SUNY DOWNSTATE MEDICAL CENTER

DEPARTMENT OF PATHOLOGY

POLICY AND PROCEDURE

☒ UNIVERSITY HOSPITAL OF BROOKLYN ☒ BAY RIDGE

Subject: POINT OF CARE TESTING (POC)

Policy No.: LAB-23

No. of Pages (including this page): 6

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Original Issue Date: 05/00

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Supersedes: 02/10

Effective Date: 02/11

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NYS CLEP Standards:
CAP Standards:
JC Standards:

Issued by: Department of Laboratories
Related Policies:

Review Date	Revisions		Director	Designee	Comments / Revisions
	No	Yes			

Discontinuation Date: _____

I. PURPOSE:

To ensure that all testing to be performed at or near a patient's bedside, with a Point of Care testing device, is performed accurately and that all applicable regulatory standards are followed.

II. POLICY:

A. All Point-of-Care Testing inclusive of waived and non-waived tests must be performed under the guidance of the Clinical Laboratory. The Laboratory Director or his/her designee will provide oversight in the areas of quality control, performance improvement, training, competency, interpretation and record keeping.

B. Only authorized testing personnel may perform tests after completion of training and demonstration of competency.

C. Request for performing Point of Care Testing must be approved by the Laboratory Director and must be justified based on the need for the clinical information in a time frame appropriate to influence patient care decisions.

D. Quality control must be performed prior to release of patient results. Test authorization by the Laboratory Director may be withdrawn from a Patient Care Unit when QC compliance does not meet required standards.

III. DEFINITION(S):

- Point of Care Testing refers to those analytical patient-testing activities provided within the institution, but performed outside the physical facilities of the clinical laboratories. The central criterion of POC testing is that it does not require permanent dedicated space.

- **POCT** = Point of Care Testing; **ABG** = Arterial Blood Gas; **ACT** = Activated Clotting Time;

  HCG = Human Chorionic Gonadotropin

- **Waived** – a sub classification of Point-of-care tests namely glucose, urine pregnancy, and occult blood as defined under CLIA (Clinical Laboratory Improvement Act of 1988)

- **Non-Waived** – POC tests are identified in levels of complexity under CLIA –88 and include ABG, Electrolytes and ACT test at UHB.

- Provider performed Microscopy Procedures (PPMP).

- **CLIA-88** – Clinical Laboratory Improvement Amendment of 1988.

IV. RESPONSIBILITIES

The following table reflects personnel authorized to perform point of care testing within the following areas: Nursing, Pharmacy, Ambulatory Services, Respiratory therapy, Emergency Department and Pathology. The Point of Care tests performed at SUNY Downstate Medical Center personnel in compliance with the New York State Department of Health, College of American Pathologist, and Joint Commission for the Accreditation of Hospital Organization and as approved by the hospital.

Point of Care Test	Authorized Persons	Testing Location
Urine Pregnancy (uHCG) (Quick View)	RN, LPN, EKG TECH,MT	ED, Satellite clinics
I-STAT System ABG, ACT Celite Hematocrit,Electrolytes.BUN,CRET, Glucose,TCO_2, PT/INR	RN, MT, RT, Perfusionist,	ICU, MICU, PICU, NICU, Cath.Lab, OR, IRRR
Whole Blood Glucose	R.N, CVT, MT, EKG/ OR TECH	Entire Hospital and Satellite Clin.
Urinalysis Dipstick/ Clinetek-50	RN, MT	Satellite clinics
Strep A Test Quidel QuickVue+	RN	Satellite clinic
Fecal Occult Blood	MD, RN, MT	ED
RAPID HIV	RN, MT	STAR CLINIC, ED
WET MOUNTS	MD	LD, CLINICS
AMNIOTIC FLUID CRYSTALLIZATION TEST (FERN TEST)	MD	LD, CLINICS
VERIFY PLATELET TEST	RN	CATH LAB
Hemoglobin Hemocue HB 201+	RN	Satellite

