

Product Instructions

Gastroccult®

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 therapy¹⁵. Standard fecal occult blood tests lose sensitivity at low pH and may be unsuitable for use with gastric samples⁴⁷.

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 gastroscopic examination or X-ray studies. (See LIMITATIONS OF PROCEDURE)

¹Tagamet is a trademark of SmithKline Beecham Corporation.

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 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.

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

Materials provided

- Gastroccult® Slides
- Gastroccult® Product Instructions

MATERIALS (Cont.)

Materials required but not provided

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

PRECAUTIONS

Slides

- For *In Vitro* Diagnostic Use.
- Protect slides from open air.
- Keep slide sealed inside special wrapper until ready to use. Gastroccult® slides present no hazard to the user.
- Do not use after the expiration date on the slide.

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.
- Gastroccult® Developer is an irritant. Avoid contact with skin. DO NOT USE IN EYES. Should contact occur, rinse promptly with water.
- Do not use after expiration date on the bottle.

NOTE: Because this test is visually read and requires color differentiation, it should not be interpreted by individuals who are color-blind or the visually impaired.

STORAGE AND STABILITY

- Do not refrigerate or freeze.
- Store box containing slides at controlled room temperature 15 to 30°C.
- Do not store slides and developer near 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.
- Protect from heat and light.

SPECIMEN COLLECTION AND HANDLING

A gastric aspirate obtained by nasogastric intubation or vomitus are appropriate samples for use with the Gastroccult® test. Sample may be applied by using applicators (sold separately), or by any other method whereby a drop of sample is applied to the reaction areas.

It is recommended that samples be tested immediately after collection. If this is not possible, the following procedure will yield satisfactory results:

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 immediately or up to 4 days after sample application; store at controlled room temperature 15 to 30°C.

Samples for blood testing may be stored, prior to application, in a clean sealed container (plastic or glass) for 24 hours at controlled room temperature 15 to 30°C, or 5 days refrigerated at 2 to 8°C.

TEST PROCEDURE

Important Note: This test requires only **Gastroccult® Developer (sold separately). DO NOT USE HEMOCCULT® DEVELOPER OR ANY OTHER DEVELOPING SOLUTION.**

- Open slide.
- Apply one drop of gastric sample to pH test circle and one drop to occult blood test area.
- Determine pH of sample by visual comparison of test area to pH color comparator. This must be done within 30 seconds after sample application.
- 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.

TEST PROCEDURE (Cont.)

- 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.
- Add one (1) 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.

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

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.

QUALITY CONTROL

The function and stability of the guaiac paper and developer can be tested using the on-slide Performance Monitor® feature located to the right of the occult blood test area. The positive Performance Monitor® area contains a hemoglobin-derived catalyst which, upon application of developer, will turn blue within 10 seconds. The color will remain stable for at least 60 seconds.

The negative Performance Monitor® area contains no such catalyst and should not turn blue upon application of developer.

The Performance Monitor® feature provides additional assurance that the guaiac-treated paper and developer are functional.

In the unlikely event that the Performance Monitor® areas do not react as expected after application of developer, the occult blood test results should be regarded as invalid. Should this occur, call 800-877-6242 or 650-845-3526 for assistance.

Quality Control of the pH test portion of the Gastroccult® slide may be performed using buffered referenced standards, standardized against National Institute of Standards and Technology. Two levels of such standards, for example, a neutral pH (pH7) and an acid pH (pH 2 to 4) are recommended.

LIMITATIONS OF THE PROCEDURE

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.

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^{15,48}.

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.

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 intubation⁶. 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.

Frequency Distribution			
Hb level (µg/mL)	Number of Samples	Number of Positive Samples	Percent Positive Samples
0-<25	127	15	11.8
25-<50	9	7	77.8
50-<200	14	14	100.0
200-320	3	3	100.0
Totals	153	39	

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.

Rosenthal et al⁷ conducted a study using gastric fluid from 4 healthy patients. The authors compared reactions obtained with the Gastroccult® test to three other methods for determining occult blood. The results are summarized in the following table.

	Effect of pH on Normal Samples			
	A	Sample B	C	D
pH	3.6	2.5	2	1.9
Hematest*	-	+	+	-
Bill-Labstix*	-	+	+	-
Hemoccult®	-	-	-	-
Gastroccult®	-	-	-	-

In the same study, blood in various concentrations was added to normal gastric samples and tested by the same methods listed above. The results are summarized in the following table.

	Occult Blood Detection in Samples of Gastric Fluid (pH<3) Added Blood (µL blood/dL)							
	20	50	100	200	500	1000	2000	4000
Hematest	+	+	+	+	+	+	+	+
Bill-Labstix	+	+	+	+	+	+	+	+
Hemoccult®	-	-	-	-	-	-	-	-
Gastroccult®	-	-	-	+	+	+	+	+

*Hematest and Bill-Labstix are trademarks of Ames Division, Miles Laboratories.

