

INTERIM LOUISIANA STATE UNIVERSITY (LSU) PUBLIC HOSPITAL

Organizational-wide Policy Signature Sheet

MEDICAL ADMINISTRATION

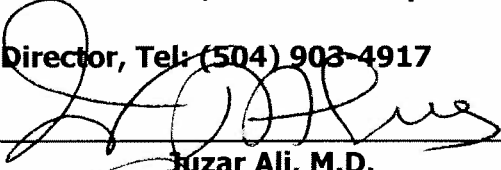
POLICY NUMBER: 5055

POLICY TITLE: Point of Care Testing

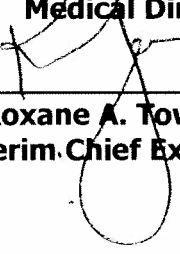
EFFECTIVE DATE: November 30, 1999
Date of Latest Review/Revision: September 26, 2011

INQUIRIES TO: Medical Director, Tel: (504) 903-4917

APPROVED:



Juzar Ali, M.D.
Medical Director



Roxane A. Townsend, M.D.
Interim Chief Executive Officer

**REVIEW/REVISION
DATES:**

<u>May 29, 2000</u>	<u>July 24, 2000</u>	<u>April 15, 2002</u>
<u>November 6, 2002</u>	<u>November 24, 2003</u>	<u>November 29, 2004</u>
<u>August 29, 2005</u>	<u>June 21, 2006</u>	<u>July 30, 2007</u>
<u>July 28, 2008</u>	<u>August 31, 2009</u>	<u>September 27, 2010</u>
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New and/or revised information since last revision is underlined for easy reference.

POLICY: The Interim Louisiana State University (LSU) Public Hospital, also known as and hereafter referred to as the Medical Center of Louisiana or MCL, adheres to the Louisiana State University Health Care Services Division Policy 5513-10: Point of Care Testing Policy.

MCL-Specific Guidance is included as Attachment I.

**LOUISIANA STATE UNIVERSITY
HEALTH CARE SERVICES DIVISION
BATON ROUGE, LA**

POLICY NUMBER: 5513-10

CATEGORY: Medical Services

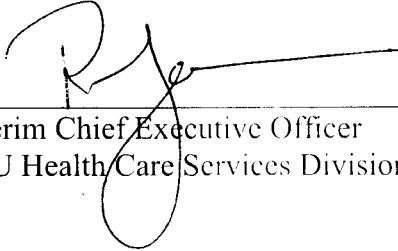
SUBCATEGORY: Laboratory Services

CONTENT: Point of Care Testing

EFFECTIVE DATE: July 25, 2008

REVIEWED: August 9, 2010

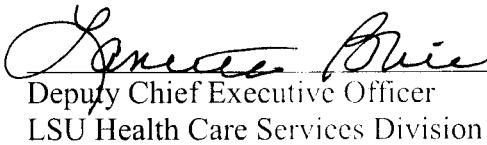
INQUIRIES TO: Michael Kaiser, Chief Medical Officer
LSU HCSD, Medical
533 Bolivar Street, Room 362
New Orleans, Louisiana 70112
Telephone: 504-568-2259 Facsimile: 504-568-2090
Telephone: 225- 922-0157 Facsimile: 225 922-1502



Interim Chief Executive Officer
LSU Health Care Services Division

8.20.10

Date



Deputy Chief Executive Officer
LSU Health Care Services Division

8/19/10

Date



Chief Medical Officer
LSU Health Care Services Division

8/19/10

Date

Effective: July 25, 2008
Reviewed: August 9, 2009

5513-10.1

**Louisiana Health Care Services Division
Point-of-Care Testing**

I. PURPOSE

To provide a systematic approach to standardize the evaluation and implementation of point-of-care testing (POCT) throughout the Louisiana State University – Health Care Services Division (LSUHCS D) in order to provide the highest quality of laboratory testing regardless of the test site.

II. SCOPE

This policy shall apply to each LSUHCS D facility that wishes to provide point-of-care testing in identified areas.

III. RESPONSIBILITIES

1. The HCS D Laboratory Operations Committee (LOC) will be responsible for overseeing the evaluation and selection of new testing equipment, development of training programs, procedures, documentation, review of test results, performance and monitoring of quality controls, corrective action, proficiency testing and equipment management, and providing a cost/benefit analysis to the Medical Staff and Administration of the facility requesting POCT.
2. The Medical Staff of the facility will be responsible for requesting and providing rationale for POCT that will include protocols for use, areas to be used within the facility, and expected volume. The medical staff will work with the laboratory director to identify specifics for repeat testing.
3. The nursing managers will be responsible for enforcing POCT policies and procedures that include quality controls per manufacturer's specification, training, performing competency evaluations for non laboratory staff and maintaining the appropriate documentation for accrediting agencies.

IV. POLICY

It is the policy of LSUHCS D to utilize POCT in identified areas by maintaining "Good Laboratory Practices" as set forth by regulatory agencies.

