

Institutional Handbook of Operating Procedures Policy 09.13.2	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO UTMB Health System
Subject: General Procedures	Responsible Entity: Pathology

I. Title

Governance of Provider Performed Microscopy Procedures (PPMP)

II. Policy

All healthcare providers, including licensed independent practitioners (LIP) responsible for performing approved microscopy procedures on clinical specimens for screening, diagnosis, or treatment assessment purposes may exercise performance of PPMP's upon documented completion of proper training and competency assessment in compliance with 42 CFR § 493.19.

All PPMP's within the UTMB Health System must be performed during the patient's visit to the medical practice using either bright-field or phase microscopy. Polarized light may not be used.

All PPMP results should be documented in the Medical Record.

UTMB respects the diverse cultural needs, preferences, and expectations of the patients and families it serves to the extent reasonably possible while appropriately managing available resources and without compromising the quality of health care delivered.

III. Scope

Microscopic examination of specimens obtained from a patient for the purpose of screening, diagnosis, or treatment is considered laboratory testing and as such comes under the Clinical Laboratory Improvement Act of 1988 (CLIA). CLIA regulations require that facilities performing laboratory testing hold a current CLIA certificate for the complexity of testing performed. A CLIA Certificate of Provider Performed Microscopy Procedures is necessary to perform tests in this category. **NOTE:** a CLIA Certificate of Waiver is not sufficient to perform microscopy procedures. Likewise, Pathology's CLIA Certificate of Accreditation does not extend to coverage of PPMP procedures performed within the UTMB Health System. UTMB Hospital Administration has delegated the authority to Pathology Clinical Services for oversight of all point of care testing within the UTMB Health System, including PPMP, The Pathology Clinical Services POCT Director shall review and approve in writing all PPMP policies and procedures before initial use, when changes in procedures occur, and periodically thereafter but at least once every three years.

IV. Regulatory Compliance

The [Clinical Laboratory Improvement Amendment](#)s requires all sites performing laboratory testing to:

- Obtain the appropriate CLIA certificate (registration, compliance, PPMP, waived testing, or accreditation) for the category and complexity of laboratory testing performed.
- Submit to inspections conducted by the Center for Medicare and
- Medicaid Services (CMS) or a CMS approved accrediting agency, and
- Maintain a valid certificate of accreditation.

Laboratory accreditation certificates are valid for two years and may be issued by CMS or a CMS-approved private non-profit accrediting agency such as The Joint Commission (TJC) and the College of American Pathologists (CAP). To maintain accreditation, a laboratory must submit to inspections by the accrediting agency.

V. Guidelines

Performance of PPMP is limited to procedures and methods listed in the approved [UTMB POCT Formulary](#). Mandatory compliance by all healthcare providers is required, and non-compliance may result in loss of testing privileges (e.g., elimination of a tests site or disapproval of a user). The use of each PPMP test (screening, diagnostic, or monitoring) is outlined in the [UTMB POCT Formulary](#) as well.

VI. Approval and Implementation Process

The table below states the process for implementing PPMP within the UTMB Health System.

Step	Responsibility	Action
1.	Physician Provider	<ul style="list-style-type: none"> Identifies a potential need for a PPMP. Calls/e-mails Pathology's POCT Director to discuss request. Submits a completed POCT Implementation Form to the POCT Director.
2.	Physician Provider and POCT director	<ul style="list-style-type: none"> Discuss the identified need for POCT. Discuss the regulatory requirements for PPMP.
3.	POCT director	<ul style="list-style-type: none"> Reviews the POCT Application/Request for completeness and clarity. Contacts the physician provider to review objective criteria for implementing PPMP procedure.
4.	POCT director and physician provider	<ul style="list-style-type: none"> Review objective scientific and utilization criteria for implementing procedure. If POCT Director and physician are in agreement on PPMP procedure, the procedure will be implemented.

