Vaginal Wet Mounts Test, Provider Performed

Wake Forest Baptist Health	**DOCUMENT TYPE:** ☒ Procedure	**ORIGIN DATE** 10/02/2019
CLIA Lab Director: Dr. Gregory Pomper Birth Center – CLIA Lab Director Dr. Joshua Nitsche	**LAB DEPARTMENT:** **POINT OF CARE TESTING COMPLIANCE**	**CONTACT:** Point of Care Testing Compliance

APPLICABLE LABORATORY(S)):
☒ North Carolina Baptist Hospital (NCBH)
☒ Lexington Medical Center (LMC)
☒ Davie Medical Center (DMC)
☒ Wilkes Medical Center (WMC)
☒ High Point Medical Center (HPMC)
☒ Westchester
☒ Clemmons

PROCEDURE STATEMENT

The purpose of this procedure is to perform Vaginal Wet Mounts 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. Each specific test site must have approval from the Point of Care Committee to perform this procedure.

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.

Responsible Department/Party/Parties:

- Procedure Owner: Point of Care Testing Compliance Manager
- 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.
- Supervision: The Laboratory Director indicated on the PPMP, Accreditation or Compliance CLIA certificate and/or their designee will supervise activities outlined in this document.
- 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.

DEFINITIONS

A. Procedure: A process or method for accomplishing a specific task or objective.
B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
C. Point of Care Testing (POCT): Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.
D. Waived Tests: Tests of low complexity as designated by the FDA; tests that are simple and have low risk for erroneous results.
E. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all laboratory testing performed on humans.
F. Quality Assurance (QA): A system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.
G. Normal (Reference) Range: The range of values for the average patient population.
H. 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.
I. 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

PROCEDURE GUIDELINES

1) Purpose

The Vaginal Wet Mount/ Potassium Hydroxide (KOH) Preparation Test enables the provider to detect the presence or absence of bacteria, fungi, parasites, and human cellular elements. The presence of bacteria, fungal elements, motile Trichomonas vaginalis, white blood cells (WBCs), and/or clue cells on a Wet Mount/KOH slide would indicate the need to treat the patient. .

2) 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 to identify the presence or absence of bacteria, fungi, parasites, and human cellular elements. Common findings using these procedures would be bacteria, fungal elements, motile Trichomas vaginalis, WBCs, and clue cells on saline mounted slides and the presence of yeast on slides mounted with KOH.

3) Procedure

A. Positive patient identification should occur per the guidelines in WFBH Patient Identification Policy.

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 Personal Protective Equipment (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 on the 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 (ensure tube is within expiration 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 under low power (10X magnification) for bacteria, fungal elements, motile *Trichomonas vaginalis*, and human cellular elements. Then examine at least 10 fields under high-dry (40X magnification) for the presence of weakly motile *Trichomonas vaginalis*, 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 in appropriate sharps 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, place a drop of saline mixture from test tube onto slide.
4. Place 1 drop of KOH onto mixture on slide (ensure KOH bottle is within expiration date.)
5. Immediately put coverslip over specimen for examination.
6. Examine slide under 40X magnification (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 in appropriate sharps container.

F. Results and Reporting:

1. Place an order for a Vaginal Wet Mount Test (**POC273**) and/or KOH (**POC272**) in WakeOne.
2. Report WBC's per high power field (hpf) as indicated:

Negative: no WBC's/hpf
Rare: < 1WBC/hpf
Few: 1 to 4 WBCs/hpf
Moderate: 5 to 10 WBC's/hpf
Many: > 10 WBCs/hpf

3. Report Positive or Negative for the presence of Trichomonas, yeast and clue cells.
4. For POC272 (KOH), report **Fungal elements seen** or **No fungal elements seen**.
5. Follow the Wake One Tip Sheet on how to order, document and result POC testing.

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 highly 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. A random examination of the cover slipped area (failure to examine the entire cover slip area) may result in false negatives.

4) Equipment

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 moistened areas with a new piece of dry lens paper.
5. Document the maintenance on the Microscope Maintenance Log ***(see Attachment D).***

The Laboratory Director or Designee should review the maintenance log for complete documentation monthly.

Note: 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 should also keep a copy of the service record.

5) Staff Education and Competency

A. Training and Competency:

1. Each testing provider and/or staff member 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 Wet Prep testing will require enrollment in an online program.

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

4. Each administrator will receive forms and education to be used for training and competency.

5. The administrator ensures that providers and staff receive initial training, six (6) month competency assessment the first year, and annual competency assessments thereafter.

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 month (the first year) and annual competency assessments of the physicians, midlevel practitioners and staff performing Wet Prep testing are performed.

B. Initial Training (Attachment A and Attachment E):

1. The initial training of physicians, midlevel practitioners or staff will require the following:
   i. Read and be familiar with the Vaginal Wet Mounts Test policy and procedure.
   ii. Complete the online Vaginal Wet Mounts, Microscope, and Proficiency Training Modules with a passing score (>=80% correct).
   iii. Prepare a Vaginal Wet Prep/KOH Test, supervised by an experienced and competent provider.
   iv. Demonstrate documentation of Vaginal Wet Prep/KOH Test results in WakeOne.

2. Proficiency Testing (PT) Training:
   New testing providers and staff will receive training on how to handle PT Materials, including the following:
   - Documentation of Proficiency Testing policy and procedure review through the MTS online read-receipt process.
   - Enrollment in the online proficiency training module and completion of the exam at the end of the module with a passing score (>=80% correct).

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

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 Vaginal Wet Mounts testing, if applicable.
   a) Blind testing
   b) Direct observation of routine testing
   c) Monitoring of QC performance by each user (not applicable to Vaginal Wet Mounts Test)
   d) Problem solving skills
   e) Direct observation of instrument checks
   f) Monitoring result reporting

3. Competency assessment for the Vaginal Wet Mounts Test will include:
   a) Enrollment in an online Vaginal Wet Mounts Test Competency exam with a passing score (>=80% correct).
   b) Demonstration of performance of the Vaginal Wet Mounts Test

c) Review of microscope maintenance log
d) Chart review of Vaginal Wet Mounts Test results

D. Proficiency Testing (PT):

Each site needs to verify the accuracy of their testing yearly. Participation in a CLIA-approved PT program will satisfy this requirement. Each site will participate in testing three times a year.

1. Proficiency Testing Guidelines:
   a) 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.
   b) The site must enroll and participate in a CMS-approved PT program or provide an Alternative Assessment for the Vaginal Wet Mounts Test.
   c) Acceptable participation means the site receives a passing grade for each PT event.
   d) For any PT event that does 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.

REFERENCES

Fischer, P., et al. The Office Laboratory, Norwalk, Conn.: Appletin-Century-Crofts, 1983.

Provider-Performed Microscopy Procedures, A Focus on Quality Practices. Centers for Disease Control and Prevention (CDC), Division of Laboratory Systems, February 2016.

Standard HR.01.06.01; Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB), January 2018.

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

RELATED PROCEDURES/POLICIES (NAVEX)

ATTACHMENTS/LINKED DOCUMENTS (TITLE 21)

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

Training / Competency Assessment Tools:

Attachment E: Fern, pH, and Wet Mount Training Assessment Tool
Attachment F: Vaginal Wet Mounts Competency Assessment Form
Attachment G: Competency Observation Form (Use with Training/Competency Forms – see Attachments E/F)

Proficiency Testing Procedure

Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas
Point of Care Waived and Non-Waived Testing
Resulting Point of Care Test in WakeOne
Understanding of Responsibilities between Testing Sites and the Clinical Laboratory for POC Testing

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Attachment A:

Vaginal Wet Mounts Test Initial Training Form

Trainee Name: _____

Trainer Name:_____

Training Assessment	Trainer Initial	Date Completed
Vaginal Wet Mounts		
Review of Vaginal Wet Mounts Policy and Procedure through MTS		
Completed online Vaginal Wet Mounts Training Module through MTS with a passing score (>=80% correct)		
Demonstration of performance of Vaginal Wet Mounts		
Demonstration of the use of the microscope		
Documentation of Vaginal Wet Mounts 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 Vaginal Wet Mounts testing. **Lab Director / Designee Signature:**	**Date:**

Attachment B:

Vaginal Wet Mounts Test Competency Assessment Form

Personnel Name: _____

Date: _____

Competency Assessment	Competency Assessed / checked by (Initial)	Date Completed
Vaginal Wet Mounts Test		
Completed online Competency challenge provided by MTS		
Completed competency test through MTS with a passing score (>=80% correct)		
Demonstration of performance of Vaginal Wet Mounts Testing		
Review of microscope maintenance log		
Review of Vaginal Wet Mounts 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 Vaginal Wet Mounts testing. **Lab Director / Designee Signature:**	**Date:**

Attachment C: Patient Log

Test Name: ______________________________________

Site Name: ____

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:** ________

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**

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

Attachment E: Fern, pH, and Wet Mount Training Assessment Tool

Clinic: _____ Date: _____

Employee Name and Signature: _____

No	Yes	N/A	No =Does not meet standard Yes =Meets standard N/A =Not applicable
			1. Review of Procedures **(MTS –Training Procedure/Policy Review Attestation)** 1) Fern Testing 2) Microscope 3) Nitrazine pH 4) Vaginal Wet Mounts 5) Proficiency Testing
			2. Completed Training (MTS) 1) Microscope 2) Fern 3) Vaginal Wet Prep 4) Nitrazine Competency 5) Proficiency Module
			3. Demonstration of performance of In Person Testing (see Competency Observation Form – Attachment G)
			• Results of Fern Testing • Results of pH Testing • Results of Vaginal Wet Mounts Testing • **SCORE =**
			4. Review Audit Form/Requirements
			5. Review Maintenance Form/Requirements
			6. Review Yearly Testing/Requirements
			Notes

Trainer:	**Date:**

Attachment F: Fern, pH, and Wet Mount Competency Assessment Tool

Clinic: _____ Date: _____

Employee Name and Signature: _____

No	Yes	N/A	No =Does not meet standard Yes =Meets standard N/A =Not applicable
			1. Review of Procedures – *assign once yearly* **(MTS –Annual (Competency) Procedure/Policy Review Attestation)** 1) Fern Testing 2) Nitrazine pH 3) Vaginal Wet Mounts
			2. Completed Competencies (MTS) 1) Fern 2) Vaginal KOH 3) Vaginal Wet Prep 4) Nitrazine Competency
			3. Demonstration of performance of In Person Testing (see Competency Observation Form – Attachment G)
			• Results of Fern Testing • Results of pH Testing • Results of Vaginal Wet Mounts Testing **SCORE =**
			4. Review Audit Form/Requirements
			5. Review Maintenance Form/Requirements
			6. Review Yearly Testing/Requirements
			Notes

Preceptor:	**Date:**

Attachment G: Competency Observation Form (Use with Training/Competency Forms – see Attachments E/F)

Nitrazine pH Competency

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

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

Fern

A.

B.

Wet Prep

1.
2.
3.
4.
5.
6.
7.
8.
9

**Fern/Wet Prep slides available from POCT Office if needed – email our team at LabPOC_Testing_DL@wakehealth.edu

Trainer/Preceptor: _____ **Date:** _____

**SCORE must be 100%. IF not; remediate at time of testing. Put one strike through wrong answer; initial and date. Have Provider correct answer.