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## Policy and Procedure

<b>Title:</b>	Fecal Occult Blood using Hemocult® SENSE®		
<b>Origination Date:</b>	<u>2/25/85</u>	<b>Section:</b>	<u>POCT</u>
<b>Effective Date:</b>	<u>10/14/08</u>	<b>Policy No.:</b>	<u>WT 2.0.V4</u>
<b>Prepared By:</b>	<u>Patty Goodlin BS, MT (ASCP)</u>	<b>Supersedes Procedure</b>	<u>08/01/04</u>
		<b>Dated:</b>	_____
<b>Revised By:</b>	<u>June W. Sloan BS, MT(ASCP) MBA</u>		
<b>Approved By:</b>	_____	<b>Date:</b>	_____
	<b>Administrative Director</b>		
<b>Approved By:</b>	_____	<b>Date:</b>	_____
	<i>Medical Director or Designee</i>		

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**PURPOSE:** This document provides instructions for performing a qualitative fecal occult blood analysis using Hemocult® SENSE® and Hemocult II® SENSE® test slides.

**1.1 PRINCIPLE:** This Hemocult® SENSE® test is based on the oxidation of alpha 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 guaiac acid (active component of guaiac paper) by hydrogen peroxide (active component of developer) to form a highly conjugated blue quinone compound. (The Hemocult II® SENSE® Slides, in cards of three tests, are designed so patients can collect serial specimens at home.)

**2 SCOPE:** Health Care Providers throughout the New Hanover Health Network (RN, LPN, Technicians, NA, Unit Coordinators, and or PCT who have demonstrated annual competency.) may perform this test.

**2.1 SPECIMEN: Stool specimens only** (Hemocult® SENSE® test slide **is not recommended** for use with gastric specimens. See the Gastric Occult blood procedure for the appropriate testing of gastric specimens.)

1. **The Hemocult® SENSE® requires only a small fecal sample.** The sample is applied to the guaiac paper of the Hemocult slide as a **THIN SMEAR** using the application stick provided.
2. To increase the probability of detecting occult blood, each card has two sample areas so separate samples can be taken from two different section of the fecal specimen

3. Hemocult® SENSE® slides may be prepared as stated above and **developed after waiting a minimum of 3 minutes.**
4. Slides containing samples may be stored up to 14 days at room temperature before developing.
5. **Serial fecal specimen analysis is recommended when screening asymptomatic patients.** Fecal specimens should be collected from bowel movements over three days since bleeding from gastrointestinal lesions may be intermittent.

Notes:

- Do not collect sample if blood is visible in the stool (obvious rectal bleeding present or active hemorrhoids) or in the urine (menstruation or urinary tract infection).
- Specimen collection must be after the first three days after a menstrual period on premenopausal women.
- Patient specimens, and all material that come in contact with them, should be handled as potentially infectious and disposed of using proper precautions.

***Special Note: This test is visually read and requires color differentiation. Individuals with blue color deficiency (color blindness) should not interpret it.***

**PREPARATION: In general, patient's diet should be carefully monitored for foods and vitamins which can cause false-positive or false-negative test results for at least 72 hours before and through out the test period.**

***Substances that cause false positive test results:***

- Red meats (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)

***Notes: Dietary iron supplements will not produce false-positive test results with this test. Acetaminophen is not expected to affect test results.***

***Substances that cause false negative test results:***

- Ascorbic acid (vitamin C) in excess of 250 mg/day
- Excessive amounts of vitamin C enriched foods, citrus fruits, and juices.
- Iron supplements only if they also contain quantities of vitamin C in excess of 250 mg/day.

**HANDLING CONDITIONS:**

1. Hemocult SENSE® Slides - test slides contain guaiac paper. Keep cover flap of slide sealed until ready to use.
2. 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. N/A

### 3 PREPARATION AND NOTES

#### Equipment and Materials:

- **Hemocult ® SENSE® Developer** (Product No. 64115)- a solution containing a stabilized mixture of less than 4.2% hydrogen peroxide and 80% denatured ethyl alcohol and an enhancer in an aqueous solution. (Blue and green striped label.) **Developer is an irritant. AVOID CONTACT WITH SKIN.**
  - **Hemocult ® SENSE® Slides (100 Test Card Kit; Product No. 64151)** containing guaiac paper. Single Slides are convenient for use when single fecal specimens are tested. (Blue and green striped label with blue bottle cap.)
- OR**
- **Hemocult II® SENSE® Slides**, ESI order number 1385600 ( **40 Patient Kits**; Product No. 64130) in cards of three tests, are designed so patients can collect serial specimens at home from bowel movements over three days. After the patient prepares the Hemocult ® card, it may be returned in person or by mail (use Hemocult ® Mailing Pouch) to the laboratory for developing and interpretation. (Blue and green striped label.)
  - Applicator Sticks

