**Hopi Health Care Center**

**Polacca, AZ**

**Waived Testing Policy and Procedure**

|  |  |  |
| --- | --- | --- |
| **Subject: Abbott Precision *Xceed Pro* Whole Blood Monitor** | | |
| **Original Effective Date:**  **05/04** | **Latest Revision:**  **10/2013** | **Due for Review:**  **Annually** |
| **Revised by: Jeanna Begay, MT** | | |
| **Distribution: ED/UC, OPD, IPU, OB, PHN, Dental, Med Staff** | | |
| **The last date of adopted, reviewed, or revised supersedes all previous versions.** | | |

1. **Introduction**

The Abbott Medisense Precision Xceed Pro Point of Care System for blood glucose testing is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary whole blood, venous, arterial, or neonatal whole blood glucose at the point of care.

Test results that are used to assess a patient’s condition or a make a clinical decision about a patient are governed by the federal regulations known as the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88). Only testing performed by staff on patients is regulated by CLIA ’88.

* + Staff performing the test should follow good laboratory practices.
  + Errors could cause inaccurate results that could lead to inaccurate diagnoses, inappropriate or unnecessary medical treatment, and poor patient outcomes.
  + The Joint Commission standards address the processes and activities related to waived testing that must be complied by all personnel performing testing.

The Precision Xceed Pro System simplifies point of care testing for healthcare professionals, providing features that enhance the reliability of testing process and that support compliance with point-of-care policies.

1. **Principle**

The test strip uses biosensor technology by employing a disposable test strip. The target area of the test strips is coated with enzymes that react in the presence of glucose to make a small electric current which passes through the strip to the contact bars and the monitor, which calculates a glucose result.

The target area may be filled by applying a drop of sample to the top of the test strip. The fill trigger electrode ensures that the test will only start once sufficient blood has been applied. Together, these features minimize the possibility of errant results due to sample application technique.

1. **Policy**

Precision XP meter operators must have specific training and orientation and demonstrate satisfactory levels of competence as described in the HHCC Waived Testing Policy and Procedure. Manufacturer’s instructions must be followed.

The HHCC Director of Nursing or designee(s) and the Clinical Laboratory Supervisor (or designee) is responsible for the direction and supervision of all the testing activities, certification, quality control, documentation and quality assurance as required by The Joint Commision, and other regulatory agencies.

1. **Supplies and Equipment**
2. Abbott Precision Xceed Pro Meter
3. Abbott Precision PCx *Plus* Blood Glucose Test Strips
4. Medisense Glucose Control Solutions (Lo and Hi)
5. Hospital approved lancet devices
6. Disposable gloves and sharps container
7. Alcohol wipes
8. **Storage and Handling**
9. Precision PCx Plus Blood Glucose Test Strips are sealed in individual foil packets. Store the test strips at room temperature between 4°C and 30°C. When stored properly, the unopened test strips remain stable until the expiration date printed on the barcode label. The barcode contains the test strip lot number, expiration date, control solution ranges and lot-specific calibration information.
   1. Use the test strip promptly after opening the foil packet.
   2. Do not use test strips after the expiration date.
   3. Do not handle the test strip with wet or dirty hands.
   4. Do not use test strips that are wet, bent, scratched, or damaged.
   5. Do not reuse test strips.
   6. Keep out of direct sunlight.
   7. Do not use the test strip if its foil packet has a puncture or tear in it.
   8. Do not scan a packet’s barcode and use a test strip from another packet. This may cause incorrect assay results to be generated.
10. Medisense Glucose Control solutions should be stored between 4°C and 30°C.
    1. They are stable for 90 days after opening or until the expiry date printed on the label, whichever comes first.
    2. When you open a new bottle, write the discard date on the bottle label.
    3. Always replace cap tightly.
    4. Discard all unused solutions 90 days after opening. DO NOT use expired controls.
    5. If control solutions have been refrigerated, allow them to reach room temperature before performing control testing.
11. **Specimen Requirements**

The Precision Xceed Pro System is designed for use with fresh whole blood. The capillary blood sample (i.e. from a finger stick) must be tested immediately.

1. Use only fresh whole blood samples.
2. Make sure the puncture site is clean and dry before lancing.
3. Collect the capillary blood using a lancing device.
4. Apply a drop of blood (2.5 microliters) to the target area at the end of the test strip. Allow the entire target area to fill with blood.
5. Avoid excessive squeezing of the puncture site.

Venous or arterial blood may be used for testing, provided the sample is used within 30 minutes of collection. Use VENOUS MODE only for venous samples that have been capped tubes and have not been mixed with air.

1. Sodium heparin, lithium heparin or EDTA must be used as an anticoagulant.
   1. Blood must be filled to the stated volume. Do not under fill.
   2. Do not use collection tubes that contain fluoride or oxalate because they may interfere with the test.
2. Use CAPILLARY or ARTERIAL MODE for all other samples.

**Infection Control:**

All users must follow standard precautions procedures for blood borne pathogens which include the following:

1. Wear gloves and other appropriate PPE’s.
2. Use a new lancet tip with each patient being tested.
3. Properly dispose of all sharps and biohazardous waste into appropriately labeled containers.
4. Unused supplies taken to a patient’s bedside during finger stick monitoring should not be used for another patient because of possible inadvertent contamination. Nursing staff should only remove one test strip and take only that strip, plus lancet, alcohol pad and swab along with the glucose meter to the patient’s bedside.
5. **Using the Monitor:**
6. *Barcode Scanner*: The barcode scanner enables you to scan the information into the monitor instead of manually entering the data using the keypad. Scanning the barcode on the test strip foil packet automatically enters the test strip information (calibration, control range, lot number, and expiration date).

To scan, hold the monitor 3-12 inches from the barcode at a 30 to 135 degree angle to the barcode, and press and hold the scan button until a visible red beam is emitted by the monitor. The monitor will beep in acknowledgement when it accepts the barcode.

1. *Data Entry Keypad*: The keypad allows you to enter ID numbers and letters or to select an option that appears on the display.
2. *On/Off Button*: Press this button to turn on the monitor. Press and hold this button for two seconds to turn off the monitor. The monitor will automatically shut itself off after 4 minutes to conserve battery life.
3. *Enter*: Press the Enter button after entering all needed information.
4. *Clear*: Press the Clear button to back up one space while entering on the keypad or to return to a previous screen.
5. *Data Port*: Located at the bottom of the monitor, this port enables the monitor automatically transfer the data through the docking station to the data management system.
6. *Battery Compartment*: The monitor holds two AA batteries to power the monitor. To prolong the battery life of the monitor, the monitor should be turned off when not in use. Data is not affected if batteries are removed.
7. *Port Protector*: Covers the test strip port and is designed to minimize the possibility of liquid entering the monitor through the strip port. Should blood or control solution come in contact with the port protector, the monitor should be cleaned and dried and the port protector replaced.
8. *Menu Tree*: When using the PXP, you will navigate between two main menus, Test Mode and Menu Mode.
   * Test Mode is used to perform patient tests and control tests.
   * Menu Mode is used for data review and proficiency tests.
9. *Important: Do not allow blood or control solution to run down the test strip into the monitor’s test strip port, as it may cause irreparable damage to the monitor.*
10. **Quality Control and Calibration**
11. Each meter is programmed to lock out users who have not performed QC within the specified frequency or when users do not obtain QC results within the acceptable range.
12. For instrument-based waived testing, the Joint Commission requires that quality control checks be performed each day on each instrument used for patient testing.
13. Quality control checks require two levels of control be run every 24 hours.
14. Quality control checks are not required on individual instruments on days when they are not used for patient testing.
15. Each time a new lot of test strips are opened, quality control (2 levels) must be run.
16. Quality control (2 levels) must be repeated when the test results contradict the clinical symptoms.
17. Invert and tap the capped control solution bottle to remove air bubbles from the tip of the bottle.
18. Do not scan one test strip foil packet’s barcode and use a test from another foil packet. This may cause incorrect results to be generated.
19. Scanning the barcode label on each test strip foil packet prior to use automatically calibrates the monitor and checks the expiration date, helping ensure reliable and accurate test results.

How to run Quality Control:

1. Press **On/Off** to turn on the monitor.
2. Press **2** to select **Control Test**.
3. Manually enter your 4-digit Operator ID, and then press **Enter**.
4. **Scan** the Low Level control barcode.
   1. If the **Unexpected Level** screen appears, you may either:
      1. Enter **1** to **ReEnter** the expected level.
      2. Enter **2** to **Continue**.
5. **Scan** the test strip barcode.
6. Open the foil test strip packet at the notch and tear down to remove the test strip.
7. With the contacts bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.
8. Gently invert the required control solution bottle 3-4 times. Remove the cap of the control solution bottle and wipe the nozzle with a clean gauze or tissue. Apply a small drop of solution to the test strip target area, allowing the target area to fill completely. Wipe the nozzle of the control solution bottle before replacing the cap.
9. Wait 20 seconds for the monitor to analyze the sample and display the test result.
10. Control test result will appear as **PASS/FAIL**. If test fails, quality control needs to be repeated.
11. When control result appears as **PASS**, Press **1-Next Level**, then proceed with the High Level Control following from Step 4 above.
12. After the high level control is completed, press **1-Exit**.
13. **Patient Test Procedure**
14. Press **On/Off** to turn on the meter.
15. Press **1** to select **Patient Test**.
16. Manually enter your 4-digit Operator ID, and then press **Enter**.
17. Manually enter the Patient ID, and then press **Enter**.
18. Confirm the Patient ID by re-entering the Patient ID.
19. Press **Scan** to scan the test strip barcode.
    1. Scanning the barcode identifies the strip type, calibrates the monitor, ensures the expiry date has not passed, records the strip lot used, and checks that the lot has been approved for use.
20. Open the foil test strip packet at the notch and tear down to remove the test strip.
21. With the contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.
22. Apply a drop of blood from the patient’s finger, transfer pipette, or syringe to the target area of the test strip.
    1. When sufficient sample has been applied, the monitor beeps, displays **Sample Accepted**, and automatically starts the test.
    2. You have up to 30 seconds to apply enough sample.
23. Wait 20 seconds for the monitor to analyze the sample and display the test result.
24. If there is a critical value (<60 mg/dL or >300 mg/dL), enter a comment code, and press **Enter**.

