VA Salt Lake City Health Care System, MC 113
500 Foothill Drive, Salt Lake City, UT 84148

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Document Title: Hospital Glucometer Procedure

Principle

The Precision XceedPro (PXP) Glucose System has been developed to allow rapid measurement of blood glucose (D-Glucose) by using an electrochemical detection technique. This biosensor system employs a disposable dry reagent strip technology, based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase (Aspergillus Niger). When a blood drop is applied to the target area of the test strip, the glucose oxide catalyzes the oxidation of glucose in the drop to produce gluconic acid. During the reaction, an electrochemical mediator transfers electrons to the electrode surface. This will generate a current that is measured by the system. The size of the current generated is proportional to the amount of glucose present in the blood drop, thus giving an accurate reading of the blood glucose concentration.

Specimen Handling and Precautions

Universal precautions will apply when working with the Precision XceedPro whole blood glucose meter. Gloves and other Personal Protective Equipment (PPE) that is considered appropriate for the patient setting are worn when obtaining blood specimens from finger sticks and when performing the whole blood glucose tests.

All blood specimens and any used reagent strips are considered to be potentially infectious. Used lancets need to be disposed of in an appropriate biohazard sharps container. Lancets are for single use only. Dispose of used gloves and other PPE appropriately. *See VAMC Infectious Control Manual for detailed instructions.* Meters contaminated with blood must be disinfected. Meters must be disinfected between each patient use.

Equipment, Supplies, Reagents & Controls

***Equipment*:**
Precision XceedPro Glucose Meter

Supplies
- Alcohol wipes
- Disposable lancets (single use only).
- Disposable gloves and PPE are needed
  Note: Single use lancets must be used. Lancets cannot be used for more than one patient.

Reagents:
Precision Exceed Pro test strips:
- Use before the expiration date
- Do not use if strips are wet, bent, scratched or damaged
- Use immediately after opening foil packet
- Do not scan packet barcode and use test strip from a different packet. Always use the same strip that you scan and open.

Maintenance:
To keep the Precision Xceed Pro meter working correctly it is important to keep the instrument clean. Before using the meter make sure the port protector (old style meter) is seated securely. Also, ensure that it is not contaminated with control solution or patient blood. If there is a small amount of contamination wipe off with alcohol wipes. If the port protector is grossly contaminated contact the Ancillary Testing Coordinator for a new one.

Quality Controls:
Medisense Hi and Lo glucose control solutions

- Store control solutions at room temperature with their bottle caps tightened.
- Do not freeze.
- Each bottle of control solution is stable for 90 days after opening, or the date on the bottle if it is sooner, if tightly closed after each use. When you first open a new bottle, write the new expiration date on the bottle label. Discard all unused solution 90 days after opening.
- Invert the control solution bottle several times to ensure thorough mixing before use.
- Invert and tap the capped control solution bottle to remove air bubbles from the nozzle of the bottle.
- After each use, replace the cap immediately.
- Do not use control solutions after the expiration date printed on the bottles and the box. The Precision XceedPro meter does not accept control solutions that have passed their manufacturer expiration date.

Quality Control

Quality control must be performed at least once per 24 hrs of use, before patient testing is done. The Precision XceedPro meters will lock out any testing until QC has been run and passed. Additional QC checks must be performed each time a new lot of test strips is used and to investigate possible instrument damage or reagent deterioration.

Quality control consists of performing a high and low glucose control using Medisense Hi and Lo glucose control solutions. If the high or low control solution fails, repeat the test. Repeat the control only once after it has initially failed, the first test may have had too little control reagent on the testing site. If the control still fails, throw the control set (high and low controls) away and begin with a fresh set of controls. Controls should pass, if controls continue to fail set the meter aside with a note stating it should not be used and call the Ancillary Testing Coordinator to replace the meter. Patient samples must be run by alternate methods (i.e. send specimens to the lab or use another meter).

Note: The most common error made when performing daily QC, is running the high control when the meter is prepared for the low level, or low control when the meter is prepared for the high

Performing quality control

1. Turn instrument on by pressing the **On/Off** button

2. **Press 2** for Control Test

3. **Press scan** to scan in your operator ID barcode on the back of VA ID badge, or manually enter the badge ID number it is the long number beginning with "25757" located just above the barcode and press **Enter**. You will be prompted to re-enter the badge number if entered manually.

