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Area	Laboratory-Point of Care
Applicability	All Beaumont Hospitals

Hemoccult SENSA

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. To describe how to perform fecal occult blood testing with Hemoccult SENSA and to provide troubleshooting directions for non-laboratory staff.

B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. PRINCIPLE AND CLINICAL SIGNIFICANCE:

A. The Hemoccult SENSA test is a rapid, *in vitro,* qualitative method for detecting fecal occult blood that cannot be detected visually. The heme portion of hemoglobin, if present in the fecal specimen, has peroxidase activity which catalyzes the oxidation of alpha-guaiaconic acid (the active component of guaiac paper) by hydrogen peroxide (the active component of the developer) to form a highly conjugated blue quinone compound.

B. The Hemoccult SENSA test is recommended for professional use as a diagnostic aid during routine physical examinations, to monitor for gastrointestinal bleeding in patients with iron deficiency anemia or recuperating from surgery, peptic ulcer, ulcerative colitis, other conditions, and in screening programs for colorectal cancer when the patient instructions are closely followed.

III. SPECIMEN COLLECTION AND HANDLING:

Always follow established procedures for Standard Precautions/Hand Hygiene when collecting and handling specimens. Hands must be washed or disinfected with antiseptic soap or an alcohol-based hand rub as outlined in the Laboratory Infection Control policy before and after gloves are used. Gloves

must be worn when performing patient testing and changed between patients.

A. Patient Preparation
    1. Patient preparation for at least 7 days prior to and continuing through the test period is critical to the interpretation of test results. False-positives may be expected in emergency medicine settings, in which adherence to "Patient Preparation and Patient Instructions" in the Hemoccult SENSA package insert is not feasible. False negatives may also be expected when bleeding from gastrointestinal lesions is intermittent.
        a. For 7 days before and during the stool collection period, avoid non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen, or asprin.
        b. For 3 days before and during the collection period, avoid vitamin C in excess of 250 mg a day.
        c. For 3 days before and during the collection period, avoid red meats (beef, lamb, and liver).
    2. See the Limitations and Interfering Substances section below for more information.
    3. For accurate results, samples from bowel movements collected on 3 different days should be tested.

B. Laboratory Test Ordering
    1. When sending a sample to the main laboratory for testing, one of the following orders must be placed into Epic to generate a laboratory order and laboratory labels:
        a. Occult Blood Screening, Stool
        b. Occult Blood Diagnostic, Stool

C. Patient Identification
    1. Patients must be identified at the bedside with at least two independent identifiers. Name and identification (ID) number from the wristband must be the primary identifiers.

D. Specimen Labeling
    1. Point of Care: Testing should be performed at the patient's bedside, when possible. If the specimen is taken to another location for patient testing, the specimen and/or test card must be labeled with the patient name and identification (ID) number (Joint Commission). Use a hand-written or computer-generated patient information label.
    2. Laboratory: Stool specimen cups and test slides sent to the main laboratory for testing must be labeled with a laboratory label.

E. Specimen Types
    1. Stool without preservatives

F. Specimen Collection, Handling, and Disposal
    1. Verify the specimen collection supplies and Hemoccult SENSA testing supplies are not expired.

2. The stool specimen is collected in a clean container.
3. From the container, use an applicator stick from the kit to obtain a small amount of fecal material and apply a **thin** smear to box A of a Hemoccult SENSA slide. Cover the entire area of the box. Using the same applicator stick, obtain a second sample from a different area of the fecal specimen and apply a thin smear to box B on the same Hemoccult SENSA slide. Close the flap and dispose of the applicator.
    a. Note: Stool may also be collected on a gloved finger during a rectal exam and smeared in the same manner to boxes A and B of the Hemoccult SENSA test slide.
4. Slides containing samples may be stored up to 14 days at room temperature (15-30°C) before developing the test.
5. Specimens and used slides must be disposed of in an approved biohazard container.

G. Specimen Acceptability Criteria
    1. Labeled specimens collected in a clean container without preservatives.
    2. Labeled slides stored at room temperature that are developed within 14 days of collection.

