



HEMOSURE®

One-step Immunological Fecal Occult Blood Test

Intended Use:

W.H.P.M.'s Hemosure® One Step Immunological Fecal Occult Blood Test is used for the qualitative detection of hemoglobin in human feces, and is indicated as a screening test for feces and as an aid in the diagnosis of fecal occult blood. The test is for use in clinical laboratories.

Summary and Explanation:

The guaiac method was developed by Van Deen in 1864 to detect occult blood. Boas began to use this method in 1901 to diagnose gastric bleeding. Since that time, numerous improvements have been introduced which utilize the peroxidase activity of heme. However, in order to get accurate test results, guaiac-based tests require that certain foods, drugs, vitamins and other substances should be avoided before and during the sample collection period. Several authors have also found that some patients with colorectal cancer or adenoma tested negative for occult blood because of the lack of sensitivity of guaiac-based methods.

Subsequent developments of latex immunochemical agglutination, single radial immunodiffusion (SRID) and of the reverse-passive hemagglutination (RDHAA) have produced test methods more sensitive to low concentrations of human hemoglobin in feces. The results of clinical studies indicate that test results are positive in only about 50-60 percent of patients with colorectal cancers and only 25-30 percent of patients with polyps. Therefore, a more sensitive means for detecting fecal occult blood is important for the diagnosis of diseases that result in gastrointestinal bleeding. Hemosure® iFOB Test actually detects lower levels of fecal occult blood than the standard guaiac tests by employing an immunospecific, double-sandwich capture method without any restrictions on food and drugs.

Principle:

Hemosure® iFOB Test is a qualitative, sandwich dye conjugate immunoassay and employs a unique combination of monoclonal and polyclonal antibodies to selectively identify hemoglobin in test samples with a high degree of sensitivity. In less than five minutes, elevated levels of human hemoglobin as low as 0.05 µg hHb/mL can be detected and positive results for high levels of hemoglobin can be seen in the test as early as two to three minutes.

As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the hemoglobin in the specimen and forms an antibody-antigen complex. This complex binds to antihemoglobin antibody in the positive test reaction zone and produces a pink-rose color band. In the absence of hemoglobin, there is no line in the positive test reaction zone. The pink-rose color bands in the control reaction zone demonstrate that the reagents and devices are functioning properly.

Reagents:

1. Hemosure® iFOB Test one test per foil pouch.
Ingredients: contains a combination of mouse monoclonal antibodies and polyclonal antibodies (Sheep or Goat) directed against human hemoglobin.
Mouse monoclonal antibody on a colloidal gold particle.
2. Buffer solution.

Materials Provided:

- Each Hemosure® iFOB Test is individually sealed in a foil pouch, sample collection tube is provided separately.
- A. Each pouch contains:
1. One Hemosure® iFOB Test cassette
 2. Desiccant
- B. Sample collection tube
Contains: 2mL preservative buffer

Materials required but not supplied:

Timer, sample container, disposable gloves, and positive & negative controls. No other equipment or reagents are needed.

Storage:

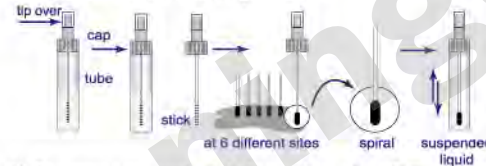
Store test device at 4-30 °C (room temperature). The test device is stable until the date imprinted on the pouch label.

Notes and Precautions:

1. The test is intended for IN VITRO DIAGNOSTIC USE ONLY.
2. Read directions for use carefully before performing this test.
3. Do not use the test beyond the expiration date indicated on the pouch label.
4. Dispose of all used tests components in a biohazard container, per clinical lab procedures.
5. Bring all reagents or components to room temperature before use.

Assay Procedure:

1. Sample Collection and Preparation



- 1) Remove cap and stick from the tube. Collect fecal sample only covering the spiral applicator.
- 2) Secure the cap back onto the tube and shake well.

Note:

- 1). Specimens collected may be stored up to six (6) days at 98.6 °F (37 °C), six (6) months at 39.2 °F (40 °C), and at least twenty (20) months at -4 °F (-20 °C).
- 2). Handle all specimens for testing as if potentially infectious. Proper precautions in handling should be maintained according to good laboratory practice.

