HOUSTON Methodist WILLOWBROOK HOSPITAL

POC.004 GASTRIC OCCULT BLOOD AND pH SCREENING

Subject:
Gastric Occult Blood (Gastroccult) and pH Screening

Effective Date:
December 2000

Applies to:
Houston Methodist Willowbrook Hospital PPT

Date Revised/Reviewed:
01/29/2019

Originating Area:
Laboratory

Target Review Date:
01/29/2021

I. GENERAL STATEMENT

A. Houston Methodist Willowbrook Hospital will adhere to all national standards and evidence-based research when completing gastric occult blood and pH screening tests to ensure the accuracy and diagnostic value of results and to ensure patient safety.
B. A physician order is required for gastric occult blood testing.
C. A physician, M.D. or D.O. will perform this PPT (Provider Performed Testing) test which includes performing, reading of the negative and positive controls on each separate card, and recording the patient test and QC result in the patient chart.
D. Laboratory will be responsible for maintaining lot to lot comparisons and periodic review of patient charts.

II. TEST PRINCIPLE

Van Deen discovered the use of guaiac for detecting blood. In this test, alpha guaiaconic acid reacts with hydrogen peroxide in the presence of heme to produce a highly conjugated blue quinine compound.

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 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.

III. CLINICAL SIGNIFICANCE

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.

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, iron or copper salts. Also, interferences from plant peroxidases are significantly reduced.

IV. SAFETY

A. Gloves must be worn when performing this test.
B. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
C. The test device should be discarded in a proper biohazard container after testing.

V. SPECIMEN REQUIREMENTS

A. Specimen Type
    1. Gastric Aspirate obtained by nasogastric intubation
    2. Vomitus
B. Specimen Handling
    1. It is recommended that samples be tested immediately after collection. If this is not possible, the following procedure will yield satisfactory results:
    2. Apply the sample in the pH Test Area and Gastroocult® Test Area.
    3. Read the pH within 30 seconds after sample application.
    4. The Gastroccult® Test Area may be developed immediately or up to 4 days after sample application; store at controlled room temperature 15ºC - 30ºC.
    5. Samples for occult blood testing may be stored, prior to applications, in a clean sealed container (plastic or glass) for 24 hours at controlled room temperature 15ºC - 30ºC or 5 days refrigerated at 2ºC - 8ºC.
    6. The patient must be identified by name and date of birth (or medical record number as needed) on the identification band prior to specimen collection.
    7. Label the slide with the patient's name at the point of collection.

VI. REAGENTS

Manufacturer's instructions for reagent handling and storing will be followed.
If there are multiple components in a reagent kit, components may only be used within the same kit lot unless otherwise specified by the manufacturer.

A. Gastroccult® Slides
    1. For In Vitro Diagnostic Use.
    2. Protect slides from open air.
    3. Keep slide sealed inside special wrapper until ready to use. Gastroccult® slides present no hazard to the user.
    4. Do not use after the expiration date on the slide.
    5. Store slides at controlled room temperature 15 to 30ºC.
    6. 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.
B. Gastroccult® 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 and eyes. Should contact occur, rinse promptly with water.
    3. Do not use after expiration date on the bottle.

d. Store developer at controlled room temperature 15 to 30ºC.
3. pH Buffers.

VII. SUPPLIES

A. Applicator Sticks
B. Gloves
C. Biohazard waste container

VIII. TRAINING AND COMPETENCY

A. Gastroccult® testing is considered a PPT and will be performed by the patient's physician.
B. Physicians will demonstrate competency. Records are maintained in the laboratory.
C. Note: Because this test is visually read and requires color differentiation, it should not be interpreted by individuals who are color blind or by the visually impaired.

