Clinician's Reference Brief: Stool-based Tests for Colorectal Cancer Screening





Guidelines from the American Cancer Society and the United States Preventive Services Task Force (USPSTF) recommend stool-based tests as effective options for screening in people at average risk for developing colorectal cancer (CRC).^{1,2}

All patients should be made aware that stool-based tests are a recommended screening option, along with a visual (structural) exam like colonoscopy.

The American Cancer Society and the USPSTF recommend that CRC screening should begin at age 45 for both men and women at average risk with either a high-sensitivity stool-based test or a visual (structural) exam.^{1,2}

Stool-based Testing Options for CRC Screening

Studies show that people at average risk for CRC are more likely to complete screening when given a choice of testing options.³ Talk to patients about all CRC screening options, including potential benefits and limitations, so they can make an informed decision. In some cases, patients may experience additional barriers to completing a timely colonoscopy, including extended wait times for appointments or geographical distance, especially if they live in a rural area.

CRC is now the leading cause of cancer death in men younger than age 50 and the second in women that age. CRC incidence rates have increased by 1% to 2% per year since the mid-1990s in those younger than age 55.4 Timely screening for individuals at average risk is essential. Evaluate and refer symptomatic patients to colonoscopy as needed, regardless of age.

Types of Stool-based Screening Tests^{1,2}



High-sensitivity fecal immunochemical test (FIT) every year



High-sensitivity guaiac-based fecal occult blood test (gFOBT) every year



Multi-targeted stool DNA test with FIT (FIT-DNA, also mt-sDNA or sDNA-FIT) every 3 years

If a person chooses to be screened with any test other than a colonoscopy, any positive or abnormal test result should be followed up with a timely colonoscopy.

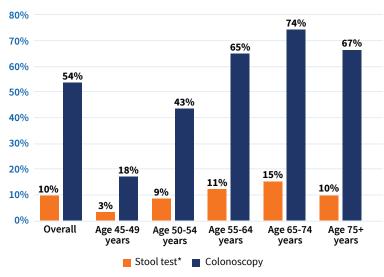
The average follow-up rate of colonoscopy within one year of a positive or abnormal stool-based test is as low as 56%.⁵

Delayed colonoscopy follow-up is associated with increased risk of colorectal cancer and advanced-stage disease at the time of diagnosis.⁶

Addressing Barriers to CRC Screening

Stool-based testing can help address some of the common barriers to colonoscopy, including perceptions that colonoscopy is unpleasant or embarrassing, the need for bowel preparation, undergoing sedation, potential need for childcare and time off work, and transportation challenges to and from screening.⁷

CRC Screening Rates by Recommended Age, 2021, US



^{*}gFOBT, FIT within the past year or sDNA test within the past three years

Modeling research suggests that the number of lives saved through stool-based testing is nearly the same as with invasive exams, as long as positive stool tests are promptly followed by colonoscopy.⁹

- sDNA-FIT annually: 27 to 31
- Colonoscopy every 5 years: 28 to 32
- Sigmoidoscopy every 5 years: 23 to 27
- Sigmoidoscopy every 10 years with annual FIT: 27 to 31

Stool-based Test Overview

FIT

Scope: Detect blood in stool by using antibodies to identify hemoglobin.⁷

FDA-approved tests available: Many options exist, including Hemoccult ICT, Hemosure iFOB (Hemosure), QuickVue iFOB Test (Quidel), and OC-Light S (Eiken)

Key information:

Accuracy¹⁰

· Sensitivity: 79%; Specificity: 94%

Sample collection

• 1 or more samples, at-home specimen collection

Benefits

- · No direct risk to the colon
- · No bowel prep
- No pretest diet or medication changes needed

Limitations

- Can miss polyps and some cancers
- · Can have false-positive test results
- · Needs to be done every year

gFOBT

Scope: Identify blood in stool by using a chemical (guaiac) to detect a molecule (heme). Due to their lower sensitivity and specificity compared with FITs, they are not the preferred option for stool-based colorectal cancer screening. Only high-sensivity tests should be used.

