# SUNY Downstate Medical Center -University Hospital of Brooklyn Network
# Department of Pathology Policy and Procedure

## Subject: Lab 23 Point of Care Quality Management

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# SUNY DOWNSTATE MEDICAL CENTER

UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

**No.** LAB-23

**Subject:** **POINT OF CARE TESTING (POC)**
**Quality Management and Quality Assurance**

**Page** **1 of 11**

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**The JCStandards: WT.01.01.01 WT.02.01.01**
**WT.03.01.01 WT.04.01.01 WT.05.01.01**

**Issued by: Department of Laboratories**

## I. PURPOSE:

To ensure that all testing to be performed at or near a patient's bedside, with a Point of Care testing is performed accurately and that all applicable regulatory standards are followed. The health care provider consistently follows and successfully adheres to the testing procedure.

## II. POLICY:

**A.** All Point-of-Care Testing inclusive of waived and non-waived tests must be performed under the guidance of the Department of Pathology 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.

**E.** Test authorization by the Laboratory Director may be withdrawn from a Patient Care Unit when QC compliance does not meet required standards.

**F.** Any test system, device and kit used in Downstate Medical Center for clinical patient results must meet the standards set in Point of Care Testing Quality Assurance Program.

## 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.

- PPMP - Provider Performed Microscopy Procedures

- PPT - Provider Performed Testing

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

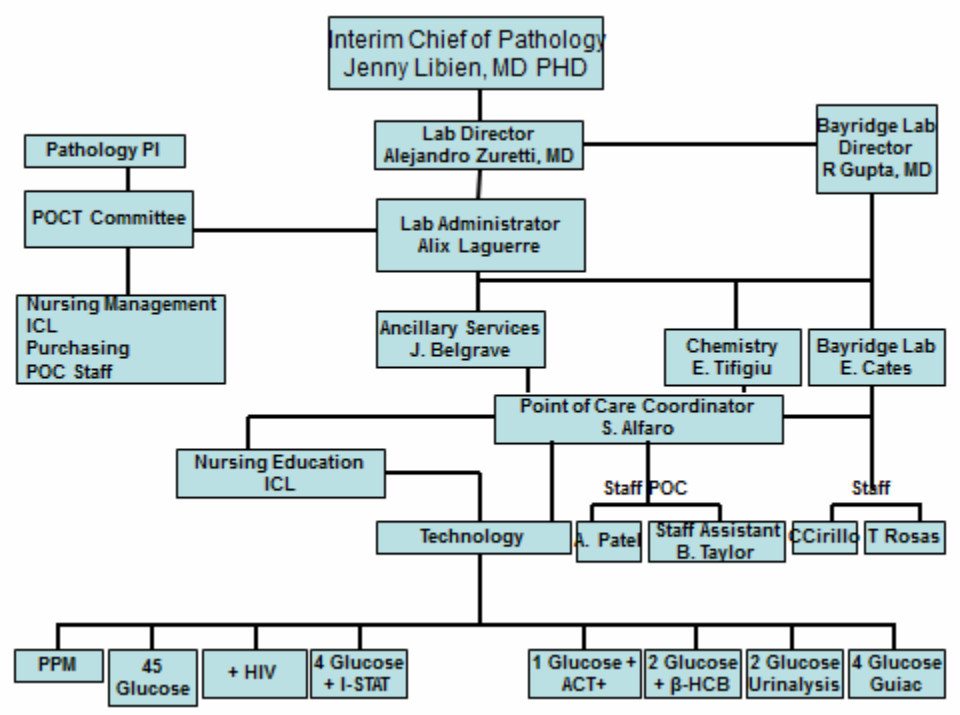
- **Proficiency Testing**: Analysis of blind samples performed by randomly selected operators for the purpose of validating test systems and operators. Proficiency testing may be used as competency assessment for the selected operators.

- **Quality Assurance (QA)**: Activities and processes intended to provide maximum confidence that the quality of patient care will satisfy stated or implied requirements/needs through specimen integrity and accurate test results.

