

Title: Fecal Occult Blood Hemocult SENA		
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Version: 2	Created: 12/19/2018	Reviewed: 02/14/2019
Approver: Cristina E. Taylor		Approved: 02/14/2019

TITLE: Fecal Occult Blood

Hemocult®Brand SENA® Method

Purpose

This procedure is intended as a rapid, qualitative invitro 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.

Scope

This procedure is intended as a guideline to all personnel assigned to the automated testing section of Concord Hospital Laboratory.

Principle of the Test

The Hemocult® SENA® test is based on the oxidation of guaiac by hydrogen peroxide to a blue colored compound. The test reacts only with released hemoglobin from lysed red blood cells. When blood is present, hemolysis is promoted by substances in the stool, primarily water and salt. 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 guaiac paper) by hydrogen peroxide (active component of developer) to form a highly conjugated blue quinone compound.

The Hemocult® SENA® test, like the Hemocult® test, is a simplified and standardized variation of the laboratory guaiac procedure for the detection of occult blood. The Hemocult® SENA® formulation includes an enhancer, which makes the test more sensitive and readable than other guaiac-based tests.

Clinical Application and Usefulness

The Hemocult® SENA® test is recommended for professional use as a diagnostic aid during routine physical examinations, for hospital patients to monitor gastrointestinal bleeding in patients with iron deficiency anemia, or recuperating from surgery, peptic ulcer, ulcerative colitis, and other conditions. This test is useful in screening programs for colorectal cancer only when the patient instructions are closely followed. Serial fecal specimen analysis is recommended when screening asymptomatic patients.

The Hemocult® SENA® test more reliably detects abnormal bleeding associated with gastrointestinal disorders than standard guaiac tests. As a result, it will have a higher sensitivity for disease but also a higher false positive rate among non-diet compliant patients. Hemocult® SENA® positive results appear as more stable, intense blue color reactions than the results of other guaiac tests, improving overall readability and precision. As with other guaiac tests, accuracy depends upon the status of the patient at the time the specimen is taken and may be affected by interfering substances.

Specimen



BIOHAZARD

All body fluids should be handled as if capable of transmitting infectious diseases. Use universal precautions when in contact with such materials. Refer to Laboratory Infection Control Policy in the Safety Manual.

Specimen Collection and Handling

- **Patient Preparation** : Patients are instructed to:
 1. Avoid consuming red meats (beef, lamb, liver) starting 3 days prior to and continuing through the test period.
 2. Patients should eat a well balanced (high residue) diet including fiber such as bran cereals, fruits, and vegetables.
 3. Avoid consuming vitamin C in excess of 250 mg a day from supplements, citrus fruits, and juices starting 3 days prior to and continuing through the test period.
***100% of RDA of vitamin C for an adult is 60 mg per day. Some iron supplements contain vitamin C in excess of 250 mg .*
 4. Avoid consuming non-steroidal, anti-inflammatory drugs such as ibuprofen, naproxen, or aspirin (more than 1 adult aspirin per day) 7 days prior to and continuing through the test period.***Acetaminophen (Tylenol) may be taken as needed.*
- **Specimen Requirement** : Prepared Hemocult® SENSA® card or stool
- **Specimen Collection**: Stool specimen is applied to the guaiac paper of the Hemocult® SENSA® test card in a thin smear using the applicator stick provided.
- **Minimum Requirement**: Specimen quantity should be sufficient to cover the end of an applicator stick, or adequately prepare the testing area on a Hemocult® SENSA® card. Note: If the specimen adequacy of the test card sample from the office/floor is questionable, a comment will be made---*Adequacy of specimen is questionable by examiner; suggest repeat testing if clinically indicated.*
- **Stability and Storage**: **1 hour in specimen container and 14 days for inoculated test card-see below for details.** Hemocult® SENSA® test cards containing stool samples may be stored up to *14 days at 18-30 °C (room temperature)* before developing. Test cards are best developed no sooner than 3 days after sample application. This allows fruit and vegetable peroxidases present in the test sample to degrade. However, if immediate testing is required, wait 3 to 5 minutes before developing prepared cards.

