



HealthPartners/GHI

Subject HEMOCCULT (SENSA) Procedure (Stool Occult Blood for GI Bleeding Only)		Attachments <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Key words Occult blood, fecal blood test, guaiac test		Number GHI-PC-CLINIC LAB-Procedures- Hemoccult v. 01- 2013
Category Provision of Care		Effective Date January 2013
Manual Clinic Laboratory Procedure Manual		Last Review Date November 2014
Issued By Clinic Laboratory – Laboratory Technical Consultants		Next Review Date November 2015
Applicable Clinic Laboratory Staff		Origination Date June 1994
		Retired Date
Level of Complexity Waived		Contact Laboratory Technical Consultants
Review Responsibility Laboratory Technical Consultants		Approved Date June 1994
<u>APPROVAL(S)</u> Laboratory Medical Director		

Clinic Lab Procedure (Pages 1-4)
Computer Order & Result Entry (Page 5-6)

I. Purpose/ Principle

This procedure provides instruction for performing the Hemoccult SENSAs test for detecting fecal occult blood from gastrointestinal (GI) bleeding. The Hemoccult SENSAs test should not be used for colorectal cancer screening. The fecal immunochemical test (FIT) should be the only test used for colorectal cancer screening.

When blood is present in the stool in large amounts, the appearance is tarry. Trace amounts (occult or hidden blood) can only be detected by special tests.

The Hemoccult SENSAs test is a rapid qualitative method for detecting fecal occult blood, which may be indicative of GI disease. Results obtained with Hemoccult SENSAs cannot be considered conclusive evidence for the presence or absence of any pathology. The test is intended to be an aid to diagnosis and not a replacement for other diagnostic procedures.

Red blood cells have peroxidase enzymes. When hemolyzed by water and salts present in the stool, the peroxidase reacts with hydrogen peroxide, releasing oxygen. The oxygen oxidizes alpha-guaiaconic acid on the test card to a blue compound. The Hemoccult SENSAs slide test from Beckman

Coulter, Inc. is a modified guaiac test. The slides contain guaiac impregnated paper and the developer is a stabilized hydrogen peroxide solution.

II. Procedure

A Hemoccult SENSE test is ordered by a provider to look for occult blood in the stool from a potential GI bleed. The specimens are collected either in the clinic by a provider during physical examination or at home by the patient.

Specimen Information

Stool: Stool collected by a provider during a digital rectal exam.

1. The provider will apply a thin layer of stool to each of the front windows of the Hemoccult SENSE card.
2. The windows will be closed and the Hemoccult SENSE card labeled with the patient Epic label.
3. The Hemoccult SENSE card will be transferred to the clinic laboratory, processed and the result reported immediately to the provider or their care team.

Stool: Stool collected by patient

Patient Preparation and Instructions are printed on the Hemoccult SENSE multi-pack envelope.

- For accurate test results, apply samples from bowel movements collected on **three different days** to slide.
- Do not collect a sample if blood is visible in your stool or urine (e.g. menstruation, active hemorrhoids, urinary tract infection).
- 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 clinic laboratory no later than 14 days after your first sample collection or send specimens in the vinyl envelope provided to HealthPartners Central Lab, 9700 W. 76th Street, Eden Prairie, MN 55344-3760.
- Protect slides from heat, light and volatile chemicals (e.g. ammonia, bleach, bromine, iodine, household cleaner).

Drug Guidelines

- For **seven** days before and during the stool collection period **avoid** non-steroidal anti-inflammatory drugs such as ibuprofen, 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.

Reagents/Equipment/Supplies

1. Hemoccult SENSE Single Slides: Do **not** use slides if pale beige paper is discolored.
 - Slides may be prepared and developed within 3 – 5 minutes of collection or prepared and stored up to 14 days at room temperature (15-30° C or 59-86° F) before developing.
2. SENSE Developer: (Blue & Green packaging). Developer is an irritant. Avoid contact with skin and eyes.

