Title: Phenazine pH Procedure

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Updated by: Nancy Toscano MT (ASCP) Date: 09/12/11
Purpose

This document outlines policies and procedures that refer to pH testing. In an effort to be concise some information may be excluded from the manufacturer’s recommended procedure. It is recommended that operators familiarize themselves with the manufacturer’s product information that accompanies each package and their manual if one exists.

Scope

Level of Personnel: All Advanced Practice Nurses, Nurse Practitioners, Certified Nurse Midwives, RN’s and MD’s who have successfully completed initial training and maintained annual competency.

Testing Site: Sites approved and on file with the Pathology service’s POCT Division.

Policy and Procedure Statement

PH paper is used by providers to determine the pH of vaginal secretions.

Principle

In the GYN setting, Ph paper is used by clinical providers to aid in the diagnosis of bacterial vaginosis (BV). The diagnosis of vaginosis requires 1) the assessment of clinical symptoms, 2) laboratory testing, including microscopic confirmation of the presence of clue cells, and 3) pH testing. The paper should turn blue in the presence of BV. ** The normal pH of vaginal secretions is 3.8-4.2; with BV the pH rises to greater than 4.5.

In the OB setting, vaginal pH measurement is used by providers to help rule out the presence of amniotic fluid when there is a question of ruptured membranes. The pH paper will turn deep blue in the presence of amniotic fluid**. The Fern Test and observation of pooling of fluid in the vagina are two methods used in conjunction with pH testing to determine the presence of amniotic fluid.

**see Limitations/Interferences

Regulatory Requirements

1. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

2. All test results must be maintained in patient records with all required information for four years

   Required information:
   1. Patient’s name
   2. Medical Record Number
   3. Patient’s gender
   4. Patient’s age or date of birth
   5. Date & time test collected, performed and reported
   6. Ordering Physician
   7. Responsible physician (if not 6)
   8. Reference or Target Range
   9. Test Performed
   10. Test units, if applicable
   11. Lab name
3. Additional information that must be retained for four years:
   1. Testing personnel records
   2. Quality control results
   3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on
      quality control and any remedial action
   4. QC charts, maintenance sheets, reference and critical ranges

4. Other
   1. Universal precautions must be observed when handling any patient specimen.
   2. A physician's order or standing order is required prior to performing test.

**Limitations/Interferences**

1. A pH screening test is highly sensitive but not very specific.
2. Color variation from tan to light olive green of the base paper will not interfere with accurate
   readings.
3. False positive results may occur from specimen contamination due to heavy vaginal discharge,
   blood, cervical mucus, semen, alkaline urine, and soap.
4. The test should not be performed on visibly bloody fluid.

**Test Kit/Supplies/Equipment**

<table>
<thead>
<tr>
<th>Product</th>
<th>Vendor</th>
<th>Distributor</th>
<th>Manufacturer #</th>
<th>Vendor ID #</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accutest™ pH Paper</td>
<td>Fisher</td>
<td>Fisher</td>
<td>PF418</td>
<td>NC0629451</td>
<td>Single roll stored at room temp</td>
</tr>
<tr>
<td>pH Buffer 4.00</td>
<td>Fisher</td>
<td>Fisher</td>
<td>SB98-500</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH Buffer 7.40</td>
<td>Fisher</td>
<td>Fisher</td>
<td>SB110-500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reagent Storage**

1. Keep roll dispenser in the original box when not in use. Lot number and expiration date are printed
   on the box.
2. Store Accutest™ pH box at room temperature; avoid excessive heat; protect against exposure to
   acid or alkaline fumes.
3. Opened rolls are discarded after 6 months
4. Color variation from tan to light olive green of the base paper will not interfere with accurate
   readings.

**Quality Control**

The Accutest™ paper must be tested with 2 levels of Certified Buffer Solutions and the results recorded
on the QC Log Sheet (Appendix C). Quality Control (QC) is run every time a new roll of Accutest™ paper
is opened or if results are in question.

1. Tear off 2 pieces of Accutest™ paper.
2. Apply on drop of pH 4.0 buffer to strip of Accutest™ paper. Shake off excess fluid.
3. Immediately match the strip color with closest color on the dispenser chart.
4. Record all Accutest™ paper lot numbers, expiration dates and QC test results on the QC log sheet
   (appendix C).
5. Repeat steps 2-5 with pH 7.4 buffer.
6. If QC fails, repeat. If QC fails a second time do not use Accutest™ paper for patient testing.
   Contact the POCT Program Coordinators via pager: 35058 or email: mghpocctcoordinators
7. Write date of successful QC and initials on pH paper storage box.

**Specimen Collection**

Use a swab to collect vaginal secretions from the patient. The Accutest™ paper is not to have contact with the patient. Per hospital policy, patient must be identified using two identifiers.

**Test Procedure**

1. Practice hand hygiene and put on gloves.
2. Remove a strip of Accutest™ paper from the roll.
3. Collect a sample of vaginal secretions.
4. Apply secretion to Accutest™ pH paper.
5. Immediately match the strip color with closest color on the dispenser chart.
6. Discard used pH paper into trash receptacle.
7. Return roll of paper to box for storage.

**Results**

**Amniotic fluid determination:**
- **Negative test:** paper remains yellow to olive-green in color (pH 4.5-6.0).
- **Positive test:** paper turns blue green to deep blue in color (pH 6.5-7.5), suggesting the presence of amniotic fluid. **

**Bacterial vaginosis determination:**
- pH < 4.5: normal pH of vaginal secretions
- pH > 4.5: abnormal, suggestive of bacterial vaginosis **

** see Limitations/Interferences

**Documentation**

Results must be recorded in one of the following manners:

1. in the patients record,
2. on a patient log, or
3. on another approved permanent record.

All records must be retained and retrievable for 4 years.

**Training/Competency Assessment**

Competency is assessed after initial training and annually (within 365 days) using at least two of the following methods: (Appendix A)

1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user’s quality control performance is monitored.
4. Written testing specific to the method.

Operators who have not completed annual competency can not perform patient testing.
References

Decon Laboratories product instructions, 2011

Cross - References

Accutest™ Test Training and Competency Assessment Record
pH by Accutest™ QC Log Sheet