Keywords: gastric, Gastric pH, Gastroccult, GOCB, occult blood, pH

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Appendix A: Gastroccult QC Log Sheet CLICK HERE
Appendix B: Gastroccult Patient Result Log CLICK HERE
Appendix C: Gastroccult Test Initial Training and Competency CLICK HERE

I. PURPOSE
This procedure provides instructions for performing gastric occult blood and pH testing using the Beckman Coulter Gastroccult Slides and Developer. Gastroccult is a rapid screening test designed for detecting the presence of occult blood and determining the pH of gastric aspirate or vomitus.

II. ORDER
A physician’s order, standard protocol, or order by another health professional authorized to request laboratory tests is required for point of care gastric occult blood and pH testing.
III. MATERIALS

<table>
<thead>
<tr>
<th>Reagents/Controls</th>
<th>Source</th>
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<tbody>
<tr>
<td>Gastroccult Slides</td>
<td>SAP Item #5332</td>
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<tr>
<td>Gastroccult Developer</td>
<td>SAP Item #5327</td>
</tr>
<tr>
<td>pH Buffer 2.0</td>
<td>POCT Office</td>
</tr>
<tr>
<td>pH Buffer 7.0</td>
<td>POCT Office</td>
</tr>
</tbody>
</table>

**Additional Supplies**
- Disposable Gloves
- JHMI Quality Control Labels
- Standard Register Item #0209N
- Applicators
- JHMI-approved Biohazard Waste Container
- NIST-Certified Timing Device

IV. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
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<th>Temperature</th>
<th>Expiration Date</th>
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<tbody>
<tr>
<td>Gastroccult Slides</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>Gastroccult Developer</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>pH Buffers (2.0 and 7.0)</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
</tbody>
</table>

A. Once a box of Gastroccult Slides or a bottle of Gastroccult Developer is opened, it is required that the consumable is labeled with the open date.
B. Never use Gastroccult Slides, Gastroccult Developer, or pH Buffers past their expiration date.
C. Do not freeze or refrigerate the Gastroccult Slides or Developer.
D. Gastroccult Slides must remain sealed inside special wrapper until ready to use.
   1. Protect from heat and light.
E. Gastroccult Developer must remain tightly capped when not in use to prevent evaporation.
   1. Due to flammability, do not store near volatile chemicals.
F. Confirm proper labeling of pH buffer aliquot vials, to include open and expiration date, prior to use. Bottles must remain tightly capped when not in use.

V. SPECIMEN TYPE

A. The preferred sample for testing is either a gastric aspirate obtained by nasogastric intubation or vomitus.

VI. SPECIMEN COLLECTION AND HANDLING

Prior to sample collection, patient identification must be verified using two unique identifiers.

A. Clean collection containers must be labeled with at least two unique patient identifiers in front of the patient (e.g. Name, DOB, MRN, and/or CSN).
B. All labeling should be done on the cup instead of the lid as applicable, which may become separated from the specimen.
C. It is recommended that samples be tested immediately after collection.
   1. If this is not possible, the following steps will need to be followed:
      a. Apply the sample to the pH Test Area and Gastroccult Test Area.
      b. Read the pH within 30 seconds after sample application.
      c. The Gastroccult Test Area may be developed immediately or up to 4 days after sample application, when stored at room temperature (15-30°C).
   2. Samples for Gastroccult blood testing only may be stored in a clean, sealed container for 24 hours at room temperature (15-30°C).

VII. SAFETY PRECAUTIONS
   A. Follow ICPM IFC023 Infection Control and Prevention: Standard and Isolation Precautions.
   B. The Gastroccult Developer is an irritant. Avoid contact with skin and eyes; should contact occur, rinse promptly with water.
   C. All patient specimens, Gastroccult Slides, and applicators must be discarded in the appropriate waste receptacle.

