A. **Purpose:** To provide stat measurements of blood glucose concentrations for rapid assessment of patients with Diabetes, Hyperglycemia, and Hypoglycemia.

B. **Principle:** The enzyme glucose dehydrogenase converts the glucose in a blood sample to gluconolactone. This reaction liberates two electrons that react with the 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. Accu-Chek Comfort Test Strips have been calibrated to deliver plasma-like values.

C. **Policy:**

1. A physician’s or PA’s order is required for routine BGM.
2. The nurse may initiate BGM if suspected hypoglycemic or hyperglycemic reactions.
3. BGM is to be performed using the Accu-Chek Inform by personnel trained and certified in its use by LifeBridge Health trainers or BGM trainer.
4. Trainers will be identified and trained by POCT Team Leader or Technical Specialist on each unit performing BGM.
5. Certified Trainers will include an in service, satisfactory completion of a written examination and performance of a test using the Accu-Chek Inform.
6. Recertification for operators and trainers will be performed yearly.
7. Agency Nurses will take an in service and test available on line on the LifeBridge Internet or by attend a class by the Educational Resource Center. If test is taken on the Internet she/he will send the completed test to the POCT Department located in the Pathology. A test score of at least an 80% must be accomplished. The POCT Department will then entered her name and RN License number into the RALS so that she will be able to the use the meter. He/she than need to perform one level of control to complete her certification.

8. Glucose Results: Category of Test may be used for Diagnostic (for: 1. Hypoglycemia  2. GTC action ). Partially or completely classify disease.

9. Certified Trainers are responsible for implementation and maintenance of certification records.

10. A record of Certified Operators and Trainers will be maintained on each nursing unit, Staff Development and in the Department Of Pathology.

11. The Bedside Testing Team Leader/ Technical Specialist will supply the Nursing Directors with a report identifying problems concerning Point-of-Care Testing.

12. Documentation of follow-up investigation and corrective actions taken will be returned to Pathology to be maintained by the Team Leader or Technical Specialist for Point-of-Care Testing.

13. The Clinical Director of Pathology has the right to remove instruments when problems are found involving noncompliance with policies and procedures.

14. If a glucose result is obtained that is $\leq 50\text{mg/dL}$ (dangerous hypoglycemia) or $\geq 400\text{mg/dL}$ (dangerous hyperglycemia), the test will be repeated on the meter/or in the Main Laboratory. Physician or PA will be notified immediately. The Physician or PA decides course of action. (Unless on tight glycemic protocol).

15. Results will be recorded in Powerform or in the Patient’s Medical Record.

16. Any date entry or corrections of data entry made by the operators will need to see Nursing Policies and Procedures for electronic entry or corrections when mistakes are made. (Data entry into Powerform was developed by Nursing and does not come under Pathology).

17. Meters will enabled to say "Use alternate method if patient is receiving maltose related therapy. See package insert for limitation. An "alternate method" as either a lab serum glucose or an iSTAT glucose.
The Accucheck Inform Glucose test methodology utilizes GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone). This test method has been found to be subject to interference by non glucose sugars such as maltose, xylose and galactose. When these non-glucose sugars are present in the patient's blood, using a GDH-PQQ glucose test strip will produce a falsely elevated glucose result. This can lead to inappropriate dosing and administration of insulin, potentially resulting in hypoglycemia, coma, or death. In addition, cases of actual hypoglycemia may be masked and go unrecognized.

Products administered in health care settings that may contain non glucose sugars:
- Extraneal (icodextrin) peritoneal dialysis solution.
- Some Immunoglobulins: Octagam 5%, Gamimune N 5%, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous (Human), and HepaGamB
- Orencia (abatacept)
- Adept adhesion reduction solution (4% icodextrin)
- BEXXAR radioimmunotherapy agent
- Any product containing, or metabolized into, maltose, galactose or xylose*.

D. Test Strip Storage and Handling:

Normal precautions are exercised when handling reagents by wearing gloves.

Test strips must be stored at room temperature. Do not freeze.

Test strips are stored in the same tightly capped vial in which they are packaged.

The vial cap is immediately replaced after removal of a test strip.

Test strips are stable until the expiration date on the vial.

Outdated strips are discarded.