- **Quality Control (QC)** Analysis of samples with known responses for the purpose of validating the proper performance for the test system.

**IV.**

# Point of Care Organizational Structure



**STATE UNIVERSITY HOSPITAL OF NEW YORK**
**AT BROOKLYN**

| PERSONNEL | RESPONSIBILITY / ACCOUNTABILITY |
|---|---|
| 1. NURSES, TECHNICIANS, RESP.THERAPIST, PERFUSIONIST | PERFORM: POCT GLUCOSE, HIV, I-STAT, URINE HCG, URINALYSIS |
| 2. NURSING EDUCATORS | EDUCATES: NURSES IN POCT GLUCOSE, HIV, URINALYSIS, URINE HCG |
| 3. POCT STAFF | EDUCATES: , I-STAT, URINALYSIS, URINE HCG, VALIDATION OF INSTRUMENTS, MONITOR QC, EVALUATION OF PROFICIENCY |
| 4. POCT COORDINATOR | SUPERVISING: POCT STAFF, NURSING EDUCATORS, NURSE OPERATORS AND TECHNICIANS |
| 5. CHEMISTRY ANCILLARY SUPERVISOR | SUPERVISING: POCT SUPERVISORS AND STAFF |
| 6. LAB MANAGER | RUNS POCT COMMITTEE, MANAGES POCT SUPERVISORS, OTHERS LABS SUPERVISORS AND STAFF |
| 7. LAB DIRECTOR | RESPONSIBLE FOR ENTIRE POCT PROGRAM |
| 8. DEPARTMENT CHAIRMAN | RESPONSIBLE FOR PATHOLOGY LABORATORY |

## V. 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 Vue) | 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 | RN, MT | Satellite clinics |
| | | |
| 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 |

## 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 and Point of Care Testing Committee 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 Point of Care Testing Committee 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 for the patient shall make the final determination of the extent to which Point of Care testing is used in the care of patients 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 certified to perform a specific test may only perform that Point of Care Procedure.
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. Training will include objective of the training, methods and material used in the training.
d. The training requirements will be tailored to the test procedures used in each patient area. Personnel certification is completed upon in-servicing, 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 problem solving skills.
3). Assessment of testing performance through 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 waived tests and non waived must be maintained in the point of care office. The certification list must include documentation of the annual certification. The Point of Care Coordinator must be informed of newly certified employees.
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 PPMT and/or PPT procedures by the credentialing process established in their respective Departments/Service.

Departments/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 or PPT should be sent to the Director of Laboratories 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 Hospital Information System / Laboratory Information System or recorded in a supplementary logbook if the Cerner Laboratory Information System is down.
d. The Nurse Manager or 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 and Result Reviewing**

a. Records 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.

e. Documentation of control records in satellites will be submitted to the Point of Care Coordinator at the end of each month for review.

f. Result Verification of interfaced results generated by instrumentation which is interfaced into the laboratory information system (LIS) are checked for integrity by comparison to parameters which are programmed in the LIS.

g. Result Verification of Manual Inputs:
    1. Patient results which are not received by an interface with the laboratory information system (LIS) must be entered manually by the technical staff after being recorded on a worksheet at the time of test performance.
    2. Manually entered patient result inputs will be reviewed monthly for transcription and data entry errors.
    3. Supervisory review of the manual data entry inputs for clerical or transcription errors will be documented by the initialing of the manual worksheets, chart reports or activity reports by the supervisory staff or their designee.

h. Reporting discrepancies and errors must be documented on a Laboratory Quality Assurance Investigation/Incident Report and submitted in accordance with the Departmental Policy and Procedure entitled Nonconforming Events.

i. Critical values are verified by repeat analysis. Once a critical value is verified by repeat analysis, a specimen must be sent to the Laboratory for confirmation.

j. The POC coordinator will review monthly patients test results selected randomly.

**VII.**

**Specimen Identification Alert after Analysis**

Occasionally a correction to a laboratory result may be required after result reporting upon notification to the laboratory of a mislabeled/misidentified specimen.

