

Glucose, Whole Blood Abbott Precision Xceed Pro System

Principle

Precision Xceed Pro (PXP) Blood Glucose Test Strips use biosensor technology. A test strip is dosed with 2.5 micro liters of whole blood then resulted in 20 seconds. The sample is applied to the target area, covering both the working electrode and the reference electrode. This area is coated with enzymes that react in the presence of glucose to make a small electric current. The current passes through the strip to the contact bars and the monitor which calculates a glucose result. The size of the 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.

Specimen Requirements

1. Fresh whole blood-capillary, venous or arterial blood. Do not use serum or plasma.
2. Test whole blood capillary samples immediately.
3. Venous or arterial blood may be used. The blood should be collected in EDTA, sodium heparin or lithium heparin collection tubes. Make sure the tube is filled to the stated volume. Do not under fill. Use the sample within 30 minutes of collection.
4. Do not use collection tubes that contain fluoride or oxalate.

Interferences

1. Test results may be erroneously low if the patient is severely dehydrated or severely hypotensive, in shock, or in a hyperglycemic-hyperosmolar state.
2. Hematocrits greater than 60% or less than 25% may cause false results. If a patient (other than neonate) has a hematocrit <25% or >60%, collect a patient sample and send to the Core Laboratory for glucose testing.
3. Neonate hematocrits greater than 65% or less than 25% may produce inaccurate results. Send these patient samples to the Core Laboratory for glucose testing.
4. Precision test strips are designed for use only with fresh whole blood samples. **DO NOT use serum, plasma, CSF, or other body fluid samples. Use of these other sample types can give falsely high results.**
5. Use between 15⁰C and 40⁰C (59⁰F and 104⁰F) and between 10% and 90% relative humidity for best results.
6. Venous and capillary blood glucose may differ by as much as 7 mg/dL, depending on the time of blood collection after food intake.

7. 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
Triglycerides	3000 mg/dL

8. Icodextrin and maltose exhibit no interference with the Precision PCx glucose measurements.

9. Venous blood samples tested in Capillary/Arterial mode can give falsely high results.

Reference Ranges

1. Fasting pediatric and adult whole blood glucose levels should range from 60 - 99 mg/dL.
2. Fasting range for newborns from 0-1 day is 41-60 mg/dL.

Reportable Range

Adult	20 – 500 mg/dL
Pediatric	20 – 500 mg/dL
Neonate (0-4 weeks)	20 – 500 mg/dL, if Hct is 25-65%

Critical Values

Adult	≤50 mg/dL or ≥500 mg/dL
Pediatric	≤50 mg/dL or ≥500 mg/dL
Neonates (0-4 weeks)	≤40 mg/dl or ≥300 mg/dl

Critical alert values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. These results must be immediately reported to the care provider and be documented in the test record as to who was contacted, the time of contact, the person making contact, and if relevant, that the results were read back.

Action Values

Adult	≤50 mg/dL or ≥350 mg/dL
Pediatric	≤50 mg/dL or ≥350 mg/dL
Neonates (0-4 weeks)	≤40 mg/dl or ≥300 mg/dL

Confirmation of Action Values

1. If the patient's glucose result is ≤50 or ≥350 for the first time, it is recommended to collect a sample and send it to the Core Laboratory for testing to confirm this result.

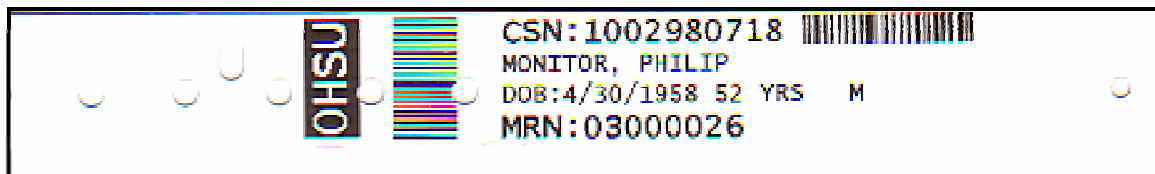
- Do not bill for the POC test when a confirmation sample is sent to the Core Lab.
2. It is recommended that all abnormal neonate glucose values be confirmed in the Core Lab.

