

CLINICALLY & FINANCIALLY

the Right Choice for **Fecal Occult Blood Testing**



The *Leader* in Fecal Occult Blood Testing



Hemosure® is a worldwide recognized iFOBT brand known for quality, accuracy and reliability. We are dedicated to saving lives and educating patients on the importance of getting screened for gastrointestinal bleeding disorders.

DGM36144-1.0



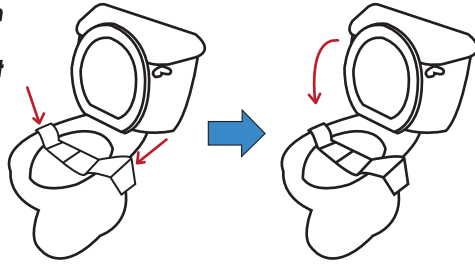
5358 Irwindale Ave., Irwindale, CA 91706 | 888.HEMOSURE (436.6787) | hemosure.com



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.

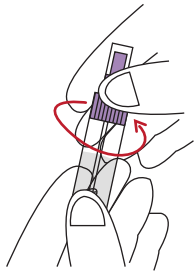


Attention!

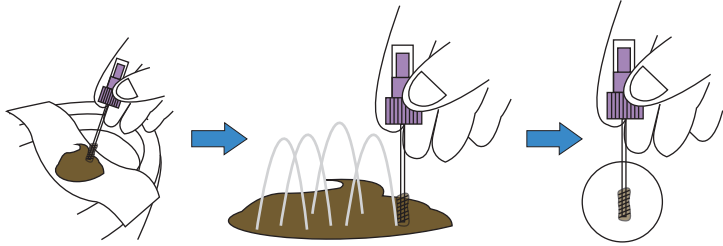
Fill out personal information on attached label on tube.

Step 2: Sample Collection

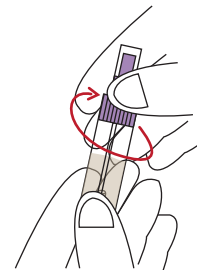
- A** Unscrew the purple cap from the sample collection tube. **DO NOT UNSCREW THE CLEAR CAP ON TOP OF THE PURPLE CAP (LAB USE ONLY). DO NOT POUR OUT THE LIQUID.**



- 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.**

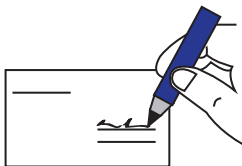


- C** Screw the applicator back into tube and secure tightly.



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.

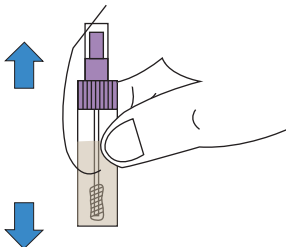


- C** Return the sample packet immediately to the clinic or laboratory by mail or in person.

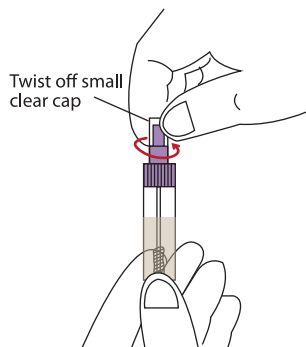


Test Procedure

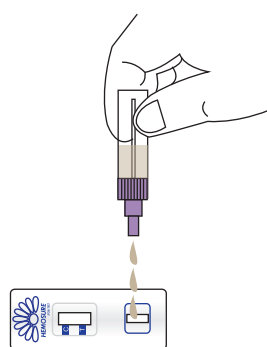
- 1** Shake the sample collection tube well.



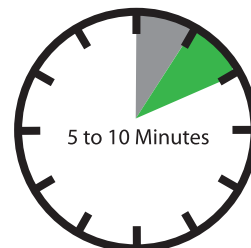
- 2** Unscrew clear tip cap of the sample collection tube.



- 3** Squeeze tube to dispense 3 drops into sample well.



- 4** Start timer, then read result within five (5) to ten (10) minutes. **DO NOT INTERPRET RESULT AFTER TEN (10) MINUTES.**



Result Reading

POSITIVE

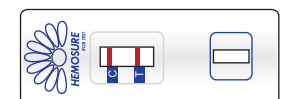
 Positive: One band appearing in the (C) region, the other in the (T) region.

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. Also if there is a band in the (T) region and not the (C) region, it would still be considered invalid.



Hemosure® Packaging Options

Hospital/Laboratory/Satellite Office

Type of Facility	Recommended Package		Packaging Information
Hospital - No Outreach/Outpatient	T1-CK30T / T1-CK50		Complete Kits Only, No Mailers Included
Hospital - Inpatient and Satellite Office	T1-CK50 at Hospital	T1-CK30 at Satellite Office	Kit Only at Hospital; Extra Tubes and Mailers for Satellite Office
Hospital - Inpatient and Satellite Office (sends tests to Lab)	T1-CK50 & T1-CT50 at Hospital Lab	PREPACK-CM25 at Satellite Office	Complete Kit & Cassettes Only at Hospital; Collection Tubes and Mailers at Satellite Office
Hospital Performing Test In-house Only	T1-CK30T / T1-CK50		Cassettes and Tubes, No Mailers
Hospital Collects Sample on Floor and Sends to Lab for Test	T1-TB50 on Floors	T1-CT50 in Lab	Collection Tubes on Floors, Cassettes Only in Lab
Reference Lab	T1-CT50 at Lab	*PREPACK-CM25 at Satellite Office	Cassettes at Lab; Tubes and Mailers at Office
POL/Physician Office Who Gives Mailers for Home Collection	T1-CK30		Complete Kit with 40% Extra Tubes & Mailers
Physician Performing Test in Office Only	T1-CK30T	T1-CK50	Cassettes and Tubes, No Mailers
Hospital or Physician Office Looking to do 2 Tests Per Patient	DUO-iFOB20 For Outpatient Clinics - Order DUO-CM10		Cassettes and Tubes (Two (2) Tubes in Each Mailer)

