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Owner Jeanna Begay
Area Administrative - Waived Testing
Applicability Hopi Health Center
References DC.02.01.01, WT.01.01.01, WT.04.01.01 + 1 more

Hemosure® Immunological Fecal Occult Blood Test

PURPOSE

To provide a reference for the POC testing staff on the performance of the Immunological Fecal Occult Blood (iFOB) assay. The specimens are collected by either the patient or the healthcare providers and submitted to the laboratory. The test assay is performed by the POC Waived Testing or Laboratory Testing staff.

SUMMARY AND EXPLANATION

The Hemosure® One Step iFOB is a more sensitive means for detecting fecal occult blood and is important for the diagnosis of disease 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, sandwich assay that is not affected by dietary peroxidases, animal blood or ascorbic acid.

This test is designated as a CLIA Waived test.

POLICY

- Only POC Waived Testing staff who have had documented and demonstrated competency assessment for the point of care testing locations will perform iFOB testing.
- iFOB Testing is for screening purposes only.

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 (hHB) as low as 50 ng 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 the 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.

MATERIALS REQUIRED

- Hemosure One Step Immunological Fecal Occult Blood Test cassette
- Fecal collection tube containing 2.0 mL of extraction buffer
- Clock or Timer
- Sample collection container
- Disposable gloves
- Positive and Negative Controls

REAGENT STABILITY & STORAGE

1. **Test cassettes:** Store test device at refrigerated or room temperature (2°C-30 °C). The test device is stable until the date printed on the pouch label.
2. **Fecal Collection Tubes:** It's recommended to use the fecal collection tube immediately after sampling. Otherwise, the tube may be safely stored up to six (6) days at room temperature and up to thirty (30) days refrigerated between 2-8°C.
3. **iFOBT Controls:** Controls should be stored refrigerated (2°C-8°C). When refrigerated, controls are stable until the labeled expiration date.

WARNINGS AND PRECAUTIONS

Test Cassette

1. The test is intended for *IN VITRO* DIAGNOSTIC USE ONLY.
2. Read directions for use carefully before performing test.
3. Do not use the test beyond the expiration date on the pouch label.
4. Use a new specimen collection tube for each test to avoid cross contamination of fecal samples.

Quality Controls

1. The Positive Control is prepared from material derived from human blood. Dispose in biohazard waste container.
2. Avoid contamination of reagents. DO NOT interchange bottle caps between Positive and Negative Controls.
3. Avoid contact with eyes, mucous membranes, skin lesions or other body surfaces. If contact occurs, flush affected areas with water for at least 10 to 15 minutes and immediately go to the Emergency Department.
4. DO NOT use controls beyond their labeled expiration dates.
5. DO NOT use any control from a container that appears to have leaked.

PATIENT LIMITATIONS

A specimen should not be collected from a patient with the following conditions that may interfere with the test results:

<ul style="list-style-type: none">• Menstrual bleeding• Constipation bleeding	<ul style="list-style-type: none">• Bleeding hemorrhoids• Urinary bleeding
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SAMPLE COLLECTION AND PREPARATION (See Figure 1)

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

The iFOB test is not recommended for use with gastric content samples.

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.

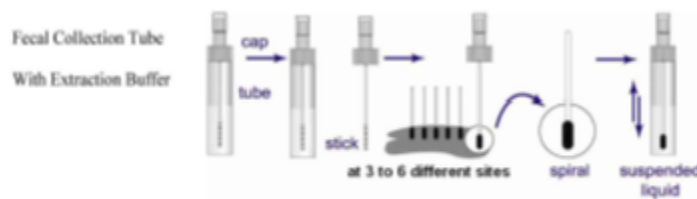


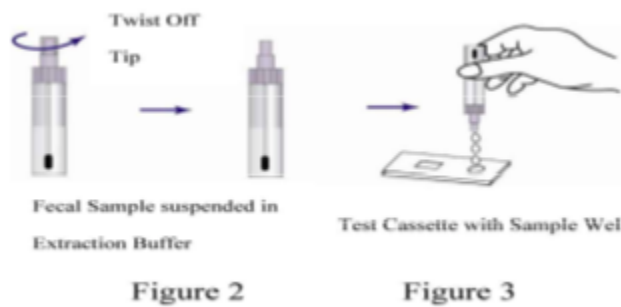
Figure 1

1. Unscrew cap of the Fecal Collection Tube and remove Applicator Stick.
2. Randomly insert the Applicator Stick into the fecal sample from at least six (6) different sites.
3. Do not clump, scoop, or fill the tube.

