

POC 4 Abbott Precision Xceed Pro Glucose Meter Procedure

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Location POC Manual

Organization Carl Vinson VAMedical Center

Comments for version 1.3

1. Call Provider Read Back Comment option #1 only.
2. Use Critical Glucose template only.

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Designated Reviewer	10/17/2022	1.2	Lisa G. Lee MT (ASCP) ATC Lisa Lee	
Approval	Lab Director	1/15/2021	1.0	Aml Girgis	Recorded when document added to MediaLab
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Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.3	Approved and Current	Minor revision	4/1/2024	4/1/2024	Indefinite
1.2	Retired	Minor revision	12/1/2021	12/1/2021	4/1/2024
1.1	Retired	Minor revision	12/1/2021	12/1/2021	12/1/2021
1.0	Retired	First version in Document Control	12/1/2021	1/15/2021	12/1/2021



PRINCIPLE:

The Precision Xceed Pro (PXP) glucose meter is intended for the quantitative measurement of glucose (D-glucose) in fresh capillary whole blood samples. The system is not for use in diagnosing diabetes, but is to be used as an aid in monitoring the effectiveness of diabetes control programs.

Precision Xceed Pro Blood Glucose Test Strips use proprietary glucose-specific chemistry that includes the glucose dehydrogenase enzyme, NAD cofactor and PQ mediator (GDH-NAD). This chemistry is used for testing glucose because it is not affected by maltose, isodextrin, and other common substances at normal therapeutic levels. It also ensures minimal measurement bias from oxygen, hematocrit, and other physiological variables. Test strips also have an exclusive blood application feature to ensure reliable sampling. After blood is applied to the target window, the fill trigger electrode ensures that the test will only start once sufficient blood has been applied. This will minimize the possibility of errant results due to sample application technique.

Each test strip is protected by a foil packet bearing an individual barcode label. The foil packet maintains the integrity of each test strip by protecting it from exposure to air, moisture, and accidental contamination. The barcode label holds information about the test strip including the lot number, calibration, expiration date, and expected control solution ranges. One quick scan provides the meter with all this information at time of test.

The reagent area of each test strip contains:

Glucose dehydrogenase (GDH-NAD)	≥ 0.03 U
NAD + (as sodium salt)	≥ 1.0 µg
Phenanthroline quinine	≥ 0.02 µg
Non-reactive ingredients	≥ 16.3 µg

The PXP meter can store up to 2,500 patient test results; 1,000 control (QC) test results; 20 proficiency test (survey) results; and 2 linearity panels.

PERFORMANCE CHARACTERISTICS:

- Assay Range: 20 -500 mg/dL (Instrument capability)
 - Sample Volume: 0.6 µL
 - Test time: 20 seconds
 - Precision: ± 15 mg below 75 mg/dL; ± 20% above 75 mg/dL
- Test results from multiple instruments are downloaded via lantronix box directly to LIS (Vista) and captured on UNIPOC for Ancillary Testing Coordinator (ATC) review.

SPECIMEN:

Fresh, capillary, whole blood from fingerstick

ROUTINE SAMPLE COLLECTION PROCEDURE:

1. The recommended puncture site is the palm-side surface of the end of the finger (not the side or the tip of the finger), across the fingerprints and not parallel to them. The middle and ring fingers are preferred.
2. DO NOT use previously punctured, infected, or edematous sites.



EQUIPMENT & MATERIALS:

Equipment:

1. Abbott Precision Xceed Pro glucose meter with AA batteries
2. VAMC computer with Pweb (data management) software installed
3. Docking station with data upload cable

Materials:

1. Glucose test strips (blue foil wrapper)
2. Alcohol swabs
3. Latex or nitrile gloves
4. Dry gauze or cotton
5. Isolation bag (as needed for isolation patients)
6. Lancets (obtained from SPD)

PREPARATION:

Assemble all materials required for fingerstick prior to beginning.