VII. Quality Management

Compliance with federal regulations is best achieved by a team effort between the testing site and point of care personnel. For this reason, a program of quality management has been established. Outlined below and summarized in table format is the program specific for PPMP's. An alternate program designed strictly for other POCT (waived and moderate complex) is outlined in [IHOP Policy 9.13.4, Governance of Point of Care Testing \(POCT\)](#).

VIII. Competency Assessments

A. Competency of physicians and LIPs is established and monitored by the Medical Staff Office during the credentialing process.

- B. Faculty** — At a given practice, faculty must declare which PPMP’s they are competent in performing. A competency roster of all faculty members will be maintained by each department’s designated Quality Management (QM) individual.
- C. Residents** — Must be trained and declared competent by the supervising faculty who will attest the resident has demonstrated the desired level of skills. Faculty will also ensure that residents adhere to standing protocols as outlined in PPMP standard operating procedures. The authorized faculty must approve a PPMP Certification form for each resident, and submit it to the Residency Training Program director, House Staff, as well as Pathology.
- D. Nurse Practitioners, Physician Assistants** —Must be trained and declared competent by the practice director. A PPMP Certification form is to be completed and a copies submitted to UTMB credentialing and Pathology. The practice director will be responsible for assuring adherence to PPMP standard operating procedures.
- E. Medical students** — May be trained but will not be allowed to report PPMP’s and therefore competency assessment is not required.

IX. Training

Training is available through Pathology for practice members desiring training other than that provided by designated or authorized faculty. Arrangements can be made by contacting the POCT Director at extension 21350.

X. Quality Assurance

- A.** Medical Staff Credentialing is responsible for keeping records of all members in the practice that are authorized to perform PPMP.
- B.** Documentation of this authorization must be kept on file in the Medical Staff Credentialing office and must be accessible to inspection officers.

PPM Quality Management Summary

Function	Healthcare Providers		Pathology	Medical Staff Credentialing
Standard Operating Procedures (SOP)	Ensure reading of PPMP procedures as applicable. Provide comments and input to written SOPs. Convey desired modifications to QM Faculty.		Responsible for conveying approved protocol changes to QM faculty.	
Competency	Faculty completes competency forms and certifies competency of residents. Forwards completed forms to QM faculty.		Maintains competency records for PT assessment purposes.	Holds documentation of healthcare providers authorized to perform testing. Forwards copies of forms to POCT director.
Quality Assurance	Adhere to standing protocol when performing PPMP.			Copies of competency for individual providers will be kept in the personnel files.

XI. Definitions

Licensed Independent Practitioner (LIP): Any individual permitted by law and UTMB to provide care and services without direction or supervision within the scope of the individual’s license and consistent with individually granted clinical privileges.

Point of Care Testing (POCT): POCT is laboratory testing performed at or near the patient site, usually by non-laboratory staff (e.g., physicians, nurses, respiratory therapists, and perfusionists). The central criterion of POCT is that it does not require permanent dedicated space. Examples include kits and instruments that are hand-carried or otherwise transported to the vicinity of the patient for immediate testing at that site. POCT does not include limited-service satellite laboratories with fixed dedicated testing space. Synonyms: bedside tests, alternative site test, near patient testing.

Provider Performed Microscopy Procedures (PPMP): Microscopic examination of a specimen obtained during a patient’s visit that is performed by the provider or by a member of the group practice using bright field or phase contrast microscope.

Test Site Management: The individual(s) within departments/clinics authorized to perform POCT who are accountable for supervising, training, and ensuring compliance of personnel with POCT policies and procedures.

XII. Related UTMB Policies and Procedures

[IHOP - 09.13.04 - Governance of Point of Care Testing \(POCT\)](#)

XIII. Additional References

[Current CLIA Regulations](#)
[CLIA Certificates Types.](#)

XIV. Dates Approved or Amended

<i>Originated:</i> 03/10/2001	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
05/03/2012	01/29/2019

XV. Contact Information

Laboratory Administration
 (409) 747-0765