

INTENDED USE

FIT-Detect+ is a rapid qualitative test for the immunochemical detection of fecal occult blood/human hemoglobin (hHb) in human fecal specimens as an aid in the diagnosis of gastrointestinal disorders such as diverticulitis, colitis, polyps, and colorectal cancer. The device is suitable for use in laboratories and physician’s offices as well as for home use. The test is recommended for use in routine physical examination, new patient screening at admission and screening and monitoring any suspected colorectal cancer and/or gastrointestinal bleeding from any source.

SUMMARY AND EXPLANATION

The American Cancer Society recommends that average-risk men and women over age 45 should be tested for fecal occult blood yearly or as often as their physician recommends¹. Normally, a person may lose up to 1.5 mL of blood per day in the stool. Blood loss greater than 3 mL may be indicative of an abnormal condition. Patients with a family history of intestinal disorders or colorectal cancer, as well as those with personal histories of inflammatory bowel diseases such as polyps, colitis, and diverticulitis, should be monitored more frequently for occult blood in the stool^{2,3}. Digital examination, proctosigmoidoscopy, or colonoscopy is also recommended. Polyps, the precursors of colorectal cancer, can be treated successfully if detected early.

FIT-Detect+ Test is designed to detect fecal occult blood that can be caused by a number of conditions such as ulcers, hemorrhoids, polyps, colitis, diverticulitis, cancer and fissures. Since these disease conditions may not produce visible symptoms in their early stages, the test may act as an early warning signal. Patients testing positive with the test must be examined thoroughly with other medical procedures^{2,3}.

PRINCIPLE

FIT-Detect+ employs solid-phase chromatographic immunoassay technology to qualitatively detect the presence of fecal occult blood (FOB) in human feces. The sample is collected in a tube with extraction buffer. The tube is shaken to mix the fecal sample in the extraction buffer. Then, 3 drops (about 110 µL) of the mixed sample solution are added into the sample well of the test device. After the sample has been dispensed into the sample well, the extracted sample migrates into the pad containing detector antibody colloidal gold. The hHb in the sample will bind to the detector antibody and migrate onto the membrane where the test and control lines are located.

On the membrane, immobilized capture antibodies form the invisible test line. When the complex of hHb and detector antibodies reaches the test line, the complex binds to the capture antibodies to form a visible reddish test line indicative of a positive result, i.e., hHb is present. When no hHb is present in the sample, no reddish test line forms. In addition to the test line, a control line on the membrane provides an internal quality control of the test device. Anti-species-specific IgG antibodies are immobilized at the control line.

These antibodies will capture any unreacted/excess antibody-gold conjugates, forming a distinct control line. The control line serves to demonstrate that: lyophilized antibodies in the dye pad have been hydrated; sufficient sample has been applied to allow for migration to the test line and beyond; chemicals are working properly; and the proper procedure was followed. If a control line does not appear within the designated incubation time, the test result is invalid, and the test should be repeated using a new test device.

REAGENTS AND MATERIALS PROVIDED

Materials Provided:

Note: the materials provided are dependent on the type of kit ordered. Please refer to the ordering information section for the quantities of each component.

- FIT-Detect+ test device in a sealed foil pouch.
- The test device contains a combination of monoclonal antibodies directed against the globin of human hemoglobin.
- Sample collection tube, with sampler, containing 2 mL extraction buffer solution (PBS)
- Sample collection paper
- Return envelope
- Instructions for use

Materials required but not provided:

- Timer
- External controls
- Gloves

Ordering Information:

- FIT-Detect+ Test Kit (FOB50F)
 - 50 Test Devices
 - 50 Sample Collection Tubes
 - 50 Sample Collection Papers
- FIT-Detect+ Test Device Kit (FOBSTRF)
 - 50 Test Devices
- FIT-Detect+ Test Tube Kit (FOBBTLF)
 - 50 Sample Collection Tubes
- FIT-Detect+ Personal Use Kit (FBPUF)
 - 20 Personal Use Kits

NOTE: Each patient sample collection kit contains 1 sample collection instruction, 1 sample collection tube, 1 collection paper, 1 biohazard bag, 1 absorbent pad

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only
- Read instructions for use carefully before performing this test procedure
- Treat fecal samples and used test materials as if they are potentially infectious
- Do not drink sample collection solution
- If the sample collection buffer is spilled, wash with plenty of water
- Do not reuse the sample tube or test device
- Do not use the sample tube or test device if damaged
- Do not use the test beyond the expiration date indicated on the sample tube label or pouch
- Dispose of the used sample tubes and test devices in accordance with state or local regulation

STORAGE AND STABILITY

- Store the kit or kit contents at 2-30°C (36-86°F) until use. DO NOT FREEZE.
- The test device is stable until the expiration date printed on the pouch
- The sample collection tube is stable until the expiration date printed on the label

SPECIMEN COLLECTION AND PREPARATION

To avoid false results, specimens should not be collected while the patient has bleeding hemorrhoids or constipation, cuts on hands, during menstrual period or immediately after menstrual period. Hands and test area should be kept clean and free from blood to avoid false positive results.

