

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



Subject: Point of Care Blood Glucose Monitoring LAB 23A

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SUNY DOWNSTATE MEDICAL CENTER

UNIVERSITY HOSPITAL OF BROOKLYN POLICY AND PROCEDURE

Subject: <u>POINT OF CARE –BLOOD GLUCOSE MONITORING (Using Xceed Pro glucose meter)</u>	No. <u>LAB-23A</u>
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Approved by: <u>Peter J. Howanitz, M.D.</u> <u>Margaret Jackson, MA, RN</u> <u>Stanley Fisher, M.D.</u> <u>Michael Lucchesi, M.D.</u>	Effective Date: <u>04/14</u> The JC Standards: WT.01.01.01, WT.02.01.01 WT.03.01.01 WT.04.01.01 WT.05.01.01 . Distribution: Emergency Dept Satellite Clinics Issued by: Department of Laboratories

I. PURPOSE:

The Precision Xceed Pro Glucose meter performs a quantitative assay designed to monitor blood glucose in patients requiring glucose monitoring. Glucose level is detected by testing fresh whole blood specimen at the bedside to provide timely and accurate results.

II. PRINCIPLE:

The Precision Xceed Pro Blood Glucose System allows rapid measurement of blood glucose (D-glucose) by using an electrochemical detection technique. This biosensor employs a disposable dry reagent strip technology, based on the glucose dehydrogenase (microbial) for glucose determination. Each test strip features an electrode containing the enzyme glucose dehydrogenase (Microbial). When a drop of blood is applied to the target area of the test strip, the glucose dehydrogenase catalyses the oxidation of glucose in the drop to produce gluconic acid. During the reaction electrons are transferred by a co-enzyme and an electrochemical mediator to the electrode surface. This generates a current that is measured by the instrument. The amount of current generated is proportional to the amount of glucose present in the blood drop and will give an accurate reading of the blood glucose concentration.

III. PERSONNEL:

Registered Nurses
Licensed Practical Nurses
Laboratory Technical Personnel
Technicians

Areas of activity are:

All Patients Units
Ambulatory Centers, Ambulatory Surgery,
Cath. Lab., Cardiology, Endoscopy,
Interventional Radiology and OPD Suites (B & D)

IV. SPECIMEN:

A. Collection Procedure/Handling Conditions:

1. Critical Elements

- Use only Precision Xceed Pro MediSense strips, or Precision Xceed Pro Control Solutions with Xceed Pro Monitor.
- Use test strips with valid expiration date only.
- Do not use test strips that are wet, bent, scratched or damaged. Use the test strip immediately after opening its foil packet.
- Use only test strips with specifically matched barcodes (from assigned packet only).
- Cover the entire target area of the test strip with the blood sample.
- No sample re-application.
- Do not touch the test strip after blood is applied to the test strip and the test starts.
- Use each test strip only once.
- Verify time and date when meter is put to use.
- Clear arterial lines before blood is drawn and applied to the test strip.
- When a Hematocrit result is outside the range of <20% or >70% the results in the glucose meter are invalid. Specimen should be sent to the Chemistry Lab.
- Sample application could be applied on the test strip “top-fill” or “end-fill”.
- When performing Xceed Pro Glucose test keep meter in a horizontal position. **Do not hold meter upright.**
- **Xceed Pro** has a build in thermometer (-20°C to 50°C). It will not function if out of range.
- Strip Temperature range for Testing (4°C to 30°C)

2. Collecting Whole Blood Samples

1. Use universal precautions. Gloves must be worn during testing events, hand hygiene performed, and gloves changed between patients.
2. Clean the puncture site with an alcohol swab and allow to dry thoroughly.
3. Hold the patient’s arm downward for at least 15 seconds to allow blood to flow to the fingertip.