H. Specimen Rejection Criteria
    1. Do not test samples if blood is visible in the stool or urine (e.g. menstruation, active hemorrhoids, or urinary tract infection).
    2. Results from specimens contaminated with the interfering substances listed in the Limitations and Interfering Substances below should be interpreted with caution.
    3. Unlabeled slides/specimen cups should not be tested.

IV. REAGENTS:

A. Hemoccult SENSA Test Slides (Cards) Containing Guiac Paper
    1. Dispensapak: 40 patient screening kits (3 slides each). Two 15 mL bottles of developer.
    2. Single Slides: 100 slides, 100 applicator sticks, Two 15 mL bottles of developer.
        a. Ingredients:
            i. Guiac paper
        b. Storage and Handling:
            i. Store at room temperature (15-30°C, 59-86°F) in original packaging.
            ii. Protect from heat and light.
            iii. Keep the cover flap of slide sealed until ready to use.
        c. Expiration:
            i. When stored as recommended, the Hemoccult SENSA slides will

remain stable until the expiration date appearing on each slide. Do not use after the expiration date.

d. Warnings/Precautions:

i. For *in vitro* diagnostic use.

ii. Do not store with volatile chemicals (e.g., iodine, bleach, bromine, ammonia, or household cleaners).

iii. Hemoccult SENSA slides present no hazard to the user.

iv. Patient specimens and all test materials should be handled as potentially infectious and disposed of using biohazard precautions.

B. Hemoccult SENSA Developer (Bottle)

1. Two 15 mL bottles of developer per kit. Available for purchase separately.

a. Ingredients:

i. Contains a stabilized mixture of < 4.2% hydrogen peroxide and 80% denatured ethyl alcohol and enhancer in aqueous solution.

b. Storage and Handling:

i. Store products at room temperature (15-30°C, 59-86°F) in original packaging. Do not refrigerate or freeze.

ii. The developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation.

c. Expiration:

i. The Hemoccult SENSA Developer will remain stable until the expiration date, which appears on each developer bottle when stored as recommended. Do not use after expiration date.

d. Warnings/Precautions:

i. For *in vitro* diagnostic use.

ii. The Hemoccult SENSA developer is an irritant, is flammable and is subject to evaporation. Avoid contact with the eyes and skin. Should contact occur, rinse promptly with water and consult a physician.

iii. Any lot number of Hemoccult SENSA developer can be used with any lot number of Hemoccult SENSA slides, as long as both are within expiration date and are “colored matched.” (i.e., blue/green-striped slides with blue capped developer with blue/green striped label.) **Do NOT interchange Hemoccult SENSA (blue/green striped) with Hemoccult test (yellow/green striped) or components from any other manufacturer.**

V. SUPPLIES:

A. Wooden Applicator Sticks
B. Timer
C. Specimen Collection Container (Optional)
D. Biological Safety Cabinet (Optional)
E. Gloves
F. Gauze or Tissue (Optional)

VI. QUALITY CONTROL (QC):

A. Quality Control Procedure
    1. Internal procedural controls (positive and negative), referred to as the performance monitor, are built-in to each Hemoccult SENSA slide and must be performed and documented with every test. Make a note in the electronic medical record along with patient result stating “QC OK”.
    2. Verify that the patient test has been developed before proceeding.
    3. Apply **one drop** of Hemoccult developer between the positive and negative circles in the performance monitor area. This area is found on the developing side of the slide inside the orange rectangle.
    4. Interpret the monitors within 10 seconds.
    5. The **positive monitor** contains a hemoglobin derived catalyst, which upon application of the developer will turn blue within 10 seconds, and the color will remain stable for at least 60 seconds.
    6. The **negative monitor** contains no catalyst and should not turn blue upon application of the developer.
    7. The test is valid and can be reported only if the positive side of the monitor shows a blue color, and the negative side shows no blue color. If the performance monitor area results are not as expected after applying the developer, the test is considered invalid.

