Wake Forest Baptist Medical Center	pH Testing using Nitrazine Paper in The Birth Center	Dept:	Pathology Laboratory
		Effective Date:	June 2019
		Revised Date:	NEW
		Contact:	Laboratory Compliance, QA & Point of Care
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Signature: GPom		**Date:** 6/5/19	
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1) **General Procedure/Guideline Statement:**

It is the policy of Wake Forest Baptist Medical Center to perform pH testing using Nitrazine paper according to established protocols.

This procedure is to be used only in The Birth Center. Physicians, midlevel practitioners and midwives who have completed required training and maintain annual competency may perform this test. Further, each specific test site must have approval from the Point of Care Committee to perform this procedure.

a) **Scope**: The site holding the PPMP CLIA certificate and the physicians, midlevel practitioners and midwives performing the test will be responsible for carrying out the activities of the procedure.

b) **Responsible Department/Party/Parties:**

i. Procedure owner: WFBMC Laboratory Compliance, QA and Point of Care.

ii. Procedure: The site holding the PPMP CLIA certificate and the physicians, midlevel practitioners and midwives performing the test will be responsible for carrying out the activities of the procedure/guideline/protocol.

iii. Supervision: The Laboratory Director as indicated on the PPMP CLIA certificate for the site performing the test will supervise activities outlined in this document.

iv. Implementation: The Laboratory Director as indicated on the PPMP CLIA certificate for the site performing the test (and/or their designee) is responsible for ensuring compliance with processes stated in this document.

2) **Definitions:**

a) ***Guideline***: A recommended process or method for accomplishing a specific task or objective. All guidelines must comply with applicable WFBMC policies and procedures.

b) ***Policy***: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBMC.

A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBMC, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.

c) **Waived Tests:** Tests of low complexity as designated by the FDA; tests that are simple and have low risk for erroneous results.

d) ***Clinical Laboratory Improvement Amendments (CLIA)*:** United States federal regulatory standards that apply to all laboratory testing performed on humans.

3) **Policy Guideline:**
This test should not be performed by individuals with color blindness.

A. Training and Competency:

1. Each testing provider will be trained initially upon hire and competency assessed annually thereafter.

2. Initial training and annual competency of the physicians, midlevel practitioners and midwives will be the responsibility of the Laboratory Director listed on the CLIA certificate and/or their designee.

3. The Laboratory Director or Unit Nursing Manager will notify Lab Compliance, QA & Point of Care of any new provider that needs to be enrolled to the University of Washington (MTS) online training modules prior to performing initial training.

4. Lab Compliance, QA & Point of Care will enroll these providers in MTS and notify the CLIA Lab Director or designee of any provider needing annual competency assessment.

5. **Initial Training:**

   a) The initial training of physicians, midlevel practitioners and midwives will require them to read and be familiar with the pH Nitrazine Test policy and procedure. Documentation of review will be through the University of Washington (MTS) online read-receipt process.

   b) Complete an online Nitrazine pH Initial Training challenge provided through MTS and obtain a passing score of 80% or more to be considered trained competent to perform the test.

   c) Take the written test through MTS and passing with an 80% score.

6. **Annual Competency:**

   a) It is a CLIA '88 and Joint Commission requirement to perform competency assessment to show that personnel are competent to continue to perform testing.

   b) Two (2) of the four (4) methods are the regulatory requirements for competency assessment of all personnel (including providers) performing Waived Testing.

      1) Blind testing

2) Direct observation of routine testing
3) Monitoring of quality control performance by each user
4) Written test

c) Competency assessment for pH Nitrazine Test will include:

1) Enrollment to the online Competency challenge provided through MTS. The passing score for this online challenge is 80%. Any score less than 80% will be investigated and retraining performed if necessary.
2) Take the written test through MTS and passing with an 80% score.

