Bowel Health (FOB) Rapid Test

Package Insert

REF	TFO-N602H-01/TFO-N602H-02/ TFO-N602H-05/TFO-N602H-10	English

【INTENDED USE】

The test is a rapid chromatographic immunoassay for the qualitative detection of Human Occult Blood in feces to aid in the diagnosis of gastrointestinal bleeding. Not for detection of colorectal tumor and other gastrointestinal tumors.

The test is for self-testing use. It is not automated. For *in vitro* diagnostic use only.

【MATERIALS】

Materials Provided

Components	Kit size	1T/kit	2T/kit	5T/kit	10T/kit
	Test cassette(s)	1	2	5	10
	Package insert	1	1	1	1
	Stool collection paper(s)	1	2	5	10
	Specimen collection tube(s) (with dilution buffer) 2 mL(0.02% Proclin 300, ≤0.02% NaN_3)	1	2	5	10

Materials Required But Not Provided

- Timer

【WARNINGS AND PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only.
- Do not use after expiration date. Do not reuse the test.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture.
- The test should remain in the sealed pouch until use. Do not use if any of the test kit content or packaging is damaged or opened.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Carefully handle the buffer - do not ingest and avoid contact with skin or eyes. If contact does occur, immediately rinse with running water.
- It is important that the timings are strictly followed to ensure accurate results.
- Keep the kit out of the reach of children. An adult may perform the test on a child.
- Do not dismantle and touch the test window of the test cassette.
- The used test should be discarded according to local regulations.
- Wash hands thoroughly before and after handling.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.
- Components provided in the kit are approved for use in the Bowel Health (FOB) Rapid Test. Do not use any other commercial kit component.
- This test provides only a preliminary test result, it could not replace medical advice. Always seek guidance from a qualified healthcare provider before making any health-related decisions.

【SPECIMEN COLLECTION AND PREPARATION】

- Specimens should not be collected during or within three days of a menstrual period, or if you suffer from bleeding hemorrhoids or blood in the urine.
- 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.
- No dietary restrictions are necessary before using the Bowel Health (FOB) Rapid Test.

Collected with stool collection paper as follows:



Unfold the stool collection paper and peel off the liner covering the adhesive tape on each end of the collection paper.



Lift toilet seat and secure the adhesive tabs of the stool collection paper to the sides of the toilet rim.



Make bowel movement onto stool collection paper. Avoid urinating on the paper. If needed, urinate in the front of the bowl, missing the collection paper.

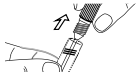
- Test should be performed immediately after the feces have been collected.

【DIRECTIONS FOR USE】

Before performing the test, allow the test cassette, buffer to equilibrate to room temperature (15-30 °C).

- Wash your hands with soap and rinse with clean water.
- The fecal specimen should be collected in the stool collection paper.
- Remove the test cassette from the foil pouch and use it within 1 hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

1



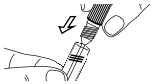
Unscrew the cap of the specimen collection tube and take out the sampling stick.

2



Randomly stab the sampling stick into the fecal specimen in **3 different sites.** Do not scoop the fecal specimen.

3



Insert the sampling stick back into the specimen collection tube and tighten the cap.

4



Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer.

5



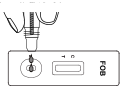
Leave the specimen collection tube for reaction for **2 minutes**.

6



Open the cap of the specimen collection tube.

7



Put the test cassette on a clean and level surface.

Invert the specimen collection tube and **transfer 2 full drops** of the diluted specimen to the specimen well (S) of the test cassette.

8



Read results at 5 minutes. Do not read results after 10 minutes.

Note: Do not move the test cassette during the waiting time.

【READING THE RESULTS】



POSITIVE

Two colored lines appear. One colored line should be in the control region (C) and the other colored line should be in the test region (T).

This result means that there is the presence of the blood in feces and that you should consult a physician.

NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of Fecal Occult Blood present in the specimen.



NEGATIVE

One colored line appears in the control line region (C). No colored line appears in the test line region (T).

This result means that the presence of the blood in feces was not detectable.



INVALID

Control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact the local distributor.

【LIMITATIONS】

1. The Bowel Health (FOB) Rapid Test will only indicate the presence of Fecal Occult Blood, the presence of blood in feces does not necessarily indicate colorectal bleeding.
2. The Bowel Health (FOB) Rapid Test provides preliminary test results and they can't be used as the sole basis for treatment or other management decision.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.
4. This test may be less sensitive for detecting upper gastrointestinal bleeding because blood degrades as it passes through the gastrointestinal tract.[1]

【SUMMARY】

Many diseases can cause hidden blood in the feces. This is also known as Fecal Occult Blood (FOB), Human Occult Blood, or Human Hemoglobin. In the early stages of gastrointestinal problems there may not show any visible symptoms, only occult blood. Traditional guaiacbased methods lack sensitivity and specificity, and also have diet restrictions prior to testing.[2]

The Bowel Health (FOB) Rapid Test is a rapid test to qualitatively detect low levels of Fecal Occult Blood. The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 50 ng/mL or 6 μg/g feces. In addition, unlike guaiac assays, the accuracy of the test is not affected by the diet of the patients.

