Routine screening test for gastric occult blood and pH.

The Point of Care Testing (POCT) program at Vanderbilt University Medical Center (VUMC) is overseen and coordinated by the POCT Steering Committee as chartered by the Medical Center Medical board. The POCT Steering Committee administers the program with the primary goal of meeting clinical needs in the most cost-efficient manner possible. In order to provide for both regulatory compliance and appropriate utilization of POCT, any clinical area wishing to perform POCT must be approved by the POCT Steering Committee and must maintain acceptable performance according to criteria set forth in Hospital Policy 20-23.

I. PRINCIPLE:

The Gastroccult test for blood is based on the reaction of alpha guaiaconic acid with hydrogen peroxide in the presence of heme to produce a highly conjugated blue quinone compound.

The Gastroccult pH test is based on changes in the color of dyes due to changes in hydrogen ion concentration.

II. PURPOSE:

Gastroccult is a qualitative screening method for detecting the presence of occult blood and determining the pH of gastric aspirate or vomitus. Results cannot be considered conclusive evidence of presence or absence of gastrointestinal bleeding or pathology.

III. SCOPE OF PRACTICE:

Gastric occult blood and pH testing may be performed by RN's, LPN's, Patient Care Partners/Technicians, OR Technicians, and Nursing Externs working in areas/units approved by the POCT Steering Committee to perform point of care gastric occult blood and pH testing. To maintain this privilege, testing must be performed in accordance with VUMC hospital POCT policy. All staff performing testing must attend POCT orientation, annual retraining, reading testing procedure at least annually, and follow established testing protocol.

IV. SPECIMEN COLLECTION:

A. Conditions for Patient Preparation

1. See manufacturer insert for patient preparation and collection procedures.
VANDERBILT UNIVERSITY MEDICAL CENTER
POINT OF CARE TESTING
GASTROCCULT (Gastric occult blood and pH Test)
PROCEDURE

B. Specimen Type

1. Small volumes (several drops) are adequate for testing.
2. Gastric aspirate obtained by nasogastric intubation or vomitus are appropriate samples.
3. Fecal specimens are not recommended.

C. Handling Conditions

1. Sample can be applied using available applicators, or by any method of applying one drop to both the occult blood and pH reaction sites.
2. Samples must be tested for pH immediately after collection.
3. The Gastroccult blood test area may be developed immediately or up to 4 days after sample application; store at controlled room temperature 15-30°C.
4. Samples for blood testing may be stored, prior to application, in a clean sealed container for 24 hours at controlled room temperature 15-30 °C, or 5 days refrigerated at 2-8 ºC.

V. REAGENTS AND SUPPLIES:

1. Beckman Coulter Gastroccult slides (test cards) containing guaiac paper
2. Beckman Coulter Gastroccult developer (stabilized aqueous solution. <2.9% hydrogen peroxide, <33% denatured ethanol in citrate buffer)

VI. REAGENT STORAGE AND STABILITY:

1. Store slides (test cards) at controlled room temperature 15° - 30°C (59 to 86°F).
2. Do not refrigerate or freeze.
3. Protect slides and developer from excessive heat and light.
4. Slides must be sealed inside provided wrapper until ready for use. Protect from open air.
5. Do not store test cards or developer near volatile chemicals.
6. Gastroccult slides and developer, stored as recommended, are stable until printed expiration dates, if quality control (QC) is acceptable.
7. All reagents must be labeled with staff initials, and valid expiration date.

VII. CALIBRATION:

N/A
VIII. QUALITY CONTROL:

A. To test the function and stability of the guaiac paper and developer, a positive and negative occult blood Performance Monitor is built into each Gastroccult test card.

B. Both performance monitors must be developed with each patient test.

C. Quality control of the Gastroccult pH test is performed by licensed Medical Technologists in the POCT center (other medical staff do not test pH quality control when testing patient samples). Prior to use, the pH of two test cards from each box are tested with appropriate buffered reference standards, which have been standardized against National Institute of Standards and Technology. Test cards are tested with a neutral standard (pH=7), and an acid standard (pH=3) to confirm function and stability of pH testing of pH portions of test cards. Boxes of test cards determined unacceptable for use will not be distributed. All boxes approved for use are labeled with opened date, indication of acceptable Quality Control, and medical technologist ID. Do not use boxes of test cards lacking this information or bearing unacceptable expiration dates. Quality control documentation is maintained in the POCT Support Center.