#### Precautions:

- Do not use after expiration date that appears on each test component.
- This test is visually read and requires color differentiation; individuals with blue color deficiency (blindness) should not interpret it.
- Patient specimens, and all materials that come in contact with them, should be handled as potentially infectious and disposed of using proper precautions.
- **Slides** (blue and green striped) Keep cover flap of slide sealed until ready to use. Protect slides from heat, light, and volatile chemicals. Hemocult ® SENSE® slides present no hazard to the user.
- **Developer** (blue and green striped label with blue cap) Hemocult ® SENSE® Developer should be protected from heat and the bottle cap kept tightly capped when not in use. It is flammable and subject to evaporation. **Developer is an irritant. Avoid contact with skin and eyes. If contact should occur, rinse promptly with water and consult a physician.**
- **Do not interchange Hemocult ® SENSE® with Hemocult ® test reagents, which are identified by yellow and green striped packaging, or with components from any other manufacturer.**

**Storage and Stability:** All unopened boxes of Hemocult ® SENSE® slides are stored at room temperature. **The unopened stock is usually maintained in the par room or cart until QC is performed, reviewed, and recorded by POCT lab personnel on the Hemocult Quality**

**Control Record.** Once QC has been performed the outside of the box is documented with the “opened” date and initials which indicates QC was performed and test results were as expected. The cards may then be distributed into the needed areas on the floor.

Slides and Developer, stored as recommended below, will remain stable until the expiration dates that appear on each slide and developer bottle.

- Store product at controlled room temperature 15 to 30° C (59- 86° F).
- Do not refrigerate or freeze.
- The Developer should be protected from heat and the bottle kept tightly capped when not in use. Do not store with volatile chemicals such as iodine, chlorine, bromine, or ammonia.
- Protect cards from heat and light.

**Do not open a new box for removing the developer.** Extra Hemocult® SENSE® developer is usually in the Par in a blue drawer. Scan out each bottle to ensure replacement. See package insert for more product order information.

#### **Calibration:** NA

- **Quality Control:** The function and stability of the slides and developer can be tested using the on-slide Performance Monitor (QC). The positive (+) and negative (-) QC areas are located under the sample windows on the developing side (back) of the slides.
  - a. **Positive QC** - contains a hemoglobin-derived catalyst, which **will turn blue within 10 seconds** after applying developer.
  - b. **Negative QC** - contains no such catalyst and should not turn blue after applying developer.

#### **Control Testing Frequency:**

1. Each month, when POCT lab personnel make rounds, the Performance Monitor (positive “+” and negative “-“ QC) area is developed on **unopened boxes of Hemocult® SENSE® slides as needed. All appropriate information is documented on the Hemocult Quality Control Record.** The “opened date” on the outside of the box indicates this QC was performed and results were as expected.
2. The positive and negative QC area is **tested each time a patient test is performed.** This QC is documented by *including a check mark (✓) next to the result in the chart to indicate that the QC was done and results were as expected (i.e. Positive ✓)*

#### **Quality Control Procedure: (also part of patient test procedure)**

1. Apply one drop of Hemocult® SENSE® Developer between the positive and negative Performance Monitor areas.
2. Read 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.

### **PATIENT TESTING PROCEDURE**

1. Open front cover flap. Using the applicator provided, collect small amount of fecal sample.

2. Apply a thin fecal smear inside box A.
3. Reuse applicator to obtain a second sample from a different part of the fecal specimen and apply another thin smear inside box B.
4. Close front cover flap and **wait a minimum of 3 minutes before applying developer to allow adequate time for the sample to penetrate the test paper.** (Slides can be stored for up to 14 days until ready to develop).
5. Open back of slide and apply two drops of Hemocult® SENSE® Developer (blue cap with blue and green striped label) to guaiac paper directly over each thin fecal smear.
6. Read results within 60 seconds. **Any trace of blue, on or at the edge of the smear, is positive** for occult blood and can be recorded prior to the end of 60 seconds. **Absence of blue at the end of 60 seconds is negative** for occult blood. (*Wait the full 60 seconds before recording a negative result.*)
7. Determine result as positive or negative. Continue to next step before charting results.
8. **Apply one drop** of Developer between the positive and negative QC areas.
9. **Read control results within 10 seconds.** If the slide and developer are functioning properly, a blue color will appear in the positive area and no blue will appear in the negative area.
  - **If the QC checks fail** to react as expected after application of developer, the **patient test results are invalid. Repeat steps 1 – 8 using a new slide is required.**
  - If repeat testing still gives unacceptable QC results, the test is again repeated using a new box of slides and new developer.
10. Chart results either manually or electronically per department protocols.

*See next page for visual and more details.*

#### **CALCULATIONS: NA**

**REPORTING RESULTS:** This procedure is used as a **screening procedure** in those nursing locations where there is an immediate need for detection of blood in fecal specimens.

