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PURPOSE:
To provide an accurate and rapid method to quantitatively measure glucose and ketones in fresh capillary, venous, arterial, or neonatal whole blood using the Precision Xceed Pro glucometer outside the laboratory setting. ***The Precision Xceed Pro can't be used to monitor critically ill patients. Critically ill patients at this facility are defined as: hyperglycemic-hyperosmolar state (with or without ketosis), severe dehydration, hypotension or shock.***

SCOPE:
Staff trained in the use of this instrument.

HAZARD PRECAUTIONS:
Gloves will be worn for this procedure. Wash or sanitize hands (following CDC guidelines) before and after procedures that involve patient contact. Hands must be cleaned before contact with clean or sterile supplies. Universal precautions must be followed.

EQUIPMENT:

- Precision Xceed Pro monitor
- Precision Xceed Pro test strips (Glucose or β-Ketone)
- Medisense Control test solutions (low and high)
- Abbott Docking Station or Cable
- Disposable single use protected lancets
- Cotton balls or 2x2 gauze squares
- Gloves
- Alcohol or Ammonia based cleaner
- Appropriate containers for contaminated disposable equipment/gowns

STORAGE:
Store strips between 39°F and 86°F (4°C and 30°C). Keep out of direct sunlight and heat.

SPECIMEN:
Use only fresh whole blood samples.
Capillary blood, heparinized (sodium heparin or lithium heparin) blood tested in less than 30 minutes. Hospital policy and procedure on specimen collection will be adhered to for this process. See Capillary Specimen Collection Procedure.

QUALITY CONTROL:
When a new lot of QC is received, POC Coordinator will run QC on it before it is distributed to the floors.

	STEPS	KEY POINTS
1.	Use a low and high control solution. Record open date and new expiration date on bottle when opened. **Good for 90 days after opened.**	Quality control checks will be done each day (every 24 hours) the meter is used. Controls must be discarded if not used within 90 days open date.
	Gently mix controls 3-4 times before each use. Expel a drop, discard then wipe tip with 2x2 gauze, cotton ball or tissue, before placing drop on strip.	Make sure instrument is flat so that liquid does not get into the port. Do not pickup instrument until strip has been removed.
2.	If results are not within expected ranges, repeat test. Check expiration date; that you ran the correct level; you mixed the vial, disposed of a drop and wiped the tip. a. If still out, contact the Point of Care Coordinator or Lab Manager. b. Patient results cannot be reported until quality control is within expected range.	All results will be downloaded to the laboratory management system when the meter is placed in the docking station. You will be unable to run a patient until the controls are run and are acceptable.
3.	Proficiency Testing will be performed twice yearly using samples from an external accredited source.	Proficiency samples shall be handled in the same manner as patient samples except will be run in the proficiency mode.
4.	As an operator you will be required to run at least one set of good controls a year or you will be locked out of the glucometer.	

Monitor Operation

	STEPS	KEY POINTS
1.	Press **On/Off** to turn on monitor.	The logo screen will appear for a few seconds followed by the product name, software version screen, self test and then the Test Mode menu. If *Glucose QC Due Now* appears, controls must be done before continuing
2.	Press **1** to select Patient Test.	After the patient test is selected, the Operator ID screen will appear.
3.	Manually enter the operator ID.	
4.	The display will prompt for a Patient ID to be entered. Press **Scan** to slowly scan the Visit ID number on the patient wristband. Do NOT enter manually.	This is extremely important as the result will go directly to the EMR. For patients that don't yet have a VID, scan the POC barcode provided in ED or FBC. Once patient ID is known, this barcode will be associated with the patient by putting a VID sticker on the page next to the barcode.
	(Note: If using instrument at one of the clinic sites use the 5 or 6 digit chart ID number.)	(Clinics: You will manually enter the result in the Lab Data Table in Practice Partner.)
5.	Press **Scan** to scan the test strip barcode.	The instrument is used the same for both glucose and ketone strips. Do not use strips beyond the expiration date. Do not use strips that are damaged in any way. Do not scan one barcode and use another test strip to ensure accurate results. The barcode contains: Lot #, Exp Date, QC Ranges, and Calibration Info.

	STEPS	KEY POINTS
6.	Open the foil test strip packet at the notch and tear down and across to expose the end of the strip to be inserted. Do not touch the strip with wet hands or gloves.	Use immediately after opening to maintain integrity. The foil protects the strip from exposure to air, moisture & accidental contamination.
7.	With the contact bars facing up, **insert** the test strip into the test strip port until it stops.	Make sure *Strip Inserted* appears in the screen. Make sure the meter is level so that liquid does not run into the port.
8.	After cleansing finger, wipe first drop off. **Apply** a drop of blood directly from the patient's finger, or a syringe to the target area on the test strip.	Make sure the monitor says apply sample. The monitor beeps when the sample is accepted and the screen will say sample accepted. Keep instrument level or strip end lower so that blood does not get in the port.
9.	If a test fails to start, add a second drop of blood to the test strip within 30 seconds.	If it still fails to start, discard strip and start over with a new strip.
10.	Wait for the monitor to analyze the sample and display the test result.	The monitor counts down 20 seconds then displays the test result.
11.	Note the test result and whether it falls outside the glucose action range: <60 or >200. Or a glucose critical value: **<40 or >400,** this result must be verified with a laboratory confirmation. Order a STAT glucose and notify the lab. Nursery will follow Standard Nursery Orders. See Addendum 1 and Hospital DKA (Diabetic KetoAcidosis) Policy for DKA Protocol.	If the test result is above or below the action range, an up or down triangle appears in front of the test result. If glucose is below 60 or above 200, and not covered by current physician orders, the physician will be notified. If glucose is a critical value, notify the physician.
12.	**Remove** the test strip from the monitor when finished testing, **before tilting monitor up to read results.** Discard.	