Quality Control

1. Perform MediSense Low and High Glucose Quality Control (QC) Solutions every 24 hours of patient testing. The monitor has a 24-hour QC Lockout.
2. In addition, QC solution testing should be performed when:
 - a. Troubleshooting the monitor
 - b. The monitor is dropped.
 - c. Patient test result is lower or higher than expected.
 - d. A new lot number of test strips is opened
3. QC ranges are programmed into the meter. If the QC test passes, the meter display reads "**PASSED**". If the QC test fails, the meter display reads "**FAILED**".
4. To perform QC tests:
 - a. Press **On/Off** to turn on monitor.
 - b. Press **2** to select Control Test.
 - c. **Scan or manually enter your 5-Digit Employee ID code.** Press enter.
 - d. **Scan** the bar code on the Low Control bottle to enter the lot number of the control. If the unexpected level screen appears; enter 1 to re-enter the expected level, or enter 2 to continue. **Scan** the test strip barcode to enter the lot number of the strips.
 - e. Place monitor on a flat surface while running control tests.
 - f. Remove test strip from foil pack. With the contact bars facing the monitor, insert the test strip into the test strip port until it stops and **STRIP INSERTED** is displayed, then **Apply Low Solution** is displayed.
 - g. Gently invert control solution 3-4 times.
 - h. Remove cap and apply a small drop of solution to the test strip target area, allowing the target area to fill completely. Replace the cap.
 - i. When sufficient sample has been applied, the monitor beeps, displays **SAMPLE ACCEPTED** and automatically starts the test.
 - j. The monitor counts down 20 seconds, displaying **ANALYZE SAMPLE**, and then displaying the control result as **PASS** or **FAIL** when complete.
 - k. Repeat this process for the high control.
5. If the QC test fails check for the following, then repeat the test with a new strip:
 - a. Eliminate any air bubbles in the control bottle's tip.
 - b. Wipe the control solution nozzle with a clean gauze or tissue. Liquid left on the tip from previous tests may have a glucose concentration higher than expected.
 - c. Calibrate the monitor using the barcode for the test strip used.
 - d. Scan the correct 5-digit lot number for the control solution.
 - e. If test results are still out of range, please repeat the test using a new box of control solutions and/or test strips. If the results are still out-of-range, call Abbott Technical Support at 1-877-529-7185.

In-Patient Procedure

1. Press **On/Off** to turn on the monitor.
2. Press **1** to select Patient Test
3. **Scan your employee ID barcode** or **Enter your 5 Digit Employee ID** on the keypad and press enter.
4. **Utilizing the OHSU wristband, scan either of the patient barcodes on the band, or manually enter the Patient CSN #** on the keypad. Press enter. (The Patient ID must be the CSN (Contact Serial Number).)



5. Patient's name, DOB and CSN will display on the meter screen, you must confirm the patient by checking the information against the wristband or verbally with the patient. **Enter the last two digits of the birth year** and press enter.
 - a. If meter displays, "**Patient data not found**", dock and update the meter with the current ADT information. Then repeat steps 1 – 12
 - b. For Emergent CBG's where no wristband is available: Enter 911 or scan the barcode on the "Emergent CBG reconciliation Card", found under the "Forms" section on the Nursing Portal or in the meter caseContact POCT for additional supply of cards.
 - c. Press #2 to continue on with test process.
 - d. Complete the "Emergent CBG reconciliation Card " and tube to Core Lab.
6. Press **scan** to scan the test strip barcode.
7. Open the foil test strip packet and remove the test strip.
8. With the contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.
9. Clean the patient's finger with alcohol prep pad or soap & water. The finger must be completely dry before performing the test.
10. When meter displays the "**Apply sample message**", lance the patient's finger to obtain a drop of blood.
11. After blood flow has begun, wipe off the first drop. Angle the puncture site downward to facilitate blood flow. Avoid "milking" the appendage; a steady firm pressure is preferable. *CLSI H4-A6
12. While keeping the meter horizontal and level, apply a drop of blood to the target area of the test strip. When sufficient sample has been applied, the monitor will beep, display "**Sample Accepted**", and the test will automatically start.

NOTE: If the test fails to start, a second drop of blood may be applied to the target area within 30 seconds of the first blood drop. If the test fails to start after the second drop is applied or if more than 30 seconds have passed, discard the test strip and repeat the test.
13. Wait for the monitor to analyze the sample and display the test result. **Do not**

remove strip until after result displays.

14. If results are unexpected or do not match the patient's history or clinical presentation, retest the patient with additional emphasis on technique. Alcohol or water left on the finger can falsely lower the result. Food residue on the finger can result in falsely elevated results.
15. After use or prior to the next patient, clean the outside of the meter.
 - a. Gloves are to be changed and hand hygiene performed between patients.
 - b. Clean meter surface when visible blood or bloody fluids are present by wiping with a disposable disinfectant wipe (e.g. PDI Sani-Cloth AF or PDI Sani-Cloth HB) to remove any visible organic material. Cleaning should be followed by disinfection (see #3).
 - c. When no visible organic material is present, after each use disinfect the exterior surface following manufacturer's directions using a disposable bleach wipe (e.g. Clorox Germicidal Wipe or PDI Bleach Wipes).
 - d. Ensure that the device remains "wet" for the duration of the contact time listed on the label of the bleach wipe.
 - e. Alcohol should never be used because it can damage the light emitting diodes (LED) readout, causing "fogging" of the plastic screens.

