Gastroccult®

**PRODUCT INSTRUCTIONS**

**TEST FOR GASTRIC OCCULT BLOOD AND pH**

**INTENDED USE**
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 for In Vitro Diagnostic Use as 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.

**SUMMARY AND EXPLANATION OF THE TEST**

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 since the occult blood test is not affected by low pH. Gastroccult® is free from interferences by normal therapeutic concentrations of cimetidine (Tagamet®), iron or copper salts. Also, interferences from plant peroxidases are significantly reduced. In contrast, guaiac-based products designed for use with fecal specimens are affected by these interferences.

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) causes a 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 gastrointestinal examination or X-ray studies.

(See LIMITATIONS OF PROCEDURE)

**PRINCIPLES OF THE PROCEDURE**

Van Deen discovered the use of guaiac for detecting blood. In this test, alpha guaiaconic acid (active component of guaiac) reacts with hydrogen peroxide (active component of developer) in the presence of 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.

The kit contains easy-to-use paper board slides consisting of standardized, high-quality filter paper treated with natural guaiac resin and dyes sensitive to hydrogen ion concentration. 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 is required. The developer is ready to use. The developing solution is sold separately.

**MATERIALS**

- Gastroccult® Developer (available separately Product No. 66115)
- Gastroccult® Developer (Product No. 66115)
- Gastroccult® Slides
- Gastroccult® Product Instructions

**TEST PROCEDURE**

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: 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.

**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® test are shown below.

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**PH Test**

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®</th>
<th>Average pH</th>
<th>pH Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH Test</td>
<td></td>
<td>1.2</td>
<td>0.8-1.7</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>1.9</td>
<td>1.6-2.7</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2.6</td>
<td>2.1-3.1</td>
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<td>4</td>
<td>3.7</td>
<td>2.2-4.4</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>4.7</td>
<td>3.4-7.5</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>7.7</td>
<td>7.1-8.5</td>
</tr>
</tbody>
</table>

**Occult Blood Test**

Gastroccult® was designed to determine the presence of occult blood in gastric samples. Classical fecal occult blood tests were not designed for use with gastric samples, although they are frequently used for this purpose. Some of the tests used to detect occult blood in gastric samples are guaiac slide-type tests for fecal occult blood and guaiac tablets. Factors common to gastric samples such as low pH, high drug concentrations, metal ions or plant peroxidases in food may affect the function of guaiac-based occult blood tests. Gastroccult® was designed to function reliably in the presence of these factors.

1. **Sensitivity**

The test will reliably detect hemoglobin levels equal to or greater than 50 micrograms/mL in gastric fluid at pH 1 through 9. This is equivalent to 30 to 50 microliters (µL) of blood per deciliter (dL) of gastric fluid based on the hemoglobin content in blood of normal adults.

2. **Precision and Reproducibility**

The test showed excellent reproducibility at hemoglobin levels >50 micrograms/mL in gastric fluid.

3. **Correlation**

Gastroccult® was compared to Hemoccult® in testing for blood in gastric aspirates at varied pH. Three hundred eighty-one (381) gastric fluid samples were used. The hemoglobin levels ranged from 0 to 1320 micrograms/mL and the pH ranged from 0.9 to 9.2. The correlations are shown in Figure 1.

In general, there was close agreement of Gastroccult® results with Hemoccult® results when the pH was >3 and the hemoglobin concentration was greater than 50 micrograms/mL. The major differences in results were observed when the pH was less than 2 and hemoglobin level less than 1000 micrograms/mL. The positive test rate for hemoglobin levels 50 to 1000 micrograms/mL, pH 2-3, was 33-50% for the Hemoccult® test compared to 100% for the Gastroccult® test. The lower pH, the buffering system in Gastroccult® provided more uniform results. Below 50 micrograms hemoglobin/mL, the detection rate for both tests was less than 100%.

4. **Specificity**

a. **Cimetidine (Tagamet)**

Normal therapeutic dosages of cimetidine, administered orally or intravenously, will not affect the Gastroccult® test. It has been reported that cimetidine can cause false-positive results when gastric samples are tested with fecal occult blood tests. The Gastroccult® test is free from such effects at cimetidine concentrations as high as 12 micrograms/mL of gastric fluid.

b. **Ascorbic Acid**

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

Other factors that may cause false-positive results include antacids, iron, aspirin, or metal ions or plant peroxidases in food. The interference (false-positive) from plant peroxidases, such as guaiac in food, is free from such effects at cimetidine concentrations as high as 12 micrograms/mL of gastric fluid.

**BIBLIOGRAPHY**