DESCRIPTION/OVERVIEW
1. Purpose
   1.1. The Roche ACCU-CHEK Inform II meter quantitatively measures glucose levels in venous, arterial, or fresh capillary whole blood.

2. Principle
   2.1. The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH), converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for the blood glucose result. The sample and environmental conditions are also evaluated using a small AC signal.
   2.2. Studies show that the ACCU-CHEK Inform II whole blood glucose result compares well with a plasma laboratory method.

REFERENCES
1. ACCU-CHEK® Inform II Test Strips package insert, 2016
2. ACCU-CHEK® Inform II Controls package insert, 2016
3. ACCU-CHEK® Inform II Linearity Test Kit package insert, 2016
4. ACCU-CHEK® Inform II Operator’s Manual

AREAS OF RESPONSIBILITY
1. POCT Accu-Chek Inform II glucose testing can be done on any inpatient or outpatient on receipt of an order from a licensed independent practitioner or nursing staff designate.
2. Staff who have satisfied the required competency requirements may perform the testing, refer to the Point-of-Care Testing (POCT) Quality Assurance procedure.

PROCEDURE
1. Equipment
   1.1. ACCU-CHEK Inform II meter
   1.2. Single Use Lancing device
   1.3. Base Unit
2. Reagents
   2.1. ACCU-CHEK Inform II Test Strips
   2.2. ACCU-CHEK Inform II Control Solutions
   2.3. ACCU-CHEK Inform II Linearity Test Kit (Laboratory Use Only)
3. Ordering Information
   3.1. ACCU-CHEK Inform II Test Strips
   3.2. ACCU-CHEK® Inform II Control Solutions are ordered through CDU.
   3.3. ACCU-CHEK Inform II Linearity Test Kits are ordered by the Laboratory.
4. Storage
   4.1. The Accu-check Inform II should be stored away from direct sunlight and extreme temperatures.
4.2. ACCU-CHEK Inform II linearity and control solutions must be stored at temperatures between 39–86 °F (4–30 °C). Do not freeze. Both solutions are stable for three months after opening or until the manufacturer’s expiration date, whichever comes first. Label both vials of control solution with the open and expiration date.

4.3. ACCU-CHEK Inform II Test Strips are stored at temperatures between 39–86 °F (4–30 °C). Use the test strips at temperatures between 61–95 °F (16–35 ºC) and relative humidity between 10–80 %. Do not freeze. Do not use strips after the manufacturer’s expiration date. When a vial of strips has been left opened, discard. Inaccurate results may be obtained using strips exposed to ambient air.

5. Calibration
5.1. Each new lot of Strips must have the Code Key information programmed into the meter before the strips can be used for testing. The POC office will do this prior to the strips being distributed to the departments.

6. Cleaning and Disinfecting
6.1. If a meter is used for a single patient, then cleaning and disinfecting the exterior surface of the meter is, at a minimum, recommended daily. If meters must be used on more than one patient, then the meters must be properly cleaned and DISINFECTED AFTER EVERY PATIENT.
6.1.1. Place meter on a level surface prior to cleaning and disinfecting. Turn meter off.
6.1.2. Use 10% bleach, i.e. Clorox Germicidal. Using solutions other than 10% bleach could result in damage to the system components.
6.1.3. When using a pre-moistened cleaning/disinfecting wipe, SQUEEZE OFF EXCESS DISINFECTING SOLUTION or blot on a dry paper towel to remove any excess cleaning/disinfecting solution.
6.2. To Clean the meter.
6.2.1. Gently wipe the exposed surfaces of the meter with a 10% bleach wipe.
6.2.2. Do not allow liquid to enter the strip port or allow pooling on the touch screen.
6.2.3. Wipe dry when done.
6.3. To Disinfect after cleaning the meter.
6.3.1. Use a new 10% bleach wipe to disinfect by gently wiping the outside of the meter according to the disinfectant manufacturer’s guidelines.
6.3.2. Make sure that no liquid enters the test strip port.
6.3.3. Allow the surface of the meter to remain damp for the time recommended by the disinfectant solution manufacturer.
6.3.4. Ensure that the meter is THOROUGHLY DRIED after disinfecting.

