

462489 EA

November 2009

Printed in U.S.A.

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Brea, CA 92821

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BECKMAN COULTER®

Hemoccult®

SENSA®

Physicians' #1 Choice in Enhanced Fecal Occult Blood Testing

Product Instructions

For *in vitro* diagnostic use

With On-Slide PERFORMANCE MONITOR® Feature

INTENDED USE

The Hemoccult® SENSE® 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 Hemoccult® SENSE® test is recommended for professional use as a diagnostic aid during routine physical examinations, for hos- pital 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 pro- grams for colorectal cancer when the Patient Instructions are closely followed.^{1,4, 22}

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

The Hemoccult® SENSE® test and other unmodified guaiac tests are not recommended for use with gastric specimens.⁹

SUMMARY AND EXPLANATION OF THE TEST

Van Deen is generally credited with the discovery that gum gua- iac, a natural resin extracted from the wood of *Guaiacum officinale*, is useful in detecting occult blood.

The Hemoccult® SENSE® test more reliably detects abnormal bleeding associated with gastrointestinal disorders than standard guaiac tests. As a result, it will have a higher sensitivity for disease but also a higher false-positive rate among non-diet compliant patients. Hemoccult® SENSE® positive test results appear as more stable, intense blue color reactions than the results of other guaiac tests, improving overall readability and precision. As with other guaiac tests, accuracy depends upon the status of the patient at the time the specimen is taken and may be affected by interfering substances.

The Hemoccult® SENSE® test, like the Hemoccult® test, is a simpli- fied and standardized variation of the laboratory guaiac procedure for detection of occult blood. The Hemoccult® SENSE® test formu- lation includes an enhancer which makes the test more sensitive and more readable than other guaiac-based tests. Because the Hemoccult® SENSE® test requires only a small fecal specimen, offensive odors are minimized and storage or transport of large fecal specimens is unnecessary.

PRINCIPLES OF THE PROCEDURE

The Hemoccult® SENSE® 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 per- oxidase activity which catalyzes the oxidation of alpha-guaiaconic acid (active component of the guaiac paper) by hydrogen perox- ide (active component of the developer) to form a highly conju- gated blue quinone compound.⁷

REAGENTS AND MATERIALS

The Hemoccult® SENSE® test consists of two main components:

- Hemoccult® SENSE® Slides (Test Cards) containing guaiac paper
- Hemoccult® SENSE® Developer—a developing solution containing a stabilized mixture of less than 4.2% hydrogen peroxide, 80% denatured ethyl alcohol and enhancer in an aqueous solution.

Hemoccult® SENSE® Single Slides are convenient for use when single fecal specimens are tested.

Hemoccult II® SENSE® Slides, in cards of three tests, are designed so patients can collect serial specimens at home from bowel move- ments over three days. After the patient prepares the Hemoccult II® SENSE® test, it may be returned in person or by mail (use Hemoccult® Mailing Pouch) to the laboratory, hospital or medical office for developing and interpretation.

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 differen- tiation, 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.

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- **Slides** (blue and green striped)
Keep cover flap of slide sealed until ready to use. Protect slides from heat, light, and volatile chemicals (e.g., ammonia, bleach, bromine, iodine, household cleaners). Hemoccult® SENSE® slides present no hazard to the user.
- **Developer** (blue and green striped label with blue bottle cap)
Hemoccult® SENSE® Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.
- Hemoccult® SENSE® 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 Hemoccult® SENSE® Developer (blue and green striped label with blue bottle cap) only with Hemoccult ® SENSE® slides.

Do not interchange Hemoccult® SENSE® with Hemoccult® test reagents, which are identified by yellow and green striped pack- aging, or with components from any other manufacturer.

STORAGE AND STABILITY

Store product at controlled room temperature (15 to 30°C) in origi- nal packaging. Do not refrigerate or freeze. Protect from heat and light. Do not store with volatile chemicals (e.g., ammonia, bleach, bromine, iodine, household cleaners).

The Hemoccult® SENSE® 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.

PATIENT INSTRUCTIONS

- For accurate test results, apply samples from bowel move- ments 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, 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 ibupro- fen, 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 ques- tions 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 is a registered trademark of McNeil Consumer Products.

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SPECIMEN COLLECTION

The Hemoccult® SENSE® test requires only a small fecal specimen. The specimen is applied to the guaiac paper of the Hemoccult® SENSE® slide as a **THIN SMEAR** using the applicator stick provided.

Hemoccult® SENSE® 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 up to 14 days at room temperature (15 to 30°C) before developing.¹⁸

Patients using the Hemoccult® SENSE® test should be instructed to return the slides to the physician or laboratory immediately after preparing the last test. **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 U.S. Postal Service approved mailing pouches.*

Fecal specimens should be collected from bowel movements over three days. To further increase the probability of detecting occult blood, separate samples should be taken from two different sec- tions of each fecal specimen.^{3, 5}

INTERFERING SUBSTANCES

In general, patients should be carefully instructed to not ingest foods and vitamins which can cause false-positive or false-nega- tive test results for at least 72 hours before and through the test period.

Substances which 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 Hemoccult® SENSE® 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

PROCEDURE

Materials Supplied:

- Hemoccult® SENSE® Slides (blue striped)
- Hemoccult® SENSE® Developer (blue cap and striped label)
- Applicator sticks
- Patient envelopes with patient sample collection instructions **
- Mailing Pouch for returning completed slides*
- Collection tissues**
- Hemoccult® SENSE® Product Instructions

*Mailing Pouches are included in Hemoccult II® SENSE® Dispensapak™ Plus (Product Number 64130) and may be ordered separately. Refer to ORDERING INFORMATION.

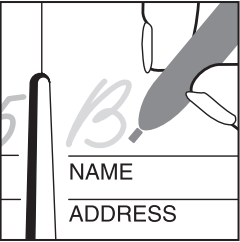
**In Dispensapak™ Plus configuration only.

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® fea- ture. Do not apply developer to the Performance Monitor® areas before interpreting test results. Any blue originating from the posi- tive Performance Monitor® area should be ignored when reading the sample test results.

3

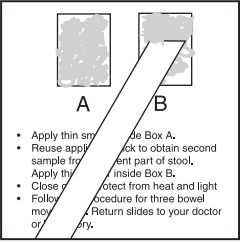
TEST PROCEDURE

Hemoccult® SENSE® and Hemoccult II® SENSE®



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.

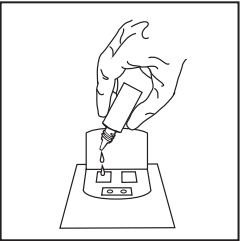


B. Preparing the Test

- 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.

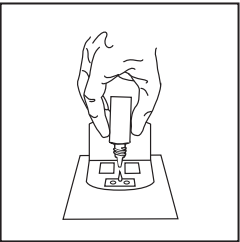
C. Developing the Test

- 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.
- Open back of slide and apply two drops of Hemoccult® SENSE® 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® Feature (Quality Control)

- The Performance Monitor® areas must be developed on every slide.
- Apply **one drop** of Hemoccult® SENSE® 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.



NOTES

- Follow the procedure exactly as outlined above.
- When preparing slides for immediate testing, wait as directed to allow adequate time for sample to penetrate the test paper before developing.

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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® SENSE® 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®SENSE® 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, contact the Technical Marketing Department at 800-877-6242 for assistance.

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.^{3, 5}

Conversely, a Hemoccult® SENSE® 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®SENSE® test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult® SENSE® 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® SENSE® test, as well as other unmodified fecal occult blood tests, should not be used to test gastric specimens. 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. Gastrocult®, available from Beckman Coulter Primary Care Diagnostics, is specifically designed to detect occult blood in gastric specimens.

Addition of a drop of water (rehydration) to the guaiac test card 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® SENSE® test.

EXPECTED RESULTS

In a general screening population of highly compliant asymptomatic individuals, a positivity rate of approximately 3% was obtained; among a similar group of less compliant individuals, a positivity rate of about 7% was observed. The false-positivity rate for colorectal disease was 1 to 3% depending on the population studied.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® SENSE®, a more sensitive and readable test than Hemoccult®, is a highly 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 (approximately 0.3 mg hemoglobin/gm feces) 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® SENSE® gave positive test results about 75% of the time at 0.3 mg Hb / gm feces. The positivity rates increased as the equivalent daily blood loss increased. Virtually all Hemoccult® SENSE® tests were positive at an equivalent daily blood loss equal to or greater than 10 mL.

The specificities of the Hemoccult® SENSE® test and the Hemoccult® test are the same when normal subjects follow the Patient Instructions as recommended. When normal subjects consume large amounts of red meat, the false-positive rate will be higher with the Hemoccult® SENSE® test. Raw fruits and vegetables in the diet give about the same number of false-positive test results when samples are tested immediately after collection. **To reduce the rate of false-positive tests due to consumption of raw fruits and vegetables, the Hemoccult® SENSE® test is best developed three days after sample application. This three day delay allows for degradation of any fruit and vegetable peroxidases that may be present in the fecal sample.**⁸⁻¹⁰

The clinical performance of the Hemoccult® SENSE® test was compared to the Hemoccult® test in multi-site clinical evaluations. The results are shown in Figure 1 and Table 1.¹⁸

Figure 1 illustrates that the Hemoccult® SENSE® test is more effective than the Hemoccult® test in detecting bleeding associated with colorectal cancer and adenomas. The differences in sensitivity between the two tests are statistically significant.^{18, 25}

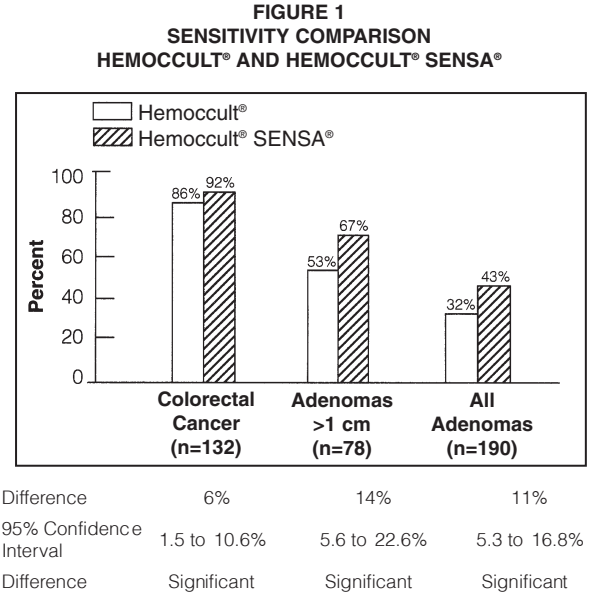
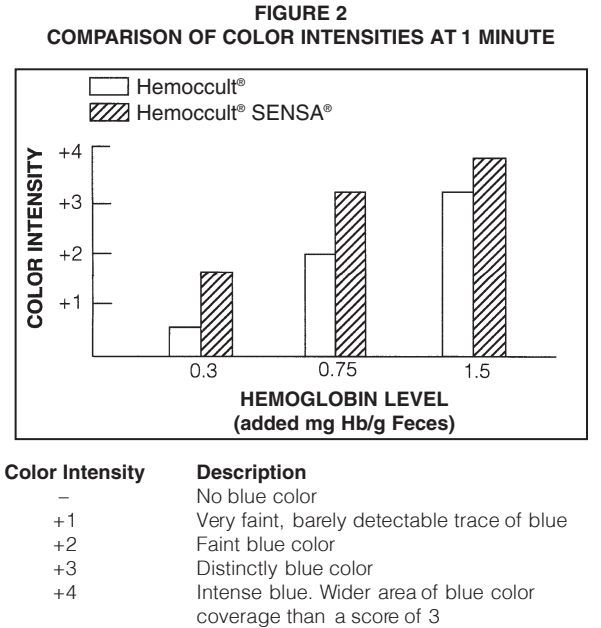


Table 1 summarizes the data comparing the specificity of the Hemoccult® SENSE® test (96.5%) to that of the Hemoccult® test (98%). In an individual study where patients were highly motivated to comply with the restricted diet, the specificity of the Hemoccult® SENSE® test was the same as the Hemoccult® test (99%).^{18, 25}

TABLE 1 COMPARISON OF SPECIFICITY Asymptomatic Individuals Confirmed and Presumed Normals on Restricted Diet		
	Hemoccult®	Hemoccult® SENSE®
No. of Cases Studied	1586	2197
Specificity	98%	96.5%
Difference in Specificity	1.5%	
95% Confidence Interval	0.5 to 2.5%	

The Hemoccult® SENSE® test is more readable than the Hemoccult® test at low but abnormal levels of hemoglobin in feces. Figure 2 compares the color intensity and stability of positive test results from samples containing different levels of added hemoglobin. Experienced and inexperienced readers preferred the more intense, stable blue color of the Hemoccult® SENSE® test, which made it easier to read a positive test result against the dark sample background. Experienced readers correctly interpreted test results a higher percentage of the time than inexperienced readers, pointing to the benefit of some training in reading guaiac-based fecal occult blood tests.

The reproducibility of test results on positive fecal specimens is improved with Hemoccult® SENSE® as a result of the increased readability of the test.^{18, 25}



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 was 90% when Hemoccult® was repeated annually.³¹⁻³²

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PRODUCT INFORMATION
All products listed are CLIA Waived.

Product Name	Product No.
<hr/>	
Hemoccult® SENSE® <i>elite</i> Dispensapak® Plus (case of 4 boxes) Each box contains: • 40 Patient Screening Kits • Two 15 mL bottles of Hemoccult® SENSE® Developer	395035
<hr/>	
Hemoccult® SENSE® Single Slides (case of 10 boxes) Each box contains: • 100 Slides • 100 Applicator Sticks • Two 15 mL bottles of Hemoccult® SENSE® Developer	64151
Hemoccult® SENSE® Single Slides (case) • 1000 Slides • 1000 Applicator Sticks • Twenty 15 mL bottles of Hemoccult® SENSE® Developer	64152
Hemoccult® <i>II</i>® SENSE® Dispensapak™ Plus (case of 4 boxes) Each box contains: • 40 Patient Screening Kits • Two 15 mL bottles of Hemoccult® SENSE® Developer	64130
Hemoccult® SENSE® Developer (box) • Twenty 15 mL bottles	64115
<hr/>	
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® <i>II</i>® 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® <i>II</i>® Dispensapak™ Plus (case of 4 boxes) Each box contains: • 40 Patient Screening Kits • Two 15 mL bottles of Hemoccult® Developer	61130
Hemoccult® <i>II</i>® (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
<hr/>	
Hemoccult® Tape (case of 12 boxes) Each box contains: • 2 Tape Dispensers • Two 15 mL bottles of Hemoccult® Developer	63202
<hr/>	
Gastrocult® Test Kit • Box of 40 Slides	66040
Gastrocult® Developer • Six 15 mL bottles	66115
Gastrocult® Straw Applicators • 40 Applicator	66140

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

For more information visit **www.hemoccultFOBT.com**

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

To order product, contact your medical supply distributor.

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