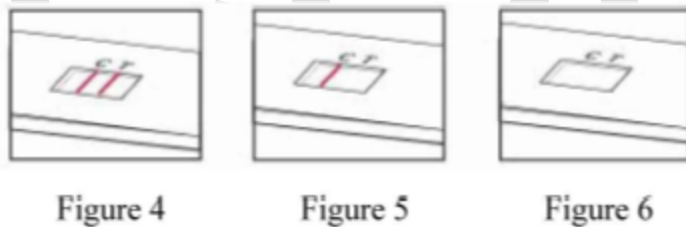
4. Return the Applicator Stick into the Fecal Collection Tube and tighten the cap thoroughly. Shake the tube to mix the sample with the Extraction Buffer.

TEST PROCEDURE (See Figure 2-3)

1. Remove the Test Cassette from its foil wrapper by tearing along the slice.
2. Shake the Fecal Collection Tube to ensure that the fecal sample is well mixed.
3. Twist off the tip of the cap on the Fecal Collection Tube. Add three (3) drops of the Extraction Buffer mixture to the Sample Well.
4. Start timer.
5. Read results within five (5) to ten (10) minutes. **Do not read after ten (10) minutes.**



INTERPRETATION OF RESULTS



- a. Positive : One band appearing in the "C" region, the other in the "T" region (Figure 4).
- b. Negative: Only one color band appearing in the "C" region (Figure 5).
- c. Invalid: No color bands appearing in the window at all, the test result is invalid. The test should be repeated with a new Test Cassette (Figure 6).

QUALITY CONTROL

Internal Quality Control

The appearance of the control band in the results window "C" region is an internal positive procedural control which validates the following:

1. *Test System*: The appearance of the control band assures that the detection component of both the test line and control line is intact, that adequate sample volume was added and that adequate capillary migration of the sample has occurred. Also, verifies the test cassette

worked properly.

2. *Operator*: The appearance of the control band indicates that an adequate volume of fluid was added to the sample well for capillary migration to occur. If the control band does not appear at the read time, the test is invalid and the test must be repeated.
3. The clearing of the background in the results area may be documented as a negative procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white and not interfere with the reading of the test. The test is invalid if the background fails to clear and obscures the observation of a distinct control band.
4. Results of the internal quality control will be recorded and documented in EHR with each patient test.

External Quality Control Procedure

Hemosure iFOBT controls are used to independently verify the functionality and performance of the test once a month and each time a new lot of test cassettes are put into use.

1. Add 3 drops of Positive or Negative Control to the sample pad using dropper bottles in place of samples.
2. Wait 5 minutes and read test results.
3. Positive test results may appear before 5 minutes. To verify a negative test result, be certain to wait a full 5 minutes.
 - Test results should not be read after 10 minutes.
4. The test is positive (+) if two lines (Control and Test) are visible in the viewing window. Any trace of a pink line in the Test line area is a positive test result.
5. The test is negative (-) if only the Control line is visible and there is not trace of a pink line in the Test line area.
6. The test is invalid if the control line does not appear, if this occurs, the test should be repeated.

RESULTS REPORTING

Reference Range: Negative

DOCUMENTATION OF PATIENT AND QUALITY CONTROL RESULTS

Results must be documented along with the initials of personnel performing the test and the date the test was performed. A functional audit trail must be maintained that allows retrieval of results.

- A. Results and internal QC are to be recorded on the patient and/or QC log.
 - Must document the results of the Internal Quality Control (i.e. "Acceptable" or "Invalid"). **Do not report patient results unless quality control is acceptable.**
- B. Document date and time the test was performed, sign or symptom, medical provider, and two patient identifiers.

- C. The initials of point of care testing personnel performing patient testing must be documented on log.
- D. Results must be entered into E.H.R. using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:**

The sensitivity of the test is 50 ng hGb/mL buffer or 50 ug 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 samples. Additionally, a 20 mg/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:**

Both Reference Laboratory and Physicians Office Laboratory (POL) studied one hundred (100) hHb-free feces extraction specimens collected in-house and were divided into five (5) groups of 20 each. The five groups of extractions sample were spiked with hHb 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 Physician's Office Laboratory and a Reference Laboratory.

The results obtained from the POL site, by persons with diverse education background and work experience, agreed 97% with the expected results. The result obtained from the Reference Laboratory agreed 99% with expected. Overall, the accuracy of the 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%.

LIMITATIONS 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 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.

REFERENCES

Hemosure® One Step Immunological Fecal Occult Blood Test Insert, 12/20/2016.

iFOBT Controls Set Instructions Insert *DGP35000-3.0*.

Approval Signatures

Step Description	Approver	Date
Medical Officer Pathologist	Noelle Blue Arm: Medical Officer Pathologist	02/2024
Chief Nurse Executive	Rachel Hamblin: Chief Nurse Executive	01/2024
Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	01/2024
Director of Quality Management	Jose Burgos: Public Health Nurse Director	01/2024
Medical Technologist	Jeanna Begay	01/2024
	Jeanna Begay	01/2024

Applicability

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References

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