7. Quality Control
7.1 Two levels of Quality Control solutions needs to be run on the meter at the following times:
7.1.1. Each day of patient testing
7.1.2. If the Accu-check Inform II meter has been dropped.
7.1.3. When a NEW VIAL of test strips is opened. Record date of initial QC on new vial of strips
7.1.4. When test results contradict clinical symptoms or anytime questionable results are obtained.

7.2. To Perform QC
7.2.1. Select the Control Test icon
7.2.2. Select the Barcode icon and scan the barcode on one control vial.
7.2.3. Select the Barcode icon and scan the barcode on the vial of test strips.
7.2.4. Insert the test strip. The meter will beep when the strip is correctly inserted.
7.2.5. Dose the test strip when the flashing drop picture appears.
7.2.6. Apply control to the front edge (yellow dosing area) of the test strip.
7.2.7. The sample is drawn into the test strip automatically.
   7.2.7.1. Once a sufficient sample has been detected, measurement begins. If sufficient
   sample is not detected the meter will display a Sample Detection error. For a
   complete list of error codes refer to the Accu-chek Inform II Operator’s
   Manual.
7.2.8. An hourglass will appear on the display while waiting for the result.
7.2.9. If QC is out of range, troubleshoot then, select the Conversation Bubble icon and
   select the appropriate comment:
   7.2.9.1. Wrong Control
   7.2.9.2. Procedural Error-Select when an error can be identified.
   7.2.9.3. Will Repeat-Select when an error cannot be identified, i.e. expired QC.
7.2.10. Select the Checkmark icon to return to the result.
   7.2.10.1. Rerun the failed control. If the meter is still out of range discontinue patient
   testing with that meter contact the POCT office for instructions 505-272-0980
   7.2.10.2. Common causes of failure include selecting the low control on the meter, but
   running the high control or vice versa; expired control solutions; and expired
   test strips.
7.2.11. Select the Checkmark icon to return to the Control Test menu.
7.2.12. Repeat the procedure with the other control.
7.2.13. Quality Control data is reviewed on a monthly basis by the POCT department
   and QC records stored in the POC office for 2 years for inspection purposes.

8. Patient Management
   8.1. Patient Identification
      8.1.1. Follow the Hospital Patient Identification procedure.
   8.2. Patient Preparation
      8.2.1. The operator must describe to the patient the purpose and the steps of the procedure
      before testing can begin.

9. Specimen Collection and Handling
   9.1. Universal Precautions apply to all POC tests.
   9.2. Testing personnel should handle all patient samples as per the hospital Bloodborne
       Pathogen Exposure Control Plan.
   9.3. Capillary, venous, and arterial fresh whole blood may be used.
      9.3.1. Test the blood sample as close as possible to the time the sample was collected but
      within 30 minutes of collection to minimize glycolysis.
      9.3.1.1. The blood glucose concentration will decrease over time because viable red blood
      cells continue to consume glucose.
   9.4. Fresh whole blood, in the absence of an anticoagulant, should be tested immediately to
      prevent clotting from affecting the results.
      9.4.1. Do not attempt to express blood from a previously punctured site. If repeat testing is
      performed, each test should be performed from a new skin puncture. Even if an old
      puncture site appears to be bleeding freely, it is likely that the clotting process has
      begun and may affect the patient result.
   9.5. Serum and plasma may NOT be used.
   9.6. Cord blood may NOT be used.
   9.7. Whole blood anti-coagulated with fluoride or Iodoacetate preservatives may NOT be used.
   9.8. Whole blood anti-coagulated with heparin or EDTA may be used.
   9.9. To collect a venous or capillary sample, refer to the Hospital’s Phlebotomy Self-Study
       Module.
10. Specimen Labeling
   10.1. Specimens for Accu-check Inform II glucose testing can be tested in the presence of the patient immediately after collection and then discarded.
   10.2. If testing is to be delayed or performed away from the patient, the specimen should be labeled as per the Hospital’s Specimen Labeling procedure.