***Bulk stool sample stability is very limited, therefore, samples greater than 1-hour-old will be rejected* for occult blood testing. Bulk samples greater than 1-hour-old risk reduced sensitivity/detection for any occult hemoglobin present. The bulk stool sample stability testing guidelines are per manufacturer. Please refer to Beckman Coulter memo sent June 5, 2009.
- **Special Handling**: Since gastrointestinal bleeding may be intermittent, fecal specimens should be collected from bowel movements over a **3 day period**. To further increase the probability of detecting occult blood, separate samples should be taken from two different sections of each fecal specimen.

Stool samples should not be collected if blood is visible in patient's stool or urine (e.g. menstruation, active hemorrhoids, urinary tract infection). **Note: Visibly bloody**

specimens for fecal occult blood testing will be rejected with notification made to the floor/office.

For the most accurate test results, collect the stool sample before there is contact with the toilet bowl water. Remove toilet bowl cleaners from the toilet tank and flush twice before proceeding with stool sample collection. Test cards should be protected from volatile chemicals (e.g. ammonia, bleach, bromine, iodine, household cleaners). Collect stool sample initially into a dry, clean container. *Application of a thin smear of the stool sample to the testing area of the card should immediately follow defecation as the stability of occult blood in bulk stool is very limited.*

Reagents and Supplies

Reagents and Supplies Utilized:

Test kit: Hemoccult® SENSA® (Beckman Coulter, Inc.)

Materials supplied:

- Hemoccult® SENSA® slides (test cards) containing guaiac paper.
- Hemoccult® SENSA® Developer- developer contains a stabilized mixture of less than 4.2% hydrogen peroxide, 80% denatured ethyl alcohol and an enhancer in an aqueous solution. **Caution:** developer is an irritant. Avoid contact with eyes and skin. Should contact occur, rinse promptly with water.
- Specimen applicators

In-House Preparation:

- Not applicable

Acceptable Reagent Performance:

- The Positive Performance Monitor turns blue within 10 seconds after adding the developer.
- The Negative Performance Monitor should **not** turn blue after adding the developer.

Storage Requirements:

- Temperature: Store at 15-30° C (room temperature), do not freeze or refrigerate, protect from light and heat Do not store with volatile chemicals (e.g. ammonia, bleach, bromine, iodine, or household cleaners).
- Stability: Until stated expiration date of cards and developer if stored as recommended. Do not use beyond expiration date.
- Labeling: all reagents are to be labeled as to content, date prepared or received, and/or placed in service.

Calibration

- Not applicable

Quality Control

QC Utilized: On-slide Positive and Negative Performance Monitors located under the sample test area on the developing side of the test card

QC Preparation and Handling: Cards are stored at room temperature, protect from light and heat

Tolerance Limits: The positive and negative performance monitors react appropriately. If the monitors do not react as expected, the test results should be regarded as invalid.

Frequency with Which Controls are Run: Positive and negative performance (control) monitors are run with every specimen.

Corrective Action when Tolerance Limits are Exceeded: Repeat test; check expiration dates and storage handling. Notify supervisor.

Recorded and Stored QC Data: Results of performance monitors are recorded in the LIS along with lot number of developer and Hemoccult card used.

Procedure

- Collect a small sample of stool specimen onto the end of an applicator
- Apply a thin smear inside box A area
- Reuse applicator to obtain a second sample from a different part of the stool specimen.
- Apply a thin smear inside box B area
- Wait 3- 5 minutes for the stool sample to penetrate the guaiac paper of the test card. A positive test may be missed, dependant on the amount of occult blood present, if the developer is added too quickly (less than 3 minutes). The proper waiting period is warranted to reduce the occurrence of false negative test results.
- Open the flap in back of the test card and apply 2 drops of Hemoccult® SENSA® developer to the guaiac paper directly over each smear.
- Read test reaction within 60 seconds
- Any trace of blue color on or at the edge of the smear is positive for occult blood.
- Apply only one drop of the developer between the positive and negative monitors.
- Read the test reaction within 10 seconds
- A blue color will appear in the positive performance monitor and no blue color will appear in the negative performance monitor. Always develop the test sample and interpret test results prior to developing the performance monitors.

