Firstep Fecal Occult Blood Test
Catalog Number: C040-C

Firstep Bioresearch, Inc.

FOR THE QUALITATIVE DETECTION OF FECAL OCCULT BLOOD IN FECES

For In Vitro Diagnostic Use

INTENDED USE

This Fecal Occult Blood (FOB) Test Device is a rapid immunological test intended for the qualitative detection of fecal occult blood in feces by professional laboratories and physician office laboratories. The test is intended for the determination of gastrointestinal (GI) bleeding, found in a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer. This FOB test device is recommended for use in (1) routine physical examinations, (2) monitoring any bleeding in patients, and (3) screening for colorectal cancer or gastrointestinal bleeding.

SUMMARY AND EXPLANATION

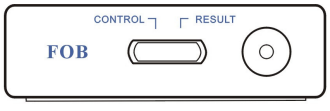
Colorectal cancer is the third most common cancer in the world. The appearance of fecal occult blood is often the first, if not the only, indicator associated with colorectal cancer and polyps. Other gastrointestinal disorders such as diverticulitis, Crohn's disease, colitis ulcer, etc. may also be associated with the presence of fecal occult blood. There are two different types of FOB tests available, the traditional guaiac FOB test and antibody based immunological FOB test. The traditional guaiac FOB tests do not provide a high degree of accuracy. Immunological FOB tests are more accurate and do not require special dietary restrictions prior to the test sample collection.

TEST PRINCIPLE

The FOB test is a "sandwich" immunoassay utilizing two monoclonal antibodies to specifically detect the presence of human hemoglobin (h-Hb) in feces. A stool specimen is collected into the Sample Bottle containing extraction buffer. If human hemoglobin is present at a level of greater than 50 ng/m in a fecal sample extract, an immuno-complex of "labeled monoclonal anti-human hemoglobin antibody – human hemoglobin – membrane coated monoclonal anti-human hemoglobin antibody" is formed. A red colored band appears in the result region, which is located in the result region of the test membrane. A similar colored band must appear in the control region located in the control region of the test membrane, indicating the test strip is functioning properly and the result is valid.

MATERIALS PROVIDED

1. Instructions for use.
2. 100 pouches and each pouch contains 1 test cassette and 1 desiccant.
3. 100 Sample Bottles and each contains sampling lid and pre-added extraction buffer.



FOB Test Cassette

Sample Bottle

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer.
2. External controls.

PRECAUTIONS

1. **For In Vitro Diagnostic use only.**
2. **Do not use test kit beyond expiration date or the pouch is damaged.**
3. **Read the entire procedure carefully prior to performing any tests.**
4. **Humidity and temperature can adversely affect results.**
5. **Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.**
6. **When the assay procedure is completed, dispose specimens carefully after autoclaving them at 121oC for at least 20 minutes. Alternatively, they can be treated with 0.5% sodium hypochloride (or house-hold bleach) for one hour before disposal. The used testing materials should be discarded in accordance with local, state and/or federal regulations.**

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 8-35°C. The Sample Bottles are suggested to be stored at 2-8°C for long term storage. The kit is stable within the expiration date printed on the label. DO NOT FREEZE or use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Patient preparation

1. Specimen should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine.
2. Alcohol, aspirin, indomethacin, reserpin, phenylbutazone, corticosteroids and other medications may cause gastrointestinal irritation resulting in occult bleeding and false positive.
3. Dietary restrictions are not necessary.

Specimen collection

1. Stool specimens can be collected at any time of the day.
2. Collect a random sample of feces in a clean, dry cup or toilet paper.
3. Unscrew the sample lid and keep the Sample Bottle in a vertical position to prevent the loss of any extraction solution as indicated in the Figure 1.
4. Insert and twist the tip of the sample lid into the stool specimen at three or more different sites (Figure 2).
5. Remove the excess sample from the sample lid by gently wiping with an absorbent tissue.
6. Collect fecal sample that is stuck to the surface of the sample lid. Do not intentionally collect any separate and large piece of fecal sample into the bottle.
7. Replace the sample lid into the bottle and secure tightly (Figure 3).
8. The specimen is ready for testing, transportation or storage. The sample collected can be stored at room temperature for up to 3 days and at 2-8ºC for up to 14 days.

