



Hemosure[®] iFOB Test
-Initial colorectal cancer screening

**Life just got easier
because
you deserve the best.**



“...in comparison with guaiac-based tests...
immunochemical tests are more patient-friendly...”

-American Cancer Society Guidelines for the Early Detection of Cancer, 2003

CLIAwaived[™].com

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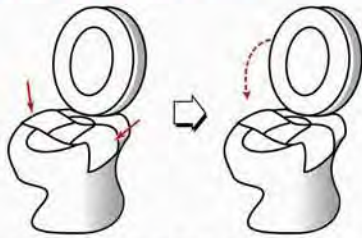
HEMOSURE[®]

One-step Immunological Fecal Occult Blood Test

Patient Instructions

STEP 1 Sample Deposit

A Lift toilet seat and position sample collection paper across the rim of the toilet bowl. Secure adhesive tabs to the sides of toilet rim. Lower the toilet seat.



B Make bowel movement onto collection paper.



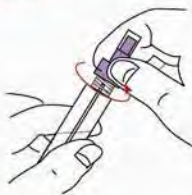
Attention!

Fill out personal information on attached label on tubes.

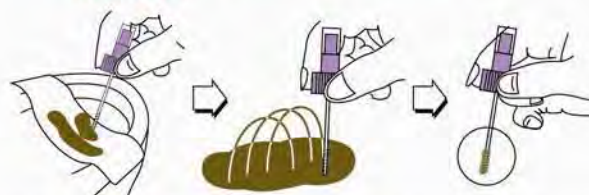


STEP 2 Sample Collection

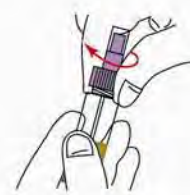
A Unscrew the purple cap from the sample collection tube. **DO NOT POUR OUT THE LIQUID.**



B Poke spiral applicator into stool at 6 different sites. Use only enough fecal material to cover the tip of the applicator. **DO NOT CLUMP, SCOOP, OR FILL THE TUBE.**



C Screw the applicator back into the tube and secure tightly.

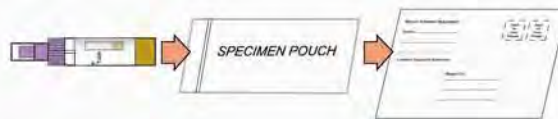


STEP 3 Sample Return

A Complete the address return envelope to your doctor or laboratory.



B Insert sample collection tube into specimen pouch and seal. Insert specimen pouch into return envelope and seal.



C Return the sample packet immediately to the clinic or laboratory by mail or in person.



Test Procedure



Shake the sample collection tube well.



Unscrew the tip cover of the sample



Squeeze tube to dispense 3 drops into sample well.



Read result at five (5) minutes. **DO NOT INTERPRET RESULT AFTER 10 MINUTES.**

Result Reading



POSITIVE

Positive:
One band appearing in the (C) region, the other in the (T) region.



NEGATIVE

Negative:
Only one band appearing in the (C) region.



INVALID

Invalid:
No bands appearing in the window at all. The test result is invalid. The test should be repeated.

Summary & Comparison

HEMOSURE[®]
FDA CLEARED & CLIA WAIVED

Traditional
GUAIAAC TEST

Test Method	Immunoassay Test	Chemical Test
Interpretation	Clear accurate reading comparable to Pregnancy test	Blue color, often difficult to interpret
Lower GI Specificity	> 96%. Highly specific for human hemoglobin	Poor. False positivity from food and medicines
Overall Sensitivity	> 87%. Detects as low as 0.05ugHB/ml. specifically of human hemoglobin	50%. Detects 90 ugHB/ml. or higher of nonspecific hemoglobin
Accuracy	>94%	<86%
Dietary or Drug Restrictions or Preparations	NONE	YES. Several days.
Samples Required	ONE required, TWO recommended	THREE required
Reimbursement	Diagnostic code 82274QW: \$22.22 Screening code G0328QW: \$22.22	Diagnostic code 82270: \$4.54 Screening code G0107: \$4.54

