GASTROCCULT® TESTING

PURPOSE:
Gastroccult® is a rapid screening test designed for detecting the presence of occult blood in gastric aspirate or vomitus. It is a useful aid in the diagnosis and management of various gastric conditions. The kit contains easy to use paper board slides consisting of standardized, high quality filter paper treated with natural guaiac resin. Application of Gastroccult® Developer (a buffered, stabilized hydrogen peroxide solution) causes a peroxidase-like reaction that turns the test paper blue if blood is present.

SCOPE:
The identification of occult blood can be useful in the early detection of gastric trauma or deteriorating gastric condition. This test has applications in the hospital, outpatient, and home care settings. Though testing for pH is offered with this product, pH testing is not done, and is not reported when performing this test.

PERSONNEL:
Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants, Physicians, Respiratory Tech. In the ambulatory setting, this includes the aforementioned personnel as well as Medical Assistants, Licensed Vocational Nurses and other licensed Technologists. Personnel who have difficulties with color discrimination must demonstrate ability to read the test.

EQUIPMENT & REAGENTS:
• Gloves
• Gastroccult slide
• Gastroccult developer
• Gastric aspirate or vomitus
• Dropper

STORAGE & STABILITY:
• Store Gastroccult® slides at room temperature (15-30° C).
• Protect slides from open air. Keep slide sealed inside special wrapper until ready to use.
• 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.
• The Gastroccult® slides and developer, stored as recommended, will remain stable until the expiration date.

SPECIMEN REQUIREMENTS:
Gastric aspirate obtained by nasogastric intubation or vomitus are appropriate samples for use with the Gastroccult® test. It is recommended that samples be tested immediately after collection. (For stored samples, see product insert.)

As part of our Bloodborne Pathogen Exposure Control Plan, standard precautions must be followed when handling specimens. Gloves should be worn while obtaining and testing the specimen.

QUALITY CONTROL & PATIENT TESTING PROCEDURE
A. Quality Control: When a new box of test cards is opened. QC is also required to be performed every 12 months when a box of test cards is opened and in use.
   1. Select one card from the box
   2. Place 1 or 2 drops of Gastroccult Developer between the Positive and Negative performance monitors
   3. Positive Gastroccult Monitor should turn blue, but the Negative Gastroccult Monitor should not have any trace of blue.
   4. Record the results on the QC log sheet
   5. Date the box and write “QC performed”

B. Patient Testing
   1. Using two patient identifiers, verify patient identification, and explain procedure to patient and/or family.
   2. If testing NOT performed immediately by person collecting the sample, then label the Gastroccult® slide with two forms of patient identification.
   3. Open slide.
   4. Apply one drop of gastric sample to the occult blood test area. (Do NOT apply sample to pH test circle).
   5. Check expiration date of developer.
   6. Apply two (2) drops of Gastroccult® Developer directly over the sample in the occult blood test area. Do not use ColoScreen® Developer or any other developing solution. IMPORTANT NOTE: Some 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 Gastroccult® Developer is added.
   7. 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.
   8. Add one (1) drop of Gastroccult® Developer between the positive and negative Performance Monitor areas.

C. Interpreting the Performance Monitor Results
   1. A blue color will appear in the positive Performance Monitor area within 10 seconds. The color will remain stable for at least 60 seconds.
   2. 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.
   3. Any blue originating from the Performance Monitor areas should be ignored when reading the specimen test results.

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4. 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.
5. Record QC results on patient’s medical record and/or Point of Care QC log.
6. In the unlikely event that the Performance Monitors do not react as expected after application of the developer, the patient results should not be reported. Discard the Gastroccult® card and repeat the test on a new slide if patient sample is still available. Record the QC failure on the Point of Care QC log.

<table>
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<tr>
<th>Test Area</th>
<th>Positive Performance Monitor</th>
<th>Negative Performance Monitor</th>
<th>Result Reported</th>
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</thead>
<tbody>
<tr>
<td>Blue</td>
<td>Blue</td>
<td>No Color</td>
<td>Positive result</td>
</tr>
<tr>
<td>No Color</td>
<td>Blue</td>
<td>No Color</td>
<td>Negative result</td>
</tr>
<tr>
<td>Any Color</td>
<td>No Color</td>
<td>No Color</td>
<td>Do not report</td>
</tr>
<tr>
<td>Any Color</td>
<td>Blue</td>
<td>Blue</td>
<td>Do not report</td>
</tr>
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</table>

RESULTS REPORTING:
Record the patient results and QC monitor results on the Gastroccult® Patient Results Log and/or in the patient's medical record. Reporting of results indicates the performance monitors reacted as expected and the results are valid. The development of any trace of blue color in the occult blood test area is regarded as a positive result. Any guaiac-positive result should be reported to the patient's provider right away.

**Note:** Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

PROCEDURE NOTES - INTERFERRING SUBSTANCES:
Many foods (e.g., under-cooked meat, raw fruits and vegetables, etc.) have peroxidase activity which can produce a positive Gastroccult® results. Thus, a positive test result does not always indicate the presence of human blood.

Ascorbic acid (vitamin C) has been shown to cause false-negative test results for occult blood. This may also occur with the Gastroccult test.

Antacids are unlikely to inhibit the test IF the gastric samples are obtained and tested at least 60 minutes after the last antacid administration and stomach irrigation.

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

Gastroccult® tests are designed as an aid to diagnosis, and are not intended to replace other diagnostic procedures such as X-ray studies or Endoscopy. Gastroccult® test results should only be used 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.

REFERENCES:
Gastroccult® Product Instructions, Beckman Coulter, Inc. August 2011
Signature Manifest

**Document Number:** SOP-0055

**Title:** Gastrocult Testing

All dates and times are in Pacific Standard Time.

Gastrocult procedure for reviewing

### SR Sup Review

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<td>Cynthia Ishizaki (024044224)</td>
<td>POC SR SUP</td>
<td>21 Jun 2013, 11:31:34 AM</td>
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### Med Dir Apprvl

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<td>Tim Hamill (023335003)</td>
<td>PA CB MED DIRECTOR</td>
<td>26 Jun 2013, 01:34:40 PM</td>
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### Quick Approval

### Approve Now

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