LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER - SHREVEPORT

POINT OF CARE TESTING

Purpose:

To insure that laboratory testing at Louisiana State University Health Sciences Center performed outside the main Clinical Laboratory or designated Special Function Laboratory is accomplished utilizing methodologies to insure valid, reliable test results and that all such testing is done in compliance with all state and federal regulations.

Definitions:

Point-of-care testing (POCT): refers to those analytical patient testing activities provided within the institution, but performed outside the physical facilities of the clinical laboratories. 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 or analytic instruments that are temporarily brought to a patient care location. POCT does NOT include limited service satellite laboratories with fixed, dedicated testing space.

Waived test: Those tests identified by the Clinical Laboratory Improvement Amendments 1988 (CLIA 88) that are simple laboratory examinations and procedures, which employ methodologies that are simple and accurate, minimizing the likelihood of erroneous results or which pose no reasonable risk of harm to the patient if the test is performed incorrectly. Test are reassessed and may be recategorized on a regular basis by CLIA. Some examples of waived tests include but is not limited to:

- non automated urinalysis, dipstick or tablet
- fecal occult blood
- urine pregnancy test
- urine HCG by visual color comparison test
- blood glucose monitoring devices cleared by the FDA for home-use
- spun microhematocrit
Moderate Complexity: A category of tests identified by the Clinical Laboratory Improvement Amendments 1988 (CLIA88) that are either automated procedures with no operator intervention during the analytical process or manual procedures with limited steps and limited reagent preparation. Test are reassessed and may be recategorized on a regular basis by CLIA. Some examples of moderately complex tests include but is not limited to:

- electrolytes
- urine microscopics
- activated clotting times
- modified waived test procedures

Policy:

1. Laboratory test data which will be utilized for the diagnosis, management or treatment of a patient must be produced in an environment which insures that the testing procedure is accurate and reliable on a consistent basis. All areas performing point-of-care testing must have an established written procedure which addresses:

   A. Competency of personnel performing the test.

   B. Quality control activities.

   C. Reporting, utilization, and maintenance of test results.

2. Laboratory tests performed at the point-of-care, both waived and moderate complexity, are required to meet all applicable standards for their designated accrediting body. Louisiana State University Health Sciences Center accreditation will be through the College of American Pathologists (CAP).

3. Testing methods classified as waived testing under federal law and regulation are required to meet all applicable standards (PA.6.4) in the Point-of-Care Testing in the Commission on Laboratory Accreditation Inspection Checklist (CAP).

4. Monitoring and review of all POCT procedures is the responsibility of the Clinical Laboratory, including quality control standards, competency of individuals performing the test and management of data.
5. A multidisciplinary committee, shall oversee the utilization of POCT within Louisiana State University Health Sciences Center. Responsibilities include:

   A. The review and approval of requests for implementation of POCT within specific areas, based on the impact on patient care and cost / benefit analysis.

   B. Review and revise hospital policy related to POCT as needed, but not less than annually.

** "Compiled List of Clinical Laboratory Test Systems, Assays, and Examinations Categorized by Complexity" (LAB-93-20.1) published Monday, July 26, 1993 Federal Register (FR) Vol. 58, No 139

________________________________________
Administrator

________________________________________
Date

Written: 12/94
Revised: 10/97, 4/03
Reviewed: 2/00, 4/03
Approved by Clinical Board: 5/16/2000, 5/20/03
Request for Approval of Point of Care Testing

1. Service / section / area where testing is to be done:
   ______________________________

2. Test being requested? ___________________________________________
   Instrument/Kit Needed (if known) _________________________________

3. Categories of individuals who will be authorized to perform test.
   (check all that apply): MD _____ RN _____
   Other _____ LPN _____
   (Specify) _____ Nursing Assistants _____

4. Requested test will be used for:
   Screening _______ Definitive diagnosis ______

5. Briefly provide a clinical justification for this request (ie., why performing this test at
   the point-of-care will result in improved patient care; convenience of the clinician is not
   in itself sufficient justification) __________________________________________
   ______________________________________________________________________
   ______________________________________________________________________
   ______________________________________________________________________

6. Provide a cost analysis for the requested test performed on a per test basis; this cost
   must include equipment, supply and quality control cost. Include anticipated volume of
   tests / year. If multiple panels are available, calculate seperately.
   Test/Panel: ________________ Cost: _____________ Volume: _____________
   Test/Panel: ________________ Cost: _____________ Volume: _____________
   Test/Panel: ________________ Cost: _____________ Volume: _____________
   Test/Panel: ________________ Cost: _____________ Volume: _____________

7. Will utilization of requested test reduce / eliminate testing currently done in the Clinical
   Lab? Indicate degree of impact (% reduction) on test volume sent to Clinical
   Laboratory.
   Reduce - Yes _______ Percentage _________% Identify which test(s) ______________________________
   No _______
   Eliminate- Yes _______ Percentage _________% Identify which test(s) ______________________________
   No effect - N/A _______
8. Individual submitting request:

Name: ____________________________________ (please print)

Credentials: ________________________________

Dept. & phone #: ____________________________

I have read and understand the Louisiana State University Health Sciences Center policy on point of care testing; I also understand that this testing cannot commence until approval from the POCT Oversight Committee has been received.

Authorization for request

__________________________________
Medical Director

__________________________________
Nursing Director

__________________________________
Hospital Administration

Submit completed form to Director of Clinical Lab or designee, Clinical Lab, extension 55719

__________________________________
DO NOT WRITE BELOW THIS LINE, FOR COMMITTEE USE ONLY.

Request Approved: ____________ Date: _________________

Request Rejected: ____________ Date: _________________

Reason Rejected:
_____________________________________________________________________
_____________________________________________________________________

Authorizing Signature: ________________________________