PERFORMANCE CHARACTERISTICS⁸

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:

Gastroccult [®] pH Value	Average pH Meter Value	Range
1	1.2	0.8-1.7
2	1.9	1.6-2.7
3	2.6	2.1-3.1
4	3.7	2.2-4.4
5-7	5.7	3.4-7.5
7+	7.7	7.1-8.5

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 now used to detect blood in gastric samples are guaiac slide-type products 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^{9-13,14}.

1. Sensitivity

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 microliters (µL) of blood per deciliter (dL) of gastric fluid based on the hemoglobin content in blood of normal adults⁹. However, positive test results may be seen with some specimens containing less than 50 micrograms hemoglobin/ mL (see EXPECTED RESULTS).

2. Precision and Reproducibility

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

Gastric fluid samples, spiked with added blood to contain 50 micrograms hemoglobin/mL at pH 1, 3 and 7, were tested 10 different times on the same day of addition, and always produced positive test results. Gastric fluid samples containing no detectable hemoglobin at pH 1, 3 and 7, were tested 10 different times on the same day and always produced negative test results.

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.

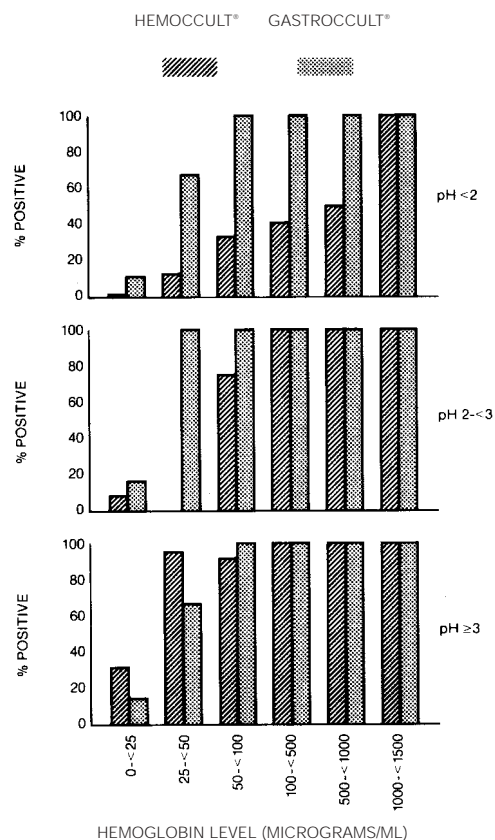
In general, there was close agreement of Gastroccult[®] results with Hemoccult[®] results when the pH was >3 and the hemoglobin concentration was greater than 50 micrograms/mL. The major differences in results were observed when the pH was less than 2 and hemoglobin level less than 1000 micrograms/mL. The positive test rate for hemoglobin levels 50 to 1000 micrograms/mL, pH<2, was 33-50% for the Hemoccult[®] test compared to 100% for the Gastroccult[®] test. At low 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[®] test¹⁵. It has been reported that cimetidine can cause false-positive results when gastric samples are tested with fecal occult blood tests^{12,13}. The Gastroccult[®] test is free from such effects at cimetidine concentrations as high as 12 milligrams/mL of gastric fluid.

**FIGURE 1
SENSITIVITY CORRELATION:
HEMOCCULT[®] VS. GASTROCCULT[®] TEST**



b. Peroxidase

The interference (false-positive) from plant peroxidases, such as horseradish peroxidase (HRP), is reduced with the Gastroccult[®] test. The peroxidase activity in 25 microliters of gastric fluid, pH 3, containing 0.2 units HRP/mL is inhibited when tested with Gastroccult[®].

c. Iron and Copper Salts

Concentrations of up to 0.02M of either iron or copper salts will not interfere with the Gastroccult[®] test. Therapeutic doses of iron or copper should never exceed this concentration.

5. Interfering Substances

a. Antacids

It is unlikely that there will be any inhibition of the occult blood test by antacids if gastric samples are tested no sooner than 60 minutes after last antacid administration and stomach irrigation. The following chart shows the antacid concentrations that would need to be reached in the gastric sample in order to significantly inhibit the detection of 600 micrograms hemoglobin/mL:

Antacid	Concentration In gastric fluids (mL/dL)
Mylanta [*] II	>2
Maalox ^{**} Plus	>5
Alternagel [*]	>10
Riopan ^{***} Plus	>10

Antacid products containing magnesium hydroxide (e.g., Mylanta II and Maalox Plus) exhibit the most inhibitory effect on the test.

b. Ascorbic Acid

Ascorbic acid (vitamin C) has been shown to cause false-negative test results for occult blood^{14,16}. This may also occur with the Gastroccult[®] test.

- * Mylanta and Alternagel are trademarks of Stuart Pharmaceuticals.
- ** Maalox is a trademark of William H. Rorer, Inc.
- *** Riopan is a trademark of Ayerst Laboratories.

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PRODUCT INFORMATION

Product Name	Product No.
Gastroccult[®] Test Kit • Box of 40 tests	66040
Gastroccult[®] Developer • Six 15 mL bottles	66115
Applicators • Bag of 40 applicators	66140
CLIA Category	Waived

For technical assistance call Technical Marketing at 800-877-6242 or 650-845-3526 or e-mail askpcd@beckman.com.

To order product contact your medical supply distributor.

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