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Owner	Jeanna Begay
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Gastroccult® Test for Gastric Occult Blood and pH

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 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 are usually unsuitable for use with gastric samples.

The Gastroccult test is not recommended for use with fecal samples.

The test is performed by the Emergency Room Providers and/or POC Waived Testing staff or submitted to the laboratory to be performed by the Laboratory staff.

This test is designated as a CLIA Waived test.

POLICY

1. Only nursing and medical staff who have had documented and demonstrated competency assessment for the point of care testing locations will perform Gastric Occult Blood and pH testing.
2. Gastric Occult Blood Testing is for screening purposes only.

SUMMARY 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 the Gastroccult developer causes a peroxidase-like reaction which turns the test paper blue if blood is present.

MATERIALS REQUIRED

- Gastroccult Slides
- Gastroccult Developer
- Gastroccult Product Instructions

PRECAUTIONS

Slides

1. For *In Vitro* Diagnostic Use.
2. Protect slides from open air.
3. Keep slides sealed inside special wrapper until ready to use.
4. Do not use after the expiration date on the slide.

Developer

1. Gastroccult Developer should be protected from heat and the bottle kept tightly capped when not in use. **It is flammable and subject to evaporation.**
2. Gastroccult Developer is an irritant. Avoid contact with skin. DO NOT USE IN EYES. Should contact occur, rinse promptly with water.
3. **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 colorblind or the visually impaired.

STORAGE & 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 slides and Developer from heat and light.

SPECIMEN COLLECTION & HANDLING

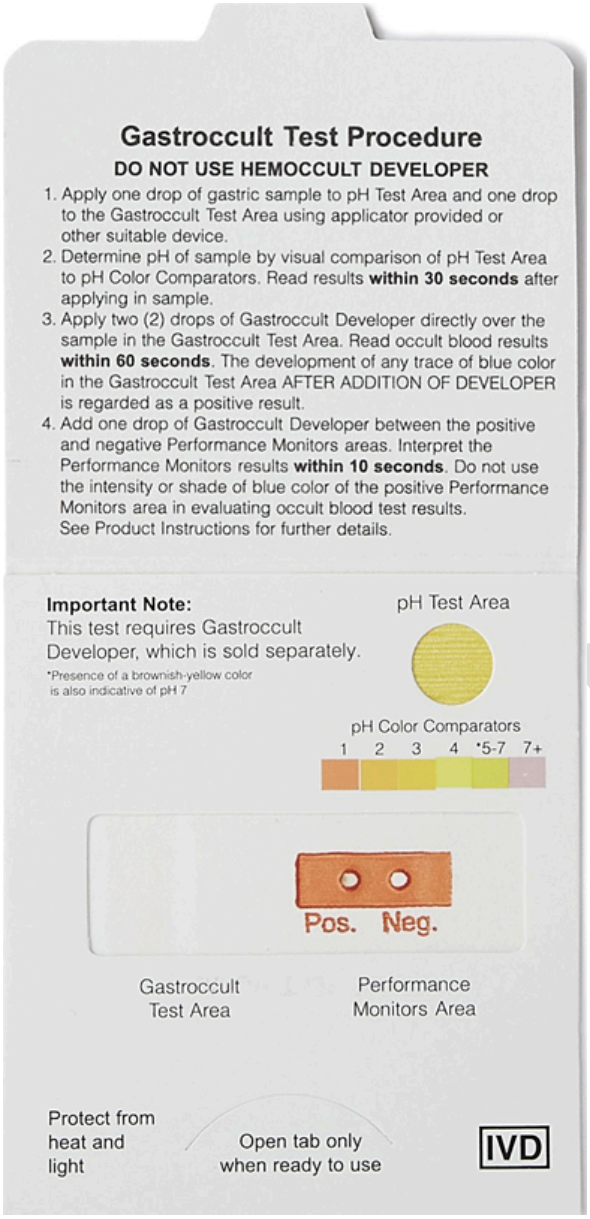
A gastric aspirate obtained by nasogastric intubation or vomitus are appropriate samples for use with the Gastroccult test. Sample may be applied by using applicators or by any other method whereby a drop of sample is applied to the reaction areas.