HEMOSURE[®] Frequently Asked Questions

- **Is Hemosure[®] FDA Cleared & CLIA Waived?**
YES.
- **Does the patient need to abstain from food and medications?**
NO.
- **Are there any times when the test should not be performed?**
YES. If the patient has a bleeding hemorrhoid or is menstruating this may interfere with the result, so choose an appropriate time.
- **What is the liquid inside the tube?**
Phosphate buffer solution (PBS) .
- **Should the liquid inside the tube be poured out?**
NO. Do not pour out the liquid.
- **Is the liquid inside the tube hazardous or toxic?**
NO.
- **How much fecal material is needed for a sample?**
Just enough fecal material to cover the tip of the applicator. Do not clump, scoop, or fill the tube. Too much fecal material will cause the test to be invalid.
- **Are there built-in controls?**
YES. There is a built-in control region on the test cassette.
- **How long does the patient's sample last?**
✓ The patient sample can last up to 6 days at 98.6 °F.
✓ If kept at 39.2 °F, the sample can last up to 6 months.
- **How should the product be disposed?**
The device itself may be disposed as solid waste. Devices tested with patient samples should be handled as potentially biohazardous materials in accordance with federal, state, and local regulations.
- **What is the shelf life of Hemosure[®]?**
24 months in room temperatures of 35.6°F~86°F.
- **Who are at high risk?**
✓ African Americans.
✓ People age 50 and above.
✓ People with a family history of gastrointestinal diseases.
- **How many tests are recommended for IFOB Testing?**
Medical research indicates higher accuracy is achieved when 2 IFOB tests are performed on 2 consecutive fecal samples due to intermittent bleeding.



TM

One Test. One Life. Hemosure.

Hemosure is the latest advanced technological breakthrough in immunological FOBT with higher sensitivity and specificity.

Better Healthcare

- Human hemoglobin specific
- Greatly reduces false positive results
- High Sensitivity and Specificity

Improve Compliance

- No diet or drug restrictions
- Clear test result in 5 minutes
- Simple and easy interpretation
- Safe and Non-Invasive
- FDA Cleared and CLIA Waived
- 4 times higher reimbursement rate than traditional FOB test

High Sensitivity

- Detects human blood in stool as low as 0.05ug hHb/ml
- Safe, odorless, and easy to use
- Low false positive results
- More accurate

High Specificity

- Monoclonal Antibody
- Detects intact human hemoglobin protein
- Enhances patient compliance

Product Number	Description
T1-CK30 (Complete Set)	T1-CT30 (30 Test Devices) T1-TB50 (50 Sample Collection Tubes) T1-CM50 (50 Patient Specimen Collection and Return Kits*)
T1-CK10 (Complete Set)	10 Test Devices 10 Sample Collection Tubes 10 Patient Specimen Collection and Return Kits*
T1-CK30T	30 Test Devices 30 Collection Tubes
T1-TB10	10 Sample Collection Tubes
T1-CM50	50 Patient Specimen Collection and Return Kits*
T1-SK50+	50 Test Strips 50 Sample Collection Tubes
T1-SK100+	100 Test Strips 100 Sample Collection Tubes
T1-TC01	iFOBT Control Set (1 Positive & 1 Negative / 0.5ml each)

* Each Patient Specimen Collection and Return Kit is consisting of:
 - Patient Instructions
 - 2 Collection Papers
 - 1 Specimen Pouch with Absorbent
 - 1 Return Mailer
 + For International Sale Only

Hemosure Complete Product Offering:		
 First Sign™ Drug of Abuse Test Dip card, cassette and built in cup format for detection of multiple drugs in urine	 WH ACCU Test™ hCG Pregnancy Test CLIA waived, cassette and dipcard format for detection of hCG in urine	 WH Ovultell™ LH Ovulation Test Cassette and dipcard format for detection of LH in urine

