HOUSTON Methodist WILLOWBROOK HOSPITAL

POC.005

Subject:
Fecal Occult Blood (Hemoccult) Screening

Effective Date:
December 2000

Applies to:
Houston Methodist Willowbrook Hospital PPT

Date Revised/Reviewed:
05/31/2019

Originating Area:
Laboratory

Target Review Date:
05/06/2021

I. GENERAL STATEMENT

A. Methodist Willowbrook Hospital will adhere to all national standards and evidence-based research when completing fecal occult blood tests to ensure the accuracy and diagnostic value of results and to ensure patient safety.
B. A physician order is required for fecal occult blood testing.
C. A physician, M.D. or D.O. will perform this PPT (Provider Performed Testing) test which includes performing, reading of the negative and positive controls on each separate card, and recording the patient test and QC result in the patient chart.
D. Laboratory will be responsible for maintaining lot to lot comparisons and periodic review of patient charts.

II. PRINCIPLE

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® SENSA® 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 by hydrogen peroxide to form a highly conjugated blue quinine compound.

III. CLINICAL SIGNIFICANCE

The Hemoccult® SENSA® 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® SENSA® test is recommended for professional use as a diagnostic aid during routine physical examinations, for hospital patients to monitor for gastrointestinal 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 the Patient Instructions are closely followed. Serial fecal specimen analysis is recommended when screening asymptomatic patients.

IV. SAFETY

A. Gloves must be worn when performing this test.
B. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
C. The test device should be discarded in a proper biohazard container after testing.

V. SPECIMEN REQUIREMENTS

A. Fecal - The specimen is applied to the guaiac paper of the Hemoccult® SENSA® slide as a THIN SMEAR using the applicator stick provided.
   1. Fecal specimens should be collected from bowel movements over three days. To further increase the probability of detecting occult blood, separate samples should be taken from two different sections of each fecal specimen.
   2. Hemoccult® SENSA® Slides are best developed no sooner than 3 days after sample application. This allows any fruit and vegetable peroxidases present in the sample to degrade. Slides containing samples may be stored up to 14 days at room temperature (15ºC - 30ºC) before developing.
   3. If immediate testing is required, wait 3 to 5 minutes before developing.

B. Patient Preparation and Instructions
   1. For accurate test results, apply samples from bowel movements collected on three different days to slide.
   2. Do not collect sample if blood is visible in your stool or urine (e.g. menstruation, active hemorrhoids, urinary tract infection). Contact your doctor.
   3. For the most accurate test results collect each stool sample before contact with the toilet bowl water. You may use any clean, dry container.
   4. Protect slides from heat, light, and volatile chemicals (e.g. ammonia, bleach, bromine, iodine, household cleaners).
   5. Remove toilet bowl cleaners from toilet tank and flush twice before proceeding.
   6. For seven days before and during the stool collection period, avoid non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen or aspirin (more than one adult aspirin a day).
   7. Acetaminophen can be taken as needed.
   8. For three days before and during the stool collection period, avoid vitamin C in excess of 250 mg a day from supplements, and citrus fruits and juices. 100% of RDA of vitamin C for an adult is 60 mg a day. Some iron supplements contain vitamin C in excess of 250 mg. Please consult the pharmacist if you have questions about medications taken regularly.
   9. For three days before and during stool collection period, avoid red meats (beef, lamb and liver).
   10. Eat a well-balanced diet including fiber such as bran cereals, fruits and vegetables.

VI. REAGENTS

A. Hemoccult® SENSA® Slides – blue and green striped
   1. Manufacturer's instructions for reagent handling and storing will be followed.
   2. If there are multiple components in a reagent kit, components may only be used within the same kit lot unless otherwise specified by the manufacturer.
   3. Store the product at controlled room temperature (15ºC - 30ºC) and in original packaging. Do not refrigerate or freeze.
   4. For in vitro diagnostic use.
   5. Slides will remain stable until the expiration date which appears on the slides when stored as recommended. Do not use after expiration date which appears on each test component.
   6. Keep cover flap of slide sealed until ready to use.
   7. Protect slides from heat, light, and volatile chemicals (e.g. ammonia, bleach, bromine, iodine, household cleaners).
   8. Hemoccult® SENSA® slides present no hazard to the user.

B. Hemoccult® SENSA® Developer – blue and green striped label with blue bottle cap.
   1. Developer will remain stable until the expiration date which appears on the developer bottle when stored as recommended.
   2. Do not use after expiration date which appears on each test component.

3. Protect developer from heat.
4. Keep the bottle tightly capped when not in use. It is flammable and subject to evaporation.
5. Hemoccult® SENSA® Developer is an irritant. DO NOT USE IN EYES. AVOID CONTACT WITH SKIN. Should contact occur, rinse promptly with water and consult a physician.

VII. SUPPLIES

A. Application Sticks
B. Gloves
C. Biohazard waste container

VIII. TRAINING AND COMPETENCY

A. Hemoccult® SENSA® testing is considered a PPT and will be performed by the patient's physician.
B. Physicians will demonstrate competency. Records are maintained in the laboratory.
C. Because this test is visually read and requires color differentiation, it should not be interpreted by individuals who are color blind or the visually impaired.

