

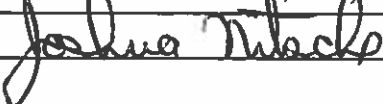


|                                                                                                                                 |                                                                        |                        |                                                              |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------|--------------------------------------------------------------|
|  <b>Wake Forest*</b><br>Baptist Medical Center | <b>Vaginal Wet Mounts<br/>(Saline and KOH)<br/>in The Birth Center</b> | <b>Dept:</b>           | <b>Pathology<br/>Laboratory</b>                              |
|                                                                                                                                 |                                                                        | <b>Effective Date:</b> | <b>June 2019</b>                                             |
|                                                                                                                                 |                                                                        | <b>Revised Date:</b>   | <b>NEW</b>                                                   |
|                                                                                                                                 |                                                                        | <b>Contact:</b>        | <b>Laboratory<br/>Compliance, QA &amp;<br/>Point of Care</b> |
| <b>Name &amp; Title:</b> Gregory Pomper, MD, Laboratory Director, Department of Pathology                                       |                                                                        |                        |                                                              |
| <b>Signature:</b>                              |                                                                        | <b>Date:</b> 6/5/19    |                                                              |
| <b>Name &amp; Title:</b> Joshua F. Nitsche, MD, CLIA Laboratory Director, The Birth Center                                      |                                                                        |                        |                                                              |
| <b>Signature:</b>                              |                                                                        | <b>Date:</b> 6/5/19    |                                                              |

**1) General Procedure/Guideline Statement:**

It is the policy of Wake Forest Baptist Medical Center to perform Vaginal Wet Mounts according to established protocols. Only 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 and the Laboratory Compliance, QA and Point of Care 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, the Laboratory Compliance, QA and Point of Care and/or the individual delegated by the CLIA Laboratory Director 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) ***Provider Performed Microscopy Procedure (PPMP)***: A procedure from a select group of moderately complex microscopic tests that is performed by a provider (physician, midlevel practitioner, or midwife) as part of a patient's visit.
- d) ***Clinical Laboratory Improvement Amendments (CLIA)***: United States federal regulatory standards that apply to all laboratory testing performed on humans.

### 3) Policy Guideline:

#### A. Training and Competency:

1. Each testing provider 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 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 automatically enroll these providers in MTS and notify the CLIA Lab Director or designee of any new provider needing six (6) months or annual competency assessment.
5. **Initial Training (Attachment A):**
  - a) New testing providers must be properly trained before testing patients. The initial training will require them to:
    1. Read and be familiar with the Vaginal Wet Mount policy and procedure. Documentation of review will be through the MTS online read-receipt process.
    2. Complete the online Vaginal Wet Mount Module provided through MTS - take the test and obtain a passing score of 80% or better.
    3. Demonstration of performance of a Vaginal Wet Mount and a KOH Preparation supervised by another previously trained and competent provider.
    4. Demonstrated documentation of each test result in WakeOne.
6. **6 Months and Annual Competency (Attachment B):**
  - a) Six (6) months after the initial training and annually thereafter, 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) The following six (6) methods are the minimum regulatory requirements for competency assessment of all personnel performing PPMP, if applicable.
  - 1. Blind testing
  - 2. Direct observation of routine testing
  - 3. *Monitoring of QC performance by each user (not applicable to Vaginal Wet Mount Test)*
  - 4. Problem solving skills
  - 5. Direct observation of instrument checks
  - 6. Monitoring result reporting
- c) Competency assessment for Vaginal Wet Mount will include:
  - 1. Enrollment to the online PPM 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 a test through MTS and passing with an 80% score.
  - 3. Demonstration of performance of Vaginal Wet Mount Testing and a KOH Preparation.
  - 4. Review of microscope maintenance log.
  - 5. Chart review of Vaginal Wet Mount and KOH Preparation Test results.

**B. Proficiency Testing (PT):**

PPM testing sites need to verify the accuracy of their testing at least twice per year. Participation in a CLIA-approved PT program will satisfy the requirement. The Birth Center will use ACP Medical Laboratory Evaluation as the Proficiency testing Provider.

- 1. **Proficiency Testing Guideline:**
  - a) The Laboratory Director as indicated on the PPMP CLIA certificate (and/or their designee) will supervise the PT program and ensure compliance with the PT standards or regulations of CLIA and/or other accrediting agencies.
  - b) The PPM site must enroll and participate in a CMS-approved PT program that offers Vaginal Wet Mount and KOH Preparation Test.
  - c) Acceptable participation means the site receives a passing grade of 80% or more for each PT event.
  - d) 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.
  - e) Refer to Proficiency Testing Procedure for information on how to handle, analyze, report, and review PT samples.
- 2. **Proficiency Testing Training (Attachment A):** New PPM providers will receive training on how to handle PT materials. Training includes:
  - a) Documentation of Proficiency Testing policy and procedure review through the MTS online read-receipt process.
  - b) Enrollment to the online Proficiency Training Module through MTS, take the test at the end of the module and must attain a passing score of 80% on the test.

**4) Principle:**

The Vaginal Wet Mount and KOH Preparation Test is a microscopic procedure performed to examine material collected from a specimen suspended in a drop of liquid on a glass slide. A wet mount is used to view cells and organisms for motility, morphological characteristics and identification. Specifically, it is used for the presence or absence of bacteria, fungi, parasites, and human cellular elements. Common findings using these procedures would be bacteria, fungal elements, motile *Trichomonas vaginalis*, white blood cells, and clue cells on saline mounted slides and the presence of yeast on slides mounted with KOH.

**5) Procedure:**

- a) Positive patient identification should occur per the guidelines in WFBH policy on **Patient Identification**.
- b) **Supplies:**
  - Gloves
  - Sterile glass slide
  - Sterile swab
  - K tube with 1 ml of normal saline
  - 10% KOH
  - 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 fornix using a sterile swab.
- d) **Slide Preparation and Test Procedure for Saline Wet Mount:**
  1. Patient testing must be performed in designated lab areas on the unit. Testing must not be performed in the patient rooms.
  2. Record patient information Patient Log. (patient label may be used)
  3. Label the slide and K tube using a small patient encounter label. (containing at least 2 identifiers)
  4. Mix the swab with 1 ml. of normal saline in test tube making sure the expiration is within date.
  5. Place a drop of this mixture on a labeled slide and place a coverslip on top. Slide must be prepared and interpreted within 20 minutes of collection.
  6. Examine slide on 10 X for bacteria, fungal elements, motile *Trichomonas vaginalis*, and human cellular elements and then at 40 X reading at least 10 fields for the presence of weakly motile *Trichomonas vaginalis*, white blood cells (WBCs), and clue cells.
  7. Record test performed, result and testing personnel initials on Patient Log.
  8. Enter Results into WakeOne.
  9. Dispose of slide into container (red biohazard container)
- e) **Slide Preparation and Test Procedure for KOH Preparation:**
  1. With the saline wet mount completed, continue to perform a KOH wet mount.
  2. Label a new slide using a small patient encounter label. (containing at least 2 identifiers)
  3. Using the same patient sample as in the wet mount; place a drop of saline mixture from test tube onto slide.
  4. Place 1 drop of KOH onto mixture on slide making sure KOH bottle is within expiration date.

5. Immediately put coverslip over specimen for examination
6. Examine slide on 40 X reading at least 10 fields for the presence of budding yeast or yeast with hyphae.
7. Record test performed, result and testing personnel initials on Patient Log.
8. Enter results into WakeOne
9. Dispose of slide and specimen into container (red biohazard container)

f) **Results and Reporting:**

1. Place an order for a Vaginal Wet Mount Test (POC273) in WakeOne.
2. Report WBC's per high power field (hpf) as indicated:
  - Rare: < 1WBC/hpf
  - Few: 1 to 4 WBCs/hpf
  - Moderate: 5 to 10 WBC's/hpf
  - Many: > 10 WBCs/hpf
3. Report Present or Not Present for the presence of Trichomonas, yeast and clue cells.
4. The following is the link to the Wake One 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>.

g) **Limitations of the Method:**

1. Failure to vigorously swirl the swab in the saline to dislodge the specimen may lead to erroneous results.
2. Non-motile *Trichomonas* could be mistaken for white blood cells. To preserve the motility, examine the specimen immediately after collection
3. Oil droplets from intravaginal medications may be mistaken for yeast. However, oil droplets vary greatly in size and are high retractile.
4. Cotton fibers from the swab may resemble fungi.
5. Microscope lighting is critical for the KOH prep examination. Too much light can wash out fungi, resulting in false negatives.
6. Failure to examine the entire cover slip area. A random examination of the cover slipped area may result in false negatives.

6) **Quality Control:**

Quality Control is not available for this test.

7) **Equipment:**

a) **Microscope Maintenance:**

1. Weekly maintenance is done 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. The Birth Center will also keep a copy of the service record in the Lab Maintenance section of the procedure manual.

**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 Pathology Laboratory 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  
Patient Identification  
Point of Care pH Testing  
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:** Vaginal Wet Mounts Test Initial Training Form  
**Attachment B:** Vaginal Wet Mounts Competency Assessment Form  
**Attachment C:** Patient Log  
**Attachment D:** Microscope Maintenance Log

**12) Revision Dates:**

| <b>Review Date</b> | <b>Revision(s)</b> | <b>Signature</b> |
|--------------------|--------------------|------------------|
|                    |                    |                  |
|                    |                    |                  |
|                    |                    |                  |
|                    |                    |                  |
|                    |                    |                  |
|                    |                    |                  |

**Attachment B:**

**Vaginal Wet Mounts (Saline and KOH) Test Initial Training Form**

Trainee Name: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

| Training Assessment                                                                                           | Trainer Initial | Date Completed |
|---------------------------------------------------------------------------------------------------------------|-----------------|----------------|
| <b>Vaginal Wet Mounts</b>                                                                                     |                 |                |
| Review of Vaginal Wet Mounts Policy and Procedure through MTS                                                 |                 |                |
| Completed online Vaginal Wet Mounts Training Module through MTS and attain a score of 80% or more on the test |                 |                |
| Demonstration of performance of Vaginal Wet Mounts                                                            |                 |                |
| Demonstration of the use of the microscope                                                                    |                 |                |
| Documentation of Vaginal Wet Mounts test result                                                               |                 |                |
|                                                                                                               |                 |                |
|                                                                                                               |                 |                |
| <b>Proficiency Test (PT)</b>                                                                                  |                 |                |
| Review of Proficiency Testing Policy and Procedure through MTS                                                |                 |                |
| Completed online Proficiency Testing Training Module through MTS                                              |                 |                |
|                                                                                                               |                 |                |
|                                                                                                               |                 |                |
| <b>Note</b>                                                                                                   |                 |                |

|                                                                                     |              |
|-------------------------------------------------------------------------------------|--------------|
| <b>Trainee Signature:</b>                                                           | <b>Date:</b> |
| <b>Trainer Signature:</b>                                                           | <b>Date:</b> |
| The personnel listed above has been deemed competent to perform Vaginal Wet Mounts. | <b>Date:</b> |
| <b>Lab Director / Designee Signature:</b>                                           |              |



**Attachment C:  
Vaginal Wet Mount (Saline and KOH) Competency Assessment Form**

**Personnel Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

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

|                                                                                     |              |
|-------------------------------------------------------------------------------------|--------------|
| <b>Personnel Signature:</b>                                                         | <b>Date:</b> |
| <b>Competency Assessed / Observed (Name and Signature):</b>                         | <b>Date:</b> |
| The personnel listed above has been deemed competent to perform Vaginal Wet Mounts. | <b>Date:</b> |
| <b>Lab Director / Designee Signature:</b>                                           |              |

Attachment D:

Patient Log

Site Name: The Birth Center

|                                                                                                                                    |                                                                                                                                    |                                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> |
| <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> |
| <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> |
| <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> | <p>Date: _____<br/>Name: _____<br/>MR#: _____</p> <p>Test performed: _____<br/>Test result: _____<br/>Testing personnel: _____</p> |

**Attachment E:**

**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:

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**Reviewed By:** \_\_\_\_\_ **/Date:** \_\_\_\_\_

\_\_\_\_\_

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**Reviewed By:** \_\_\_\_\_ **/Date:** \_\_\_\_\_

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