

Background

The Hemocult II SENSEA^{elite} test is a qualitative guaiac method for detecting fecal occult blood. It is not a test for colorectal cancer or any other specific diseases. It is recommended for professional use as a diagnostic aid during routine physical examinations, to monitor for 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 followed.

Specimen Collection and Handling

A. Patient Preparation

Patients should follow the Patient Instructions at least 7 days prior to and continuing through the test period.

Patient Instructions

- Do not collect specimens during, or until three days after your menstrual period, or while you have bleeding hemorrhoids or blood in your urine.

Eat a well balanced diet, with the following exceptions:

Avoid:

7 days prior and during testing:

- No more than one adult aspirin (325 mg) a day
- No other non-steroidal anti-inflammatory drugs such as ibuprofen (Motrin*, Advil**). **NOTE:** Please talk to your physician or pharmacist if you have any questions about medications you take regularly.

3 days prior and during testing:

- No red meat (beef, lamb, or liver)
- No more than 250 mg vitamin C from supplements, and citrus fruits and juices. An average orange contains approximately 70-75 mg vitamin C. 100% of the recommended daily allowance of vitamin C is 60 mg.

NOTE: Some iron supplements contain vitamin C in excess of 250 mg.

B. Specimen Collection

The Hemocult II SENSEA^{elite} test requires only a small fecal specimen. The specimen is applied to the guaiac paper of the Hemocult II SENSEA^{elite} Test Card as a THIN SMEAR using the Applicator Stick provided.

Slides containing samples may be stored for up to 14 days at room temperature (15 to 30° C) before developing.

Patients should be instructed to return completed Slides (Test Cards) to the physician or laboratory after preparing the last test and according to the patient instructions. **IMPORTANT NOTE:** Current U.S. Postal Regulations prohibit mailing completed slides in standard paper envelopes. Physicians who wish their patients to return Slides by mail must instruct them to use only the U.S. Postal Service approved Mailing Pouch provided in the patient kit.

Fecal specimens should be collected from bowel movements on three different days. To further increase the probability of detecting occult blood, separate samples should be taken from two different areas of each fecal specimen.

Materials and Reagents

- A. Hemocult II SENSEA^{elite} Slides
- B. Hemocult SENSEA Developer
- C. Applicator Sticks
- D. Patient Envelopes with instructions for diet and sample collection
- E. Mailing Pouch for returning completed slides
- F. Collection Tissues
- G. Hemocult II SENSEA^{elite} Product Instructions

Storage and Stability

Store all test components at controlled room temperature (15 to 30°C), in original packaging. Do not refrigerate or freeze. Protect slides from heat and light. Do not store near volatile chemicals (e.g., iodine, chlorine, bromine, or ammonia). Do not use after expiration date.

*Motrin is a registered trademark of McNeil Consumer & Specialty Pharmaceuticals

**Advil is a registered trademark of Wyeth Consumer Healthcare

Procedure

A. Identification

Fill in patient information in the space provided on the front of the slide.

B. Preparing The Test

1. Collect a small fecal sample on the end of the applicator.
2. Apply a **thin smear** inside Box A.
3. Reuse the applicator to obtain a second sample from a different part of the stool. Apply a **thin smear** inside Box B.
4. Close cover and let dry.
5. Repeat steps 1 through 4 for Day 2 and Day 3.
6. Slides are best developed no sooner than three days after sample application to allow for degradation of fruit and vegetable peroxidases that may be present in the fecal sample.
7. If testing immediately, wait 3 to 5 minutes before developing. Otherwise, slides may be stored for up to 14 days at room temperature (15 to 30°C) until ready to develop.

C. Developing The Test

1. Open the flap on the back of the slide and apply two drops of Hemocult SENSEA Developer directly over each smear.
2. Read test results within 60 seconds.

Interpretation

A. Negative Result

No detectable blue on or at the edge of the smear.

B. Positive Result

Any trace of blue on or at the edge of the smear.

C. Considerations

1. Occasionally, a light blue discoloration may be noticed on the guaiac test paper. This discoloration does not affect the test's accuracy or performance when it is developed and interpreted according to the recommended procedure. When developer is added to the fecal smear on a discolored slide, the blue background color migrates outward. A blue ring forms at the edge of the wetted circle, leaving the guaiac paper around the fecal smear off white in color. Interpretation is the same as above. Proper storage will help prevent blue discoloration.

2. Some fecal samples have a high bile content which causes them to appear green. A distinct green color (not blue), appearing on or at the edge of the sample within 60 seconds after adding developer, should be interpreted as negative. However, a blue or blue-green color should be interpreted as positive.
- D. Consult the Product Instructions for a full explanation of limitations and interfering substances.

Quality Control

Hemocult II SENSEA^{elite} is a waived test under CLIA. The following manufacturer recommendations for quality control should be performed on each Hemocult II SENSEA^{elite} slide.

A. Procedure

1. Perform quality control procedure only after patient test areas have been developed, read and interpreted.
2. Apply one drop of Hemocult SENSEA Developer between the positive and negative Performance Monitors area.
3. Read result within 10 seconds.

B. Interpretation

If the slide and developer are functional, a blue color will appear in the positive Performance Monitors area, while no blue will appear in the negative Performance Monitors area.

If the Performance Monitors area does not perform as described, disregard test results and call Technical Marketing at (800) 877-6242.

Comments and Technical Assistance

A. Precautions

1. Because this test is visually read and requires color differentiation, it should not be interpreted by people who are color-blind or visually impaired.
2. Patient specimens, and all materials that come in contact with them, should be handled as potentially infectious and disposed of with proper precautions.
3. Hemocult SENSEA Developer is an irritant and is flammable. **Avoid contact with eyes and skin.** If contact occurs, rinse promptly with water. See Material Safety Data Sheet for further details.

Hemoccult II SENSEA^{elite}

Physicians' #1 Choice in Enhanced Fecal Occult Blood Testing



4. Do not interchange components of the Hemoccult test with components of the Hemoccult II SENSEA^{elite} test or any other manufacturer's tests.
5. Do not use Hemoccult II SENSEA^{elite} for testing gastric samples or other body fluids.

B. Helpful Tips

1. Refer to the Product Instructions for additional interpretation help.
2. Color interpretation chart available upon request.
3. Technical assistance may be obtained by calling: (800) 877-6242, or by sending an email to askpcd@beckman.com.

References

Refer to Manufacturer's Instructions.

Review and Update

Reviewed by: _____

Title: _____

Review Date: _____



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