PERFORMANCE PARAMETERS:

MEMORY:

Patient Test Results: 2,500

Control Test Results: 1,000

Operator IDs: 6,000

Test Strip Lots: 36

Proficiency Test Results: 20

Glucose Linearity Results: 20 results (1 panel, 5 levels, 4 replicates per level)

Patient IDs: 6,000

Sample Size: 0.6 μ L

Test Time: 20 seconds

Assay Range: 20 – 500 mg/dL



STORAGE REQUIREMENTS:

Meter Operating Temperature: 59° F to 104° F (15° C to 40° C)

Meter Storage Temperature: -4° F to 122° F (-20° C to 50° C)

Test Strip Storage Temperature: 30° F to 86° F (4° C to 30° C)

Test Strip Operating Temperature: Use between 59° F to 104° F (15° C to 40° C)

Keep test strips and control solutions out of direct sunlight.

Altitude: Up to 7,200 feet (2,195 meters)

Dublin, Georgia: 300 feet altitude

Humidity: From 10% to 90% non-condensing

Mains Supply Voltage Fluctuations: \pm 10%

Transient Over-Voltages: \pm 1.5 KV Rated

CALIBRATION:

Standard Preparation:

N/A

Calibration Procedure:

Test strip calibration is performed each time a packet is scanned.

QUALITY CONTROL:

One set (low and high level) control solution must be tested and both levels must 'Pass' every 24 hours or only on days a patient is tested when meter is rarely used. Additional testing can be performed to meet competency review requirements. Each certified operator must perform a minimum of one set of QC (low and high) per year to meet competency review.

PATIENT TEST PROCEDURE: (Patient testing mode only)

1. Press **On/Off** to turn meter on.
2. Press **1** to select **Patient Test**.



3. Manually enter OPERATOR ID via keypad, and then press **Enter**.
 4. Press **Scan** to scan patient armband or manually enter **complete 9-digit SSN**.
 5. Confirm patient ID if manually entered by re-entering complete SSN to ensure it is correct.
 6. If discrepancy in numbers, must enter two more times until two numbers match.
 7. Press **Scan** to scan test strip barcode, press **Enter**.
 8. Open the foil test strip packet and remove test strip.
 9. With contact bars facing up, insert test strip into the strip port until it stops and **Strip Inserted** is displayed.
 10. Perform fingerstick and apply drop of blood to target window. **Sample Accepted** appears and testing automatically begins.
 11. Wait for the monitor to analyze sample and display result after 20 seconds.
 12. For critical values, enter required comment: "Call Provider and Readback" by pressing #1. If normal value, no comment codes required.
 13. Repeat critical values to ensure accuracy. Enter comment code again.
 14. If wrong patient is tested or suspect erroneous result, enter comment code 3 "Test Error".
- Use comment code #3 if result is not consistent with physical symptoms AND ruled out common errors in technique.
15. Remove test strip and discard in biohazard waste container.
 16. Press **1** for **Next Patient** or **2** for **Patient History** or **Menu** to return to **Menu Mode** or press **On/Off** to turn meter off.
 17. Dock meter to download data to UNIPOC.
 18. Prepare nurse Progress Note or Glucose Critical Value template and include provider name, date, and time of notification of critical value and any other comments appropriate.

CONTROL TEST PROCEDURE: (Control testing mode only)

1. Press **On/Off** to turn meter on.
2. Press **2** to select **Control Test**.
3. Manually enter operator ID.



8. Ensure samples are at ambient room temperature, mix well, wipe away any specimen on the tip of the bottle, and apply drop to ensure target window is completely full. Wipe cap of bottle and tighten.
9. Wait for meter to analyze sample and display result.
10. Press **1** for **Next Test**, return to step 5 and proceed with next sample.
11. Repeat steps 5-9 for all samples.
12. Dock meter to download data to UNIPOC.

LINEARITY TEST PROCEDURE: (Linearity Test mode only)

1. Press **On/Off** to turn meter on.
2. Press **Menu** button for **Menu Mode**.
3. Press **4** to select **Linearity Test**.
4. Manually enter operator ID #.
5. Select appropriate Linearity Panel.
6. Scan the CVC kit lot #, and then press **Enter**.
7. If **New Panel** screen appears, you may either: Press **1** to **Re-Enter** Kit Lot #, or Press **2** to **Replace Panel** Lot #.
8. Select the number of the level of the next test to run. If you press **6** for **New Panel**, the meter will prompt you to confirm that you wish to replace existing panel.
9. There can be up to 4 replicates per level. The number in the parentheses indicates number of replicates already run for that level. When a level is full, the number 4 will appear in parentheses indicating that all 4 replicates have been completed for this level.