4. Prick the side of fingertip with an automatic lancing device. Pricking the side of the fingertip is generally less painful than the center of the fingertip.
5. Squeeze the finger gently to get a single, large, hanging drop of blood. Avoid squeezing the puncture excessively. **Eliminate the first drop of blood.**
6. Apply the **second drop** of blood directly to the target area of the test strip, covering the entire area.
7. If necessary, the blood can be collected in a heparin-coated capillary tube and then applied to the test strip.
8. When results <70 mg/dl repeat finger stick immediately for validation. If blood glucose still <70 mg/dl initiate hypoglycemic treatment protocol.

3. Collecting Arterial Blood Samples

1. Clear the arterial line before drawing a blood sample. Draw blood sample into a syringe that contains sodium or lithium heparin.

Caution: A false low glucose result can be obtained if:

- a) Sufficient flush is not withdrawn from the arterial line (actual volume required to be removed is dependent upon length of line), or
 - b) If liquid heparin is used to anti coagulate the sample and the ratio of blood to heparin is not controlled or not taken into consideration.
2. Use the sample within 30 minutes of collection.
 3. Mix the syringe several times immediately before applying the sample to the target area on the test strip.
 4. Allow a drop of blood to form at the tip of the syringe.
 5. Cover the entire target area on the test strip with the blood sample. The syringe can briefly touch the test strip without affecting the test result.

4. Collecting Venous Blood Samples:

1. Collect the venous blood sample in a collection tube containing sodium or lithium heparin, ensuring that the test tube is completely filled.
Do not use collection tubes that contain fluoride or oxalate.
2. If the blood is collected from an intravenous line, clear the line before drawing the sample into a syringe that contains sodium or lithium heparin. Use the sample within 30 minutes of collecting it.
3. Invert the tube with the sample several times immediately.
4. Use a disposable transfer pipette to obtain a sample from the center of the collection tube.
5. Apply a drop of blood directly to the target area on the test strip, covering the entire area.

5. Heel Stick Samples:

1. Select the site. Puncture should be made on the most medial or lateral, portions of the plantar or flat surface of the heel. **On heel stick puncture do**

not puncture through previous site or cold /cyanotic areas.

2. It is also important to select the appropriate lancet device based on infant's weight.
3. Warm the site. The site should be wrapped in a heel warmer or warm cloth for approximately five minutes.
4. Wear gloves and use universal precaution.
5. Hold foot with a moderately firm grip. **NEVER** milk or massage the foot because this causes hemolysis or mixture of interstitial fluid with the blood.
6. Cleanse the site. A sterile alcohol pad should be used to clean the site. The alcohol should be allowed to air dry before puncture.
7. Position safety lancet over site and activate. Once activated, the safety lancet cannot be reused.
8. Wipe off the first drop of blood because it is most likely to contain an excess of intracellular and interstitial fluid.
9. **Eliminate the first drop of blood.** Apply the second drop of blood directly to the target area of the test strip, covering the entire area.

V. EQUIPMENT/MATERIALS/REAGENTS:

A. Equipment:

Precision Xceed Pro meter.

B. Materials:

All materials must be stored at room temperature. (Between 39° and 86°F) (4°and 30°C)

- a) Precision Xceed Pro monitor.
- b) Precision Xceed Pro glucose strips.
- c) Precision controls solutions Low and High.

Materials management (Central Sterile) will maintain supplies necessary to perform blood glucose testing. Glucose Strips and Control Solutions (Low, High) will be provided for training and certification.

C. Reagent Preparation:

No reagent preparation required.

VI. QUALITY CONTROL

A. Daily Quality Control

Quality controls are performed each day of use on each instrument. Controls include: Low and a High levels. Each control level has a defined acceptable range. All controls must be within acceptable limits, prior to the testing of patient specimens. When a control is outside the acceptable limit, check control lot number in use, the expiration date on the vial and the date open. If the control results are outside the expected range, retest the control. Check the instructions. If the results are outside the range again, contact the Point of Care Staff at extension X 1679.

B. Critical Storage Elements

1. Use only MediSense Precision Control Solutions.
2. Store the control solutions at room temperatures, between 39°F and 86°F (4° and 30°C).
3. Keep bottle caps fully tightened.
4. Each bottle of control solution is **stable for 90 days after opening.**
5. **When a new vial of control is opened, write the current and expiration date on the vial. Discard all unused solutions 90 days after initial opening date.**
6. **Additional** quality control testing using two levels of control solutions will be performed when:
 - a. the Precision Xceed Pro Blood Glucose Meter was dropped.
 - b. results are questionable based on clinical signs and symptom.
 - c. a new vial of test strips is opened.
 - d. meter is replaced.
 - e. battery is replacement.

C. Quality Control Step by Step Procedure:

1. Press ON/OFF to turn on monitor.
2. **Press 2- Control test.**
3. Scan or Enter **Operator ID. Operators must use Xceed Pro assigned ID number.**
4. Scan or Enter Control Level Lot Number.
5. Scan or Enter **Test Strip Lot Number.**
6. Insert Strip and place control solution on strip.
7. If result is PASS, enter comment number corresponding to clean meter (10), to comply with documentation requirements. Then, proceed with next level followed by No Action required comment code (0).
8. If result FAIL, press appropriate number (ex. 1 -'REPEAT TEST').
9. If after repeating, controls still FAIL, change box or obtain a new lot of controls from the Point of Care Office. **If a control fails, do not test patient samples. Obtain backup meter from Chemistry on the second floor and document in the log book the reason for the exchange of meter.**
10. Use of controls can **alert** you to the following **problems**:
 - a) Test strips may have been exposed to excessive moisture or heat and strips may have deteriorated.
 - b) Control solution may have expired.
 - c) Patients results would be inaccurate.

VII. STEP BY STEP PROCEDURE FOR TESTING PATIENT'S SPECIMEN:

Testing is to be performed on Physician's request.

1. Press ON/OFF to turn the monitor on.
2. **Press 1- Patient test**
3. Scan or Enter **Operator ID. (4 digits)** Operators use Xceed Pro assigned ID number.
4. Scan or Enter **Patient ID. Use PT. financial account # (7 digits) serial number, NOT MR #.**
5. Scan or Enter **Test Strip Lot Number.**
6. Select site and perform finger stick Using **Universal precautions.**

7. **Eliminate the first drop** and then proceed with the sample testing.
8. If results are other than expected, put in comment code that is appropriate for your area. (See Section VIII -Reporting Results).
9. Any time results are manually entered into a patient chart or on to proficiency forms they must be checked to avoid recording errors.

VIII. REPORTING RESULTS:

A. RESULTS

1. Reference Ranges for non-diabetic, non-Pregnant adults fasting values are: **74 to 106 mg/dl**
2. One to two hours after meals: Less than **< 140 mg/dl**
3. **Reporting of Critical Values in Patient Specimens**
Each critical result is documented in the meter by using the appropriate comment code:
Comment Codes

0	No Action Required.	
1	Repeat Test.	
10	Clean exterior of Meter (DO NOT USE ALCOHOL)	
11	Out of range result for "Neonates"	Caregiver Notified <35 or >150mg/dl
12	Out of range result for "Pediatrics"	Caregiver Notified <70 or >200mg/dl
13	Initiate Hypo/Hyperglycemia Protocol	Caregiver Notified <70 or >450mg/dl
14	Out-Patient	Provider / Caregiver Notified <70 or >450mg/dl
15	CTICU Intensive Insulin Infusion	Caregiver Notified <60 or >140mg/dl

Repeat Finger Stick if <70 mg/dl. Follow Hypoglycemic Protocol. Critical values that are <50 mg/dl or >450 mg/dl are verified by repeat analysis. If a critical value is verified by repeat analysis, a specimen must be sent to the chemistry department for retesting.

B. Reportable Range **28-450 mg/dl**

C. Data Upload

A) Frequency:

Once per shift (as prompted by meter 12hrs).

B) Docking Station:

To begin the data upload, place the monitor in the docking station. Once the connection is established, communication between the monitor and QCM3 application software and the LIS (Laboratory Information System) Department will begin automatically. The monitor can send and receive data. Automatic data transfer (upload/download) between the Precision Xceed Pro Monitor and a PC in LIS Department running the QCM 3 application software. When this occurs, the monitor will display the following message:

"Please wait for Data Upload".

The circulating arrow, displayed on the meter's LCD screen, indicates data transfer (upload/download) is in process.

Testing is preempted while the monitor is sending or receiving data.

The monitor must not be removed until the data transmission is complete.
(If removed the Data transfer will be incomplete and operator access may be affected).

C) Detection of Data Errors

This procedure will be performed to provide a monitoring tool for checking the current Point of Care interfaces (Sybase) for errors in transmission of patient's results to the Cerner Laboratory Information System (LIS). This data is obtained from Point of Care testing instrument and then downloaded to the LIS for physician's view.

Procedure:

- a) Coordinator will daily randomly review 5-10 patient test results generated from the Xceed Pro glucose meter.
- b) Results will be compared for accuracy between QCM3 and LIS.
- c) Coordinator will verify the review of these documents by initializing the results generated from both systems.
- d) Any discrepancies will be documented in an incident report and sent to the Pathology Performance Improvement Committee.

IX. MAINTENANCE:

A. Routine Maintenance

Cleaning and maintenance of the Xceed Pro Blood glucose meter will be performed and documented daily. The daily maintenance will include the following:

Clean instrument, display screen, and workstation exterior daily with water and mild soap solution. If meter becomes highly contaminated with blood, a 10% bleach solution should then be used to clean meter, followed by soap and water.

DO NOT USE ALCOHOL.

After cleaning, perform control and when prompted for comment code, record in meter this cleaning procedure by entering comment code #10.

B. Replacing the Batteries

The Precision Xceed Pro Monitor requires two (2) AA alkaline batteries. Use the following procedure to install new batteries in the Precision Xceed Pro monitor.

1. Turn the Xceed Pro Monitor off by pressing the On/Off button on the keypad.
2. Turn the monitor over to view the battery compartment.
3. Press the tab on the battery compartment cover and lift the cover up.
4. Remove and discard the used batteries.
5. Insert the new batteries, using the + and – symbols in the battery compartment to position the new batteries with the correct polarity.
6. Run QC after each battery change.

C. Non-Functioning Meter Replacement

1. If troubleshooting does not resolve the problem the operator will notify the Point of Care staff at Ext.1679 or the Clinical Chemistry Laboratory, ext. 2921. Get a back-up Precision Xceed Pro Blood Glucose Meter from the Core Chemistry laboratory on the second floor. Operators' will sign log documenting the need for meter replacement. Same Procedure applies for evening and holiday shifts.
2. The Point of Care staff will evaluate malfunctioning meters, will test all levels of

- controls and perform linearity checks.
3. If any control level tests out of range Point of Care staff will replace the meter and the non- functioning meter will be taken out of operation and send to the manufacturer for replacement.

PROFICIENCY TESTING:

Procedure:

1. Point of Care staff will distribute proficiency samples to the operators of the Xceed Pro in designated locations.
2. Operators will analyze specimens in the proficiency testing mode.
Proficiency specimens will be processed in the same manner as patient specimens.
3. P.O.C. staff will mail Proficiency Testing results to the Accrediting Agency (CAP). Clinical pathology Director will review all survey evaluation reports. Point of Care staff will compile data and distribute the data to the Department of Nursing Performance Improvement and to the Nursing Institute of Continuous Learning for information and /or corrective action, when indicated.
4. Corrective Action plan will be documented and implemented as necessary by the Department of Nursing and by the Point of Care Coordinator.

