PROCEDURE: Point of Care Testing Authorization and Responsibilities

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Purpose:
To establish responsibilities for the authorization and performance of any laboratory testing that is done outside the Department of Laboratories (Point of Care testing, near patient testing, bedside testing etc.) and which is performed by non laboratory personnel in or near the location in which care is being provided to the patient.

Definition:
A laboratory test is defined as anytime a sample is removed from the human body and an action occurs that translates into a result, whether the result is a number, the presence or absence of a substance or reaction (e.g. Positive or Negative).

Regulations and Standards:
The St. Louis Children's Hospital Point of Care Testing is governed by the Clinical Laboratory Improvement Amendments (CLIA) and the accreditation standards of the College of American Pathologist (CAP). The accreditation standards of the Joint Commission also govern POCT.

License and Authority:
The Department of Laboratories holds and maintains all licenses to perform clinical laboratory testing for St. Louis Children's Hospital and is responsible for over-sight of the POCT program. The POCT section of the Department of Laboratories is responsible for over-sight of the POCT program. The POCT section is responsible for insuring POCT meets or exceeds quality care and safety standards established by SLCH Hospital, CLIA, CAP and JCAHO and is in full compliance with all applicable regulatory and accreditation agencies.

Scope of Testing:
Any laboratory testing performed for the purpose of preventing, diagnosing or treating disease, for the assessment of health or the impairment of health outside of the SLCH Department of Laboratories is considered point of care testing and must be included in the SLCH POCT program.

Level of Testing
Point of Care testing within SLCH includes waived and non-waived testing as defined by CLIA. Refer to the POCT testing for a complete list of approved point of care tests, locations, instruments, test kits and methods.
Equipment and Materials

POCT is only performed using instruments, test kits and technologies approved by the Department of Laboratories at SLCH.

Personnel:

1. Authorization to perform POCT is granted to nursing and other qualified personnel who have been successfully trained and who annually successfully complete competency testing for the specified procedure(s).

Point of Care Coordinator or staff will be notified when an agency nurse on a nursing unit that performs Point of Care testing is brought on to work as a staff nurse. This is for waived testing only and Point of Care staff will assess competency and document. The SLCH individual responsible for agency nurses is the Float Pool Nursing Manager.

Regardless of the procedures/instruments a person may be authorized to use, only procedures and instruments authorized for a specific location may be performed in that location and only for that location's patient census.

2. Documentation of training and annual competency testing is kept in the POC area of the lab or online when applicable. Analyzer operator lists are maintained and kept in the POC area of the Core Lab.

Accountability and Responsibility

1. Level of Responsibility  Medical Director(s)
   a. Ensures program is in compliance with all regulations set forth by CLIA, CAP and JCAHO. Ensures medical acceptability of results. The Medical Director is available by pager 24 hours/7 days a week to help with any questions or clinical concerns regarding Point of Care testing.

2. Level of Responsibility  Point of Care Coordinator/Point of Care Staff
   a. Meets with Medical Director at least monthly to review quality control, quality assurance data and any other testing or procedural issues regarding Point of Care testing.
   b. Ensures accuracy of testing by reviewing Quality Control records and patient results.
   c. Ensure accuracy of testing by maintaining instrumentation, supplies and inventory.
   d. Trains operators or designated trainers to perform testing in compliance with policies and procedures.
   e. Facilitates managers or educators and designees to see that competency is checked for all Point of Care testing.
   f. Notifies manager or designee of testing performed not in accordance with policies and procedures.
   g. The Point of Care Coordinator/Staff is available by pager 24 hours/7 days a week to help with any questions or clinical concerns regarding Point of Care testing.
   h. Ensures program is in compliance with regulations set forth by CLIA, CAP and JCAHO.
   i. Procedures are reviewed yearly and signed by the Medical Director or designee.
3. **Level of Responsibility – Managers or Designees/Educators**
   a. Ensures all operators are trained for Point of Care testing their location is authorized to perform.
   b. Ensure all operators have competency checked annually for all Point of Care testing their location is authorized to perform.
   c. Work in conjunction with the POC staff to ensure testing is performed according to policies and procedures.

4. **Level of Responsibility – Point of Care Testing Operators**
   a. Perform testing in accordance with policies and procedures.

**Locations:**

1. Testing may only be performed in POCT authorized patient care areas/locations by the authorized Personnel assigned to that patient care area/location.

2. Testing may only be performed on the patient population that is assigned to the respective (authorized) patient care area/location.

**Standards:**

Point of Care testing will be considered for approval, authorized for use and that approval/authorization continued so long as the minimum standards below are met and compliance is consistent. Persistent failure to follow these standards and or recurring patterns of non-compliance will result in the revocation of POCT privileges. Other criteria may be used for either approval or revocation as is mandated by federal/state regulation or accreditation standard.

Point of Care testing must:

1. Provide a clear benefit and or advantage to patient care with respect to managing, diagnosing, treatment and or safety over conventional laboratory testing.

2. Be performed in conjunction with the appropriate quality controls (QC) procedures, and QC must be performed by the trained personnel that perform patient testing.

3. Be performed only as a consequence of a valid physician order with results reported to the physician, or authorized care giver.

4. Be consistently performed in accordance with all applicable SLCH department of laboratories and nursing policies and procedures regarding point of care testing and patient safety.

5. Be consistently performed in accordance with all applicable SLCH/BJC Health Care system policies and procedures.

6. Be continuously in compliance with all federal and state regulations and accreditation agency standards regarding lab testing, point of care testing and patient safety.
Documentation

1. Documentation in the patient’s permanent record of a valid physicians order. Documentation may include nurse’s notes, physician progress notes and or history.

Sample Identification

1. Proper patient identification and identification of test specimens and the associated results must be maintained at all times.
2. Any specimen taken from the patient's bedside must be labeled according to the laboratory specimen labeling policy.
3. All whole blood specimens assayed at the patient’s bedside must be identified in the POCT instrument with the correct patient account number.

Specimen Retention at Point of Care Testing

All specimens tested at Point of Care are discarded after testing is completed. This includes all syringes, swabs, urines, stools, gastric contents and whole blood specimens.

Maintenance Records for Point of Care Testing

Maintenance records as required by the specific instrument are kept at Point of Care testing for three months. This is daily, weekly and monthly maintenance. Yearly maintenance is kept for one year with the instrument. After this time records are kept in the Clinical Laboratory Point of Care testing area. Service reports are kept with the instrument at Point of Care.

Results are reviewed by an exception report Mon through Friday for Point of Care interfaced results.

Safety

Gloves must be worn during testing procedures for Point of Care. Proper hand hygiene performed and gloves changed between patients. See Collection of Diagnostic Blood Collection.

This is also on the Training protocol and yearly competency checklist.

SLCH only uses auto disabling single-use fingerstick and heel devices for assisting monitoring blood glucose and other point of care testing. The devices are designed to be used only once and which the blade is retracted and made unusable.

Infection control policy at SLCH in effect to prevent transmission of infection via portable or handheld testing devices is in compliance with the manufacturer’s guidelines that the device must be disinfected after each patient use. See AccuChek Glucose procedure. This is also on the competency for the AccuChek

In the O.R. and Cath lab all equipment is disinfected between cases.

Location of online document:S:\CLINLAB\Point Of Care\procedures and documents\Policies and General Information\POC General procedures\POC Testing Authorization and Responsibilities.doc
Written By: ______________________________________________

Technical Supervisor: ___________________________ Date: ______________

Medical Director: ___________________________ Date: ______________

Annual Review: Medical Director/Designee: ___________________________ Date: ______________

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