TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	10/9/2016
Department:	Core	**Due Date:**	10/25/2016
		Implementation:	**10/25/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Occult Blood SGAH.U04 v1

Note: this has been converted to a system SOP

Description of change(s):

Minor formatting changes, no impact on test performance

Section	Reason
Header	Add WAH
4,6	Remove individual section labeling instructions and add general one
10.5	Review data moved from section 6
15	Update to new standard wording
16	Form moved from section 19
17	Update PI revision date

This revised SOP will be implemented on October 25, 2016

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Occult Blood**	
Prepared by	Leslie Barrett and Daniel Adjei	Date: 7/28/2010
Owner	Robert SanLuis	Date: 10/3/2016

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Occult Blood	Oxidation of guaiac	OCBL

Synonyms/Abbreviations
Guaiac Test

Department
Core Lab

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2. ANALYTICAL PRINCIPLE

The Hemoccult® SENSA® test is a simplified and standardized variation of the guaiac procedure 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.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	• For seven days before and during the stool collection avoid non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen, or more than one adult aspirin a day. • For three days before and during the stool collection period avoid vitamin C in excess of 250 mg a day and red meat. Eat a well balance diet including fiber such as bran cereals fruits and vegetables.
Specimen Collection and/or Timing	• A small fecal specimen, three serial fecal specimens are recommended when screening asymptomatic patients. • Avoid contact with toilet bowl water. • Do not collect specimens during a menstrual period, or while experiencing bleeding hemorrhoids or blood in the urine.
Special Collection Procedures	The stool specimen should be collected in a clean dry container, and then apply to the test card.
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Stool An inoculated Hemocult Slide
Collection Container	Any clean dry container
Volume - Optimum **- Minimum**	Small stool specimen n/a

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Criteria	
Transport Container and Temperature	Any clean dry container or hemocult card at room temperature
Stability & Storage Requirements	Slides containing samples may be stored up to 14 days at room temperature before developing
	Refrigerated: Not acceptable
	Frozen: Not acceptable
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Stool with visible blood. (This is usually due to menstruation or active hemorrhoids) Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	None
Other Considerations	None

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Hemoccult SENSA® Slide	Beckman Coulter, cat. # 64151
Hemoccult SENSA® Developer	Beckman Coulter, cat. # 64115

4.2 Reagent Preparations and Storage

Assay Kit	
Reagent a	Hemoccult SENSA® Slide
Reagent b	Hemoccult SENSA® Developer
Container	N/A
Storage	Store at room temperature (15-30°C). Protect from heat and light.
Stability	Stable until the date printed on the vial
Preparation	None

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Note: Do not interchange Hemoccult® SENSA® with Hemoccult test reagents (yellow/green striped bottle) or with reagents from another manufacturer.

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

6.1.1 Internal Control

Controls	Supplier and Catalog Number
Internal Positive Control	Included in each Hemoccult® SENSA® card (see 4.1)
Internal Negative Control	Included in each Hemoccult® SENSA® card (see 4.1)

6.1.2 External Control

Controls	Supplier and Catalog Number
External Positive Control - Fecal Occult Blood Camco Positive Control Solution	Cambridge Diagnostics Products Cat. # 700-C-1
External Negative Control - Deionized water	Not specified

6.2 Control Preparations and Storage

Control	**Internal Procedural Controls**
Contents	Positive performance monitor area on Hemoccult® SENSA® card: a hemoglobin derived catalyst impregnated into the test card. Negative performance monitor area on Hemoccult® SENSA® card: no catalyst.
Preparation	None
Storage	Store at 15-30° C
Stability	Stable until manufacturer's expiration date

Control	**External Positive Control -** Fecal Occult Blood Camco Positive Control Solution
Contents	7.5mL of 5 mg/dL bovine hemoglobin in an aqueous buffered solution containing a preservative
Preparation	None

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Storage	Store at room temperature, in a cool, dry and dark place. Keep capped when not in use. Do not expose to heat, direct sunlight or other strong light.
Stability	Stable until manufacturer's expiration date

Control	**External Negative Control** - Deionized water
Contents	Deionized water
Preparation	None
Storage	Store at room temperature
Stability	Stable until manufacturer's expiration date

6.3 Frequency

- Internal procedural controls are performed with each test.
- The external positive and negative controls are performed once per week and whenever a new lot of Hemoccult SENSA® Slides is introduced.

6.4 Tolerance Limits and Criteria for Acceptable QC

6.4.1 Internal Controls

The Performance Monitor **positive** area of the Hemoccult Card will turn **blue** when the developer has been added within 10 seconds and will stay stable for 60 seconds. The Performance Monitor **negative** area will not turn a color.

Note: Always develop the test, read the results, interpret them and make a decision as too whether the fecal specimen is positive or negative for occult blood **BEFORE** developing the Performance Monitors. Do not apply Developer to Performance Monitors before interpreting test results. Any blue originating from the Performance Monitors should be ignored in the reading of the specimen test results.

6.4.2 External Controls

The positive control will turn **blue** when the developer has been added within 30 seconds.
The negative control will not turn a color.