**Confirmatory testing is not required.** All Hemocult® SENSE® results are recorded in the patient's chart (Electronic, Progress Notes, or designated area of chart per department protocols) and reviewed by the nurse in charge of that patient and by the Physician. **Follow up testing is performed as ordered by the primary care giver.**

**Manually written results are recorded in words including a check mark (✓) next to the result to indicate QC was done and results were as expected (i.e. Positive ✓)**

**Reference value:** Negative

**Positive:** The appearance of any blue color, on or at the edge, of the smear within 60 seconds.

**Negative:** No blue color, on or at the edge of smear, at the end of 60 seconds. (*Wait the full 60 seconds before recording a negative result.*)

**Invalid Result:** If the QC checks fail to react as expected after application of developer. Repeat patient and QC testing using a new slide is required.

## INTERPRETING THE HEMOCCULT® BRAND SENSE® TEST

### Negative Smears\*

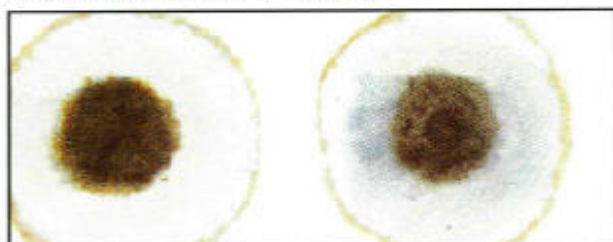


### Sample Report: Negative

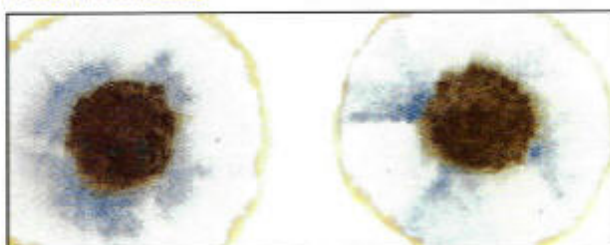
No detectable blue on or at the edge of the smears indicates the test is negative for occult blood.

(See Product Instructions -  
**LIMITATIONS OF PROCEDURE**).

### Negative and Positive Smears\*



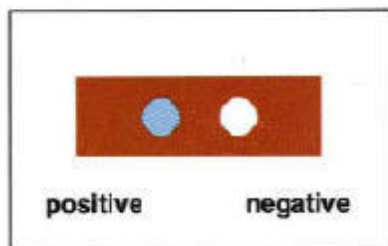
### Positive Smears\*



### Sample Report: Positive

Any trace of blue on or at the edge of one or more of the smears indicates the test is positive for occult blood.

## ON-SLIDE PERFORMANCE MONITOR® FEATURE



### Positive

A blue color will appear within 10 seconds after application of developer and remain stable for at least 60 seconds if test system is functional.

### Negative

No blue color should appear after application of developer if test system is functional.

Any blue originating from the PERFORMANCE MONITOR® areas should be ignored when reading the specimen test results.

**Neither the intensity nor the shade of the blue from the positive Performance Monitor® area, as illustrated, should be used as a reference for the appearance of positive test results.**

\*Above illustrations are an artist's rendition. Each illustration shows two smears from a single fecal sample as displayed on a single Hemocult® SENSE® test slide.

CPT Code: 82270 blood, occult, feces, screening.

## PROCEDURE NOTES AND ATTACHMENTS:

### Procedural notes:

1. 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 Monitor feature. **Do not apply developer to the QC area before interpreting test results.**
2. Neither the intensity nor the shade of blue from the positive QC area should be used as a reference for the appearance of positive test results.
3. The Hemocult test has a high sensitivity for disease but also has a higher false-positive rate among non-diet compliant patients.
4. Occult blood results are reported in words as either positive or negative.
5. This test requires Hemocult® SENSE® Developer. **Do not use Gastrocult Developer or any other developing solution. The developer and slides are color coded to a quick guide to the correct developer. Do not use slides with different stripes of color than that of the developer.**
6. The Hemocult® SENSE® test and other unmodified guaiac tests are not recommended for use with gastric samples.

### Attachments:

1. [Hemocult Outpatient Instructions](#)
2. [Hemocult Quality Control Record](#)
3. [NHHN Initial Competency Certification Form](#)
4. [NHHN Annual Competency Validation Form](#)

4.3.2

4.3.3

4.3.4

### Limitations:

1. Bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently. Blood, if present, may not be distributed uniformly in the fecal specimen. Consequently, a test result may be negative even when disease is present.
2. A Hemocult SENSE 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 Hemocult® SENSE® test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemocult® SENSE® 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.

3. See previous section for false positive and false negative results.

- 6 RECORDS: The following records should be kept current and updated at all times.**
- 1. Hemocult Quality Control Record** - maintained by POCT laboratory personnel for a minimum of 2 years.
  - 2. Competency Validation forms on all staff doing fecal occult blood testing** maintained by nursing personnel in employee's records.

**6.2**

**6.3**

**6.4**

**6.5**

**REFERENCES:**

Product Instructions: Beckman Coulter, Inc./ 4300 N Harbor Blvd., Fullerton, CA 92834-3100;  
Hemocult® SENSE®; 462489.E; October 2002

**7.2**

**7.3**

**7.4**

**Review Date**

**Revision Date**

**Signature**


**END**