IX. PROCEDURE

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

A. Patient Testing
1. A physician order is required for gastric occult blood and pH testing.
2. The patient must be identified by name and date of birth (or medical record number as needed) on the identification band prior to specimen collection.
3. Label the slide with the patient's name at the point of collection.
4. Open slide.
5. Apply one drop of gastric sample to pH test circle and one drop to occult blood test area.
6. Determine pH of sample by visual comparison of test area to pH color comparator. This must be done within 30 seconds after sample application.
7. 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.
8. Read occult blood results within 60 seconds.
9. The development of any trace of blue color in the occult blood test area is regarded as a positive result.
10. Perform the Quality Control on the card (see below).

B. Quality Control
1. Add one (1) drop of Gastroccult® Developer between the positive and negative Performance Monitor® areas.
2. 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.
3. 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.
4. Any blue originating from the Performance Monitor® areas should be ignored when reading the specimen test results.
5. 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.

6. Verify the QC is acceptable before releasing patient results.
7. Dispose of test card, applicator sticks, and any other contaminated supplies or material in an appropriate biohazardous waste container.

C. Reporting Results
1. The positive Performance Monitor® area contains a hemoglobin-derived catalyst which, upon application of developer, will turn blue with 10 seconds. The color will remain stable for at least 60 seconds.
2. The negative Performance Monitor® area contains no such catalyst and should not turn blue upon application of developer.
3. 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, do not report the patient results, call the laboratory for assistance. The cards and developer must be returned to Laboratory if they have expired or if they fail the quality control check.
4. 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 (pH 7) and an acid pH (pH 2 to 4) are recommended. These studies will be performed in the lab with each new lot number of slides and developer.
5. Record the pH, the test results and quality control results ("Controls OK") in the progress notes of the chart, flowsheet and indicate the date, the time the test was performed and the initials of the person performing the test.
6. Expected result are negative for gastric occult blood.
7. Expected pH result is <4.0.

X. LIMITATIONS

A. Test results should be scrutinized in light of the patient's clinical condition. Any test result exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional diagnostic tests.
B. Laboratory staff is available 24/7 to assist with troubleshooting or other unusual situations.
C. Antacids and Ascorbic Acid may inhibit the detection of hemoglobin.
D. 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.
E. 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.

XI. AUTHORATATIVE REFERENCES

Gastroccult® Product Instructions, ©1982 Beckman Coulter, Inc., Version 461780.D, September 2001.

Revision History

Revison	Date	Changed by	Summary of Changes
1	April 2008	New Revision format October 24, 2016	• Updated to hospital format
2	May 19, 2009	New Revision format October 24, 2016	• Revised SOP based on updated package insert. Test Principle, Clinical Significance, Specimen Collection and Handling, Patient Preparation, Reagents, Testing Personnel, Calibration, Quality Control, Calculations, Reference Interval, Interpretation, Interfering Substances, and Limitations of Procedure were added to the SOP. The references were updated.
3	February 28, 2010	New Revision format October 24, 2016	• Reviewed and approved.
4	May 23, 2011	New Revision format October 24, 2016	• Reviewed and approved.
5	October 24, 2016	Anita Farr	• Updated logo and hospital name. • Revised Revision History table. • Revision also for recording QC.
	January 29, 2019	Tamika Simon	• No revisions. Require Med Director Policy Tech Approval.

APPROVAL AND REVIEW

PROCEDURE TITLE: POC.004.003 Gastric Occult Blood and pH Screening

DATE: April 2005

PREPARED BY: Nursing Policy

REVISED: ~~August 18, 2008~~ May 19, 2009 5/21/09

REVISED BY: Geri Williams

ACCEPTED BY: Hazel L. Awalt M.D.
Medical Director

DATE: 5-26-09

SUPERSEDES METHOD DATED: April 2005

DIRECTOR or DESIGNEE REVIEW

SIGNATURE	√ TITLE	√ REASON	DATE
	Medical Director: ____ Designee:_____	Annual:_____ Other:_____	
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	Medical Director: ____ Designee:_____	Annual:_____ Other:_____	
	Medical Director: ____ Designee:_____	Annual:_____ Other:_____	
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