Test strips are used at temperatures between 14° and 40°C (57° and 104°F) and <85% humidity.

E. Coding (Calibration) of the Accu-Chek Inform System:

Coding is always verified by matching the code on the Accu-Chek Inform System display screen with the code number printed on the side of the vial of test strips.

The meter is “calibrated” when the instrument is turned on with the Code Key inserted. Place the new Code Key in the meter and discard the old Code Key.
It is recommended that the Code Key be changed with each new vial of test strips.

1. **Procedure for Coding (Calibration) of the Accu-Chek Inform System:**
   
a. Gather the following items for calibration:
   - Accu-Chek Inform System
   - Test strips with appropriate Code Key.
   - Remove the Code Key from the test strip box.
   
b. Compare the three-digit number on the Code Key with the number on the test strip vial.
   
c. Remove old Code Key from Accu-Chek from the Accu-Chek Inform Meter, if necessary
   
d. Snap the new Code Key (slots facing toward the meter) into the Code Key slot with the printed side facing up.
   
e. Leave the Code Key in the meter.

2. **Enter Test Strip Codes:**
   The test strip displayed by the Accu-Chek Inform System must match the code of the test strips in use. If not, the meter must be recoded (re-calibrated) and the new code information must be entered in the Accu-Chek Inform System. Test strip code information must be verified and/or re-entered in the Accu-Chek Inform System by the operator whenever a patient or quality control test is performed.

   a. Procedure for Enter Test Strip Codes:
      To enter the test strip code on the Accu-Chek Inform System (if reagent editing is allowed):
      
      1. Press the power ON button.
      2. Press the power ON button.
      3. Enter (or scan) the operator ID and press the forward arrow button. Select Control Test or Patient Test.
         If Control Test was selected, select a control level and verify the solution lot number.
         If Patient Test was selected, enter (or scan) the patient ID using the patient’s armband, and press the forward arrow button.
      4. Verify the strip code information.
      5. Verify the strip lot in one of the following ways:
         Only view (and visually confirm) the required strip lot number.
         Enter the current strip lot number.
         Verify the current strip lot number by pressing YES or NO.
         Scan the test strip vial barcode.
         If YES is pressed to confirm the lot, the user will be prompted to insert a test strip and begin testing.
If NO is pressed, the Replace Code Key screen is displayed. Proceed to replace the code key as follows:
Replace the existing code key with the code key packaged with the vial of test strips that are to be used.
Press the large button under the touch screen to progress to the next screen.
If the strip lot is defined on the meter, confirm the use of the strip code by pressing YES and continue with testing.
If the strip lot is undefined, and the meter is configured to allow lots to be managed at the meter level, a message will appear asking if the strip lot should be added. Pressing YES will allow the meter to be updated with the new code key information.
If the strip lot has not previously been entered into the meter, a message will appear asking if the strip lot should be added. Press YES and then enter the expiration date. The next screen ask you to verify that the control ranges assigned to this lot are correct. Press ACCEPT to verify the control ranges. Once the control ranges are verified, the Verify Strip Lot screen is again displayed. Press YES to verify the lot number.
Proceed with patient or QC testing.

F. Specimen Collection and Handling:

Capillary, venous, and arterial whole blood specimens may be used for testing on the Accu-Chek Comfort System with Accu-Chek Comfort Curve Test Strips.

The capillary sample must be tested immediately after collection.

Blood glucose determination using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to minimize the effect of glycolysis. Mix sample thoroughly.

For best results with arterial and venous blood, the following anticoagulants/preservatives are recommended: heparin and EDTA.

Serum separator tubes and red-topped tubes are acceptable if blood is used immediately before the clotting process begins.

Iodoacetate or fluoride/oxalate should not be used as a preservative.

Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strip.

Sufficient sample size is required to ensure accurate results.
G. **Patient Preparation:**

The purpose of the test and the steps of the procedure will be explained to the patient prior to performing the test.

Universal precautions must be observed when the operator is handling blood products.

If the patient is able, the patient should wash his/her hands prior to testing with capillary samples taken from the finger.

Fresh capillary whole blood samples for use with the Accu-Chek Inform System are to be taken from the fingertip.

Venous and arterial blood samples may also be used with the Accu-Chek Inform System and Accu-Chek Comfort Test Strips.

