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Beckman Coulter, Inc.
4300 N. Harbor Blvd.
Fullerton, CA 92834-3100
http://www.beckmancoulter.com/pcd



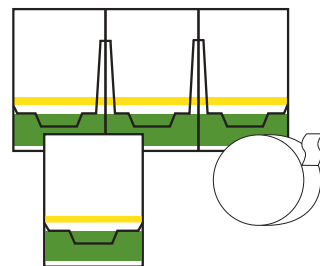
Hemocult[®] BRAND

Physicians' #1 Choice in Fecal Occult Blood Testing

Product Instructions

For *in vitro* diagnostic use

With On-Slide PERFORMANCE MONITOR[®] Feature



INTENDED USE

The Hemocult[®] test is a rapid, convenient and 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 diseases.

The Hemocult[®] test is recommended for professional use as a diagnostic aid during routine physical examinations, for hospital patients to monitor for gastrointestinal 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 closely followed.^{1,4,26}

Serial fecal specimen analysis is recommended when screening asymptomatic patients.^{3,5}

The Hemocult[®] test and other unmodified guaiac tests are not recommended for use with gastric specimens.⁶

SUMMARY AND EXPLANATION OF THE TEST

Van Deen is generally credited with the discovery that gum guaiac, a natural resin extracted from the wood of *Guaiacum officinale*, is useful in detecting occult blood. The Hemocult[®] test is a simplified and standardized variation of the laboratory guaiac procedure for detection of occult blood. The test contains a specially prepared, stabilized guaiac paper and is ready for use without additional preparation.

PRINCIPLES OF THE PROCEDURE

The Hemocult[®] 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 (active component of the guaiac paper) by hydrogen peroxide (active component of the developer) to form a highly conjugated blue quinone compound.⁷

MATERIALS AND REAGENTS

- Hemocult[®] Slides (Test Cards) or Tape (in plastic dispenser) containing guaiac paper
- Hemocult[®] Developer— a developing solution containing a stabilized mixture of less than 5.0% hydrogen peroxide and 75% denatured ethyl alcohol in an aqueous solution
- Applicator Sticks
- Patient Screening Kit Dispensing Envelopes with Patient Instructions*
- Flushable Collection Tissues**
- Mailing Pouches** (for returning completed Test Cards)
- Hemocult[®] Product Instructions

Hemocult[®] Single Slides are convenient for use when single fecal specimens are tested.

Hemocult II[®] Slides, in cards of three tests, are designed so patients can collect serial specimens at home from bowel movements on three different days. After the patient prepares the Hemocult II[®] test, it may be returned in person or by mail (use Hemocult[®] Mailing Pouch**; refer to SPECIMEN COLLECTION for detailed mailing information) to the laboratory, hospital or medical office for developing and interpretation.

Hemocult[®] Tape is designed to complement Hemocult[®] slides and is best suited for in-office and bedside examinations.

* Hemocult II[®] patient kit configurations only. (Product Nos. 61100 and 61130).
** Dispensapak[™] Plus configuration only (Product No. 61130).

PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use after expiration date which appears on each test component.
- Because this test is visually read and requires color differentiation, it should not be interpreted by individuals with blue color deficiency (blindness).
- Patient specimens, and all materials that come in contact with them, should be handled as potentially infectious and disposed of using proper precautions.
- **Slides** (yellow and green striped) Keep cover flap of slide sealed until ready to use. Protect slides from heat, light, and volatile chemicals. Hemocult[®] slides present no hazard to the user.
- **Developer** (yellow and green striped label with yellow bottle cap) Hemocult[®] Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.

- Hemocult[®] Developer is an irritant. **DO NOT USE IN EYES. AVOID CONTACT WITH SKIN.** Should contact occur, rinse promptly with water and consult a physician.

IMPORTANT: Use Hemocult[®] Developer (yellow and green striped label with yellow bottle cap) only with Hemocult[®] Slides and Tape. **Do not interchange Hemocult[®] with Hemocult[®] SENSA[®] test reagents, which are identified by blue and green striped packaging, or with components from any other manufacturer.**

STORAGE AND STABILITY

Store product at controlled room temperature (15 to 30°C) in original packaging. Do not refrigerate or freeze. Protect from heat and light. Do not store with volatile chemicals (e.g., ammonia, bleach, bromine, iodine and household cleaners). The Hemocult[®] Slides and Developer will remain stable until the expiration dates which appear on each slide and developer bottle when stored as recommended.

