CONCORD HOSPITAL
Laboratory Services
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Title: POC GEN General Policy

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TITLE: Point of Care Testing (POCT) General Policy

Policy: General Description and Policies Regarding POCT

Purpose: To standardize and define POCT at Concord Hospital, thus assuring quality patient care.

Point of Care (POC) refers to any laboratory procedure performed and results documented outside of the central laboratory. These testing procedures may be performed by laboratory and non-laboratory personnel who have been appropriately trained and certified through Concord Hospital Laboratory established training programs. The Point of Care testing areas include hospital based, out patient, and hospital owned physician practices performing laboratory testing.

Centralized coordination of the POC testing program is maintained by the Laboratory:

Point-of-Care Test Medical Director:	**Gary York, MD**
Laboratory Director:	**Debra Willey, MT(ASCP)**
Technical Operations Manager:	**Cheryl Okma MT(ASCP) MSA**
Point-of-Care Specialist:	**Suzanne Chute, BB(ASCP)**

Point-of-Care Specialist: **Amber Lundell, MT(ASCP)**

Responsibilities: Point of Care testing programs at Concord Hospital are under the direction, authority, jurisdiction and ultimate responsibility of the Director of Laboratories. A Point-of-Care Policy Committee exists and consists of representatives from Laboratory, Medical and Nursing services; as well as Material and Risk Management. Certain responsibilities have been established for those involved in Point of Care Testing.

Laboratory – Point of Care Specialist
Responsibilities:

- Coordinate with supervisors and educators the training and certification of all personnel performing testing outside the hospital's main testing laboratory.
- Appoint a certified trainer to assist in training personnel at sites where applicable.
- Daily review of results of POCT to ensure appropriate documentation.
- Review and evaluate all quality control and follow up with supervisors of test sites when necessary.
- Evaluate instrumentation and implement all testing procedures (including replacement of malfunctioning instruments).
- Coordinate all written procedures (using the CLSI standards) and designing of documentation forms.
- Assure that each testing site has the appropriate forms and procedure manual.
- Monitor compliance with all federal, state, and local governmental regulations and voluntary accreditation standards.
- Maintain certification, competency, and proficiency records on all personnel performing POCT.
- Provide proficiency and competency testing specimens.
- Perform linearity, calibration, and maintenance of instrumentation utilized in point of care testing where applicable.

Clinical Leaders
Responsibilities:

- Assure participation and documentation in quality control, maintenance, competency and proficiency testing programs by all certified personnel.
- Review area performance reports monthly.
- Take appropriate action when a poor performance is noted.
- Assist Point of Care Specialist in implementing corrective action when an individual is non-compliant.

Designated Trainer
Responsibilities:

- Act as liaison between lab and unit staff.
- Train staff eligible for POCT responsibilities.

- Assist in training staff eligible for phlebotomy responsibilities.
- Observe and document assessment of competency initially, at six months, and annually thereafter of all staff members.

Testing Personnel
Responsibilities:

- Perform and document daily quality control.
- Document any corrective action required when test results are unacceptable.
- Perform and document all maintenance as outlined in the testing procedure manual.
- Participate in competency and proficiency testing programs.
- Document patient results following institution's policy.
- Documentation that all testing personnel have been tested for color blindness. If a POC staff member does demonstrate that they are visually colored impaired, their POCT responsibilities will be adjusted accordingly.

Training: At POC test sites, the initial training on a new instrument will be conducted by the Point-of-Care Specialist in conjunction with the test system manufacturer's representative. The proper documentation of quality control, maintenance, and proficiency testing will be set up and demonstrated by the Point-of-Care Specialist. The site educator and the Point of Care Specialist will be responsible for scheduling training sessions for individuals and groups to include both written and skill tests for staff. These sessions will be mandatory for all staff before they can be certified to perform POCT or phlebotomy. Since attendance is mandatory, records will be kept and will become part of the performance standards taken into consideration during an employee's annual review.

Some testing procedures may not require educational sessions, and skill tests may be conducted on the unit by the certified trainer for that unit. The trainer or a supervisor must contact the Point-of-care specialist in the Laboratory when an eligible staff member will be trained in POCT. The POC Specialist will meet with the staff member to review the procedure, documentation, and quality assurance that applies to the POC test. The certified trainer will instruct personnel in the technical aspects of the test. The POC Specialist and the trainer will assess the initial competency.

