TRAINING UPDATE

Lab Location:	SGAH	**Date Distributed:**	1/1/2014
Department:	Micro	**Due Date:**	1/31/2014
		Implementation:	**1/15/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Gastroccult SGAH.M37.1

Description of change(s):

Section	Reason
4.2	Added additional storage requirements
16	Removed date of Gastroccult pkg insert, added form

This revised SOP will be implemented on January 15, 2014

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

Approved draft for training (version 1)

Technical SOP

Title	**Gastroccult**
Prepared by	Hollie Genser Date: 2/15/2012
Owner	Ron Master Date: 11/26/2013

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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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Gastroccult Slide Test	Change in pH	GOBL

Synonyms/Abbreviations
None

Department
Microbiology

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2. ANALYTICAL PRINCIPLE

The Gastroccult slide includes both a specially buffered guaiac test for occult blood and a pH test based on the principle that certain dyes change color with changes in hydrogen ion concentration. This test is designed to be used with gastric samples. The occult blood test is not affected by normal therapeutic concentrations of cimetidine (Tagamet), iron or copper salts. Also, interferences from plant peroxidases are significantly reduced. Most guaiac-based products designed for use with fecal specimens are affected by these interferences, which are commonly encountered in gastric samples.

When a gastric specimen containing blood is applied to Gastroccult test paper, the hemoglobin from lysed blood cells in the sample comes in contact with the guaiac. Application of Gastroccult Developer (a buffered, stabilized hydrogen peroxide solution) creates a guaiac/peroxidase-like reaction, which turns the test paper blue if blood is present. As with any occult blood test, results with the Gastroccult test cannot be considered conclusive evidence of the presence or absence of upper gastrointestinal bleeding or pathology. The Gastroccult test is designed for use as a preliminary screening aid and is not intended to replace other diagnostic procedures such as gastroscopic examination or X-ray studies (See Limitations of Procedure).

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	It is recommended that samples be tested immediately after collection if possible. If this is not possible, the following procedure will yield satisfactory results: Apply the sample in the pH Test Area and Gastroccult Test Area. Read the pH within 30 seconds after sample application. The Gastroccult Test Area may be developed immediately or up to 4 days, at room temperature 15-30^{o}C, after sample application.
Special Collection Procedures	N/A
Other	N/A

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3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Gastric aspirate (nasogastric intubation or vomitus)

Criteria	
-Other Acceptable	None
Collection Container	Clean sealed container (plastic or glass)
Volume - Optimum **- Minimum**	Sufficient amount of test material for application to the reaction area. 1 ml
Transport Container and Temperature	Clean sealed container (plastic or glass). Same as below.
Stability & Storage Requirements	Samples may be stored, prior to application, at room temperature 15-30^{o}C for 24 hours, or refrigerated at 2-8^{o}C for 5 days. Frozen: Unacceptable
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and cancel the test with the appropriate LIS English text code for "test not performed" message. Example: Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	N/A
Other Considerations	N/A

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Gastroccult Kit	Beckman Coulter Inc. Cat # 66040
Gastroccult Developer	Beckman Coulter Inc. Cat # 66115

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.

Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Gastroccult Developer is an irritant. Avoid contact with skin. DO NOT USE IN EYES. Should contact occur, rinse promptly with water.

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Assay Kit	
Reagent	Gastroccult Developer, in a 10 ml vial and ordered separately. A developing solution containing a stabilized mixture of less than 2.9% hydrogen peroxide and 30% denatured ethyl alcohol in a citrate-buffered aqueous solution.
Component	Test slides for inoculation (40 tests per kit)
Storage	• Developer: Room temperature. Protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation. • Slides: Protect slides from open air. Keep flap of slide sealed until ready to use. Store box containing slides at controlled room temperature 15-30^{o}C in plastic storage pouch provided. • Do not refrigerate or freeze • Do not store slides or developer near volatile chemicals (e.g., iodine, chlorine, bromine, or ammonia) • Protect from heat and light
Stability	Stable until expiration on vial label or card label.
Preparation	The developer is ready to use. Slides are ready for use.