B. Quality Control Failure Procedure
    1. Verify expiration dates on test slides and developer bottles. Do not use if product is past expiration date.
    2. Verify proper storage conditions:
        a. Developer bottle is tightly capped to avoid evaporation.
        b. Test slide cover flap remains tightly sealed until ready for use.
        c. Maintain room temperature conditions, protection from heat and light.
    3. Verify appropriate Hemoccult SENSA Developer (blue/green) is used with Hemoccult SENSA test slides.

4. Verify all aspects of the test procedure are followed correctly (sample collection, application of sample to the slide, waiting period, developing patient test, and developing QC).
5. Repeat testing with a new card and using a bottle of developer.
6. If performance monitor still fails, repeat the test with a slide and developer from a new kit.
7. Additional QC Notes:
    a. Do **not** apply developer to the performance monitor area **before** interpreting patient test result.
    b. Occasionally a light blue discoloration may be noticed on the test paper. This discoloration does not affect the accuracy of the performance of the test when the proper procedure is followed. When the 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 wet area, leaving the filter paper around the fecal smear off-white in color. Any blue on or at the edge of the smear is positive for occult blood.
8. If the instructions above do not resolve the issue, take the slides and developer out of use. Contact the appropriate main laboratory supervisory staff or the site-specific POC department below. For POC testing, a specimen may also be sent to the main laboratory for testing.
    a. Farmington Hills: Call the POC at 947-521-7167.
    b. Grosse Pointe: Call Point of Care at 313-473-1831.
    c. Lenox: Call Point of Care at 313-473-1831.
    d. Livonia: Call the POC at 947-521-7167.
    e. Royal Oak: Call Ancillary Testing at 248-898-8012.
    f. Troy: Call Decentralized Testing at 248-964-8009.

VII. PROCEDURE:

A. Wait at least 3-5 minutes after specimen application before developing the slide.
B. Open the back flap of the slide to expose the fecal smears.
C. Apply **two drops** of Hemoccult SENSA Developer directly over each fecal smear.
D. Read and interpret the results within 60 seconds. Results must be interpreted by individuals who have passed a colorblindness test or functional assessment.
E. After the patient test has been interpreted, perform the QC (performance monitor) as outlined in the Quality Control section above.

VIII. INTERPRETATION OF RESULTS:

A. Interpretation of Hemoccult SENSA tests may only be performed by those that have passed a colorblindness test or functional assessment.

B. Any blue color on or at the edge of the smear is considered positive for occult blood. A blue or blue-green color should be interpreted as positive.

C. Some specimens have a high bile content which causes the feces to appear green. A distinct green color (no blue) should be interpreted as negative.

D. Any blue originating from the positive performance monitor area should be ignored when reading the sample test result.

IX. EXPECTED VALUES:

A. Negative

B. In a general screening population of asymptomatic individuals, a positivity rate of approximately 3-7% was obtained depending on how well they followed the preparation instructions.

X. UNEXPECTED RESULTS:

A. If the performance monitor does not react as expected, the test result must be regarded as invalid and repeat testing is indicated.

B. As with all diagnostic tests, results should be scrutinized in light of a patient's specific condition. Any results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional testing and diagnostic procedures such as sigmoidoscopy, colonoscopy, barium enema, or other X-ray studies.

XI. REPORTABLE RANGE:

Positive or Negative

XII. REPORTING RESULTS:

A. Point of Care Resulting

1. All Hemoccult test results should be documented in the patient's electronic medical record along with a note indicating that the QC was acceptable. Clinicians may use the "Hemoccult SmartPhrase" created in the hospital information system in order to verify that all required entries are accounted for when resulting Hemoccult tests in electronic medical record progress notes.
    a. Navigate to "Epic Notes". Search for the Smart Phrase by typing ".hemo", ".hemoccult", ".sensa", or ".stool".
    b. Name, current date and time, and acceptable QC result will automatically populate. Change as needed.
    c. Toggle to "Hemoccult SENSA Result" to select the result (positive or negative) from the drop-down list.
    d. "Sign" the note to enter it in the patient's chart.

