A. PURPOSE:
Gastroccult® is a rapid screening test designed for detecting the presence of occult blood and determining the pH of gastric aspirate or vomitus.

The Gastroccult Slide Test is an aid in the diagnosis and management of various gastric conditions, which may be encountered in intensive care areas, the emergency room, surgical recovery room, and other clinical settings. 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. Standard fecal occult blood tests lose sensitivity at low pH and may be unsuitable for use with gastric samples. The Gastroccult test is not recommended for use with fecal samples.

Test Summary
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 use with gastric samples. The occult blood test is not affected by low pH. Gastroccult is free from interference by normal therapeutic concentrations of Tagamet, iron or copper salts. Also, interference from plant peroxidases is significantly reduced. Most guaiac-based products designed for use with fecal specimens are affected by this interference, 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 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.

B. Principle:
In this test, alpha guaiaconic acid (active component of guaiac) reacts with hydrogen peroxide (active component of the developer) in the presence of heme (peroxidative type of catalyst present in hemoglobin) to produce a highly conjugated blue quinone compound. The pH test is based on changes in the color of dyes due to changes in hydrogen ion concentration.

C. Policy:
1. A physician/PA’s order is required
2. LifeBridge Health Trainers will be identified and trained on each unit performing Gastroccult.
3. Certified Trainers will include an in service, satisfactory completion of a written examination and performance of a test.
4. Recertification will be performed yearly.
5. A record of Certified Operators and Instructors will be maintained on each nursing unit, Staff Development, and with the Department of Pathology.
6. Bedside Testing will supply a report identifying problems to the Director of each unit.
7. Documentation of follow-up investigation and corrective actions taken will be returned to Pathology to be maintained by Bedside Testing.
8. Only the results for the test ordered by the physician will be performed and recorded.
9. Results will be recorded in the Glucose Meter under other tests.
10. If a mistake is found after completing entering the results, the operator needs to inform Point-of-Care Testing so that the incorrect results can be removed. The operator needs to re-enter the correct results into the meter.

D. Specimen Type: Gastric secretion

E. Patient Preparation: N/A

F. Handling Conditions:
Either gastric aspirate obtained by nasogastric intubation or vomitus is an appropriate sample for use with the Gastroccult test. Sample may be applied by using the applicators provided in the kit, or by any other method whereby a small amount of test material is applied to the reaction areas.
Apply the sample in the pH Test Area and Gastroccult Test Area (for occult blood). Read the pH within 30 seconds after sample application. The Gastroccult Test Area may be developed and read after 60 seconds.

G. **Storage Requirements:**

   It is recommended that the samples be tested immediately after collection.

I. **Rejection Criteria:** N/A

J. **EQUIPMENT AND MATERIALS**

   1. **Equipment:** Gastroccult Test

   2. **Materials/Supplies:**
      a. Gastroccult Slides
      b. Gastroccult Developer
      c. Applicators

K. **Preparation:** N/A

L. **Performance Parameters:** The pH test area on the Gastroccult slide was compared to a pH meter for accuracy using gastric specimens. The results correlated well as shown in the following table:

<table>
<thead>
<tr>
<th>Gastroccult pH Value</th>
<th>Average pH Meter Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.2</td>
<td>0.8 - 1.7</td>
</tr>
<tr>
<td>2</td>
<td>1.9</td>
<td>1.6 - 2.7</td>
</tr>
<tr>
<td>3</td>
<td>2.6</td>
<td>2.1 - 3.1</td>
</tr>
<tr>
<td>4</td>
<td>3.7</td>
<td>2.2 - 4.4</td>
</tr>
<tr>
<td>5-7</td>
<td>5.7</td>
<td>3.4 - 7.5</td>
</tr>
<tr>
<td>7+</td>
<td>7.7</td>
<td>7.1 - 8.5</td>
</tr>
</tbody>
</table>

M. **Storage Requirements:**

   Do not refrigerate or freeze. Store at controlled room temperature (59-86°F) in original packaging. Protect from heat and light. Do not store with volatile chemicals (e.g. iodine, chlorine, bromine, or ammonia). The Gastroccult slides and developer, stored as recommended, will remain stable until the expiration dates, which appear on each slide and developer bottle.

   **Slides:** Do not use after the expiration date, which appears on each slide. Keep flap of slide sealed until ready to use.

