A. PURPOSE:
The Hemoccult® test is a rapid, convenient and qualitative method for detecting fecal occult blood, which may be indicative of gastrointestinal disease. It is not a test for Colorectal cancer or any other specific diseases.

The Hemoccult test is recommended for professional use as a diagnostic aid during routine physical examinations for hospital patients, to monitor for bleeding in patients with iron deficiency anemia or recuperating from surgery, peptic ulcer, ulcerative colitis and other conditions, and in screening programs for colorectal cancer when Patient Instructions are followed.

The Hemoccult test and other unmodified guaiac tests are not recommended for use with gastric specimens.

Test Summary
Van Deen is generally credited with the discovery that gum guaiac, a natural resin extracted from the wood of Guaiacum officinale, is useful in detecting occult blood. The Hemoccult test is a simplified and standardized variation of the laboratory guaiac procedure for occult blood. The test contains a specially prepared, stabilized guaiac paper and is ready for use without additional preparation.

To prepare the test, a stool specimen is applied directly to the guaiac paper of the slide. The test is then developed by applying a hydrogen peroxide solution to the back of the smeared sample. If the abnormal amount of blood is present in the stool specimen, a blue color will appear on or at the edge of the fecal smear within 60 seconds after adding developer.

B. Principle:
The Hemoccult test is based on the oxidation of guaiac by hydrogen peroxide to a blue-colored compound. The heme portion of hemoglobin, if present in the fecal specimen, has peroxidase activity which catalyzes the oxidation of alpha guaiaconic acid (active component of the guaiac paper) by hydrogen peroxide (active component
of the developer) to form a highly conjugated blue quinone compound.

C. Policy:
1. A physician/PA’s order is required.
2. Hemoccult will only be performed by RNs on GIDC and the ER at Sinai Hospital.
3. Hemoccult will only be performed by RN’s, tech, Dr in ER at NW hospital.
4. Doctors not having this test listed under their credentials will require yearly competencies.
5. If a test needs to be performed, either the unit will send to sample to the Main Laboratory for testing or the physician may perform the test.
6. On the Nursing unit where testing is approved, LifeBridge Health Certified Trainers will include an in service, satisfactory completion of a written examination and performance of a test.
7. Recertification will be performed yearly.
8. A record of Certified Operators and Instructors will be maintained on each nursing unit, and with the Department of Pathology.
9. If test is not performed at bedside, hemoccult slide should be labeled with the patient’s name and medical record number.
10. Bedside Testing will supply a report identifying problems to the Director of each unit.
11. Documentation of follow-up investigation and corrective actions taken will be returned to Pathology to be maintained by Bedside Testing.
12. Results will be recorded in the glucose meter and transmitted into Powerform. In outpatient locations the results will be recorded either in the Point-of-Care Testing Result Sheet or in special Cerner software available in that location. Northwest will record their results in PowerForm.
13. For correction involving patient identification or result entry in glucose meter, POCT will be notified and corrections made. For problems in outpatient locations, it is their responsibility to make corrections.

D. Specimen:

1. Specimen Type: Fecal

2. Patient Preparation: N/A

3. Handling Conditions: A fecal sample should be collected from the toilet bowl with the aid of a container, toilet tissue, or collection tissue. A small amount of feces is applied as a thin smear to the Hemoccult slide or tape using the applicator stick provided. Hemoccult slides may be prepared and developed after 3 to 5 minutes. Fecal samples should not be collected if hematuria, hemorrhoids or obvious rectal bleeding is present. Pre-menopausal women should avoid collecting samples during or in the first three days after a menstrual period.
4. **Storage Requirements:** It is recommended that the samples be tested immediately after collection. Store all test components at a controlled room temperature (15 to 30°C), in original packaging. Do not refrigerate or freeze. Protect slides from heat and light. Do not store near volatile chemicals (e.g., iodine, chlorine, bromine, or ammonia). Do not use after expiration date.

5. **Rejection Criteria:** N/A

E. **Equipment and Materials:**

1. **Equipment:** Hemoccult Test

2. **Materials/Supplies:**
   a. Hemoccult Slides
   b. Hemoccult Developer
   c. Applicators Sticks

F. **Preparation:** N/A

G. **Performance Parameters:**

   The Hemoccult test has been the subject of extensive evaluation in the laboratory, in clinical practice, at leasing medical centers, including the Mayo Clinic and the Sloan-Kettering Cancer Center, and in mass screening studies. Clinical studies using the radiochromium method suggests that a daily blood loss of 2 to 3 mL is the lower limit of abnormality and may indicate gastrointestinal pathology. Based on in vitro studies, using a representative sample of fecal specimens with whole blood added, the Hemoccult test can be expected to give a positive result about 50% of the time when the equivalent daily blood loss is 2 to 3 mL. The rate of positivity increases as the equivalent daily blood loss increases. Virtually all Hemoccult tests will be positive at an equivalent daily blood loss of 10mL.

   **Slides:** Keep cover flap of slide sealed until ready to use. Protect Slides from heat, light and volatile chemicals. Hemoccult Slides present no hazard to the user.

   **Developer:** Hemoccult Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.

   Hemoccult Developer is an irritant. Avoid contact with skin. DO NOT USE IN EYES. Should contact occur, rinse promptly with water.

H. **Calibration:** N/A
I. Standard Preparation: N/A

J. QUALITY CONTROL:

1. Materials Used: Hemoccult Slides and Developer

2. Preparation and Handling: Hemoccult Developer is an irritant. Avoid contact with skin. DO NOT USE IN EYES. Should contact occur, rinse promptly with water.

3. Frequency Run: N/A

4. Tolerance Limits: Bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently. Also, blood, if present may not be distributed uniformly in the fecal specimen. Consequently, a test result may be negative even when disease is present.

