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48667.306 Fecal Occult Blood Detection (Hemoccult Test)

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Version History

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FECAL OCCULT BLOOD DETECTION (HEMOCCULT® TEST)

PURPOSE

Rapid, convenient, qualitative detection of fecal occult blood as an indicator of gastrointestinal disease in ambulatory or inpatient care settings.

When using the test as a screening tool for colorectal cancer or other gastrointestinal diseases in asymptomatic patients serial analysis is recommended as bleeding may be intermittent.

PRINCIPLE

The Hemoccult® test is composed of guaiac impregnated paper enclosed in a cardboard frame which permits sample application on one side, and development and interpretation on the reverse side. When a fecal specimen containing occult blood is applied to the test paper, contact is made between hemoglobin and guaiac. A chemical reaction will occur upon addition of the developer solution, resulting in a blue discoloration of the paper within 60 seconds.

TESTING PERSONNEL

Competent clinical providers, including licensed physicians, nurse practitioners, physician assistants, midwives and registered nurses. Housestaff enrolled in an ACGME accredited postgraduate program may perform the test under supervision of a competent licensed physician. Staff who have difficulties with blue color discrimination must demonstrate their ability to interpret the test.

REAGENTS, EQUIPMENT AND MATERIALS

- Gloves
- Hemoccult Test Cards
- Hemoccult Developer
- Applicator

REAGENT STORAGE

Test Cards

Store test cards at room temperature (15 - 30º C), protected from heat, light, and volatile chemicals, such as ammonia, iodine and bleach. Do not refrigerate or freeze.

Developer

Keep bottle tightly capped when not in use. Protect from heat, as developer is flammable and subject to evaporation.

Products are stable until their expiration date. They must not be used past that date.

SPECIMEN REQUIREMENTS

Preparation for Testing

For optimal use of Hemoccult® slides in the home setting, it is recommended that patients follow certain diet and drug guidelines: starting at least 7 days prior to and continuing through the sample collection period patients should adhere to a well balanced diet containing fiber and avoid aspirin and other nonsteroidal anti-inflammatory (NSAID) drugs. For three days prior to and during the collection period Vitamin C and red meats should be avoided. For details refer to the Hemoccult® patient instructions in Appendix A.

Volume

Only a small fecal sample obtained during a digital rectal exam or from a stool sample is required. The specimen is applied as a thin smear to the guaiac paper.

Specimen Handling

Follow Universal Precautions when handling specimens. Gloves should be worn while obtaining and testing the specimen. Gloves must not be contaminated with urine, vaginal discharge, or other body fluids that may contain blood.

Stability of sample

Once the stool sample has been placed on the Hemoccult® card it is stable at room temperature for 14 days. Cards with fecal samples that were stored for more than 14 days should not be developed.

Specimen Labeling

The test card must be labeled with the patient's name and Medical Record Number when:

- testing is performed away from the patient
- more than one test is performed at the same time
- the test card is submitted to the Clinical Laboratory for testing
- test cards are given to the patient for home use and subsequent mailing to the Clinical Laboratory for testing

PROCEDURE

1. Using two patient identifiers, verify patient identification, and explain procedure to patient and/or family.
2. Check expiration dates of developer and slide.
3. If testing is NOT performed immediately by person collecting the sample, then label Hemoccult® test card with at least two forms of patient identification: Patient Name, Medical Record Number, and /or Date of Birth.
4. Don gloves; wear a mask and protective eyewear whenever the potential for a splash exposure exists.
5. To perform test, open front flap.
6. Using the gloved finger or applicator, apply a very thin smear of stool specimen to Box A and Box B from two different sites of the stool specimen. Close cover flap.

7. If testing immediately, **wait 3-5 minutes before developing to allow adequate time for sample to penetrate the test paper.**
8. Open the perforated window on the back of the slide.
9. **Apply two drops** of Hemoccult® developer to the back of Boxes A and B.
10. **Read results within 60 seconds**. The reading time is important, because the color reaction may fade after 2-4 minutes. Any trace of blue color within or on the outer rim of the specimen is positive for occult blood.
11. Develop the Performance Monitor areas (see Quality Control below). This must be done every time a Hemoccult® test card is developed.

QUALITY CONTROL

Note:
The procedure for developing the sample test must be completed, and interpreted before proceeding with the development of the Hemoccult® performance monitor areas.

1. **Apply one drop** of Hemoccult® developer between the positive and negative Performance Monitor areas on the reverse side of the slide.
2. Read results within 10 seconds.
3. Positive Performance Monitor area should turn blue, but the Negative Performance Monitor should not have any trace of blue.
4. Any blue originating from the positive Performance Monitor area should be ignored when reading the sample test results.
5. If Quality Control fails, do not report patient results. Discard the test card and developer.
6. Repeat the test on a new slide if there is still stool available for testing.

RESULTS AND REPORTING

Record patient results as either “positive” or “negative” in the patient’s medical record **only if** the performance monitors on the card yield expected quality control results, i.e., positive control shows positive result (blue color) and negative control negative result (no color). **Do not enter patient result** if either or both performance monitors yield unexpected results - thus recording of patient results indicates documentation of expected positive and negative internal quality control results.

Recording the actual results for the internal quality performance monitors in the patient record is optional.

The table summarizes possible results in test and performance monitor areas and results reported:

Test Area	Positive Monitor	Negative Monitor	Result Reported
Blue	Blue	No Color	Positive Result
No Color	Blue	No Color	Negative Result
Any Color	No Color	No Color	Do Not Report
Any Color	Blue	Blue	Do Not Report

LIMITATIONS

Results obtained with Hemoccult® tests cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. False negative results may be obtained, since most bleeding occurs intermittently. Hemoccult® tests are designed as a preliminary screen and are not intended to replace other diagnostic procedures such proctosigmoidoscopy, barium enema or X-ray studies. Hemoccult® will detect only hemoglobin released upon hemolysis of the red cell.

The Hemoccult® test should not be used to test gastric specimens.

INTERFERING SUBSTANCES

Substances that can cause <u>false-positive</u> results:

- Red meat (beef, lamb, liver)
- Aspirin (>325 mg/day) and other NSAID drugs
- Corticosteroids, phenylbutazone, reserpine, anticoagulants, antimetabolites, chemotherapeutics
- Alcohol in excess
- Application of antiseptic preparations containing iodine
- Peroxidases in fruits and vegetables

Dietary iron supplements and acetaminophen **are not expected** to affect test results.

Substances that can cause <u>false-negative</u> results:

- Ascorbic acid (Vitamin C) > 250 mg / day (including iron supplements containing >250 mg / day vitamin C)
- Excessive amounts of vitamin C rich foods (citrus fruits and juices)

CONFIRMATORY TESTING

Confirmatory testing is not required. However, at the discretion of the provider, per departmental policies or standardized procedures additional tests or procedures may be performed routinely, or when the Hemoccult® test yields unexpected or discrepant results.

REFERENCE:

Hemoccult® Product Instructions (2009)
Beckman Coulter, Inc
Fullerton, CA 92834-3100
http://www.beckman.com/products/RapidTestKits/hemoccult.asp

DISTRIBUTION:

A. Point of Care Master Procedure Book (2M14)

B. Approved Point of Care Testing Locations