OCCULT BLOOD IN FECES

I. Introduction and Clinical Significance

The Hemoccult SENSA® fecal occult blood is a rapid, convenient, 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 disease. It is not recommended for use with gastric samples. The test more reliably detects abnormal bleeding associated with gastrointestinal disorders than standard guaiac slide tests. As a result, it has a higher sensitivity for disease and also a higher false-positive rate among non-diet compliant patients.

II. Principle

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 (the active component of the guaiac paper) by hydrogen peroxide (the active component of the developer) to form a highly conjugated blue quinone compound.

III. Reagents

A. Hemoccult SENSA® Slides

The test cards contain quaiac paper.

B. Hemoccult SENSA® Developer

This is a developing solution containing a stabilized mixture of hydrogen peroxide and denatured alcohol.

IV. Precautions

- A. For *in vitro* diagnostic use only.
- B. Do not use after the expiration date.
- C. Developing Solution should be protected from heat and light. The bottle should be kept tightly capped when not in use. It is flammable and subject to evaporation.
- D. Developer is an irritant. **Avoid contact with eyes and skin.** If contact occurs, the solution should be rinsed off promptly with water.
- E. Because this test is visually interpreted and requires color differentiation, it should not be interpreted by individuals with blue color blindness.
- F. Patient specimens, and all materials that come in contact with them, should be handled as potentially infectious agents and disposed of with proper precautions.

V. Stability

- A. Do not refrigerate or freeze. Store at room temperature (15-30°C). Protect from heat and sunlight. Do not store with volatile chemicals such as iodine, chlorine, bromine, or ammonia.
- B. The slides and developer, when stored as recommended, will remain stable until the expiration dates.

VI. Patient Preparation:

Patients should follow the PATIENT INSTRUCTIONS for at least 7 days before and continuing through the test period. Physicians may elect not to place a patient on the recommended dietary restrictions. Roughage in the diet can increase accuracy by helping to uncover "silent" lesions that bleed intermittently.

VII. Patient Instructions

- A. Do not collect samples during, or until three days after your menstrual period, or while you have bleeding hemorrhoids or blood in your urine.
- B. Do not consume the following drugs, vitamins and foods for 7 days prior to testing:
 - 1. Aspirin or other non-steroidal anti-inflammatory drugs.
 - 2. Vitamin C in excess of 250 mg per day from all sources, dietary and supplemental. *
 - 3. Red meat (beef, lamb), including processed meats and liver
 - 4. Raw fruits and vegetables, especially melons, radishes, turnips and horseradish.

*Caution: some iron supplements contain quantities of Vitamin C which exceed 250 mg per day.

- C. Collect samples from three consecutive bowel movements or three bowel movements closely spaced in time.
- D. Protect the slides from heat, light and volatile chemicals, such as iodine or bleach.
- E. Keep the cover flap of the slides closed when not in use.

VIII. Specimen Collection

- A. The test requires only a small fecal specimen.
- B. The specimen is applied to the guaiac paper of the slide as a **THIN SMEAR** using the applicator stick provided.
- C. Using a ballpoint pen, write the patient name, age, address, phone number, sample collection date and physician name on the front of the slide in the space provided.
- D. Return the slides to the physician or laboratory immediately after preparing the last test.

IX. Procedure

A. Preparing the Test

- Using the applicator, apply a thin smear inside of Box A and Box B.
- 2. Close the cover flap.
- 3. If testing is performed immediately, wait **3 to 5 min** before developing the slide. Slides can be stored up to 14 days until ready to develop.

B. **Developing the Test**

- 1. Open the perforated window in the back of the slide. Apply two drops of developer to the back of each smear.
- 2. Interpret the results within 60 sec. Any trace of blue color on or at the edge of the smear is positive for occult blood.

C. Quality Control

- 1. Apply <u>one drop only</u> of developer between the positive and negative "Performance Monitor" areas.
- 2. Interpret the results within 30 sec. A blue color should appear in the positive performance monitor, and no blue color should appear in the negative performance monitor.
- 3. If the performance monitors do not produce the correct results, the patient results are not valid and should not be reported. If stool was received, the test must be repeated with a new card and/or bottle of developer. If the specimen was received from client already inoculated on a card, check to make sure the card is not expired. Contact the client; explain test failure and request recollection. Notify Micro supervisor of test failure and provide card lot information and expiration date for documentation.

Note: Always develop the patient test, interpret the results, and make a decision as to whether the patient's fecal specimen is positive or negative before developing the performance monitors. Any blue color originating from the performance monitors should be ignored in the interpretation of the patient specimen test results.

X. Reporting

- 1. Report as positive or negative for occult blood.
- 2. Record the results in the O & P log book, and enter them into the computer.

XI. Reference

Hemoccult SENSA® ". Beckman Coulter, Inc. Fullerton, CA. January 2001.

Document Control Effective 09/05/2001

Microbiology Director Approval: Dr. Ann Robinson 09/05/2001 Medical Director Approval: Dr. Joseph Schappert 03/10/2010 Microbiology Supervisor Reviews: Jerry Claridge 09/04/2001, 09/04/2002, 07/23/2003, 10/02/2003, 04/2004, 11/2005, 08/2006, 03/2007, 10/2008, 02/2009, 06/2011, 03/2013, Jason Ammons 05/2015

Revisions & Updates: