**Hopi Health Care Center**

**Polacca, AZ**

**Waived Testing Policy and Procedure**

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| **Title: Hemosure® Immunological Fecal Occult Blood Test**  |
| **Responsible Person: Kendrick Fritz, Supervisory Medical Technologist**  |
| **Standards/Regulations: DC.02.01.01, WT.01.01.01, WT.04.01.01, and WT.05.01.01** |
| **Distribution: Laboratory,** **ED/UC, OPD, IPU, OB, Med Staff** |
| **Original Effective** **Date:** **07/12/2010** | **Reviewed/Revised:**6/2018 | **Review Interval:**Annual | **Due for Review:**6/2019 |
| **HHCC Website: Chapter: Departmental Policies and Procedures** **Folder: Laboratory Policy & Procedure** |

**PURPOSE:**

To provide a reference for the POC testing staff on the performance of the iFOB assay.

The specimens are collected by either the patient or the healthcare providers. The test assay is performed by the POC Waived Testing staff or Laboratory Testing staff.

**SUMMARY AND EXPLANATION:**

A more sensitive means for detecting fecal occult blood 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 guaic 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 CLA Waived test.

**POLICY**

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

**PRINCIPLE:**

Hemosure® One Step Immunological Fecal Occult Blood Test is a qualitative, sandwhich 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.

**REAGENTS & MATERIALS REQUIRED:**

1. Hemosure One Strep Immunological Fecal Occult Blood Test cassette
2. Fecal collection tube containing 2.0 mL of extraction buffer
3. Clock or Timer
4. Sample collection container
5. Disposable gloves
6. Positive and Negative Controls

**REAGENT STABILITY & STORAGE**

1. Test devices:

Store test device at 35.6ºF-86 ºF (2ºC-30 ºC). The test device is stable until the date printed on the pouch label.

1. Fecal Collection Tubes:

If Fecal Collection Tube is not used immediately after sampling, it may be safely stored up to fourteen (14) days at ambient room temperature as high as 98.6 ºF (37 ºC), up to six (6) months in the refrigerator at 39.2ºF(4ºC) or for twelve (12) months in freezer at -4ºF (-20 ºC).

1. iFOBT Controls:

-Avoid contamination of reagents. DO NOT interchange bottle caps between Positive and Negative Controls.

-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 consult your physician.

-DO NOT use controls beyond their labeled expiration dates.

-DO NOT use any control from a container that appears to have leaked.

-Dispose in biohazard waste container.

**WARNINGS AND PRECUATIONS:**

1. The test is intended for IN VIVO 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.

**PATIENT LIMITATIONS:**

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

-Menstrual bleeding -Bleeding hemorrhoids

-Constipation bleeding -Urinary bleeding

**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.



1. Unscrew cap of the Fecal Collection Tube and remove Applicator Stick.
2. Randomly insert the Applicator Stick into the fecal sample from three (3) to six (6) times.
3. Do not clump, scoop, or fill the tube.
4. Return the Applicator Stock in the Fecal Collection Tube and tighten the cap thoroughly. Shake the tube to mix the sample with the Extraction Buffer.

**ASSAY 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.



1. Interpretation of Results:



1. Positive : One band appearing in the “C” region, the other in the “T” region.(Figure 4)
2. Negative: Only one color band appearing in the “C” region. (Figure 5)
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 Cassette.(Figure 6)

**REFERENCE RANGE: Negative**

**Documentation of Results:**

When documenting results in the paper chart or E.H.R., do so by writing or entering the test result and internal quality control result. The test result must be documented along with the initials of the personnel performing the test and date the test was performed. A functional audit trail must be maintained that allows result retrieval.

1. Results are to be recorded on the test log.
2. Document date test was performed, sign or symptom, provider, and two identifiers.
3. The initials of personnel performing patient testing must be documented on the log.
4. 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.

**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 proper assembly of the *Test Device*.
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

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. Follow the assay procedure.
2. When running controls, add 3 drops of Positive or Negative Control to the sample pad using dropper bottles in place of samples.

ii. Wait 5 minutes and read test results.

1. Positive test results may appear before 5 minutes. To verify a negative test result, be certain to wait a full 5 minutes.
2. Test results should not be read after 10 minutes.
3. Neither the intensity nor the shade of the line produced by the Positive Control should be used as a reference for the appearance of a positive result.
4. Results of the quality control must be recorded in the Point of Care QC logbook.

**PERFORMANCE CHARACTERISTICS:**

1. Sensitivity:

The sensitivity of the test is 50 ng hGb/mL buffer or 50 ug hHb/g feces.

1. 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.

1. 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 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, agree 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%.

1. 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 –*RSQ0001-1*

iFOB Controls Set Instructions Insert *DGP35000-3.0*

**This Policy & Procedure was originated, reviewed and approved by the following:**

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 Kendrick Fritz, Laboratory Supervisor Date

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 Noelle E. Blue Arm, Laboratory Director Date