POCT Program
Massachusetts General Hospital - Pathology Service
55 Fruit Street, Boston, MA 02114

Title: Hemoccult Sensa Fecal Occult Blood Procedure

Cross References: Hemoccult Sensa Fecal Occult Blood Training and Competency Record
Hemoccult Sensa Outpatient Patient Result-QC log
Hemoccult Sensa Patient Care Services QC Log
Hemoccult Sensa Slides and Developer Lot Documentation
MGH POCT QC Storage Ordering and Documentation Guide
Hemoccult Sensa Job Aid

Contents

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Purpose

This document outlines policies and procedures that deal with fecal occult blood testing. In an effort to be concise, some information may be excluded from the manufacturer's recommended procedure. It is recommended that operators familiarize themselves with the manufacturer's product information that accompanies each package and their manual if one exists.

Scope

Level of Personnel: All RNs, NPs, PCAs, MAs, who have successfully completed initial training and maintained annual competency.

Testing Site: All sites approved and on file with the Department of Pathology's POCT Division.

Policy and Procedure Statement

Hemoccult Sensa ® Test Kits are used as a routine colo-screening test for the qualitative detection of fecal occult blood, which may be an indication of gastrointestinal disease. It is NOT a test for colorectal cancer or other specific diseases.

The manufacturer recommends this test for professional use as a diagnostic aid during routine physical exams for hospital patients, to monitor bleeding in patients with iron deficiency anemia or recuperating from surgery, peptic ulcer, ulcerative colitis and other conditions, and screening programs for colorectal cancer when Patient Instructions are followed (See Manufacturers Product Instructions).

Additional information can be found on the manufacturer's insert provided with each box of slides.

Regulatory Requirements

I. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

II. All test results must be maintained in patient records with all required information for four years

Required information:

1. Patient's name
2. Medical Record Number
3. Patient's gender
4. Patient's age or date of birth
5. Date & time test collected, performed and reported
6. Ordering Physician
7. Responsible physician (if not 6)
8. Reference or Target Range
9. Test Performed
10. Test units
11. Lab name

III. Additional information that must be retained for four years:

1. Testing personnel records
2. Quality control results
3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
4. QC charts, maintenance sheets, reference and critical ranges

IV. Other

1. Universal precautions must be observed when handling any patient specimen.
2. A physician's order or standing order is required prior to performing test.

3. The Hospital Hand Hygiene policy must be adhered to at all times.

Critical Elements

1. The On Slide Performance Monitor is performed on each slide after patient testing.
2. Do not use Hemoccult Sensa® testing for gastric testing.
3. Only approved lots obtained through Materials Management/O&M may be used with this procedure.

Limitations/Interferences

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

1. Substances that can cause false-positive test results:

- 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)
- A high bile content may cause 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 the developer, should be interpreted as negative for occult blood.

Dietary iron supplements will not produce false-positive test results with Hemoccult SENSA tests.

Acetaminophen is not expected to affect test results.

2. Substances that can cause false-negative test results:

- Ascorbic acid (vitamin C) in excess of 250 mg per day
- Excessive amounts of vitamin C-enriched foods such as citrus fruits and juices
- Iron supplements which contain quantities of vitamin C in excess of 250 mg per day

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 and 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 Hemoccult blood.

Test Kit/Supplies/Equipment

Products	Vendor	Manufacturer #	People Soft#	Storage	Comments
Instant-Recall Memory Timer	Fisher Scientific		Fisher #: 02-401-7		
Hemoccult Sensa ® Slide	O&M# 5891-64151PHC	64151PHC	20363	RT (15-30°C,59-86°F)	Packaged as single cards – no developer
Hemoccult Sensa ® Developer	O&M# 5891-64115PHC	64115PHC	20374	RT (15-30°C,59-86°F)	Individual bottles of developer
Hemoccult Sensa Dispensapak Plus	O&M# 5891-64130PHC	64130PHC	028114	RT (15-30°C,59-86°F)	Packaged as triple card sets for patient home use; has two bottles of developer

Materials supplied in the Hemoccult Sensa DIspensapak Plus:

1. Hemoccult SENSA Slides (blue striped)
2. Hemoccult SENSA Developer (blue cap and striped label)
3. Applicator sticks
4. Patient envelopes with patient sample collection instructions (Hemoccult SENSA Dispensapak Plus)
5. Mailing pouch for returning slides (Hemoccult SENSA Dispensapak Plus)
6. Collection tissues (Hemoccult SENSA Dispensapak Plus)
7. Hemoccult SENSA product instructions

Storage and Stability

- Do not refrigerate or freeze.
- Slides should be protected from extreme heat and light or volatile chemicals (e.g., iodine, chlorine, bromine, or ammonia.
- The Hemoccult Sensa Slides and Developer will remain stable until the expiration dates which appear on each slide and developer bottle when stored as recommended appear on each slide and developer bottle when stored as recommended.

