Wake Forest Baptist Health	**Fern Test (Amniotic Fluid Crystallization Test)**	**Dept:**	**Pathology Laboratory**
		Effective Date:	**11/2008**
		Revised Date:	**07/2019**
		Contact:	**Laboratory Compliance, QA & Point of Care**
Name & Title: Gregory Pomper, MD, Laboratory Director, Department of Pathology			
Signature:		**Date:**	

1) General Procedure/Guideline Statement:

It is the policy of Wake Forest Baptist Health to perform Fern Test according to established protocols. For sites holding a CLIA certificate of Provider-Performed Microscopy Procedures (PPMP), only physicians and midlevel practitioners who have completed required training and maintain annual competency may perform this test.

For sites holding a CLIA certificate of Accreditation or Compliance, staff that 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, Accreditation or Compliance CLIA certificate and the physicians, midlevel practitioners or trained staff performing the test will be responsible for carrying out the activities of the procedure.

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

i. Procedure owner: WFBH Laboratory Compliance, QA and Point of Care.
ii. Procedure: The site holding the PPMP, Accreditation or Compliance CLIA certificate and the physicians, midlevel practitioners, and trained staff performing the test will be responsible for carrying out the activities of the procedure/guideline/protocol.
iii. Supervision: The Laboratory Director indicated on the PPMP, Accreditation or Compliance CLIA certificate and/or their designee will supervise activities outlined in this document.
iv. Implementation: The Laboratory Director indicated on the PPMP, Accreditation or Compliance CLIA certificate 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 WFBH 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 WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters

within which faculty, staff, students, visitors and others are expected to operate.

c) ***Provider Performed Microscopy Procedure (PPMP)*:** A procedure from a select group of moderately complex microscopic tests that is performed by a provider (physician or midlevel practitioner) as part of a patient's visit.

d) ***Non-Waived Tests:*** Tests of moderate or high complexity as designated by the FDA.

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

f) ***Medical Training Solutions (MTS):*** MTS's Lab Training and Competency Assessment system provides a comprehensive on-line resource for building competency, improving the quality of laboratory services, and meeting regulatory requirements by the University of Washington, Department of Laboratory Medicine.

3) Policy Guideline:

A. Training and Competency:

1. Each testing provider and staff will be trained initially and competency assessed at 6 months and annually thereafter.

2. Initial training, 6 months and annual competency of the physicians, midlevel practitioners or staff performing Fern testing will require enrollment in online program.

3. Each clinic will appoint an administrator in order to monitor training and competency.

4. Each administrator will be educated.

5. The administrator will make sure that providers and staff receive initial training, six (6) month and annual competency assessments.

6. The Laboratory Director listed on the CLIA certificate and/or their designee will oversee the Training and Competency process, assuring that initial training, 6 months and annual competency assessments of the physicians, midlevel practitioners and staff performing Fern testing are performed.

B. Initial Training (Attachment A):

1. The initial training of physicians, midlevel practitioners or staff will require:
   i. Read and be familiar with the Fern Test policy and procedure.

   ii. Complete a written exam with a passing score to be considered competent to perform the test.

C. 6 Months and Annual Competency (Attachment B):

1. Six (6) months after the initial training and annually thereafter, it is a CLIA '88 requirement to perform competency assessment to show that personnel are competent to continue to perform testing.

2. The following six (6) methods are the minimum regulatory requirements for competency assessment of all personnel performing Fern testing, if applicable.

    1) Blind testing
    2) Direct observation of routine testing
    3) *Monitoring of QC performance by each user (not applicable to Fern Test)*
    4) Problem solving skills
    5) Direct observation of instrument checks
    6) Monitoring result reporting

3. Competency assessment for Fern Test will include:

    1) Enrollment in an online Fern Test Competency challenge
    2) Take an exam and receive a passing score
    3) Demonstration of performance of Fern Testing
    4) Review of microscope maintenance log
    5) Chart review of Fern Test results

D. Proficiency Testing (PT):

Each site needs to verify the accuracy of their testing at least twice per year. Participation in a CLIA-approved PT program will satisfy this requirement. Each site will use a proficiency testing provider which sends testing three times a year.