Conversely, a Hemoccult test result may be positive on specimens from healthy patients. This may be due to interfering substances in the diet or to medications. It may also be due to low but detectable levels of blood loss, common to both healthy adults and patients with gastrointestinal disease.

Therefore, as with any occult blood test, results with the Hemoccult test cannot be considered conclusive evidence of the presence of absence of gastrointestinal bleeding or pathology. Hemoccult tests are designed for preliminary screening as an aid to diagnosis. they are not intended to replace other diagnostic procedures such as sigmoidoscopy, colonoscopy, barium enema, or other x-ray studies.

The Hemoccult test as well as other unmodified fecal occult blood test should not be used to test gastric specimens. Interfering factors, such as low pH high drug concentration, metal ions or plant peroxidade in food, may affect the function of guaiac-based occult blood tests.

Hemoccult test results are visually determined. It is important to observe the Hemoccult guaiac test paper for color change within 60 seconds after adding developer as the color can fade after a few minutes. Any trace of blue on or at the edge of the smear indicates the test is positive or occult blood.

Addition of a drop of water (rehydration) to the guaiac slide prior to the addition of the developer increases the sensitivity of the test, but also increases the number of false-positive test results. For this reason, rehydration is not a recommendation procedure for the Hemoccult test.

5. Corrective Action: N/A
6. **Recording and Storage of Data:** Will be maintain in the Department of Pathology for at least two years.

K. **Procedure:**

1. Apply gloves
2. Collect a small fecal sample on one end of the applicator
3. Apply a thin smear inside Box A.
4. Reuse the applicator to obtain a second sample from a different part of the stool. Apply a thin smear inside Box B.
5. Close cover. Dispose of applicator in waste container
6. If testing immediately, wait 3 to 5 minutes before developing.
7. Open the flap in the back of the slides and apply two drops of Hemoccult Developer directly over each smear.
8. Interpret results within 60 seconds.
9. Discard slide, applicator, and gloves in appropriate biohazard container.
10. Wash hands.

L. **Expected Results:**

   In a general screening population of asymptomatic individuals, the Hemoccult test will yield a positively rate of approximately 2 to 5%. The false-positively rate in such a population would be approximately 1 to 2%.

   Positivity rates for fecal occult blood test have been shown to vary in each patient population depending on diet, age, predisposition to colorectal disease and other factors that may be associated with bleeding gastrointestinal lesions.

M. **Limitations:**

   Procedure which can be performed to determine if positive blood test is due to dye present or bleeding associated with patient receiving blue food coloring in tube feeding:

   Collect four samples from separate areas of the stool following a bowel movement. Smear the sample on each of two Hemoccult slides.

   To one of the slides, add two drops of Hemoccult developer to each sample window. Observe for any color formation.

   To other slide, add two drops of aqueous ethyl alcohol (70% minimum alcohol concentration). Observe for any color formation.

   Four possible test outcomes can occur on the slides:

   No blue color observed for any of the slides. Negative test, no dye interference.
Blue color observed only for the slides where ethanol was added, indicating presence of the blue dye.

Blue color observed only for the slide which Hemoccult developer was added, indicating presence of blood in the stool sample.

Blue color observed in both slides, which is an inconclusive result. The blood could be from the dye or both.

N. Calibration: N/A

O. Reporting Results:

1. Negative Results - no detectable trace of blue on or at the edge of the smear

2. Positive Results - any trace of blue on or at the edge of the smear

Considerations

a. Occasionally, a light blue discoloration may be noticed on the guaiac test paper. This discoloration does not affect the test’s accuracy or performance when it is developed and interpreted according to the recommended procedure. When developer is added to the fecal smear on a discolored slide, the blue background color migrates outward. A blue ring forms at the edge of the wetted circle, leaving the guaiac paper around the fecal smear off-white in color. Interpretation is the same as above. Proper storage will help prevent blue discoloration.

b. Some fecal samples have a high bile content, which causes them to appear green. A distinct green color (not blue), appearing on or at the edge of the sample within 60 seconds after adding developer, should be interpreted as negative. However, a blue or blue-green color should be interpreted as positive.

P. Procedure Notes:

1. Reference Range: N/A

2. Critical Value: N/A

3. Reporting Format: Results are recorded in Powerform using the glucose meter, on Point-Of-Care Result Sheet, or in Cerner software only available in specific outpatient doctor's offices. Northwest will record results in Powerform.

5. **Protective Equipment Requirements:** gloves

Q. **Limitations of Procedure:**

1. **Linearity:** N/A

2. **Interfering Substances:** In general, patients should not ingest foods and vitamins which can cause false-positive or false-negative test results, for at least 72 hours prior to and continuing through the test period. Aspirin and other non-steroidal anti-inflammatory drugs should be avoided for at least seven days prior to and continuing throughout the test period.

Substances, which can cause false-positive test results, include red meat (beef, Lamb) as well as processed meats and liver. In addition, some raw vegetables and fruits, which are high in peroxidase, such as horseradish, turnips, melons, and radishes, can cause false-positive results when fecal specimens are tested immediately after collection.

Substances, which can cause false negative results, are ascorbic acid (Vitamin C) in excess of 250 mg/day, excessive amounts of Vitamin C enriched foods (citrus fruits and juices), and Iron supplements which contain quantities of Vitamin C in excess of 250 mg per day.

3. **Chemical Interference:**

4. **In vivo Interference:**

R. **REFERENCES:**

Hemoccult Test Package Insert
Beckman Coulter, Inc
1050 Page Mill Road
Palo Alto, CA  94304

S. **ATTACHMENTS:** N/A