F. **Procedure:**

1. The following items should be gathered and taken to the patient’s bedside:
   a. Accu-Chek Inform System.
   b. Accu-Chek Comfort Curve Test Strips
   c. Single use, disposable lancets.
   d. Alcohol swab.
   e. Cotton ball, tissue, or gauze for wiping finger after stick.
   f. Gloves are required for universal blood collection precautions.

2. Explain the purpose of the test and the steps of the testing procedure to reassure the patient.

3. If the patient is able, ask the patient to wash his/her hands with warm water and soap rinse and dry prior to testing capillary samples. If the patient is unable, cleanse the puncture site with an alcohol swab and allow it to thoroughly dry. (Alcohol at the puncture site must be dry or an error code/inaccurate result may occur).

G. **Patient Testing:**

1. The Accu-Chek Inform System is set up to store the following information about each patient test:
   a. Test Result
   b. Operator ID
   c. Patient ID
   d. Test Strip Information
   e. Test Time and Date
f. Comment(s)
g. Meter Serial Number

2. Any patient result that exceeds the critical ranges established notifies the physician/PA who decides course of care unless this is a trend of the patient.
3. The appropriate comment(s) is/are entered in the Accu-Chek Inform System by the operator, if necessary.
4. Only LifeBridge Health certified operators may perform a blood glucose test on the Accu-Chek Inform System.
5. Only single-use disposable lancets are to be used.
6. Blood glucose must be ordered by the physician/PA.
7. Universal precautions must be used when collecting specimens and performing test procedures.
8. Test strips must be stored at room temperature. Do not refrigerate or freeze. Tests strips are stored in the same capped vial in which they were packaged and are stable until the expiration date on the vial.
9. Only the strip that you are going to use immediately is to be taken out of the vial. The vial cap is immediately replaced after removal of the test strip. No strips are to be left outside of vial.
10. Outdated test strips must be discarded.
11. A physician/PA will be notified according to parameters specifically ordered.
12. Capillary, venous, and arterial whole blood specimens may be used with the Accu-Chek Inform System and Accu-Chek Comfort Curve Test Strips.
13. The capillary samples must be tested immediately after collection.
14. Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to minimize the effects of glycolysis.
15. For best results with arterial and venous blood, the following anticoagulates/preservatives are recommended: heparin and EDTA.
16. Serum separator tubes and red-top tubes are acceptable if blood is used immediately before the clot process begins.
17. Iodoacetate or fluoride/oxalate should not be used as a preservative.
18. Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strips.
19. Sufficient sample size is required to ensure accurate results.

H. Procedure:

1. The following equipment should taken to the patient’s bedside prior to testing:
   a. Accu-Chek Inform System
   b. Accu-Chek Comfort Curve Strips
   c. Single-use, disposable lancets
   d. Alcohol Swab
   e. Cotton ball, tissue, or gauze for wiping finger after stick.
   f. Gloves
2. Press power ON button.
3. Enter the operator ID (Clock Number) or scan your Barcode Operator ID Number. Press the forward arrow button.

4. Select Patient Test.

5. Enter the Patient ID:
   a. Sinai Hospital will use (12 digits) or scan Patient’s Armband for Positive Patient ID.
   b. Northwest Hospital will use account number (12 digits) or scan Patient’s Armband for Positive Patient ID.

Never use a label to enter or scanning patient identification. Press forward arrow button.

6. Verify the strip lot in one of the following ways:
   a. Only view (and visually confirm) the required strip lot number.
   b. Enter the current strip lot number.
   c. Verify the current strip lot number by pressing YES or NO.
   d. Scan the test strip barcode.
   e. If the strip lot on the meter does not match the code key, the Replace Code Key screen is displayed. See “entering Test Strip Codes”.
   f. Remove only the test strip from the vial that you are going to use for this patient. Immediately replace the cap on the vial. Do not leave loose strips in carrying case, etc.
   g. When the flashing strip icon appears, on the meter display, gently insert test strip with the yellow target area or test strip window facing up. (Insert the end with the silver bars). **NOTE:** Insert test strip BEFORE dosing.
   h. When the flashing drop icon appears on the meter display, obtain the blood sample. You may use a whole blood capillary, venous, arterial blood sample. (Follow the manufacturer’s instructions if using a lancet device). If using the Accu-Chek Comfort Test Strip:
      Touch and hold drop of blood to the curved edge of the yellow target area. The blood is drawn into the test strip automatically. **IMPORTANT:** 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.
   i. An hourglass will appear on the display while waiting for the result.
   j. Enter up to three programmed comments and one custom comment, if necessary. Then press the forward arrow button to record the test and return to the Main Menu screen in order to run the next test.
   k. Remove the test strip from the meter and discard into biohazard container.
   l. Press the power OFF button to turn the Accu-Chek Inform System off.
   m. Document the blood glucose result in Powerform or in the patient’s medical record.

**Comments:**
One of the following comments may be added to a result:
Scanned wrong level of control
Operator Error
Cleaned Meter
Sent Specimen to Lab
Result confirmed, Caregiver notified
Repeat test
Insulin Drip, (MD not notified)
Replaced bottle of strips
Replaced controls
QNS

I. Trouble shooting:

a. If HI is displayed, the blood glucose result may be higher that the reading range of the meter. Refer to the test strip package insert for more information. If this contradicts the patient’s condition, perform a quality control with the glucose control solution and a new test strip. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip. If HI still appears on the patient test, you will need to draw a specimen and send it to the Main Laboratory. If the control result is not within the acceptable range, call
   1. Sinai: Ann Bengzon (beeper #1546) or Pauline Kamenyi (Vocera, 21000)
   2. Northwest: Joann O’Connor (Extension 55816)
   3. Main Laboratory for assistance

b. If the error message “testing error-133 A glucose overflow error has occurred, type 71” appears on the display, the blood glucose result may be extremely high and above the meter’s reading range. If this contradicts the patient’s condition, perform a quality control check with glucose control solution and a new test strip. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip. If the error still appears on the patient test, draw a blood sample and send to the Main Laboratory for testing. If the control result is not within the acceptable range, call
   1. Sinai: Ann Bengzon (beeper #1546) or Pauline Kamenyi (Vocera, 2100)
   2. Northwest: Joann O’Connor (Extension 55816)
   3. Main Laboratory for assistance

c. If LO is displayed, the blood glucose result may be lower than the reading range of the meter. Refer to the test strip package insert for more information. If this contradicts the patient’s condition, performed a quality check with glucose control solution and a new test strip. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip. If LO still appears on...
the patient test, draw a blood sample and send to the Main Laboratory for testing. If the control result is not within the acceptable range, call
1. Sinai: Ann Bengzon (beeper #1546) or Pauline Kamenyi (Vocera, 21000)
2. Northwest: Joann O’Connor (Extension 55816)
3. Main Laboratory for assistance
If a Strip Defect error message appears on the display, the test strip may be damaged or the test was not performed correctly. The test strip should be inserted into the meter prior to applying blood to the strip. If this display appears before the blood is placed on the strip, remove the test strip and reinsert. If the error display remains, repeat the test with a new strip.

d. If the meter displays “Error 88-Bad Dose”, there is an incorrect amount of blood on the strip. a second drop of blood may be applied to the test 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.

e. Press OK. Refer to “Storage/Maintenance of the Accu-Chek Inform "System” section for proper usage and handling recommendations. After ensuring proper handling, repeat the test. If the message persists call
1. Sinai: Ann Bengzon (beeper #1546) or Pauline Kamenyi (Vocera, 21000)
2. Northwest: Joann O’Connor (Extension 55816)
3. Main Laboratory for assistance

J. Documentation of Blood Glucose Results:

The date, time and operator ID who performed the test must be recorded along with the result on the patient’s medical record.

K. Expected Results:

Adult:
Normal Range: 70-105 mg/dL Critical Range: 50 and below or 400 and above
Children, age 29 days to 18 years: (At Sinai Hospital)
Normal Range: 70-105 mg/dL Critical Range: 50 and below or 300 and above

L. Quality Control Testing:

Quality control records will be retained for a minimum of two years.

Written By: Ann Bengzon Date: 05/21/2013
Effective Date: 05/21/2013
The Accu-Chek Inform System is set up to store the following information about each quality control test:

1. Test Result
2. Operator ID
3. Control Level
4. Control Level
5. Test Strip Information
6. Test Time and Date
7. Comments(s), if appropriate
8. Meter Serial Number

Control tests are performed every 24 hours using two levels of controls.

