FOB Rapid Test Cassette(Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographic assay for the qualitative rapid detection of fecal occult blood (FOB) in human feces.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PROUDCT SPECIFICATION

1T/BOX,10T/BOX,20T/BOX,25T/BOX,40T/BOX，50T/BOX

INTENDED USE

The FOB Rapid Test Cassette is a lateral flow immunochromatographic assay for the qualitative detection of human hemoglobin in feces. It is intended to be used in as a useful aid to detect gastrointestinal bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer. This test is recommended for professional use only and all results must be interpreted together with other clinical information or other diagnosis methods available to the physicians.

SUMMARY

Fecal occult blood (FOB) refers to blood in the feces that is not visibly apparent and it is generally defined as a blood loss of less than 50mL/d. An estimated 1-5% of large tested populations have a positive fecal occult blood test. Of those, about 2-10% have cancer, while 20-30% have adenomas. Other causes include bleeding peptic ulcer, Angiodysplasia of the colon, and sickle cell anemia.[1-3] Colorectal cancer is the third most common cancer in the world. The appearance of occult blood in human fecal specimen is often associated with gastrointestinal diseases, which might cause colorectal cancer if not treated promptly and properly.

Traditional guaiac-based method lacks sensitivity and specificity, and has diet restriction prior to testing. Latest immunochromatographic fecal occult blood test (IFOBT) uses specific antibodies to detect hemoglobin, which are superior to low sensitivity stool guaiac test for fecal occult blood (gFOBT) for colorectal cancer screening.[4,5]The FOB Rapid Test is an immunochromatographic fecal occult blood test (IFOBT) designed to specifically detect low levels (50ng/mL hemoglobin) of human fecal occult blood. It is highly sensitive for human hemoglobin (hHb) compared to the Guaiac and Hemoporphyrin methods. The results of this FOB rapid test are not affected by dietary peroxidases, animal blood and ascorbic acid.

PRINCIPLE

The FOB Rapid Test is a sandwich lateral flow immunochromatographic assay that employs a unique combination of polyclonal and monoclonal antibodies to selectively identify hemoglobin in fecal samples with a high degree of sensitivity. The test cassette consists of: 1) a pink colored conjugate pad containing monoclonal anti-hHb antibody conjugated with colloid gold (anti-hHb conjugates) and 2) a nitrocellulose membrane cassette containing a test band (T band) and a control band (C band). The T band is pre-coated with another monoclonal anti-hHb antibody, and the C band is pre-coated with goat anti-mouse IgG antibody. When a fecal sample fluid collected and prepared for testing using the fecal collection tube is added into the sample well of the test cassette, the sample fluid migrates by capillary action across the cassette. hHb if present in the specimen at or higher than 50 ng/mL will bind to the anti-hHb conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibody, forming a pink colored T band, indicating a FOB positive test result. Absence of this band suggests that the concentration of hHb in the specimen is below the detectable level, indicating a FOB negative result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a pink colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS

Materials Provided:

Test devices. Each cassette is pouched with a package of desiccant.
Extraction diluents (1.5 mL/bottle)
Instruction for use.

Materials Required but Not Provided

Timer
An absorbent disposable tissue or a clean disposable cup

PRECAUTION FOR USERS

1. For **professional in vitro diagnostic use** only.
2. Read the instruction inserts carefully before performing the test.
3. Samples that have touched the toilet water should not be used for testing
4. Do not reuse or use kit after the expiration date.
5. Do not open the pouch until ready to perform the assay.
6. Do not use if the pouch is opened or damaged before testing.
7. Do not mix components from kits with different lot number.
8. Avoid microbial contamination of reagents.
9. Wear gloves during the whole process and avoid reagents or specimen spilling-out. Wash hands thoroughly afterwards.
10. Dispose the used kit after decontamination of all liquids or solid wastes by following the local law or laboratory rule.

STORAGE AND STABILITY

The FOB test kit can be stored at any temperature between 2-30℃. **Do not freeze.** The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:
   Menstrual bleeding Bleeding hemorrhoids
   Constipating bleeding Urinary bleeding
2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, these medicines might be temporarily discontinued for 7 days prior to and during the test period.

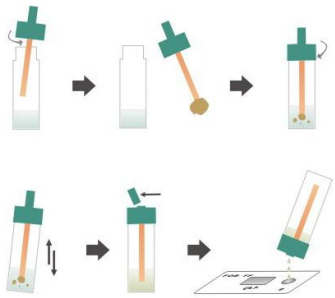
SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures:

1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the specimen collection tube and remove the applicator stick. Be careful not to spill or spatter solution from container.
3. Insert the stick into fecal specimen at several different sites.
4. Collect a thin smear of specimen on the probe tip only. Remove excess sample from the stick by gently wiping with an absorbent tissue.
5. Replace the stick in the tube and tighten securely.