For technical assistance, contact the Technical Marketing Department at Beckman Coulter, Inc. (1-800-877-6242).

Procedure Notes: 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 addition of the developer, should be interpreted as negative for occult blood.

Occasionally, a light blue discoloration may be noticed on the guaiac test paper. This discoloration does not impede the accuracy or performance of the test when it is developed and interpreted according to the recommended procedure. When the developer is added directly over the smear on a discolored slide, the blue background color migrates outward. A blue ring will form at the edge of the wetted area, leaving the guaiac paper around the fecal smear off-white. Any blue color on or at the edge of the smear is positive for occult blood.

Calculations

- Not applicable

Reporting Results

Reporting Format: Report as Positive or Negative

Reference Range: Negative

Limitations of Procedure

- Hemoccult® SENSA® test and other unmodified guaiac tests are not recommended for use with gastric specimens.
- **Do not interchange** Hemoccult® SENSA® with Hemoccult® test reagents, or with any other components from any other manufacturer.
- Bowel lesions, including some polyps and colorectal cancers, may bleed intermittently or not at all. Blood, if present, may not be uniformly distributed throughout the stool sample. Consequently, a test result may be negative for occult blood even when a disease state is present. Conversely, a test may be positive on specimens from healthy patients. This may be due to interfering substances in the diet or to medications (listed below). It may also be positive due to low but detectable levels of blood loss, common to both healthy adults and patients with gastrointestinal disease. The Hemoccult® SENSA® test is not intended to replace other diagnostic procedures.
- Sensitivity of the Hemoccult® SENSA® test is at a detection level of 2-3 ml of blood loss per day which is equal to 0.2-0.3 mg of hemoglobin per 1 gm of stool. The sensitivity is approximately 75 % at this lower detection level.
- In general, patients should be carefully instructed to not ingest foods and vitamins/supplements which can cause false-positive or false-negative results for at least 72 hours prior to and continuing through the test period. If following any part of the dietary recommendations is an issue, the patient should consult with the physician.
False positive results may occur when patients:
 - Consume red meat (beef, lamb, liver)
 - Ingest aspirin (greater than 325 mg/day) and other non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen, and indometacin. *Tylenol does not affect test results.*
 - Ingest corticosteroids, resperine, anti-metabolites, anticoagulants, phenylbutazone, and cancer chemotherapy drugs.
 - Ingest alcohol in excess
 - Apply antiseptic preparations containing iodine (povidone/iodine mixture)

False negative results may occur when patients:

- Ingest ascorbic acid (vitamin C) in excess of 250 mg/day
- Consume excess amounts of vitamin C enriched foods, citrus fruits and juices
- Iron supplements which contain quantities of vitamin C in excess of 250 mg/day
- Patients should be instructed to return the labeled slides to the physician or laboratory shortly after preparing the last slide (test card) via the special mailer pouch provided.
- To reduce the rate of false positive tests due to consumption of raw fruits and vegetables, the Hemoccult® SENSA® test is best developed 3 days after sample application. This 3 day delay allows for the degradation of any fruit and vegetable peroxidases that may be present in the stool sample.

Fecal Occult Blood Hemocult SENSE

REFERENCES

- 1) Hemocult® SENSE® package insert, revised October 2002, Beckman Coulter, Inc.,

DISTRIBUTION

Automated Testing

HISTORICAL APPROVAL

Initiated by: Lorraine Weston MLT (ASCP) Date: 9/2004
Adopted: 10/2004
Approved: Cristina Taylor MD Date: 12/14/04
Revised : 6/2009 Sylvia Stacy MLS(ASCP)^{CM} 12/19/18

Retyped:

Supercedes: Hemocult, 11/1994