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Title: Point of Care - Point of Care -Vaginal pH Nitrazine Test		
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TITLE: Vaginal pH Nitrazine Test

Purpose: This procedure provides instructions to perform Vaginal pH Nitrazine testing. Nitrazine pH paper is used as a semi-quantitative screening test to rapidly determine the pH of vaginal secretions within the range of pH 4.5-7.5.

Principle: Nitrazine paper is used to identify changes in the normally acidic pH of the vagina (< 4.5).

Used in conjunction with the Fern Test, it can help detect ruptured fetal membranes by detecting small quantities of amniotic fluid in vaginal secretions. Premature rupture of the fetal membranes before onset of labor may lead to fetal infection and subsequent mortality. The risk is largely eliminated by the induction of labor.

Similarly, the vaginal pH can be used along with patient symptoms, physical examination, and microscopic wet-mount and potassium hydroxide preparation, to diagnose vaginitis. A pH of > 4.5 is frequently found in patients with bacterial vaginosis and trichomoniasis. *Candida* vaginitis is associated with a normal vaginal pH.

The Nitrazine paper is impregnated with an indicator dye Phenaphthazine. The dye gives a broad range of colors from yellow through blue. A negative test (i.e. normal vaginal pH) will show a yellow color corresponding to a pH of < 4.5. A positive test (i.e. abnormal vaginal pH) will be golden to deep blue corresponding to a pH > 4.5.

Specimen:

All body fluids should be handled as if capable of transmitting infectious diseases. Use universal precautions when in contact with such materials. Refer to Laboratory Infection Control Policy.

Patient preparation:

None

Specimen Requirement:

Vaginal secretions from the posterior vaginal pool collected according to clinical protocol.

Specimen Handling Conditions:

Do not touch the swab or pH paper to the mucus plug in the cervix.

Test sample immediately after collection.

Interferences:

• False-positive results may occur from specimen contamination due to heavy vaginal discharge, blood, cervical mucus, semen, alkaline urine and soap.

• For rupture of fetal membranes, false-negative results can be produced by prolonged rupture of fetal membranes (longer than 24 hours) or when only a small quantity of fluid has leaked.

• Do not use nitrazine paper if it is discolored. Discard and open new pH Nitrazine paper dispenser.

Reagents and Supplies:

Vaginal Nitrazine pH paper:

Unopened container is stable until manufacturer's expiration date printed on container.

Once opened, container is stable for 6 months.

Protect from direct light and keep at room temperature in dry area.

Protect against exposure to acid or alkaline fumes.

Color chart (included in container)

pH QC/calibrating reference standard buffer solutions:

Reference standard buffer solutions pH 5.0

Reference standard buffer solutions pH 7.0

*Both are stable at room temperature (18-30C), until the manufacturer's expiration date on the bottle.

Plastic pipettes

Logs for QC and Patient results (as applicable).

Quality Control:

Two (2) levels of QC (5.0 pH & 7.0 pH) are run every 30 days and when opening a new roll

• Gather the buffers, Nitrazine paper, and QC log sheet.

• Check that the buffer solutions and Nitrazine paper are not expired and have been stored at room temperature.

• Record the date, lot numbers and expiration dates of the pH buffer solutions and Nitrazine paper on the pH Nitrazine QC log sheet.

• Wearing clean gloves tear off pieces of pH Nitrazine paper of the desired length.

• Using a new plastic pipette for each buffer solution, apply a drop of pH 5.0 buffer to the Nitrazine paper.

**Do not dip paper into QC bottle.*

**Do not touch the tip of the pipette to the pH Nitrazine paper.*

**Once the buffer is dispensed onto the pH Nitrazine paper, discard pipet. DO NOT REUSE pipet.*

**Discard any unused buffered solution that might remain in the pipette. Do not return unused buffered solution to the bottle.*

• Immediately match the strip color with the closest color on the dispenser color chart. *Buffer pH result must match manufacturer's result.*

• Repeat steps for pH 7.0 buffer.

• Verify that all of the QC buffer results are within acceptable range by comparing the results obtained to the control range on the pH Nitrazine QC Log sheet.

• Place a √ in the QC Pass/ Fail box on the QC Log sheet to note whether QC passed or failed.

• Discard the used pH paper into an appropriate waste container.

QC Corrective Action:

• Check to make sure that the Nitrazine paper and pH buffers have not expired.

• Repeat test

• If repeat test fails, open a new container of pH paper, repeat test.

• If new container of pH paper fails, open new bottle of pH buffer solution and repeat the test.
• If the test fails with new buffers and Nitrazine paper, DO NOT PERFORM ANY PATIENT TESTING until the quality control issues are resolved and the expected results are obtained and recorded.
• Document all QC failures and repeat QC testing on QC log sheet.
• Contact Point of Care office for assistance (email pointofcare@crhc.org or ext. 4643 or 4645).

Patient Test Procedure:
• Tear off pieces of pH Nitrazine paper of the desired length.
• Touch the specimen to the Nitrazine paper.
Perform the pH Nitrazine before putting the vaginal sample on the glass slide for Ferning. This will prevent any contamination that may come from the glass slide.
• Immediately match the strip color with the closest color on the dispenser color chart.

Patient Result procedure:
- 4 Family Place -Enter result in HIS with paper lot and expiration date. Or downtime form if applicable.
- CHMG – Enter results on patient log sheet and HIS.

Reportable range:
pH range: 4.5 – 7.5

Reference Values:
pH of < 4.5 is consistent with normal vaginal secretions.

Interpretation/Reporting: Refer to container color chart

pH Nitrazine color	pH Nitrazine Value
Yellow	**4.5**
Golden Tan	**5.0**
Light Olive Green	**5.5**
Dark Olive Green	**6.0**
Blue-Green	**6.5**
Blue	**7.0**
Dark Blue/Purple	**7.5**

Amniotic fluid detection:
pH of amniotic fluid: 7.0-7.5.
A **negative** test (absence of amniotic fluid) will show a yellow to olive-green color, corresponding to a pH of <4.5 to 6.0.
A **positive** test (presence of amniotic fluid) will appear blue-green, blue to dark blue/purple, corresponding to a pH of 6.5-7.5.

Bacterial Vaginosis detection:

pH < 4.5 is consistent with **normal** vaginal secretions.
pH > 4.5 is **abnormal**, and is suggestive of bacterial vaginosis.

Procedure Notes:

• The Nitrazine test is highly sensitive but not very specific.
• Most studies report a 5% false-positive rate and a 1% false-negative rate for detection of rupture of membranes.

Limitations of Procedure:

• The results of this test are interpreted in conjunction with other clinical information.
• Personnel performing this test may seek the opinion(s) of other qualified testing personnel when encountering unusual results or when there is uncertainty about a conclusion.
• When practical, repeat testing with a new specimen may be used to reconcile the situation.

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