   **Developer:** Gastroccult Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation. Do not use past expiration date.
N. CALIBRATION

1 Standard Preparation: N/A

2 Calibration Procedure: N/A

O. QUALITY CONTROL:

1. Materials Used: Gastroccult Slides and Developer

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

3. Frequency Run: N/A

4. Tolerance Limits: The test will reliably detect hemoglobin levels equal to or greater than 50 micrograms/mL in gastric juice at pH 1 through 9. This is equivalent to 30 to 50 uL of blood per dL of gastric fluid based on the hemoglobin content in blood of normal adults. However, positive test results may be seen with some specimens containing less than 50 micrograms hemoglobin/mL.

5. Corrective Action: N/A

6. Recording and Storage of Data: N/A

P. PROCEDURE

A. Test Procedure:
   Apply gloves.
   Obtain specimen in clear container.

   pH Test:
   1. Apply one drop of gastric sample to pH test circle and one drop to occult blood test area using applicator provided or other suitable device.
   2. Determine pH of sample by visual comparison pH test area to pH color comparison. Read result within 30 seconds after applying sample.

   Gastroccult Test:
   1. Apply two drops of Gastroccult Developer directly over the sample and one drop between the positive and negative Performance Monitor areas.
   2. Read occult blood results within 60 seconds. The development of any blue color in the occult blood test area after the addition of developer is regarded as
a positive result. Do not use the intensity or shades of blue of the positive Performance Monitor area in evaluating occult blood test results.

Discard slide, applicator, and gloves in appropriate biohazard container.
Wash hands.
Record results for pH, Gastroccult Test and Performance Monitor in Powerform or on the Point-of-Care Result Sheet.

Q. **Expected Results:**

A study was done with 153 gastric aspirates from 50 intubated healthy adults who had fasted for a minimum of 8 hours prior to intubation. The pH of the samples ranged from 1.3 to 7.8 and hemoglobin levels ranged from 0 to 320 micrograms hemoglobin/mL. The frequency distribution for the hemoglobin level in gastric aspirates of these subjects and the results obtained with the Gastroccult tests are shown below:

<table>
<thead>
<tr>
<th>Hb level (Mcg/mL)</th>
<th>Number Samples</th>
<th>Number Positive Samples</th>
<th>Percent Positive Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - &lt;25</td>
<td>127</td>
<td>15</td>
<td>11.8</td>
</tr>
<tr>
<td>25 - &lt;50</td>
<td>9</td>
<td>7</td>
<td>77.8</td>
</tr>
<tr>
<td>50 - &lt;200</td>
<td>14</td>
<td>14</td>
<td>100.0</td>
</tr>
<tr>
<td>200 - 320</td>
<td>3</td>
<td>3</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>153</strong></td>
<td><strong>39</strong></td>
<td></td>
</tr>
</tbody>
</table>

It is expected that gastric aspirates from some normal individuals may give positive test results as shown above. However, the positive test reactions obtained with these samples (50-200 micrograms hemoglobin/mL) are usually very faint (trace) blue. Intermediate concentrations (200-500 micrograms hemoglobin/mL) will produce moderate blue test results. Higher concentrations of hemoglobin in gastric aspirates (500-1000) micrograms hemoglobin/mL) will produce darker blue color test results.

R. **Limitations:**

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.

**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.

S. Procedure which can be performed to determine if positive test is due to dye present or gastric bleeding associated with patient receiving blue food coloring in tube feeding:
1. Collect a gastric sample- apply one drop of sample to occult blood test area on each of two gastric slides.
2. To one of the slides, add two drops of Gastroccult developer to each sample window. Observe for any color formation.
3. To the other slide, add two drops of aqueous ethyl alcohol (30% minimum alcohol concentration). Observe for any color formation.

Four possible test outcomes can occur on the slides:

No blue color observed for any of the slides. Negative test, no dye interference.

Blue color observed only for the slide where the ethanol was added, indicating presence of the blue dye.

Blue color observed only for the slide where the Gastroccult developer was added, indication the presence of blood in the sample.

Blue color observed in both slides, which is an inconclusive result. The blue could be from the blood present, from the dye, or both.

T. Calibration: N/A

U. REPORTING RESULTS: Results will be recorded in the Glucose Meter under other tests.

V. PROCEDURE NOTES:

1. Reference Range: The test showed excellent reproducibility at hemoglobin levels ≥ 50 micrograms/mL gastric fluid.

2. Critical Value: N/A

3. Reporting Format: N/A


5. Protective Equipment Requirements: gloves
W. LIMITATION OF PROCEDURE:

1. Linearity: N/A

2. Interfering Substances: N/A

3. Chemical Interference:

4. In vivo Interference:

X. REFERENCES:
Gastroccult Test Package Insert
Beckman Coulter, Inc.
1050 Page Mill Road
Palo Alto, CA 94304.

Y. ATTACHMENTS: N/A