5. CALIBRATORS/STANDARDS

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Buffer Solution pH 2.00	Manufacturer: Lab Chem Inc Cat #:LC12220-1
Buffer Solution pH 7.00: Traceable to NIST	Manufacturer: La-Mar-Ka, Inc. Cat #: 0225

6.1.1 PH:

6.1.1.1 External Controls:

6.1.1.1.1 Apply one drop of pH 7 to pH test circle, interpret pH of sample within 30 seconds.

6.1.1.1.2 Apply one drop of pH 2 to pH test circle, interpret pH of sample within 30 seconds.

6.1.2 Occult Blood:

6.1.2.1 External Controls:

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6.1.2.1.1 Apply one drop of Camco Positive Control Solution to occult blood test area. Apply two drops of Gastroccult Developer directly over the sample in the occult blood area and interpret within 60 seconds. The positive internal control contains a hemoglobin-derived catalyst, which will turn blue within 10 seconds after applying developer.

6.1.2.1.2 Apply one drop of de-ionized water to occult blood test area. Apply two drops of Gastroccult Developer directly over the sample in the occult blood area and interpret within 60 seconds. The negative internal control contains no catalyst and should not turn blue after applying developer.

6.1.2.2 Internal Controls:

6.1.2.2.1 Add one drop of Gastroccult Developer between the positive and negative Performance Monitor areas. Interpret the Performance Monitor results. A blue color will appear in the positive Performance Monitor area within 10 seconds. The color will remain stable for at least 60 seconds. No blue should appear in the negative Performance Monitor area when developer is added. Note: If the sample is applied in such a way that it contacts the Performance Monitor areas, the negative Performance Monitor area may appear positive. This should be avoided.

6.1.3 Results for the positive and negative internal and external controls for each patient test result must be documented on the log indicating the positive and negative internal controls were in range.

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Controls	Buffer Solution pH 2.00 Buffer Solution pH 7.00: Traceable to NIST
Control	Camco Positive Control Solution 5 mg/dL bovine hemoglobin in an aqueous buffered solution with preservative
Control	De-ionized Water
Storage	Store at controlled room temperature 15-30^{o}C
Stability	Stable until expiration on vial label or card label.
Preparation	All controls are ready to use.

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6.3 Frequency
Quality control, both internal and external, should be performed with each patient tested.

6.4 Tolerance Limits
If results are not as expected (see section 6.1), record results on Corrective Action Log along with the resolution; notify a Supervisor and repeat the test. Do not report out test results until the quality control issue is resolved.

6.5 Review Patient Data
Review patient results for any unusual patterns or trends. Contact your Supervisor if any are noticed.

6.6 Documentation
Refer to local policies and procedures for quality control documentation and to Quest Diagnostics records management program for record retention requirements.

6.7 Quality Assurance Program
- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials. 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 must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Consult the Laboratory QC program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform
Not applicable

7.2 Equipment
None

7.3 Supplies
None

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.

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.

Important Note: This test requires Gastroccult Developer, which is provided as part of this product. **Do not use Hemoccult Developer or any other developing solution**.

Step	Action
1	Open slide.
2	Apply one drop of gastric sample to pH test circle and one drop to occult blood test area.
3	Determine pH of sample by visual comparison of test area to pH color comparator. This must be done within 30 seconds after sample application.
4	Apply two (2) drops of Gastroccult Developer directly over the sample in the occult blood test area. **Important Note**: Occasional gastric samples may be highly colored and appear as blue or green on the test area. Test results should only be regarded as positive if additional blue is formed after developer is added.
5	Read occult blood results within 60 seconds. The development of any trace of blue color in the occult blood test area is regarded as a positive result. Record results.
6	Add one (1) drop of Gastroccult Developer between the positive and negative Performance Monitor areas.
7	Interpret the Performance Monitor results

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

A. A blue color will appear in the positive Performance Monitor area within 10 seconds. The color will remain stable for at least 60 seconds.

