

FOB Test Cassette
for feces
(Revised May 25, 2007)

Intended Use

The FOB (Fecal Occult Blood) test is an in-vitro immuno-chromatographic assay for qualitative detection of human hemoglobin in feces. It is intended for professional and laboratory use only.

Summary

The presence of occult blood in human feces is often associated with gastrointestinal diseases, such as colon polyps, colorectal cancer, ulcerative colitis, and Crohn's disease. Early detection and treatment of these diseases by fecal occult blood screening can significantly reduce colorectal cancer. Immuno-chromatographic assay is more sensitive and more specific than the traditional guaiac assay. Also unlike the guaiac assay, patient does not need special dietary control.

Principle

The FOB test employs a unique combination of two monoclonal antibodies to selectively detect human hemoglobin in fecal samples. The test device contains pad coated with gold colloidal conjugated with anti-human hemoglobin antibodies, a nitrocellulose membrane coated anti human hemoglobin antibodies at the Test band and goat anti mouse antibodies at the Control band area. Once proper amount of the fecal liquid sample is added into the test device, it migrates across the test device by capillary action. If the fecal sample contains human hemoglobin at 10 ng/ml or higher, the Test band will appear as a red-purple band. If human hemoglobin level is less than detectable in the fecal sample, there is no Test band. The Control band will appear regardless of presences of human hemoglobin in the sample.

Storage and Stability

The FOB test kit can be stored at room temperature or 4-30°C (40-86°F). Do not freeze. The test device is sensitive to humidity and as well as to heat. Perform the test immediately after removing the test device from the foil pouch.

Warnings

1. For in vitro diagnostic use only.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not re-use the test kit.
4. Do not use it beyond the expiration date.
5. Do not eat or smoke while handling specimens.
6. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
7. Avoid splashing or aerosol formation.
8. Clean up spills thoroughly using an appropriate disinfectant.
9. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

Specimen preparation

1. Specimen collection should not be performed during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine, false-positive test results may be obtained.
2. Dietary restrictions are not necessary.
3. Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.

Specimen Collection

1. Only fecal specimens should be used in this assay. It can be collected from toilet paper or caught in a clean container. Specimen should avoid contamination of toilet water.
2. Unscrew the top of the sample collection device and use the sample collection stick to collect stool sample by dipping the stick randomly into 3 different places of the same stool sample.
3. Put the sample collection stick containing the sample back into the sample collection device and screw it tightly. Shake it very well.
4. Sample collected can be store at room temperature (below 30 °C) for 5 days or refrigerated at 4 to 8 °C for 7 days.

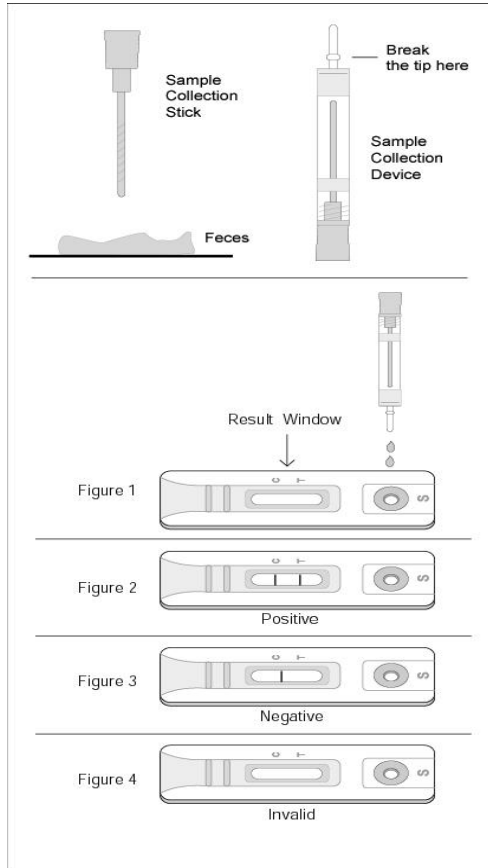
Procedure of the Test

1. Bring the extracted sample to room temperature if it is refrigerated. Then mix the extracted sample well by shaking the sample collection device a few times.
2. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
3. Hold the sample collection device so that the device tip facing up, then break off the tip of the collection device. Squeeze 2 drops of the extracted sample into the sample well (Figure 1).
4. As the test kit begins to work, you will see purple color move across the Result Window in the center of the Test Disk.
5. Interpret test results at 10 minutes. Do not read after 10 minutes.

Caution: The above interpreting time is based on reading the test results at room temperature of 15 to 30 °C. If your room temperature is significantly lower than 15 °C, then the interpreting time should be properly increased.

Interpretation of the Test

1. A color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band or "C" band.
2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band or "T" band.



Positive Result: The presence of two color bands ("C" and "T" bands) within the result window, no matter how faint the "T" band is (no matter which band appears first), it indicates a positive result (Figure 2).

Negative Result: The presence of only one purple color ("C") band within the result window indicates a negative result (Figure 3).

Invalid Result: If after performing the test no purple color band is visible within the result window, the test is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested (Figure 4).

Limitations of the Test

1. The FOB test is only intended for the detection of human hemoglobin in feces.
2. As with other FOB tests, results obtained by this FOB test should not be considered as conclusive evidence of the presence or absence of human hemoglobin in feces. This FOB test is used for preliminary screening only. It is not intended to replace other diagnostic procedures or tests.
3. The presence of blood in stools may be other than colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritations. If a positive result is obtained, additional diagnostic procedures should be performed to determine the cause and source of the occult blood in the fecal specimen.
4. Negative results do not exclude bleeding since it can be intermittent. False negative results may occur when occult blood is not evenly distributed throughout the bowel movement and fecal formation.

5. Some colorectal polyps and colorectal cancers may bleed intermittently or not at all at early stages.

Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Quality Control

Procedural Control: The test device has a procedure control, the Control band ("C" band). Presence of the "C" band indicates that prop amount of sample is used and the reagents migrated properly. Note: Presence of the "C" band does not mean that the antibody coated at "T" band area is accurately detecting the presence or absence of human hemoglobin in the sample.

External Control: Operators should always follow the proper regulatory guidelines to running of external quality controls, such as external negative and positive controls.

Performance Characteristics

Sensitivity: One hundred human hemoglobin free feces extraction specimens collected in-house were divided into five groups. Thus, each group had 20 specimens. The five groups of fecal extraction specimens were spiked with human hemoglobin for five different concentrations respectively: 0, 5, 10, 25, 50 of human hemoglobin per ml. The specimens were blind labeled and tested with this Fecal Occult Blood Rapid Test at three Physicians Office Laboratories (POL) and a Reference laboratory (RL).

The results obtained from POL have 100% agreement with the expected results. While compare to colonoscopy (gold standard) for a sample size of 300, the relativity sensitivity is 82% for adenomas > 1cm.

Specificity: This Fecal Occult Blood Rapid Test is specific to human hemoglobin. The following substances were spiked in both positive and negative specimens. They did not interfere the results.

Substance	Concentration (µg/ml)
Beef Hb	100
Fish Hb	100
Chicken Hb	100
Horse Hb	100
Sheep Hb	100
Broccoli	Extraction
Cantaloupe	Extraction
Horseradish	Extraction
Tumip	Extraction
Cauliflower	Extraction
Vitamin C	Dietary Supplement
Iron	Dietary Supplement

References

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