



HEMOSURE[®] iFOB TEST

-Immunochemical Fecal Occult Blood Test (FIT)



Clinically and Financially the right choice for Fecal Occult Blood Testing

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

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Better Healthcare

- No dietary or drug restrictions
- Greatly reduces false positive results
- Offers superior analytical performance

Cost Effective

- 40% extra Collection Tubes and Patient Home Kits (T1-CK30 only)
- Higher Reimbursement (ROI)

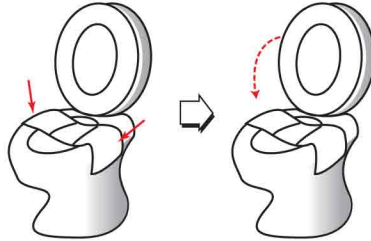
High Sensitivity

- Human hemoglobin specific
- Detects human blood in stool as low as 50ng hHB/mL
- Provides rapid, clear, easy to read test results

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.

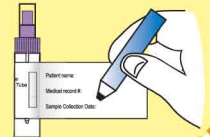


B Make bowel movement onto collection paper.



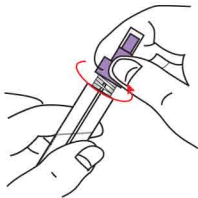
Attention!

Fill out personal information on attached label on tubes.

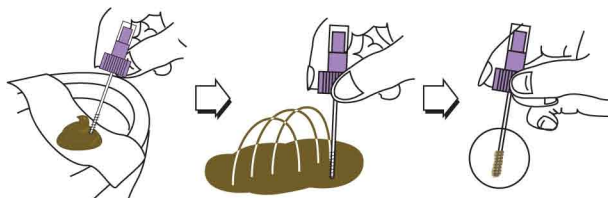


STEP 2 Sample Collection

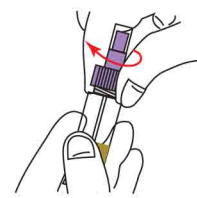
A Unscrew the purple cap from the sample collection tube. **DO NOT POUR OUT THE LIQUID.**



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.**

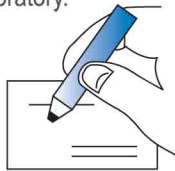


C Screw the applicator back into the tube and secure tightly.



STEP 3 Sample Return

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



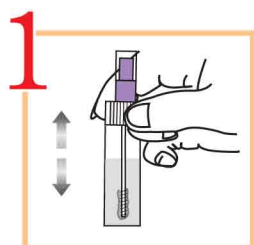
B Insert sample collection tube into specimen pouch and seal. Insert specimen pouch into return envelope and seal.



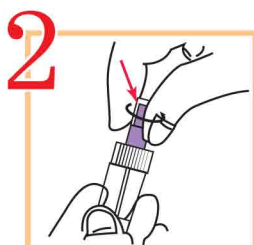
C Return the sample packet immediately to the clinic or laboratory by mail or in person.



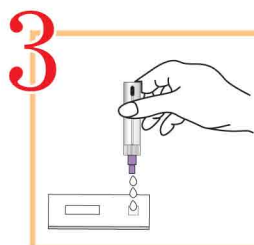
Test Procedure



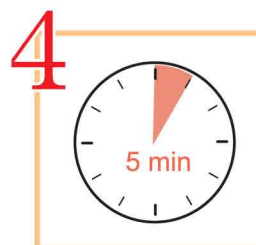
Shake the sample collection tube well.



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.



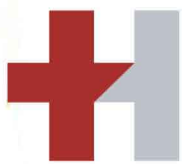
NEGATIVE

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.



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Summary & Comparison

	HEMOSURE [®] FDA CLEARED & CLIA WAIVED	Traditional GUAIAIC 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 positive from food and medicines
Overall Sensitivity	> 87%. Detects as low as 50ng hHB/mL Human hemoglobin specific	50%. Detects 90,000ng hHB/mL or higher of nonspecific hemoglobin
Accuracy	>97%	<86%
Dietary or Drug Restrictions or Preparations	NONE	YES. Several days.
Samples Required	ONE required	THREE required
Average Reimbursement	Diagnostic code 82274QW: \$22.38 Screening code G0328QW:	Diagnostic code 82272: \$4.58 Screening code 82270:

HEMOSURE[®] 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-globin. 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 this 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 cassette. For facilities that require QC testing, Hemosure carries a positive and negative control set (Part# T1-TC01).

• 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.

• How much fecal material is needed for a sample?

Just enough fecal material to cover the tip of the applicator is needed. Do not clump, scoop, or fill the tube. Too much fecal material will cause the test to be invalid. (If patient returns the collection tube filled with too much fecal material, transfer the applicator to a new collection tube to dilute the specimen.)

• How long does the patient sample last?

- ✓ The patient sample can last up to 14 days at 98.6°F.
- ✓ If kept at 39.2°F, the samples can last up to 6 months.

• How should the product be disposed?

The device itself may be disposed as solid waste. Devices 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?

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



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Product Numbers	T1-CK30	T1-CK10	PRE-PACK iFOB20	DUO-iFOB 20 *	T1-CK30T	T1-CK50
Test Cassettes	30	10	20	20	30	50
Collection Tubes	50	10	● (Packed in Mailer)	● (Packed in Mailer)	30	50
Mailers	50	10	20 (1 tube per mailer)	DUO-CM10 10 (2 tubes per mailer)	●	●

* DUO Package recommended for two (2) consecutive samples.

Test cassettes, collection tubes and home kit mailers can be purchased separately.
For more information contact customer service.

Items Sold Separately:

T1-CT30 - Tests Cassettes 30/box

T1-CT50 - Tests Cassettes 50/box

T1-TB50 - Collection Tubes 50/box

T1-CM50 - Home Kit Mailers 50/box

DUO-CM10 - Home Kit Mailers 10/box
(2 Specimen tubes, pre-packed in each mailer)

Prepack-CM25 - Home Kit Mailers 25/box
(1 Specimen tube, pre-packed in each mailer)

Controls:

T1-TC01 - Negative/Positive 5ml each



To order product, contact your medical supply distributor. For more information on Hemosure[®] iFOB Test, call customer service at:

1-888-Hemosure (436-6787) or e-mail sales@hemosure.com
Visit us at www.hemosure.com.