IX. PROCEDURE

A. Patient Testing
   1. The patient must be identified by name and date of birth (or medical record number as needed) on the identification band prior to specimen collection.
   2. Label the slide with the patient's name at the point of collection.
   3. Using applicator provided, collect small fecal sample.
   4. Apply thin smear covering Box A
   5. Reuse applicator to obtain second sample from a different part of feces. Apply thin smear covering Box B.
   6. Close cover flap. Dispose of applicator in biohazard waste container.
   7. If immediate testing is required, wait 3 to 5 minutes before developing.
   8. Open back of slide and apply two drops of Hemoccult® SENSA® Developer to guaiac paper directly over each smear.
   9. Read results within 60 seconds. Any trace of blue on or at the edge of the smear is positive for occult blood.
   10. The Performance Monitor® areas must be developed on every slide. Apply one drop of Hemoccult® SENSA® Developer between the positive and negative Performance Monitor® areas.
   11. Read the results within 10 seconds. If the slide and developer are functional, a blue color will appear in the positive Performance Monitor® area and no blue will appear in the negative Performance Monitor® area.
   12. Neither the intensity nor the shade of blue from the Positive Performance Monitor® area should be used as a reference for the appearance of positive test results. Any blue originating from the positive Performance Monitor® area should be ignored when reading the sample test results.

B. Quality Control
   1. Quality control is performed on each slide.
   2. The function and stability of the slides and developer can be tested using the on-slide Performance Monitor® feature. The positive (+) and negative (-) Performance Monitor® areas are located under the sample area on the developing side of the slides.
   3. The positive Performance Monitor® area contains a hemoglobin-derived catalyst which will turn blue within 10 seconds after applying developer.
   4. The negative Performance Monitor® area contains no such catalyst and should not turn blue after applying developer.

5. The Performance Monitor® feature provides assurance that the guaiac paper and developer are functional.
6. In the unlikely event that the Performance Monitor® areas do not react as expected after applying developer, the test results should be regarded as invalid and should not be reported. Should this occur, call the laboratory for assistance. The cards and developer must be returned to Laboratory if they have expired or if they fail the quality control check.

C. Reporting Results
1. Normal patient –Negative.
2. Unexpected test results should be correlated with other clinical findings to validate such results.
3. Negative – no development of a blue color in the test area.
Positive – development of any trace of blue on or at the edge of the smear.
4. Record test results and quality control results ("controls OK") in the progress notes of the patient inpatient flow sheet or computer document and indicate the date and time the test was performed as well as the initials of the physician who performed the test.
5. Report the patient test as positive or negative after verification that the positive and negative Performance Monitor® controls performed as expected.

X. LIMITATIONS

A. 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.

B. Conversely, a Hemoccult® SENSA® test 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.

C. Therefore, as with any occult blood test, results with the Hemoccult® SENSA® test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult® SENSA® 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.

D. The Hemoccult® SENSA® test, as well as other unmodified fecal occult blood tests, should not be used to test gastric specimens. Interfering factors, such as low pH, high drug concentrations, metal ions, or plant peroxidase in food, may affect the function of guaiac-based occult blood tests. Gastroccult®, available from Beckman Coulter Primary Care Diagnostics, is specifically designed to detect occult blood in gastric specimens.

E. Addition of a drop of water (rehydration) to the guaiac test card 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 recommended procedure for the Hemoccult® SENSA® test.

F. Interfering Substances
In general, patients should be carefully instructed to not ingest foods and vitamins which can cause false-positive or false-negative test results for at least 72 hours before and through the test period.
1. Substances which can cause false-positive test results:
   a. Red meat (beef, lamb and liver).
   b. Aspirin (greater than 325 mg/day) and other non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin and naproxen.
   c. Corticosteroids, phenylbutazone, reserpine, anticoagulants, antimetabolites, and cancer chemotherapeutic drugs.
   d. Alcohol in excess.
   e. The application of antiseptic preparations containing iodine (povidone/iodine mixture).

f. Dietary iron supplements **will not** produce false-positive test results with Hemoccult® SENSA® tests.
g. Acetaminophen is not expected to affect test results.

2. Substances which can cause false-negative test results:
   a. Ascorbic acid (Vitamin C) in excess of 250 mg per day.
   b. Excessive amounts of vitamin C enriched foods, citrus fruits and juices.
   c. Iron supplements which contain quantities of vitamin C in excess of 250 mg per day.
3. Notes
   a. Follow the procedure exactly as outlined above. When preparing slides for immediate testing, wait as directed to allow adequate time for sample to penetrate the test paper before developing.
   b. Occasionally, a light blue discoloration may be noticed on the guaiac test paper. This discoloration does not affect the accuracy or performance of the test when it is developed and interpreted according to the recommended procedure. When developer is added directly over the fecal smear on a discolored slide, the blue background color migrates outward. A blue ring forms at the edge of the wetted area, leaving the guaiac paper around the fecal smear off-white in color. Proper storage of Hemoccult® SENSA® Slides will help prevent blue discoloration.
   c. Some specimens have a high bile content which causes the feces to appear green. A distinct green color (no blue), appearing on or at the edge of the smear within 60 seconds after adding Hemoccult® SENSA® Developer, should be interpreted as negative for occult blood. A blue or blue-green color should be interpreted as positive for occult blood.

XI. AUTHORATATIVE REFERENCES

A. Hemoccult® SENSA® Product Instructions, Beckman Coulter, Inc.

Method History

Date	Summary of Changes
April 2008	• Updated to hospital format
May 19, 2009	• Revised SOP based on updated package insert. Test Principle, Clinical Significance, Specimen Collection and Handling, Patient Preparation, Reagents, Testing Personnel, Calibration, Quality Control, Calculations, Reference Interval, Interpretation, Interfering Substances, and Limitations of Procedure were added to the SOP. The references were updated.
2/28/2010	• Reviewed and approved
5/23/2011	• Reviewed and approved
05/06/2019	• Updated Reporting Results • Updated Authoritative References