PATIENT PREPARATION and INSTRUCTIONS

Patients should follow the PATIENT INSTRUCTIONS at least 7 days prior to and continuing through the test period. Roughage in the diet can increase test accuracy by helping uncover "silent" lesions which bleed intermittently.^{5,8,9}

PATIENT INSTRUCTIONS

- For accurate test results, apply samples from bowel movements collected on **three different days** to slide.
- Do not collect sample if blood is visible in your stool or urine (e.g., menstruation, active hemorrhoids, urinary tract infection). **Contact your doctor.**
- For the most accurate test results collect each stool sample before contact with the toilet bowl water. You may use any clean, dry container.
- Return completed slides to your doctor or laboratory no later than 14 days after your first sample collection.
- Protect slides from heat, light, and volatile chemicals (e.g., ammonia, bleach, bromine, iodine and household cleaners).
- Remove toilet bowl cleaners from toilet tank and flush twice before proceeding.

Drug Guidelines

- For **seven** days before and during the stool collection period, **avoid** non-steroidal anti-inflammatory drugs such as ibuprofen (Motrin[®], Advil[®]), naproxen or aspirin (more than one adult aspirin a day).
- Acetaminophen (Tylenol[®]) can be taken as needed.
- For **three** days before and during the stool collection period, **avoid** vitamin C in excess of 250 mg a day from supplements, and citrus fruits and juices.

Diet Guidelines

- For **three** days before and during stool collection period, **avoid** red meats (beef, lamb and liver).
- Eat a well balanced diet including fiber such as bran cereals, fruits and vegetables.

Notes:

1. Please talk to your doctor or pharmacist if you have any questions about medications you take regularly.
2. 100% of RDA of vitamin C for an adult is 60 mg a day.
3. Some iron supplements contain vitamin C in excess of 250 mg.

* Tylenol & Motrin are registered trademarks of McNeil Consumer & Specialty Pharmaceuticals.
** Advil is a registered trademark of Wyeth Consumer Healthcare.

SPECIMEN COLLECTION

The Hemocult[®] test requires only a small fecal specimen. The specimen is applied to the guaiac paper of the Hemocult[®] Slide as a **THIN SMEAR** using the Applicator Stick provided.

Hemocult[®] Slides are best developed no sooner than 3 days after sample application. This allows any fruit and vegetable peroxidases present in the sample to degrade.^{8,10} Slides containing samples may be stored for up to 14 days at room temperature (15 to 30°C) before developing.¹⁸

Patients using the Hemocult II[®] screening test should collect fecal specimens from bowel movements 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.^{3,5} The completed Test Card should be returned to the physician or laboratory no later than 14 days after the first sample collection.



ATTENTION - Healthcare Professionals U.S. POSTAL SERVICE REGULATIONS FOR MAILING DIAGNOSTIC (CLINICAL) SPECIMENS

U.S. Postal Service (USPS) Regulations, as documented in the Federal Register, require specific mailing systems for all diagnostic (clinical) specimens, which include fecal occult blood tests (FOBTs). The regulations require the international biohazard symbol on the inside of packaging for solid (or dried) specimens to serve as a warning should it open during processing. Also healthcare professionals must assess the *risk group* of a patient's specimen to determine proper mailable packaging. A *risk group* is a ranking of a microorganism's ability within a patient's sample to cause injury through disease. The healthcare professional makes the assessment based upon the known medical condition and history of the patient.

Hemocult[®] brand FOBTs have a mailing system* designed to meet the USPS regulations. The table below provides a summary of the risk groups as described in the regulations and how patients can safely package and return their completed Hemocult II[®] FOBTs.

Risk Group	Fecal Sample	Risk to Individual/Community	Packaging Required
1	Normal	None or very low	Mail in Hemocult [®] Mailing Pouch.
2 or 3	Can cause human/animal disease	Moderate to High / Low	Place completed FOBT into a sift-proof container (e.g. plastic zip-lock bag) before placing into Hemocult [®] Mailing Pouch.
4	Serious pathogen	High	In these limited circumstances refer to the regulations as posted in the Federal Register.

* Hemocult[®] brand mailing system has incorporated the international biohazard symbol in its Mailing Pouch. Mailing Pouches are included in Hemocult II[®] Dispensapak Plus (Product No. 61130) and may also be ordered separately (Product No. 62200). Refer to PRODUCT INFORMATION for a listing of all Hemocult[®] brand occult blood products.

