MICRO.KIT.10.0 GASTRIC OCCULT BLOOD WITH PH

PRINCIPLE

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. The pH may be useful in evaluating antacid therapy.

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. 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. Most guaiac-based products designed for use with fecal specimens are affected by these interferences, 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.

OWNERS

Supervisor, Regional Microbiology

SPECIMEN

Either gastric aspirate obtained by nasogastric intubation or vomitus is an appropriate sample for use with the Gastroccult test.

No special patient preparation is necessary. Sample applied to the occult blood test area may be developed immediately or within four days.

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 result does not always indicate the presence of human blood.

REAGENTS

The kit contains:

A. Standardized high-quality filter paper treated with natural guaiac resin and dyes sensitive to hydrogen ion concentration. Paper is packaged into easy-to-use, cardboard slides for convenience. Do not use after expiration date which appears on each slide.

B. 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. The Developer is ready to use. Do not refrigerate or freeze. Store at controlled room temperature (15-30^{o}C) in original packaging. Protect from heat and light. Do not store with volatile chemicals (e.g., iodine, chlorine, bromine, or ammonia). Do not use after expiration date on bottle.

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

EQUIPMENT

A. Gastroccult Slides
B. Gastroccult Developer
C. Applicators
D. Watch with second hand or timer
E. Gloves

CALIBRATION

Not applicable

QUALITY CONTROL

A. Performance Monitor:
The function and stability of the slides and developer can be tested using the on-slide Performance Monitor feature. The positive and negative areas are located under the sample windows on the developing side of the slides.

B. The positive Performance Monitor area contains a hemoglobin-derived catalyst which will turn blue within 10 seconds after applying developer. The negative Performance Monitor area contains no such catalyst and should not turn blue after applying developer.

C. If the Performance Monitor areas do not react as expected after applying developer, the test results should be regarded as invalid. Let the supervisor or lead tech know of the quality control failure.

PROCEDURE

IMPORTANT NOTE: This test requires Gastroccult Developer, which is provided as part of this product. DO NOT USE HEMOCCULT DEVELOPER OR ANY OTHER DEVELOPING SOLUTION.

A. Log specimen on the Occult Blood log using the aliquot label.

B. Open slide.

C. Apply one drop of gastric sample to pH test circle and one drop to occult blood test area.

D. Determine pH of sample by visual comparison of test area to pH color comparator. This must be done within 30 seconds after sample application.

E. Apply two (2) drops of Gastroccult Developer directly over the sample and one (1) drop between the positive and negative Performance Monitor areas.

IMPORTANT NOTE: Occasional 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 Developer is added.

F. Read occult blood results within 60 seconds. The development of any blue color in the occult blood test area is regarded as a positive result.

G. Interpret the Performance Monitor results. A blue color will appear in the positive Performance Monitor area within 10 seconds and the color will remain stable for at least 60 seconds. No blue should appear in the negative Performance Monitor area when Developer is added.

NOTES: If the sample is applied in such a way that it contacts the Performance Monitor areas, the negative side 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. Any trace of blue indicates a positive test for occult blood.

CALCULATIONS
Not applicable

EXPECTED VALUES
Occult Blood: Negative -- no blue color
Gastric pH: Not defined

INTERPRETATION
The test will reliably detect hemoglobin levels equal to or greater than 50 micrograms/ml in gastric juice at pH 1 through 9. It is expected that gastric aspirates from some normal individuals may give positive test results. 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.

REPORTING RESULTS

A. Record the patient and quality control result on the log sheet along with the initials of the person who performed the test.

If	Misys	QLS
Negative	1. Function: MEM 2. Worksheet: Site specific 3. Test: OBGST 4. OBGAS :enter "NEG" 5. OBPH :enter one of the following values or ranges: 1 2 3 4 5-7 7+ 6. Accept: A	3,3,1 Allow release – Y Worklist – Site specific Accession – Enter OBGAS – NEGATIVE OBPH – enter one of the following values or ranges: 1 2 3 4 5-7 7+
Positive	1. Function: MEM 2. Worksheet: Site specific 3. Test: OBGST 4. OBGAS :enter "POS" 5. OBPH :see above 6. Accept: A	3,3,1 Allow release – Y Worklist – Site specific Accession – Enter OBGAS – POSITIVE OBPH– see above

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. Gastroccult tests are designed for preliminary screening as an aid to diagnosis, and are not intended to replace other diagnostic procedures.

REFERENCE

A. Product Instructions, Gastroccult, SmithKline Diagnostics, Inc., 1996