1. Laboratory personnel receiving the alert must document all pertinent information regarding the specimen(s) including: name, date, medical record number … and the name, title and contact location of the informant.

2. The Laboratory Information Systems and Point of Care sections should be notified.
    a. Point of Care personnel revise and issue a corrected report as "No Results" with the appended comment 'Patient Misidentification reported by informant_____ (name) @ _____ (date/time)' to the incorrectly identified result.

    b. LIS personnel initiate a reversal of billing charges and inform all appropriate laboratory sections of the corrective action.

3. LIS personnel generate a Laboratory Incident Investigation. Report to be submitted to the Laboratory Administrator within 24 hours of the event.

4. The person responsible for the primary sample collection must take responsibility for identifying and accepting the sample and providing proper information.

Person responsible is required to complete and sign the Specimen Identity Verification Form.

5. A copy of the Specimen Identity Verification form should accompany the QA/Incident Report to the Laboratory Administrator.

**VIII. 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 (PPE) 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.
c. Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients, according to Standard Precautions.
d. The auto disabling single use finger stick device are designed to be used only once.
e. Handheld or portable testing devices must be disinfected after each patient use with a germicidal disposable wipe. (Sani-cloth)
f. Hospital Administration is responsible for making available the appropriate PPE to personnel.

**IX. Compliance**

a. **The failure of testing individuals to follow the** policies and procedures outlined in the Point of Care Manual and regulatory standards 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. Indicators and Audits are presented in the Point of Care Testing committee 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.

**X. Quality Indicator Measurements**

Quality Indicators measurement are tracked using a dashboard to monitor pre-analytic, analytic, and post-analytic phases of the testing process.

1. Pre Analytical - Competency of Users in Point of Care Testing
Maintenance Function of Instruments
Patient Identification Valid Patient ID

2. Analytical - Proficiency Testing

3. 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

**XI. Implementation and Validation of Point of Care Testing**

1. To ensure system performance accuracy, assess potential for error; identify method to method differences and to meet regulatory guidelines, all instruments must be calibrated and checked for linearity, accuracy, and precision. Correlations are to be performed against a reference method before the instrument is deemed acceptable.
2. Method of implementation are defined in each individual test procedure. The point of care testing will verify or establish performance specifications for waived and non waived tests which are applicable and/or clinically relevant.
3. Results of all validation studies should be summarized in a report and submitted to the director for approval before implementation.
4. All validation and verification procedures, data and analysis records will be retained for two years beyond the life of the instrument or the use of the test in accordance with regulatory requirements

## XII. Proficiency

The Laboratory participates in external proficiency testing from the College of American Pathologist (CAP) and the New York State Department of Health.

a. Proficiency samples are introduced into the laboratory's routine workflow and processed in similar manner to patient samples, where possible manner.
b. Laboratory personnel shall not engage in inter-laboratory communication concerning proficiency testing samples and/or results before the submission of results to the proficiency testing provider.
c. Repeat analysis of proficiency samples will not be performed unless repetitive analysis is performed in the routine analysis for patient samples

**XIII. Attachments**

**Point of Care Policy and Procedures**

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 23E - Point of Care Rapid Malaria Test
f. Lab 23G – POC – Urinalysis Visual Using Multistix 10G
g. Lab 23H – HIV Counseling and Testing in Star Program
h. Lab-23I – Amniotic Fluid Crystallization Test
i. Lab-23J – Vaginal Wet Mounts
j. Lab23L --- Point of Care Hemoglobin Test

