

Title:

pH Analysis with Nitrazine Paper

Target Audience: This module is available to aid in assessing competency for all clinical staff who perform this testing.

Contents

Instructions	2
Learning Objectives	2
Policy & Procedure	3-6
Job Aid	7
Posttest	8

pH Analysis with Nitrazine Paper

The material in this module serves as an educational tool and an aid in assessing competency for those performing this test within your facility.

- Read this module which includes the policy and procedure pertinent to this testing.
- If you have any questions about the material, ask your supervisor or facility POC Coordinator.
- Complete the online post test for this module.
- The [Job Aid](#) on page 7 may be customized to fit your department and then used as a quick reference guide.
- Completion of this module will be recorded under My Learning in PeopleLink.

Learning Objectives:

When you finish this module, you will be able to:

1. Demonstrate the proper procedure for performing quality control and testing with Nitrazine paper.
2. Identify the correct specimen requirements for pH Analysis with Nitrazine paper.
3. Identify limitations of testing with Nitrazine Paper.

Analysis of pH with Nitrazine[®] (Phenolphthazine) Paper by Bristol-Myers Squibb[®]

I. PRINCIPLE

Nitrazine[®] paper affords a simple, convenient method of determining the pH of solutions for chemical, biological, and clinical purposes. Clinically, Nitrazine[®] has been valuable in determining the pH of urine and nasal/vaginal, ocular, and salivary secretions. The use of Nitrazine[®] paper for pH is used to indicate potentially ruptured membranes in women through testing of vaginal secretions.

Nitrazine[®] tests the pH (acidity or alkalinity) of the vaginal fluid. The amniotic fluid is generally 7 to 7.5, whereas vaginal secretions are in the range of 4.5 to 5.5. Urine pH is 5.5 to 6.5. The Nitrazine[®] test uses test paper similar to litmus paper, which changes color in an acid or base environment. This paper contains a dye that reacts with vaginal specimen and can be compared with a standard color chart (See Interpretation of Results section of this procedure). Blood can produce a false reading of ruptured membranes when the membranes are intact, because maternal blood (pH 7.35-7.45) is basic like amniotic fluid.

With its range of sharp color changes, Nitrazine[®] Paper gives definitive results accurately and promptly at the pH range of greatest clinical interest—from the moderately acid pH of 4.5 to the slightly alkaline pH of 7.5. This paper also indicates whether the test solution is strongly acid below pH 4.5 or more alkaline than 7.5.

Note: Nitrazine[®] testing is used as a screening tool and is not a definitive test.

II. PROCEDURE

A. Specimen Type

Nitrazine[®] paper can be used to determine the pH of vaginal secretions. Bloody secretions, cervical mucous, and vaginal infections can cause false positive results.

pH Analysis with Nitrazine Paper

B. Test Method Instructions

1. Tear off a few inches of Nitrazine® paper. It is important that the paper is secure in the holder before tearing. The roll should snap tightly. Hold the container on both sides with your fingers and tear.
2. Touch paper to the vaginal secretions.
3. The color should be matched immediately with the closest color on the chart supplied in the dispenser. Each color corresponds to a specific pH.
4. Ensure that the following is recorded in the patient's medical record: date, time, test result, and initials of person who performed test.

C. Reagents

1. Nitrazine® paper
2. Quantimetrix® Dropper Plus Urine Controls, Levels 1 & 2
3. KOVA-Trol Urine Controls, Level I and Level 3

Nitrazine paper must be stored at room temperature. Nitrazine paper is stored in the same tightly capped container in which it is packaged. **The Nitrazine paper is sensitive to moisture so the container must be immediately closed after removal of the needed paper.** Avoid exposure to excessive heat. The Nitrazine paper is **stable until the expiration date on the container.** Outdated paper is discarded. Quality control must be run each time a new container of Nitrazine paper is opened. **The new container of Nitrazine paper must be dated and labeled "QC'd" on the container to verify quality control was performed. Ex. QC - 1/1/08.**

Quantimetrix® Dropper Plus Urine Controls must be stored at 2- 8°C (35.6 - 46.4°F) when not in use . Do not freeze. When stored at 2-8°C, the controls are stable until the expiration date stated on the label. **After the initial use, the opened Urine control bottles, when stored at 2-8°C, are stable until the expiration date stated on the label.** The opened controls may also be stored at room temperature. Do not store above 30°C (86°F). When stored at room temperature (20-25°C or 68-77°F), the controls are stable for one month or until the original expiration date, whichever comes first. The date the control was placed at room temperature and the new one month expiration date must be recorded on the control bottle label. Discard the controls if turbid or any evidence of microbial contamination is present.

pH Analysis with Nitrazine Paper

Kova-Trol Urine Controls must be stored at 2- 8°C (35.6 - 46. 4°F) when not in use. Do not freeze. Un-reconstituted controls stored at 2-8°C are stable until the expiration date stated on the label. **After reconstitution, the controls, when stored at 2-8°C, are stable for a maximum of 7 days .** Do not store at room temperature (20-25°C or 68-77°F). The useful life may be extended up to one month by storing reconstituted control in single use aliquots frozen at -20° to -40°C. Kova-Trol urine controls are stored and reconstituted by the lab.

D. Quality Control

Two levels of Quality Control must be performed each time a new package of Nitrazine® paper is opened and results documented on the Nitrazine Paper Quality Control Log. Quantimetrix® Dropper Plus Urine Controls Levels 1 and 2 or Kova-Trol Urine Controls Levels 1 and 3 are to be used for quality control testing. **The Nitrazine paper container must be dated and labeled “QC’d” on the container to verify quality control was performed. Ex. QC - 1/1/08.**

Successful quality control must be achieved before patient testing can be performed.