Out-Patient Procedure

1. Press **On/Off** to turn on the monitor.
2. Press **1** to select Patient Test
3. **Scan your employee ID barcode** or **Enter your 5 Digit Employee ID** on the keypad and press enter.
4. Enter the patient's correct **MRN**, including preceding zeros.
5. Press **scan** to scan the test strip barcode.
6. Open the foil test strip packet and remove the test strip. Do not touch white tip portion of strip to avoid contamination.
7. With the contact bars facing up, insert the test strip into the test strip port until it stops and meter displays **Strip Inserted**.
8. Clean the patient's finger with alcohol prep pad or soap & water. The finger must be completely dry before performing the test.
9. When meter displays the "**Apply sample message**", lance the patient's finger to obtain a drop of blood.
10. After blood flow has begun, wipe off the first drop. Angle the puncture site downward to facilitate blood flow. Avoid "milking" the appendage; a steady firm pressure is preferable.
11. While keeping the meter horizontal and level, apply a drop of blood to the white target area of the test strip. When sufficient sample has been applied, the monitor will beep, display "**Sample Accepted**", and the test will automatically start.

NOTE: If the test fails to start, a second drop of blood may be applied to the target area within 30 seconds of the first blood drop. If the test fails to start after the second drop is applied or if more than 30 seconds have passed, discard the test strip and repeat the test.
12. Wait for the monitor to analyze the sample and display the test result. **Do not remove strip until after result displays.**

13. If results are unexpected or do not match the patient's history or clinical presentation, retest the patient with additional emphasis on technique. Alcohol or water left on the finger can falsely lower the result. Food residue on the finger can result in falsely elevated results.
14. After use or prior to the next patient, clean the outside of the meter thoroughly.
 - a. Gloves are to be changed and hand hygiene performed between patients.
 - b. Clean meter surface when visible blood or bloody fluids are present by wiping with a disposable disinfectant wipe (e.g. PDI Sani-Cloth AF or PDI Sani-Cloth HB) to remove any visible organic material. Cleaning should be followed by disinfection (see #3).
 - c. When no visible organic material is present, after each use disinfect the exterior surface following manufacturer's directions using a disposable bleach wipe (e.g. Clorox Germicidal Wipe or PDI Bleach Wipes).
 - d. Ensure that the device remains "wet" for the duration of the contact time listed on the label of the bleach wipe.
 - e. Alcohol should never be used because it can damage the light emitting diodes (LED) readout, causing "fogging" of the plastic screens.

Results Reporting

1. Dock the meter utilizing a docking station cradle or cable. Results for hospital inpatients will be uploaded into Epic and patient list in the meter will be updated. This process can take from 2 -4 minutes to complete.
2. If upload not successful, wait one minute and retry. If still unsuccessful, contact ITG Helpdesk (4-2222).
3. If results do not post to the Epic chart in a timely manner, contact ITG Helpdesk (4-2222).
4. Report all critical results to provider.
5. If the patient result is a first time less than 50 mg/dL, or greater than 350mg/dL value, a plasma sample sent to the Core Lab is recommended.

Data Transfers

1. Data transfer (Docking) is performed a minimum of every **6 hours** to exchange information between the glucometer and Epic for inpatient meters and once every two weeks for outpatient.
2. QC and patient testing cannot be performed if the data transfer is not performed within the minimum designated time.
3. Data transfers must be performed:
 - a. Every 6 hours (Two weeks for outpatient) to avoid lock out.
 - b. When entering a patient's CSN and the "**Patient data not found**" message is displayed.
 - c. When the memory of the meter is full and the display reads, "**NO ROOM FOR NEW TEST DATA**".
 - d. When requested by POCT staff.
4. To transfer data, perform the following:
 - a. Log on to the computer that has docking station attached to it.
 - b. Place meter into the docking station; make sure the meter turns on.
 - c. Data transfer will automatically take place. Meter will read "**Data Transferring**".
 - d. Remove meter once message displays of "**Upload successful**".

- e. Meter will automatically turn off when complete.

Reagents

1. Test Strips

- a. The barcode on the strips contains the lot number, expiration date, manufacturer control solution ranges and calibration information.
- b. Open foil protected strips by gently tearing at notch and removing test strip.
- c. With clean, dry hands the test strip may be touched anywhere on the strip.
- d. Store strips between 39° – 86°F (4° – 30°C), good until expiration date.
- e. Use strips between 59° – 104°F (15° – 40°C)
- f. When dosing a strip with patient's blood, if the test does not start immediately additional sample can be applied within 30 seconds of the first dose.
- g. Always use test strip from the packet that was scanned.

2. Control Solutions

- a. Store the control solutions between 4° and 30°C.
- b. Control solutions are stable for 90 days after opening.
- c. **Write the 90 days expiration in Month/Day/Year format on the QC bottles when a new set is opened.**
- d. Always replace cap tightly.

References

1. Operator's Manual for Blood Glucose Monitoring, Abbott Diabetes Care Inc. Alameda, CA, 2007, Precision XceedPro
2. Blood Glucose Test Strips, Precision PCX Plus, Package Insert
3. Tietz, Norbert, Ph. D. Fundamentals of Clinical Chemistry. Philadelphia, WB Saunders Company, 2001: p.37.
4. CLSI H4-A6. Procedures and Devices for the collection of Diagnostic Blood Specimen by Skin Puncture; Approved Standard-Sixth Edition, Vol 24, No. 21, 2008