VIII. PERFORMING QUALITY CONTROL (QC) TESTS
   A. Internal Performance Monitors:
      1. Each Gastroccult slide contains two Performance Monitors to test the function and stability of the Gastroccult consumables. Both results must be acceptable in order for results of any kind to be reported.
      2. Negative Performance Monitor:
         a. Upon application of the Gastroccult Developer, this area on the Gastroccult slide will not develop any color.
      3. Positive Performance Monitor:
         a. Upon application of the Gastroccult Developer, this area on the Gastroccult slide will turn blue within 10 seconds and remain stable for at least 60 seconds.
      4. If either of these Performance Monitors fails to react as expected, the test is reported as Invalid and must be repeated using a new bottle of Gastroccult Developer and/or a new box of Gastroccult Slides. Refer to Corrective Action below.
   B. Two levels of External Quality Control (pH buffer 2.0 and 7.0) will be performed:
      1. At least once per week on each opened box of Gastroccult Slides and on each opened bottle of Gastroccult Developer.
      2. Initially when opening new Gastroccult Slides, Gastroccult Developer, or pH buffer.
      3. By all new operators as part of initial hands-on training prior to testing patient specimens.
      4. At least once a year by each operator to demonstrate compliance with competency regulations.
      5. Performance Monitors must be checked after each test - patient and quality control.
   C. Procedure:
      1. Prepare materials for testing:
         a. Put on gloves.
         b. Verify that Gastroccult Slides and Developer, and pH buffers are dated and within the manufacturer's expiration date.
         c. Remove two Gastroccult Slides from their plastic wrap and label with the level of QC to be performed (e.g. pH 2.0, pH 7.0, or lot number in use).
         d. Set timer to 30 seconds.
            i. Note: Use of a wall clock or wristwatch to time the test is insufficient; a NIST-certified timer must be used.
2. Perform the test:
   a. Record the applicable information onto the Gastroccult QC Log Sheet (Appendix A).
   b. Mix the pH buffers and Gastroccult Developer gently by inversion, then apply one drop of pH buffer 2.0 to the pH test circle on one Gastroccult slide and one drop of pH buffer 7.0 to the pH test circle on the other slide.
   c. Press start on timer.
   d. Determine pH by visual comparison of the pH test circle to the pH color comparator on the slide and record the result on the Gastroccult QC Log Sheet.
      i. Note: This interpretation must occur within 30 seconds of sample application.
   e. Set timer to 10 seconds.
   f. Add one drop of Gastroccult Developer between the positive and negative Performance Monitors areas, then press Start on the timer.
   g. Interpret the results within 10 seconds.
      i. If the Gastroccult Slides and Developer are functional, a blue color will appear in the positive Performance Monitor area, and the Negative Performance area will remain the same paper color.

D. Corrective Action:
1. If any QC test fails to give the expected results:
   a. Verify Gastroccult Developer, Gastroccult Slides, and pH buffers are within their expiration dates and that they have been properly stored.
   b. Ensure proper testing technique is being used, repeating testing with the same materials.
   c. If QC fails a second time:
      i. If the pH area fails, replace the pH buffer(s) with a new bottle and repeat testing.
      ii. If the Performance Monitors fail, replace the Gastroccult Developer with a new bottle and repeat testing.
   d. If QC fails a third time, replace the Gastroccult Slides with an unopened box and repeat testing.
   e. If QC fails with the new Gastroccult Developer and/or pH Buffer(s) and Gastroccult Slides, DO NOT PERFORM ANY PATIENT TESTING. Contact the POCT Office (5-2645) or by sending a CORUS Message to "POCT Consult".
2. Note any QC failures and corrective actions in the Comment Section of the Gastroccult QC Log Sheet.

IX. PATIENT TEST PROCEDURE
A. Prepare for the test:
1. Confirm that Gastroccult Slides and Developer are not expired and that QC testing has been performed successfully within the last week. If not, QC must be completed prior to patient testing. Refer to Performing Quality Control (QC) Tests.
2. Put on gloves.
3. Confirm proper specimen labeling, with at least two unique patient identifiers on the cup, not the lid, as applicable.
4. Remove a slide from the box and wrapper, and label with at least two unique patient identifiers.
   a. Note: This can be accomplished by writing the identifiers, or by placing a patient label on the Gastroccult Slide.
5. Set timer to 30 seconds.
   a. Note: Use of a wall clock or wristwatch to time the test is insufficient; a NIST-certified timer must be used.
B. Perform the patient test:
1. Apply one drop of gastric sample to pH test circle and one drop to the occult blood test area on the Gastroccult Slide.
2. Press Start on the timer.
3. Within 30 seconds, determine the pH of the gastric sample by visual comparison of the test area to the pH color comparator on the slide.
4. Set timer to 60 seconds.
5. Apply two drops of Gastroccult Developer directly over the sample in the occult blood test area.
6. Press Start on the timer.
7. Within 60 seconds, read the occult blood results. Development of any trace blue color is regarded as a positive result.
8. Add one drop of Gastroccult Developer between the positive and negative Performance Monitors areas.
9. If the Gastroccult Slide and Developer are functional, a blue color will appear in the positive Performance Monitor area and the negative Performance Monitor area will remain unchanged.
10. If a computer is not in the same room as that in which patient testing is performed, complete the Gastroccult Patient Result Log (Appendix B). If a computer is available in the same room as testing, immediately result the test in the patient's electronic medical record.
11. Discard the Gastroccult Slide in the appropriate waste receptacle.