SAMPLE COLLECTION

1. Write your information on sample collection tube label using a ballpoint pen. Write your name, date of birth (DOB), gender and the date of the collection.
2. Prepare the sample collection paper, peel off the cover strip from the adhesive tape on each end of the paper. Lift the toilet seat and spread the paper across the bowl. Secure the paper on one side of the rim and then the other, close the seat.
3. Deposit the fecal sample on collection paper or in a clean container.

NOTE: Do not allow collection paper or feces to come into contact with toilet water or urine.

4. Unscrew the collection tube cap from the sample collection tube, remove the sampler from the tube.
5. Randomly insert the grooved end of the sampler into the fecal sample in at least 6 different sites. Ensure the grooved end of the sampler is completely covered with fecal sample.

6. Insert the sampler into the sample collection tube and firmly tighten it. **Do not reopen.**

7. Ensure the sample collection tube is closed. After the sample has been collected release the adhesive tabs on the collection paper and flush the paper with the feces.

SAMPLE APPLICATION

1. Ensure you have filled in your information on label of the sample collection tube.
2. Wrap the absorbent pad around the tube.
3. Place the wrapped tube into the biohazard bag and seal.
4. Place the sealed biohazard bag containing the sample collection tube into the return envelope. Remove the tape from the envelope and seal.
5. Return the sample collection tube as soon as possible to your doctor or laboratory in the envelope provided.

NOTE: The extracted fecal sample may be stored at room temperature for up to 10 days.

PERFORMING TEST

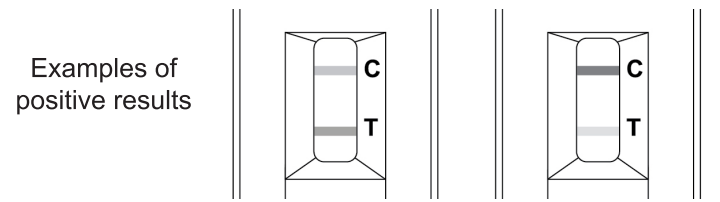
1. Shake the sample collection tube vigorously for 20-30 seconds to ensure the sample is well mixed with the buffer. Some small amounts of sample may not dissolve; this is normal.
2. Remove test device from its foil pouch by tearing at the notch.
3. Tap the collection tube on a hard surface to dislodge any trapped air in the top of cap.
4. Unscrew tip cap on the sample collection tube.
5. Holding the tube vertically above the sample well of the FIT-Detect+ device, squeeze the tube gently to dispense 3 drops into the sample well.
6. Read the result in 5-10 minutes. Important: Do not read the results after 10 minutes.

INTERPRETATION OF RESULTS

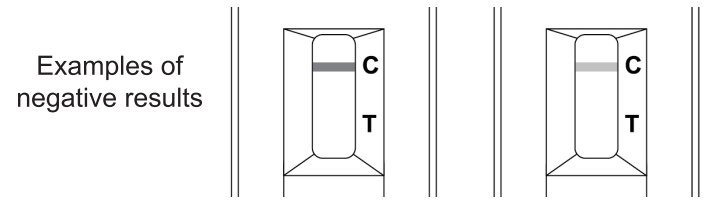
Positive:
A reddish line appearing in the control position (C) and another reddish line in the test position (T), indicates that human hemoglobin has been detected in the sample.

NOTE: Any reddish line in the test position (T), no matter how faint is a positive result. One line may be darker or lighter than the other, but even very faint reddish lines remain valid.

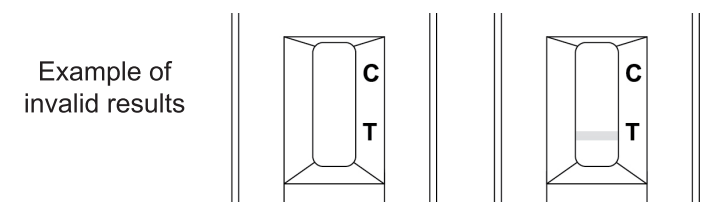
Any positive should be followed up with further examination to establish the source of bleeding.



Negative:
Only one red line appearing in the control position (C), with NO reddish line in the test position (T), indicates that human hemoglobin has not been detected in the sample.



Invalid:
If no reddish line appears in the control position (C), the test result is invalid and the sample remaining in the sample collection tube should be re-tested with a new test device.



QUALITY CONTROL

The FIT-Detect+ device contains a built-in control line that serves as an internal procedural control. The presence of the control line indicates that: an adequate sample volume was used; the reagents migrated properly; and the control antibody reagents are working properly.

Good laboratory practice recommends the use of external positive and negative controls to assure that test reagents are working properly, and that the user has performed the test correctly. If the controls do not perform as expected, review the instructions for use to see if the test was performed correctly; repeat the test or contact Polymedco Technical Services before testing patient specimens. Contact your supplier or Polymedco Technical Services for information about purchasing controls.