Figure 1

Figure 2

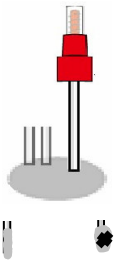
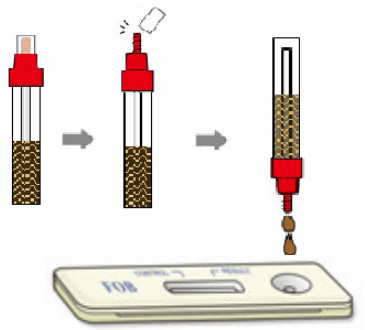


Figure 3

PROCEDURE

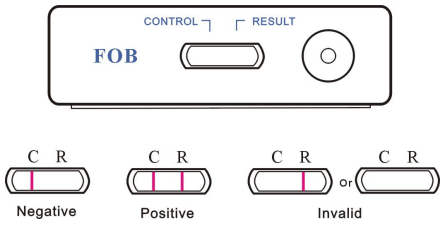
1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Shake the Sample Bottle several times.
3. Holding the Sample Bottle upright, unscrew the top cap of the bottle.

4. Squeeze 3 drops of the sample solution to the test sample well, as in the illustration.
5. Read the test results after 5-10 minutes. It is important that the background is clear before the result is read. **A positive result maybe read sooner than 5 minutes**.



*Note: If two colored bands are visible within 10 minutes, the test result is positive and valid. After 10 minutes, only the C line shows color development, the result is negative.**Don't read result after 10 minutes**"*

INTERPRETATION OF RESULTS



Positive: If two colored bands are visible within 5-10 minutes, the test result is positive and valid. The test result can be read as soon as a distinct colored band appears in the result region.
Negative: If result region has no color band and the control region displays a colored band, the result is negative and valid.
Invalid: If there is no distinct color band visible in the control region regardless of the readings in the result region, the test is invalid. A new test should be used to reevaluate the specimen.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. A number of conditions, as mentioned in the "Patient Preparation" section, can cause false positive results.
2. Intermittent tumor bleeding and irregular distribution of blood in the feces also contribute to false negative results.
3. Urine and excessive dilution of fecal samples with water from toilet bowl may cause erroneous results.
4. FOB test is not for use in testing urine, gastric specimens or other body fluids.
5. As with all diagnostic tests, the definitive clinical diagnosis must not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. FOB test is designed for the preliminary screening and should not replace other diagnostic procedures such as colonoscopy or sigmoidoscopy, etc

PERFORMANCE CHARACTERISTICS

1. Sensitivity: The analytical sensitivity of this test is 50 ng h-Hb/ml fecal sample extract, which is about 5 µg h-Hb/gram stool.
2. Reproducibility: Positive and negative fecal samples spiked to target h-Hb concentrations of 0 ng/mL, 37.5 ng/mL, 50 ng/mL, 62.5 ng/mL, 200 ng/mL, 1,000 ng/mL, and 2,000 ng/mL were repeated tested in multiple assay (30x) by both laboratory professionals and staff from physician office laboratories (POL). The test results were compared and found to be highly consistent with a 99.0% agreement between the results from POL and results from laboratory professional. The overall accuracy of this FOB test by POL was 96.7%.
3. Accuracy: A validation study using 620 hemoglobin negative fecal sample extracts and 28 positive extracts, was performed with this FOB test and another FDA approved commercial immunological FOB test. It was found that this FOB test has a 99.7% test Accuracy.
4. Specificity: This FOB test is specific for the detection of h-Hb, h-Hb-S, h-Hb-C, from whole human blood at a concentration of 50 ng/mL. This FOB test does not detect hemoglobin from a cow, horse, pig, sheep, chicken, or rabbit.
5. Interference Testing: Positive and negative samples were added with 1 mg/mL of interference factors extracted from ground raw meat from beef, pork, goat, rabbit, chicken & Horseradish Peroxidase and assayed with this FOB test. It was found that there was no cross-reaction with test results for both the negative and positive fecal samples. Acetaminophen, Aspirin, Ampicillin, Vitamin C, Atropine, Caffeine, Gentisic acid, Glucose, Human albumin, Urea and Uric acid were added to both negative and positive fecal samples and assayed with this FOB test. The results showed that there is no change of the interpretation of the FOB test results before and after the addition of these additives. No interference was found with any of the substances at the following concentrations:

Substance	Concentration
Acetaminophen	20 mg/dL
Aspirin	20 mg/dL
Ampicillin	40 mg/dL
Vitamin C	40 mg/dL
Atropine	40 mg/dL
Caffeine	40 mg/dL
Gentisic acid	40 mg/dL
Glucose	2000 mg/dL
Human albumin	2000 mg/dL
Urea	4000 mg/dL
Uric acid	10 mg/dL

REFERENCES

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CE EC REP

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REF	CATALOG NUMBER		DO NOT REUSE
IVD	IN VITRI DIAGNOSTIC MEDICAL DEVICE		USE BY
	TEMPERATURE LIMITATION	LOT	BATCH CODE
	CONSULT INSTRUCTIONS FOR USE		MANUFACTURER
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

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