V. PROCEDURES/GUIDELINES

A. Authorization for Point of Care Testing

a. Point of Care testing in patient areas and the method used in the testing requires review by the Laboratory Director or his designee prior to implementation.
b. The Clinical Laboratory staff will assist in the evaluation of methods and instrumentation and will work with the Directors of the Patient Care Services of each area where Point of Care testing is performed in the Development of a test protocol, training guidelines and record keeping systems.
c. There will be a physician order for the test placed through the Cerner Laboratory Information System.
d. Requests for Point of Care testing are reviewed by the department of pathology upon receiving the completed “Point of Care” testing request form. (see attachment G)

B. Testing Protocol

a. In general, non-waived point of care testing will be considered definitive for the purpose of care and treatment of patients. However, the practitioner caring will determine final determination of the extent to which Point of Care testing is used in the care of patients for the patient based on established laboratory protocols. Verification of test results can be made at any time by sending a sample to the clinical laboratory for analysis.
b. In each area where patient Point of Care testing is performed the Nursing Supervisors or Designee will determine and identify those staff members who will perform testing and those who will direct or supervise testing.
c. Members of the Clinical Laboratory staff will assist in the development of the test procedure. The procedure must include the following:

- Principle
- Specimen requirements and collection
- Instrument Calibration (if applicable)
- Quality Control requirements and remedial action instruments
- Equipment performance evaluation
- Procedure – stepwise

- Reference Ranges, Result interpretation and remedial action
- Test ordering and result reporting in Cerner LIS
- Record keeping
- References – see attached protocols for each POC test

C. Personnel Training

a. Authorized staff that has been certified to perform the specific test may only perform that Point of Care testing.
b. The director or designee, working with the Institute of Continuous Learning is responsible for assigning trainer, for coordinating and documenting the training competency and for ensuring that only properly trained staff members perform the test.
c. The Clinical Laboratory will develop the training guidelines and train the trainers.
d. The training requirements will be tailored to the test procedures used in each patient are. Personnel certification is completed upon in-serving, and is required to be renewed six months after first training and annually thereafter. Documentation of certification is maintained in the employee's personnel folder.
Participants must demonstrate competency according to the established validation criteria:

1). Visual Observation of the operator performing the test and ensuring that written policy and procedures are consistently followed.
2). Evaluation of a problem solving skills.
3). Assessment of testing performance through an external proficiency testing.
4). Direct observation of instrument maintenance and function checks.
5). Monitoring the recording and reporting of test results.
6). Review of intermediate test results (QC, PT results, and preventive maintenance)

e. A current list of the personnel certified to perform the waived tests must be maintained in the patient care unit and a current copy must be sent to the laboratory. The certification list must include documentation of the annual certification.
f. The testing personnel must be assessed annually for competence. Testing personnel are required to perform and complete proficiency test according to the standards established by the College of American Pathologist, New York State Department of Health and The Joint Commission for the Accreditation of Hospitals Organization.

Exception:
Clinicians are authorized to perform Physician Performed Microscopy (PPM) Procedures by the credentialing process established in their respective Departments/Service.

Department/Services must submit the names of individuals to the Director of Laboratories once credentialed to perform the procedure. An updated list of all Physicians who are credentialed for PPM should be sent to the Director of Laboratories at the end of each calendar year.

D. Testing Performance

a. Patient identification, preparation and testing must be performed in strict accordance with the test procedures.
b. Test results are acceptable only if all Quality control criteria are met. Refer to testing procedures attached to this policy for specific POCT Quality Control guidelines.
c. Test results must be entered in the Cerner Laboratory Information System or recorded in a supplementary logbook if the Cerner LIS is down.
d. The Nurse Manager of designee will be responsible for the direct supervision of all Point of Care testing in the unit and for the review of quality control records on a daily basis.

e. Test verification can be achieved by sending an order and sample to the clinical laboratory for analysis, when necessary.

