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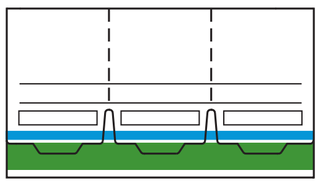
Safe...Simple...Life-Saving

BECKMAN COULTER.

Hemoccult II® SENSA® elite

Physicians' #1 Choice in Enhanced Fecal Occult Blood Testing



PRODUCT INSTRUCTIONS

For *in vitro* diagnostic use

INTENDED USE

The Hemoccult II® SENSA® *elite* 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 II® SENSA® *elite* 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.[1,4,22]

Serial fecal specimen analysis is recommended when screening asymptomatic patients.[3,5]

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

Hemoccult II® SENSA® *elite* is the same format and chemistry as Hemoccult® SENSA®, therefore it provides the same performance. The *elite* version provides clarified diet instructions, easier patient sampling, and easier processing.

PRINCIPLES OF THE PROCEDURE

The Hemoccult II® SENSA® *elite* 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

- Hemoccult II® SENSA® *elite* Slides (Test Cards) containing guaiac paper
- Hemoccult® SENSA® 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
- Applicator Sticks
- Patient Screening Kit Dispensing Envelopes with Patient Instructions
- Flushable Collection Tissues
- Mailing Pouches (for returning completed Test Cards)
- Hemoccult II® SENSA® *elite* Product Instructions

The Hemoccult II® SENSA® *elite* Test Card is designed so patients can collect serial specimens at home from bowel movements on three different days. After the patient prepares the Hemoccult II® SENSA® *elite* 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 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** (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, and household cleaners). Hemoccult II® SENSA® *elite* Slides present no hazard to the user
- **Developer** (blue and green striped label with blue bottle cap)
  Hemoccult® SENSA® Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.
- Hemoccult® SENSA® 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® SENSA® Developer (blue and green striped label with blue bottle cap) only with Hemoccult® SENSA® and Hemoccult II® SENSA® elite Slides (Test Cards).***
- ***Do not interchange Hemoccult® SENSA® with Hemoccult® test reagents, which are identified by yellow and green striped packaging, or with components from any other manufacturer.***

STORAGE AND STABILITY

Store Test Cards and Developer 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 Hemoccult II® SENSA® *elite* Slides and Hemoccult® SENSA® Developer will remain stable until the expiration dates which appear on each slide and developer bottle when stored as recommended.

PATIENT PREPARATION and INSTRUCTIONS

FIRST: Preparation before taking the test

Okay to Eat!
- Pork, chicken, turkey and fish
- Fruits and vegetables
- High-fiber foods (e.g., whole wheat bread, bran cereal, popcorn)
- Acetaminophen (Tylenol*)
- Up to one adult aspirin (325 mg) a day

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 a day 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.

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

SECOND: Taking the test on 3 different days

IMPORTANT

- ***Do not take test if blood is visible in your stool or urine (e.g., menstruation, active hemorrhoids, urinary tract infection).***
- ***Remove toilet bowel cleaners from toilet tank and flush twice before collecting stool.***
- ***For best results, prevent stool from contacting toilet water. Other clean, dry containers may be used if desired.***
- ***Protect Test Card from heat, light, and volatile chemicals (e.g., ammonia, bleach, bromine, iodine, and household cleaners).***

1 **Write your name**, ID# (if known), and physician's name on front of Test Card.

2 Fill in **Day 1** Collection Date. Open **Day 1** flap.

3 Urinate before bowel movement, if possible. Collect stool using one of the following options.

Tissue + Plastic Wrap (preferred)

- Flush toilet.
- Obtain 2 foot piece of plastic wrap (not included).
- Lift lid and seat of toilet.
- Secure plastic wrap across back half of bowl, allowing middle to hang down just above water.

- Unfold tissue (provided) halfway.
- Place on top of plastic wrap.
- Lower seat.

- Have a bowel movement.

Go to **4**.

OR

Tissue Alone

- Flush toilet.
- Unfold tissue (provided) completely.
- Float tissue on surface of water.

- Allow edges to stick to sides of bowl.

- Have a bowel movement.

Go to **4**.

4 Obtain a small stool sample with provided Applicator Stick. Apply thin smear in box **A**.

5 Reuse Applicator Stick to obtain a 2nd sample from a different part of stool. Apply thin smear in box **B**.

Flush tissue and stool ONLY. Discard stick and plastic wrap (if used) in waste container.

6 Close flap. Store Test Card in the patient kit envelope. Let dry. Do not store smeared Test Card in any moisture-proof material (e.g., plastic bag).

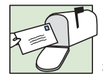
Day 2 Day 3

7 Repeat steps **2** through **6** for **Day 2** and **Day 3**.

THIRD: Returning the test

IMPORTANT

Current U.S Postal Regulations prohibit mailing completed Test Cardsin any standard paper envelope. Use the Mailing Pouch provided in Patient Screening Kit.



1. Insert completed and overnight air-dried Test Card into enclosed U.S. Postal Service approved mailing pouch.
2. Peel tape from flap. Fold flap over. Press firmly to seal.
3. Deliver or mail sealed Mailing Pouch to your physician or laboratory within **10 days** of **Day 1** Collection Date.

SPECIMEN COLLECTION

The Hemoccult II®SENSA® *elite* test requires only a small fecal specimen. The specimen is applied to the guaiac paper of the Hemoccult II® SENSA® *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.[18]

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.[3,5]

INTERFERING SUBSTANCES

In general, patients should be carefully instructed to not ingest foods, vitamins or medications which can cause false-positive or false-negative test results.

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 II® SENSA® *elite* 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

Follow the procedure exactly as outlined below.

SAMPLE COLLECTION

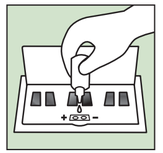
Instruct patients to complete the Hemoccult II® SENSA® *elite* Test Card as described in the Patient Preparation and Instructions section.

DEVELOP TEST

IMPORTANT

- ***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.***
- ***If immediate developing is required, wait 3-5 minutes to allow the sample to penetrate the guaiac paper.***
- ***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.®***
- ***Any blue originating from the positive Performance Monitor® should be ignored when reading the sample test results.***

Developing the Test
- Open large back flap of Test Card to expose all six fecal smears.
- Apply **two drops** of Hemoccult® SENSA® Developer to guaiac paper directly over each smear.
- **Read and interpret results within 60 seconds.** Any trace of blue on or at the edge of any smear is positive for occult blood.



Developing the Performance Monitor® (Quality Control)
- The Performance Monitor® must be developed on every Test Card.
- The Performance Monitor® provides an internal control for the entire Slide (Test Card).
- Apply **one drop** of Hemoccult® SENSA® Developer between the positive and negative Performance Monitor®.
- **Read results within 10 seconds.** If the Test Card and Developer are functional, a blue color will appear in the positive Performance Monitor® and no blue will appear in the negative Performance Monitor.®
- Neither the intensity nor the shade of the blue from the positive Performance Monitor® should be used as a reference for the appearance of positive test results.
- Any blue originating from the positive Performance Monitor® 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 II® SENSA® *elite* 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® SENSA® 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® (Quality Control)

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

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® provides an internal control for the entire Slide (Test Card).

The Performance Monitor® provides assurance that the guaiac paper and Developer are functional. In the unlikely event that the Performance Monitor® area does 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 II® SENSA® *elite* 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 II® SENSA® *elite* test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult II® SENSA® *elite* 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 II® SENSA® *elite* test, as well as other unmodified fecal 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 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.[4,10,7] For this reason, **rehydration is not a recommended procedure** for the Hemoccult II® SENSA® *elite* 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® SENSA®, a more sensitive and readable test than Hemoccult®, is a highly effective method for detecting bleeding associated with colorectal cancer.

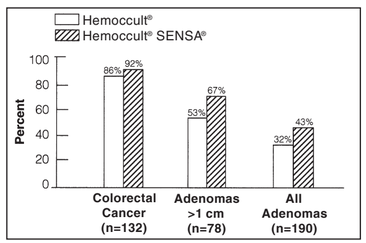
Clinical studies[20] using [51Cr] chromium–labeled blood cells suggest that a daily blood loss of 2-3 mL (approximately 0.3 mg hemoglobin/g feces) is the lower limit of blood loss that may be associated with gastrointestinal pathology. Based on *in vitro* studies in which fecal samples from asymptomatic, normal volunteers were spiked with fresh whole blood, Hemoccult® SENSA® gave positive test results about 75% of the time at 0.3 mg Hb/g feces. The positivity rates increased as the equivalent daily blood loss increased. Virtually all Hemoccult® SENSA® tests were positive at an equivalent daily blood loss equal to or greater than 10 mL.

The specificities of the Hemoccult® SENSA® 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® SENSA® 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® SENSA® test is best developed three days after sample application.**[9,10]

The clinical performance of the Hemoccult® SENSA® 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® SENSA® 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.[18,21]

FIGURE 1
SENSITIVITY COMPARISON
HEMOCCULT® AND HEMOCCULT® SENSA®



	Colorectal Cancer (n=132)	Adenomas >1 cm (n=78)	All Adenomas (n=190)
Difference	6%	14%	11%
95% Confidence Interval	1.5 to 10.6%	5.6 to 22.6%	5.3 to 16.8%
Difference	Significant	Significant	Significant

Table 1 summarizes the data comparing the specificity of the Hemoccult® SENSA® 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® SENSA® test was the same as the Hemoccult® test (99%).[18,21]

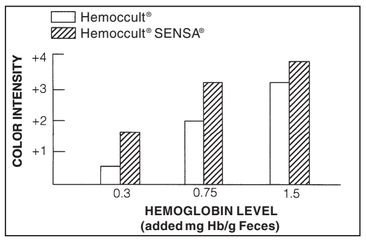
TABLE 1
COMPARISON OF SPECIFICITY
Asymptomatic Individuals
Confirmed and Presumed Normals on Restricted Diet

	Hemoccult®	Hemoccult® SENSA®
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® SENSA® 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® SENSA® 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® SENSA® as a result of the increased readability of the test.[18,21]

FIGURE 2
COMPARISON OF COLOR INTENSITIES AT 1 MINUTE



Color Intensity	Description
-	No blue color
+1	Very faint, barely detectable trace of blue
+2	Faint blue color
+3	Distinctly blue color
+4	Intense blue. Wider area of blue color coverage than a score of 3

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 annually[23-25] and 15-21% when performed biennially.[26] The program sensitivity for detecting colorectal cancer was 90% when Hemoccult® was repeated annually.[27,28]

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PRODUCT INFORMATION

All products listed are CLIA waived.

Product Name	Product No.

HemoccultII® SENSA® *elite* Products

Hemoccult II® SENSA® *elite* Dispensapak™ Plus **395035**
- 40 Patient Screening Kits
- Two 15 mL bottles of Hemoccult® SENSA® Developer

Hemoccult® SENSA® Products

Hemoccult® SENSA® Single Slides **64151**
- 100 Slides
- 100 Applicator Sticks
- Two 15 mL bottles of Hemoccult® SENSA® Developer

Hemoccult® SENSA® Single Slides **64152**
- 1000 Slides
- 1000 Applicator Sticks
- Twenty 15 mL bottles of Hemoccult® SENSA® Developer

Hemoccult II® SENSA® Dispensapak™ Plus **64130**
- 40 Patient Kits
- Two 15 mL bottles of Hemoccult® SENSA® Developer

Hemoccult® SENSA® Developer **64115**
- Twenty 15 mL bottles

Hemoccult® Products

Hemoccult® Single Slides **60151**
- 100 Slides
- 100 Applicator Sticks
- Two 15 mL bottles of Hemoccult® Developer

Hemoccult® Single Slides **60152**
- 1000 Slides
- 1000 Applicator Sticks
- Twenty 15 mL bottles of Hemoccult® Developer

Hemoccult II® Dispensapak™ **61100**
- Case of 100 Patient Kits
- Six 15 mL bottles of Hemoccult® Developer

Hemoccult II® Dispensapak™ Plus **61130**
- 40 Patient Kits
- Two 15 mL bottles of Hemoccult® Developer

Hemoccult® Developer **62115**
- Twenty 15 mL bottles

Hemoccult® Mailing Pouches **62200**
- Box of 100 pouches

Gastroccult® Products

Gastroccult® Test Kit **66040**
- Box of 40 Slides

Gastroccult® Developer **66115**
- Six 15 mL bottles

Gastroccult® Straw Applicators **66140**
- 40 Applicators

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

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

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