gFOBTs) have been the most common form of stool tests used in the US prior to FIT becoming widely available. Modern high-sensitivity tests have much higher cancer and adenoma detection rates than older tests, resulting in fewer missed cancers. Hemoccult II SENSA is the only test in this category for which published performance data is available. Screening guidelines now specify that only high-sensitivity forms of guaiac-based tests should be used for colorectal cancer screening. **Hemoccult II and similar older guaiac-based tests should not be used for colorectal cancer screening.**

GFOBT BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER	SPECIFICITY FOR CANCER	NUMBER OF STOOL SAMPLES
Hemoccult II SENSA	Beckman Coulter	61.5%-79.4%[4]	86.7%-96.4%[4]	3

FIT-DNA is a stool test that looks for increased levels of altered DNA biomarkers that are released into the stool as cells from colorectal cancer and adenomas degenerate. Cologuard is the only stool DNA test currently marketed in the US and combines testing for these DNA biomarkers with a high-quality FIT (a "FIT-DNA" test).

FIT-DNA BRAND NAME	MANUFACTURER	SENSITIVITY FOR CANCER	SPECIFICITY FOR CANCER	NUMBER OF STOOL SAMPLES
Cologuard	Exact Sciences	92.3%[7]	89.8%[7]	1

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Visit **nccrt.org** or **cancer.org/colonmd** to find additional clinical practice tools and learn more about 80% in Every Community, the national initiative to reach colorectal cancer screening rates of 80% and higher across the US.

View the NCCRT June 2016 Implementing FIT webinar: **http://nccrt.org/webinars**

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NATIONAL Colorectal Cancer ROUNDTABLE

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