

**FHN**

Procedure Title:	Hemoccult SENS <sup>a</sup> Fecal Occult Blood
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## Hemoccult SENS<sup>®</sup>A Fecal Occult Blood

### **PRINCIPLE:**

The Hemoccult SENS<sup>®</sup>A 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.

The Hemoccult SENS<sup>®</sup>A 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.

### **SPECIMEN REQUIREMENTS:**

Patient Preparation:

- For accurate test results, apply samples from bowel movements collected on **three different days** to slide.
- Do not collect sample if blood is visible in stool or urine (e.g., menstruation, active hemorrhoids, urinary tract infection).
- For the most accurate test results collect each stool sample before contact with the toilet bowl water. Use any clean, dry container.
- **Drug Guidelines**
  - 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).
  - Acetaminophen (Tylenol) can be taken as needed.
  - 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.
- **Diet Guidelines**
  - For **three** days before and during stool collection period, **avoid** red meats (beef, lamb and liver).
  - Eat a well-balanced diet including fiber such as bran cereals, fruits and vegetables.

Specimen Type and Collection Method:

- The Hemoccult SENS<sup>®</sup>A test requires only a small fecal specimen. The specimen is applied to the guaiac paper of the Hemoccult SENS<sup>®</sup>A slide as a **THIN SMEAR** using the applicator stick provided.
- 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.

- For the most accurate test results collect each stool sample before contact with the toilet bowl water. Use any clean, dry container.

#### Special Handling or Storage Conditions:

- Hemocult SENSE 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. 8-10 Slides containing samples may be stored up to 14 days at room temperature (15 to 30°C) before developing.
- Patients using the Hemocult SENSE test should be instructed to return the slides to the physician or laboratory immediately after preparing the last test.

#### Criteria for Specimen Rejection:

- Cards that have had sample applied greater than 14 days ago.

### **EQUIPMENT, REAGENTS, AND SUPPLIES:**

#### Reagents:

- Hemocult SENSE Slides (Test Cards) containing guaiac paper
- Hemocult SENSE Developer– a developing solution containing a stabilized mixture of less than 4.2% hydrogen peroxide, 80% denatured ethyl alcohol and enhancer in an aqueous solution.
- Applicator sticks

#### Storage Requirements:

- Store product at controlled room temperature (15 to 30°C) in original packaging. Do not refrigerate or freeze. Protect from heat and light. Do not store with volatile chemicals (e.g., ammonia, bleach, bromine, iodine, household cleaners).
- The Hemocult SENSE Slides and Developer will remain stable until the expiration dates which appear on each slide and developer bottle when stored as recommended.
- **Slides** (blue and green striped)
  - Keep cover flap of slide sealed until ready to use. Protect slides from heat, light, and volatile chemicals (e.g., ammonia, bleach, bromine, iodine, household cleaners). Hemocult SENSE slides present no hazard to the user.
- **Developer** (blue and green striped label with blue bottle cap)
  - Hemocult SENSE Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.

#### Warnings and Precautions:

- Hemocult SENSE Developer is an irritant. **DO NOT USE IN EYES. AVOID CONTACT WITH SKIN.** Should contact occur, rinse promptly with water and consult a physician.

### **QUALITY CONTROL:**

The function and stability of the slides and developer can be tested using the on-slide Performance Monitors feature. The positive (+) and negative (-) Performance Monitors areas are located under the sample area on the developing side of the slides.

Frequency of Performance:

- Performed with every patient test.

Acceptable Limits:

- The positive Performance Monitors area contains a hemoglobin derived catalyst which will turn blue within 10 seconds after applying developer. The negative Performance Monitors area contains no such catalyst and should not turn blue after applying developer.

Corrective Action:

- The Performance Monitors feature provides assurance that the guaiac paper and developer are functional. In the unlikely event that the Performance Monitors areas do not react as expected after applying developer, the test results should be regarded as invalid. Should this occur, contact the Technical Marketing Department at 800-877-6242 for assistance.

Recording QC Data:

- QC is reported on the appropriate log sheet with each patient test.

**PROCEDURE:**

- Label card with patient first & last name, DOB, date and time of collection.
- Using applicator provided, collect small fecal sample.
- Apply thin smear covering Box A.
- Reuse applicator to obtain second sample from a different part of feces. Apply thin smear covering Box B.
- Close cover flap. Dispose of applicator in waste container.
- Slides are best developed no sooner than three days after sample application to allow for degradation of any fruit and vegetable peroxidases that may be present in the fecal sample. However, if immediate testing is required, wait 3 to 5 minutes before developing.
- Open back of slide and apply two drops of Hemoccult SENSE Developer to guaiac paper directly over each smear.
- **Read results within 60 seconds.**
- Any trace of blue on or at the edge of the smear is positive for occult blood.
- The Performance Monitors areas must be developed on every slide.
- Apply **one drop** of Hemoccult SENSE Developer between the positive and negative Performance Monitors areas.
- **Read results within 10 seconds.**
- If the slide and developer are functional, a blue color will appear in the positive Performance Monitors area and no blue will appear in the negative Performance Monitors area.
- Neither the intensity nor the shade of the blue from the Positive Performance Monitors area should be used as a reference for the appearance of positive test results.

- Any blue originating from the positive Performance Monitors area should be ignored when reading the sample test results.

### **REPORTING RESULTS:**

#### Reference Intervals:

- Normal – Negative
- Abnormal – Positive

#### Reporting Abnormal Results:

- Abnormal results should be reported to the provider.

#### Reporting Format:

- Negative – NEG or Negative
- Positive – POS or Positive

#### Result Entry:

- All results should be reported on the appropriate log sheet and in the patient chart.

### **LIMITATIONS OF PROCEDURE:**

- 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 SENS A 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 SENS A test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult SENS A 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 SENS A 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, is specifically designed to detect occult blood in gastric specimens.
- 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 SENS A test.
- 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.
  - **Substances which can cause false-positive test results:**
    - Red meat (beef, lamb and liver)

- Aspirin (greater than 325 mg/day) and other non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin and naproxen
- Corticosteroids, phenylbutazone, reserpine, anticoagulants, antimetabolites, and cancer chemotherapeutic drugs
- Alcohol in excess
- The application of antiseptic preparations containing iodine (povidone/iodine mixture)
- **Substances which can cause false-negative test results:**
  - Ascorbic acid (vitamin C) in excess of 250 mg per day
  - Excessive amounts of vitamin C enriched foods, citrus fruits and juices
  - Iron supplements which contain quantities of vitamin C in excess of 250 mg per day

*Dietary iron supplements **will not** produce false-positive test results with Hemocult SENSE*

*Acetaminophen is not expected to affect test results.*

#### **COMPETENCY REQUIREMENTS:**

- Staff new to testing will be required to complete at minimum a return demonstration and assigned quiz.
- Existing staff will be required to complete an annual quiz AND one of the following:
  - Return demonstration
  - Blind sample

#### **PROCEDURE NOTES:**

- Follow the procedure exactly as outlined. Always develop the test, read the results, interpret them, and decide whether the fecal specimen is positive or negative for occult blood BEFORE developing the Performance Monitors feature. Do not apply developer to the Performance Monitors areas before interpreting test results. Any blue originating from the positive Performance Monitors area should be ignored when reading the sample test results.
- Serial fecal specimen analysis is recommended when screening asymptomatic patients.

#### **REFERENCES:**

Hemocult SENSE package insert 6/15. Beckman Coulter, Inc., Brea, CA 92821

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