B. Laboratory Resulting

1. Print the approprate Outstanding List from Epic.
2. Attach a label for each patient on the Laboratory Hemoccult SENSA Result Log.
3. Perform testing and document the test reult and performance monitor results.
4. Enter the patient results and performance monitor results into the Outstanding List.
5. Verify the results.
6. Perform a clerical check and document on the Laboratory Hemoccult SENSA Result Log.

XIII. SYSTEM DOWNTIME:

A. If the hospital information system is down, follow department's downtime procedure and verify that all notes are documented on paper chart for later result entering/scanning when the system becomes available. Verify that date/time of test, result and QC outcome are documented.

XIV. LIMITATIONS AND INTERFERING SUBSTANCES:

A. False positive results may be caused by the following:
    1. Eating red meat (beef, lamb, liver) during the three days prior to specimen collection.
    2. Eating raw fruits and vegetables high in peroxidase (horseradish, turnips, melons, radishes) when fecal samples are tested immediately after collection.
    3. Substances that can irritate the gastrointestinal tract and cause bleeding (aspirin > 325 mg/day, ibuprofen, indomethacin, naproxen etc.).
    4. Corticosteroids, phenylbutazone, reserpine, anticoagulants, antimetabolites and cancer chemotherapeutic drugs.
    5. Alcohol in excess.
    6. The application of antiseptic preparations containing iodine (povidone/iodine mixture).
    7. Low but detectable levels of blood loss, common to both healthy adults and patients with gastrointestinal disease.
    8. Developing the positive performance monitor prior to the patient test.

B. False negative results may be caused by the following:
    1. Ascorbic acid (Vitamin C) intake of more than 250 mg/day.
    2. Excessive amounts of Vitamin C enriched foods, citrus fruits and juices.
    3. Iron supplements that contain quantities of Vitamin C in excess of 250 mg/day.

C. 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.

D. Dietary iron supplements will **not** produce false-positive results with Hemoccult SENSA.

E. The Hemoccult SENSA test may **not** be used for gastric specimens.

XV. TROUBLESHOOTING:

A. Testing personnel will initiate basic corrective actions when results are questionable or if the performance monitor (positive and negative internal controls) does not react as expected after applying the developer. Patient results are invalid if quality control fails and must not be reported. If problem remains unsolved, refer to this troubleshooting guide for additional corrective actions, contact the site-specific Point of Care department, and send a specimen to the laboratory for analysis, if needed.

B. See the QC Failure Procedure and Limitations and Interfering Substances sections for more information.

C. Any result exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional testing, at the clinician's discretion.

XVI. REFERENCES:

A. Point of Care Testing Approval Process

B. The Joint Commission. (2022) Standard NPSG.01.01.01 EP 1 in The Joint Commission. Comprehensive accreditation manual. Hospital edition. Oak Brook, IL: The Joint Commission.

C. Hemoccult SENSA package insert, Beckman Coulter, Inc. 250 S. Kraemer Blfd., Brea, CA, 92821. Rev. 462489.EF, June 2015. www.beckmancoulter.com/rapides

Attachments

Hemoccult SENSA Laboratory QC Documentation.pdf

Hemoccult SENSA Result Log.pdf

Hemoccult SENSA Training and Competency Assessment.pdf

Hemoccult SENSA Training Guide.pdf

Laboratory Hemoccult SENSA Result Log.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	8/8/2024

CLIA Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	7/31/2024
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	7/29/2024
CLIA Medical Directors	Ryan Johnson: OUWB Clinical Faculty	7/24/2024
CLIA Medical Directors	John Pui: Chief, Pathology	7/24/2024
CLIA Medical Directors	Masood Siddiqui: Staff Pathologist	7/24/2024
Policy and Forms Steering Committee Approval (if needed)	Jessica Czinder: Point of Care Coordinator	7/24/2024
CP System Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	7/23/2024
	Caitlin Schein: Staff Physician	7/18/2024
Technical Director	Nga Yeung Tang: Tech Dir, Clin Chemistry, Path	7/2/2024
POC Best Practices	Jessica Czinder: Point of Care Coordinator	6/17/2024
	Jessica Czinder: Point of Care Coordinator	6/17/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne