Overview

Useful For
Colorectal cancer screening
Screening for gastrointestinal bleeding

Method Name
Immunochemical

NY State Available
Yes

Specimen

Specimen Type
Fecal

Specimen Required
Supplies: T682 Fecal Occult Blood Test Kit
Container/Tube: Fecal Occult Blood Test Kit (T682)

Specimen Volume: Sample must fill the grooved portion of the sample probe
Collection Instructions:
1. Collect a random stool specimen.
2. See Fecal Occult Blood Test Kit (T682) package insert for instructions.
3. Specimen must be collected in specific sample vial within 4 hours of defecation.

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
- Oncology Test Request (T729)
- Gastroenterology and Hepatology Client Test Request (T728)

Specimen Minimum Volume
Sample must cover the entire grooved portion of the sample probe.

Reject Due To
No specimen should be rejected.

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal</td>
<td>Refrigerated (preferred)</td>
<td>30 days</td>
<td>FOBT</td>
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</table>
Test Definition: FOBT
Occult Blood, QL, Immunochemical, F

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Ambient</td>
<td>15 days</td>
<td></td>
<td>FOBT</td>
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Clinical and Interpretive

Clinical Information

Colorectal cancer (CRC) is 1 of the most commonly diagnosed cancers in the United States (US), and the second leading cause of cancer-related deaths. CRC almost always develops from adenomatous polyps, yet patients remain asymptomatic until the cancer progresses to a fairly advanced stage. Screening for colorectal cancer is strongly advocated for by the US Preventive Services Task Force, the American Cancer Society, the American College of Gastroenterology, and other clinical societies, due to the high incidence of disease and decrease in mortality with medical intervention. Men and women at average risk for colorectal cancer should be screened at regular intervals beginning at age 50, continuing until age 75. Individuals with certain high-risk factors (age, African-American race, inflammatory intestinal disorders, family history of colon cancer, obesity, diabetes, poor diet) may consider earlier screening strategies.

Several options are available for CRC screening and includes fecal occult blood testing (FOBT), sigmoidoscopy, and colonoscopy. FOBT historically utilized guaiac-based tests that identify the presence of hemoglobin based on a nonspecific peroxidase reaction. Guaiac-based FOBT is no longer recommended for cancer screening because it does not detect most polyps and cancers. Furthermore, the false-positive rate with guaiac tests is high if patients do not follow the recommended dietary (withholding notably meat, certain vegetables, iron supplements) or pharmaceutical (withholding nonsteroidal anti-inflammatory drugs, vitamin C) restrictions. Finally, multiple stool collections are needed for optimal interpretation of guaiac-based FOBT results.

Fecal immunochemical testing (FIT) has evolved as the preferred occult blood test for colorectal cancer screening due to the lack of specificity and sensitivity of guaiac-based methods. FIT specifically detects the presence of human hemoglobin, eliminating the need for dietary and medication restrictions. For colorectal cancer screening only a single collection is required. The specificity of FIT is routinely >95% with reported sensitivities ranging from 40% to 70% based on the patient population. The clinical specificity of FIT is 97% based on internal studies conducted at Mayo.

To evaluate occult GI bleeding in patients with anemia or iron deficiency, the HemoQuant test should be used (HQ / HemoQuant, Feces). Neither FIT nor guaiac testing detects upper gastrointestinal (GI) bleeding because globin and heme are degraded during intestinal transit. In contrast, the HemoQuant test detects occult bleeding equally well from all sources within the GI tract. The HemoQuant test utilizes a specific fluorometric method that will detect any hemoglobin or heme-derived porphyrins in the stool, is very sensitive, and provides quantitative results.

Reference Values

Negative

This test has not been validated in a pediatric population, results should be interpreted in the context of the patient's presentation.

Interpretation

This is a quantitative assay but results are reported qualitatively as negative or positive for the presence of fecal occult blood; the cutoff for positivity is 100 ng/mL hemoglobin. The following comments will be reported with the qualitative result for patients >17 years:

-Positive results; further testing is recommended if clinically indicated. This test has 97% specificity for detection of
lower gastrointestinal bleeding in colorectal cancer.

-Negative results; this test will not detect upper gastrointestinal bleeding; HQ / HemoQuant, Feces test should be ordered if clinically indicated.

Cautions
Fecal immunochemical tests do not detect upper gastrointestinal (GI) bleeding due to the breakdown of globin during intestinal transit; HemoQuant is the most sensitive test to detect upper and lower GI bleeding.

Patients with hemorrhoids or females who are menstruating should not undergo occult blood testing until the bleeding has ceased.

Urine and excessive dilution of specimens with water from the toilet bowl may cause erroneous test results.

Supportive Data
Clinical pathologic correlative studies.

Clinical Reference


Performance

Method Description
The OC-Auto Micro 80 fecal occult blood test is an automated immunoassay utilizing polyclonal anti-human hemoglobin A0 (HbA0) antibodies to specifically detect the presence of human hemoglobin in feces. When the HbA0 antibody infused latex particles are added to a fecal sample and agitated, the antigen-antibody reaction is initiated and the particles begin to agglutinate. This agglutination is measured as an optical change, with the increase in absorbance directly proportional to the concentration of hemoglobin in the sample. The quantitative hemoglobin concentration is translated and reported as a qualitative result.(Package insert: OC-Auto Micro 80 FOB Test, 10/12/2009, Polymedco, Courtlandt Manor, NY)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday
Analytic Time
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
7 days refrigerate

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
82274

G0328-Government payers (if appropriate)

LOINC® Information

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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>FOBT</td>
<td>Occult Blood, QL, Immunochemical, F</td>
<td>29771-3</td>
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<tbody>
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