4) Purpose:

pH Nitrazine testing is used as a screening test to detect small quantities of amniotic fluid in vaginal secretions, based on the difference in pH between vaginal secretions and amniotic fluid. It is used in conjunction with the Fern Test to help detect ruptured membranes. Premature rupture of the membranes before onset of labor may lead to fetal infection and subsequent mortality. The risk is largely eliminated by induction of labor.

5) Procedure:

a) Positive patient identification should occur per the guidelines in WFBH policy on Patient Identification.

b) **Supplies:**

1. All unused nitrazine paper must remain in the original container. Transfer to any other container may cause nitrazine paper to deteriorate and become unreactive.
2. Work areas and specimen containers should be free of detergents and other contaminating substances.
3. Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of the paper may indicate deterioration.
4. Store rolls at room temperature between 15-30°C (59-86° F). Do not store the nitrazine paper container in direct sunlight.
5. Never use nitrazine paper after the expiration date printed on the container label.
6. Discard nitrazine paper that has been exposed to extreme temperature or stored in direct sunlight.

c) **Quality Control**

1. Quality control for NitraTest paper is performed by the Clinical Laboratory prior to release to inpatient care sites from Pharmacy. NitraTest paper will not be issued to patient care areas unless the quality control checks are acceptable. The Clinical Laboratory will maintain quality control documentation records.

2. In the event Quality Control must be performed on the unit the following procedure should be used.

3. Quality Control Supply
   a) Quantimetrix Urine QC (Level 1 and 2). These controls will not routinely be kept on the unit. Please contact the Point of Care Department for access to these controls.

4. Quality Control Procedure:
    a) Tear off pieces of NitraTest paper of the desired length just prior to use.
    b) Apply 1 drop of QC Level 1 material to the strip of NitraTest paper and shake off excess fluid.
    c) Immediately note the strip color and pH level of the NitraTest paper and document on the QC log.
    d) Tear off another piece of NitraTest paper
    e) Apply 1 drop of QC Level 2 material to the strip of NitraTest paper and shake off excess fluid.
    f) Immediately note the strip color and pH level of the NitraTest paper and document on the QC log.
    g) If the NitraTest paper does not produce the expected color reaction, repeat QC test.
    h) If either QC fails a second time, do not use the NitraTest paper for patient testing. Discard and open a new roll.

d) **Specimen Collection and Handling:**
1. Standard PPE precautions must be observed at all times when handling body fluids.
2. Collect vaginal secretions from the posterior vaginal pool.
3. Do not touch the swab or Nitrazine paper to the mucus plug in the cervix.
4. Test sample immediately after collection.

e) **Testing Procedure:**
1. Testing on the unit should occur in the designated lab testing areas, not the patient rooms.
2. Record patient information on Patient Log. Patient label may be used.
3. Check the expiration date on the test strip container. The expiration date is documented by Clinical Laboratory when Quality Control is completed. If product is expired, discard and obtain fresh product from the Pharmacy.
4. Tear off a piece NitraTest paper of the desired length.
5. Use sterile exam gloves. No lubrication should be used on exam gloves or speculum.
6. Apply patient sample from swab onto the strip of NitraTest paper. Shake off any excess fluid.
7. Immediately match the strip color with the closest color on the Nitrazine color chart. Avoid laying the strip directly on the Color Chart, as this will result in the secretion soiling the chart. Clean with WFBH approved disinfecting wipes if accidentally contaminated.
8. Persons who have difficulty with visual color discrimination must have the test read by another competent staff.
9. Record test performed result and testing personnel initials on Patient Log.

f) **Reference Range:**

1. Normal vaginal secretions have a pH of 4.5 – 5.5.
2. Amniotic fluid has a pH of 7.0 – 7.5. When membranes rupture, the amniotic fluid leaks into the vagina and raises the pH of the vaginal secretions.

