PROCEDURE

Title: Bedside Glucose Testing with the XceedPro

Procedure #: 2015POC01

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/2/2015

Title: Laboratory Administrative Director

Accepted by: _____ Date: 6-2-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 6/2/15

Review of procedure every two years

Reviewed by: _____ Date: _____

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Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Discontinued testing date: _____

Policy Title: Precision XceedPRO™ Blood Glucose Testing Procedure Policy

Audience: Laboratory Staff, Nursing Staff

References and Citations: National Committee for Clinical Laboratory Standards. Ancillary blood glucose testing in acute and chronic care facilities; Approved Guideline, NCCLS Document C30-A [ISBN 1-56238-232-2]. NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania, 19085. 1994., Tietz, N.: Fundamentals of Clinical Chemistry, 2nd Ed., W. B. Saunders Co., Philadelphia, PA; 1976, p. 243; and 3rd edition 1987, p. 429., Tietz, N.: Fundamentals of Clinical Chemistry, 3rd Ed., W. B. Saunders Co., Philadelphia, PA; 1987, p. 427., National Diabetes Data Group: "Classification and Diagnosis of Diabetes Mellitus and Other Categories of Glucose Intolerance," Diabetes 28, 1039-1057., Henry, John Bernard M.D.: "Clinical Diagnosis and Management by Laboratory Methods," 17th Ed., p. 1433, 1984., National Committee for Clinical Laboratory Standards. Clinical Laboratory Procedure Manual - 2nd Edition; Approved Guideline (1992). GP2-A2., College of American Pathologists Laboratory Accreditation Program Point-of-Care Testing Inspection Checklist. 325 Warkegan Road. Northfield, IL 60093-2750, PRECISION XCEEDPRO Blood Glucose Testing System Operator's Manual for Blood Glucose Monitoring 2007, Abbott Diabetes Care

A. PRINCIPLE

The PRECISION XceedPRO System allows rapid measurement of blood glucose levels using an electrochemical detection technique, which measures the electrical current resulting from the enzymatic cleavage of glucose. This technology can obtain accurate results over a broad range of patient hematocrit levels and sample types. This is a definitive test.

B. CLINICAL SIGNIFICANCE

The PRECISION XceedPRO Blood Glucose Testing System enables healthcare professionals to obtain rapid blood glucose testing results to aid in the diagnosis/treatment/maintenance of hypoglycemia and diabetes.

C. SPECIMEN TYPE/OBTAINING THE SPECIMEN

1. Capillary whole blood obtained by using the following procedure will be utilized with the PRECISION XceedPRO Testing System:

    a. Use only fresh whole blood samples.

    b. Make sure no water or alcohol remains on the puncture site.

    c. Collect the capillary blood using a lancing device and an appropriate technique.

    d. Avoid squeezing the puncture site excessively.

    e. Wipe away the first drop of blood and apply the second drop of blood directly to the target area of the test strip, covering the entire area.

2. Venous or arterial whole blood should not be used.

D. MATERIALS

1. Equipment needed:

   a. PRECISION XceedPRO Blood Glucose Testing System

   b. PRECISION XceedPRO Blood Glucose Testing Strips

   c. Medisense® Glucose Control Solutions (high and low)

   d. Lancing device

   e. Alcohol wipes

   f. PRECISION XceedPRO Testing Procedure

   g. PRECISION XceedPRO Docking Station

2. Storage and Handling

   a. Do not use XceedPRO Test strips after the Expiration Date indicated on the strip cover, or if the Precision XceedPRO meter gives an "Invalid Lot Not on List" message.

   b. Test Strips should be stored at room temperature between 18-30° C (64-86° F), and away from direct sunlight. Test Strips should never be refrigerated.

   c. Test Strips should be used immediately after removing from individual packet.

   d. Do not use MediSense ™ Control Solutions after expiration dates printed on the bottle. Control Solutions should be stored at room temperatures and remain tightly capped when not in use. Do not refrigerate Control Solutions. The date of opening should be written on control bottles, and the bottles should be discarded after 90 days or on the manufacturer's expiration date, whichever comes first.

E. CALIBRATION VERIFICATION

1. Linearity testing will be performed as needed with lot changes.

F. QUALITY CONTROL PROGRAM

1. One low and one high control solution test will be performed in the following instances:

   - Per 24 hour shift of use
   - With each new lot number of strips

The Point of Care Supervisor will program these options into each PRECISION XceedPRO instrument. Upon programming, the instrument will enforce these options by not allowing patient testing until the aforementioned has been performed and is within expected limits. Control specimens will be tested in the same manner and by the same personnel as patient samples.

2. Target ranges for controls are determined by the manufacturer and are listed on the foil packet of each strip. When the barcode on the strip is scanned into the instrument, the control ranges are automatically programmed. An "X" will appear in front of a test result that is Out-of Range. Statistical data is generated by the QC Manager program on a monthly basis to ensure a valid target range.

