



**HEMOSURE®**  
One-step Immunological Fecal Occult Blood Test  
For Professional Use Only



### Intended Use:

Hemosure® One Step Immunological Fecal Occult Blood Test is a rapid, immunochemical device for the qualitative determination of Fecal Occult Blood by laboratories or physician's offices. It is useful in determining gastrointestinal (GI) bleeding in a number of GI disorders, e.g. diverticulitis, colitis, polyps, and colorectal cancer.

### 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 standard guaiac 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 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 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 and Materials Provided

**Hemosure® One Step Immunological Fecal Occult Blood Test** contains;

1. One test strip individually sealed in a foil pouch. Each Test Strip contains a combination of mouse monoclonal antibodies and polyclonal antibodies (sheep or goat) directed against human hemoglobin.
2. One Fecal Collection Tube containing 2.0 mL of extraction buffer.

### Material required but not supplied:

Timer, sample container and disposable gloves.

### Storage:

Store test device at 2-30 °C (room temperature). The test device is stable until the date imprinted on the pouch label.

If fecal Collection Tube is not used immediately after sampling, it may be stored at 4 °C for up to six (6) months or at -20 °C for up to 12 months.

### Warnings and Precautions:

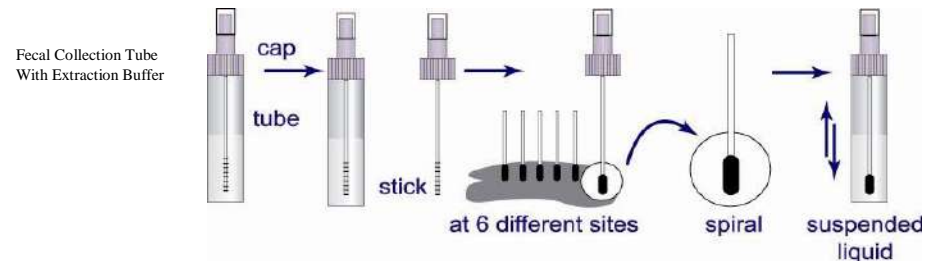
1. The test is intended for IN VITRO DIAGNOSTIC USE ONLY.
2. Read directions for use carefully before performing this test.
3. Do not use the test beyond the expiration date on the pouch label.

### Assay Procedure:

#### 1. Sample Collection and Preparation

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

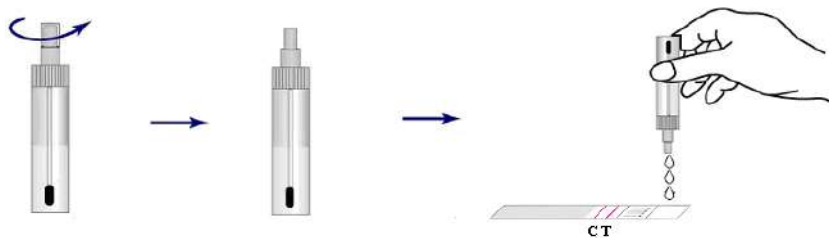
Fecal samples should be collected using disposable gloves. Although no interference was noted with the toilet water testing, it is advisable to avoid samples coming in contact with toilet bowl water. If this is unavoidable, recommend that the user flush the toilet thoroughly, before sample collection, to avoid possible contamination from residual hHb, which may lead to false positive results.



- 1) Warm the Fecal Collection Tube with Extraction Buffer to room temperature.
- 2) Loosen cap of the Fecal Collection Tube and remove Applicator Stick.
- 3) Randomly insert the Applicator Stick into the fecal six (6) times.
- 4) Return the Applicator Stick into the Fecal Collection Tube and tighten the cap thoroughly. Shake the tube to mix the sample with the Extraction Buffer.

