

I. TITLE **Occult Blood, Stool**

ASSAY	METHOD	LIS CODE	EPIC CODE
Occult Blood, Stool	Hemoccult [®] SENSA [®]	OCCULT OCCSCR	LAB3525

SYNONYMS/ABBREVIATIONS

Fecal Occult Blood, Hemoccult, Guaiac Test, FOBT

II. PRINCIPLE

The Hemoccult[®] SENSA[®] test is a simplified and standardized variation of the guaiac procedure utilizing gum guaiac, a natural resin extracted from the wood of *Guaiacum officinale*, for the detection of occult blood. The Hemoccult[®] SENSA[®] test is based on the oxidation of guaiac by hydrogen peroxide to form a blue colored compound when hemoglobin is present in a stool specimen. Oxidation of alpha guaiaconic acid (present in the guaiac paper) by hydrogen peroxide (present in the developer) is catalyzed by peroxidase (present in the heme portion of the hemoglobin) to form a highly conjugated blue quinone compound.

III. SPECIMEN REQUIREMENTS**A. Patient Preparation**

Fasting/Special Diets- Patient should:	<ul style="list-style-type: none"> ▪ Avoid red meats (beef, lamb and liver) for three days before and during the stool collection period. ▪ Avoid vitamin C in excess of 250 mg a day from supplements, citrus fruits and juices for three days before and during the stool collection period. ▪ Eat a well balanced diet including fiber such as bran cereals, fruits and vegetables. ▪ Avoid non-steroidal anti-inflammatory drugs such as Ibuprofen (Advil[®], Motrin[®], Nuprin[®], etc.), Naproxen (Aleve[®], Naprosyn[®], Anaprox[®]), Indomethacin (Indocin[®]) or aspirin (>325 mg/day) for seven days before and during the stool collection period. Acetaminophen (Tylenol[®]) can be taken as needed.
Patient Preparation	<ul style="list-style-type: none"> ▪ Since bleeding from gastrointestinal lesions may be intermittent, fecal samples for testing should be collected from three consecutive bowel movements or three bowel movements closely spaced in time. ▪ Fecal samples should not be collected if hematuria or obvious rectal bleeding, such as from hemorrhoids is present.

	<ul style="list-style-type: none"> ▪ Pre-menopausal women must be instructed to avoid collecting fecal samples during or in the first three days after a menstrual period. ▪ Patients using the Hemocult should be instructed to return the slides to the physician or laboratory immediately after preparing the test.
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B. Specimen Type

CRITERIA	
Type Preferred	<ul style="list-style-type: none"> ▪ Stool (feces) is the only acceptable sample for use with the Hemocult® SENSEA test. The test requires only a small fecal sample. The sample is applied to the to the guaiac paper of the Hemocult® SENSEA slide as a THIN SMEAR using an applicator stick. Gastric samples are not acceptable. ▪ To further increase the probability of detecting occult blood, separate samples should be taken from two different sections of each fecal sample.
Number of Cards: Optimum Minimum	Three Hemocult® SENSEA® cards. One Hemocult® SENSEA® card.
Collection Container	<ul style="list-style-type: none"> ▪ The stool sample should be collected in a clean, dry container and avoid contact with toilet bowl water. The toilet tank must be void of toilet bowl cleaners prior to proceeding with specimen collection if the sample is to be taken from the toilet bowl. ▪ Hemocult® SENSEA® card.
Stability and Storage Requirements	<ul style="list-style-type: none"> ▪ Hemocult® SENSEA slides may be prepared and developed immediately or prepared and stored up to 14 days at room temperature (15-30°) before developing. ▪ Store cards at room temperature. ▪ The cards are stable until the manufacturer’s expiration date. ▪ Return completed cards to the laboratory no later than 14 days after the first specimen collection.
Unacceptable Specimens and Actions to Take	<ul style="list-style-type: none"> ▪ Reject other specimen sources. Unmodified guaiac tests are not recommended for use with gastric specimens. There are separate “Gastrocult” cards for gastric specimens; refer to the local business unit policy for handling. ▪ Reject specimens submitted on expired cards. ▪ Reject specimens collected over 14 days before receipt.