Expansion of POCT testing outside the confines of this policy or written approved protocols is prohibited without the written consent of the Chief Medical Officer or his designee.

Effective: July 25, 2008
Reviewed: August 9, 2009

5513-10.2

V. PROCEDURE

Any hospital that wishes to expand POCT by adding new tests or new location for testing shall submit a request in writing, signed by the Hospital Medical Director, to the LOC for possible actions listed in section III item 1 of this policy.

VI. IMPLEMENTATION

This policy and any subsequent revisions to this policy shall become effective upon the approval date and signature of the Chief Executive Officer of LSUHCSD (or designee).

MCL-SPECIFIC GUIDANCE

- A. The Chief Executive Officer (CEO) delegates the Department of Pathology with the responsibility for:
- developing reasonable testing criteria for clinical areas
 - overseeing quality control practices for “waived” testing
 - monitoring testing results
 - auditing clinical areas to determine adherence to regulatory guidelines
 - reporting compliance findings to the Associate Hospital Administrator, Patient Care Services or designee for review and action, as appropriate.

B. **Definitions**

For the purpose of the MCL-Specific Guidance, the following definitions shall apply:

Attending staff physicians – according to the MCL Medical Staff Bylaws, medical staff charged by the academic departments of the medical schools affiliated with the Medical Center of Louisiana to actively supervise clinical training of house staff physicians.

Hospital Center – according to the MCL Medical Staff Bylaws, the principal organizational element of the clinical staff. At MCL, the Hospital Centers are:

- Medicine – Dermatology, Family Medicine, Medicine, Neurology, Neurosurgery and Rehabilitation
- Women and Newborn Center – Obstetrics/Gynecology and Newborns
- Outpatient Services – Ambulatory Care and Emergency Services
- Pediatrics – Children’s Services
- Professional Support Services – Anesthesia, Pathology and Radiology
- Psychiatry
- Surgery – Cardiothoracic, Dental and Oral, General Surgery, Ophthalmology, Orthopedics, Otolaryngology, Plastic, Urology and Vascular Surgeries.

Hospital Center Director – according to the MCL Medical Staff Bylaws, the principal person of each Hospital Center responsible for monitoring patient care delivered by the clinical staff and administrative activities of the Hospital Center.

House staff physicians – according to the MCL Medical Staff Bylaws, interns, residents and fellows assigned to MCL by the Louisiana State University Health Sciences Center, Tulane University Health Sciences Center and other medical schools affiliated with the Medical Center of Louisiana.

Moderately Complex Tests – category of tests that are classified based on their level of complexity requiring adherence to strict regulatory standards.

Point of care testing (POCT) – term that describes “waived” testing, provider performed microscopy procedures and moderately complex testing that are performed outside the laboratory setting and at the patient’s point of service.

Provider performed microscopy and non-microscopy procedures – moderately complex testing performed by licensed physicians and/or licensed nurse practitioners, under the supervision of a licensed physician.

“Waived” testing – laboratory testing performed by non-laboratory personnel near or at the patient’s location with a low risk of generating erroneous results.

C. **Point of Care Testing (POCT) Performed by Non-Physicians**

PLEASE NOTE: “**Waived**” Testing may only be performed by licensed practical nurses (LPNs), registered nurses (RNs), and nurse practitioners.

Moderately Complex Testing applies to Prothrombin Time/ International Normalized Ratio (PT/INR) may only be performed by RNs, nurse practitioners and pharmacists.

Provider Performed Microscopy and Non-Microscopy Procedures may only be performed by nurse practitioners.

Information regarding physician performed POCT procedures can be found in Section D of the MCL-Specific Guidance.

1. It is the responsibility of the Department of Pathology to ensure that the following criteria are in place:
 - provision of patient testing oversight and technical expertise
 - adherence to “waived” and/or moderately complex testing quality control standards
 - determination of each clinical area’s competence for continued performance of testing via oversight audits
 - selection of methodology and instrumentation
 - analysis of the appropriateness of use of the procedure by the clinical areas
 - monitoring of the results of oversight audits to determine compliance
 - reporting results to the Division of Patient Care Services for review and action, as appropriate

- approval of written testing procedures for the performance of the “waived” and/or moderately complex testing
 - required demonstration of managerial and user knowledge in units that fail to meet the required standards.
2. It is the responsibility of the Associate Hospital Administrator, Patient Care Services or designee to ensure that the following criteria are in place:
- review of oversight audit results to ensure compliance
 - collaboration with clinical areas, as appropriate, to generate and implement corrective action plans
 - revoking of testing privileges within clinical areas chronically found out of compliance.
3. It is the responsibility of the RN Manager and/or department director of each clinical area performing testing to ensure that the following criteria are in place:
- identification of staff members who shall be responsible for performing testing
 - identification of staff members to supervise and/or direct testing activities
 - insurance of compliance with required procedures when performing testing
 - initial and ongoing competency training and testing of staff members performing testing
 - provision of current and complete written procedures to staff for each test performed within their area
 - compliance with the quality control guidelines required for each “waived” and/or moderately complex test performed within their area, inclusive of the quality control log, if applicable.