Comment Codes:

0 – No Action Required

1 – Repeat Test

2 – Confirmed by Lab

3 – MD Notified

4 – Wrong QC ran-Repeat

1. After reviewing the patient’s result, you can select one of the following options:
   1. **1-Next Patient**
   2. **2-Patient History**
   3. **Menu** to return to the **Menu Mode** menu
   4. **On/Off** to turn off the monitor
2. **Result Reporting**
3. **Normal Range**: Fasting blood glucose levels should range from **70-110 mg/dL** for adults.
4. **Critical Values** (number at which action must be taken)
   1. The critical glucose range for point of care is **less than 60 mg/dL** or **greater than 300 mg/dL**.
   2. For all critical glucose values, a comment code must be entered.
   3. The operator must repeat the test and request blood glucose to be analyzed by the laboratory by ordering either a Basic Metabolic Profile or Comprehensive Metabolic Profile.
5. **Reportable Range** (range of accurate results) is **20-500 mg/dL**.
6. **Documentation of Results**

When documenting results in the paper chart or EHR do so by writing or entering the result and include the reporting units (i.e. mg/dL). The test result must be documented along with the initials of the personnel performing the test and date the test was performed. A functional audit trail must be maintained that allows result retrieval.

1. Results are to be recorded on the test log.
2. Document date test was performed, sign or symptom, provider, and two identifiers.
3. The initials of personnel performing patient testing must be documented on the log.
4. Results must be entered into EHR.
5. **Data Upload**

**Meters must be docked weekly.**

Once the test results have been collected during a prescribed period of time, they can be uploaded into the data management system. The data management system provides a simple and automated way to collect report and transfer data.

1. To start the upload of data, simply place the Precision Xceed Pro Monitor into the docking station. The monitor will first turn on if it isn’t already, and then automatically upload data to the data management system. After upload is complete, the monitor will display **Upload Successful**, **Turning Off** and then shut down.
2. During communications, this screen appears and the arrows rotate to indicate that the system is working. The arrows may occasionally pause. During data upload, the monitor cannot be used for testing.

Note: If the monitor is removed before data transmission is complete, some data may not be uploaded. The data will be uploaded as part of the next data transmission.

If a problem occurs with the data upload, an error message may appear on the monitor. If the monitor is removed from the docking station while an upload is in process, the monitor will display **Last upload incomplete**, **Redock Meter**, **Turning Off**. Then the monitor will shut down.

After a data upload error has occurred, the monitor will display a warning each time it is turned on. The monitor may still be used for testing by pressing **1** to **Continue**. Once the monitor has successfully been docked, the warning will disappear.

1. **Maintenance**

The Precision Xceed Pro Monitor requires little routine maintenance. During testing, the sample remains outside the monitor, which significantly reduces the possibility of contamination.

Cleaning the Exterior Surface

* Cleaning the exterior surface of the Precision Xceed Pro Monitor daily is recommended. The Joint Commission recommends cleaning after each patient for infection control.
* The monitor needs to be cleaned only with a damp cloth or a sponge and a mild detergent. Turn off the monitor while it is being cleaned. Do not immerse or autoclave the monitor or flood it with any liquid.
* Acceptable cleaning solutions include alcohol and ammonia based cleaners. Recommended are solutions are Sani-Cloth, Sani-Cloth Plus, and Super Sani-Cloth.
* Bleach or hydrogen peroxidase based cleaners will fade the monitor keypad.
* Hype-Wipe ®, Dispatch ®, and Virox® 5 wipes are not recommended as they may fade the monitor keypad. Cleaning solutions not listed have not been tested and may damage the monitor.
  + Important: If a pre-packaged wipe is used for cleaning, excess fluid should be squeezed out to keep liquid from entering the monitor. Permanent damage could occur.

Replacing the Port Protector

The port protector is designed to minimize the possibility of liquid entering the monitor through the strip port. Should blood or control solution come in contact with the port protector, the monitor should be cleaned and port protector replaced with a new, dry port protector. After cleaning the monitor, dry the area around the port protector thoroughly.

1. Lift the port protector from its left or right edge.
2. Pull gently away until the protector separates from the monitor.
3. Rest the flat bottom of the new port protector on the ledge of the test strip port.
4. Gently push both sides of the port protector until you hear the tabs snap into place. There should be no gap between the port protector and the monitor around the edges.

Battery Life

The average alkaline battery life is approximately 60 days, based on an average of 9 tests per day and monitor being shut off within 2 minutes of it not being used (depending on barcode usage). Battery life will vary based upon actual use.

Replacing the Batteries

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

1. Turn the Precision Xceed Pro Monitor off by pressing the On/Off button on the keypad.
2. Turn the monitor over and remove the battery door.
3. **Data Review**

The Precision Xceed Pro Monitor stores the results of up to 2,500 patient tests, 1,000 control tests, 20 proficiency tests, and 2 linearity panels. This data can be retrieved by the following categories:

* Patient by Operator ID (OperID): This will show test results performed by a particular operator.
* Patient by Patient ID (PatID): This will show tests results performed for particular patient, starting with the most recent test.
* All Patient Data: This will display the test results for all patients, starting with the most recent test.
* Control Data: This will show control test results, starting with the most recent test.
* Proficiency Data: This will show proficiency test results, starting with the most recent test.
* Linearity Data: This will show linearity results, by level and order.

1. Press the **On/Off** button to turn the monitor on.
2. Press the **Menu** button.
3. Press **1** to select **Data Review**.
4. Manually enter your 4-digit Operator ID.
5. Choose the category of data to review:

1-Patient by OperID

2-Patient by PatID

3-All Patient Data

4-Control Data

5-Proficiency Data

6-Linearity Data

1. **Troubleshooting**

Troubleshooting Patient Test Results:

Reasons Glucose Results May Be Higher than Expected:

* Hematocrit is lower than the acceptable limit for the test strips, as indicated on test strip package insert.
* Serum or plasma samples were used instead of whole blood.
* Venous blood tested in arterial/capillary mode.

Reasons Glucose Results May Be Lower than Expected:

* Hematocrit is higher than the acceptable limit for the test strips, as indicated on test strip package insert.
* Hyperglycemic-hyperosmolar state (with or without ketosis).
* Severe dehydration, hypotension or shock.
* Water or alcohol remaining on the puncture site.
* Venous or arterial whole blood sample not tested within 30 after collection.
* Arterial or capillary blood tested in venous mode.

Note: If test results appear higher or lower than expected for reasons not described above, please repeat the test using a new test strip.

Troubleshooting Out-of-Range Control Test Results:

Repeat the test for that control solution:

* Eliminate any air bubbles in the control bottle’s tip.
* Wipe the control solution nozzle with a clean gauze or tissue before and after each use. Liquid left on the tip from previous tests may have a glucose concentration higher than expected.

1. **Limitations**
2. Precision PCx Plus test strips are designed for use with fresh whole blood samples. DO NOT use serum or plasma samples.
3. Use between 15°C and 40°C and between 10% and 90% humidity for best results.
4. Hematocrit range is 20-70% for glucose measurements <300 mg/dL and 20-60% for glucose measurements ≥ 300 mg/dL.
5. Test results may be erroneously low if the patient is severely dehydrated or severely hypotensive, in shock or in a hyperglycemic-hyperosmolar state (with or without ketosis).
6. The test strip has been evaluated with neonatal blood. As a matter of good clinical practice, caution is advised in the interpretation of neonate glucose values below 50 mg/dL.
7. Do not use during intravenous infusion of high-dose ascorbic acid or during xylose absorption testing.
8. Extremely high levels of the following substances at the following concentrations do not affect results: uric acid, 20 mg/dL; unconjugated bilirubin, 40 mg/dL; ascorbic acid, 3 mg/dL; cholesterol, 500 mg/dL; and triglycerides, 3000 mg/dL.
9. **References**
10. *Abbott Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System*, ART20746 Rev. A 01/10.
11. *Abbott Precision PCx Plus Blood Glucose Test Strips* Insert, ART13676 Rev. A 07/07.
12. *Medisense Glucose Control Solutions* Insert, ART19686 Rev. A 04/10.

**This Policy & Procedure was originated, reviewed and approved by the following:**

|  |
| --- |
| Revised By: Jeanna Begay, MT |
| Approved By: Medical Laboratory Director |
| Annual Review: |
| Annual Review: |

|  |
| --- |
| Date: |
| Date: |
| Date: |
| Date: |