MAYO CLINIC LABORATORIES

# Test Definition: FOBT

Occult Blood, QL, Immunochemical, F

## 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

### Ordering Guidance

This test will not detect upper gastrointestinal bleeding. If clinically indicated, order HQ / HemoQuant, Feces.

### 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)

## Reject Due To

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

## Specimen Minimum Volume

See Specimen Required

## Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Fecal | Refrigerated (preferred) | 30 days | FOBT |
| | Ambient | 15 days | FOBT |

## Clinical & Interpretive

### Clinical Information

Colorectal cancer (CRC) is one of the most commonly diagnosed cancers in the United States, 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 United States 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, 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 this 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

1. Imperiate TF, Ransohoff DF, Itzkowitz SH, et al: Multitarget stool DNA testing for colorectal-cancer screening. N Engl J Med 2014;370(14):1287-1297

2. Robertson DJ, Lee JK, Boland CR, et al. Recommendations on fecal immunochemical testing to screen for colorectal neoplasia: A consensus statement by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2017;152(5):1217-1237

3. Rex DK, Boland CR, Dominitz JA, et al. Colorectal cancer screening: Recommendations for physicians and patients from the U.S. Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2017 Jul;153(1):307-323. doi: 10.1053/j.gastro.2017.05.013

4. Levin B, Lieberman DA, McFarland B, et al: Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. CA Cancer J Clin 2008 May-June;58(3):130-160. doi: 10.3322/CA.2007.0018

5. Whitlock EP, Lin JS, Liles E, Beil TL, Fu R: Screening for colorectal cancer: a targeted, updated systematic review for the U.S. Preventive Services Task Force. Ann Intern Med 2008 Nov 4;149(9):638-658

6. Hol L, Wilschut JA, van Ballegooijen M, et al: Screening for colorectal cancer: random comparison of guaiac and immunochemical faecal occult blood testing at different cut-off levels. Br J Cancer 2009 Apr 7;100(7):1103-1110. doi: 10.1038/sj.bjc.6604961

7. Levi Z, Rozen P, Hazazi R, et al: A quantitative immunochemical fecal occult blood test for colorectal neoplasia. Ann Intern Med 2007 Feb 20;146(4):244-255

8. Tannous B, Lee-Lewandrowski E, Sharples C, et al: Comparison of conventional guaiac to four immunochemical methods for fecal occult blood testing: implications for clinical practice in hospital and outpatient settings. Clin Chem Acta 2009 Feb;400(1-2):120-122. doi: 10.1016/j.cca.2008.10.023

## 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. Polymedco, Inc; 06/2016)

### PDF Report
No

### Specimen Retention Time
7 days

### Performing Laboratory Location
Rochester

## Fees & Codes

### Test Classification
This test has been cleared, approved, or is exempt by the US 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

| Test ID | Test Order Name | Order LOINC Value |
|---|---|---|
| FOBT | Occult Blood, QL, Immunochemical, F | 29771-3 |

| Result ID | Reporting Name | LOINC® |
|---|---|---|
| FOB | Occult Blood, Fecal | 29771-3 |