

Section 9	Clinical Affairs Policies	07/31/97 Originated
Subject 9.13	General Procedures	08/01/2015- Reviewed w changes -Reviewed w/o changes
Policy 9.13.4	Governance of Point of Care Testing	08/01/2015- Effective Pathology - Author

Governance of Point of Care Testing (POCT)

Definitions

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.

Waived Test. Waived tests are approved by the FDA for home use and employ methods that are straightforward and accurate such that the likelihood of erroneous results or patient injury is negligible.

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.

Policy

All “point of care tests” within the UTMB Health System will be performed in accordance with local, state and federal regulatory requirements. UTMB Hospital Administration has delegated to Pathology Clinical Services the authority for oversight of all POCT within the Health System. As such Pathology’s Director of POCT has the authority to establish and approve all testing policies and procedures dealing with POCT for all UTMB waived and provider performed microscopy procedure (PPMP) Clinical Laboratory Improvement Amendment (CLIA) certificates. All vendors of point-of-care tests must follow the UTMB Vendor Policy, [IHOP 9.7.2](#), *Industry Vendor Visitation: UTMB Clinical Enterprise*.

The Pathology Clinical Services POCT Director shall review and approve in writing waived testing and PPMP 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 three years.

All POCT 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.

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Regulatory Compliance

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

1. obtain the appropriate CLIA certificate of registration/accreditation
2. submit to inspections conducted by the Center for Medicare and Medicaid Services (CMS) or a CMS approved accrediting agency,
3. POCT is limited to the tests 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 test sites or disapproval of a user)..

The use of each point of care test (screening, diagnostic, or monitoring) is outlined in the [UTMB POCT Formulary as well](#).

Process for POCT Approval and Implementation

The process for implementing POCT within the UTMB 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	<ul style="list-style-type: none"> • Identifies a potential need for POCT • Calls/e-mails Pathology'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	<ul style="list-style-type: none"> • Discusses the identified need for POCT
3.	POCT Director	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Reviews objective scientific and utilization criteria for implementing the test • If in agreement on tests currently in the formulary, implements the test • If in agreement to implement new tests and not in agreement with tests currently approved 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.