IX. TESTING PROCEDURE:

➢ Observe standard precautions

1. Collect gastric sample.
2. Open slide.
3. Apply one drop of sample to slide pH test area.
4. Apply one drop of sample to slide occult blood test area.
5. Determine pH of sample within 30 seconds, by visual comparison of test area to pH color comparator on the slide.
6. Apply two drops of Gastroccult Developer directly over sample in occult blood test area. Interpret result within 60 seconds.
7. Add one drop of Gastroccult Developer between the positive and negative Performance Monitor areas.
8. Interpret results within 10 seconds. If the slide and developer are functional, blue color will appear in the positive area, and the negative area will remain colorless.
9. If the Performance Monitor areas do not react as expected after applying the developer, regard patient results as invalid. Follow the corrective action steps outlined below:
Corrective Action:

1. Check expiration date of Gastroccult test cards and developer used.
2. If supplies not expired, retest patient sample with a different test card from the kit.
3. If needed, retest patient sample with test card and developer from a different box of Gastroccult supplies. If Performance Monitors yield expected results with test card from the second box of supplies, discontinue use of test cards and developer from the original box. Notify POCT Support Center at phone # 3-5707 for pick-up of bad supplies.
4. If still unable to obtain expected results send patient sample to laboratory and notify POCT Support Center at phone # 3-5707.

X. RESULTS:

A. The pH value of the gastric sample is interpreted as the closest color match to a numerical value within the comparator range.
B. Blue color formed after Gastroccult developer is applied to the occult blood test area indicates the presence of blood in the sample and should be reported as “Positive”.
C. 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.
D. pH test results are reported/recorded in whole numbers of 1 through 7+.
E. Occult blood test results are reported/recorded as “Positive” or “Negative” for gastric occult blood.

XI. DOCUMENTATION:

A. The following information is required to be documented with patient results in the permanent medical record:
   1. Date and Time of patient testing
   2. Test card lot number and expiration date
   3. Developer lot number and expiration date
   4. Results of occult blood positive and negative performance monitor
   5. Identification of staff performing testing.

B. The POCT Support Center maintains Gastroccult pH quality control documentation.
XII. QUALITY ASSESSMENT:

The manager or designee has oversight of the following requirements:

- All POCT performed in patient care areas has been approved by the Diagnostic Laboratories and the State of Tennessee.
- Testing is performed only by staff approved by the Diagnostic Laboratories and the State of Tennessee.
- All staff are trained prior to testing, and assessed for competency annually.
- Individuals responsible for staff training and/or compliance review, (quality control and patient documentation), have attended appropriate training sessions provided by the POCT Support Center.
- Initial training records, current annual competency records and “designated” trainer records must be accessible.
- Notification to the POCT Support Center of any changes or transfer of testing personnel.
- Current testing procedures and accessible to all testing staff.
- Quality control and maintenance procedures are performed, documented and reviewed for compliance by the manager or designee at least weekly, and are accessible for two years following review. Any corrective action is noted, and filed with records.
- Routine review of random patient medical records by manager or designee to verify compliance with patient test result documentation as described in testing procedures. Examples must be available for inspections.
- All testing supplies are stored and labeled according to instructions found in individual testing procedures.
- CAP proficiency testing, as required, is performed according to accompanying instructions and results and requested information returned to the POCT Support Center within specified time frame.

Diagnostic Laboratories POCT Support Center Provides:

- Technical support
- Training
- Content of training materials and testing procedures
- Validation and implementation of testing methodologies
- Assistance with request for testing privileges

The POCT Steering Committee is chartered by the VUMC Medical Board and has the authority to revoke testing privileges.
XIII. PROCEDURE NOTES:

1. 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.
2. Any blue originating from the Performance Monitor areas should be ignored when reading the specimen test results.
3. Neither the intensity nor the shade of the blue from the positive Performance Monitor area should be used as reference for the appearance of positive test results.
4. DO NOT use Gastroccult slides or developer to test for fecal occult blood.
5. DO NOT use Hemoccult slides or developer to test for gastric occult blood.
6. If Gastric occult blood/ph testing is not available due to lack of supplies, untrained staff, or any other problem that prevents accurate testing, alternative hospital laboratory testing must be done.

XIV. SAFETY:

- Observe standard precautions.
- Treat all patient specimens as potentially infectious and dispose of with proper precautions.
- Developer is an irritant. Avoid contact with skin and eyes.
- Developer is flammable and subject to evaporation.
- For In Vitro Diagnostic Use.

XV. LIMITATIONS:

1. This test is read visually and requires color differentiation. It should not be interpreted by staff with blue color blindness.
2. These test slides are designed as an aid to diagnosis and are not intended to replace other diagnostic procedures.
3. The Gastroccult test cannot be used to test for fecal occult blood.
4. The results of the Gastroccult test cannot be considered conclusive evidence of the presence or absence of upper gastrointestinal bleeding or pathology.
5. Interfering Substances: Incompletely cooked red meat and some raw vegetables may cause a false positive; Antacid products and Ascorbic acid (Vitamin C) may cause a false negative.

REFERENCES:

2. VUMC POCT Support Center.
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