Example: 1 – Level 1 (4)

10. Press **Scan** to scan test strip.
11. Open foil packet and remove test strip.
12. With contact bars facing up, insert the test strip into the test strip port until it stops and **Strip Inserted** is displayed.
13. Apply sample to target window ensuring complete filling. **Sample Accepted** and test automatically begins.



14. Wait for meter to analyze sample and display test result.

15. You can select one of the following options:

Press **1-New Level**

Press **2-Same Level**

Press the **Menu** button to return to **Menu Mode**

16. Press **On/Off** to turn meter off.

17. Dock meter to download data to UNIPOC.

DATA UPLOAD:

Once the test results have been collected, they can be uploaded into the data management system (UNIPOC).

To start the upload of data, simply place the Precision Xceed Pro meter into the docking station. The meter will first turn on if it isn't already and then automatically upload data to the data management system.

During communication, the **Please Wait - Data Uploading** screen appears and the arrows rotate indicating the system is working. The arrows may occasionally pause. During data upload, the meter cannot be used for testing. After upload is complete, the meter will display **Upload Successful**, Turning Off and then shut down.

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

Note: If a problem occurs with the data upload, an error message may appear on the meter. If the meter is removed from the docking station while an upload is in process, the meter will display **Last upload incomplete, Re-dock meter, Turning Off**. The meter will then shut down.

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

If downloading is interrupted during the process, no data will be lost and the meter will continue downloading when re-docked.

CALCULATIONS:

N/A

Read glucose value directly from meter LED screen.



REPORTING:

When the meter is docked, data will flow through Lantronix box to Abbott server. VistA picks up the data and sends to appropriate medical record (autodocumentation).

PROCEDURE NOTES:

Operating Guidelines for Samples:

1. Always wear gloves and follow VAMC’s biohazard safety policies and procedures when performing tests involving patient blood samples.
2. Make sure the meter and test strips are at ambient room temperature.
3. Use only control solutions specified in the strip package insert to verify performance of meter.
4. Use only Precision Xceed Pro Blood Glucose test strips.
5. Store control solutions and test strips according to manufacturer’s instructions.
6. Do not use test strips beyond expiration date printed on foil packet.
7. Do not use test strip if foil packet has a puncture or tear.
8. Do not use test strips that are wet, bent, scratched, or damaged. Use immediately upon opening.
9. Use each test strip only once.
10. Do not scan a test strip barcode and then use a different strip from different packet.
11. Completely fill target window.
12. Do not remove or disturb test strip while testing is in progress.
- 13. Do not allow blood or control solution to run down the test strip into the meter’s port. This will cause irreparable damage to the meter.**

How to Obtain a Good Capillary Sample:

1. Use only fresh whole blood samples collected from fingerstick.
2. Make sure sampling site is thoroughly cleaned and dry before lancing.
3. Use only appropriate lancing device and good technique.
4. Completely fill target window.



(‘L’ for 50 – 69 mg/dL)

(‘H’ for 111 – 449 mg/dL)

Note: ‘L’ or ‘H’ will be displayed by the value in the patient record.

Analytical Capability: 20 – 500 mg/dL

Values below 20 will show ‘<20’ and values greater than 500 will show ‘>500’.

PROCEDURE FOR CRITICAL OR ACTION RESULTS:

1. Initial critical value, add comment “Call Provider and Read Back” by pressing #1 and “enter”.
2. Repeat test within 10 minutes to verify critical result and, if confirmed, enter the required comment by pressing #1 and enter AGAIN. (Comment must be in ALL critical value test reports.)
3. If >15% variability in results, do a third test.
4. Call attending or assigned provider the results as soon as reasonably possible (<30 minutes) and obtain ‘read back’ of the information.
5. Complete Critical Glucose template for ALL CRITICAL VALUES. Document all critical values obtained.
6. Provider should order a laboratory confirmatory glucose for all initial critical tests.
7. Follow provider orders or standing operating procedure for low or high values.

