HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Parasitology)		
Document:	Internal Policy and Procedure		
Title:	Faecal Occult Blood		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 Rapid, qualitative method for detecting occult blood in the stool which may be indicative of asymptomatic gastrointestinal diseases such as colorectal cancer, polyps or colitis.

2. DEFINITONS:

N/A

3. POLICY:

3.1 This is a rapid, convenient, and non-offensive qualitative method for detecting occult blood in the stool. It is intended for professional use as an aid in the diagnosis of asymptomatic gastrointestinal conditions that may manifest themselves by the presence of occult blood in the stool. This test is recommended for use in routine hospital testing, mass screening programs for colorectal cancer, and in testing of postoperative patients and new born infants.

4. PROCEDURE:

4.1 **Specimen:**

4.1.1 Stool sample – Prior to defecation, the toilet should be flushed. Using one end of applicator stick, a small stool sample is collected by stabbing the stool and applying a thin smear to the center of the Hema Screen™ slide. It is recommended that stool smears be collected from at least three (3) bowel movements and two (2) samples per stool to increase the probability of detecting occult blood in each stool. Test may be developed immediately or stored at room temperature for up to 21 days.

4.1.2 Clinic staff must instruct the patient in the proper manner to label and prepare the slide before the patient collects the stool sample. A red-meat-free, high residue diet is recommended, starting two days before testing and continuing throughout the test period. Raw fruits and vegetables which contain peroxidase-like substances (turnips, broccoli, horseradish, cauliflower, cantaloupe, parsnips, red radish, etc.) should be avoided during the test period. Clinic staff should provide the client with a suggested diet to be used during the test period.

4.2 **Quality Control:**

4.2.1 Internal Quality Control (positive and negative Performance Monitors) must be performed and documented for all individual patient tests performed.

4.2.2 Patient results may be reported only when both the Positive and Negative Performance Standards give the expected results.

4.2.3 Corrective action must be performed and documented whenever the Positive or Negative Performance Standards fail to give expected results.

4.3 **Method:**

4.3.1 Slide identification:

4.3.1.1 Identify each slide with patient's name, phone number, address and date.

4.3.2 Slide Preparation:

4.3.2.1 With applicator, apply very thin smear of stool inside Oval where indicated with Roman Numeral I. Using the same applicator repeat from a different portion of the stool for Oval II. Discard the applicator in the trash after use.

4.3.3 Slide Development:

4.3.3.1 On back of slide, open perforated section, marked 1 and 2.

4.3.3.2 Apply two or more drops of Hema Screen™ Developing Solution to exposed test paper.

4.3.3.3 After thirty (30) seconds and before two (2) minutes read results. Any trace of blue is positive for occult blood No indication of blue is negative.

4.3.3.4 Performance Standards Development:

4.3.3.4.1 Performance standards on the slides allow for testing the function and stability of the slides and developer. A positive performance standard and a negative performance standard are located under the perforated flap on the back of the slide. It is important that the Performance Standards be developed after specimens to avoid interference or prejudice of test interpretation.

4.3.3.4.2 Add 1 drop of developer directly onto control area (between positive (+) and negative (-) performance standards).

4.3.3.4.3 Read results within 30 seconds. The positive standard contains a haemoglobin derived catalyst. After addition of the developer, a blue colour should appear within seconds. The negative standard should not show a blue colour. If the standards do no react as expected, the test results should be regarded as invalid. Contact Immunostics, Inc. for assistance.

4.3.3.4.4 Document results of the performance standards on the patient test record.

4.3.3.5 A light blue discoloration may be noticed on the guaiac test paper, which does not affect the accuracy or test performance when interpreted according to the recommended procedure. When developer is added directly over the fecal smear on a discoloured slide, the blue color migrates outward and forms a blue ring at the edge of the wetted area, this blue ring would be considered a negative result. The guaiac paper around the fecal smear will remain off-white in color. Any blue or the edge of the fecal smear would be considered a positive result. Proper storage will prevent discoloration. A distinct green color (no blue), due to a high bile content appearing at the edge of the smear should be interpreted as negative for occult blood. However, a blue or blue-green color should be interpreted as positive for occult blood.

4.4 **Results:**

4.4.1 It is important that the Hema Screen™ Slides be read thirty (30) seconds to two (2) minutes after Hema Screen™ Developing Solution has been applied. The Color Reaction will tend to fade after two to four minutes.

4.4.2 Neither the intensity nor the shade of blue as seen in the positive performance standard should be regarded as an indication of what the blue from a positive fecal specimen should look like.

4.4.3 Any trace of blue within the thirty (30) second to two (2) minutes time interval is a positive test result.

4.4.4 Any positive result should be followed up by further diagnostic procedures to determine the source of the occult bleeding.

4.5 **Limitation of the Procedure:**

4.5.1 Results obtained with Hema Screen™ are designed for preliminary screening only and are not intended to replace diagnostic procedures such as barium enema, proctosigmoidoscopic examination or other X-ray studies. The test should not be considered as conclusive evidence for the presence or absence of gastrointestinal bleeding or pathology. Individuals suffering from color blindness should not interpret this test. Gastrointestinal cancers and adenomas do not always bleed.

4.5.2 There are some oral medications such as aspirin, corticosteroids, reserpine, phenylbutazone, indomehacin, etc., that can cause gastrointestinal irritation and occult bleeding in some patients. Ascorbic acid (vitamin C) taken in units greater than 250 mg per day may cause false negative

results. Iron or preparations containing iron may cause false positive results. Two days prior to and during the test period such medications should be avoided. Patients with bleeding from other conditions such as hemorrhoids, dental work, constipation or menstrual bleeding should not be tested while such conditions are present. Do not collect a specimen if the patient is using rectal preparations. The patient's physician should be consulted when discontinuing prescription medications.

5. MATERIALS AND EQUIPMENT:

5.1 Hema screen™ Slides (Immunostics, Inc., available in single slides, catalog number HS-50; or triple slides, catalog number HSPP-50 or HS-34). The test system uses a special electrophoresis paper impregnated with guaiac resin and contains both positive and negative performance standards.
5.2 Hema Screen™ Developing solution (Immunostics, Inc., catalog number HSDV-8)– contains a stabilized mixture of hydrogen peroxide and 75% denatured ethyl alcohol in aqueous solution
5.3 Applicator Sticks
5.4 Clock or Timer (to time at least two minutes)
5.5 Quality Control

6. RESPONSIBILITIES:

6.1 The assigned technetium will perform the test

7. APPENDICES:

N/A

8. REFERENCES:

8.1 Hema Screen™ product information sheet (Immunostics, Inc. 09/04). Technical service: 800-722-7505

9. APPROVALS:

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