I. PURPOSE:
To establish a multidisciplinary approach that ensures the quality of laboratory diagnostic testing done within the medical center that includes the accuracy of test results, the turnaround time of test results with subsequent therapy changes and maximizing customer satisfaction at the lowest cost.

II. POLICY:
All laboratory diagnostic testing procedures will be approved by CentraCare Laboratory Services (CCLS) before being incorporated into any care center/department working procedure according to the criteria of the Point of Care Laboratory Testing Program. Quality monitoring and maintenance protocols will be recommended, reviewed, approved, rejected, and/or returned for improvement on an ongoing basis. Charges for the test will be made under the designated Clinical Laboratory Improvement Act (CLIA '88) number.

III. DEFINITION:
A. Laboratory Diagnostic Test: Any procedure done on a sample that has been withdrawn from a patient and subjected to a protocol that results in a qualitative or quantitative value that is used in deciding a course of treatment given to a patient.

IV. PROCEDURE:
A. Establishment Of Responsibility:
1. Department/Care Center Directors must contact the Director of Laboratory Operations when a procedure or instrument providing the service defined above is under consideration for addition to their department’s work unit operations.
2. The Point of Care Laboratory Technical Specialist and Laboratory Coordinator, along with the Director of the Laboratory Operations and the Laboratory Services Medical Director, in conjunction with the requesting director and/or physicians, as well as a representative from the appropriate Department/Care Center involved, will evaluate the procedure according to selected criteria that include:
   a. The accuracy, cost, billing compliance and service delivery parameters (including turnaround time) of the new procedure for patient use.
   b. The need for the proposed instrument in lieu of the existing CCLS testing capabilities.
   c. Requirements for bringing this instrument/procedure into operation.
   d. Ongoing maintenance and monitoring to include quality control and quality assurance.
3. Based on the above evaluation, the Director of the Laboratory Operations and the Laboratory Services Medical Director, along with the Point of Care Laboratory Technical Specialist, Laboratory Coordinator and a member of the department/care center staff of the clinical area using the procedure will serve as the Point of Care Laboratory Testing Management Group and will recommend or disapprove the new procedure.
4. If not approved by CCLS, the Director or Physician requesting the procedure may ask for a review by Operations Improvement.

5. If approved, establishment of the procedure will proceed according to the following:

B. Establishment Of Point Of Care Laboratory Testing Procedure:

1. CCLS, through their Point of Care Testing Program, will offer consultation and assistance in:
   a. Validation/Verification of the new instrument or procedure according to current laboratory standards.
   b. Development of written policies and procedures for each laboratory test, according to the NCCLS standards, with authorization and approval from the CentraCare Laboratory Services Medical Director and/or laboratory designee.
   c. Maintaining the integrity of the Point of Care Laboratory Testing Program to include quality control, quality assurance, proficiency testing, training and competency assessment of testing personnel. The Point of Care Laboratory Technical Specialist or laboratory designee will review the documentation initially, and periodically thereafter.

2. CCLS will provide ongoing consultative support on the integrity of the operation through the Point of Care Laboratory Testing Program.
   a. Recommendations will be made to the resource person designated by the Department/Care Center Director and/or physician initiating the instrument or procedure.
   b. Documentation of recommendations will be kept in the Point of Care Laboratory Testing Program records.
   c. In the event of inadequate quality assessment, the Point of Care Laboratory Technical Specialist will request, and the Laboratory Point of Care Testing Management Group will require, timely performance improvement and compliance.

3. Responsibilities of Department/Care Center performing Point of Care Laboratory Testing are outlined on the last page of this policy.

4. Responsibility for the Point of Care Laboratory Testing Program being in compliance with CLIA and JCAHO regulations will reside with the Director of the Laboratory Operations and CentraCare Laboratory Services Medical Director.
   a. The Point of Care Laboratory Technical Specialist will periodically review approved Point of Care laboratory testing sites to assure conformance to established standards.
   b. If the Department/Care Center’s practice and procedure are found to be deficient by the Point of Care Laboratory Testing Specialist, the Director of Laboratory Operations and CentraCare Laboratory Services Medical Director will convene a committee consisting of the Vice President for Medical Affairs and the Vice President of Hospital Operations. This committee will reserve the right to suspend the testing in question until such time that CCLS determines that compliance is achieved.

V. RESPONSIBILITIES OF CARE CENTER/DEPARTMENT PERFORMING POINT OF CARE LABORATORY TESTING

A. Identify a designated Point of Care testing resource person to work with the Point of Care Laboratory Technical Specialist.

B. Provide a list of all personnel approved to perform Point of Care testing to Point of Care Laboratory Technical Specialist.
C. Provide evidence of adequate competency training. Document annual competency through use of validation checklists, staff performance of liquid quality control, proficiency testing and/or blind sample testing.

D. Perform and record quality control according to CCLS Policy. Perform and record troubleshooting and corrective action when control limits are exceeded. Document that no patient testing was performed until corrective action and QC was found to be satisfactory.

E. Perform and record daily, weekly, monthly and quarterly maintenance, and repair if required.

F. Perform proficiency testing as directed and approved by the CCLS.

G. Date reagents when received on the Department/Care Center. Responsible for proper storage of reagents. For reagents that require refrigeration, certified thermometers will be available and the temperature of the refrigerator will be taken and recorded daily. Results found to be out of control will be documented with appropriate corrective action.

H. All reagents will be dated and initialed when opened. Outdates will be placed on reagents when opened. Note expiration date on reagent daily prior to patient’s testing, and never use reagents that have expired.

I. Perform and document QC on new reagents and/or lot numbers as required by manufacturer’s instructions.

VI. REFERENCES:

National Guidelines/National Standards
Clinical Laboratory Improvement Act of 1988 (CLIA 1988)
The Joint Commission Laboratory Standards. (2011). Introduction to Operations, Standards LD.04.01.01 through LD.04.05.15

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