X. EXPECTED RESULTS
The Gastroccult test will reliably detect hemoglobin levels equal to or greater than 50 µg/mL in gastric samples at pH 1-9. Results are expected to be Negative; however, gastric aspirates from some normal individuals may give positive results.

XI. RESULTS INTERPRETATION
A. Positive: Presence of additional blue color over the sample in the occult blood test area after the addition of the Gastroccult Developer, given the appropriate Performance Monitors reactions.
   1. Samples containing 50-200 µg hemoglobin/mL are usually very faint (trace) blue.
   2. Intermediate concentrations, 200-500 µg hemoglobin/mL, will produce moderate blue test results.
   3. Higher concentrations of hemoglobin, 500-1000 µg hemoglobin/mL will produce darker blue test results.
B. Negative: Absence of additional blue color over the sample in the occult blood test area after the addition of the Gastroccult Developer, given the appropriate Performance Monitors reactions.
C. Invalid: If the positive Performance Monitor and/or negative Performance Monitor does not react as expected, no patient results can be reported until the failures are corrected.

Note: All test results should be considered in relation to a specific patients’ condition and therapy; questionable results or results that do not match the clinical condition should be reported to the patient's provider to determine if additional follow-up is needed.

XII. RESULTS REPORTING
All patient test results must be manually documented on the Gastroccult Patient Result Log (see Appendix B) if there is not a computer in the room where testing is performed. The log must then be used to ensure results are properly documented in Epic using Manual Entry. If there is a computer in the testing room, patient result entry must occur immediately following the completion of testing.

A. Each of the fields must be filled out completely when completing the Gastroccult Patient Result Log.
   1. Record the patient's gastric occult blood results as "Positive" or "Pos" for a positive result, or "Negative" or "Neg" for a negative result.
      a. Note: Do not use (+) or (-) for recording gastric occult blood test results.
   2. Record the patient's pH results as the number corresponding to the closest match on the color comparator.
B. See Epic Tips and Trics on how to [Enter/Edit Results].

In the event of an Epic downtime, all patient results must be recorded on the Gastroccult Patient Result Log until the downtime is over, at which time all patient results must be manually entered in Epic.

XIII. INTERFERENCES
Refer to the package insert for a full list of the Interfering Substances for the Gastroccult test.

A. If gastric samples are tested no sooner than 60 minutes after last antacid administration and stomach irrigation, inhibition of the occult blood test is unlikely.
   1. Antacid products containing magnesium hydroxide exhibit the most inhibitory effect on the test.
B. Vitamin C has been shown to cause false-negative test results with the Gastroccult test.

XIV. LIMITATIONS
A. The results of the Gastroccult cannot be considered conclusive evidence of the presence or absence of upper gastrointestinal bleeding or pathology.
   1. Many foods have peroxidase activity which can produce a false-positive Gastroccult test result.
B. Because the Gastroccult test is visually read and requires color differentiation, it should not be interpreted by people who are color-blind or visually impaired.
C. The Gastroccult test is not recommended for use with fecal samples.
D. Gastroccult test results should be used in conjunction with other information relevant to the clinical status of the patient.

XV. PROCEDURAL NOTES
A. Some gastric samples may be highly colored and appear as blue or green on the test area upon sample application. Test results should only be regarded as positive if additional blue is formed after Gastroccult Developer is added.
B. Interferences should be kept in mind when interpreting the results of the Gastroccult test.

XVI. OPERATOR TRAINING
A. Testing may only be performed by currently certified staff members who have been trained by a Point of Care Coordinator, Nurse Educator, or designated unit trainer. Training records must be kept in the employee's personnel file, and a copy sent to the Point of Care Testing Office.
B. Initial training will include:
   1. Review the policy online.
   2. Completion of the Initial Training and Competency Assessment Checklist (see Appendix C), to be kept in the employee's personnel file.
   3. Successful performance and documentation of all external quality control (pH buffers and Performance Monitors).
   4. Passing score on the quiz from the MyLearning module.

XVII. OPERATOR COMPETENCY
In order to maintain competency, operators must successfully complete all levels of external quality control (pH buffers and Performance Monitors) and the MyLearning module quiz once a year. The competency calendar follows the fiscal year: July 1-June 30.
XVIII. REFERENCES

XIX. SIGNATURES

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<th>Electronic Signature(s)</th>
<th>Date</th>
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<tbody>
<tr>
<td>William Clarke</td>
<td>03/03/2023</td>
</tr>
<tr>
<td>Medical Director of Point of Care Testing</td>
<td></td>
</tr>
</tbody>
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