Fecal Occult Blood (FOB) Test Cassette

Instructions For Use

Cat No： FOB 532

* Please carefully read the instructions before use.

INTENDED USE

Atlas Link One-Step Fecal Occult Blood (FOB) Test Cassette is a rapid and convenient immunochromatographic assay used for the qualitative detection of hemoglobin in human fecal samples. It is intended for professional use as an aid in the diagnosis of colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Fecal occult blood (FOB) refers to blood in the feces that is not visibly apparent. Presence of hemoglobin indicates internal bleeding associated with pathological conditions of gastrointestinal tract such as colon polyps, colorectal carcinoma, ulcerative colitis and Crohn's disease.

Atlas Link One-Step FOB Test is an antigen-capture immunochromatographic assay, detecting the presence of hemoglobin in fecal samples. Monoclonal antibodies specifically against human hemoglobin are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the Test Zone on the nitrocellulose membrane. When a fecal sample is added, it rehydrates the gold-antibody conjugate. If hemoglobin is present in any of the samples it will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antibodies, forming a visible pink line (Test line), indicating a positive result. If hemoglobin is absent in the sample, no pink line will appear in the Test Zone (T).

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Desiccant.
- Fecal Specimen Collection tube with sample buffer (2 ml/tube).
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

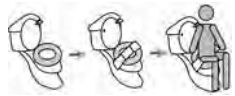
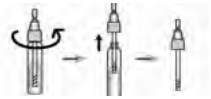
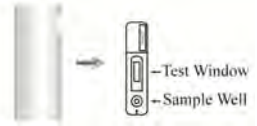
- Glove.
- Clock or timer.

WARNING AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against bio-hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

TEST PROCEDURES

Allow test, specimen collection tube, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing and collect a random sample of feces in a clean, dry specimen collection container.

Place the sample collection pad on top of the toilet and deposit stool sample.	
Unscrew the cap of the fecal specimen collection tube and take out specimen collection stick.	
Stab the specimen collection stick into the fecal specimen in at least 3 different sites (Do not scoop the fecal specimen).	
Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.	
Remove the test cassette from the sealed pouch and use it as soon as possible. Caution: Do not touch the test window and the membrane inside.	
Hold the fecal specimen collection tube upright and break off the tip with hands. Invert the vial and add four full drops (150 µl) of the specimen without air bubbles into the Sample Well of the cassette.	
Read the result within 15 minutes. NOTE: Specimens with high concentrations of FOB may produce positive result in as little as 1 minute. Confirm negatives in 15-30 minutes. DO NOT INTERPRET RESULTS AFTER 30 MINUTES	

Note:

- Best results will be obtained if the assay is performed within 6 hours after collecting fecal samples. The collected specimen may be stored for 3 days at 2-8°C if not tested within 6 hours.
- Specimens prepared in the specimen collection tube may be stored for 3 days at room temperature (2-8°C) if not tested within 1 hour after preparation

RESULT INTERPRETATIONS

Negative

A pink colored band appears only at the control region (C), indicating a negative FOB result.

Positive

A clear pink control band (C) and a detectable test band (T) appear, indicating a positive FOB result.

Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The Fecal Specimen Collection Device containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an in vitro diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrate superior accuracy in detecting hemoglobin in fecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity:

Atlas Link One-Step FOB Test can detect human hemoglobin in human fecal samples. The analytical sensitivity of the test for human hemoglobin (HB), HB-C, HB-S is 200 ng/ml feces.

Specificity:

Atlas Link One-Step FOB Test is specific to human hemoglobin. No cross reactivity test with the following materials on Atlas Link One-Step FOB test

SUBSTANCES	CONCENTRATIONS
Swine Hemoglobin	1 mg/ml
Chicken Hemoglobin	1 mg/ml
Equine Hemoglobin	1 mg/ml
Goat hemoglobin	1 mg/ml
Bovine hemoglobin	1 mg/ml
Fish hemoglobin	1 mg/ml
Rabbit hemoglobin	1 mg/ml
Sheep hemoglobin	1 mg/ml

Accuracy:

Accuracy of the Atlas Link One-Step FOB Test Device has been evaluated by a comparison study with a leading commercial FOB test device at external clinical sites. Three hundred ninety-five clinical samples were studied. Only 4 samples were discordant, the agreement is 98.98%. The detailed results were tabulated below:

Comparison of Atlas Link One-Step FOB Test

	Results of Atlas Link One-step FOB test	Subtotal

		Positive	Negative	
Results of Commercial kits	Positive	241	0	241
	Negative	4	150	154
Subtotal		245	150	395

Diagnostic sensitivity: 241 / 241 = 100%
Diagnostic specificity: 150 / 154 = 97.4%
Total agreement: (241+150) / 395 = 98.98%

3. Interference
The following substances and conditions were found not to interfere with the test. List of potentially interfering chemical analytes and concentrations tested are as follows:

Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Ascorbic acid	20 mg/dl
Caffeine	20 mg/dl
Gentesic acid	20 mg/dl
Phenylpropanolamine	20 mg/dl
Salicylic acid	20 mg/dl
EDTA	80 mg/dl
Benzoylecgonine	10 mg/dl
Atropine	20 mg/dl
Cannabinol	10 mg/dl
Ethanol	1%
Methanol	1%
Heparin	1%
Citrate	3.2%
Albumin	2,000 mg/dl
Glucose	2,000 mg/dl
Bilirubin	2,000 mg/dl

4. Reproducibility
The precision was determined by replicate assays of both positive and negative samples with devices from three different production lots. The resultant data indicated no appreciable between lot variation when testing both positive and negative samples across three different lots.

REFERENCES

1. Screening for colorectal cancer using the fecal occult blood test : a critical literature review.
2. European Journal of Oncology Nursing Vol. 5(4) 234-243, 2001.
3. Fecal occult blood test for colorectal cancer screening. Annals of oncology 13:51-56, 2002.
4. Should organized fecal occult blood test screening be established? Annals of oncology 13:57-60, 2002.
5. Review article : fecal occult blood testing for colorectal cancer. Aliment Pharmacol Ther 1998; 12:1-10.

INDEX OF SYMBOLS

LOT	Do not reuse	LOT	Batch code
REF	In vitro diagnostic medical device		Use by
	Temperature limitation	Σn	Contains sufficient for < n > tests
	Caution	REF	Catalog number
	Manufacturer		Consult instructions for use
EC REP	Authorised representative in the European community	CE	CE Mark

Manufactured by:
Atlas Link (Beijing) Technology Co., Ltd
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Website: https://www.invitro-test.com

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