E. Record Keeping

a. Record must be kept for a minimum of two years to enable the tracking of numbers, expiration dates and, if applicable, instrument performance.
b. Logbooks must include test name, method/instrument ID, if applicable, reagent and QC lot numbers, expiration dates and patient identification (name and MR#), date test performed and initials of tester.
c. The individual performing the test is responsible for proper documentation of the quality control, patient information and test results. The Clinical Laboratory will review the quality control on a regular basis.
d. Logbooks containing QC data must be retained for two years within each Point of Care testing area. Logbooks containing instrument maintenance and/or troubleshooting records must be retained with the instrument for the life of instrument.

F. Safety

a. Laboratory testing involves potential exposure to blood and body fluids. Therefore, universal precautions, as defined in the Infection Control Manuals, must be followed.
b. The individual performing the test is responsible for using the appropriate personal protective equipment and work practices as defined in the test procedure for safe handling of patient samples and the proper disposal of the waste generated, i.e., used strip, kit, reagent, etc.

G. Compliance

a. Failure to meet the above standards by a testing individual will deem the individual unauthorized to perform testing and will require recertification of the individual.
b. Compliance reports will be presented and discussed during the monthly Laboratory Performance Improvement. Meetings and other interdisciplinary performance forums.
c. Performance that is below 90% for three consecutive months and failures to improve will result in probation for that nursing unit. Performance that does not improve or does not reach 90% curving the next three months will result in discontinuance of Point of Care for the analyte in question at that specific location. During the period of time when a unit is on probation the Clinical Laboratory Point of Care staff will notify the supervisor of the unit about the potential consequences of failing to improve.

H. Quality Indicator Measurements

a. Quality Indicators measurement are tracked using a dashboard to monitor pre-analytic, analytic, and post-analytic phases of the testing process.
b. Pre Analytical - Competency of Users in Point of Care Testing
Maintenance Function of Instruments
Patient Identification Valid Patient ID

c. Analytical - Proficiency Testing

d. Post Analytical - Documentation of Out of Range Results
Percent of Certified Users
Percent of days that QC was charted
Percent of test documented in log book
Percent of completed Patient Logs

VI. ATTACHMENTS

Point of Care

a. Lab 23A – Blood Glucose Monitoring (Using Xceed Pro Glucose meter)
b. Lab 23B – POC Urine Pregnancy - Quidel Quick Vue One Step Urine Hcg
c. Lab 23C – POC - Occult Blood – Hemoccult SENSA Slide Method
d. Lab 23D – Point of Care Analysis I-STAT Analyzer
e. Lab 23G – POC – Urinalysis Visual Using Multistix 10G
f. Lab 23H – HIV Counseling and Testing in Star Program
g. Lab-23I – Amniotic Fluid Crystallization Test
h. Lab-23J – Vaginal Wet Mounts
i. Lab-23K – Platelet Function Test Verify Now System Accumetrics
j. Lab 23L - Point of Care Hemoglobin Hemocue HB 201+

VII. REFERENCES

CLIA –88, CAP Laboratory Standards Program 2006; JCAHO Standards 2006, NYSDOH Laboratory Standards Sept. 2006

SUNY Downstate Medical Center

University Hospital
Point of Care Testing Request Form

To be completed by testing location

Name of Equipment: _____

Name of Sales Contact: _____

Manufacturer: _____

Floor/Unit: _____

Chief of Service: _____

Staff Designated to perform testing:

Number of operators to be trained:

Test to be performed:

Projected volume of testing:

Describe what factors require that his test be performed at the point of care instead of in the laboratory:

_____

_____

_____

_____

Explain how the patient outcome/care will improve as a result of this test being performed at the bedside:

_____

_____

_____

_____

Signature: _____ Date _____

Route to: Alix Laguerre, Clinical Laboratory Administrator, Box 37

To be completed by: Pathology Department Administration

Test complexity: Waived Moderate Complex Highly Complex
Cost Benefit Analysis Done: Yes No
Projected Implementation Date:

Approved: _____ **Denied:** _____

Peter J. Howanitz, MD _____
Director, Clinical Laboratories