- NOTE: Any lot number of developer may be used with any lot number of slides as long as both are within expiration date and both products packaging is green and blue (SENSA).
3. Hemoccult II SENSAs slides dispensed in multi-packs of 3 and are designed so patients can collect serial specimens at home from bowel movements over three days. Multipacks contain –
 - Patient envelope with instructions for diet and sample collection,
 - Collection supplies, (tissue toilet bowl drape and applicator sticks),
 - US Postal Service-approved Hemoccult mailing pouch for specimen return.
 4. Store product at room temperature 15-30° C (59-86° F) in original packaging. Protect slides from heat and light. Do **not** store near volatile chemicals (e.g. iodine, chlorine, bromine or ammonia). Be careful that bleach or the disinfectant towels containing bleach do not come in contact with slides and cause a false result.
 5. Do **not** refrigerate or freeze.
 6. Protect SENSAs Developer from heat and keep bottle tightly capped when not in use. It is flammable and subject to evaporation. Avoid contact with eyes and skin as it is an irritant. If developer comes in contact with eyes or skin, rinse promptly with water. Do **not** leave uncapped or exposed to heat.

Procedure

A. Instruct patient to:

1. Read and follow directions on the Hemoccult packet carefully,
2. Follow drug and diet guidelines advised on package,
3. Write their name and the appropriate collection date on the front of each slide, and do not tear the sections apart. This will keep slides in the proper order of collection.

B. Instruct patient to return the sample cards within 14 days of completion for proper results, to either a HealthPartners Clinic laboratory or mailed directly to HealthPartners Central Lab, 9700 W. 76th Street, Eden Prairie, MN 55344-3760.

C. Instructions for slide development:

1. Check expiration date on card. Open windows on back of slide.
2. If specimen was recently applied, wait 3-5 minutes before developing.
 - **It is important that the patient specimen area be tested BEFORE the QC test area as the Positive control might “bleed” into the patient specimen area.**
3. Apply **2 drops** of developer to each patient test specimen window on the back side of the slide.
4. Read results within 60 seconds. Report as positive (any trace of blue color development on or at the edge of the stool smear) or negative (no blue color development). Note on report how many samples were tested; Example, negative x 3.
5. After patient testing is completed, proceed to testing the QC areas.

D. Quality Controls:

- A positive and negative control (performance monitor) appears on each card under the sample windows on the developing side of the slides. The performance control test allows the user to verify the reactivity of the paper and developer used in each Hemoccult SENSAs slide test.
1. **After developing and interpreting the patient test, apply ONE drop of Developer in the middle of the control area and read within 10 seconds.**

IMPORTANT NOTE:

The performance monitors should be done after the patient test, so that any blue from the positive control area is not read as positive if near the patient window.

2. If the slide and developer are functional, a blue color will appear on the positive side and no blue will appear on the negative side.
 3. If either control does not give the expected results, the patient result cannot be reported and the samples should be recollected.
 4. Record on the log sheet a check mark if the control results were OK, and the lot numbers of the Hemocult SENSE slide and developer used for each patient test.
- Any blue color developed in the Performance Control Area acts as verification of correct product performance. (The shade or intensity of the blue color developed with the performance control is not indicative of the blue color that may develop from the patient sample.) In the event that the Performance Control Areas do not react as expected after applying developer, the test results should be regarded as invalid and unreportable.

Expected Values/Reference Ranges

Negative

All positive results are flagged and reported via the electronic medical record.

Recording and Reporting Results

Patient results are recorded on the Hemocult monthly worksheet and entered into SmartTerm. See "Computer Order and Result Entry" below.

- Fecal Occult Blood Tests collected in the clinic during a patient exam should be brought to the laboratory and performed **WAITING** (minimum of 3-5 minutes after stool application). The Provider and patient are waiting for this result. Enter results immediately into SmartTerm.
- Hemocult SENSE II slides (3-slide pack) returned to the clinic should be developed and reported as routine in the clinic laboratory. Specimens must be resulted in the location at which they were received.