g) **Interpretation of Results**

pH 4.5 – 6.0 Negative for amniotic fluid
pH 7.0 – 7.5 Positive for amniotic fluid

h) **Reporting of Results**
   1. Place an order for POCT Nitrazine pH (**POC299**) in WakeOne.
   2. pH results must be documented in the patient electronic medical record.
   3. The following is the link to the WakeOne Tip Sheet on how to order, document and result POC Test.
      http://ishare.wakehealth.edu/WakeOne/TipsAndTricks/Point%20of%20Care%20Test%20-%20Ordering%20Documenting%20and%20Resulting.pdf

**NOTE: Both Nitrazine tests and Fern test should be performed together to confirm the rupture of membranes. For the steps on how to perform Fern Test, refer to Fern Test (Amniotic Fluid Crystallization Test) in The Birth Center procedure.

i) **Limitations of the Method:**
   1. Blood, mucous, alkaline antiseptics, vaginal infections and alkaline urine – may cause false positives for Nitrazine pH test results.
   2. Possible presence of any of these contaminants makes test inaccurate and voids results.

6) **Review/Revision/Implementation:**
   a) **Review Cycle**: This policy and procedure shall be reviewed by CLIA Laboratory Director at least every two (2) years from the effective date.

   b) **Office of Record**: After authorization, the Pathology Laboratory shall house this policy and procedure in a database and shall be the office of record for this policy and procedure.

7) **Related Governing Policies and Procedures:**
   Understanding of Responsibilities Between Testing Sites and the Clinical Laboratory for Point of Care Testing (POCT)
   Point of Care Waived and Non-Waived Testing
   Patient Identification
   Resulting Point-of-Care Test in WakeOne
   Fern Test (Amniotic Fluid Crystallization Test) in The Birth Center

8) **References:**

   a) Fischer, P., et al. The Office Laboratory, Norwalk, Conn.: Appletin-Century-Crofts, 1983.
   b) Provider-Performed Microscopy Procedures, A Focus on Quality Practices. Centers for Disease Control and Prevention (CDC), Division of Laboratory Systems, February 2016.
   c) Standard HR.01.06.01; Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB), January 2019.
   d) University of Washington, Department of Laboratory Medicine, Lab Training and Competency Assessment System (MTS), PPM Training Library, accessed May 2019.

9) **Attachment:**
   Attachment A: Written Exam
   Attachment B: Patient Log

10) Revision Dates:

Review Date	Revision(s)	Signature

Attachment A:

Point of Care pH Nitrazine Test
WRITTEN EXAM
Circle the correct answer

A score of 80% must be achieved.

1. Nitrazine pH paper must be kept in its original container until ready to test to obtain a credible test reaction.
   a. True
   b. False

2. You can use Nitrazine paper even if expired, as long as quality control results are valid.
   a. True
   b. False

3. Nitrazine paper is very sensitive but not very specific which means a positive Nitrazine (pH 7.0-7.5) always indicates amniotic fluid is definitely present.
   a. True
   b. False

4. If a Fern test is negative and the Nitrazine is positive (pH 7.0-7.5), this indicates probable membrane rupture. No need to retest either Fern or Nitrazine test.
   a. True
   b. False

6. To read test, HOLD STRIP CLOSE TO COLOR BLOCKS AND:
   a. Blow it
   b. Match it
   c. Shake it

7. Amniotic fluid has a pH of:
   a. 4.5 – 5.5
   b. 7.0 – 7.5
   c. 5.0 – 6.0

8. Normal vaginal secretions have a pH of:
   a. 4.5 – 5.5
   b. 7.0 – 7.5
   c. 5.0 – 6.0

9.Challenge #1

Test 1	
pH	Reaction Interpretation
Result:	Pos or Neg for Amniotic Fluid

10. Challenge #2

Test 2	
pH	Reaction Interpretation
Result:	Pos or Neg for Amniotic Fluid

Validated By: _____ Date: _____

Attachment D:

Patient Log

Site Name: The Birth Center

Date:______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______
Date:______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______
Date:______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______
Date:______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______	**Date:**______ **Name:** ______ **MR#:** ______ **Test performed:** ______ **Test result:** ______ **Testing personnel:** ______