D. Physician Performed Point of Care Testing

1. It is the responsibility of the Department of Pathology to ensure that the following criteria are in place:
- provision of training and competency testing materials
 - provision of technical expertise on testing procedures.
2. It is the responsibility of the appropriate Hospital Center Director to ensure that the following criteria are in place:
- attending staff physicians are competent and remain competent
 - house staff physicians are trained and declared competent by a supervising attending staff physician
 - house staff physicians remain competent
 - testing accuracy is evaluated semi-annually
 - physicians follow testing procedure protocols

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- testing privileges are revoked for physicians found incompetent to perform “waived” testing and physician performed microscopy and non-microscopy procedures.
3. It is the responsibility of the RN Manager or designee to maintain training and competency documentation on physicians performing POCT. **Documentation of competency must be maintained on file within the nursing units for quick retrieval when visited by accrediting agencies.**

PLEASE NOTE: The Department of Pathology is not responsible for maintaining competency documentation.

- E. The following laboratory tests are considered “waived” at the Medical Center of Louisiana and may be performed by LPNs, RNs and nurse practitioners only:
- urine macroscopic examination (dipstick)
 - hemoglobin, blood, quantitative (by hand held finger stick device)
 - urine pregnancy test
 - blood glucose
 - pH test (rupture of membrane)
 - HIV-1/HIV-2 Antibody Test, Rapid, Waived Protocol
 - Hemoglobin A1c (HbA1c).
- F. The following test is considered moderately complex at the Medical Center of Louisiana and may be performed by RN's, nurse practitioners and pharmacists:
- Prothrombin Time/International Normalized Ratio (PT/INR).
- G. The following tests may be performed by licensed physicians and licensed nurse practitioners and are considered provider performed procedures:

Provider Performed Non-Microscopy Tests

- Strep A test
- occult blood
- Helicobacter pylori (H. Pylori) test.

Provider Performed Microscopy Tests

- urine sediment exam
- vaginal wet preps/KOH preps
- Fern test.

- H. POCT results can be used to assist in the choice of appropriate patient care. Such testing does not preclude the use of more definitive testing to support medical diagnosis or treatment, if medically necessary.
- I. If provider performed microscopy procedures are performed by a physician, oversight shall be provided by the designated Hospital Center Director.
- J. The oversight audit process for LPNs, RNs, nurse practitioners and pharmacists performing POCT shall be completed by the Department of Pathology and shall ensure:
- accuracy and usefulness of testing results, including quality control measures and staff competency
 - adherence to current, mandated guidelines and manufacturer's recommendations
 - execution of appropriate corrective action when quality control or patient results are out of range
 - observation of suitable specifications for supply storage
 - attainment of a positive correlation between point of care testing and laboratory test results, where appropriate
 - maintenance of "good laboratory practices" as set forth by regulatory agencies.
- K. The Department of Pathology shall ensure that the following standards for nurse practitioners performing provider performed microscopy procedures are met:
- provision of training, competency assessments and testing expertise
 - adherence to semi-annual competency testing guidelines through the Department of Pathology's oversight audit process.
- L. **Approval Protocol for Adding/Modifying Point of Care Testing**
1. Any changes or additions to lab testing performed outside the laboratory setting, i.e., point of care testing, must be evaluated and approved by the Director of Pathology or designee to ensure that they meet organizational goals as well as state law and federal regulations.
 2. The clinician who identifies the need for an addition and/or modification to point of care testing shall submit a completed Request for Approval for New POC Test or Device form (See Exhibit I) to the Director of Pathology or designee. All information requested must be completed and submitted.
 3. The Director of Pathology or designee, in conjunction with the MCL Medical Director, shall evaluate the request and determine if the request will be forwarded to the LSU HCSD Laboratory Operations Committee for consideration and approval.

4. If the request is approved, the Director of Pathology or designee shall communicate the decision to the clinician and direct the Department of Pathology to complete instrument performance and competency training requirements to implement the test/procedure. If the request is not approved, the clinician will be notified by the Director of Pathology or designee.

M. References

The following references were used in the development of the MCL-Specific Guidance:

- MCL Medical Staff Bylaws
- The Joint Commission standards
- Clinical Laboratory Improvement Amendments (CLIA) '88.



**Interim LSU Hospital/Medical Center of Louisiana
Request for Approval for New POC Test or Device**

*Please provide all information requested. Submit form to both **Fred Brazda, M.D.**, Deputy Director of Laboratories and LIS, LSU HCSD and **Joyce Majonos**, Medical Laboratory Director, ILH/MCL
fbrazda@lsuhsc.edu jmajon@lsuhsc.edu f: 903-1602*

1. Date of request:

2. Name of test requested:

3. Location(s) of proposed testing:

4. Estimated number of tests performed per week:

5. Rationale:

6. Name of requestor:

Department:

Phone#

Pager#

e-mail