LIMITATIONS

- Results are not conclusive evidence of the presence or absence of gastrointestinal bleeding caused by cancer or other pathology.
- As with any immunochemical test, a positive FIT- Detect+ result should not be considered a conclusive diagnosis for gastrointestinal bleeding or pathology.
- Immunochemical FOB testing has been shown to be valuable in preliminary screening, particularly of asymptomatic populations, or as an aid to diagnosis. The test is not intended to totally replace other diagnostic procedures such as colonoscopy, flexible sigmoidoscopy, or other imaging studies such as double contrast barium enema or CT colonography.
- Because gastrointestinal lesions may bleed intermittently and blood in feces is not distributed uniformly, a negative test result does not assure absence of lesions.

- A test result may be negative even when disease is present, because bowel lesions, including some colorectal cancers and significant polyps, may not bleed at all or may bleed intermittently, or the blood may not be uniformly distributed in a fecal specimen and therefore missed during sampling.
- Results may be positive for samples from patients without significant bowel pathology. Usually, the reasons for such false positive results are obscure, but in some cases, certain medications may cause gastrointestinal irritation resulting in occult bleeding.
- FOB testing is recommended annually by the American Cancer Society (2018) for average-risk women and men, 45 years of age and older.⁴ However, patients with significant risk factors such as a family history of colorectal cancer should be screened earlier and more often.
- The intended use of FIT-Detect+ has not been established with pediatric patients (21 years or below).

PERFORMANCE CHARACTERISTICS

Sensitivity (Analytical Detection Limit)
Using dilutions of material with known hemoglobin concentration assayed by standard reference methodology, the analytical detection limit, or sensitivity, of FIT-Detect+ has been set at 50 ng hHb/mL buffer or 50 µg Hb/g feces.

Method Comparison Study
The performance of FIT-Detect+ was evaluated in comparison with a commercially available predicate device in a reference laboratory study. Five (5) different sample concentrations, 0, 37.5, 50, 62.5, and 500 ng hHb/mL, were tested using the FIT-Detect+ device and the predicate device using 8 replicates for each concentration, for a total of 40 samples. At each concentration, all results with the FIT-Detect+ agreed 100% with expected results and the results of the predicate.

Reproducibility Study
The performance of FIT-Detect+ was also evaluated in a study at three physicians’ office laboratory (POL) sites. Five (5) different concentrations, 0, 37.5, 50, 62.5, and 500 ng hHb/mL, were prepared by spiking hHb into the extraction buffer. Each concentration was divided into 60 vials for each test. These vials were labeled for blind study. Each site tested a total of 100 tests with blinded samples of 5 concentrations, 20 samples per concentration, for a total of 300 samples. The results obtained from the three POL sites agreed 99.7% with the expected results.

Specificity
FIT-Detect+ is specific for human hemoglobin. Samples containing the following substances (per mL of buffer or g of feces), when spiked in both positive and negative samples, did not interfere with the test results.

Potentially Interfering Substance	Concentration Tested
Beef Hb	1 mg/mL
Pig Hb	1 mg/mL
Horse Hb	1 mg/mL
Rabbit Hb	1 mg/mL
Iron	1 mg/mL
Ascorbic Acid	5 mg/mL
Sheep blood	0.1 mL/g feces
Goat blood	0.1 mL/g feces
Chicken blood	0.1 mL/g feces
Beef meat extract (fresh/boiled)	1 mL/g feces
Chicken meat extract (fresh/boiled)	1 mL/g feces
Fish meat extract (fresh/boiled)	1 mL/g feces
Horse meat extract (fresh/boiled)	1 mL/g feces
Pork meat extract (fresh/boiled)	1 mL/g feces
Rabbit meat extract (fresh/boiled)	1 mL/g feces
Goat meat extract (fresh/boiled)	1 mL/g feces
Cauliflower extract (fresh/boiled)	1 mL/g feces
Broccoli extract (fresh/boiled)	1 mL/g feces
Parsnip extract (fresh/boiled)	1 mL/g feces
Cantaloupe extract (fresh/boiled)	1 mL/g feces
Red radish extract (fresh/boiled)	1 mL/g feces
Raw turnip extract (fresh/boiled)	1 mL/g feces
Toilet water	0.1 mL/g feces
Fluoride	0.1 mL/g feces

REFERENCES

1. American Cancer Society. Colorectal Cancer Screening Guidelines: <https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/colorectal-cancer-screening-guidelines.html>
2. Mitchell SH, Schaefer DC, Dubagunta S. *Am Fam Physician*. 2004 Feb 15;69(4):875-81.
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4. Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults:2018 guidelines update from the American Cancer Society. *CA Cancer J Clin*. 2018;68(4):250-281. doi:10.3322/caac.21457

FIT-Detect+

polymedco

Helping save lives through early detection.

Manufactured for:

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SYMBOL KEY (ISO 15223-1)

Read instructions for use

Item number

Storage temperature

Expiration date

Do not reuse

For in vitro diagnostic use

Lot number

Manufacturer

Unique identification barcode