STEPS	KEY POINTS
13. Before doing the next patient be sure to clean the instrument. See Maintenance Section for cleaning instructions. The operator can <u>select</u> one of the following options. Press **1** – Next Patient. Press **2** – Patient History. Refer to the section entitled Data Review for Patient History for further information.	If 1 is selected, the scan Patient ID screen will appear. Return to step 4 to continue with testing on the next patient. Make sure you have cleaned the instrument between patients. If 2 is selected, the monitor will display the last test result for this patient as well as allow the operator to view previous results.

LINEARITY RANGE:

Glucose: 20-400 mg/dl	Results less than 20 will be reported as <20 mg/dl. Results greater than 400 will be reported as >400 mg/dl.
Ketones: 0.0-8.0 mmol/L	Results greater than 8.0 will be reported as >8.0 mmol/L.

EXPECTED RESULTS:

Glucose

- The **expected** glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dl. Two hours after meals, levels should be less than 140 mg/dl.
- **Action Range**: If glucose is below 60 or above 200, and <u>not</u> covered by current physician orders, the physician will be notified.
- **CRITICAL VALUES: <40 or >400** All critical value results must be verified with a laboratory confirmation. Order a STAT glucose and call the lab.

Ketones

- The Blood β ketone test measures β-hydroxybutyrate (β-OHB)
- Normally, levels of β-OHB are expected to be less than 0.6 mmol/l.
- If the blood β-ketone result is 0.0 mmol/l and the blood glucose result is 300 mg/dl or higher, or the results are not consistent with physical symptoms, repeat both the ketone and the glucose tests with new test strips.
- If the blood β-ketone result is between 0.6 and 1.5 mmol/L and the blood glucose result is 300 mg/dl or higher, this may indicate development of a problem that could require medical intervention.
- If the blood β-ketone result is higher than 1.5 mmol/L and the blood glucose result is 300 mg/dl or higher, this may indicate the risk of developing diabetic

ketoacidosis (DKA).

LIMITATIONS:

GLUCOSE

1. Use between 15°C and 40°C (59°F – 105°F) and between 10% and 90% relative humidity for best results.
2. Do not use during intravenous infusion of high-dose ascorbic acid or during xylose absorption testing.
3. Use only with fresh whole blood (no more than 30 minutes after collection). DO NOT use serum or plasma samples.
4. Reasons glucose results may be **higher** than expected:
   - Hematocrit is lower than the acceptable limit (≤20%)
   - Serum or plasma samples were used instead of whole blood
   - Venous blood tested in arterial/capillary mode
5. Reasons glucose results may be **lower** than expected:
   - Hematocrit is higher than the acceptable limit (≥70% when glucose measurement is 300 mg/dl or less); (>60% when glucose measurement is >300 mg/dl)
   - **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 minutes after collection
   - Arterial or capillary blood tested in venous mode
6. The glucometer **cannot be used in hyperglycemic patients,** if you get over 400 you **cannot** use the glucometer, you must have the lab draw blood and run the sample in the lab or you can use the i-STAT (in ER). The glucometer will not give accurate results in this type of patient, and if you use it you will be treating the patient on inaccurate results and could harm the patient or even cause death.

KETONES

1. Use between 64°F and 86°F (18°C and 30°C) and between 10% and 90% humidity.
2. Use ketone strips only on adults. These strips have not been evaluated for arterial or neonatal samples.

3. Hematocrit range is between 30% and 60%.

4. Test results may be erroneously **low** if the patient is severely dehydrated, or severely hypotensive, or in a hyperglycemic-hyperosmolar state.

MAINTENANCE:

The monitor needs to be cleaned **after every patient.** Turn off the instrument to clean. Acceptable cleaning solutions include alcohol and ammonia based cleaners or with a damp cloth or sponge and a mild detergent. Do not immerse or autoclave the monitor or flood with any liquid. Bleach or hydrogen peroxide based cleaners will fade the monitor keypad.

If the meter is used on a patient in isolation (specifically enteric isolation), place the meter in an Abbott isolation bag (made especially for the glucometer), when removed from the room clean with germicidal bleach wipes.

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 the port protector may need to be replaced. Call the laboratory for replacement.

REFERENCES:

Abbott MediSense® Precision ™ Xceed Pro *Operator's* manual for Blood Glucose Monitoring. 05/2013

Precision Xceed Pro Glucose Plus Test Strips Package Insert. Abbott Diagnostics. 01/2012

Precision Xceed Pro Blood ß-Ketone Test Strips Package insert. Abbott Diagnostics. 12/2010

LEVEL OF APPROVAL:

Standards Committee

ADDENDUM 1

DKA PROTOCOL

Follow the GRH Adult DKA Protocol for Critically Ill Patients

The following are the lab specific protocol from the DKA Protocol:

Establish diagnosis: Blood glucose >250 mg/dl, venous pH <7.3, serum bicarbonate <18 mEq/L, ketonuria or ketonemia.

Initial Labs: Comprehensive Metabolic Profile (CMP), Venous Blood Gas (VBG), Ketones, Magnesium, Phosphate, and CBC with differential; plus UA. If infection suspected Blood cultures x2.

If the POC Glucose (CBGs) are over 400, the glucometer can no longer be used until the lab gets 400, then the CBG must check within 20%, if it doesn't check within 20% do not use the glucometer.

Frequent Labs (run on the ABL)**:**

Lab Glucose every hour until 400 or less; then CBG by glucometer every 60 min or as needed.

BMP and VBG every 2 hours until DKA resolved. The results from the ABL are entered into Paragon, the rest of the parameters are run on the EXL (BUN, Creatinine, Ca).

Ca++ and PO4 every 2 hours if phosphate added to IV fluids.