Institutional Handbook of Operating Procedures Policy 09.13.04	
Section: Clinical Policies	Responsible Vice President: EVP & COO Clinical Enterprise
Subject: General Policies	Responsible Entity: Laboratory Services

I. Title

Governance of Point of Care Testing (POCT).

II. Policy

A. Point of Care Testing within the UTMB Health System will be performed in accordance with state and federal regulatory requirements. UTMB Hospital Administration and Clinical Laboratory Improvement Amendment (CLIA) Directors have delegated to Laboratory Services the authority for oversight of all POCT within the Health System. As such, the Laboratory Service's Director of POCT has the authority to establish and approve all testing policies and procedures related to POCT for all UTMB waived, provider performed microscopy procedures (PPMP), and moderately complex procedures that fall under clinic or hospital CLIA certificates along with enforcement of Quality Control (QC) guidelines. POCT tests follow the manufacturer's package insert guidelines. All vendors of point-of-care tests must follow UTMB's Vendor Policy, IHOP 09.07.02, and Vendor Management Policy.

B. The Laboratory Service's POCT Director shall review and approve in writing waived testing, PPMP, and moderately complex policies and procedures before initial use of a test for patient testing, when changes in procedures occur and periodically thereafter, but at least once every two years.

C. Point of Care Testing should be performed and documented by the person performing the test according to POCT 13.1.3 Patient Test Management policy.

III. Regulatory Compliance

The Clinical Laboratory Improvement Amendments require all sites performing laboratory testing to:

- Obtain the appropriate CLIA certificate of registration/accreditation.
- Submit to inspections conducted by the Center for Medicare and Medicaid Services (CMS) or a CMS approved accrediting agency.
- Maintain a valid certificate of laboratory accreditation certificates.

Laboratory accreditation certificates only applies to moderate complexity testing performed in a POCT environment and will operate under the main laboratory. The areas performing moderate complexity testing must comply with the lab accreditation regulatory requirements. Laboratory accreditation certificates are valid for two years and issued by CMS or a CMS-approved private non-profit accrediting agency such as the College of American Pathologists (CAP). To maintain accreditation, a laboratory must submit to required inspections by the accrediting agency (biennial for CAP and the Joint Commission).

IV. Regulatory Agencies

The following statements define the primary regulation by which point of care testing operate and the accrediting agencies subscribed by UTMB.

A. Clinical Laboratory Improvement Amendment of 1988 (CLIA '88): Federal regulations that set standards for performance of all laboratory testing, in all laboratories.

B. The Joint Commission: an independent, not-for-profit organization dedicated to improving the quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations. The Joint Commission has also been approved as an accrediting agency for laboratories by CMS. Inspection frequency: triennial, unannounced.

C. College of American Pathologists (CAP): an independent, not-for-profit organization approved by CMS to accredit laboratory services.
Inspection frequency: biennial, unannounced.

V. Level of Complexity Testing

The chart below provides testing requirements for various levels of test complexity.

Level of Complexity	Certificate	Requirements
Waived Tests	CLIA Certificate of Waiver or Provider Performed Microscopy Procedures	• Have valid (current) certificate of waiver. • Follow manufacturer's instructions and POCT 13.1.1 POCT Quality Management policy to perform the test. • Maintain the Joint Commission hospital accreditation standards.
Provider Performed Microscopy Procedures	CLIA Certificate of Provider Performed Microscopy Procedures	• Medical Director of site holds certificate.
Moderate Complexity	CLIA Certificate of Accreditation CAP Accreditation Certificate	• Possess a valid certificate. • Follow manufacturer's instructions, standard operating procedures, and POCT 13.1.1 POCT Quality Management policy to perform the test. • Follow applicable CAP regulatory requirements. • Routine unannounced inspections or in response to a complaint. • Maintain the CAP laboratory accreditation standards. • Laboratory services holds the CAP accreditation certificate.

VI. Process for POCT Approval and Implementation

Point of Care Testing is limited to the tests listed in the approved UTMB POCT Formulary. Mandatory compliance by all healthcare providers is required; non-compliance may result in dismissal of testing privileges. The UTMB Approved Formulary is located on the UTMB website at http://intranet.utmb.edu/poc/pocformulary.

The use of each point of care test (screening, diagnostic, or monitoring) is outlined in the same document (formulary) above.

The process for implementing POCT within UTMB's Health System is outlined below. Further responsibilities for implementation are delineated for testing personnel, test site management, and POCT laboratory.

Step	Responsibility	Action
1.	Physician Provider	• Identifies a potential need for POCT. • Call/e-mail Laboratory Service's POCT Director to discuss request. • Submits a completed POCT Bedside Testing Implementation form (POCT Forms BST 09I) to the POCT Director.
2.	Physician Provider and POCT Director	• Discusses the identified need for POCT.
3.	POCT Director	• Reviews the POCT application/request for completeness and clarity. • Determines whether the request represents a new test. • If the request is unclear or does not represent a new test, contacts the physician provider and reviews objective criteria for implementing the test.
4.	POCT Director and Physician Provider	• Reviews objective scientific and utilization criteria for implementing the test. • If the test is listed currently in the formulary, implements the test. • If the test is not listed in the formulary, the POCT Director determines the clinical need for the test and if clinically necessary, will approve the new test and have it placed on the formulary.

VII. Definitions

Point of Care Testing (POCT): Point of care testing is performed at the site of "Patient Care" usually by non-laboratory staff (e.g., physicians, nurses, respiratory therapists, and perfusionists). POCT is often accomplished using portable handheld devices and test kits. Small bench analyzers or fixed equipment can also be used when handheld devices are not available. The goal is to collect the specimen and obtain the results in a short period of time at or near the location of the patient so that the patient's treatment plan can be adjusted if necessary.

Provider Performed Microscopy Procedure: A moderately complex test using a bright-field or phase contrast microscope performed by healthcare providers.

Waived Testing: As defined by CLIA, waived tests are simple tests with a low risk for an incorrect result. They include tests that the manufacturer applies to the FDA for waived status by providing

scientific data that verifies that the CLIA waiver criteria have been met. Sites that perform only waived testing must have a CLIA certificate and follow manufacturer's instructions.

Moderate Complexity Testing: Subject to inspection, and must meet the CLIA quality system standards, such as those for proficiency testing, quality control and assessment, and personnel requirements. Laboratories or sites that perform these tests need to have a CLIA certificate, be inspected, and must meet the CLIA quality standards described in 42 CFR Subparts H, J, K and M.

Test Site Operators: The individual(s) within departments/clinics authorized and trained to perform POCT.

Test Site Manager: 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 and enforcement of QC guidelines.

VIII. Relevant Federal and State Statutes

42 CFR Subparts H, J, K and M

IX. Related UTMB Policies and Procedures

IHOP 09.07.02- Vendor Management Policy

X. Dates Approved or Amended

Originated: 07/31/1997	
Reviewed with Changes	*Reviewed without Substantive Changes*
05/03/2012	04/04/25
05/03/2015	
11/30/2018	
09/02/2021	

XI. Contact Information

Point-of-Care Testing Department – 409-747-2497