REPORTING FORMAT:

Autoverification and autodocumentation in Vista. Values reported in ‘mg/dL’.

LIMITATIONS OF THE PROCEDURE:

1. Glucometer testing is used for “monitoring” only and not a diagnostic tool.
2. All glucometers are validated for use in capillary mode only. Only capillary whole blood should be used.
3. If peripheral circulation is impaired, collection of capillary blood from approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. A laboratory serum/plasma glucose is indicated. This may apply in the following

circumstances of **critically ill patients:**

- Severe dehydration



- Hypotension
- Shock
- Decompensated heart failure
- Peripheral arterial occlusive disease

4. In acute cases, POC glucose monitoring via capillary sample may have occurred before the patient could be evaluated for any limitations, as above. If this is discovered, switch to lab draw immediately and monitor patient for any adverse events.

5. The PXP has not been cleared by FDA to be used on “critically ill patients” and capillary testing should not be performed in this case. Venous sample glucose testing should be performed instead.

Recognition of Critically Ill Patient

HR=heart rate; RR=respiratory rate; SBP=systolic blood pressure; UO=urinary output

CLINICAL OBSERVATIONS			
APPEARANCE	NERUOLOGICAL	RESPIRATORY	CARDIOVASCULAR
Grey	Unresponsive or eyes open to pain only	Silent chest RR <8 >30 b/min	HR <50 b/min HR >150 b/min SBP <60 mmHg
Blue mottled skin	Fitting	Agonal respirations	UO - Anuric

TROUBLESHOOTING PATIENT TEST RESULTS:

NOTE: Plasma glucose concentration (Lab) is on average 10-12% higher than whole blood glucose concentration.

Reasons Glucose Results May Be Higher Than Expected:

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

Reasons Glucose Results May Be Lower Than Expected:



1. Use only RNA Medical brand Calibration Verification Control (CVC) kit that is compatible with the type of test strip being used.
2. Eliminate any air bubbles in the CVC bottle's tip.
3. Calibrate the meter using the barcode for the test strip used.
4. Confirm that CVC solutions and test strips have been stored with the ranges specified on their respective package inserts.
5. Check CVC bottle for open bottle expiration date.
6. Use new test strip for each test.
7. Use only Precision Xceed Pro test strips.
8. Confirm that the CVC solution tested (levels 1-5) matches the level requested on the display.

ERROR MESSAGES:

<u>Error Message</u>	<u>Explanation</u>	<u>Remedy</u>
(BLANK)	Meter has little or no power	Verify batteries in place correctly. Replace batteries.
Low Battery 1-Turning Off	Battery power getting low. Testing available for limited time.	Install new batteries.
Temperature Outside Range 43.9° C Testing Disabled 1-Exit	Temperature outside meter operating temperature range	Press 1 to Exit . Turn Off. Allow to return to room temperature



Error Message

Explanation

Remedy

09/25/09 7:00 am

1-Patient Test
2-Control Test
 Glucose QC
 Due in 28 min.
 (QC Due Now)

Time requirement for QC

QC due in time remaining

09/25/09 7:00 am

1- Patient Test
2-Control Test

Upload Due Now

Meter requires an upload.

Dock the meter and wait for
meter to turn off.

Upload Successful, Turning Off

**Low, High
Control Test
Required**

1- Exit
2-Continue

QC timed interval expired.

Perform control testing.

Test Memory
Upload Required

1-Exit
2-Continue

Upload interval expired.

Dock the meter.



Error Message

Explanation

Remedy

Patient ID
 xxxxxxxx
Patient Data
Not Found

1-ReEnter ID
 2-Continue

System cannot confirm
 patient ID

Press **1** to **ReEnter ID**

Scan or Enter
Patient ID

Invalid ID
 Strip Lot

Scanned Patient ID similar
 to test strip barcode

Re-Enter patient ID

Scan or Enter
Strip Lot

Invalid Lot
 Barcode

Barcode scanned not accepted.