B. No blue should appear in the negative Performance Monitor area when developer is added. **Note**: If the sample is applied in such a way that it contacts the Performance Monitor areas, the negative Performance Monitor area may appear positive. This should be avoided.

C. Any blue originating from the Performance Monitor areas should be ignored when reading the specimen test results.

D. Neither the intensity nor the shade of the blue from the positive Performance Monitor area should be used as a reference for the appearance of positive test results.

10.2 Reporting Results

1. Occult blood: Positive or negative

2. Ph: 1-10

10.3 Units of Measure
Not applicable

10.4 Clinically Reportable Range (CRR)
Not applicable

10.5 Repeat Criteria and Resulting

IF the result(s) are …	THEN…
Inconclusive	Repeat the test(s). Notify a supervisor.

11. EXPECTED VALUES

11.1 Reference Ranges
1. Occult Blood: Negative

2. Ph: <4

11.2 Critical Values
None established

11.3 Priority 3 Limit(s)
None established

12. CLINICAL SIGNIFICANCE

The identification of occult blood can be useful in the early detection of gastric trauma or deteriorating gastric condition, while pH may be of use in evaluating antacid therapy.

13. PROCEDURE NOTES

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

A. Because this test is visually read and requires color differentiation, it should not be interpreted by the visually impaired.

B. **Gastroccult Developer is an irritant. Avoid contact with skin. DO NOT USE IN EYES. Should contact occur, rinse promptly with water.**

14. LIMITATIONS OF METHOD

A. As with any occult blood test, the results of the Gastroccult test cannot be considered conclusive evidence of the presence or absence of upper gastrointestinal bleeding or pathology.

B. Note: Many foods (e.g., incompletely cooked meat, raw fruits and vegetables, etc.) have peroxidase activity, which can produce a positive Gastroccult test result. Thus, a positive test result does not always indicate the presence of human blood.

C. Gastroccult tests are designed as an aid to diagnosis, and are not intended to replace other diagnostic procedures such as gastroscopic examination or X-ray studies. There is disagreement in the literature regarding the exact therapeutic significance of varying levels of upper gastrointestinal bleeding.

D. Gastroccult test results should be used only in conjunction with other information relevant to the clinical status of the patient. A positive test result may suggest the need for more careful monitoring of the patient.

14.1 Analytical Measurement Range (AMR)
N/A

14.2 Precision
N/A

14.3 Interfering Substances
Many foods (e.g., incompletely cooked meat, raw fruits and vegetables, etc.) have peroxidase activity, which can produce a positive Gastroccult test result.

14.4 Clinical Sensitivity/Specificity/Predictive Values
50 µg/ml of hemoglobin

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Current Product Insert for Gastroccult
4. Gastroccult Blood QC Log (AG.F157)

17. REFERENCES

1. Rosenthal, P., Thompson, J. and Singh, M: Detection of Occult Blood in Gastric Juice. *J. Clin. Gastroenterol*. 6:119-121, 1984.
2. Data on file, Product Development Department, Beckman Coulter, Inc.
3. Norfleet, R.G., Rhodes, R.A. and Saviage, K: False-positive "Hemoccult" reaction with cimetidine. *N. Engl. J. Med.* 302:467, 1980.
4. Gastroccult, *Test For Gastric Occult Blood And pH*. Beckman Coulter, Inc. September 2001.
5. GASTROCCULT procedure, MI162.004, Quest Diagnostics Nichols Institute, Chantilly

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	11/26/13		Update owner	L. Barrett	R. Master
000	11/26/13	4.2	Added additional storage requirements	R. Master	R. Master
000	11/26/13	16	Removed date of Gastroccult insert, added form	R. Master	R. Master
000	11/26/13	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. Master

19. ADDENDA

None