INTERFERING SUBSTANCES

Substances that can cause false-positive test results:¹¹⁻¹⁴

- Red meat (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)

Dietary iron supplements **will not** produce false-positive test results with Hemocult[®] tests.¹¹

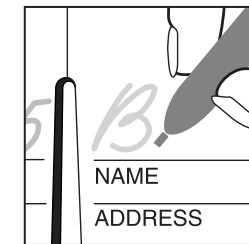
Acetaminophen is not expected to affect test results.¹⁴

Substances which can cause false-negative test results:¹⁵

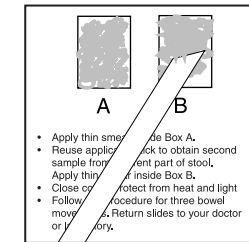
- Ascorbic acid (vitamin C) in excess of 250 mg per day
- Excessive amounts of vitamin C enriched foods (citrus fruits and juices)
- Iron supplements which contain quantities of vitamin C in excess of 250 mg per day

TEST PROCEDURE Hemocult[®] and Hemocult II[®]

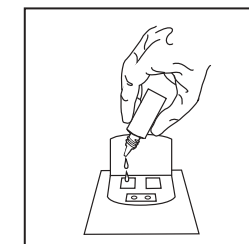
IMPORTANT NOTE: Follow the procedure exactly as outlined. Always develop the test, read the results, interpret them, and decide whether the fecal specimen is positive or negative for occult blood BEFORE developing the Performance Monitor[®] feature. Do not apply developer to the Performance Monitor[®] areas before interpreting test results. Any blue originating from the positive Performance Monitor[®] area should be ignored when reading the sample test results.



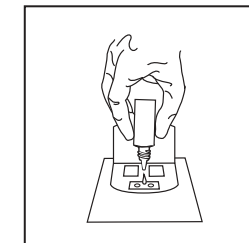
- A. Identification**
- Using a ball-point pen, write patient name, age, address, phone number, sample collection date and physician name on front of slide in space provided.



- B. Preparing the Test**
- Using applicator provided, collect small fecal sample.
 - Apply thin smear covering Box A.
 - Reuse applicator to obtain second sample from a different part of feces. Apply thin smear covering Box B.
 - Close cover flap. Dispose of applicator in waste container.



- C. Developing the Test**
- Slides are best developed no sooner than three days after sample application to allow for degradation of any fruit and vegetable peroxidases that may be present in the fecal sample. However, if immediate testing is required, wait 3 to 5 minutes before developing to allow adequate time for sample to penetrate the test paper.
 - Open back of slide and apply two drops of Hemocult[®] Developer to guaiac paper directly over each smear.
 - **Read results within 60 seconds.** Any trace of blue on or at the edge of the smear is positive for occult blood.



- D. Developing the Performance Monitor[®] (Quality Control)**
- The Performance Monitor[®] areas must be developed on every slide.
 - Apply **one drop** of Hemocult[®] Developer between the positive and negative Performance Monitor[®] areas.
 - **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.
 - Neither the intensity nor the shade of the blue from the Positive Performance Monitor[®] area should be used as a reference for the appearance of positive test results.
 - Any blue originating from the positive Performance Monitor[®] area should be ignored when reading the sample test results.

Occasionally, a light blue discoloration may be noticed on the guaiac test paper. This discoloration does not affect the accuracy or performance of the test when it is developed and interpreted according to the recommended procedure. When developer is added **directly over** the fecal smear on a discolored slide, the blue background color migrates outward. A blue ring forms at the edge of the wetted area, leaving the guaiac paper around the fecal smear off-white in color. Any blue on or at the edge of the smear is positive for occult blood. Proper storage of Hemoccult® Slides will help prevent blue discoloration.

Some specimens have a high bile content which causes the feces to appear green. A distinct green color (no blue), appearing on or at the edge of the smear within 60 seconds after adding Hemoccult® Developer, should be interpreted as negative for occult blood. A blue or blue-green color should be interpreted as positive for occult blood.

PERFORMANCE MONITOR® FEATURE (Quality Control)

The function and stability of the slides and developer can be tested using the on-slide Performance Monitor® feature. The positive (+) and negative (-) Performance Monitor® areas are located under the sample area on the developing side of the slides.

