



Asan Easy Test[®] FOB/Tfr

IVD

Rapid Diagnostic kit for Human Hemoglobin and Human Transferrin

Caution: Please read the precautions and test procedure in this manual before using.

Immunochromatography

INTENDED USE

The Asan Easy Test FOB/Tfr is colored immunochromatographic assay for the qualitative detection of human hemoglobin and human transferrin in human fecal specimen to detect gastrointestinal bleeding.

EXPLANATION OF THE TEST

Detection of fecal occult blood is important in the diagnostic evaluation of patients with suspected gastrointestinal bleeding. Various immunological tests for fecal occult blood have been developed for clinical application. Hemoglobin is the target of all these immunological tests. The major problem has been a high incidence of false negative results in patients with early cancer or colon polyps. The hemoglobin is unstable in feces and loses its antigenicity due to conversion into globin by enterobacteria. In addition, hemoglobin is slightly degraded by proteases in the feces and is also absorbed by mucin with a consequent reduction in immunological reactivity. Transferrin is a blood derived component that may be leaked into gastrointestinal tract and then discharged with the feces in gastrointestinal diseases. Transferrin is stable in feces and a good marker to detect loss of blood from the upper and lower intestine (gastrointestinal bleeding). The simultaneous determination of human hemoglobin and human transferrin will improve the accuracy of fecal occult blood screening test.

PRINCIPLE OF THE TEST

The Asan Easy Test FOB/Tfr, a rapid, visual Immunochromatographic in vitro test, was designed to qualitative detection of human hemoglobin and human transferrin in fecal samples to detect gastrointestinal bleeding. The test contains pre-coated membrane strip which has anti-human hemoglobin antibody(T1) and anti-human transferrin antibody(T2) on the test line("T" zone) and goat anti-mouse antibody on the control line("C" zone). Colored gold colloidal reagents are labeled with anti-human transferrin antibody and anti-human hemoglobin antibody. When human hemoglobin or human transferrin are present in fecal sample, the mixture of colloidal gold conjugate and diluted fecal sample moves along the membrane chromatographically by capillary action. The Human hemoglobin or human transferrin in the fecal sample react with complex of anti-human transferrin and anti-human hemoglobin gold conjugates. As this mixture migrates to the test line("T1" and "T2" zone), the transferrin or hemoglobin and colloidal gold conjugates complex is captured by another anti-human transferrin and anti-human hemoglobin pre-coated in test line, and forms a visible line. When human transferrin or human hemoglobin is absent in the fecal sample, no visible colored line in the test line. The control line("C") should always appear if the test procedure is performed properly.

MATERIALS PROVIDED

The Asan Easy Test FOB/Tfr kit contains following items to perform the assay.

1. Asan Easy Test FOB/Tfr device in aluminum pouch.
2. Sample collection tubes with assay buffer (2.0ml)
3. Instructions manual for use.

PRECAUTIONS

1. For *in-vitro* diagnostic use only
2. Do not eat drink, smoke, store or prepare foods within the work area.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. The test device is sensitive to humidity as well as to heat.
5. Use the test immediately after removing from the pouch.
6. Do not use the test kit beyond the expiration.
7. The assay buffer contains sodium azide as preservative. Sodium azide is potentially explosive and toxic. Should be handled carefully to avoid ingestion and skin contact.
8. 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.
9. Do not change the usage of the product or components.
10. Do not re-use the product because it is disposable.

SPECIMEN COLLECTION AND STORAGE

1. The test may be performed using fresh human feces.
2. If specimens are not immediately tested they should be refrigerated at 2-8 °C . For prolonged storage, freezing is recommended. They should be brought to room temperature prior to use.
3. Unscrew and remove the collection tube applicator stick. Take sample from various insides and surfaces of the feces specimen. (at different 3~4 sites) Fill up the ditch with sample. (not too much)
4. Re-insert the applicator stick with feces sample into the tube and screw the cap tightly.
5. Shake and mix well the tube vigorously to provide a extraction and suspension.
6. The specimen is now ready to be stored at 2~8 °C transported or tested. Fecal samples in the buffer are stable for up to 4 days at room temperature. But, in case of storage time is long, store at refrigerator.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.

2. When ready to test, remove the test device from the aluminum pouch and place it on a clean and dry.
3. Record patient's details(name, ages and date) on the sample collection tube label.
4. Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction buffer.
5. Unscrew the lower cap of the extraction tube using a piece of tissue paper. Discard 1 or 2 drops of sample.
6. Hold the extraction tube vertically and dispense 2~3drops of sample into the sample well of the test device.
7. Interpret test results at 5 to 10 minutes.

* CAUTION: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C . If your room temperature is significantly lower than 15°C , then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

1. A color band will appear in the upper section ("C" zone) of the window to show that the test is working properly. This band is the Control Band.
2. The down section ("T" zone -"T1" or "T2") of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is the test band.

A. NEGATIVE RESULTS:

The presence of only one color band(control band) within the window indicates a negative result



B. POSITIVE RESULTS:

The presence of two color bands ("T1" or "T2" band and "C" band) within the result window regardless of which band appears first indicates a positive result.

-Positive for Hemoglobin : Two bands appears.(T1, C)



- Positive for Transferrin : Two bands appears.(T2, C)



- Positive for Hemoglobin & Transferrin : Three bands appears.(T1, T2, C)



* T1 : Hemoglobin, T2 : Transferrin C : Control line

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.



STORAGE & EXPIRATION

1. Asan Easy Test[®] FOB/Tfr should be stored at 1 to 30°C (33.8-86 °F) .
2. Expiration date of this kit is 24 months after its manufacture date.

LIMITATION OF THE TEST

1. This test kit is to be used for the qualitative detection of human hemoglobin and transferrin in fecal samples. A positive results suggests the presence of human hemoglobin or human transferrin 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 and transferrin, 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 in 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.



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