7. **Proficiency Testing Guideline:**
    1) The Laboratory Director as indicated on the CLIA certificate (and/or their designee) will supervise the PT program and ensure compliance with the PT standards, regulations of CLIA and/or other accrediting agencies.
    2) The site must enroll and participate in a CMS-approved PT program that offers the Fern Test.
    3) Acceptable participation means the site receives a passing grade for each PT event.
    4) For any PT event that did not receive a passing grade, the Laboratory Director (and/or Designee) must evaluate and document possible reasons for failure and any corrective action that may be necessary.
    5) Refer to Proficiency Testing Procedure for information on how to handle, analyze, report, and review PT samples.

8. **Proficiency Testing Training (Attachment A):** New testing providers and staff will receive training on how to handle PT materials. Training includes:
    1) Documentation of Proficiency Testing policy and procedure review through the MTS online read-receipt process.
    2) Enrollment in the online proficiency training module, completion of the exam at the end of the module with a passing score.

4) Principle:

The Fern Test enables the provider to detect amniotic fluid leakage from the membrane surrounding the fetus during pregnancy. If rupture of the membrane has occurred, evidence of amniotic fluid will be present. Amniotic fluid will crystallize to form a fern pattern when air-dried on a glass slide and this is due to the relative concentrations of sodium chloride, protein, and carbohydrate in the fluid. A positive test shows the presence of fern-like patterns

characteristic of amniotic fluid crystals.

5) Procedure:

a) Positive patient identification should occur per the guidelines in WFBH policy on http://ishare.wakehealth.edu/GoverningPolicy/Policies/Patient%20Identification.pdf

b) **Supplies:**
- Gloves
- Sterile speculum
- Sterile swab
- Sterile glass slide
- Microscope

c) **Specimen Collection and Handling:**
1. Standard PPE precautions must be observed at all times when handling body fluids.
2. Obtain a sample of vaginal secretion from the posterior vaginal pool using a sterile swab.
3. Collect a sample from the external cervical os if pool of fluid is not evident.
4. Do not touch the mucus plug in the cervix.

d) **Slide Preparation:**
1. Make a very thin smear by gently rubbing the swab containing fresh amniotic fluid against the glass slide.
2. Label the slide using a small patient encounter label containing at least 2 identifiers.
3. Allow smear to air dry.
4. Do not wave, blow or apply heat to the slide to hasten drying.
5. Do not place a cover slip on the specimen.

e) **Testing Procedure:**
1. Testing should be performed in lab designated areas of the clinic only. Not in patient rooms.
2. Record patient information on Patient Log. Patient encounter label may be used.
3. View slide under low power (10x) and look for fern-like pattern. The ferning pattern resembles frost on a window pane and will be easily seen in most fields if the test is positive.
4. Switch to high-dry (40x) to confirm ferning pattern.
5. Dispose of glass slides in appropriate sharps container.
6. Record test performed, result, and testing personnel initials on Patient Log.

f) **Results and Reporting:**
1. Place an order for a Fern Test **(POC244**) in WakeOne.
2. Report **Positive** or **Negative** for ferning 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 Ferning and Nitrazine tests should be performed together to confirm the rupture of membranes. For the steps on how to perform Nitrazine test, refer to

http://intranet.wakehealth.edu/uploadedFiles/User_Content/Departments/Pathology/Documents/19July2019-PointOfCare-pH-Nitrazine-Test.pdf procedure.

g) **Limitations of the Method:**
1. False positive results may occur from specimens contaminated with blood, urine, semen, or cervical mucous.
2. False negative results may occur from prolonged rupture of the membranes (longer than 24 hours).
3. False negative results may occur if only a small volume of fluid has leaked.
4. Erroneous results may result when the slide is examined before it is completely dried or if a dirty slide is used.

6) Quality Control:
Quality Control is not available for this test.

7) Equipment:

a) **Microscope Maintenance:**
1. Weekly maintenance is performed on the microscope used for testing to ensure cleanliness of the scope and an accurate reading of the specimen.
2. Clean off dust in the microscope area.
3. Clean the oculars, stage, and the condenser with a swab or lens paper moistened with a commercially available lens cleaner.
4. Dry off with a new piece of dry lens paper.
5. Document the maintenance on the Microscope Maintenance Log ***(see Attachment A).***
6. The Laboratory Director or Designee should check the maintenance log for complete documentation and reviewed monthly.

b) **Calibration:**
Microscope maintenance is performed annually by Trimedx to ensure continued efficiency and quality of the equipment. Records will be maintained by Trimedx and will be available upon request in the event of an inspection. Each clinic will also keep a copy of the service record.

8) 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 Laboratory Compliance, QA & Point of Care shall house this policy and procedure in a database and shall be the office of record for this policy and procedure.

9) 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
Competency Assessment for Non-Waived Testing
Proficiency Testing Procedure
http://ishare.wakehealth.edu/GoverningPolicy/Policies/Patient%20Identification.pdf
Resulting Point-of-Care Test in WakeOne

10) 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 2018.
d) University of Washington, Department of Laboratory Medicine, Lab Training and Competency Assessment System (MTS), PPM Training Library, accessed May 2019.

11) Attachment:

Attachment A: Fern Test Initial Training Form
Attachment B: Fern Test Competency Assessment Form
Attachment C: Patient Log
Attachment D: Microscope Maintenance Log

12) Revision Dates:

11/08, 03/11, 05/14, 06/17

Review Date	Revision(s)	Signature
07/2019	In Section 3) Policy; Training and Competency, Initial Training for Fern Test, 6 Months and Annual Competency for Fern Test is detailed, and Proficiency Testing (PT) is detailed. Section 4) Principle explains the Fern Test and why it is performed. Section 6) QC explains that there is no QC for this test. Section 7) Equipment lists the equipment needed to perform the Fern Test and tells how to keep a microscope in working order. Section 9) Related Governing Policies and Procedures, Section 10) References, and Section 11) Attachments have more content than the previous procedure.	

Attachment A:

Fern Test Initial Training Form

Trainee Name: _____

Trainer Name:_____

Training Assessment	Trainer Initial	Date Completed
Fern Test		
Review of Fern Test Policy and Procedure through MTS		
Completed online Fern Test Training Module through MTS and attain a score of 80% or more on the test		
Demonstration of performance of Fern Testing		
Demonstration of the use of the microscope		
Documentation of Fern test result		
Proficiency Test (PT)		
Review of Proficiency Testing Policy and Procedure through MTS		
Completed online Proficiency Testing Training Module through MTS		
Note		

Trainee Signature:	**Date:**
Trainer Signature:	**Date:**
The personnel listed above has been deemed competent to perform Fern Test. **Lab Director / Designee Signature:**	**Date:**

Attachment B:

Fern Test Competency Assessment Form

Personnel Name: _____

Date: _____

Competency Assessment	Competency Assessed / checked by (Initial)	Date Completed
Fern Test		
Completed online Competency challenge provided by MTS		
Completed competency test through MTS with 80%		
Demonstration of performance of Fern Testing		
Review of microscope maintenance log		
Review of Fern Test results		
Other competency assessment method:		
Note:		

Personnel Signature:	**Date:**
Competency Assessed / Observed (Name and Signature):	**Date:**
The personnel listed above has been deemed competent to perform Fern Test. **Lab Director / Designee Signature:**	**Date:**

Attachment C:

Patient Log

Site Name: ____________________

Date:____________________ **Name:** ____________________ **MR#:** ____________________ **Test result:** ______________ **Testing personnel:** __________	**Date:**____________________ **Name:** ____________________ **MR#:** ____________________ **Test result:** ______________ **Testing personnel:** __________	**Date:**____________________ **Name:** __________________ **MR#:** ___________________ **Test result:** _____________ **Testing personnel:** ________
Date:____________________ **Name:** ____________________ **MR#:** ____________________ **Test result:** ______________ **Testing personnel:** __________	**Date:**____________________ **Name:** ____________________ **MR#:** ____________________ **Test result:** ______________ **Testing personnel:** __________	**Date:**____________________ **Name:** __________________ **MR#:** ___________________ **Test result:** _____________ **Testing personnel:** ________
Date:____________________ **Name:** ____________________ **MR#:** ____________________ **Test result:** ______________ **Testing personnel:** __________	**Date:**____________________ **Name:** ____________________ **MR#:** ____________________ **Test result:** ______________ **Testing personnel:** __________	**Date:**____________________ **Name:** __________________ **MR#:** ___________________ **Test result:** _____________ **Testing personnel:** ________

Attachment D:

Microscope Maintenance Log

Microscope Location: ______________________________**Year:**_________

Jan		Feb		Mar		Apr		May		June	
Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials

Week 1												
Week 2												
Week 3												
Week 4												
Week 5												

	July		Aug		Sept		Oct		Nov		Dec	
	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials
Week 1												
Week 2												
Week 3												
Week 4												
Week 5												

Problems encountered and corrective actions taken:

Reviewed By:	**/Date:**	**Reviewed By:**	**/Date**