It is recommended that the 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 occult 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 (2 to 8°C).

TEST PROCEDURE



Important Note: This test requires only Gastroccult Developer.

1. Open slide.
2. Apply one drop of gastric sample to pH Test Area circle and one drop to Gastroccult Test Area.
3. Determine pH of sample by visual comparison of test area to pH Color Comparators. This must be done within 30 seconds after sample application.
4. Apply two (2) drops of Gastroccult Developer directly over the sample in the Gastroccult 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.

5. Read occult blood results within **60 seconds.** The development of any trace of blue color in the Gastroccult Test Area is regarded as a positive result. Record results on appropriate log.
6. Add one (1) drop of Gastroccult Developer between the positive and negative Performance Monitor Area. A blue color will appear in the positive Performance Monitor area within 10 seconds. The color will remain stable for at least 60 seconds.
7. Interpret the Performance Monitor results and record results on the *Gastric Occult Blood Patient Result Log*.

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

Internal Quality Control

The function and stability of the guaiac paper and developer is tested using the on-slide Performance Monitor feature located to the right of the occult blood test area. The Performance Monitor feature provides additional assurance that the guaiac-treated paper and developer are functional.

- 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.

In the 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, all 800-877-6242 for assistance.

External Quality Control

Quality Control of the pH test portion of the Gastroccult slide is performed by the laboratory bi-weekly using buffered referenced standards, standardized against National Institute of Standards and Technology. Two levels of such standards, a neutral pH (pH 7) and an acid pH (pH 2) are used.

INTERPRETATION OF RESULTS

1. **Positive Result:** Any trace of blue color in the Gastroccult Test Area. In addition to the positive and negative reaction in the Performance Monitor Area.
2. **Negative Result:** No blue color in the Gastroccult Test Area. In addition to the positive and negative reaction in the Performance Monitor Area.
3. **Invalid Result:** Any shade of blue appearing in the Performance Monitor areas should be ignored when reading the specimen test results.

REFERENCE RANGES

Negative

DOCUMENTATION OF PATIENT AND QUALITY CONTROL RESULTS

Results must be documented along with the initials of personnel performing the test and date test was performed. A functional audit trail must be maintained that allow retrieval of results.

1. POCT personnel performing the Gastroccult Test must document the interpreted patient results on the *Gastric Occult Blood Patient Result Log*.
2. Must document the results of the Performance Monitors (Internal QC). i.e. ("Acceptable" or "Invalid"). **Do not report patient results unless internal quality control is acceptable.**
3. Document date test was performed, clinical sign or symptom, provider, and two patient identifiers. The Card expiration date and Developer lot number and expiration date must be documented and entered into E.H.R.
4. Results must be entered into E.H.R. using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

LIMITATIONS OF THE PROCEDURE

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.

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.

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. There is a disagreement in the literature regarding the exact therapeutic significance of varying levels of upper gastrointestinal bleeding.

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.

PERFORMANCE CHARACTERISTICS

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. 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.

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 30-50 µL of blood per deciliter 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.

Specificity

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 milligrams/mL of gastric fluid.

The interference (false positive) from plant peroxidases, such as horseradish peroxidase, is reduced with the Gastroccult test.

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

Interfering Substances

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.

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

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

REFERENCES

Gastroccult® Product Instructions, ©2015 Beckman Coulter, Inc. March 2015.

Approval Signatures

Step Description	Approver	Date
Medical Officer Pathologist	Noelle Blue Arm: Medical Officer Pathologist	01/2023
Chief Nurse Executive	Rachel Hamblin: Chief Nurse Executive	01/2023
Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	01/2023
Medical Technologist	Jeanna Begay	01/2023
	Jeanna Begay	01/2023