   Note: When manually entering in the Operator Badge ID number; leave off the last digit in the sequence of numbers. This number is not programmed into the meter, it is a check digit.

4. Following the prompt on the display screen; **scan** or manually enter the low control solution lot number, press **Enter**

5. Following the prompt on the display screen; **scan** or manually enter the test strip lot number, press **Enter**

6. Following the prompt on the display screen; open foil test strip, remove strip and insert it into the meter's test strip port with the contact bars facing up.

7. Following the prompt on the display screen; gently invert the required control solution 3-4 times to mix the control. **Apply** a drop to the white target area on the test strip.

8. The display screen will start a countdown from 20 seconds when sample is accepted.

9. Note the results – PASS or FAIL

10. The operator may select one of the following: Press 1 to continue and test the next level if PASS is noted on the meter. Press 2 to repeat the control if FAIL is noted on the meter. Enter the reason code 1.

    * *Repeat the control only once if it has initially failed, the first test may have had too little control reagent on the testing site. If the control still fails, throw the control set (high and low controls) away and begin with a fresh set of controls. Controls should pass, if controls continue to fail set the meter aside with a note stating it should not be used and call the Ancillary Testing Coordinator to replace the meter.*

      Patient samples must be run by alternate methods (i.e. send specimens to the lab or use another meter

11. Once controls have been run, and both the low and high controls have PASSED, the meter is ready for patient testing.

12. Turn off monitor once testing is done to preserve the batteries.

Specimen

Fresh capillary whole blood from a finger stick

Patient Preparation and Assessment

Wash the patient's hand with soap and water and dry thoroughly. Warm water stimulates the flow of blood to the fingers, making it easier to obtain a sample for testing. Having the patient hang his or her arm down to the side for 10-15 seconds before the finger stick will also make the procedure easier. Cleanse the site with alcohol prep and allow the area to dry.

NOTE: "*The use of a glucose meters for critically ill patients constitutes modification of the manufacturer's instructions, unless the manufacturer specifically states the meter has been validated for use on critically ill patients. Since the validation process for this type of method modification is very extensive and beyond the capability of most VA laboratories THE VA DOES NOT RECOMMEND THE USE OF GLUCOSE METERS FOR CRITICALLY ILL PATIENTS".* (AT-20 Document Version:07)

Therefore, the glucose meters assigned/deployed in VA Salt Lake City Health Care System should not be used for critically ill patients.

If a rapid glucose test is needed for a critically ill patient, then completely fill a green/yellow (lithium heparin) from an arterial line. Apply the arterial blood sample to the glucose strip by applying a small drop of blood with a pipette.

****Definition of critically ill patient for laboratory point-of-care testing****

A patient with a mean arterial pressure less than 60 mmHg despite the use of vasopressors.

Collection

1. Use disposable sterile lancets. Hold lancet firmly on side of the patient's finger with moderate pressure.

2. Depress plunger with index finger to make a puncture. Immediately release plunger while holding lancet on site. Discard the lancet.

3. Gently squeeze the finger to obtain a drop of blood.

4. Avoid squeezing the puncture site excessively.

5. Capillary whole blood specimens must be tested immediately upon collection.

6. Apply the drop of blood directly to the target area of the test strip. Sample volume required is 0.6 µL.

    * ***Note****: A second drop may be applied within 30 seconds.*

Patient Testing

1. **Press On/Off** to turn on monitor.

2. **Press 1** to select Patient Test.

3. Following the prompt on the display screen; press **Scan** to scan the **Operator ID** barcode, or manually enter the Operator ID via the keypad, then press Enter. If entered manually, the Operator ID must be verified by entering it a second time.

4. Following the prompt on the display screen; press **Scan** to scan the **Patient ID** barcode, or manually enter the Patient ID (patient's full SSN) via the keypad, then press Enter. If entered manually, the Patient ID must be verified by entering it a second time.
    - *NOTE: If the patient's wristband appears to be scratched, or if the patient wristband does not scan into the instrument, please replace the patient's wristband. This is to avoid any clerical errors with manually entering the patient's full SSN into the meter.*

5. Following the prompt on the display screen; press **Scan** to scan the test strip barcode, or manually enter the test strip lot number via the keypad, then press Enter

.

