Keywords: amniotic, NitraTest, nitrazine, pH, vaginal secretion

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I. PURPOSE

This procedure provides instructions for performing pH Nitrazine testing at the point of care. pHizatest® Paper is used as a semi-quantitative screening test at the point of care to rapidly determine the pH of vaginal secretions within the range of pH 4.5 - 7.5.

II. ORDER

A physician’s order, standard protocol, or order by another health professional authorized to request laboratory tests is required for point of care pH Nitrazine testing.
III. MATERIALS

<table>
<thead>
<tr>
<th>Reagents/Controls</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>pHizatest® Paper</td>
<td>McKesson Item #835415</td>
</tr>
<tr>
<td>pH Buffer 5.0</td>
<td>POCT Office</td>
</tr>
<tr>
<td>pH Buffer 7.0</td>
<td>POCT Office</td>
</tr>
</tbody>
</table>

Additional Supplies
- Disposable Gloves
- JHMI "Date Opened" Labels: Standard Register #0509N
- JHMI-approved Biohazard Waste Container

IV. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>pHizatest® Paper</td>
<td>Room Temperature (15-30°C)</td>
<td>Unopened: Manufacturer's expiration date. Opened: 6 months, or manufacturer's expiration date, whichever comes first.</td>
</tr>
<tr>
<td>pH 5.0</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>pH 7.0</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
</tbody>
</table>

A. The pHizatest® Paper dispenser roll and pH Buffer aliquots must be labeled with the open date and expiration date, as referenced above.
   1. Note: It is recommended to label the dispenser roll, in case it is separated from the box.
B. Never use pHizatest® Paper or pH Buffers past the manufacturer's expiration date.
C. Protect the pHizatest® Paper from exposure to the following:
   1. Direct sunlight.
   2. Acid or alkaline fumes.
D. Keep the pH Buffer aliquots tightly capped when not in use.

V. SPECIMEN TYPE

The preferred sample for testing is vaginal secretions.

VI. SPECIMEN COLLECTION AND HANDLING

Prior to specimen collection, patient identification must be verified using two unique identifiers.

A. If the patient specimen was placed in a collection container, rather than being directly introduced to the pHizatest® Paper, the container must be labeled with at least two patient identifiers in front of the patient (e.g. Name, DOB, MRN, and/or CSN).
   1. Note: All labeling must be done on the cup instead of the lid as applicable, which may become separated from the specimen.
It is recommended that all samples be tested immediately following collection.

VII. SAFETY PRECAUTIONS
A. Follow ICPM IFC023 Infection Control and Prevention: Standard and Isolation Precautions.
B. Wear gloves at all times when handling the pHizatest® Paper.
C. Avoid unnecessary exposure to pH buffer solutions. Wash areas of contact with water immediately.
D. All patient specimens, used pH paper, and gloves must be discarded in the appropriate JHMI-approved biohazard container or waste receptacle.

VIII. PERFORMING QUALITY CONTROL (QC) TESTS
A. Two levels of External Quality Control, pH 5.0 and pH 7.0, will be performed:
   1. At least once per week on each opened container of pHizatest® Paper and bottle of pH buffer solution.
   2. When opening a new container of pHizatest® Paper or bottle of pH buffer solution.
   3. When patient results are questionable.
   4. By all new operators as part of initial hands-on training prior to testing patient specimens.
   5. At least once a year by each operator to demonstrate compliance with ongoing competency regulations.
B. Procedure:
   1. Prepare materials for testing:
      a. Put on gloves.
      b. Verify that pH buffers and pHizatest® Paper are dated and within the manufacturer's expiration date.
      c. If the end of the pH paper is discolored, discard.
      d. Tear off two lengths of pHizatest® Paper and place on an absorbent surface covering (i.e. chucks, paper towel, etc).
   2. Perform the test:
      a. Record the applicable information on the pH Nitrazine QC Log Sheet (see Appendix A).
      b. Mix the pH buffers gently by inversion, then uncap and dispense one drop of pH buffer solution onto one length of pH paper for pH 5.0, and one length of pH paper for pH 7.0.
      c. Immediately match the color on the pH paper with the closest color on the Color Chart in the pHizatest® Paper dispenser.
         i. Note: Colors are unstable and results must be interpreted within 60 seconds.
      d. Record the actual number value of the pH test results on the pH Nitrazine QC Log Sheet.
      e. Discard the used pH paper into a JHMI-approved biohazard waste container.
      f. Both levels of QC must pass before patient testing can be performed.
C. Corrective Action:
   1. If any QC test fails to give the expected results:
      a. Verify pHizatest® Paper and pH Buffer Solution aliquots are within the expiration date and that they have been properly stored.
         i. NOTE: Reminder that pHizatest® Paper has a 6-month open stability, and must be dated appropriately and discarded after 6 months.
      b. Ensure proper technique is being used, repeating testing with the same materials.
      c. If QC fails a second time, open and date a new bottle of pH Buffer solution. Repeat test.
      d. If QC fails a third time, open and date a new container of pHizatest® Paper. Repeat test.
      e. If QC fails with the new pHizatest® Paper and pH Buffer solution(s), DO NOT PERFORM ANY PATIENT TESTING. Contact the POCT Office (5-2645), by emailing POCTGroup@exchange.johnshopkins.edu, or by sending a CORUS message to “POCT Consult” if this is a critical issue after-hours that cannot wait until the next business day.
   2. Note any QC failures and corrective actions in the Comment Section of the pH Nitrazine QC Log Sheet.
IX. PATIENT TEST PROCEDURE

A. Prepare for the test:
   1. Confirm pHizatest® Paper is not expired and that QC testing has been performed successfully and documented within the last week. If not, QC must be completed prior to patient testing. Refer to Performing Quality Control (QC) Tests.
   2. Put on gloves.
   3. Confirm patient identity per unit policy, and proper specimen labeling, as applicable.
   4. Tear off a length of Nitrazine pH paper from the dispenser.