Specimen Collection

Label fecal occult blood card with two patient identifiers per hospital policy. Collect a small fecal sample on the end of applicator stick.

Test Procedure

Check the expiration date of the developer before using.

1. **Identification (two identifiers required)**: Before opening the slide label with patient's name and/or date of birth and patient medical record number
2. **Follow hand hygiene protocol and put on gloves.**
3. **Preparing the Test:**

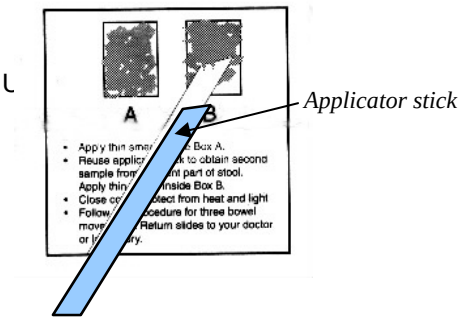
Using applicator provided, collect small fecal sample.

Apply a THIN smear inside Box A with the applicator stick

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.



4. **Developing the Test:**
5. Wait 3-4 minutes before applying the developer
6. Open flap on backside of slide and apply 2 drops of Hemoccult Sensa® Developer to the guaiac paper directly over each smear.

Read **patient** results within 60 seconds!

Interpretation of the Hemoccult Sensa Test

1. Negative Smears (fig. 1)

No detectable blue on or at the edge of the smears indicates the test is negative for occult blood.

Negative (fig.1)

2. Positive Smears (fig. 2)

Any trace of blue on or at the edge of one or more of the smears indicates the test is positive for occult blood.

Positive (fig.2)

Do not report any results unless the "On Slide Performance Monitor" produces an acceptable result. Document the Performance Monitor results on the Patient/Quality Control log sheet.

Performance Monitor Feature (Quality Control Monitoring)

The function and stability of the slides and developer must be tested using the **"On Slide Performance Monitor"** (fig. 4). It is performed on EVERY SLIDE as part of the test procedure. The positive (+) and negative (-) Performance Monitor areas are located under the sample area on the developing side of the slides.

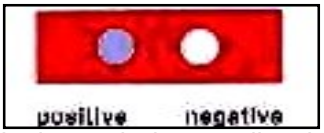
Procedure to develop performance monitor:

1. Apply ONE DROP ONLY of Hemoccult Sensa® Developer BETWEEN the (+) and (-) Performance Monitor areas.
2. Read the **Performance Monitor results within 10 seconds**: a BLUE color will appear in the (+) area, and NO BLUE will appear in the (-) area if the kit is functional.
3. **If neither occurs, discard the slide and repeat the test using another slide**. If the problem reoccurs, try the following:
    - Repeat the test using a new developer
    - Repeat the test using a card and developer from a new box (verifying first that it is an approved lot).
    - Notify the POCT Coordinators at 6-1462 or 3-5392.

Positive: A blue color will appear within 10 seconds after application of developer and remain stable for at least 60 seconds if the test system is functional. The positive Performance Monitor area contains a hemoglobin-derived catalyst, which will turn blue within 10 seconds after applying developer.

Negative: No blue color should appear after application of developer if the test system is functional. The negative performance Monitor area contains no such catalyst and should not turn blue after applying developer.

On Slide Performance Monitor (fig. 4).



Any blue originating from the Performance Monitor areas should be ignored when reading the specimen test results.
Neither the intensity nor the shade of the blue from the positive Performance Monitor areas, as illustrated, should be used as a reference for the appearance of positive test results.

The Performance Monitor feature provides assurance that the fecal occult blood paper and developer are functional. In the unlikely event that the Performance Monitor areas do not react as expected after applying developer, the results should be regarded as invalid. Should this occur, contact the POCT Coordinators at 3-5392 or 6-1462.

Only those patient results that have demonstrated acceptable On Slide Performance are to be accepted and acted upon. The Performance monitor results must be documented concurrently on the patient's chart or the QC log sheet.

Hemoccult Sensa Slides and Developer Lot Documentation

A single lot of slides and developer is sequestered at Owens and Minor for use at MGH. When a new lot is received, the POCT Coordinators are notified. The procedural controls on the Hemoccult cards are documented with each test and are considered the same as external controls. External validation of the cards is not required.

Reference Range

Patient test: Negative

Documentation

The patient's results and the Performance monitor results must be recorded concurrently in one of the following manners:

1. in the patient's record, or
2. on Fecal Occult Blood Patient/ QC log or
3. on another approved permanent record.

All records must be retained and retrievable for 4 years.

Training/Competency Assessment

Competency is assessed after initial training and annually using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user's quality control performance is monitored.
4. Written testing specific to the method.

References

Hemoccult Sensa ® Slide package insert. Beckman Coulter Inc. 4300 N. Harbor Blvd. Fullerton, CA 92834-3100

www.beckmancoulter.com/pcd

Cross - References

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