2. Test Procedure

- 1) Shake the sample collection tube.
- 2) Open pouch and place test device on a flat surface.
- 3) Open the tip cover of the sample collection tube and squeeze tube to dispense 3 drops into sample well. Read result at five minutes. DO NOT INTERPRET RESULT AFTER 10 MINUTES.



3. Result Reading



- 1) Positive: One color band* appearing in the "C" region, the other color band* appearing in the "T" region.
- 2) Negative: Only one color band* appearing in the "C" region.
- 3) Invalid: No color band* appearing in the window at all even there is one color band in the "T" region, the test result is invalid. The test needs to be repeated.

Color band*: A visible color band can be easily seen at regular room light without any difficulty when test results are read at five minutes.

Performance Characteristics:

1. Sensitivity:
Positive results can be seen in the tests when the levels of human hemoglobin in feces are as low as 0.05 µg hHb/mL.
2. Specificity:
The Hemosure® iFOB Test is specific for human hemoglobin. Hemoglobin from horse, pork, fish, beef, chicken, rabbit, rat, goat,

and mouse do not react with the Hemosure® iFOB Test . In addition to aqueous extracts of broccoli, cantaloupe, cauliflower, horseradish, parsnip, raw turnip, red radish, a 20mg/mL solution of horseradish peroxidase and toilet bowl deodorizers, fresheners, cleansers were also found to have no interference with the Hemosure® iFOB Test.

Limitation for the Procedure:

1. Hemosure® iFOB Test is a valuable aid in the early detection of gastrointestinal bleeding. However, since bowel lesions, including some polyps and colorectal cancers may not bleed or bleed intermittently, the blood may not be uniformly distributed in a fecal sample, a test result can be negative even when disease is present.

2. Hemosure® iFOB Test results can be positive samples from healthy patients. This may be because certain medications may cause gastrointestinal irritation resulting in occult bleeding.

3. As with any occult blood test, Hemosure® iFOB Test can not be considered as a conclusive diagnostic for gastrointestinal bleeding or pathology. It can only be regarded as a preliminary screening or as an aid to diagnosis. They are not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy or other x-ray studies.

Internal Quality Control:

The Hemosure® iFOB test kit contains a built-in Control feature, the Control Line (C-Line). The function of C-Line is to ensure the specimen volume was sufficiently collected. All of the reagents were reacted and migrated toward the proper places on the test strip. The invalid test is formed when a C-line does not react and form. The whole procedure needs to be scrutinized and reviewed. Testing along with a new device needs to be repeated again.

Expected Results:

Healthy persons have no or very little blood in feces. However,

patients suffering from colorectal cancer or other fecal occult blood associated disease will have increased blood in feces because of gastrointestinal bleeding. Hemosure® iFOB Test yields a positive result when hemoglobin in human stool sample reaches 0.05µg hHb/mL. Compared with guaiac tests, this method requires no restricted diet and it has higher sensitivity. Studies by Reference Laboratory and Physicians Office Laboratory(POL) showed that the accuracy of Hemosure® One Step Immunological Fecal Occult Blood Test is 97%. A comparison study was also conducted on Hemosure® One Step Immunological Fecal Occult Blood Test and a predicate device. The correlation was over 99%.

Reference:

1. Boad, I. (1901) *Über Okkulte Magerblutungen. Dtsch Med Wochenschr* 27:315-321
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3. Adams, E.C., Layman K.M. *Immunochemical confirmation of gastrointestinal bleeding. Ann. Clin. Lab. Sci.* 4:343; 1974.
4. Saito, H., et al. *An immunological occult blood test for mass screening of colorectal cancer by reverse-passive hemagglutination (RPI-IA). Japanese J. Gastroenterology* 61:2831; 1984.
5. Heinrich, H.C. (1984) *Ultrasensitiver immunochemie okkultblutnachweis im Stuhl. In: Frühmorgen P (ed) Prävention und Früherkennung des kolorektalen Karzinoms, 1st ed. Springer, Berlin Heidelberg New York, pp. 59-82.*

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