An additional competency is required 6 months from initial training. The POC Specialist will contact the certified trainer on the unit when this is due for a staff member. The trainer will be responsible for the competency assessment of the individual by direct observation and document on evaluation form. This form will be sent to the POC Specialist.

Annual recertification will be mandatory for all personnel performing POCT and phlebotomy. All staff attending a mandatory educational and skills seminar will accomplish this. Attendance will be documented and records will be kept. Any staff who do not remain competent in a particular area of POCT or phlebotomy will loose the privilege.

Procedure Manual: Procedures are to be written for each test performed outside of the hospital's

main testing laboratory. The procedure manual will contain all the information necessary for the correct performance of each test. A copy of all the pertinent procedures will be readily available to all personnel performing testing at all times. These procedures will be reviewed annually and revised as necessary by the Point of Care Specialist. Testing personnel are required to initially review all procedures and to document knowledge of any revisions made.

Nursing procedures written for any ancillary testing procedures are to be reviewed by the Point of Care Policy Committee before being released to the nursing units.

Quality Control: Quality control functions must be performed and documented each day of patient testing. The results of the quality control **must** fall within the specified limits. If the quality control falls outside of those limits, action must be taken to determine the cause of such failure and to correct the failure. Then the controls must be repeated successfully before patient testing can continue. The corrective action taken shall be documented. If the cause of failure cannot be determined and corrected, personnel must contact the supervisor or Point of Care Specialist. Managers will receive a monthly report on the quality control performance of their unit. Unit managers are responsible for assuring compliance. Deficiencies in quality control may result in temporary suspension of testing at this site. Suspension will be lifted dependent upon an action plan to correct the deficiencies agreed upon by the Clinical Leader and POC Specialist.

Proficiency Testing: Proficiency samples will be provided by the laboratory to all areas performing tests for which applicable proficiency programs exist. Staff will test the sample as they would a patient. The responsibility of testing will be rotated among all staff members. All results are submitted to the proficiency testing organization and the data analyzed on an individual as well as a group basis. Test performance is considered acceptable at a score of 80% or better.

Unsatisfactory performance on 2 of 3, or 2 consecutive proficiency tests can result in the state not allowing testing to be performed at this facility until 3 proficiency challenges can be satisfied. When a proficiency test is reported as “Unacceptable”, an Exception Response form will be completed and filed with the survey results. The Exception Response form addresses reasons for the unacceptable result, the investigative process, and any corrective actions that may follow.

When a survey is not available for proficiency testing, an alternative method will be used. This will entail running two samples that have been tested in the main laboratory, and on the POC instrument. The results will be compared for accuracy. This responsibility of testing will be rotated among all staff members.

If a PT challenge is ungraded due to lack of consensus, late submission of results, failure to submit results, or an error in completing the result form, a self evaluation will be conducted. The ungraded results will be compared to the results published in the summary report. A written explanation of the self evaluation and the ungraded survey results will be filed with all other survey results.

Interlaboratory communication regarding proficiency testing results, prior to result submission, is prohibited. Proficiency testing specimens run in this laboratory are prohibited for referral to another laboratory.

Equipment: Equipment used for ancillary testing will be limited to that approved by the Point of Care Policy Committee.

Vendors: Vendors who wish to introduce new laboratory test kits, reagents, and instruments are required to present any new items to the Point of Care Specialist for regulatory review, evaluation, and recommendation before Concord Hospital purchases or acquires such items. If vendors make their initial contact with medical, nursing, and/or ancillary staff, these staff should refer the request to the Point of Care Specialist.

Results: All Point of Care testing results must be reported on a daily log sheet or in the LIS, following the guidelines established by individual departments and approved by the Point of Care Policy Committee.

REFERENCES	Clinical Laboratory Management Review, What is the Point of Point-of-Care Testing?, July/Aug 1997. Clinical Laboratory Management Review, Point-of-Care Testing: Managing People and Technology, July/Aug, 1997. General Policy for Ancillary Testing at Brockton Hospital, Brockton, Ma. 1996
DISTRIBUTION	Laboratory, Patient Care Units, PSCs, Nursery, OR, Cath Lab, ED, WIUCC, FHC, Specials Radiology
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