6. Open the foil test strip packet at the notch and tear up or down to remove the test strip.

7. With the contact bars facing up, insert the test strip into the test strip port until it stops.

8. The operator will see the following: Apply Sample.

9. Apply a drop of blood to the target area on the test strip. The test will automatically start a 20 second countdown.

10. Note the result and whether it falls within the Action Range (<50 or >450).

11. Steps to take if the Patient is within the Action Range (<50 or >450):

    - Repeat the test immediately.

    - Draw a gray top tube and send it to the lab for verification.

    - Notify Physician

    - DOCUMENT in CPRS using the *Finger Stick Glucose Critical Value* template. (For help finding the template view the notes at the end of the procedure.)

12. If the result is above or below the Action Range, you will be directed to enter a Comment Code – enter 1 to repeat test. Remove the strip from the monitor and repeat the test.

13. The operator can select one of the following options:

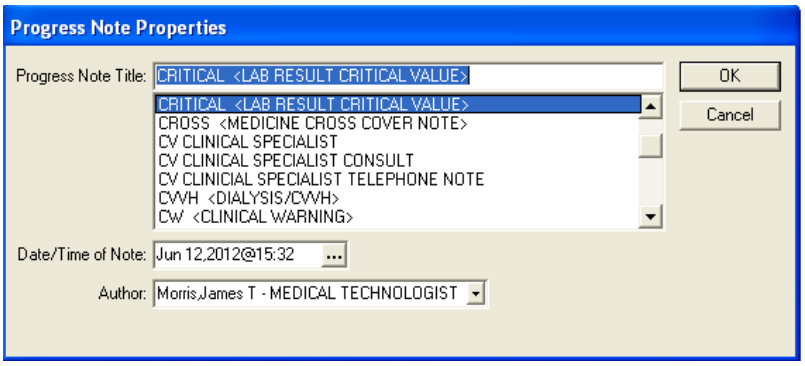
    - press 1 – next patient
    - press 2 – repeat test

14. If after repeating a test within of the Action Range (<50 or >450) and it repeats within of the Action Range, you will be directed to enter a Comment Code, enter 11.

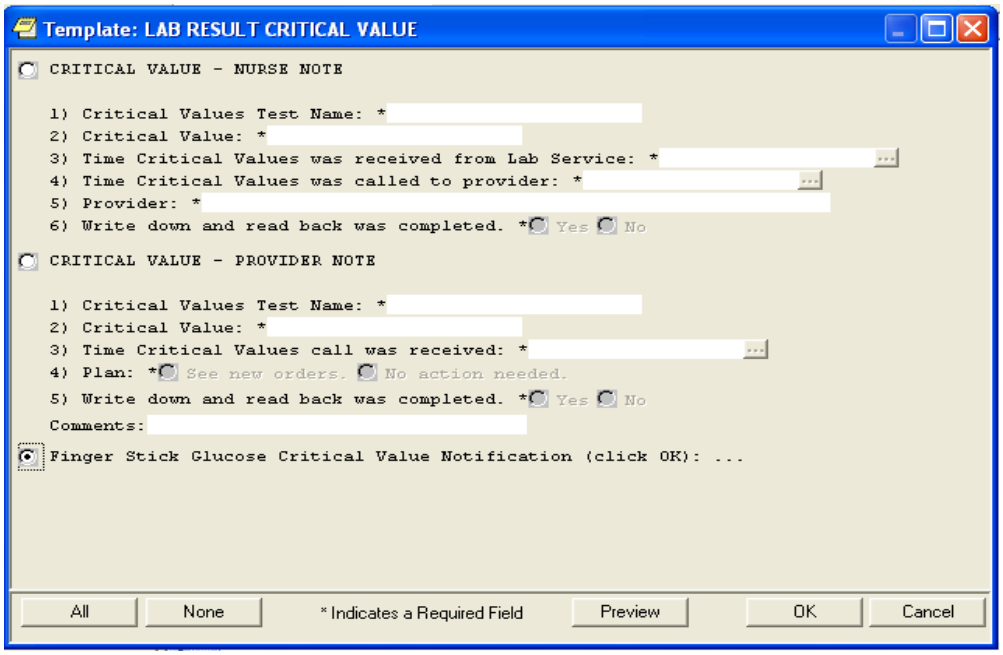
15. Draw a gray top tube and send it to the lab for verification if the result is<50 or >450. A gray top is used to stabilize the glucose by keeping it from being metabolized by the red blood cells, a marble top will not stabilize the glucose and the result will be decreased. **Note: A second blood draw is not needed if gray top tube have since been sent to the laboratory in step 11.**