1. Re-scan barcode.

Reasons: Scanner beam did not
 cross bars of the code; barcode
 damaged or poorly printed;
 not of type specified.

Scan or Enter
Strip Lot

Invalid Lot
 Date Expired

Expired lot of test strips.

Discard and scan new lot of strips.



Error Message

Explanation

Remedy

Strip Lot
 3576843190247
Is Not on the Strip List
 1-ReEnter Lot
 2-Continue

Strip lot scanned is not in the system for use. New lot that has not been entered.

Call ATC to enter lot number into system, re-dock meter to upload new lot number.

Operator ID
 123456
Is Not on the Operator List
 1-ReEnter ID

Operator is NOT in system.

Contact ATC or Nurse Ed. to be properly trained.

Operator ID
 123456
Date Expired
 1-ReEnter ID
 2-Continue

Operator ID has expired.

Contact ATC to be re-entered.

Operator ID
 Expires in xx Days
 1-Continue

Operator ID due to expire in listed number of days.

Press **1** to **Continue** testing.
 Contact ATC immediately.



Error Message

Explanation

Remedy

P:Smith, John
<20 mg/dL
Glucose
09/3/09 7:00 am
1-Next Patient
2-Patient History

Result is below measuring limit
of the meter.

Repeat test with new strip.
If repeats, follow policy for
critical value.

**Strip
Error
Wet of Damaged**
1-New Strip
2-Exit

Test strip or port is wet, defective,
contaminated, or wrong strip.

Remove old strip.
Press **1** and proceed with
new strip.

**Assay
Error
xxxx**
1-New Strip
2-Exit

Problem with strip.
(4327-strip removed during
Testing)
(4330-Too high to read or
problem with strip)

Press **1** to repeat test with
new strip.

Unexpected Level
Low expected
High entered
1-ReEnter Lot
2-Continue

Wrong solution used to test.

Repeat test with correct level.

XXX
1-Previous 6
2-Next 3

Not able to recall previous
result (may not have been downloaded)

Press **1** to view **Previous** or,
2 to view the **Next** result.



If Ancillary Testing Coordinator (ATC) cannot be reached, contact Abbott Technical Support Center at 1-877-529-7185 available 24/7.

MAINTENANCE:

The Precision Xceed Pro meter requires very little routine maintenance since patient blood does not come in contact with the meter. During testing, the sample remains outside the meter, which significantly reduces the possibility of contamination. Always ensure the yellow test strip port protector is in place prior to testing any solution – patient sample or QC solutions.

CLEANING THE EXTERIOR SURFACE:

Wipe down the exterior of the PXP meter between each patient and daily with **Sani-cloth** cloth only. Unacceptable cleaning solutions include alcohol and ammonia based cleaners, Hype-Wipe, and Virox 5 wipes are not recommended. Other cleaning solutions have not been tested and may damage the meter.

Turn off the meter prior to cleaning. Do not apply cleaning solution directly to the meter. If using a pre-packaged wipe, squeeze out excess fluid prior to use. Do not immerse or autoclave the meter or flood with any liquid. **Liquids must not enter the test strip port! Permanent damage will occur and the meter must be replaced.**

Operators will wipe meters clean after each patient and when visibly soiled with blood or other body fluids. Allow 3-5 minutes to air-dry before next patient use.

Operator’s Manual – 11-1.

OPERATOR/TRAINER TRAINING:

1. Instruction on the intended uses of POC blood glucose testing within the VAMC and limitations of the test system.
2. Instruction on critical high and critical low values with appropriate follow-up actions by the operator and provider.
3. Explain potential influences on test results including:



- Limitations inherent to the method
- Drugs, metabolites and endogenous substances that may interfere with the glucose monitoring system.
- Consequences of applying insufficient blood for a test.
- Samples with extremely high or low hematocrit values.
- Factors related to sample types and collection procedures.
- Physiological factors on blood samples.