6.4.3 Corrective Action for Failed Controls

IF …	**THEN…**
Any control does not produce the expected result	The test is invalid. Do not report patient results. Repeat testing using a new card. Do not report patient results until acceptable QC

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	results are obtained. If repeat testing does not produce acceptable QC, then notify supervisor immediately.

6.5 Documentation

The results of the controls are documented on the appropriate manual QC log sheet.

6.6 Quality Assurance Program

- For each new lot number of reagent the internal and external control must be tested. Performance of the new lot must be equivalent to the previous lot.
- Training must be successfully completed and documented prior to performing this test. This procedure will be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing.
- All technologists are tested for color blindness as part of the pre-employment testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Not Applicable

7.2 Equipment

Not Applicable

7.3 Supplies

Applicator sticks

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	If the specimen is a raw stool follow these directions:
1.	Collect a small stool sample on the end of an applicator stick.
2.	Open the front tab of the Hemoccult Slide.
3.	Apply thin smear covering Box A.
4.	Obtain a second sample from a different part of stool. Apply thin smear covering Box B.

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8.1	If the specimen is a raw stool follow these directions:
5.	Close cover flap.
6.	Slides are best developed no sooner than three (3) days after the sample application to allow for degradation of any fruit and vegetable peroxidases that may be in the fecal sample. However, if immediate testing is required, wait 3 to 5 minutes before developing.
7.	Open the flap in back of slide and apply 2 drops of Hemoccult Developer to guaiac paper directly over each smear.
8.	Read results within 60 seconds
9.	ANY TRACE OF BLUE ON OR AT THE EDGE OF THE SMEAR IS POSITIVE FOR OCCULT BLOOD.

8.2	If the specimen is submitted on the Hemoccult Slide:
1.	Begin with 8.1 step 6 and proceed to 8.1 step 8.

8.3	External Control Testing
1.	**Positive Control**: Gently mix the Fecal Occult Blood Camco Positive Control by several inversions. Place one drop on the 'control' area on the back of the Hemoccult SENSA Slide.
2.	After the drop has been absorbed, add two (2) drops of Developer to the 'control' area.
3.	A blue color should form within thirty (30) seconds. Read result up to thirty seconds Disregard any colors that form after thirty seconds If no color forms, the test is **invalid** and the patient results **must not be reported**. Refer to section 6.4 for corrective action. **Note**: The blue color from the positive control should not be regarded as the intensity required from a positive patient test for occult blood in the stool.
4.	**Negative Control**: Place one or two drops of deionized water on the 'control' area on the back of the Hemoccult SENSA Slide.
5.	After the water has been absorbed, add two (2) drops of Developer to the 'control' area
6.	No color should form within thirty (30) seconds. If any color forms, the test is **invalid** and the patient results **must not be reported**. Refer to section 6.4 for corrective action.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Results

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

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

10.2 Rounding

Not applicable

10.3 Units of Measure

Not applicable

10.4 Clinically Reportable Range (CRR)

Not applicable

10.5 Review Patient Data

Review Patient results for unusual trends such as an unusually high percentage of positive results.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…
Negative	Report as NEG in the LIS
Positive	Report as POS in the LIS

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

This is a test for detecting fecal occult blood which may be indicative of gastrointestinal diseases. It is not a test for colorectal cancer or any other specific diseases.

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13. PROCEDURE NOTES

- **FDA Status:** Approved/cleared
- **Validated Test Modifications:** None

Fecal specimens should be collected from bowel movements for three days. To further increase the probability of detecting occult blood, separate samples should be taken from two different sections of each fecal specimen.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

- 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.
- Conversely, a Hemoccult SENSA 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.
- Therefore, as with any occult blood test, results with the Hemoccult SEMSA test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology. Hemoccult SENSA 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 SENSA test, as well as other unmodified fecal occult blood tests, should not be used to test gastric specimens. Interfering factors, such as low pH, high drug concentrations, metal ions or plant peroxidase in food may affect the function of guiac-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 guiac 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. For this reason, Rehydration in not a recommended procedure for the Hemoccult SENSA test.

14.3 Interfering Substances

Substances which can cause false-positive test results:

- Corticosteroids, phenylbutazone, reserpine, anticoagulants, antimetabolites, and cancer chemotherapeutic drugs

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- Alcohol in excess
- The application of antiseptic preparations containing iodine (providone/iodine mixture)

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

Current package insert for Hemoccult SENSA®
Occult Blood Quality Control Log (AG.F31)

17. REFERENCES

1. Package insert, Hemoccult SENSA® , Beckman Coulter, Inc., June 2015
2. Package insert, Fecal Occult Blood Camco Positive Control Solution, Cambridge Diagnostics Products, 3/10.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP U002.001		
000	10/3/16		Update owner	L Barrett	R SanLuis
000	10/3/16	Header	Add WAH	L Barrett	R SanLuis
000	10/3/16	4,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
000	10/3/16	10.5	Review data moved from section 6	L Barrett	R SanLuis
000	10/3/16	15	Update to new standard wording	L Barrett	R SanLuis
000	10/3/16	16	Form moved from section 19	L Barrett	R SanLuis
000	10/3/16	17	Update PI revision date	L Barrett	R SanLuis
000	10/3/16	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None

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