- There are two ways to Find the *Finger Stick Glucose Critical Value* template:

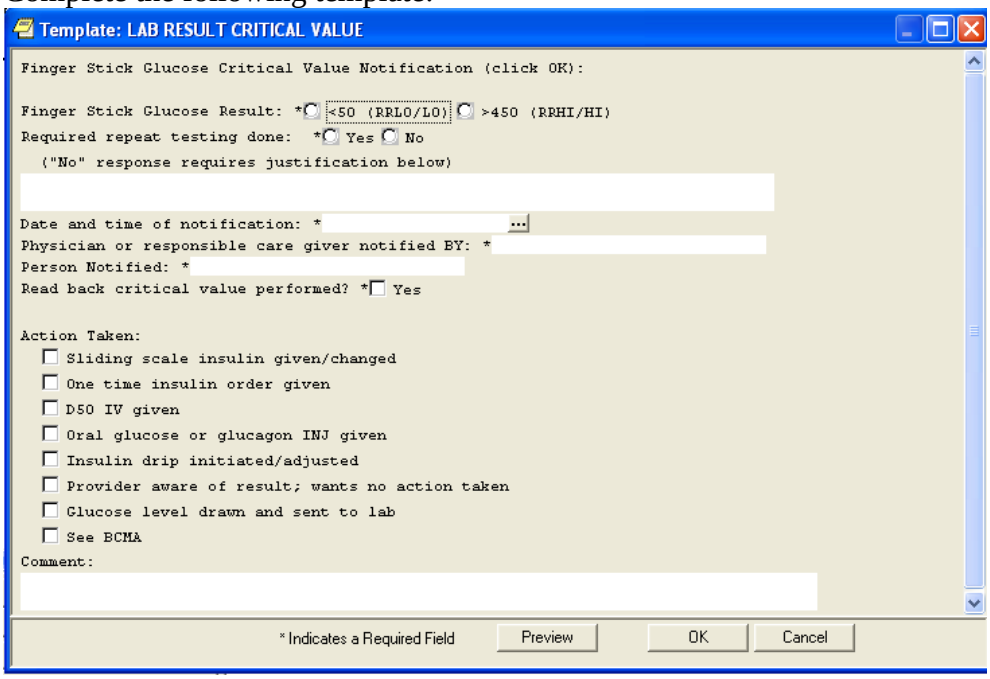
  New Progress Note or Addendum:
  - While in the Notes tab in CPRS create a new progress note or addendum
  - Type Critical and the following note will be displayed:



  - Click OK when "CRITICAL <LAB RESULT CRITICAL VALUE>" is highlighted.
  - This is the note that will appear:



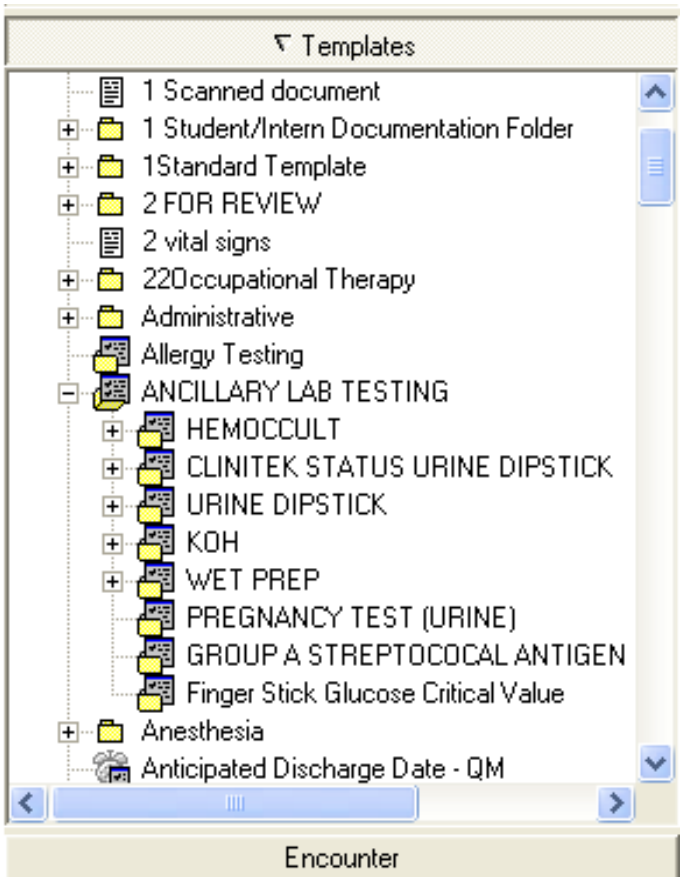
- Click on the Finger Stick Glucose Critical Value Notification radio button and then click on OK.
- Complete the following template:



