


Microscope Policy and Procedure

	<b>DOCUMENT TYPE:</b> <input checked="" type="checkbox"/> Procedure	<b>ORIGIN DATE</b>  <p style="text-align: center;">10/02/2019</p>
<b>CLIA Lab Director:</b> Dr. Gregory Pomper  <b>Birth Center - CLIA Lab Director</b> Dr. Joshua Nitsche	<b>LAB DEPARTMENT:</b>  <b>POINT OF CARE TESTING COMPLIANCE</b>	<b>CONTACT:</b>  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 note the required annual maintenance and the weekly or as needed cleaning maintenance for microscopes. Each clinic will contact Trimedx at 877-874-6339 to schedule preventative or needed maintenance.

Weekly or as needed cleaning maintenance will be performed by testing personnel and documented on the Microscope Maintenance Log. The CLIA Lab Director or Designee will review the Microscope Maintenance Log monthly to ensure completeness and document this review by signing and dating the log. After the review, completed logs will be filed and kept in a designated location.

Any problems that occur with the operation of the microscope must be documented under the Problems section of the Microscope Maintenance Log. Give a brief description of the problem and the actions taken to correct the problem. The microscope should not be used for testing until the issue is resolved.

**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.

## POLICY GUIDELINES

### 1. Microscope Maintenance:

- a. Weekly maintenance is done on the microscope used for testing to ensure cleanliness of the scope and an accurate reading of the specimen.
- b. Clean off dust in the microscope area.
- c. Clean the oculars, stage, and the condenser with a swab or lens paper moistened with a commercially available lens cleaner.
- d. Dry off moistened areas with a new piece of dry lens paper.
- e. Document the maintenance on the Microscope Maintenance Log (see Attachment A).
- f. The Laboratory Director or Designee should review the maintenance log for complete documentation monthly.

### 2. 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 Clinic should also keep a copy of the service records.

**3. Staff Education and Competency:**  
(see Policy/Procedure for specific Provider Performed Test)

**REFERENCES**

**RELATED PROCEDURES/POLICIES (NAVEX)**

**ATTACHMENTS/LINKED DOCUMENTS (TITLE 21)**

Attachment A – Microscope Maintenance Log  
Attachment B – Problem/Corrective Action Log

***Proficiency Testing***

***Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas***

***Point of Care Waived and Non-Waived Testing***

***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: 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 (Refer to Attachment B if more space needed):

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<b>Reviewed By:</b>	<b>/Date:</b>	<b>Reviewed By:</b>	<b>/Date:</b>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Attachment B:

<b>Problem / Corrective Action Log</b>			
<b>Site:</b> _____		<b>Test:</b> _____	
<b>Date</b>	<b>Initials</b>	<b>Problem/Error</b>	<b>Corrective Action</b>

**Monthly Manager Review:** \_\_\_\_\_ **Date:** \_\_\_\_\_