Atlas Medical

Fecal Occult Blood Test Device (Feces)

IVD *For In-Vitro diagnostic and professional use only*

2 30°C Store at 2-30°C CE

INTENDED USE

The Fecal Occult Blood Test Device (FOB) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.

The Fecal Occult Blood Test Device (FOB) is a rapid test for qualitative detection of low levels of fecal occult blood in the human feces within 5 minutes.

PRINCIPLE

The Fecal Occult Blood Test is a qualitative membrane strip based immunoassay for the detection of human hemoglobin from blood in feces. In this test procedure, anti-hemoglobin antibody is immobilized in the test line region of the test kit. After an adequate volume of test specimen is placed in the specimen pad, it reacts with hemoglobin antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized hemoglobin antibody. If the specimen contains hemoglobin antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain hemoglobin antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

MATERIALS PROVIDED

- Test device (contains anti-hemoglobin antibody particles and anti-hemoglobin antibody coated on the membrane).
- Buffer supplied in Extraction Tubes.
- Package insert

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer

PRECAUTIONS

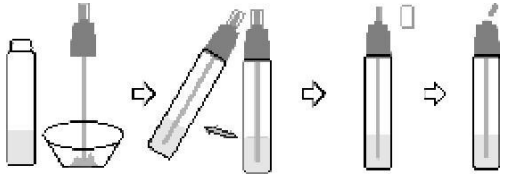
- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the testing 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 being tested.
- Humidity and temperature can adversely affect results.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Do not use the kit if the pouch wasn't sealed well.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

SPECIMEN PREPARATION

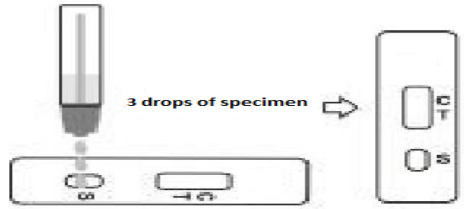
- The Fecal Occult Blood Test can be performed used on feces.
- Collect sufficient quantity of feces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.
- Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.
- Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 5 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
- Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.



PROCEDURE

Allow test device, specimen collection tube, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Hold the specimen collection tube upright and break off the tip of the specimen collection tube. Invert the specimen collection tube and transfer **3 drops (approximately 100 µl) of the extracted specimen** to the specimen well (S) of the test device, then start the timer. **Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.**
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

POSITIVE:*

Two lines appear. One red line should be in the control region (C) and another red or pink line should be in the test region (T).

NEGATIVE:

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

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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

- A procedural control is included in the test. A red line

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

- Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

- The FOB One Step Fecal Occult Blood Test Device (Feces) is for *in vitro* diagnostic and professional use only.
- The FOB One Step Fecal Occult Blood Test Device (Feces) will only indicate the presence of human hemoglobin in the specimen and the presence of blood in feces may be other than colorectal bleeding.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Other clinically available tests are required if questionable results are obtained.

PERFORMANCE CHARACTERISTICS

1. Sensitivity

The Fecal Occult Blood Test will detect the concentration of human hemoglobin is equal to or greater than 40ng/ml.

2. Accuracy

A side-by-side comparison was conducted using the Fecal Occult Blood Test and commercially available FOB rapid tests. 542 clinical Specimens from three Professional Point of Care sites were evaluated with the Test and the commercial kit. The following results are tabulated from these clinical studies:

Agreement with Commercial FOB Rapid Test

		Commercial FOB Rapid Test		Total
		Positive	Negative	
FOB	Positive	203	1	204
	Negative	1	337	338
Total		204	338	542

The agreement between these two test kits is 99.51% for positive specimens, and 99.70% for negative specimens. This study demonstrated that the Fecal Occult Blood Test is substantially equivalent to the commercial device.

3. Cross Reactivity and Interference

a) Specimen containing the following substances at the standard concentration was tested on both HB positive and negative specimens and showed no effects on test results at the standards concentration. No cross reactivity or interference was observed to the test kit.

Analytes	Conc (mg/mL)	Specimens	
		Positive	Negative
Beef hemoglobin	0.5	+	-
Chicken hemoglobin	0.5	+	-
Pig hemoglobin	0.5	+	-
Goat hemoglobin	0.5	+	-
Horse hemoglobin	0.5	+	-
Rabbit hemoglobin	0.5	+	-

b) Potentially cross-reactive endogenous substances including common components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the HB positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the test kit.

Analytes	Conc (mg/mL)	Specimens	
		Positive	Negative
Albumin	20 mg/ml	+	-
Bilirubin	10 µg/ml	+	-
Hemoglobin	15 mg/ml	+	-
Glucose	20 mg/ml	+	-
Uric Acid	200 µg/ml	+	-
Lipids	20 mg/ml	+	-

c) Some other common biological analytes were spiked into the HB positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc (µg/mL)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20.000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-

4. Reproducibility

Reproducibility studies were performed for Fecal Occult Blood Test at three physician office laboratories (POL). Sixty (60) clinical specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were > 99%. The inter-site agreement was > 99%.

REFERENCES

1. Ransohoff, D.F. and Lang, C.A.; Improving the Fecal Occult-Blood Test; The New England Journal of Medicine; (1996) 334 (3):189-190.
2. Yamamoto M., Nakama H., Cost-effectiveness analysis of immunochemical occult blood screening for colorectal cancer among three fecal sampling methods: Hepatogastroenterology, 2000 Mar-Apr, 47 (32) 396-399.
3. St. John, D.J.B., et al.; Evaluation of New Occult Blood Test for Detection of Colorectal Neoplasia; Gastroenterology; (1993) 104:1661-1668.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry