DESCRIPTION/OVERVIEW

1. PURPOSE
   1.1. The Roche ACCU-CHEK® Inform meter quantitatively measures glucose levels in whole blood.

2. PRINCIPLE
   2.1. The enzyme glucose dehydrogenase converts the glucose in a blood sample to gluconolactone. This reaction liberates two electrons that react with a coenzyme electron acceptor, the oxidized form of the mediator hexacyanoferrate (III), forming the reduced form of the mediator, hexacyanoferrate (II). The test strip employs the electrochemical principle of biamperometry. The meter applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the system and is proportional to the level of glucose in the blood sample.

   2.2. ACCU-CHEK® Comfort Curve test strips have been calibrated to deliver plasma equivalent values.

REFERENCES

5. Roche ACCU-CHEK® Operator’s Manual

AREAS OF RESPONSIBILITY

1. Point of Care Glucose testing can be done on any inpatient or outpatient at University Hospital on receipt of an order from a physician, provider or nursing staff designate.
2. Staff who have satisfied initial and annual competency requirements may perform the testing.

PROCEDURE

1. EQUIPMENT
   1.1. ACCU-CHEK® Inform meter
   1.2. Lancing device
   1.3. Base Unit

2. REAGENTS
   2.1. ACCU-CHEK® Comfort Curve Test Strips
   2.2. ACCU-CHEK® Comfort Curve glucose control solutions
   2.3. ACCU-CHEK® Comfort Curve Linearity Test Kit (Laboratory Use Only)
3. ORDERING INFORMATION
   3.1. ACCU-CHEK® Comfort Curve Test Strips and Comfort Curve glucose Control Solutions are ordered through CDU.
   3.2. Linearity Test Kits are ordered by the Laboratory.

4. STORAGE
   4.1. The ACCU-CHEK Inform system is stored away from direct sunlight and extreme temperatures.
   4.2. Store the meter and strips in the same environment in which they are to be used.
   4.3. ACCU-CHEK® Comfort Curve linearity and control solutions must be stored at room temperature. Do not freeze. Both solutions are stable for three months after opening or until the manufacturer’s expiration date, whichever comes first.
   4.4. ACCU-CHEK® Comfort Curve Test Strips must be stored at room temperature. Do not freeze. Do not use strips after the manufacturer’s expiration date. When a vial of strips has been left opened, discard.
   4.5. If the ACCU-CHEK Inform system is to be stored for an extended period of time, the battery pack is removed to avoid leakage or damage.

5. CALIBRATION
   5.1. The meter is “calibrated” when the instrument is turned on with the Code Key inserted. Place the new Code Key in the meter with every new lot number of test strips and discard the old Code Key.
   5.1.1. For accurate results, the test strip code displayed by the ACCU-CHEK Inform system must match the code of the test strips in use. If not, the meter must be recoded (recalibrated) and the new code information must be entered in the ACCU-CHEK Inform system. Incorrect coding may result in inaccurate results.
   5.2. Calibration verification/linearity/AMR is performed by the Point of Care Testing Department every six months, when a new lot of test strips are put into use or when a glucose meter demonstrates questionable performance.
   5.2.1. For details on performing a linearity test, review the Roche ACCU-CHEK® Linearity Test Kit package insert.

6. MAINTENANCE ON ACCU-CHEK® Inform meter
   6.1. Cleaning
      6.1.1. Remove the meter and unplug the base unit in preparation for cleaning.
      6.1.2. Use a soft cloth slightly dampened (NOT WET) or pre-moistened wipe with one of the following:
      6.1.2.1. Soapy water
      6.1.2.2. 70% isopropyl alcohol solution
      6.1.2.3. ammonium chloride (quaternary ammonium compounds)
      6.1.2.4. bleach
      6.1.3. If using commercially available pre-moistened disinfecting cloths, SQUEEZE OFF EXCESS DISINFECTING SOLUTION or blot on a dry paper towel to remove any excess disinfecting solution.
6.1.4. While carefully avoiding the meter/base connectors and base unit circuitry, gently wipe exposed surfaces of the meter and base unit. (Ensure that no streaks remain on the touch screen.)

6.1.5. Dry the meter with a dry cloth or gauze and visually verify that no solution is seen in the connector at the completion of cleaning. Always thoroughly dry the meter and base unit before putting back into use or plugging in the base unit.

6.1.6. Once completely dry, plug in the base unit and resume use of the system.

6.2. Disinfecting

6.2.1. Remove the meter from the base unit prior to disinfecting.

6.2.2. Acceptable active ingredients for disinfecting solutions include:
   6.2.2.1. 1:10 dilution of sodium hypochlorite
   6.2.2.2. ammonium chloride (up to .25% of each quaternary ammonium compound)
   6.2.2.3. ammonium chloride (up to .25% of each quaternary ammonium compound) with isopropyl alcohol (up to 55%)

6.2.3. Do not use cleaners containing the chemicals polyhexanide, phenol, or ether or prepared solutions or wipes containing a mixture of bleach and detergent on the ACCU-CHEK Inform system. Use of cleaners containing these chemicals could result in damage to the ACCU-CHEK Inform system.

6.2.4. If using commercially available pre-moistened disinfecting cloths, **SQUEEZE OFF EXCESS DISINFECTING SOLUTION** or blot on a dry paper towel to remove any excess disinfecting solution.

6.2.5. Wipe the meter thoroughly, while avoiding the strip port, code key slot, and connector.

6.2.6. Lay the meter on a flat surface while wiping over the strip port area, making sure that no liquid enters the strip port.

6.2.7. Allow the meter to air dry for the recommended contact time according to the disinfecting solution product labeling.

6.2.8. Dry the meter with a dry cloth or gauze and visually verify that no solution is seen in the connector at the completion of disinfecting. **Ensure that the meter (including connectors) is thoroughly dried after disinfecting.**

6.3. Correlation Testing

6.3.4. Performed by the POCT Department twice yearly.

7. QUALITY CONTROL

7.1. Two levels of Quality Control solutions should be run on the meter at the following times:
   7.1.1. Each day of patient testing
   7.1.2. If the ACCU-CHEK Inform meter has been dropped
   7.1.3. After the battery in the ACCU-CHEK Inform system has been replaced
   7.1.4. When a new lot number of test strips is opened
   7.1.5. When test results contradict clinical symptoms or anytime questionable results are obtained.

7.2. 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.

7.3. If QC is out of range, document corrective action and rerun. If it is still out of range discontinue patient testing and contact the Point-of-Care office at 272-0980.
7.4. Quality Control data is reviewed on a monthly basis by the Point-of-Care department and QC records are kept for 2 years in the Point-of-Care office.

8. PATIENT MANAGEMENT
8.1. Patient Identification
   8.1.1. Patient identification may be the patient’s name, date of birth, medical record number, financial number or assigned trauma alert name.
   8.1.2. The University of New Mexico Health Sciences Center (UNMHSC) does not recognize a patient’s social security number or room number as a patient identifier.

8.2. Patient Preparation
   8.2.1. The operator must describe to the patient the purpose and steps of the procedure before testing can begin.

9. SPECIMEN COLLECTION AND HANDLING
9.1. Standard precautions apply to all point of care tests.
9.2. Testing personnel should handle all patient samples as per the Bloodborne Pathogen Exposure Plan.
9.3. Capillary, venous and arterial fresh whole blood may be used.
9.4. Serum and plasma may NOT be used.
9.5. Whole blood anticoagulated with heparin or EDTA may be used.
9.6. Whole blood anticoagulated with fluoride may NOT be used.
9.7. Test the blood sample as close as possible to the time the sample was collected and within 30 minutes of collection to minimize glycolysis.
9.8. The blood glucose concentration will decrease over time because red blood cells continue to consume glucose.
9.9. Fresh whole blood, in the absence of an anticoagulant, should be tested immediately to prevent clotting from affecting the results.
9.10. To collect a venous, capillary, or heel sample refer to the University Hospital Phlebotomy Self-Study Module.
9.11. 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 with the formation of fibrin strands and microclots.

10. SPECIMEN LABELING
10.1. Specimens for glucose testing should be tested at the patient’s bedside immediately after collection and then discarded. Specimen labeling is not required.
10.2. If testing is to be delayed, the venipuncture specimen must be labeled with two unique identifiers.

11. PATIENT TESTING
11.1. Press power ON button on the meter.
11.2. Scan your operator ID. Press the forward arrow button.
11.3. Select Patient Test.
11.4. Scan the patient ID. Press the forward arrow button.
11.5. Scan the test strip barcode.
11.6. Remove a test strip from the vial. Immediately replace the cap on the vial.
   11.6.1. If the vial cap is damaged, has visible plastic strands, or does not close properly, do not use the test strips.

Title: Point of Care Testing: ACCU-CHEK Inform
Owner: Point of Care Testing Coordinator
Effective Date: 8/20/07
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11.7. When the flashing strip icon appears on the touchscreen, gently insert test strip into the test strip slot with the yellow target area or test strip window facing up. (Insert the end with the silver bars.)

11.7.1. **Note:** Insert test strip BEFORE dosing.

11.8. When the flashing drop icon appears on the touchscreen, obtain a blood sample. You may use a capillary, venous, arterial or neonatal (including cord) whole blood sample.

11.9. Gently mix venipuncture specimen before testing.

11.9.1. Touch and hold drop of blood to the curved edge of the yellow target area on the test strip.

11.9.2. The blood is drawn into the test strip automatically.

11.9.3. If you see any yellow color in the target area or test strip window after you have applied the initial drop of blood, a second drop of blood may be applied to the strip within 15 seconds of the first drop. If more than 15 seconds have passed, the test result may be erroneous, and you should discard the test strip and repeat the test.

11.10. An hourglass will appear on the display while waiting for the result.

11.11. Enter comments, if necessary.


11.13. Then press the forward arrow button to return to the Main Menu screen in order to run the next test.

11.14. Remove the test strip from the meter and discard it in a biohazardous waste receptacle.

11.15. Press the power **OFF** button to turn off the ACCU-CHEK Inform system.

11.16. The meter must be turned off prior to docking the meter.

12. RESULT REPORTING

12.1. Patient results should be immediately recorded in the permanent medical record.

12.2. Results that appear to be inconsistent with patient therapy or condition should be viewed as questionable and the test should be repeated by the lab reference method.

12.3. If the ACCU-CHEK Inform system displays anything other than a numerical blood glucose result, refer to the *ACCU-CHEK Inform System Operator’s Manual*.

13. REFERENCE INTERVAL AND CRITICAL VALUES

13.1. All POC testing 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. A comment must be placed in the glucose meter indicating the action taken on the critical result.

13.2.1. Press Enter Notes and choose a comment that corresponds to the patient’s current situation. Press OK.

13.3. The treating physician/provider has discretion to choose if critical values should be repeated by the laboratory reference method.
REFERENCE INTERVAL:
Fasting Blood glucose levels:

<table>
<thead>
<tr>
<th>Age</th>
<th>Interval</th>
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<tbody>
<tr>
<td>0 – 1 Month</td>
<td>55 – 90 mg/dl</td>
</tr>
<tr>
<td>1 Month – 15 years</td>
<td>60 – 115 mg/dl</td>
</tr>
<tr>
<td>≥16 years</td>
<td>60 – 126 mg/dl</td>
</tr>
</tbody>
</table>

CRITICAL RANGE:

<table>
<thead>
<tr>
<th>Age</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 3 months</td>
<td>≤50 mg/dL or ≥250 mg/dL</td>
</tr>
<tr>
<td>≥ 3 months</td>
<td>≤50 mg/dL or ≥500 mg/dL</td>
</tr>
</tbody>
</table>

REPORTABLE RANGE: 10 – 600 mg/dl

14. INTERFERING SUBSTANCES AND LIMITATIONS
14.1. Use test strips before the expiration date printed on the test strip bottle label.
14.2. If the patient is experiencing symptoms not consistent with the blood glucose result obtained on the glucose meter, a confirmation test should be performed using the laboratory reference method.
14.3. Use only fresh whole blood for patient testing.
14.4. Abnormal hematocrits can cause abnormal glucose results.
   14.4.1. At glucose concentrations below 200 mg/dL, low hematocrits (below 20%) may cause elevated results, and high hematocrits (above 65%) may cause reduced results versus a whole blood reference.
   14.4.2. At glucose concentrations above 200 mg/dL, low hematocrits (below 20%) may cause elevated results, and high hematocrits (above 55%) may cause reduced results versus a whole blood reference.
   14.4.3. Patients with hematocrits below or above the above criteria should only be tested using the laboratory reference method.
14.5. If the patient is currently using drug therapies that contain or are metabolized to maltose or galactose, do not use the ACCU-CHEK Inform system to test glucose. Certain therapies can elevate the levels of maltose or galactose in the blood. For example:
   14.5.1. Peritoneal dialysis solutions containing icodextrin (e.g. EXTRANEAL).
   14.5.2. Certain types of intravenous immunoglobulin therapies (e.g. Octagam 5%).
   14.5.3. Intravenous solutions containing maltose as a means for patient hydration.
14.6. This list is not intended to be all-inclusive and may not include recently introduced new drugs; therefore, always consult the drug package insert to determine whether it contains or is metabolized to maltose or galactose.
14.7. Do not use during xylose absorption testing.
14.8. In situations of decreased peripheral blood flow, fingerstick blood testing may not be appropriate, as it may not reflect the true physiological state. Examples would include, but are not limited to:
   14.8.1. Severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar nonketotic state
   14.8.2. Hypotension
14.8.3. Shock
14.8.4. Peripheral vascular disease

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

14.9. Do not use blood collected in tubes containing fluoride. Sodium fluoride interferes with test results.

14.10. Altitudes up to 10,150 feet do not affect results.

14.11. Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dL, depending on the time of blood collection after food intake. In the fasting state, the difference between capillary and venous glucose is minimal.

14.12. Do not use serum or plasma samples.

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

14.14. For best results with venous and arterial blood, the following anticoagulants/preservatives are recommended: Heparin and EDTA. Serum separator tubes are acceptable if whole blood is used immediately. Iodoacetate containing anticoagulants are not recommended.

14.15. The following compounds, when determined to be in excess of their limitation, may produce elevated glucose results:

14.15.1. Galactose > 10 mg/dL can give falsely elevated test results. Glucose values in neonates demonstrating symptoms of galactosemia should be confirmed with a laboratory reference.

14.15.2. Maltose > 16 mg/dL, delivered intravenously, can give falsely elevated test results.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limitation</th>
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<tr>
<td>Bilirubin (unconjugated)</td>
<td>&gt;20 mg/dL</td>
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<tr>
<td>Lipemic Samples</td>
<td>&gt;5000 mg/dL</td>
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<tr>
<td>Acetaminophen</td>
<td>&gt;8 mg/dL</td>
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<td>Uric Acid:</td>
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<tr>
<td>Hypoglycemic range</td>
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<td>Euglycemic range</td>
<td>&gt;12 mg/dL</td>
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<tr>
<td>Hyperglycemic range</td>
<td>&gt;16 mg/dL</td>
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</table>

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**CLIA Classification**

<table>
<thead>
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<th>Use</th>
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<td>If definitive, how will results be used?</td>
<td>Used as a basis for treating the diabetic patient. A glucose screen for the neonate and pediatric population.</td>
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**DEFINITIONS**

None

**SUMMARY OF CHANGES**

Replaces POCT Glucose Testing SureStep Pro & SureStep Flexx
## RESOURCES/TRAINING

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<th>Resource/Dept</th>
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## DOCUMENT APPROVAL & TRACKING

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<th>Approval</th>
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<td>Nursing Director</td>
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<tr>
<td>Medical Director</td>
<td>Matthew Luke, MD; Rapid Response Laboratory</td>
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## ATTACHMENTS

None