Notes

1. False positive may be caused by red meat in the diet, aspirin or peroxide-containing vegetables (present in raw vegetables, not cooked vegetables).
2. False negatives may be caused by ingestion of ascorbic acid in excess of 250 mg/day.
3. Slides may be prepared and stored for up to 14 days. Hemoglobin is stable in a dried state for 14 days.
4. Hemocult SENSE should not be used for other specimen types (such as gastric specimens) because the RBC's may not be lysed for accurate analysis.

IMPORTANT NOTE:

In the rare occasion a patient has applied the stool sample to the incorrect side of the Hemocult SENSE slide the test should be cancelled and the provider and care team notified for recollection.

References

1. Beckman Coulter, Inc. Diagnostics Hemocult SENSE package insert, November 2009.
HEMOCCULT (SENSE) Procedure (Stool Occult Blood for Upper GI Bleeding Only) v. 01-2013

**Computer Order and Result Entry
Worksheet HEMOC
(HEMOCCULTS TO CL)**

ORDERING:

Test codes:

- OCBQ1 (Occult Blood, Exam 1) EPIC 4532
- OCBQ2 (Occult Blood, Exam 2) EPIC 4533
- OCBQ3 (Occult Blood, Exam 3) EPIC 4534

NOTE:

HealthPartners Providers should order Epic 4532 (OCBQ1) for a single Hemocult SENSE Test (formerly Epic 0066) and Epic 4534 (OCBQ3) for dispensapaks sent home with the patient.

When entering the collection date, use the most recent date written on the Hemocult cards. If no dates are given, use today's date. Enter collection time if given or use (Unknown).

NOTE: Patient instructions, as stated by the manufacturer, say that the completed cards should be returned to the laboratory no later than 14 days after the first collection. If no dates are given on the cards, assume the card was returned within the 14 day limit.

RESULTING:

WORKSHEET:

Function MEM Worksheet CM__ - your clinic location (CLINIC MICRO)
Riverway and North Suburban locations: Worksheet HEM__ - your clinic location
(HEMOCCULTS – Your clinic location)

RESPONSE:

NOTE: If results are invalid (control line not visible), re-test per procedure instructions.

SQ Order: OCBQ1 or OCBQ2 or OCBQ3	(A battery which includes the OCB1 or OCB2 or OCB3 test for the result and QA tests to document your kit quality tests.)	
Code	Name	Response
OCCON or OCCN2 or OCCN3	OCB Pos Control	Y or N Y (=YES, blue color appeared in the positive control area) N (=NO, no blue color appeared in the positive control area)
OCBAC or OCBC2 or OCBC3	OCB Neg Control	Y or N Y (=YES, no blue color appears in the negative control area N (=No, a blue color did appear in the negative control area)
OCKIT or OCKT2 or OCKT3	OCB Kit Lot Number	Enter the lot number (12345) from the kit box. If there is a letter in the kit lot number, put a ; in front of the lot number (;A1234)
OCRG1 or OCRG2 or OCRG3	OCB Reagent Lot Number	Enter the lot number (12345) of the reagent.

		If there is a letter in the kit lot number, put a ; in front of the lot number (;A1234)
OCB1 or OCB2 or OCB3	Occult Blood, Exam 1 or Occult Blood, Exam 2 or Occult Blood, Exam 3	POS or NEG

COMPUTER CREDITING INFORMATION:

- If the Hemoccult cards are expired or have become discolored due to improper handling, do the following:
 - Fill out a credit form and fax to Central lab: Note either of the following reasons;
 - BLUE-HCARD (Unable to Perform Due to Discoloration of Card)
 - EXPIR-HCARD (Unable to Perform Hemoccult Due to Expiration of Card)

Author/Reviewer(s)
 ANicholas/AKHoward
 GCardnial
 SLHuber
 KEKaestner
 KNOlson

Approved by
 Laboratory Medical Director