	<ul style="list-style-type: none"> Reject specimens received on cards other than Hemocult[®] SENSE[®] cards.
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C. **Specimen Handling**

CRITERIA	SPECIAL NOTATIONS
Timing Considerations	Collect up to three stool specimens from bowel movements on three different days.
Storage	Store cards at room temperature (15-30°C) in original packaging. Do not refrigerate or freeze. Protect cards from heat, light and volatile chemicals (iodine, ammonia, bleach, household cleaners and toilet bowl cleaners.) Cards may be stored for up to 14 days at room temperature (15-30°C) before developing.
Transport	NOTE: Current U.S. Postal Regulations prohibit mailing completed test slides in standard paper envelopes. Physicians who wish their patients to return slides by mail must instruct their patients to use only U.S. Postal Service approved mailing pouches.

IV. **REAGENTS**

A. **Reagent Summary**

REAGENTS/KITS	SUPPLIER
Hemocult [®] SENSE [®] Single Slides	Beckman Coulter Product #64151 (Box includes 100 single cards, 100 applicator sticks and two 15 mL bottles of Hemocult Developer)
Hemocult [®] SENSE [®] Developer- if ordered separately.	Beckman Coulter Product # 64115 (twenty 15mL bottles)

V. **PROCEDURE NOTES**

A. **Special Precautions**

- Proper storage of cards will help prevent blue discoloration of the guaiac paper.

B. **Possible Sources of Error**

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

- **Substances which can cause false positive results:**
 - Red meat (beef, lamb and liver)
 - Aspirin (>325 mg/day) and other anti-inflammatory drugs (i.e. Ibuprofen, Indomethacin, Naproxen, etc.)
 - Corticosteroids, Phenylbutazone, Reserpine, anticoagulants, antimetabolites and cancer chemotherapeutic drugs
 - Alcohol in excess
 - Antiseptic iodine preparations (providone/iodine mixture)

- **Substances which can cause false negative results:**
 - Ascorbic acid (vitamin C) >250 mg/day
 - Excessive amounts of vitamin C from citrus fruits or juices
 - Iron supplements containing vitamin C >250 mg/day

VI. LIMITATIONS OF METHOD

- Bowel lesions, including some polyps and colorectal cancers, may not bleed or may bleed intermittently. When blood is present in the stool, it may not be distributed evenly throughout the specimen. Results cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or disease. This is a screening test developed as an aid to diagnosis. It is not intended to replace other diagnostic procedures such as sigmoidoscopy, colonoscopy, barium enema or other x-ray studies.
- Detection Limit: Clinical studies 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. Hemocult[®] SENSE[®] gives positive test results about 75% of the time at 0.3 mg Hb/gm feces.

VII. SAFETY

- Hemocult[®] SENSE[®] Developer is **flammable** and an **irritant**. **Avoid contact with skin and eyes.** Should contact occur, rinse promptly with water and consult a physician.
- Patient specimens and all materials that come in contact with the specimens must be presumed infectious and handled using universal precautions. Strict adherence to safety procedures is required at all times.
- Dispose of all specimens and related material in biohazard waste containers.
- Appropriate personal protective equipment must be used at all times. A buttoned lab coat, face shield and gloves are required.
- Refer to the product information and MSDS for handling, storage and first aid information for reagents used in this procedure.
- Warnings highlighted in this procedure will alert you to take steps to reduce your risk of injury. Report all accidents to your supervisor.

VIII. REFERENCES

1. Hemocult® SENSE package insert, Beckman Coulter, Inc., 4300 N. Harbor Blvd., Fullerton, CA 92834-3100, 462489.E October 2002.
2. Rozen, P., et. al., "Performance characteristics and comparison of two immunochemical and two guaiac fecal occult blood screening tests for colorectal neoplasia," *Digestive Diseases and Sciences*, Vol. 42, No. 10:2064-2071, October 1997.
3. Levin, B., et. al., "Screening for colorectal cancer: A comparison of 3 fecal occult blood tests," *Archives of Internal Medicine*, Vol. 157:970-976, May 1997.
4. Baker, J., et. al., "Readability and sensitivity of two guaiac-based fecal occult blood tests," *Gastroenterology*, Vol. 94, No. 5:A18, 1988.