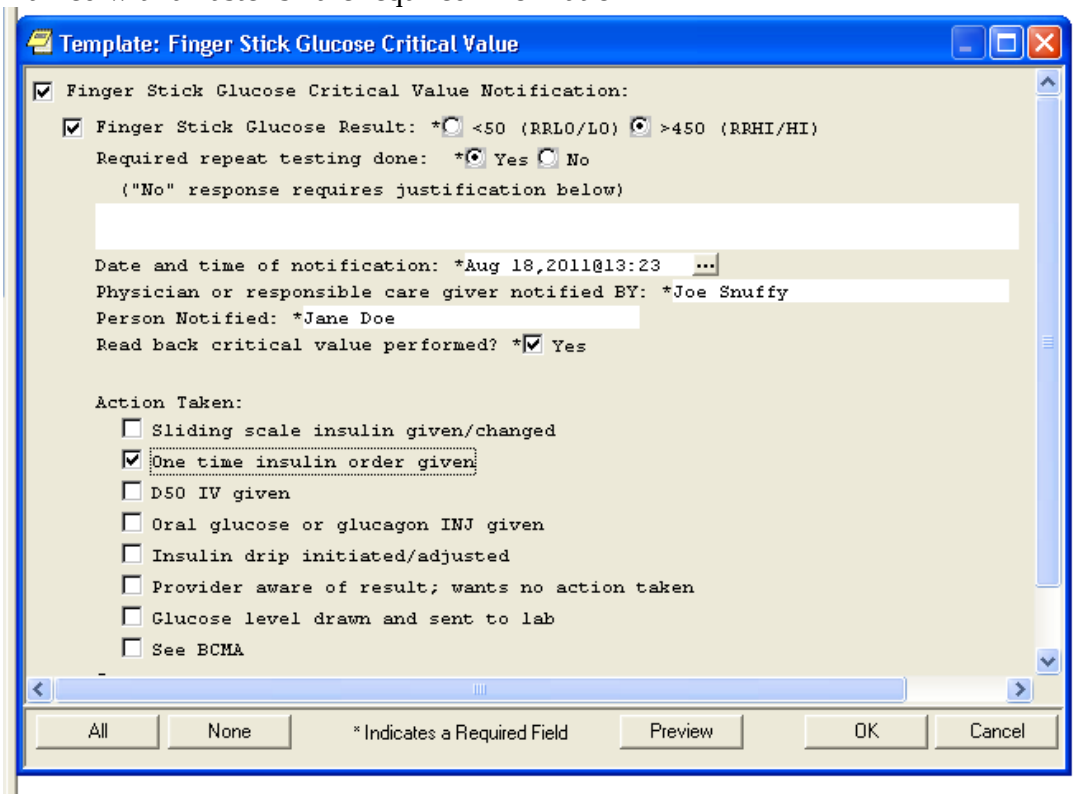
Note: Fields marked with an asterisk (*) are required information.

CPRS Template:

- While under the Notes tab in CPRS click on Templates
- Expand the Shared Templates menu and click on ANCILLARY LAB TESTING (See below).