X. EMPLOYEE CERTIFICATION:

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.

Training and certification of personnel will be conducted by the Institute of Continuous Learning annually.

Participants must demonstrate competency in the use of Precision **Xceed Pro Blood Glucose Meter**. This according to the established validation criteria:

- a) Visual Observation of the operator performing the test and ensuring that written policy and procedures are consistently followed.
- b) Evaluation of a problem solving skills.
- c) Assessment of testing performance through an external proficiency testing (CAP).
- d) Direct observation of instrument maintenance and function checks.
- e) Monitoring the recording and reporting of test results.
- f) Review of intermediate test results (QC, PT results, and preventive maintenance).

XI. PERFORMANCE IMPROVEMENT:

The summary of the Performance Improvement Report will be prepared monthly by the Point of Care staff and reviewed by the Pathology Performance Improvement Committee and then disseminated to the designated UHB Nursing Performance Improvement Managers, designated Nursing Leadership, Director of Nursing, and Assistant Director of Nursing, which in turn will share this information with the respective head nurses, clinical staff members and the Department Performance Committee. Appropriate corrective responses will be generated and forwarded to Point of Care Coordinator, who will forward this data to Pathology Performance Improvement Committee.

A copy of this report will be forwarded to the Institute Of Continuous Learning for

distribution to the educators.

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 Testing 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.

XII. VALIDATION:

1. Implementation and Validation Of Xceed Pro Instruments

A. Implementation.

- a. Instrument identification.
- b. Assessing the potential for error to assure system accuracy.
- c. Identify method to method differences.

B. Validation:

- a. Precision; Two control levels Low and High Tested Ten Times each. (With-in run). Acceptable precision; < 6% CV for the high control and < 10% CV for low control.
- b. Linearity check; performed using manufacturer prepared material, 5 preset levels each tested in triplicate. Results meet manufacturers' acceptance standards. Performed twice annually.
- c. Correlation studies must be conducted, comparing results between the current reference method used in the Chemistry Laboratory Radiometer ABL 800 and the new Xceed Pro meter to be implemented. Performed twice annually. Correlation must also be performed between two Xceed Pro meters when implementation of new instrumentation is considered. Three (3) samples must be used. Correlation studies will be acceptable if the correlation coefficient (R) factor between instruments is 0.950-1.05.

A meter will be deemed operational when the above requirements are met.

2. Validation of a new lot of Glucose testing strips.

Procedure:

- a) The New Lot Number strip will be used to test **Low and High** controls (known values).
- b) Two randomly selected meters will be used, to test 10 replicates of the old and new lots of strips.
- c) All values must be recorded, the mean determined and coefficient of variation calculated.

Criteria for Acceptance:

- a) All values obtained for Low and High controls must be within acceptable range determined in the enclosed literature sent from manufacturer.

XIII. Interference:

**Do not use during intravenous infusion of high-dose ascorbic acid.
Do not use during xylose absorption testing.**

XIV. REFERENCES:

1. ABBOTT'S Medisense Precision Xceed Pro Operating Manual
2. Medisense Precision Xceed Pro Blood Glucose Test strip-Product insert.
3. Medisense Precision Xceed Pro Control Solution -Product Information.
4. Davidson and Henry, Clinical Diagnosis and Management by Laboratory Methods. Seventeen Edition. W.B. Saunders Company, Philadelphia, PA. 1984

Date Reviewed	Revision Required		Responsible Staff Name and Title
01/08	Yes	No	Alix R, Laguerre, Lab Administrator
01/09	Yes	No	Alix R, Laguerre, Lab Administrator
02/10	Yes	No	Alix R, Laguerre, Lab Administrator
02/11	Yes	NO	Peter Howantiz, Medical Director
04/13	Yes	No	Sandra Alfaro,POC Coordinator