FDA-approved tests available: Multiple tests exist, including Hemoccult II SENSA (Beckman Coulter)

Key information:

Accuracy¹⁰

Sensitivity: 31%-79%; Specificity: 87%-98%

Sample collection

3 samples, at-home specimen collection

Benefits

- · No direct risk to the colon
- · No bowel prep

Limitations

- · Can miss polyps and some cancers
- · Can have false-positive test results
- Needs to be done every year

FIT-DNA

Scope: Identify blood, as well as genetic alterations in stool that are associated with colorectal cancer.⁷

FDA-approved tests available: Cologuard (Exact Sciences); Cologuard Plus (Exact Sciences)

Key information:

Accuracy¹⁰

- Cologuard:¹¹
 - Sensitivity: 92%; Specificity: 87%
- Cologuard Plus:12
 - Sensitivity: 95%; Specificity: 93%

Sample Collection

 1 sample, at-home specimen collection; process more involved than that of FIT or gFOBT and requires special reagents

Benefits

- · No direct risk to the colon
- No bowel prep
- · No pretest diet or medication changes needed

Limitations

- Can miss polyps and some cancers
- Can have false-positive test results
- Needs to be done every 3 years

Checklist for High-quality Stool-based Screening Programs

- ☑ Talk with your patients about stool-based screening tests as an option for CRC screening.
- ☑ Remember, stool-based tests are for people at average risk of developing CRC (no personal or family history of colorectal cancer, adenomas, or genetic syndromes). Individuals deemed at high risk should have screening by colonoscopy.
- ☑ Recommend regular screening starting at age 45 for men and women.
- ☑ Use only high-sensitivity FIT or guaiac-based FOBT tests, or FIT-DNA tests.
- ☑ Stool samples obtained by digital rectal exam have low sensitivity for cancer and should never be used for CRC screening.
- All patients who have a positive or abnormal stool test should follow up with colonoscopy.

Additional Resources



STEPS for Increasing Colorectal Cancer Screening Rates: A Manual for Primary Care Practices



Dos and Don'ts of Colorectal
Cancer Screening



NCCRT Colonoscopy
Needs Calculator



American Cancer Society Colorectal
Cancer Screening Guidelines and
Resources for Your Patients



NCCRT Lead Time Messaging Guidebook



Mailed FIT Implementation Guide & Online Course

References

- 1. Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2018;68(4):250-281. doi:10.3322/caac.21457
- 2. US Preventive Services Task Force, Davidson KW, Barry MJ, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement [published correction appears in *JAMA*. 2021 Aug 24;326(8):773. doi:10.1001/jama.2021.12404]. *JAMA*. 2021;325(19):1965-1977. doi:10.1001/jama.2021.6238
- 3. Patel SG, Dominitz JA. Screening for colorectal cancer. *Ann Intern Med.* 2024;177(4):ITC49-ITC64. doi:10.7326/AITC202404160
- 4. Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024 [published correction appears in *CA Cancer J Clin*. 2024 Mar-Apr;74(2):203. doi: 10.3322/caac.21830]. *CA Cancer J Clin*. 2024;74(1):12-49. doi:10.3322/caac.21820
- 5. Mohl JT, Ciemins EL, Miller-Wilson LA, Gillen A, Luo R, Colangelo F. Rates of follow-up colonoscopy after a positive stool-based screening test result for colorectal cancer among health care organizations in the US, 2017-2020. *JAMA Netw Open*. 2023;6(1):e2251384. doi:10.1001/jamanetworkopen.2022.51384
- 6. Corley DA, Jensen CD, Quinn VP, et al. Association between time to colonoscopy after a positive fecal test result and risk of colorectal cancer and cancer stage at diagnosis. *JAMA*. 2017;317(16):1631-1641. doi:10.1001/jama.2017.3634
- 7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Colorectal cancer screening, version 1, 2024. Accessed October 24, 2024. https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf
- 8. Siegel RL, Wagle NS, Cercek A, Smith RA, Jemal A. Colorectal cancer statistics, 2023. *CA Cancer J Clin*. 2023;73(3):233-254. doi:10.3322/caac.21772
- Knudsen AB, Rutter CM, Peterse EFP, et al. Colorectal Cancer Screening: An Updated Decision Analysis for the U.S. Preventive Services Task Force [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2021 May. (Technical Report, No. 202s.) Accessed October 24, 2024. https://www.ncbi.nlm.nih.gov/books/NBK570833/
- 10. Gómez-Molina R, Suárez M, Martínez R, Chilet M, Bauça JM, Mateo J. Utility of stool-based tests for colorectal cancer detection: a comprehensive review. *Healthcare (Basel)*. 2024;12(16):1645. doi:10.3390/healthcare12161645
- 11. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med*. 2014;370(14):1287-1297. doi:10.1056/NEJMoa1311194
- 12. Imperiale TF, Porter K, Zella J, et al; BLUE-C Study Investigators. Next-generation multitarget stool DNA test for colorectal cancer screening. *N Engl J Med*. 2024;390(11):984-993. doi:10.1056/NEJMoa2310336