After clicking on *Finger Stick Glucose Critical Value* the template will appear. All fields marked with an asterisk are required information



- Repeat testing is required for all first-time critical/action results. Not performing repeat testing can be done after the physician is notified and

action is being taken and monitored by subsequent glucose results. (e.g. insulin drip, sliding scale insulin) If in doubt, repeat the test. If the patient is in the Medical Intensive Care Unit (MICU) and on a insulin drip, sliding scale insulin the physician does not need to be notified for each critical/action result.

16. If a result is inconsistent with the patient's clinical picture repeat the test.

NOTE: *Do not run tests on other employees. This is only to be done by Employee Health or the Emergency Department when an employee comes in needing care. Doing so can result in administrative action and in the loss of glucometer privileges*

Emergency Testing:
In the event of an emergency where patient ID/barcode is not available (example: fallen visitor/employee, patient removed ID) you can enter in the patient ID with 111111111. After the emergency event you MUST e-mail/call the Ancillary Testing Coordinator with the patient information so the result can be added to the patient chart. If notification is not made to the Ancillary Testing Coordinator within 24 hours of the event, disciplinary actions will be taken against the testing personnel.

Reporting Results

- Fasting Values75-110 mg/dL.

- Results, date and time of collection, patients name and full Social Security Number, physician, and operator name and ID number will automatically be uploaded from the meter to VISTA and the Precision XceedPro data management system via the docking station.

Limitations

- Whole blood glucoses <20 mg/dL and >500 mg/dL are outside the linearity range of the Precision XceedPro monitor system.

- The Precision Xceed Pro test strips are designed for use with fresh whole blood samples. DO NOT use serum or plasma samples.

- High hematocrit above 70% cause inaccurately low results and low hematocrit below 20% cause inaccurately high results.

- Dehydration and excessive water loss may cause inaccurately low test results.

- Testing should be performed between 59-104 degrees F and between 10-90% relative humidity for best results.

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

Interfering Substances

- High levels of acetaminophen, up to 20 mg/mL, will not affect results. Therapeutic levels of acetaminophen are from 10-30 µg/mL.

- High levels of the following substances at the following concentrations do not affect results: uric acid 23.5 mg/dL, ascorbic acid 5 mg/dL, cholesterol 500 mg/dL, triglycerides 1,500 mg/dL, maltose 110 mg/dL, and galactose 45 mg/dL.

Quality Assurance

- Linearity studies are done on each meter before placing it in service and every time there is a test strip lot change. Linearity material from RNA Medical is used. Five concentrations are run in triplicate and the average of each concentration must be within 12.0 mg/dL or 20% of RNA Medical assayed values. This is done in the laboratory by the Ancillary Testing Coordinator.

- Daily Quality Control.

- CAP Proficiency Program Surveys.

- Correlation studies between lab results and the meters are done every 6 months. Meter results and lab results should be within +/- 15% of each other, fasting.

- If there is a problem with any of these methods, the problem must be evaluated, documented, and if not resolved the meter taken out of service.

- Calibration verification is done every six months.

- Venous Blood may be tested on the meter by the Ancillary Testing Coordinator or Senior Staff for Quality Assurance purposes only.

References

- College of American Pathologist, Commission on Laboratory Accreditation, Laboratory Accreditation Program, Inspection Checklist for 'Point of Care Testing', 2012.

- Department of Veterans Affairs, Veterans Health Administration, Clinical Laboratory Assessment Tool. VHA Handbook 1106.1, Compliance. Version .07. Revised 6/2/16.

- Precision Xceed Pro, Point of Care System, Healthcare Professional Operators Manual for Blood Glucose Monitoring, Abbott Laboratories, 2008.

- Precision Xceed Pro Blood Glucose Strip, Product Insert Rev. C, Abbott Laboratories, 01/12

Revision History

Section	Change	Date	Requester	Approver
Header	Update header	02/01/2017	Hung Ho	E. Hart MD
Font, Size	New Time Roman, 12	02/01/2017	Hung Ho	E. Hart MD
Patient Preparation and Assessment	Added VA policy on use of glucose meter for critically ill patient	05/15/2017	Ola, Peters Ayoade	K. Walsh
Patient testing	Outside to within; Critical value from >500 to >450. Added draw blood to step 11	05/15/2017	Ola, Peters Ayoade	K. Walsh