Intended Use:

Hemosure® One Step Immunological Fecal Occult Blood Test is a rapid, convenient and odorless qualitative, sandwich dye conjugate immunoassay for the determination of human hemoglobin in feces, and is a useful aid in the diagnosis and therapy of gastrointestinal disorders.

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 peroxides 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 and of the 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® One Step Immunological Fecal Occult Blood Test actually detects lower levels of fecal occult blood than the standardguaiac tests by employing an immunospecific, double-sandwich capture method without any restriction on foods and drugs.

Principle:

Hemosure® One Step Immunological Fecal Occult Blood Test is a qualitative, sandwich dye conjugate immunoassay and employs a unique combination of monoclonal and polyclonal antibodies to selectivity 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 forming 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 correctly.

Reagents:

1. Hemosure® One Step Immunological Fecal Occult Blood 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® One Step Immunological Fecal Occult Blood Test individually sealed in a foil pouch, and sample collection tubeis provided separately.

A. Each pouch contains:
   1. One Hemosure ® One Step Immunological Fecal Occult Blood Test cassette
   2. Desiccant

B. Sample collection tube
   Contains: 2mL preservative buffer

Material required but not supplied:

Timer, sample container and disposable gloves.
No other equipment or reagents are needed.

Storage:

Sample collection tube after collecting sample should be stored refrigerated (2-8oC) if not used immediately. Store test device at 4-30 oC (room temperature). The test device is stable until the data imprinted on the pouch label.

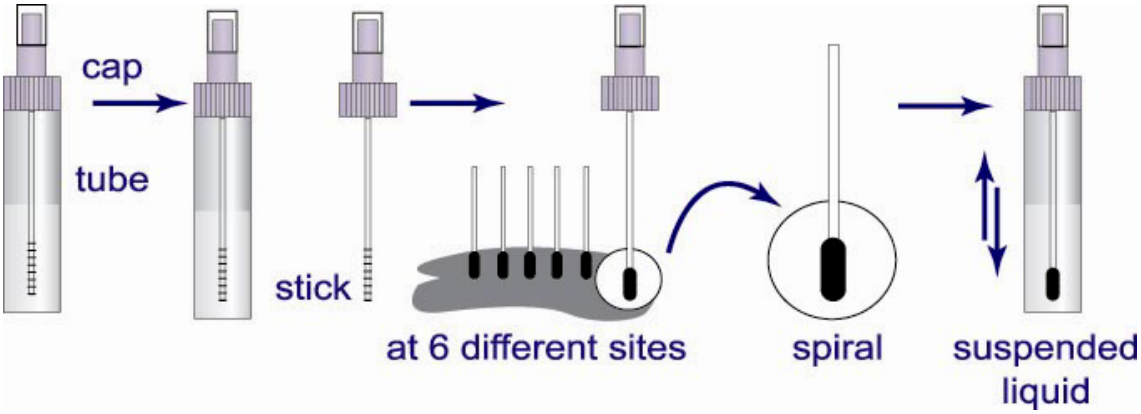
Notes and Precautions:

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.

Assay Procedure:

1. Sample Collection and Preparation



1) Remove cap and stick from the tube. Poke the stick into the fecal sample six times at different sites.

2) Secure the cap back onto the tube and shake well.

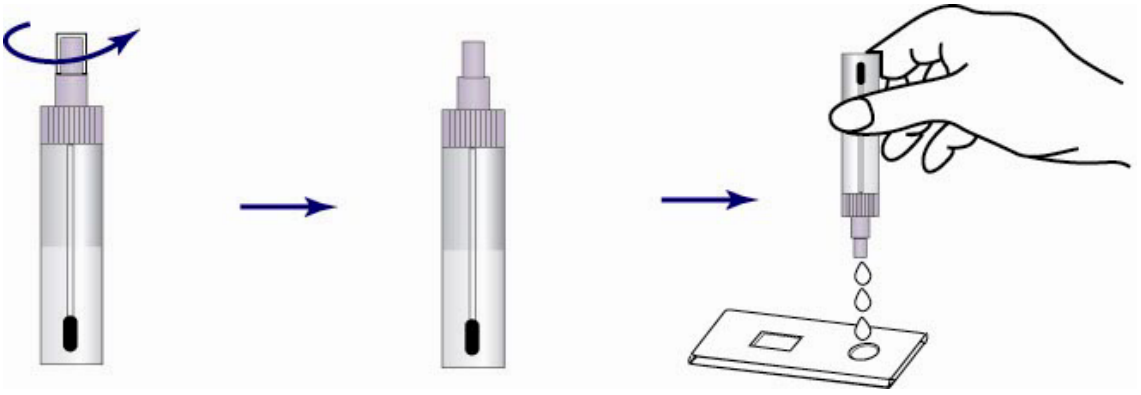
NOTE: Handle all specimens for testing as if potentially infectious. Proper precautions in handling should be maintained according to good laboratory practice.