If the quality control test using two levels of controls falls within the acceptable control range, it is acceptable to proceed with patient testing.

If a quality control result falls outside of the acceptable control range, the problem must be corrected before proceeding with patient testing.

In areas where the Accu-Chek Inform System is not being used daily, quality control is only performed on days that patient testing occurs.

Internal proficiency testing to verify meter accuracy and operator competency will be performed.

Glucose control solutions must be stored at room temperature. Do not freeze.

Glucose control solutions are stable for three months after opening or until the expiration date, whichever comes first.

The date the vial is opened should be written on the vial label.

Any outdated glucose control solution will be discarded.

The test strip lot number and the acceptable glucose control ranges are found on the label of the vial of test strips.

Test strips must be stored at room temperature. Do not refrigerate or freeze. Test strips are stable until the expiration date. Test strips must be stored in the same capped vial in which they were packaged, and the vial cap must be immediately replaced after removed of a test strip.

Test strips are not to be stored outside of the vial or in the carrying case.

A. Quality Control Procedure:

Written By: Ann Bengzon
Date: 05/21/2013
Effective Date: 05/21/2013
1. Equipment needed for quality control testing:
   a. Accu-Chek Inform System
   b. Accu-Chek Comfort Curve Test Strips
   c. Comfort Curve Glucose Control Solutions 2-Levels

2. Gloves
3. Press power ON button.
4. Enter operator ID number (clock number) or scan barcode on badge, the press the forward arrow button.
5. Select Control Test.
6. Select the desired control level: Level 1 and Level 2.
7. Verify the lot number of the control solution in one of the following ways:
   a. Only view (and visually confirm) the required glucose control solution lot number.
   b. Enter the current glucose control solution lot number.
   c. Verify the current glucose control solution lot number by pressing YES or NO. Control lot numbers must be scanned. Yes and No option is not allowed).
   d. Scan the test strip vial code. If the glucose control solution lot number does not match entry in the meter, enter the lot number and expiration date from the control solution bottle. (Verify the strip lot in one of the following ways:
   e. Only view (and visually confirm) the required strip lot number.
   f. Enter the current strip lot number.
   g. Verify the current strip lot number by pressing YES or NO. Control lot numbers must be scanned. Yes and No option is not allowed).
   h. Scan the test strip vial barcode.
      If the strip lot on the meter screen does not match the code key, the Replace Code Key screen is displayed. See “entering Test Strip Codes).
8. Remove the test strip from the vial and replace the vial cap immediately.
9. When the flashing strip icon appears on the meter display, gently insert test strip with the yellow target area or test window facing up. (Insert the end with the silver bars).
   NOTE: Insert test strip BEFORE dosing.
10. Using the Accu-Chek Comfort Curve Test Strip:
    a. Touch and hold drop of glucose control solution to the curved edge of the yellow target area.
    b. The glucose control solution is drawn into the test strip automatically.
11. An hourglass will be displayed on the Accu-Chek Inform Meter while waiting for the result.
12. Enter the appropriate comment(s), if needed. Then press the forward arrow button to record the test and to test the next level of control or to proceed to patient testing.
13. Remove the used strip(s) and gloves and place into biohazard container.
14. Results will be downloaded to a computer in the Pathology Department.

B. Documentation of Quality Control Result:

1. Date, time, operator ID, meter serial number, and quality control results are transmitted to a computer where the results are reviewed by Point-of-Care Testing and reports sent to Directors on a monthly basis.
2. If quality control test results fall within the acceptable range, it is acceptable to proceed with patient testing.
3. If quality control test results fall outside the acceptable range, corrective actions must be taken to correct the problem before testing can proceed.

