

Background

The Hemoccult 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, for hospital patients, 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 to and during the test period: Non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen, or aspirin (more than one adult aspirin a day).
Note: acetaminophen (i.e., Tylenol or equivalent) is allowed.
- Avoid 72 hours prior to and during the test period: Vitamin C in excess of 250 mg per day (from all sources, dietary and supplemental), Red meat (rare, cooked and processed beef, lamb and liver).

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

B. Specimen Collection

- A fecal specimen should be collected from the toilet bowl with the aid of any clean, dry container.
- Remove toilet bowl cleaners from toilet tank and flush twice before proceeding.
- A small amount of feces is applied as a thin smear to the Hemoccult slide using the applicator stick provided.
- Hemoccult slides may be prepared and developed after 3 to 5 minutes, or prepared and stored for up to 14 days at controlled room temperature (15 to 30° C) before developing. Patients should return all slides to a physician or lab within 10 days of first day of collection. If returning by mail, patients must use only U.S. Postal Service approved mailing pouches.**
- Since bleeding from gastrointestinal lesions may be intermittent, fecal samples for testing should be collected from bowel movements collected on three different days. To further increase the probability of detecting occult blood, separate samples should be taken from **two** different sections of each fecal specimen.

Materials and Reagents

- A. Hemoccult Slides (Test Cards) or Tape (in plastic dispenser) containing guaiac paper
 - B. Hemoccult 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. Hemoccult Product Instructions
- *Hemoccult II patient kit configurations only
**In Dispensapak Plus only

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.

Procedure

A. Identification

Fill in patient information in the space provided on the front of each 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.
5. 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 Hemoccult 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 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 (no 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

Hemoccult is a Waived test under CLIA. The following manufacturer recommendations for quality control should be performed on each Hemoccult slide.

A. Procedure

1. Perform quality control procedure only after patient test area has been developed, read and interpreted.
2. Apply one drop of Hemoccult Developer between the positive and negative Performance Monitors areas.
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 areas do not perform as described, disregard test results and call Technical Marketing at 1(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. Hemoccult 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.
4. Do not interchange components of the Hemoccult test with components of the Hemoccult SENSE test or any other manufacturer's tests.
5. Do not use Hemoccult for testing gastric 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: 1 (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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