*Optional – Available with pre-address mailers.

Complete Kits

PRODUCT NO.	DESCRIPTION
T1-CK10	10 tests and 10 specimen collection tubes/home kits
T1-CK30T	30 tests and 30 specimen collection tubes
T1-CK30	30 tests and 50 specimen collection tubes/home kits
T1-CK50	50 tests and 50 specimen collection tubes
PRE-PACK iFOB20	20 tests and 20 home kits w/ 1 pre-packed specimen collection tube in each
DUO-iFOB20	20 tests and 10 home kits w/ 2 pre-packed specimen collection tubes in each

For more information on Hemosure® iFOB Test Kit:

Call 888-HEMOSURE (436-6787), or visit hemosure.com, or email us at sales@hemosure.com.

Item Sold Separately

PRODUCT NO.	DESCRIPTION
PREPACK-CM25	Home kit w/ 1 pre-packed specimen collection tube in each 25/pk
DUO-CM10	Home kit w/ 2 pre-packed specimen collection tubes in each 10/pk
T1-CM50	Home kit mailers 50/pk (no tubes)
T1-TB10	Specimen collection tubes 10/pk
T1-TB50	Specimen collection tubes 50/pk
T1-TC01	Positive/negative control set 5mL/ea
T1-CT30	Test cassettes only 30/pk
T1-CT50	Test cassettes only 50/pk

"The ACG supports the joint guideline recommendation that older guaiac-based fecal occult blood testing be abandoned as a method for CRC screening... the ACG recommends the FIT as the preferred cancer detection test."

- Reprinted by permission from Macmillan Publishers Ltd: The American Journal of Gastroenterology (2320970223955), copyright (2009)



HEMOSURE®



#1 Physician's Choice!

CLIA
WAIVED

Summary & Comparison	HEMOSURE® FDA Cleared & CLIA Waived	Traditional GUAIC TEST
TEST METHOD	Immunoassay test	Chemical test
INTERPRETATION	Clear accurate results	Blue color, often difficult to interpret
LOWER GI ANALYTICAL SPECIFICITY	> 96%. Highly specific for human hemoglobin	Poor. False positive from food and medicines
ANALYTICAL SENSITIVITY	> 87%. Detects as low as 50ng hHB/mL human hemoglobin specific	50%. Detects 90,000ng hHB/mL or higher of nonspecific hemoglobin
ANALYTICAL ACCURACY	> 97%	< 86%
DIETARY OR DRUG RESTRICTIONS OR PREPARATIONS	NONE	YES. Several days.
SAMPLES REQUIRED	ONE required	THREE required
AVERAGE REIMBURSEMENT	Diagnostic code 82274QW: Screening code G0328QW: \$15.92	Diagnostic code 82272: \$ 4.23 Screening code 82270: \$ 4.38

The reimbursement information provided herein is based on published information and is intended for illustration purposes only. The information provided herein is in no way intended to provide customer with reimbursement recommendations or guidance. Customer should verify coding, charge and payment levels with the appropriate third party payer before seeking reimbursement.

Frequently Asked Questions

How does Hemosure iFOB test differ from a guaiac-based test?

In comparison with guaiac-based testing, Hemosure has a higher specificity due to its unique combination of monoclonal and polyclonal antibodies that are specific to human hemoglobin. A traditional guaiac test reacts with the peroxidase activity of heme protein in blood and is nonspecific for human hemoglobin. Therefore, certain foods and medication can interfere with the results of a guaiac test and cause false positive results. Hemosure's iFOB test is not affected by food or medication.

Are there any times when the test should not be performed?

Yes. If the patient has a bleeding hemorrhoid(s) or is menstruating, these may interfere with the result, so choose an appropriate time.

What is the liquid inside the tube?

Phosphate Buffer Solution (PBS).

Is the liquid inside the tube hazardous or toxic?

No.

Are there built-in controls?

Yes There is a built-in control region on the test strip. For facilities that require QC testing, Hemosure carries a positive and negative control set (Part #: T1-TC01 & T1-TC02).

Does using Hemosure's FOB test help increase patient compliance?

Yes. Due to ease of collection, and no dietary or medication restrictions, patient's are much more likely to return a sample for testing.

How should the product be disposed?

The device itself may be disposed as solid waste. Device tested with a patient sample should be handled as potentially bio-hazardous material in accordance with federal, state, and local regulations.

What is the shelf life of Hemosure iFOB test?

24 months from date of manufacture when kept at room temperature (35.6°F–86°F).

DGM36144-1.0