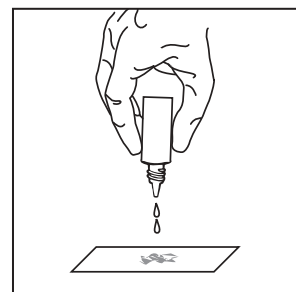
The positive Performance Monitor® area contains a hemoglobin-derived catalyst which will turn blue within 10 seconds after applying developer. The negative Performance Monitor® area contains no such catalyst and should not turn blue after applying developer.

The Performance Monitor® feature provides assurance that the guaiac paper and developer are functional. In the unlikely event that the Performance Monitor® areas do not react as expected after applying developer, the test results should be regarded as invalid. Should this occur, call the Technical Marketing Department at 800-877-6242 or 650-845-3526 for assistance.

TEST PROCEDURE FOR HEMOCCULT® TAPE



- Tear a strip of tape from the dispenser
- Apply a thin smear of fecal sample. Wait 3 to 5 minutes.



- Apply two drops of Hemoccult® Developer to the reverse side of the tape, directly behind the smear.
- **Read the results on the reverse side of the smear within 60 seconds.** Any trace of blue on or at the edge of the smear is positive for occult blood.

Checking Function and Stability

The function and stability of the Hemoccult® Tape and Developer can be tested by applying a small drop of diluted whole blood (1:5000 in distilled water) to an unused portion of the tape and applying two drops of Hemoccult® Developer to the reverse of the tape, directly behind the drop of diluted blood. If the tape and developer are functional, a blue color will appear.

LIMITATIONS OF PROCEDURE

Bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently. Also, blood, if present, may not be distributed uniformly in the fecal specimen. Consequently, a test result may be negative even when disease is present.⁵

Conversely, a Hemoccult® 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.¹⁶

Therefore, as with any occult blood test, results with the Hemoccult® test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult® 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.

The Hemoccult® test, as well as other unmodified occult blood tests, should not be used to test gastric specimens.⁶ Interfering factors, such as low pH, high drug concentrations, metal ions, or plant peroxidase in food, may affect the function of guaiac-based occult blood tests. Gastroccult®, available from Beckman Coulter Primary Care Diagnostics, is specifically designed to detect occult blood and measure pH in gastric specimens.

Addition of a drop of water (rehydration) to the guaiac slide prior to the addition of the developer increases the sensitivity of the test, but also increases the number of false-positive test results.^{4, 10, 17} For this reason, **rehydration is not a recommended procedure** for the Hemoccult® test. Hemoccult® SENSA®, also available from Beckman Coulter Primary Care Diagnostics, offers increased sensitivity without significant increase in false-positive results.

EXPECTED RESULTS

In a general screening population of highly compliant asymptomatic individuals, the Hemoccult® test will yield a positivity rate of approximately 2 to 5%. The false-positivity rate in such a population would be approximately 1 to 2%.¹⁸

Positivity rates for fecal occult blood tests have been shown to vary in each patient population depending on diet, age, predisposition to colorectal disease, and other factors that may be associated with bleeding gastrointestinal lesions.^{16, 19}

PERFORMANCE CHARACTERISTICS

Early detection of colorectal cancer in asymptomatic, average risk individuals is necessary to reduce mortality. The detection of occult blood in stool using Hemoccult® is an effective method for detecting bleeding associated with colorectal cancer.

Clinical studies²⁰ using [⁵¹Cr] chromium - labeled blood cells suggest that a daily blood loss of 2 - 3 ml is the lower limit of blood loss that may be associated with gastrointestinal pathology. Based on *in vitro* studies in which fecal samples from asymptomatic, normal volunteers were spiked with fresh whole blood, Hemoccult® gave positive test results about 50% of the time at 0.3 mg Hb / gm of feces. The positivity rates increased as the equivalent daily blood loss increased. Virtually all Hemoccult® tests were positive at an equivalent daily blood loss equal to or greater than 10 mL.¹⁸

Gregor²¹⁻²³ pioneered the clinical use of Hemoccult® guaiac paper slides for the detection of bleeding associated with colorectal cancer in office practice patients. His reports, involving 900 patients, showed a positive test rate of 5%. Barium enema examination showed 1% to have asymptomatic colon cancer. Another 3% had some other type of bowel pathology (i.e., polyps, diverticulitis, etc.). A false-positive rate of 1% was reported.