11. Patient Testing
   11.1. Press the power button to turn the meter on.
   11.2. Enter your operator identification (ID) by selecting the Barcode icon and scan your operator ID.
   11.3. Select Patient Test.
   11.4. Enter the patient ID by selecting the Barcode icon and scan the patient’s financial number.
      11.4.1. The meter will display a Patient Confirmation screen. Ensure that the displayed patient information is correct and select the Check Mark icon.
      11.4.1.1. If the information is not correct select the X icon and scan the correct patient ID.
   11.5. Select the Barcode icon and scan the barcode on the vial of test strips.
   11.6. Remove a test strip from the vial. Immediately replace the cap on the vial.
   11.7. Hold the test strip so the lettering “ACCU-CHEK” is facing upwards. Slide the strip into the strip port as far as it goes in the direction indicated by the arrows on the test strip. The meter will beep when the strip is correctly inserted.
      Note: Insert test strip BEFORE dosing.
   11.8. When the flashing drop picture appears obtain a blood sample.
   11.9. If a sample is drawn into a Heparin or EDTA tube or syringe, gently mix the sample before testing.
   11.10. Apply the drop of blood to the front edge (yellow dosing area) of the test strip.
   11.11. The blood is drawn into the test strip automatically.
      11.11.1. Once a sufficient sample has been detected, measurement begins. If sufficient sample is not detected the meter will display a Sample Detection error. For a complete list of error codes refer to the Accu-check Inform II Operator’s Manual.
   11.12. An hourglass will appear on the display while waiting for the result.
   11.13. When the meter displays the result it will also indicate if the result is in normal range, out of normal range, or if it is a critical value. A comment must be entered if the result is critical.
      11.13.1. To enter a comment, select the Conversation Bubble icon and select the appropriate comment, i.e. Nurse Notified, followed by the Check Mark icon.
   11.14. Then select the Checkmark icon to return to the Main Menu.
   11.15. Remove the test strip from the meter and discard it in a biohazardous waste receptacle.
   11.16. Press the power button to turn off the meter.
   11.17. The meter must be turned off prior to docking.

12. Result Reporting
   12.1. Patient results will be immediately recorded electronically in the patient’s permanent medical record unless the “Procedural Error” comment is selected.
   12.2. Results that appear to be inconsistent with patient therapy or condition should be viewed as questionable and the test should be repeated or a specimen should be sent to the laboratory. (Refer to Interfering Substances and Limitations section 14.)
   12.3. If the Accu-check Inform II meter displays LO the result is <10 mg/dL and if it displays HI the result is >600 mg/dL. Reference Interval and Critical Values

13. Reference Interval and Critical Values
13.1. All POCT done in the hospital has a reference interval (normal reference range) validated with those tests performed on laboratory instruments. The reference interval thus correlates to that of the laboratory. See the table below for reference range values.

13.2. All critical values must be reported to the appropriate provider.

13.3. The treating provider has discretion to choose if critical values should be repeated by the laboratory reference method.


14. Interfering Substances and Limitations

14.1. Caution should be taken to clear arterial lines before blood is drawn.

14.2. Do not use serum or plasma samples.

14.3. If peripheral circulation is impaired, collection of capillary blood is not advised as the results might not be a true reflection of the physiological blood glucose level. Examples would include, but are not limited to:

14.3.1. Severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar non-ketotic syndrome.

14.3.2. Hypotension

14.3.3. Shock

14.3.4. Sepsis

14.3.5. Peripheral arterial occlusive disease.

NOTE: In these situations, a venous or arterial whole blood sample may be used.

14.4. The system has been tested with capillary neonatal blood. As a matter of good clinical practice, caution is advised in the interpretation of neonate glucose values below 50 mg/dL.

14.5. Blood concentrations of galactose >15mg/dL will cause overestimation of blood glucose results.

14.5.1. Glucose values in neonates suspect for galactosemia should be confirmed using the laboratory reference method.

14.6. Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3mg/dL will cause overestimation of blood glucose results.

14.7. Lipemic samples in excess of 1800 mg/dL may produce elevated results.

14.8. Patients with a hematocrit below 10% or above 65% should only be tested using the laboratory reference method. Abnormal hematocrits can cause abnormal glucose results.

14.9. This system has been tested at altitudes up to 10,000 feet.

14.10. The system is not for use in diagnosis or screening of diabetes mellitus.

14.11. Error codes can be found in the Operator’s Manual.

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**SUMMARY OF CHANGES**

Replaces POCT Accu-Chek Inform II, 05/08/2018

Added “Record date of initial QC on new vial of strips” 7.1.3
### RESOURCES/TRAINING

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### DOCUMENT APPROVAL & TRACKING

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