B. Perform the patient test:
   1. Bring the strip of pH paper into contact with the specimen, either by dipping the paper into the pool of suspected amniotic fluid or by touching the paper to the exam speculum.
   2. Within 60 seconds, match the color of the pH paper to the closest color on the Color Chart supplied with the pHizatest® Paper dispenser.
   3. If a computer is not in the same room as that in which patient testing is performed, complete the pH Nitrazine Patient Result Log (see Appendix B). If a computer is available in the same room as testing, immediately result the test in the patient's electronic medical record.
   4. Discard the used Nitrazine pH paper and consumables into a JHMI-approved biohazard receptacle.

X. EXPECTED RESULTS

pH values within the range of 3.8 to 4.5 are considered indicative of vaginal fluid, whereas pH values within the range of 7.0 to 7.5 are indicative of amniotic fluid.

XI. RESULTS INTERPRETATION

The pHizatest® Paper covers a pH range of 4.5 to 7.5, with a sensitivity of 0.5. Each container includes a Color Chart that must be utilized within 60 seconds after application of sample to the pH paper to determine the pH value of the specimen. The pH paper color that most closely matches the Color Chart is the reported pH value of the specimen.

Note: All test results should be considered in relation to a specific patient's condition and therapy; inconsistent results should be repeated or supplemented with additional test(s), per unit policy.

XII. RESULTS REPORTING

All patient test results must be manually documented on the pH Nitrazine Patient Result Log (see Appendix B) if there is not a computer in the room where testing is performed. This log must then be used to ensure results are properly documented in Epic using manual entry. If there is a computer in the testing room, patient result entry must occur immediately following the completion of testing.

A. Each of the fields must be filled out completely when completing the pH Nitrazine Patient Result Log.
   1. Record the patient’s pH value exactly as it appears on the color chart of the pHizatest® Paper dispenser used for testing.

B. Refer to unit policies and procedures for the steps to document pH Nitrazine values on the appropriate flowchart.
   1. Documentation of POC QC Completion must be included with each patient result recorded in the EMR.

In the event of an Epic downtime, all patient results must be recorded on the pH Nitrazine Patient Result Log until the downtime is over, at which time all patient results must be manually entered in Epic.
XIII. INTERFERENCES
A. Salt solutions and enzymes may cause deviations in pH Nitrazine results.
B. False positives may be seen in the presence of:
   1. Soap.
   2. A rise in pH due to infections such as trichomoniasis or bacterial vaginosis.
   3. Blood, semen, and/or cervical mucus.
C. False negatives may be seen with:
   1. Too little fluid analyzed.
   2. Prolonged leaking of fluid.

XIV. LIMITATIONS
A. NitraTest™ Paper is not to be used for pH determinations of urine and/or gastric fluid.
B. The accuracy of NitraTest™ Paper is affected by salts, proteins, and other factors, as indicated in the Interferences section. Deviations may, under certain conditions, exceed 0.5 pH units.
C. Do not touch the NitraTest™ Paper with bare fingers. Gloves must be worn at all times when completing testing - QC and patient.
D. The color of undeveloped pHizatest® Paper may vary from lot to lot, from tan to olive green.
   1. NOTE: Color variation does not affect the paper’s response to pH changes, or the accuracy of the pH reading.
E. The Color Chart may vary slightly from lot to lot. As such, only the Color Chart accompanying each specific box of pHizatest® Paper should be used for result interpretation.
   1. NOTE: If the Color Chart is missing, discard the container and open a new box of pHizatest® Paper. The open date must be recorded and QC completed and documented prior to use on patient specimens.
F. Avoid color comparison under fluorescent lights alone. For greatest accuracy, color comparisons should be done in a combination of fluorescent light and daylight.

XV. OPERATOR TRAINING
A. Testing may only be performed by currently certified staff members who have been trained by a Point of Care Coordinator, Nurse Educator, or designated unit trainer. Training records must be kept in the employee's personnel file, and a copy sent to the Point of Care Testing Office.
B. Initial Training will include:
   1. Review the policy online.
   2. Completion of the Initial Training and Competency Assessment (see Appendix C), to be kept in the employee's personnel file.
   3. Successful performance and documentation of quality control (pH 5.0 and pH 7.0).
   4. Passing score on the quiz following the MyLearning module.
C. All of the above must be completed prior to any patient testing.

XVI. OPERATOR COMPETENCY
In order to maintain competency, operators must successfully complete and document both levels of quality control and the MyLearning module and quiz at least once a year. The competency calendar follows the fiscal year: July 1 - June 30. Any testing personnel who fails to meet these competency requirements will no longer be eligible to perform patient testing, and will require retraining should they wish to be reinstated.
XVII. REFERENCES

XVIII. SIGNATURE

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>William Clarke</td>
<td>06/28/2021</td>
</tr>
<tr>
<td>Medical Director</td>
<td></td>
</tr>
<tr>
<td>Andrew Satin</td>
<td>06/28/2021</td>
</tr>
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