Quality Control Procedure:

1. Remove the controls from the refrigerator and allow them to come to room temperature (20-25°C), for approximately 15 to 30 minutes depending on the volume remaining in the bottle. Mix gently by inversion to assure homogeneity of the contents. Avoid foaming.
2. Tear off a few inches of Nitrazine® paper. It is important that the paper is secure in the holder before tearing. The roll should snap tightly. Hold the container on both sides with your fingers and tear.
3. Remove cap off Level 1 control and invert bottle. While holding the Nitrazine paper, apply one drop of control to the paper. Do not aspirate excess control back into the bottle. Turn paper on its side and drain excess control onto absorbent material.
4. The color must be matched immediately with the closest color on the chart supplied in the dispenser.
5. Record quality control results on the Nitrazine Paper Quality Control Log.
6. Repeat for Level 2 control.
7. Manufacturer Expected pH ranges must be recorded on the control log. These may be found on the package insert in the box with the controls. **These ranges change with every new lot number of control.**
8. Compare quality control results with the manufacturer expected values. If within range, **record the date and “QC” on the container. Ex. QC - 1/1/08.** If controls are not within range, the controls must be repeated until the results are within range before using the Nitrazine Paper for patient testing.

NOTE: Patient testing may not be performed if controls do not demonstrate expected results. The following corrective action must be taken until acceptable results are obtained:

- a. Repeat test using paper from the same container.
- b. Repeat test using a new control solution.
- c. Repeat test using paper from a new container or roll.
- d. Contact Point of Care office

E. Interpretation of Results

The amniotic fluid is generally 7 to 7.5, whereas vaginal secretions are in the range of 4.5 to 5.5. Urine pH is 5.5 to 6.5.

<i>Membranes Probably Intact</i>	
Yellow	pH 5.0
Olive Yellow	pH 5.5
Olive Green	pH 6.0
<i>Ruptured Membranes</i>	
Blue Green	pH 6.5
Blue Gray	pH 7.0
Deep Blue	pH 7.5

Ensure that the following is recorded in the patient's medical record: date, time, test result, and initials of person who performed test.

F. Method Limitations

The accuracy of all colorimetric tests is affected to some extent by salts, protein, and certain other factors which produce specific errors under certain conditions. The deviation may, under extreme conditions, exceed 0.5 pH unit. Therefore, when greater accuracy is desired or there is uncertainty about a test solution, it should first be tested electrometrically and then with Nitrazine® to determine the Nitrazine® correction factor. The correction factor will be consistent for a given type of buffer system and once it is determined, routine pH measurements with Nitrazine® paper may be depended upon for accuracy.

JOB AID

Nitrazine Paper

Nitrazine paper is a screening test used to determine the pH of vaginal secretions to indicate potentially ruptured membranes in pregnant women. **Nitrazine paper should be examined immediately after removing it from the vagina.** The amniotic fluid generally has a pH of **7 to 7.5**, whereas vaginal secretions are in the range of **4.5 to 5.5**, and urine pH is **5.5 to 6.5**. Bloody secretions, cervical mucous, and vaginal infections can cause false positive results. Blood has a pH of 7.35 - 7.45, which is in the pH range of amniotic fluid. Infections can cause the pH of the vagina to change resulting in an elevated pH giving a false positive result also.

Controls - Two levels of liquid quality control are required for **every** roll of paper when it is first opened. The controls used are Quantimetrix Dropper plus Urine Controls. The controls are stable when stored in the refrigerator until the expiration date supplied by the manufacturer. Controls that are stored at room temperature are stable for 30 days from the date they are placed at room temperature, as long as it is within the original expiration date stated on the bottle. Room temperature controls must be dated with the date the control was placed at room temperature **and** the new 30 day expiration date.

Paper - Nitrazine paper is stored at room temperature and can be used until the expiration date supplied by the manufacturer. **The paper is sensitive to moisture and must be kept tightly closed.** Paper exposed to moisture in the air may give inaccurate results. The **open date and “QC’d” must be recorded** on the package of Nitrazine paper to verify quality controls were performed on the Nitrazine paper upon opening.

The Nitrazine Control log **must be filled out completely.** The expected values for each control level must be filled in on the log. **These values change with every lot number of control.** The expected values are **located on the manufacturer insert in the box with the controls.** Results of quality control testing must be recorded on the QC Log and compared to the expected results. **If any result does not fall within the expected range, the control must be repeated. Patient testing must not be performed until control results are acceptable.**

Enter the test result in the patient's chart or EMR.

Posttest

Name: _____

Date: _____

Acknowledgement of Module Content review (Check appropriate response):

I have read the module contents: pH Analysis with Nitrazine Paper

Yes ☐ No ☐

1. Nitrazine paper can be used to determine the pH of vaginal secretions.
 - a) True
 - b) False
2. A pH of 7.0 or higher in the upper vagina is consistent with leakage of amniotic fluid.
 - a) True
 - b) False
3. The Nitrazine paper should be examined within 5 minutes after it is removed from the vagina.
 - a) True
 - b) False
4. Bloody secretions, cervical mucous, and vaginal infections can cause false positive results.
 - a) True
 - b) False
5. Control results must be compared to the expected values supplied by the manufacturer on the package insert in the box of controls to determine if they are acceptable.
 - a) True
 - b) False
6. Patient testing can be performed even if controls do not perform as expected.
 - a) True
 - b) False
7. Two levels of liquid controls must be performed and documented:
 - a) Daily
 - b) Weekly
 - c) With each roll of paper
 - d) Each day of patient testing
8. What must be recorded on the nitrazine paper container upon opening?
 - a) Open date
 - b) "QC'd" (for Quality Control performed)
 - c) Nothing
 - d) Both a and b