3. Whenever Quality Control values fall out-of-range, repeat the test for that control solution and observe the following guidelines:

   a. No air bubbles are in the control bottle's nozzle.

   b. Enter the correct 5-digit lot number for the control solutions.

   c. Check storage temperatures: Solutions and test strips must be stored between 39°F and 86°F (4°C and 30°C).

   d. Check that the bottles of controls have not been open for more than 90 days.

   e. Use a new test strip for each test.

   f. Use only Precision XceedPRO Plus Test Strips.

   g. QC results will appear on the meter as either PASS or FAIL. The Laboratory Point of Care Supervisor will get a numerical value in the computer so that QC can be monitored for trending. The QC must say Pass before continuing with a patient test.

   h. If Q.C. test results are out of range despite meeting the above criteria, please repeat the test using a new box of control solutions and/or test strips. If the results are still out of range, call the lab for support.

   i. The corrective action taken for troubleshooting out-of-control values will be scanned or manually entered into the XceedPRO meter using a 1-2 digit comment code, or electronically recorded on the monthly QC review.

4. If, through Quality Improvement Studies, the ranges are found inaccurate for our facility, a statistically valid range will be established by repetitive analysis.

5. Quality Control test results are uploaded into the MediSense QC Manager Data Management System. These are reviewed electronically by the POCT Supervisor and stored in the computer system for at least two (2) years.

6. The Quality Control Program is monitored by the Point of Care Supervisor with documented review at least monthly, as well as periodic review during the month.

G. PROCEDURAL STEPS

1. Before beginning the test:

   a. Check patient's Identification by asking the patient for his or her stated full name and date of birth as well as verifying the patient's armband for correct identification. These are the 2-patient identifiers defined by this facility in order to meet Joint Commission's National Patient Safety Goals. Do not use the patient's location for identification purposes.

   b. Check the patient for conditions that might affect test interpretation. If conditions are present, initiate appropriate strategies. If any of the following conditions are known by other laboratory testing, please use an alternate test, (serum glucose)

Condition	Strategy
ANEMIA	<20% Hematocrit. Interpret with caution. May cause higher glucose results. Try to use alternate method.
POLYCYTHEMIA	>70% Hematocrit. Interpret with caution. May cause lower glucose results. Try to use alternate method.
Patient is severely dehydrated; severely hypotensive, in shock or a patient in a hyperglycemic-hyper osmolar state (with or without Ketosis)	Could lower result. Interpret with caution. Try to use alternate method.
Acetaminophen	>100 mg/mL could lower results. Interpret with caution. Try to use alternate method.

2. Wear gloves at all times during the blood glucose test procedure, and dispose of all contaminated materials as stated in hospital safety procedures.

3. Perform blood glucose testing or control testing:

   a. Press On/Off to turn on monitor.

   b. Press 1 to select patient test or press 2 to select control test.

   c. Press Scan to scan the Operator ID barcode.

   d. Press Scan to scan the Patient ID barcode, or the High/Low control bottle barcode.

e. Press Scan to scan the test strip barcode.

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

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

h. Apply a drop of blood directly from the patient's finger, or drop of control solution to the target area on the test strip.

i. Wait for the monitor to analyze the sample and display the test result.

j. Note the test result and whether it falls outside the action range.

k. Remove the test strip from the monitor when finished testing.

l. Always clean the meter using a Sani-cloth between each patient use.

m. Dock the meter in the docking station so that the results can transmit to HMS

4. All patient blood glucose results are uploaded from the QC Manager Data Management System into the LIS and will include the following:

   a. Test Result with unit of measure (i.e., mg/dL) and reference ranges.

   b. Date/Time

   c. Operator Identification

   d. Appropriate Comments

   e. Action Taken (when critical values are obtained)

5. The patient's nurse reviews the results. They should evaluate them for clerical errors and any unusual or unexpected test result.

6. If results are higher or lower than expected, refer to the following list for possible cause.
   Reasons Glucose Results May Be Higher Than Expected:

   a. Hematocrit <20%

   b. Serum or plasma samples were used instead of whole blood.

   c. Room temperature >104F (40C)

   d. Relative humidity >90%

   Reasons Glucose Results May Be Lower Than Expected:

a. Hematocrit >70%

b. Room temperature <59F (15C)

c. Relative humidity < 10%

d. Acetaminophen >100 mg/mL

e. Hyperglycemic-hyperosmolar state (with or without ketosis)

f. Severe dehydration, hypotension or shock

g. Water or alcohol remaining on the puncture site.

DO NOT TEST PATIENT SAMPLES UNTIL QUALITY CONTROL TESTING IS SATISFACTORY!

7. Whole blood glucose measurements above 400 mg/dl or below 40 mg/dl are outside the reportable range of the PRECISION XceedPRO System and should be repeated by the Laboratory. They should be reported only as >400 mg/dl or <40 mg/dl.

8. When the glucose result is above or below the critical values, personnel shall:

   a. Repeat the test

   b. Contact the physician, or per physician orders

   c. Recheck patient value on blood drawn by Laboratory if requested by the physician. The PRECISION XceedPRO system will automatically order a venous glucose in the laboratory when the patient results are out of the reportable range of 40mg/dl to 400mg/dl. The nurse can call and cancel the venous glucose based on physician order or nursing assessment of symptomatic hypo/hyperglycemia.

9. SYSTEM WILL NOT ALLOW YOU TO TEST PATIENT SAMPLES UNTIL QUALITY CONTROL TESTING IS SATISFACTORY!

H. REFERENCE RANGES: Due to the testing system, reference ranges are taken from published results in the manufacturers' insert, as well as ADA guideline.
For non-diabetic, non-pregnant adults (from one-month and up):
- See patient report

I. MAINTENANCE

Other than cleaning the outside of the instrument and changing the batteries, there is no routine maintenance. When repair is needed, the instrument is sent to the vendor for replacement.