## II. REFERENCES

CLIA –88, CAP Laboratory Standards Program 2011; JCAHO Standards 2011, NYSDOH Laboratory Standards Sept. 2011

| Date Reviewed | Revision | Required (Circle One) | Responsible Staff Name and Title |
|---|---|---|---|
| **09/03** | **Yes** | **No** | Alix Laguerre, Laboratory Administrator |
| **11/04** | **Yes** | **No** | Alix Laguerre, Laboratory Administrator |
| **11/05** | **Yes** | **No** | Alix Laguerre, Laboratory Administrator |
| **05/06** | **Yes** | **No** | Alix Laguerre, Laboratory Administrator |
| **11/06** | **Yes** | **No** | Alix Laguerre, Laboratory Administrator |
| **10/07** | **Yes** | **No** | Sandra Alfaro, POC Coordinator |
| **10/08** | **Yes** | **No** | Sandra Alfaro, POC Coordinator |
| **01/09** | **Yes** | **No** | Sandra Alfaro, POC Coordinator |
| **02/10** | **Yes** | **No** | Sandra Alfaro, POC Coordinator |
| **08/10** | **Yes** | **No** | Sandra Alfaro, POC Coordinator |
| **11/11** | **Yes** | **NO** | Sandra Alfaro, POC Coordinator |
| **04/13** | **Yes** | **No** | Sandra Alfaro, POC Coordinator |
| **11/14** | **Yes** | **NO** | Sandra Alfaro, POC Coordinator |

# 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 Laboratory**

# TEST METHOD VALIDATION SUMMARY SHEET

**QMS S1(j) Performance Validation**

**ANALYTE:** _____**INSTRUMENT:**_____

**METHOD:**
_____

| | |
|---|---|
| ☐ | **Specimen Requirements** |
| ☐ | **Accuracy Verification**<br>**Manufacturer's claim:** |
| ☐ | **Precision Verification**<br>**Manufacturer's claim:** |
| ☐ | **Reportable Range Verification**<br>**Manufacturer's claim:** |
| ☐ | **Reference Range Verification** |
| ☐ | **Critical Value Definition** |
| ☐ | **Interference & Carryover** |
| ☐ | **Proficiency Test Enrollment / Data**<br>**Test Agency:** ☐ **NYS** ☐ **CAP** |
| ☐ | **Validation Report (Summary and Conclusion)** |
| ☐ | **Notification re: New Analyte** ☐ **NYS** ☐ **CAP** |
| ☐ | **LIS Setup – test code, billing, etc.** |

| | |
|---|---|
| | |
| ☐ | **Test Procedure including quality control specification, bench excerpts, handouts, etc.** |
| ☐ | **Staff Training** |

**NOTE: Documents related to initial validation must be retained for the period that the test and method are in use + 2 yrs after discontinuation.**

**DEPARTMENT OF PATHOLOGY**
**SPECIMEN IDENTITY VERIFICATION FORM**

*****This form is to be used in limited cases to verify the identity of 'irreplaceable' specimens**.***

**Situation 1. PRE-ANALYSIS**: where results have NOT been posted to the Laboratory Information System:

_____ **MISLABELED** I,_____(print HCP name, title, pager #), certify that the specimen described below which I submitted to the Laboratory labeled as belonging to Patient #1 (incorrect information), was in fact obtained from Patient #2 (correct information).

_____ **UNLABELED** I, _____ (print HCP name, title, pager #) certify that the specimen described below which I submitted to the Laboratory unlabeled actually belongs to Patient # 2 (correct information).

_____ **MISMATCHED** I, _____ (print HCP name, title, pager #) certify that the information below represents the correct patient information for the specimen submitted to the laboratory with conflicting information between the specimen label and requisition.

**Situation 2. POST RESULTS RELEASE**: where results have been posted to the Laboratory Information System:

_____ **MISLABELED SPECIMEN ALERT NOTED AFTER REPORTING RESULTS**

_____incorrect requisition _____incorrect label

**SPECIMEN/PATIENT INFORMATION**:
Collection Date: _____ Receipt Date/time: _____ Specimen Type _____
Accession #: _____ Tests requested: _____

| | Incorrect Information | **Correct Information** |
|---|---|---|
| **Patient name** | | |
| **Medical record number** | | |
| **Location** | | |

**VERIFICATION:**

**I take responsibility for the primary sample identification and acceptance; I have provided the proper patient information; and I request that the specimen be analyzed and the results be issued.**

_____ _____

**Signature of physician/health care provider form** **Signature of lab staff completing**

_____ _____

**Date/ Clinical Service or Department** **Date received**