Fecal Immunochemical Test (FIT) for Colorectal Cancer Screening

CLINICAL APPLICATION

Each year 146,000 new cases of colorectal cancer (CRC) are diagnosed in the U.S., and 60 percent of these patients have metastatic disease at the time of diagnosis. About 56,000 CRC patients die of their disease each year, and it's estimated that more than half could have been saved by effective screening and earlier diagnosis. Unfortunately, compliance with screening tests is low.

Screening tests for fecal occult blood have been shown to significantly reduce CRC mortality. The guaiac method has been used for many years, but it requires a three- to five-day abstention from aspirin, NSAIDS, red meat, poultry, fish, certain vegetables, and vitamin C. The guaiac method also detects blood of upper GI origin, which is usually due to gastric inflammatory disease rather than CRC.

The Fecal Immunochemical Test (FIT) for occult blood has solved many of these problems. This method is highly specific for the globin portion of human hemoglobin and is easy for patients to use. It requires no dietary or medication restrictions, and it does not detect blood of upper GI origin. This means better patient compliance and fewer false-positive tests due to gastric inflammation or medications.

PAML offers the FIT as a screening test for colorectal cancer. Each single-use kit contains easy-to-understand instructions and a patient-friendly collection device. There is also a useful brochure that discusses CRC and screening.

Quick Facts

Screening for colorectal cancer can save lives.

The FIT for occult blood offers these benefits:
- No dietary or medication restrictions required.
- Easy collection.
- Improved patient compliance.
- Fewer false-positive results.
- Stable 15 days at room temperature, 30 days refrigerated.
- 30-day sample stability refrigerated (in collection device).

The American Cancer Society provides the following recommendations:
- “In comparison with guaiac based tests for the detection of occult blood, immunochemical tests are more patient-friendly and likely to be equal or better in sensitivity and specificity.”
- Annual testing for fecal occult blood is recommended after age 50 for all men and women at average risk for colorectal cancer.

**TEST INFORMATION**

**Fecal Immunochemical Test (FIT) for Colorectal Cancer Screening**

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>Fecal Immunochemical Test (FIT)</th>
</tr>
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<tbody>
<tr>
<td>METHOD</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>ORDER CODE</td>
<td>IFOBT</td>
</tr>
<tr>
<td>CPT CODES</td>
<td>82274 (Yearly screen billed to medicare as g0328.)</td>
</tr>
<tr>
<td>SPECIMEN</td>
<td>Random stool sample collected with the polymedco collection probe. Scrape stool with surface of probe. Stool must cover the grooved portion of probe. There are no dietary restrictions, and only a single, one-day sample is necessary. Store and transport at room temperature. Collection devices are available from PAML supply department.</td>
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<tr>
<td>COMMENTS</td>
<td>Alternative sample: obtain sample from toilet paper, not from toilet bowl. If polymedco collection probe is not used, store and transport refrigerated. Stability: 15 days at room temperature, 30 days refrigerated.</td>
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<tr>
<td>SCHEDULE</td>
<td>Tuesday – Saturday</td>
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<tr>
<td>TURNAROUND</td>
<td>1-3 Days</td>
</tr>
<tr>
<td>RANGES</td>
<td>Negative</td>
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</tbody>
</table>

**SELECTED REFERENCES**


www.paml.com
Questions & Answers

Fecal Immunochemical Test (FIT) for Occult Blood

Why is an immunochemical test for occult blood better than the guaiac method?
Immunochemical tests for fecal occult blood are highly specific for the globin portion of the human hemoglobin molecule. This makes them far more specific than the guaiac method, which reacts with any dietary substance—hemoglobin or otherwise—having peroxidase-like activity.

What does the American Cancer Society recommend?
The American Cancer Society recommends annual screening for fecal occult blood in all patients over 50 years of age who are at average risk for colorectal cancer. Regarding the FIT test, the ACS notes the following:

“In comparison with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly and are likely to have equal or better sensitivity and specificity.”

Are dietary restrictions necessary for the FIT test?
No. Because of its high specificity, the FIT test detects human blood only of lower gastrointestinal origin. False-positive results are therefore very rare.

In contrast, the guaiac method requires significant patient preparation to avoid false-positive results. This involves a three- to five-day abstinence from any dietary source of peroxidase activity, including red meat, poultry, fish, certain vegetables (broccoli, cauliflower, melons, radishes), vitamin C (including citrus fruits, juices or over the counter supplements), and medications like aspirin or NSAIDS. Inadequate preparation can lead to a false-positive guaiac and unnecessary followup tests.

What about bleeding from the upper GI tract?
Upper GI bleeding is most commonly due to inflammatory conditions and can lead to a positive guaiac test. Since fecal occult blood testing is used to screen for colorectal cancer, this is considered a false positive. In contrast to guaiac, the FIT test does not react with blood of upper GI origin because the globin proteins are absorbed or degraded in the small intestine.

How is the FIT test performed?
This test is very patient-friendly. The collection tube has small plastic probe built into the cap. The patient simply unscrews the cap, dips the probe into the feces, and screws the cap back into the sample tube. The tube is then returned to the lab for testing. This is much easier and cleaner than swabbing feces onto a guaiac test paper.

What about sample stability?
The FIT sample is stable for seven (7) days at room temperature and 14 days if refrigerated. Guaiac samples are generally less stable.

What are the advantages of the FIT test?
Compared to guaiac testing, the FIT test has several advantages:

• No dietary or medication restrictions are necessary.

• Fewer false positives due to inadequate dietary preparation or upper GI bleeding.

• Reduced numbers of unnecessary follow-up tests and subsequent patient anxiety.

• Easier collection and improved patient compliance.

• 15-day specimen sample stability at room temp (in collection device). 30-day sample stability refrigerated (in collection device).

SELECTED REFERENCES
1. Noninvasive Testing for Colorectal Cancer: A Review
3. Emerging Technologies in Screening for Colorectal Cancer

What about patients at greater than average risk for colorectal cancer?
• The following individuals are at higher risk:
  • A personal history of colorectal cancer or adenomatous polyps.
  • A personal history of chronic inflammatory bowel disease.
  • A family history of colorectal cancer or adenomatous polyps in a first-degree relative younger than 60, or in two first-degree relatives of any age.
  • A known family history of hereditary colorectal cancer (familial adenomatous polyposis or hereditary nonpolyposis colon cancer).

Persons at higher than average risk require regular colonoscopic surveillance.