Guidelines from the American Cancer Society, the US Preventive Services Task Force, and others recommend Fecal Immunochemical Tests (FIT), High-Sensitivity Guaiac-Based Fecal Occult Blood Tests (HS-gFOBT) and FIT-DNA tests 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.

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

80% by 2018

The number of colorectal cancer cases is dropping thanks to screening. We are helping to save lives. We can save more.
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 tests (FIT), high-sensitivity 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 a colonoscopy.

Use reminder and recall systems for health care providers and EHRs to improve 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.

*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.*

*Development of the Clinician’s Reference was supported, in part, by the American Cancer Society and Centers for Disease Control and Prevention comprehensive cancer control technical assistance and training cooperative agreement #5NU38DP004969.*
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.

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

*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.

<table>
<thead>
<tr>
<th>GFOBT BRAND NAME</th>
<th>MANUFACTURER</th>
<th>SENSITIVITY FOR CANCER</th>
<th>SPECIFICITY FOR CANCER</th>
<th>NUMBER OF STOOL SAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoccult II SENSA</td>
<td>Beckman Coulter</td>
<td>61.5%-79.4%4</td>
<td>86.7%-96.4%4</td>
<td>3</td>
</tr>
</tbody>
</table>

**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).

<table>
<thead>
<tr>
<th>FIT-DNA BRAND NAME</th>
<th>MANUFACTURER</th>
<th>SENSITIVITY FOR CANCER</th>
<th>SPECIFICITY FOR CANCER</th>
<th>NUMBER OF STOOL SAMPLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cologuard</td>
<td>Exact Sciences</td>
<td>92.3%7</td>
<td>84.4%7</td>
<td>1</td>
</tr>
</tbody>
</table>
Key Sources


Other Information Sources


Visit nccrt.org or cancer.org/colonmd to find additional clinical practice tools and learn more about 80% by 2018.