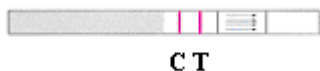
## 2. Test Procedure

- 1) Open the pouch and place the strip on a flat surface. (Bring the pouch to the room temperature before opening to avoid condensation of moisture.) Label the strip with patient or control identification.
- 2) Shake well the sample collection tube. Open the tip cover of the sample collection tube and squeeze tube to dispense 3 drops onto the sample area of the strip. Do not dispense sample above the MAX (maximum) line.
- 3) Start timer.
- 4) Read result within five (5) to ten (10) minutes. **DO NOT INTERPRET RESULT AFTER TEN (10) MINUTES.**

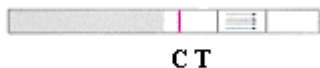


## 3. Interpretation of Results

- 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. The test should be repeated with a new test strip.

## Performance Characteristics:

1. Sensitivity:  
The sensitivity of the test is 50ng hHb/mL buffer or 50 µg hHb/g feces.
2. Specificity:  
Hemosure® One Step Immunological Fecal Occult Blood Test is specific for human hemoglobin. Hemoglobin from horse, pigs, fish, beef, chicken, rabbit, rat, goat, and mouse do not react with Hemosure® One Step Immunological Fecal Occult Blood Test. Aqueous extracts of broccoli, cantaloupe, cauliflower, horseradish, parsnip, raw turnip, and red radish were tested with and without human hemoglobin present in the samples. Additionally, a 20mg/mL solution of horseradish peroxidase, with and without human hemoglobin present, was also tested. No interference was observed. Toilet bowl deodorizers/fresheners, cleaners also did not interfere with Hemosure® One Step Immunological Fecal Occult Blood Test.

## 3. Accuracy:

Reference Laboratory and Physicians Office Laboratory (POL) Studies One hundred (100) hHb-free feces extraction specimens collected in-house were divided into five (5) groups of 20 each. The five groups of extractions sample were spiked with hHb/mL at the following concentrations: 0, 37.5, 50, 62.5 and 2,000 ng hHb/mL. The specimens were blinded and tested with Hemosure® One Step Immunological Fecal Occult Blood Test at a Physicians Office Laboratory and a Reference Laboratory.

The results obtained from the POL site, by persons with diverse education background and work experience, agreed 99% with expected. Overall, the accuracy of Hemosure® One Step Immunological Fecal Occult Blood Test is 97%.

## 4. Comparison Studies:

Fifty (50) specimens were also tested in-house with Hemosure® One Step Immunological Fecal Occult Blood Test and a predicate device. The correlation between Hemosure® One Step Immunological Fecal Occult Blood Test and the predicate device was over 99%.

## Limitation for the Procedure:

1. A negative result can be obtained even when a GI disorder is present. Some bowel lesions, including some polyps and colorectal cancer, may not bleed at all or may bleed intermittently, or the blood may not be uniformly distributed in a fecal sample.
2. Certain medications may cause gastrointestinal irritation resulting in occult bleeding. This may result in a false positive test result.
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. The test results can only be regarded as a preliminary screening or as an aid to diagnosis. It is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy or other x-ray studies.
4. Abnormal hemoglobins were not tested for potential cross-reactivity.
5. Color blind users may see the Control and Test lines as gray rather than pink-rose lines.

**Reference:**

1. Adams, E.C., Layman K.M. *Immunochemical confirmation of gastrointestinal bleeding. Ann.ehn. Lab. Sci.* 4:343; 1974.
2. 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.
3. Saito H. *Screening for colorectal cancer by immunochemical fecal occult blood testing (Review). Jpn J Cancer Res* 1996; 87:1011-102.
4. Ribet, A., Frexinos, J., and Escourrou, J. "Occult-blood test and Colorectal Tumors." *Lancet, Vol. I (1980):417.*
5. Allison JB, Takawa IS, Ransom LJ, Adrian AL. *A comparison of fecal occult blood test for colorectal –cancer screeing. N Engl J Med* 1996; 334:155-159.



DO NOT REUSE



IN VITRO DIAGNOSTIC MEDICAL DEVICE



TEMPERATURE LIMITATION



CONSULT INSTRUCTIONS FOR USE



MANUFACTURER



AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY



BATCH CODE



USE BY



SUFFICIENT FOR



CATALOGUE NUMBER



**WHPM, Inc.**  
**5358 Irwindale Avenue**  
**Irwindale, California USA**



**Medical Device Safety Service GmbH**  
**Schiffgraben 41, 30175 Hannover, Germany**

