Overview

Useful For
Colorectal cancer screening
Screening for gastrointestinal bleeding

This test has **not been validated for** testing of patients with hemoglobinopathies.

Method Name
Immunochemical

NY State Available
Yes

Specimen

Specimen Type
Fecal

Specimen Required

Supplies: Fecal Occult Blood Test Kit (T682)

Container/Tube: Fecal Occult Blood Test Kit

Specimen Volume: Specimen must fill the grooved portion of the sample probe

Collection Instructions:

1. Collect a random stool specimen.

2. See Fecal Occult Blood Test Kit 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
See Specimen Required

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information
**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>
</tr>
</thead>
<tbody>
<tr>
<td>Fecal</td>
<td>Refrigerated (preferred)</td>
<td>30 days</td>
<td>FOBT</td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>15 days</td>
<td>FOBT</td>
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</table>

**Clinical and Interpretive**

**Clinical Information**

Colorectal cancer (CRC) is one of the most commonly diagnosed cancers in the 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 and 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.

A variety of options are available for colorectal cancer screening including: fecal occult blood testing (FOBT), sigmoidoscopy, colonoscopy, and multimarker Cologuard testing that includes genetic markers of colorectal cancer. Historically occult blood tests utilized guaiac-based tests that were susceptible to dietary interferences, but the FOBT test utilizes fecal immunochemical testing (FIT) specific for 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 greater than 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 Clinic but can be limited by gastrointestinal bleeding from a non-colorectal cancer source. In a recent study of 10,000 average risk participants, Cologuard detected colorectal cancer, precancerous lesions, and polyps with high-grade dysplasia with higher sensitivity than FIT testing.(1) However, Cologuard had slightly lower specificity than FIT testing in that study. Cologuard requires an entire bowel movement for testing versus 1 small sample for FIT. Current societal guidelines endorse the use of FIT and Cologuard interchangeably with 1-year based screening for FIT versus a suggested 3-year DNA based screening for average risk population, recognizing that the testing interval for the latter is uncertain.(2,3)

**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 older than 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 hemoglobin 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.

Because gastrointestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, a negative test result does not assure absence of lesion.

Certain medications such as aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) may cause gastrointestinal irritation and subsequent bleeding in some patients, causing positive 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, 06/2016 Polymedco, Courtlandt Manor, NY)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday

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