The specimen is now ready for testing, transportation or storage.

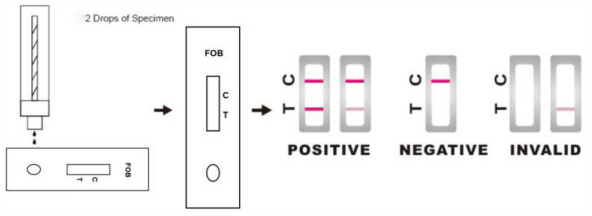
Note: Specimens collected may be stored at room temperature below 30°C for one day, six (6) months at 2°C~8°C, and up to two (2) years at <-20°C.



TEST PROCEDURE

Test device, patient's specimens, and controls should be brought to room temperature (10-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test cassette from the foil pouch, place it on a clean and flat surface, and label the cassette with patient or specimen ID number.
2. Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction diluents.
3. Holding the tube vertically, carefully break the tip of the purple cap.
4. Invert the collection tube and carefully dispense 2 drops of the liquid into the sample well of the test cassette and start timer. **If red mixture does not migrate upward on the membrane after 10s, add one more drop of the buffer solution to the sample pad.**
5. Read results in 5 minutes. Strong positive results may be observed sooner. **Don't read result after 10 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the above illustration)

Negative Result

Only one pink line appears in Control line, and no line in Test line. The test indicates that the hHb is below 50ng/mL.The result is negative.

Positive Result

In addition to a pink colored Control line, a distinct pink colored line will also appear in the test region (T). The test indicates that the concentration of hHb in the specimen is equal or higher than 50ng/mL. The result is positive. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

Invalid Result

If no Control Line is developed, the assay is invalid regardless of color development on the Test line as indicated below. Repeat the assay with a new cassette.

LIMITATIONS OF THE ASSAY

1. Failure to follow the procedures of assay and test result interpretation may give inaccurate results.
2. As with any diagnostic test, the FOB Rapid Test may not be considered as a conclusive diagnosis for gastrointestinal bleeding or pathology. It is not intended to replace other diagnostic procedures such as G.I. fibro scope, endoscopy, colonoscopy, or X-ray analysis.
3. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.
4. A negative result can be obtained even when a gastrointestinal disorder is present. For example, some polyps and colorectal cancers may bleed intermittently or not at all during certain stages of the disease.
5. The FOB Rapid Test has not been tested for toilet water interference and that samples that have touched the toilet water should not be used for testing.
6. The FOB Rapid Test has not been tested on abnormal blood from Thalassemia and Sickle Cell patients.

PERFORMANCE

1. **Cut-off value:** The analytical sensitivity of the test is 50ng/mL or 6ug hemoglobin/g feces.

2. Prozone effect: It is observed that this FOB test can detect 2mg/mL hemoglobin.

3. **Accuracy:** There were 120 human hemoglobin free feces extraction specimens over 10 days from in house and grouped these samples into 6 in an evenly distributed number 20. The 6 groups of extraction samples were spiked with human hemoglobin for six different concentrations, respectively 0ng/mL; 20ng/mL; 40ng/mL; 50ng/mL; 100ng/mL; 2000ng/mL.The results obtained agreement 98% with the predicate device.

4. **Specificity:** The FOB Rapid Test is specific to human hemoglobin. The following substances, when spiked in both positive and negative specimens, did not interfere with the test results.

Chicken Hemoglobin	500ug/mL	Pork Hemoglobin	500ug/mL
Beef Hemoglobin	2000ug/mL	Goat Hemoglobin	500ug/mL
Horse Hemoglobin	500ug/mL	Sheep Hemoglobin	500ug/mL
Rabit Hemoglobin	60ug/mL		

5. Interference testing:

The following substances were added to human Hemoglobin free and 50ng/mL controls. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20mg/dL	Acetylsalicyclic Acid	20mg/dL
Ampicllin	40mg/dL	Ascorbic Acid	40mg/dL
Atropine	40mg/dL	Caffeine	40mg/dL
Gentisic acid	40mg/dL	Gentisic acid	40mg/dL
Glucose	2000mg/dL	Human Albumin	2000mg/dL
Urea	4000mg/dL	Uric Acid	10mg/dL

6. **Reproducibility:** Each 10 tests of three batches of FOB Rapid Tests tested by confirmed positive samples produced same positive results, and Each 10 tests of three batches of FOB Rapid Tests tested by negative samples produced negative results.

7. Clinical performance:

The FOB Rapid Test has been compared with another leading commercial rapid test using clinical specimens.

Method		Other Rapid Test		Total
FOB Rapid Test	Results	Positive	Negative	Result
	Positive	47	2	49
	Negative	1	579	580
Total Result		48	581	629

Relative sensitivity: 97.9%
Relative specificity: 99.7%
Accuracy: 99.5%

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Code:GKPD046-1 Effective date: May 28, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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