2. Test Procedure

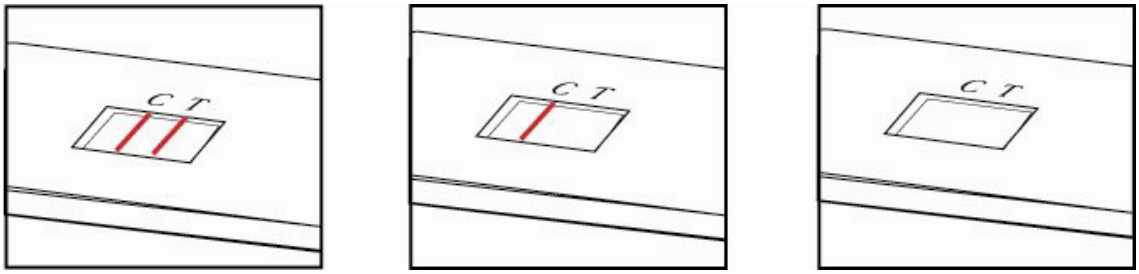
1) Shake well the sample collection tube.

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 band appearing in the "C" region, the other in the "T" region.

2) Negative: Only one color band appearing in the "C"region.

3) Invalid: No color bands appearing in the window at all, the test result is invalid.

Performance Characteristics:

1. Sensitivity:

Positive results can be seen in the tests when the levels of human hemoglobin in feces as low as 0.05 μg hHb/mL.

2. Specificity:

The Hemosure® One Step Immunological Fecal Occult Blood Test is specific for human hemoglobin. Hemoglobin from horse, pork, fish, beef, chicken, rabbit, rat, goat, and mouse do not react with the Hemosure® One Step Immunological Fecal Occult Blood Test. In addition to aqueous extracts of broccoli, cantaloupe, cauliflower, horseradish, parsnip, raw turnip, and red radish, a 20mg/mL solution of horseradish peroxidase and toilet bowl deoderizers/freshners, cleaners were also found no interference with the Hemosure® One Step Immunological Fecal Occult Blood Test.

3. Accuracy:

According to Reference Laboratory and Physicians Office Laboratory (POL) Studies, the overall accuracy of Hemosure® One Step Immunological Fecal Occult Blood Test is 98%.

Limitation for the Procedure:

1) Hemosure® One Step Immunological Fecal Occult Blood Test is a valuable aid in the early detection of gastrointestinal bleeding device. However, since bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently, or the blood may not be uniformly distributed in a fecal sample, a test result maybe negative even when disease is present.

2) Hemosure® One Step Immunological Fecal Occult Blood Test results may be positive for samples from healthy patients. This may be because certain medications may cause gastroin testinal irritation resulting in occult bleeding.

3) As with any occult blood test, Hemosure® One Step Immunological Fecal Occult Blood Test may not be considered as a conclusive diagnostic for gastrointestinal bleeding or pathology, they 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.

Reference:

1. Boad, 1. (1901) Uber Okkulte Mageriblutungen. Dtsch Med Wochenschr 27:315-321.

2. Van Deen, J. (1984 Tincture guaijaci, und ein Ozontrager, als Reagens aufsehr eringe Blutmengen, namentlich in medicoforensischen fallen. Arch Holland Beitr Katura F ilk 3:228-231.

3. Adams, E.C., Layman K.M. Immunochemical confirmation of gastroin testinal bleeding. Ann.ehn. Lab. Sci. 4:343; 1974.

4. Salto, 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 immunochemistry okkultblutnach weis im Stuhl. In: Fruhmorgen P (ed) Pravention und Fruherkennung des kolorektalen Karinoms, 1st end. Springer, Berlin Heidelberg New York, pp. 59-82.