SUNY DOWNSTATE MEDICAL CENTER

UNIVERSITY HOSPITAL OF BROOKLYN

POLICY AND PROCEDURE

	No. LAB-23A
Subject: **POINT OF CARE –BLOOD GLUCOSE MONITORING (Using PCx glucose meter**	**Page 1 of 9**
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I. PURPOSE:

The precision PCx 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. PRINICPLE:

The Precision PCx 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 and 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 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:

I. Collection Procedure/Handling Conditions:

1. Critical Elements:

- Use only Precision PCx MediSense strips, or Precision PCx Control Solutions with PCx 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.
- If the test fails, apply a second drop of blood to the target area within 30 seconds. If the test fails after the second drop is applied, or of more than 30 seconds have elapsed, discard the used test strip and repeat the test using a new strip. **Do not exceed 30 seconds.**
- Do not touch the test strip after blood is applied to the test strip and the test starts.
- Use each test strip only once.
- Clear arterial lines before blood is drawn and applied to the test strip.
- When a glucose result is <300 mg/dl and the hemocrit results outside the range of 20% or 70% the results are invalid. Specimen should be sent to the Chemistry Lab.
- When a glucose result is >300 mg/dl and the hemocrit results outside the range of 20% or 60% the results 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 PCx Glucose test keep meter in a horizontal position. **Do not hold upright**.

2. Collecting Whole Blood Samples:

- Use universal precautions.
- Clean the puncture site with an alcohol swab and allow to dry thoroughly.
- Hold the patient’s arm downward for at least 15 seconds to allow blood to flow to the fingertip.
- Prick the side of the fingertip with an automatic lancing device. Picking the side of the fingertip is generally less painful than the center of the fingertip.
- Squeeze the finger gently to get a single, large, hanging drop of blood. Avoid squeezing the puncture excessively. **Eliminate the first drop of blood.**
- Apply the **second drop** of blood directly to the largest area of the test strip, covering the entire area.

- If necessary, the blood can be collected in a heparin-coated capillary tube and then applied to the test strip.

3. Collecting Arterial Blood Samples:

- Clear the arterial time 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.
- Use the sample within 30 minutes of collection.
- Mix the syringe several times immediately before applying the sample to the target area on the test strip.
- Allow a drop of blood to form at the tip of the syringe.
- 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:

- 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.
- If the blood is collected from the 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.
- Invert the tube with the sample several times immediately.
- Use a disposable transfer pipette to obtain a sample from the center of the collection tube.
- Apply a drop of blood directly to the target area on the test strip, covering the entire area.

5. Heel Stick Samples:

- Select the site. Puncture should be made on the most medial or lateral, portions of the plantar or flat surface of the heel. **On the heel stick puncture do not puncture through previous site or cold / cyanotic areas**.
- It is also important to select the appropriate lancet device based on infant's weight.
- Warm the site. The site should be wrapped in a heel warmer or warm cloth for approximately five minutes.
- Wear gloves and use universal precaution.
- 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.
- Cleanse the site. A sterile alcohol pad should be used to clean the site. The alcohol should be allowed to air dry before puncture.
- Position safety lancet over the site and activate. Once activated, the safety lancet cannot be reused.
- Wipe off the first drop of blood because it is most likely to contain an excess of intracellular and interstitial fluid.
- **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 PCx meter.

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

a) Precision PCx monitor.
b) Precision PCx 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 <u>each day of use on</u> 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 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 the bottle caps fully tightened.
4. Each bottle of control solution is **<u>stable for 90 days after opening.</u>**
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 PCx 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 PCx 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 PCx assigned ID number.
4. Scan or Enter **Patient ID. Use PT. financial account # (7 digits) serial number, <u>NOT MR #.</u>**
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 then expected, put in comment code that is appropriate for your area. (See Section VIII –Reporting Results).

VIII. REPORTING RESULTS:

A. Results:

A. Reference Ranges for non-diabetic, non-Pregnant adults fasting values are: **74 to 106 mg/dl**

One to two hours after meals: Less than **<140 mg/dl**

B. Reporting of Critical Values in Patients 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	**<60 or >200mg/dl.**
13	Initiate Hypo/Hyperglycemic Protocol	Caregiver Notified	**<70 or >450mg/dl.**
14	Adult Outpatient Out of Range Result	Caregiver Notified	**<50 or >450mg/dl.**
15	CTICU Intensive Insulin Infusion	Caregiver Notified	**<60 or >140mg/dl.**

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) <u>Frequency:</u>

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

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 PCx Monitor and the PC in LIS Department running the QCM3 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 view 5-10 patient test results generated from the PCx 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 PCx 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 be used to clean meter, followed by soap water.

DO NOT USE ALCOHOL.

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

B. Replacing the Batteries:

The Precision PCx Monitor requires two (2) AA alkaline batteries.

Use the following procedure to install batteries in the Precision PCx monitor.

1. Turn the PCx 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 the 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 PCx 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 the 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 PCx 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 Accredited 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 **PCx 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 the report will be forwarded to the Institute of Continuous Learning for distribution to the educators.

XII. VALIDATOPM:

1. Implementation and Validation of PCx 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 PCx meter to be implemented. Performed twice annually. Correlation must also be performed between two PCx meters when implementation if new instrumentation is considered. Three (3) samples must be used. Correlation studies will be acceptable if the correlation coefficient ® 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. REFERENCES:

1. ABBOTT'S Medisense Precision PCx Operating Manual.
2. Medisense Precision PCx Blood Glucose Test strip-Product insert.
3. Medisense Precision PCx Control Solution-Product Information.

Date Reviewed	Revision Required		Responsible Staff Name and Title
1/2008	Yes	No	Alix Laguerre, MS
	Yes	No	