Standard Operating Procedures
*C*linical and *T*ranslational *R*esearch *C*enter

Title:	**Point of Care Testing**		
Approved By:	Christina Wang MD	**Effective Date:**	March 19, 2012
Number of Pages:	Page 1 of 3	**Revised Date:**	

Purpose: This procedure defines guidelines for Point of Care Testing (POCT)

Point of Care Testing refers to those analytical patient testing activities provided under the clinical laboratory's CLIA certificate, but performed outside the physical facilities of the clinical laboratories by non-clinical laboratory personnel. POCT is considered to be definitive testing. Tests that can be performed as POCT are defined as waived, non waived moderate complexity or provider performed microscopy (PPM) under Federal Guidelines of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)

POCT Testing device means a portable laboratory instrument used in proximity of the patient and maintained as per laboratory standards. The device:

- Performs tests on biological specimens that require no preparation after collection;

- Provides results without calculation or discretionary intervention by the testing personnel; and

- Functions without testing personnel calibration or maintenance (other than basic cleaning or resetting pursuant to the manufacturer's instructions).

Procedure:

It is the policy of CTSI that all POCT is performed in compliance with applicable standards and regulatory requirements.

I. The clinical laboratory Director, or unit Director, is responsible for all POCT. All equipment, specimen, and performance criteria must be approved by the Director.

II. Only properly trained and approved personnel may perform POCT. The clinical laboratory provides orientation and training materials; it is the responsibility of the testing site to conduct competency testing. All individuals performing POCT must have documented competency assessment at least semiannually during the first year and annually thereafter. Should test methodology or instrumentation change, competency shall be reevaluated prior to use of the new test.

III. Competency for POCT is assessed using at least two of the following methods per person per test:

- Performance of a test on a blind specimen
- Direct observation by the supervisor or qualified designee
- Monitoring of each user's quality control performance
- Use of a written test specific to the test assessed.

IV. Written procedures that have been approved by the laboratory Director are available for each point of care test. Testing personnel are expected to follow the instructions contained in the applicable written procedure.

V. Proficiency testing must be performed for all POCT.

VI. All POCT will be reviewed at regular intervals by designated members of the Department of Pathology and Laboratory Medicine. If the quality of POCT falls below acceptable levels, testing will be discontinued at the performing site until the quality is deemed satisfactory.

VII. Nursing designees, clinical laboratory POCT coordinators and the clinical laboratory Director will review performance at all sites and will make recommendations on a periodic basis for performance improvement.

VIII. All POCT shall meet appropriate safety and laboratory practices as defined by manufacturer's recommendations, applicable accrediting agencies, and UCLA Health System policy/ procedure.

It is the policy of UCLA Health System that all POCT is performed in compliance with applicable standards and regulatory requirements.

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Appendices: