I. Purpose
The Glucose assay is used for the quantitation of glucose in human serum or plasma. Blood glucose determinations are the most frequently performed clinical chemistry laboratory procedures, commonly used as an aid in the diagnosis and treatment of diabetes. Elevated glucose levels (hyperglycemia) may also occur with pancreatic neoplasm, hyperthyroidism, and adrenal cortical hyperfunction as well as other disorders. Decreased glucose levels (hypoglycemia) may result from excessive insulin therapy or various liver diseases, including cancer.

II. Principle
The ACCU-CHEK Inform II system quantitatively measures glucose in whole blood. The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase from Acinetobacter calcoaceticus, recombinant in E. coli, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless electrical DC current that the meter interprets for a glucose result. The sample and environmental conditions are also evaluated using a small AC signal. The system is calibrated with venous blood containing various glucose concentrations and is calibrated to deliver plasma-like results. The reference values are obtained using a validated test method. This test method is referenced to the hexokinase method and is traceable to an NIST standard. The ACCU-CHEK Inform II test system is considered to be Waived Testing by CLIA standards.

III. Authority and Oversight
The ACCU-CHEK Inform II blood glucose monitoring program resides under the authority of the Glen Rose Medical Center Laboratory. The testing system is monitored by the laboratory’s point-of-care technologist. Policies and procedures related to the program are developed in cooperation and compliance with the policies of the following involved departments within the facility. In addition, all competent members (see IV. Competency and Training below) of these departments can perform testing.

- Laboratory
- Nursing
- Administration
- Pharmacy
- Surgery
- Other departments as necessary

IV. Competency and Training
A. All Staff performing testing on the ACCU-CHEK Inform II system must be trained and competency monitored.
B. Training and competency of users will be offered and monitored by the point-of-care technologist in the laboratory as well as supervisors in the department in which the ACCU-CHEK Inform II system is utilized
C. Trainers must meet the requirements listed on the Certification and Proficiency checklist (attached) prior to offering and monitoring training and competency of users.

WT.01.01.01, WT.02.01.01, WT.03.01.01, WT.04.01.01, WT.05.01.01
<table>
<thead>
<tr>
<th>Specimens</th>
</tr>
</thead>
</table>

**A.** The following fresh whole blood sample types may be used:
- 1. Venous whole blood
- 2. Arterial whole blood
- 3. Capillary (non-neonate finger stick and neonate heel stick) whole blood

**B.** The following anticoagulants are acceptable (do not use any other anticoagulants for meter testing):
- 1. Lithium or Sodium Heparin; EDTA

**C. Specimen Collection Procedure**

1. Assemble the materials you will need to collect a blood sample (gloves, skin preparation pad, auto-disabling single-use lancet device, and gauze or cotton ball).
2. Wash hands and don gloves and any other personal protective equipment as required by infection control and isolation policies and procedures.
3. Follow all GRMC infection control protocols when testing isolation patients.
4. Assess the patient for compromised peripheral blood flow. Fingertips should be warm and pinkish when the hand is gently massaged from the palm outward to the fingertips. Fingertips should not appear pale, bluish or mottled. Patients with compromised peripheral blood flow are not good candidates for finger stick testing.
5. Select the finger site for puncture. It is preferred to select the side of a middle or ring finger that has not been punctured recently.
6. Enhance blood flow to the selected puncture site by means of:
   - a. Warming the intended puncture site
   - b. Instructing the patient to flex and move the arm, wrist, hand and fingers while you are assembling your supplies and preparing the system for testing
   - c. Positioning the intended puncture site below heart level
   - d. Gently massaging in an outward (distal) direction from the palm and the base of the finger to the fingertip.
7. Cleanse the puncture site by means of. Allow the site to air dry completely before puncturing.
8. Advise the patient of imminent puncture.
9. Using ACCU-CHEK® Safe-T-Pro Plus lancet:
   - a. Twist off the protective cap of the Safe-T-Pro Plus lancet and discard
   - b. Choose the desired depth setting
   - c. Hold the Safe-T-Pro Plus lancet tip against the puncture site
   - d. Press the purple trigger button
   - e. Withdraw the Safe-T-Pro Plus lancet from the site
10. Hold the puncture site downward and gently apply intermittent proximal to distal pressure along the finger toward the puncture site to express a blood drop. Do not
apply strong repetitive pressure at the fingertip as it may cause hemolysis or contamination of the sample with tissue fluid and may lead to questionable results.
11. Wipe the first drop away. This is advantageous because it ensures that the cleansing agent is dry, it stimulates blood flow and clears interstitial fluid from the sample¹.
12. Apply a well-formed drop to the ACCU-CHEK Inform II test strip as described in the patient testing procedure that follows.
13. Apply gentle direct pressure to the puncture site for several minutes and elevate the hand to reduce blood flow to the fingertip. Check the site to ensure that it is no longer bleeding before leaving the patient bedside.
14. Discard all sample collection and testing materials appropriately.
15. Wash hands before leaving the patient room. Clean and disinfect according to facility policy. See section IX. Maintenance below for detailed instructions on cleaning and disinfecting.

VI. Supplies
   A. Materials
      Reagent strips are supplied Refer to Package Insert for composition.
   B. Preparation
      Refer to package insert for preparation instructions.
   C. Storage
      Unopened reagent strips are stable until the expiration date when stored at 15 to 30°C.

VII. Quality Control
   A. Quality control testing is performed as a primary means of ensuring on-going proper performance of the ACCU-CHEK Inform II system. The procedure below describes the steps taken to perform quality control testing on the ACCU-CHEK Inform II system. Low and high quality control testing is performed on the following occasions:
   B. Frequency
      QC material must be run at least every 24 hours of finger stick glucose testing
      When glucose results are questionable
      When a new strip vial is opened and placed into service
   C. Materials
      ACCU-CHEK Inform II Control Level 1 (Low) and Control Level 2 (High), the lot and range information will be available in meter.
   D. Corrective Action

WT.01.01.01, WT.02.01.01, WT.03.01.01, WT.04.01.01, WT.05.01.01
Patient results should not be released until controls are within acceptable ranges. The instruments are loaded with acceptable limits and will flag with “out of Range” or “Fail” when QC is outside acceptable ranges. The ACCU-CHEK Inform II system should be returned to the lab for corrective action or any other maintenance to correct QC failures prior to patient testing.

E. QC Procedure

1. Turn on the ACCU-CHEK Inform II meter.
2. Enter or your operator ID
   NOTE: If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. DO NOT attempt to perform tests under another operator’s ID.
3. From the Main Menu, touch Control Test.
4. Select the level of control that you wish to test
5. Confirm that the meter is coded (calibrated) to the same test strip code that is printed on the test strip vial. Contact your supervisor or Point-of-Care technologist if you are unable to confirm the correct test strip code.

NOTE about reagents: Reagents are not to be used past their expiration date. ACCU-CHEK Inform II strips expire on the date printed on the strip vial label. ACCU-CHEK Inform II Control and linearity solutions expire on the date printed on the vial label, or 3 months from opening, whichever comes first. Whenever an operator opens a vial of controls or linearity solution, he/she must handwrite the expiration date and his/her on the vial. That date will be either 3 months from opening or the date printed on the vial label, whichever comes first.
6. The meter will display a picture of a test strip with a downward flashing arrow on the meter indicating that you are ready to insert a test strip into the meter. Remove a test strip from the vial and immediately recap the vial. Insert the test strip into the meter in the direction of the arrows and with the “ACCU-CHEK” lettering facing upward. The meter will display a flashing drop above the test strip icon when the test strip is properly inserted indicating that you are ready to apply control solution.
7. Apply control solution to the front edge of the test strip. The solution will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress. You will get an error message if the sample is insufficient. If this occurs, you will need to repeat the test.
8. The measurement is complete when the result is displayed on the meter screen. See the “Interpretation of Results” and “Troubleshooting” sections below for guidance on what to do if your result is “Fail” or shows an “out of range” message associated with the result.
9. Remove the test strip and dispose of it appropriately.
10. Touch the comment button (○) to enter an appropriate comment(s)
11. Touch the ✅ button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.

F. Quality Control Interpretation
   1. Any result that shows an “out of range” message or “Fail” is an indication that the system may not be performing correctly for patient testing.
   2. Patient testing may not be performed if quality control testing results are not within acceptable limits and the meter will not display the patient testing option if scheduled quality control results exceed acceptable limits.

G. Troubleshooting and Corrective Action
   Quality control results must be within established limits. Take the following actions if your results are not within established limits:
   1. Add a comment(s) to the out-of-range result indicating that the test will be repeated.
   2. Repeat the test one time using the same test strip vial, control solution(s) and meter.
   3. If the result is in range, you may proceed to patient testing.
   4. If the repeat test using the same test strip vial is still out of range, repeat the test using a different test strip vial. If the result is within range, you may proceed with patient testing using the new test strip vial. Discard the vial that failed quality control testing.
   5. If the repeat test using the different test strip vial remains out of range, repeat the test using a new vial of control solution. If the result is within range, you may proceed with patient testing. Discard the control vial that failed quality control testing.
   6. If the repeat test using the new control vial remains out of range, remove the meter and all of the test strips and controls you used from service and deliver them to the laboratory for further investigation.

H. Guidance for interpreting on-screen message and error codes:

<table>
<thead>
<tr>
<th>Letter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>Identifies the notification as an Error. The information notifies the operator that an error has occurred.</td>
</tr>
<tr>
<td>W</td>
<td>Identifies the notification as a Warning. The information does not block the operator from continuing, but rather gives the operator information that may suggest an alternate workflow is required.</td>
</tr>
<tr>
<td>I</td>
<td>Identifies the notification as Informational only. Informational notifications present the operator with contextual information, and</td>
</tr>
</tbody>
</table>
VIII. Patient Testing

Carefully assess the patient for any indication that bedside glucose testing may not be appropriate (See Section XI. Limitations below for patient assessment guidance).

A. Take the meter and testing supplies to the patient location.
B. Wash hands and don personal protective equipment (gloves, gowns, etc.) as required by infection control and isolation policies and procedures.
C. Greet and identify the patient
D. Explain the procedure to the patient.
E. Turn on the ACCU-CHEK Inform II meter.
F. Enter your operator ID

NOTE: If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. DO NOT attempt to perform tests under another operator’s ID.

G. From the Main Menu, touch Patient Test.
H. Enter the patient identification in the ACCU-CHEK Inform II system
I. Confirm that the meter is coded (calibrated) to the same test strip code that is printed on the test strip vial by scanning the barcode
J. Contact the Point-of-Care technologist in the laboratory if you are unable to confirm the correct test strip code.
K. You will now see a picture of a test strip with a downward flashing arrow on the screen indicating that you are ready to insert a test strip into the meter.
L. Remove a test strip from the vial and immediately recap the vial. Insert the test strip into the meter in the direction of the arrows and with the “ACCU-CHEK” lettering facing upward. The meter will display a flashing drop above the test strip icon when the test strip is properly inserted indicating that you are ready to apply a blood sample.

NOTE about reagents: Reagents are not to be used past their expiration date. ACCU-CHEK Inform II strips expire on the date printed on the test vial label. ACCU-CHEK Inform II Control and linearity solutions expire on the date printed on the vial label, or 3 months from opening, whichever comes first. Whenever an operator opens a vial of controls or linearity solution, he/she must handwrite the expiration date and his/her on the vial. That date will be either 3 months from opening or the date printed on the vial label, whichever comes first.

M. Collect an acceptable blood sample according to Section IV. Part C, Part 1-15
N. Wipe away the first drop of blood
O. Apply blood to the front edge of the test strip. The sample will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip.
P. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.
Q. After the sample has been obtained, apply gentle pressure to the puncture with a clean gauze square or cotton ball site for several minutes. If the patient is conscious and capable, enlist the patient’s assistance with applying pressure.
R. The measurement is complete when the result is displayed on the screen. Depending upon how high or low the result is, it may appear in a numeric or non-numeric format. See Interpretation of Results section below for interpretation of each result format.
S. Remove the test strip and dispose of it
T. Touch to enter up to three appropriate comment(s) as required in the “General Policies” section of this manual.
U. Touch the button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.
V. Document the result in the patient chart by means of entering results in CPSI
W. Follow up on any results that exceed critical or reportable limits according to policy.
X. Clean and disinfect everything as necessary

IX. Maintenance-Cleaning and Disinfecting Accu-Chek Inform II Meters

A. DO's:
2. Do follow all GRMC safety and infection control policies when handling, cleaning and disinfecting ACCU-CHEK Inform II meters.
3. Do, if you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system component and please contact ACCU-CHEK Customer Care at 1-800-440-3638 for assistance: Clouding of the touch screen display, on/off-button button malfunction, clouding of the infrared data port and/or barcode scanner, or quality control results outside of the specified ranges.
4. Do obtain and dispose of acceptable cleaning and disinfection materials/products per facility guidelines.

B. DO NOT's:
1. Do Not clean or disinfect the meter while performing any type of test.
2. Do Not allow pooling of liquid on the touch screen.
3. **Do Not** spray anything onto the meter or base unit.
4. **Do Not** immerse the meter or base unit in liquid.
5. **Do Not** get liquid into the test strip port! If liquid does get into the test strip port, immediately dry the components with a dry cloth or gauze pad. If solution is allowed to collect in any meter opening, severe damage to the system can occur. If you suspect that moisture may have entered the strip, perform glucose control testing.
6. **Do Not** wipe the electrical connectors on the back of the base unit.
7. **Do Not** use any cleaning and disinfecting product other than that which is recommended by the manufacturer, identified in this procedure and provided through normal procurement policies and procedures.

X. **Reporting Results**
   
   A. **Ranges**
   
<table>
<thead>
<tr>
<th>Serum/ Plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reportable Range: 26-550 mg/dL</td>
</tr>
<tr>
<td>Reference Range: 75-100 mg/dL</td>
</tr>
<tr>
<td>Alert Levels: &lt;40 or &gt;400 mg/dL</td>
</tr>
</tbody>
</table>

   B. Outside of these ranges
   
   If the finger stick glucose results come back outside of the reportable range (Less than 40 or greater than 400 mg/dL), the patient MUST be collected and the specimen sent to the laboratory for confirmation testing.

   C. **Release of Results**
   
   After results have been reviewed and found to be acceptable by testing personnel, they should be entered into the appropriate information system/patient chart.
   
   **NOTE:** In addition, records of patient information, QC performed, and maintenance should be documented on the Glucometer Record (attached)

   D. **Linearity** is performed by the laboratory at six-month intervals. Also, correlations with the primary instrument are performed every six months. See the *ACCU-CHEK Inform II Operator’s Manual* for complete instructions on performing linearity testing.

XI. **Procedure Notes**

   A. **Downtime and Instrument Malfunction**
   
   1. If the ACCU-CHEK Inform II system becomes inoperable at any time:
   2. Call the laboratory for assistance in troubleshooting or meter replacement
   3. Call ACCU-CHEK Customer Care at **1-800-440-3638** for assistance any time you have questions or concerns regarding the ACCU-CHEK Inform II system.
   4. It is recommended to try and use another ACCU-CHEK Inform II meter or collect a traditional venous blood specimen and send to the laboratory for testing.

XII. **Limitations**

   The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.

   A. Hematocrit should be between 10–65 %.

WT.01.01.01, WT.02.01.01, WT.03.01.01, WT.04.01.01, WT.05.01.01
B. Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
C. Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
D. Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
E. If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensate heart failure NYHA Class IV, or peripheral arterial occlusive disease.
F. This system has been tested at altitudes up to 10,000 feet.
G. The performance of this system has not been evaluated in the critically ill.
H. In any or all cases listed above, it is recommended to acquire a traditional venous and send to the laboratory for testing.

XIII. Attachments
   A. Accu-Chek Inform II System Skills Checklist
   B. Certification and Proficiency Checklist
   C. ACCU-CHEK Inform II System Test
   D. Certificate of Attendance and Training
   E. Glucometer Record

XIV. References
   C. Roche Diagnostics Accu-Chek Inform II System. Operators Manual © 2012-2013, Roche Diagnostics. All rights reserved.
   D. Roche Diagnostics Procedure Manual Template for Accu-Chek Inform II System. © 2012-2013, Roche Diagnostics. All rights reserved.
   E. Roche Diagnostics Accu-Chek Inform II System In-Service Plan for Blood Glucose Testing. © 2012 Roche Diagnostics. All rights reserved. 4830-00-1112