

MEDICAL CENTER OF LOUISIANA

Organizational-wide Policy Signature Sheet

MEDICAL ADMINISTRATION

POLICY NUMBER: 5055

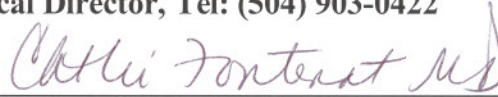
POLICY TITLE: "Waived" and Provider Performed Microscopy Testing

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INQUIRIES TO: Medical Director, Tel: (504) 903-0422

APPROVED:



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Medical Director**

REVIEW/REVISION

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New and/or revised information since last revision is underlined for easy reference.

“WAIVED” AND PROVIDER PERFORMED MICROSCOPY TESTING

I. POLICY STATEMENT

It is the policy of the Medical Center of Louisiana (MCL), in compliance with Louisiana State University Health Care Services Division (LSU HCSD) Policy 5513-08: Point-of-Care Testing, to provide quality patient care services by designating point of care testing on identified laboratory tests. 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 Assistant Administrator of Patient Care Services or designee for review and action, as appropriate.

II. DEFINITIONS

For the purpose of this policy, 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.

Point of care testing – term that “waived” testing **and** provider performed microscopy procedures shall be referred to within this policy.

Provider performed microscopy procedures – procedures performed by licensed physicians and/or licensed nurse practitioners, under the supervision of a licensed physician, that can only be performed by using a microscope on specimens that are not easily transportable.

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

III. PURPOSE

The purpose of this policy is to:

- delineate appropriate responsibility to ensure that designated testing performed within the Medical Center of Louisiana meets the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission standards
- delegate the responsibility of quality control oversight of “waived” testing to the Department of Pathology
- specify that point of care testing is performed under the Clinical Laboratory Improvement Amendments (CLIA) certificate for that area. No procedure performed by non-laboratory personnel is performed under the Pathology CLIA certificate.
- define the Department of Pathology’s scope of responsibility regarding provider performed microscopy procedures.

IV. GENERAL GUIDELINES

A. **“Waived” Testing and Provider Performed Microscopy Procedures Performed by Medical Laboratory Technologists, Laboratory Technicians, Licensed Practical Nurses (LPN), Registered Nurses (RN) and Nurse Practitioners**

PLEASE NOTE: Provider Performed Microscopy Procedures can **only** be performed by Nurse Practitioners, not LPNs or RNs.

1. It is the responsibility of the Department of Pathology to ensure that the following criteria are in place when Medical Laboratory Technologists, Laboratory Technicians, LPNs, RNs and nurse practitioners perform “waived” testing and provider performed microscopy procedures:

- provision of patient testing oversight and technical expertise
 - adherence to “waived” testing quality control standards
 - determination of each clinical area’s competence for continued performance of testing via oversight audits
 - 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” test
 - required demonstration of managerial and user knowledge in units that fail to meet the required standards
 - provision of training and proficiency testing materials for provider performed microscopy procedures.
2. It is the responsibility of the Assistant Administrator of Patient Care Services or designee to ensure that the following criteria are in place when Medical Laboratory Technologists, Laboratory Technicians, LPNs, RNs and nurse practitioners perform “waived” testing and provider performed microscopy procedures:
- 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 when Medical Laboratory Technologists, Laboratory Technicians, LPNs, RNs and nurse practitioners perform “waived” testing and provider performed microscopy procedures:
- 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
 - 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” test performed within their area, inclusive of the quality control log, if applicable.

B. “Waived” Testing and Provider Performed Microscopy Procedures Performed by Physicians

1. It is the responsibility of the Department of Pathology to ensure that the following

criteria are in place when physicians perform “waived” testing and microscopy procedures:

- provision of training and proficiency 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 when physicians perform “waived” testing and microscopy procedures:

- 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
- testing privileges are revoked for physicians found incompetent to perform “waived” testing and physician performed microscopy procedures.

3. It is the responsibility of the Department of Medical Staff Services/Graduate Medical Education (GME) to maintain training and competency documentation on physicians performing “waived” testing and microscopy procedures.

C. The following laboratory tests are considered “waived” at the Medical Center of Louisiana and may be performed by Medical Laboratory Technologists, Laboratory Technicians, 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 / 2 Antibody Test, Rapid, Waived Protocol.

D. MCL does not allow the performance of the following tests as a “waived” test:

- micro hematocrit
- ovulation test
- sed rate
- cholesterol.

E. The following tests may be performed by licensed physicians and licensed nurse practitioners:

Provider Performed Non-Microscopy Tests

- Strep A test
- occult blood

- Helicobacter pylori (H. Pylori) test.

Provider Performed Microscopy Tests

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

- F. “Waived” testing and provider performed microscopy procedure 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.
- G. If provider performed microscopy procedures are performed by a physician or within their scope of practice, oversight shall be provided by the designated Hospital Center Director.
- H. The oversight audit process for LPN, RN and nurse practitioner performed “waived” testing and provider performed microscopy procedures shall be performed by the Department of Pathology and shall ensure:
- accuracy and usefulness of testing results, including quality control measures (for “waived” testing only) 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.

V. APPROVAL PROTOCOL FOR ADDING OR CHANGING ALREADY DESIGNATED “WAIVED” TESTS AND/OR PROVIDER PERFORMED MICROSCOPY PROCEDURES

- A. Any changes to already designated “waived” tests or and/or provider performed microscopy procedures must be approved by the Director of Pathology or designee prior to implementation.
- B. The clinician who identifies the need for an addition and/or change to “waived” testing or provider performed microscopy procedures shall contact the Director of Pathology or designee and provide the following information:
- the name of the new test or the proposed alternate methodology to add or replace

- the existing test/procedure
 - the unit/location
 - utilization and projected volume
 - rationale for conducting test at the patient's location and not in the laboratory, and/or justification for changing the methodology.
- C. 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.
- D. 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 and implement the test/procedure. If the request is not approved, that information will be communicated to the clinician.

VI. OVERSIGHT BY LOUISIANA STATE UNIVERSITY HEALTH CARE SERVICES DIVISION (LSU HCSD)

- A. LSU HCSD, through their Laboratory Operations Committee, has developed a systematic approach to standardize the evaluation and implementation of point-of-care testing throughout LSU HCSD in order to provide the highest quality of laboratory testing regardless of the test site.
- B. The LSU HCSD Laboratory Operations Committee is responsible for:
- overseeing the evaluation and selection of new testing equipment
 - the development of training programs, procedures and documentation
 - the review of test results
 - the performance and monitoring of quality controls
 - corrective action
 - proficiency testing and equipment management and
 - providing a cost/benefit analysis to the MCL medical staff and the Administrative Council.
- C. If MCL wishes to expand point-of-care testing by adding a new test(s) or a new location(s) for testing, a written request, approved and signed by the MCL Medical Director, shall be submitted to the LSU HCSD Laboratory Operations Committee for consideration and approval.
- D. The expansion of point-of-care testing outside the confines of this policy or written approved protocols at MCL is prohibited without consideration and approval of the LSU HCSD Laboratory Operations Committee and written consent of the LSU HCSD Chief Medical Officer or designee.

VII. REFERENCES

The following references were used in the development of this policy:

- LSU HCSD Policy 5513-08: Point-of-Care Testing
- MCL Medical Staff Bylaws
- 42 CFR 493.19
- 42 CFR 493.15
- The Joint Commission standards.