

FOB Monlabtest®



IVD

Measurement of Fecal Occult Blood

Only for professional in vitro diagnostic use.
Store at 2 - 30°C.

INTENDED USE

FOB MonlabTest® is a rapid, visual immunochromatographic test for the qualitative detection of human blood hemoglobin in fecal samples. This test is intended as an aid in the diagnosis of lower gastrointestinal (g.i.) disorders. The test is recommended for professional use.

SUMMARY

The primary use of FOB MonlabTest® is to screen for lower g.i. pathologies, such as colorectal cancers and large adenomas that bleed. Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer death in the United States. Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality. Earlier commercially available FOB MonlabTest® utilized the guaiac test, which requires special dietary restriction to minimize false positive and false negative results. FOB MonlabTest® are specially designed to detect human hemoglobin in fecal samples using immunochemical methods, which improved specificity for the detection of lower g.i. disorders, including colorectal cancers and adenomas.

PRINCIPLE

The FOB MonlabTest® has been designed to detect human hemoglobin in fecal samples through visual interpretation of color development in the test. The test contains a membrane strip, which is pre-coated with anti-human hemoglobin antibody on the test line region (T) and goat anti-mouse antibody on the control line region (C). An anti-human hemoglobin antibody colloidal gold conjugate pad is placed at the end of the membrane. When human hemoglobin is present in the patient fecal sample dissolved in buffered saline, the mixture of colloidal gold conjugate and extracted sample moves along the membrane chromatographically by capillary action. This mixture then migrates to the test region (T) and forms a visible line as the antibodies complex with the human hemoglobin. When human hemoglobin is absent in the extracted sample, no visible color band will form on the test region (T). Therefore the presence of a color band in the test region (T) indicates a positive result. A colored band will always appear at the control region (C) to serve as a procedural indicator for the proper performance of the cassette.

REAGENTS AND MATERIALS SUPPLIED

- Individually wrapped test cassette. Each test cassette contains one test strip with anti-human hemoglobin monoclonal antibody coated membrane and colored anti-human hemoglobin monoclonal antibody pad.
- Sample Collection Tubes: Each contains 2ml of 0.9% NaCl with 0.02% sodium azide.
- Test instruction.

MATERIALS REQUIRED BUT NOT SUPPLIED

- A clean dry container or receptacle for the collection of fecal sample.
- A piece of tissue paper to prevent solution from splashing.

STORAGE AND STABILITY

The test cassette is to be stored at room temperature in the sealed pouch for the duration of the shelf-life.

PRECAUTIONS

- The test cassette should remain in the sealed pouch until use. Do not use it after the expiration date.
- All patient samples should be treated as if capable of transmitting disease.
- Buffered Saline contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extracted samples, always flush with copious quantities of water to prevent azide build up.
- Patients should closely follow the specimen collection procedures. Patients should not collect samples during their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.

SPECIMEN COLLECTION

- Collect a random sample of feces in a clean dry container or receptacle.
- Unscrew and remove the collection tube applicator stick. Be careful not to spill or spatter solution from container.
- Collect random sample by using the applicator stick. Take sample from various surfaces of the feces specimen.
- Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the Sample Collection Tube.
- The specimen is now ready to be stored at 4-8 °C, transported or tested.

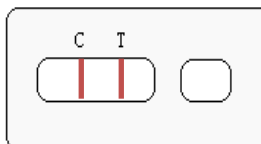
TEST PROCEDURE

- Review "Specimen Collection" instructions. Test cassette, patient's samples, and controls should be brought to room temperature (10-30°C) prior to testing. Do not open pouches until ready to perform the assay.
- Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour. Remove the test cassette from its protective pouch (bring the cassette to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the cassette with patient or control number.
- Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction solution.
- Using a piece of tissue paper, break the tip of the collection tube using a twisting motion. Hold the collection tube vertically and dispense 2~3 drops (about 90-135µl) of solution into the sample well of the test cassette.
- Observe the result in 5 minutes. Strong positive results may be observed sooner. Do not interpret after 8 minutes.

INTERPRETATION OF RESULTS

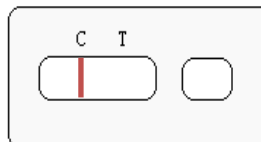
Positive

Two red lines are visible in the control ("C") and test ("T") region of the test window. The intensity of the test line may be less than that of the control line; this still means positive result.



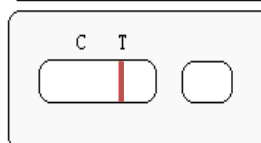
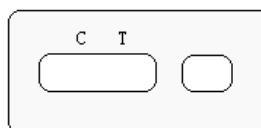
Negative

The control line appears in the test window, but the test line is not visible.



Invalid

The test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing cassette.



LIMITATION OF PROCEDURE

- This test cassette is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. The presence of blood in stools may be due to several causes, besides colorectal bleeding, such as hemorrhoid, blood in urine or stomach irritations.
- All colorectal bleedings may not be due to precancerous or cancerous polyps. The data obtained by this test should be used in conjunction with other clinical findings and testing methods, such as barium enema, sigmoidoscopy or colonoscopy gathered by the physician.
- Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
- Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results.
- This test may be less sensitive for detecting upper g.i. bleeding because blood degrades as it passes through the g.i. track.

QUALITY CONTROL

- A procedural control is included in the test. A colored line appearing on the Control region (C) of the membrane indicates proper performance of the test and the cassette.
- A clear background in the window is considered an internal negative control. However, when the fecal samples are tested, the background may appear slightly yellowish due to the original color of the fecal samples. This is acceptable as long as it does not interfere with the interpretation of test result. The test is invalid if the background fails to clear and obscures the reading of the result.

PERFORMANCE CHARACTERISTICS

Sensitivity

The samples were tested with the three lots. A total of 360 samples were tested. To verify that FOB MonlabTest® has the same performance characteristic as other tests currently marketed, a commercially available Applied Biotech, INC. SureStep™ FOB Test was tested side by side using six levels of FOB concentration (controls of 0, 10, 20, 40, 60 µg/l and 0.5 g/l).

The results indicated that FOB MonlabTest® detects human Hb concentrations at 40µg/l and has the same performance characteristic as other tests currently marketed. And sample containing as high as 0.5g/l hemoglobin can still test positive.

Specificity

The specificity of FOB MonlabTest® was determined from cross-reactivity studies with known amounts of the following materials. The samples would be tested in duplicate, and each time use different type. No materials above interferes the cassettes' results at the concentrations tested.

The hemoglobin molecule in humans is an assembly of four globular protein subunits. Each subunit is composed of a protein chain tightly associated with a non-protein heme group. A heme group consists of an iron atom held in a heterocyclic ring, known as a porphyrin. Our antibody directs to the globular protein subunit which called globulin moiety here. So the porphyrins will not affect the result.

Selected Analyte	The Concentrations Tested
Bovine hemoglobin	0.5 g/l
Pig hemoglobin	0.5 g/l
Rabbit hemoglobin	0.5 g/l
Mouse hemoglobin	0.5 g/l
Fish hemoglobin	0.5 g/l
Goat hemoglobin	0.5 g/l

Selected Analyte	The Concentrations Tested
Horse hemoglobin	0.5 g/l
Sheep hemoglobin	0.5 g/l
Bilirubin	2 g/l
Vitamin C	2 g/l
Horse radish peroxidase	2 g/l

Accuracy

FOB MonlabTest® has been tested compared with a leading commercial FOB test. The results show that the relative accuracy of FOB MonlabTest® is 99.3%.

Test method		Other FOB test		Total
		Positive	Negative	
FOB MonlabTest®	Positive	288	3	291
	Negative	5	816	821
Total		293	819	1112

Relative Sensitivity: $288 / 293 \times 100\% = 98.3\%$

Relative Specificity: $816 / 819 \times 100\% = 99.6\%$

Relative Accuracy: $(288 + 816) / 1112 \times 100\% = 99.3\%$

REFERENCES

- Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests.
- Chinese Pharma Copoeia Annex XIX C 2 Accelerated Testing Study.
- Review criteria for the qualitative assessment of fecal.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer		For <i>in vitro</i> diagnostic use only
	Don't re-use		Consult instructions for use
	Contains sufficient for <n> tests		Keep dry
	Catalogue Code		Temperature limitation
	Lot Number		Use by

PACKAGING

CHEM-9001C-25	25 FOB Tests MonlabTest®
CHEM-9001C-50	50 FOB Tests MonlabTest®