【PRINCIPLE】

The Bowel Health (FOB) Rapid Test is a qualitative, lateral flow rapid chromatographic immunoassay for the detection of Human Occult Blood in feces. The membrane is pre-coated with anti-Hemoglobin antibody on the test line region of the test. During testing, the specimen reacts with the colloid gold particle coated with anti-Hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-Hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-Hemoglobin antibody, goat anti-mouse IgG coated on the membrane, and contains anti-Hemoglobin antibody coated particles, mouse IgG coated particles.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

Note: It is suggested to use the test cassette within one hour after removing it from the foil pouch.

【QUALITY CONTROL】

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

【PERFORMANCE CHARACTERISTICS】

LOD	Sensitivity	Specificity	Overall Accuracy
50 ng/mL or 6 μg/g	98.3%	98.0%	98.2%

Performance data obtained by clinical study with 110 participants enrolled. Other rapid test has been utilized as reference method.

Hook Effect

No high-dose hook effect was detected at the concentration up to 10,000 ng/mL.

Precision-Repeatability

No difference was detected in intra lot.

Precision-Reproducibility

No difference was detected between days, sites, lots and operators.

Interfering Substances

Following potentially interfering substances does not interfere with the test results: 1% Clorox, 1% Frosch, 1% Mr. Muscle, 1% Toilet water, 1 mg/mL Broccoli extract, 1 mg/mL Cantaloupe extract, 1 mg/mL Red radish extract, 250 μg/mL Vitamin C, 2000 μg/mL Iron ($FeCl_3$•$6H_2O$), 4.74 mg/dL aspirin, 0.5 mg/ml salicylic acid, 4.74 mg/dL bilirubin, 100 mg/dL cholesterol, 10 mg/ml paracetamol, 10 mg/ml ibuprofen, 10 mg/ml montmorillonite powder, 15 g/dL albumin, 600 mg/dL Glucose, 198.2 mg/dL Urea and 48.58 mg/mL Uric acid.

Cross Reactivity

No cross-reactivity was observed when tested with Bovine hemoglobin, Chicken hemoglobin, Porcine hemoglobin, Goat hemoglobin, Horse hemoglobin and Rabbit hemoglobin at the concentration of 1mg/mL and Horseradish Peroxidase at the concentration of 2mg/ml.

【ADDITIONAL INFORMATIONS】

1. **How does the test cassette work?**
   Bowel Health (FOB) Rapid Test detects human blood in feces. The rate of disease progression is not indicated by this test.
2. **When should the test kit be used?**
   You can do this test at home as an early diagnosis of gastrointestinal bleeding when you have the symptoms such as abdominal pain, acid reflux, belching, change in bowel habits, weight loss, anemia, diarrhea.
3. **How much occult blood could be detected out in the fecal specimen?**
   The Bowel Health (FOB) Rapid Test can detect levels of fecal occult blood as low as 50 ng/mL or 6 μg/g.
4. **Can the result be incorrect?**
   The result can be incorrect if test gets wet before performing the test or if the quantity of feces dispensed in the dilution buffer is too much or not sufficient.
   Besides, due to immunological principles involved, there exist the chances of false positive or false negative results in rare cases under proper use and normal conditions. A consultation with the doctor is always recommended for such tests based on immunological principles.
5. **How to interpret the test if the color and the intensity of the lines are different?**
   The color and intensity of the lines have no importance for result interpretation. The test should be considered as positive whatever the color intensity of the test line is.
6. **What is the line that appears in the control C region?**
   When this line appears, it only means that the test unit is performing well.
7. **What is a false positive result?**
   A false positive test result means the FOB is not present but shows detected by the device. The most common causes of a false positive test are cross reactants or unknown interference in the sample.
8. **What is a false negative result?**
   A false negative test means the FOB is present but is not detected by the device. When the specimen concentration is below the minimum detectable limitation (50 ng/mL) of the product, there is a risk of false negative result appear.
9. **What do I have to do if the result is positive?**
   If the result is positive, it means that the Human Occult Blood were detected in feces and that you should consult a doctor to show the test result. Then, the doctor will decide whether additional analysis should be performed.
10. **What do I have to do if the result is negative?**
    If the result is negative, it means that it was not possible to detect the Human Occult Blood. However, if the symptoms persist, it is recommended to see a doctor.

【BIBLIOGRAPHY】

1. Tsung-Hsien Chiang, Yi-Chia Lee, Chia-Hung Tu, Han-Mo Chiu, Ming-Shiang Wu. Performance of the immunochemical fecal occult blood test in predicting lesions in the lower gastrointestinal tract. CMAJ 2011; 183(13): 1474-1481.
2. Chien-HuaChiang, Jen-EingJeng, Wen-MingWang, Bing-HongJheng, Wan-TingHsu, BaiHsiunChen. A Comparative Study of Three Fecal Occult Blood Tests in Upper Gastrointestinal Bleeding. The Kaohsiung Journal of Medical Sciences 2006; 22(5): 223-228.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer	UDI	Unique device identifier

CE 0123

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Summary of safety and performance is available on website: https://ec.europa.eu/tools/eudamed/

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