



Asan Easy Test[®] FOB

Diagnostic kit for fecal occult blood in human stool
Caution : Please read the precautions and test procedure in this manual before using.

IVD

Immuno chromatography

EXPLANATION OF THE TEST

The Asan Easy Test[®] FOB contain pre-coated membrane strip which has anti-human hemoglobin antibody on the test line ("T" region) and goat anti-mouse antibody on the control line ("C" region). Colored gold colloidal reagents are labeled with anti-human hemoglobin antibody. When human hemoglobin is present in fecal sample, the mixture of colloidal gold conjugate and diluted fecal sample moves along the membrane chromatographically by capillary action. At first, human hemoglobin in the fecal sample react with anti-human hemoglobin antibody and forms the complex of hemoglobin and colloidal gold conjugates. As this mixture migrates to the test line ("T" region), the hemoglobin and colloidal gold conjugates complex is captured by another anti-human hemoglobin pre-coated in test line, and forms a visible line. When human hemoglobin is absent in the fecal sample, no visible colored line in the test line. The "control line ("C" region)" should always appear if the test procedure is performed properly.

MATERIALS PROVIDED

- Asan Easy Test[®] FOB kit contains following items to perform the assay.
1. Test device in aluminium pouch with a desiccant.
 2. Sample collection tubes with assay buffer.
 3. Instructions manual for use.

PRECAUTIONS

1. For *in-vitro* diagnostic use only
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1. Specimens should be obtained and handled by specialist in accordance with standard feces collection method.
2. The test should be performed using fresh human feces.
3. Do not collect specimens during menstrual period. If patients suffer from hematuria or hemorrhoids, or if they have strained during bowel movement, it may occur false positive result.
4. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8°C for up to 48 hours or at -20 for longer periods.
5. Fecal specimen in the assay buffer are stable for up to 4 days at room temperature or at 2~8°C for longer periods.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
3. Record patient's details (name, ages and date) on the sample collection tube label.
4. Unscrew sample collection stick.
5. Take a portion of feces from inside and surface of fecal specimens at 3~4 different sites thoroughly.
6. Re-insert the stick with specimen into the tube and screw a cap tightly.
7. Shake the sample collection tube thoroughly to mix with specimen and assay buffer.
8. Unscrew another cap on the bottom of sample collection tube and discard 1~2 drops of buffer.
9. Hold the collection tube vertically and dispense 3 drops (about 100 microl) of buffer into sample well(S) of the test device.
10. Interpret test results at 5~10 minutes. Do not interpret after 10 minutes.

(NOTE: The above interpretation time is based on reading test results at room temperature (15~30°C). If your room temperature is significantly lower than 15°C, the interpretation time may be increased.)

INTERPRETATION OF THE TEST

A. NEGATIVE RESULTS:

The presence of only one purple color band ("C" band) within the window indicates a negative result.



B. POSITIVE RESULTS:

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.



C. INVALID RESULTS:

If No band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



LIMITATIONS OF THE TEST

1. This test kit 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.
2. Although the test is highly accurate in detecting human hemoglobin, a low incidence of false positive results may occur refer to the "specimen collection and storage"
3. A negative result can be obtained even when disorder condition is present, due to some polyps and colorectal cancers may bleed intermittently or not at all. Occult blood may not be uniformly distributed throughout a fecal sample.
4. A single test result cannot be used to make a definitive diagnosis and that such a diagnosis should be made by the physician after all clinical and laboratory findings have been evaluated.
5. This test may be less sensitive for detecting upper gastrointestinal bleeding because blood degrades as it pass through the gastrointestinal track.

STORAGE & EXPIRATION

1. Asan Easy Test[®] FOB should be stored at 2~28°C (35.6~82.4 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

This clinical test was performed using a total of 254 specimens. Each specimen was tested with Asan Easy Test[®] FOB and OC-HEMO CATCH LIGHT. The results are summarized in the following tables.

n= 254	OC-HEMO CATCH LIGHT		Total	
	Positive	Negative		
Asan Easy Test [®] FOB	Positive	120	122	
	Negative	1	131	
Total		121	133	254

※ Relative Sensitivity : 99.1%, Relative Specificity : 98.5%

※ Detection limit : 50 ng/ml

B. CROSS REACTIVITY

The Asan Easy Test[®] FOB is specific for human hemoglobin and does not show any cross-reaction with the hemoglobin from bovine, pig, rabbit, horse and sheep concentrations up to 1 mg/ml.

REFERENCES

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