139 Colorectal Cancers Reported by 103 Physicians

	Total		Localized		Metastasized	
	No.	%	No.	%	No.	%
Silent	47	34	40	85	7	15
Semi-Silent	46	33	31	67	15	33
Symptomatic	43	31	23	53	20	47
Unclassified	3	2				

Ostrow, et al.²⁴ conducted a study in 20 healthy volunteers who received various quantities of radioactive chromium-tagged [⁵¹Cr] red blood cells, instilled via nasogastric tube. The authors compared the reaction obtained with the Hemoccult® test and two other chemical methods for detecting fecal blood, with actual blood loss simultaneously determined by radioassay of each fecal specimen.

As shown in the table below, the relative sensitivity of the Hemoccult® test was found to be about one-fifth that of other tests, significantly reducing the number of false-positive reactions normally encountered with the other procedures. This low level of false positives with the Hemoccult® test was noted even on an unrestricted diet.

Relative Sensitivity of Various Tests for Fecal Occult Blood

	Hemoccult®	Bench Guaiac	Orthotolidine
Relative sensitivity to instilled blood	+	++++	+++
Percent of false-positive reactions, unrestricted diet	1%	56%	32%
Percent of false-positive reactions, meat-free diet	1%	32%	23%

Based on Ostrow²⁴

Prospective, randomized controlled clinical trials extending for up to 18 years have demonstrated that the Hemoccult® products are effective in detecting occult blood in stool as an early indication of colorectal cancer. In clinical trials that enrolled over 339,000 individuals, mortality from colorectal cancer was reduced up to 33% when fecal occult blood tests were performed annually²⁷⁻²⁹ and 15-21% when performed biennially.³⁰ The program sensitivity for detecting colorectal cancer when Hemoccult® was performed annually was 90%.^{31, 32}

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PRODUCT INFORMATION

All products listed are CLIA Waived.

Product Name	Product No.
Hemoccult II® SENSA® elite Dispensapak™ Plus (case of 4 boxes) Each box contains: • 40 Patient Screening Kits • Two 15 mL bottles of Hemoccult® SENSA® Developer	395035
Hemoccult® SENSA® Single Slides (case of 10 boxes) Each box contains: • 100 Slides • 100 Applicator Sticks • Two 15 mL bottles of Hemoccult® SENSA® Developer	64151
Hemoccult® SENSA® Single Slides (case) • 1000 Slides • 1000 Applicator Sticks • Twenty 15 mL bottles of Hemoccult® SENSA® Developer	64152
Hemoccult II® SENSA® Dispensapak™ Plus (case of 4 boxes) Each box contains: • 40 Patient Screening Kits • Two 15 mL bottles of Hemoccult® SENSA® Developer	64130
Hemoccult® SENSA® Developer (box) • Twenty 15 mL bottles	64115
Hemoccult® Single Slides (case of 10 boxes) Each box contains: • 100 Slides • 100 Applicator Sticks • Two 15 mL bottles of Hemoccult® Developer	60151
Hemoccult® Single Slides (case) • 1000 Slides • 1000 Applicator Sticks • Twenty 15 mL bottles of Hemoccult® Developer	60152
Hemoccult II® Dispensapak™ (case of 2 boxes) Each box contains: • 50 Patient Kits (Triple Slide and Applicator Sticks ONLY) • Three 15 mL bottles of Hemoccult® Developer	61100
Hemoccult II® Dispensapak™ Plus (case of 4 boxes) Each box contains: • 40 Patient Screening Kits • Two 15 mL bottles of Hemoccult® Developer	61130
Hemoccult II® (case of 10 boxes) Each box contains: • 34 Triple Slides • 102 Applicator Sticks • Two 15 mL bottles of Hemoccult® Developer	61200
Hemoccult® Developer (box) • Twenty 15 mL bottles	62115
Hemoccult® Mailing Pouches (box) • 100 pouches	62200
Hemoccult® Tape (case of 12 boxes) Each box contains: • 2 Tape Dispensers • Two 15 mL bottles of Hemoccult® Developer	63202
Gastroccult® Test Kit • Box of 40 Slides	66040
Gastroccult® Developer • Six 15 mL bottles	66115
Gastroccult® Straw Applicators • 40 Applicators	66140

Also available, 8-1/2 x 11" color guide to test interpretation for Hemoccult® SENSA®, Hemoccult® or Gastroccult®.

For more information visit www.hemoccultFOBT.com

For technical assistance call Technical Marketing at 800-877-6242 or 650-845-3526 or e-mail askpcd@beckman.com

To order product, contact your medical supply distributor.

Manufactured by: CLIAwaived, Inc
858-481-5031

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