4. Explanation of the differences observed in glucose concentrations between whole blood and serum/plasma specimens.
5. Explanation of the policy for the timing of tests, with provisions for emergency testing and flexibility for special medical orders.
6. Instruction on or demonstration of procedures for obtaining adequate blood samples from the finger.
7. Instruction on the operation of the testing instrument used by VAMC – Abbott PXP.
8. Instruction on how to document required critical value comments in a report and subsequent Progress Note in the medical record.
9. Infection control instruction that conforms to VAMC policy.
10. Proper frequency and procedure for QC testing, reagents, operator proficiency, and actions to be taken in the event of error or QC failure.
11. Normal instrument operation, maintenance, troubleshooting, and disinfecting.
12. Instruction on the sources of potential error specific to the system or procedure.

**Factors Influencing Accuracy of Test Results
From Improper Fingertick Collection**

PROBLEM	POTENTIAL IMPACT	RECOMMENDATION
Using a previously punctured site	Accumulated fluid will contaminate the blood specimen (decreases glucose)	Obtain blood specimen from a fresh, non-punctured site



Improperly cleaning the puncture site with alcohol	Residual alcohol causes rapid hemolysis and adversely affects glucose results (increases glucose)	Allow puncture site to air dry after cleansing with alcohol
Not wiping away the first drop of blood	Excess tissue fluid in blood specimen (decreases glucose)	Wipe away first drop of blood after the puncture is performed
Milking the puncture site to obtain the blood drop	Hemolysis and/or contamination of blood with tissue fluids	Hold the puncture site downward and apply gentle, intermittent pressure proximal to the puncture site
Edema at the puncture site	May give a falsely low glucose result	Fingerstick collection not recommended
Patient has peripheral vascular disease or a condition that impairs/decreases circulation to the periphery	False low glucose	Fingerstick collection not recommended
Patient is dehydrated	False low glucose	Fingerstick collection not recommended
Patient is in shock	False low glucose	Fingerstick collection not recommended
Patient has severe edema	False low glucose	Fingerstick collection not recommended
Patient has severe edema	False low glucose	Fingerstick collection not recommended
Patient is hypotensive	False low glucose	Fingerstick collection not recommended



VHA Directive 2009-004

Use and Processing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities

Cleaning and Disinfection Requirements for point-of-care (POC) instrumentation:

CDC defines **'cleaning'** as the removal of organic and inorganic material from objects and surfaces; while **'low-level disinfection'** is a disinfection process that will inactivate most vegetative bacteria, some fungi and some viruses, but cannot be relied upon to inactivate resistant organisms. Low-level disinfection is used for items and equipment that is non-invasive to patients. Non-critical reusable items (glucometer) may be decontaminated where they are used and do not need to be transported to a central processing area.

CDC recommendations:

- Assign a glucometer to each individual patient if possible. Clean and disinfect glucometers if they must be shared between multiple patients.
- Restrict the use of fingerstick capillary blood sampling devices to individual patients.
- Maintain supplies and equipment, such as fingerstick devices and glucometers, within individual inpatient rooms, if possible.
- Use single-use lancets that permanently retract after puncture.
- Never reuse fingerstick devices and lancets. Dispose them at point of use in an approved sharps container. Lancets in a pen should **NOT** be used per recent CDC document.
- Thoroughly clean all visible soil or organic material (e.g. blood) from the glucometer before disinfection.
- Disinfect the exterior surfaces of the glucometer after each use following the manufacturer's directions. Use Dispatch wipes (1:10 bleach equivalent).

REFERENCES:

Abbott Diagnostics, Inc., 'Precision Xceed Pro Operator's Manual for Healthcare Professionals', 2008.

NCCLS, Volume 17, ppgs 13-14, Para 9.1.1

NCCLS, Vol 22, C30-A2, ppgs 10-11

Journal of Medicine, October 2007, Vol 68, No 10



VHA Directive 2009-004, Use and Processing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities, Cleaning and Disinfection Requirements for point-of-care (POC) Instrumentation.

CDC MMWR; 54:220-3, 'Transmission of hepatitis B Virus among persons undergoing blood glucose monitoring in long term care facilities (LTC).

Joint Commission Standard IC.02.02.01, Accreditation process guide for laboratories. The standard states: "The laboratory reduces the risk of infections associated with laboratory equipment, devices, and supplies."