M. Linearity Testing:

1. The Accu-Chek Inform System stores the following information about each linearity tests:
   a. Test Result
   b. Operator Id
   c. Linearity Level
   d. Linearity Lot Information
   e. Test Time and Date
   f. Strip Information
   g. Comment(s)
   h. Meter Serial Numbers

2. Linearity tests are performed by the Technical Specialist / Point-of-Care Testing Team Leader.
3. Linearity is performed before the blood glucose meter is put into use.
4. The reportable range of each instrument is verified by Dr. Hansen.
5. If a patient test result falls outside of the linear range, it is verified by the laboratory by sending a specimen to the Main Laboratory.
6. The linear reporting range of each Accu-Chek Inform System is 50mg/dL to 400mg/dL and is posted in the Policy and Procedure and on the label attached to the carrying case.
7. Linearity records are retained for two years.
8. The correct Linearity test kit is used:
   Accu-Chek Comfort Curve Linearity Test Kit is used with Accu-Chek Comfort Curve Test Strips.

2. Procedure

   To record a linearity test in the Accu-Chek Inform System:
   a. Press power ON button
   b. Enter (or scan) your operator ID, then press the forward arrow button.
   c. From the Main Menu screen, press the forward arrow button.
   d. Select Admin…
e. Select Linearity Test.

f. Verify the linearity lot displayed on the Accu-Chek Inform System.
   1. Select YES if the linearity lot number in the display is the same as the linearity lot you wish to use. Continue with step 8.
   2. Select NO to enter the linearity lot for the solution you wish to use.

h. Enter the expiration date of the linearity solution.

i. Select the linearity solution number for the first test.

i. Perform linearity test.

j. Select comment(s), if necessary, and press the forward arrow button to return to the Linearity Test screen.

k. Press the forward arrow button to record the test.

l. Select the linearity solution number for the next test or press power OFF to turn the Accu-Chek Inform System off.

N. Proficiency Testing

1. Policy
   The Accu-Chek Inform System stores the following information about each proficiency test:
   a. Test Result
   b. Operator ID
   c. Sample ID
   d. Test Time and Date
   e. Strip Information
   f. Comment(s)
   g. Meter Serial Number

   Proficiency tests are performed by any LifeBridge Health certified operators. Proficiency tests are performed every four months. Sinai and NW are enrolled in an external proficiency program provided by CAP (College of American Pathologist).

2. Procedure
To record a proficiency test in the Accu-Chek Inform System:

a. Press the power ON button.
b. Enter (or scan) your operator ID, the press the forward arrow button.
c. Press the forward arrow button to display the Main Menu 2 screen.
d. Select the Proficiency.
e. Enter (or scan) the sample ID and press the forward arrow button.
f. Verify the strip lot in one of the following ways:
   1. Only view (and visually confirm) the required strip lot number.
   2. Enter the current strip lot number.
   3. Verify the current strip lot number by press YES or NO.
   4. Scan the test strip vial barcode.
   If the strip lot on the meter screen does not match the code key, the
   Replacement Code Key screen is displayed. See “entering Test Strip
   Code”.
g. Perform the proficiency test.
h. Enter comment(s), if necessary.
i. Press the forward arrow button to return to the Main Menu 2 screen to run
   the next sample. Or press the power OFF button to turn the Accu-Chek
   Inform System off.
j. Remove the strip and discard it into biohazard container.

O. Transferring Data from the Accu-Chek Inform System

1. Policy
   Data is transferred from an Accu-Chek Inform System to a computer with
   specialized software immediately upon docking the meter in the base unit.
   Transferring data from the Accu-Chek Inform System is the responsibility of the
   operator.
   Data is transferred before the Accu-Chek Inform System memory is cleared.
   Result information can only be cleared from the Accu-Chek Inform System every
   seven days.
   By placing the Accu-Chek Inform meter into the docking station the information
   is transmitted to a computer in the Main Laboratory.

P. Storage / Maintenance of the Accu-Chek Inform System

Policy

The Accu-Chek Inform System is handled with care. Sudden shocks caused by
dropping or rough treatment may affect performance. If the Accu-Chek Inform
System is dropped, performance is verified by quality control testing.
The Accu-Chek Inform System is stored away from direct sunlight and extreme
temperatures.

Written By: Ann Bengzon                                                        Date: 05/21/2013
Effective Date: 05/21/2013                                                      15
Store the meter and strips in the same environment in which they are to be used. Do not expose the meter to excessive sources of heat for prolonged periods of time while obtaining a blood glucose result. Potential sources of heat can be, but are not limited to:
- Leaving the meter under a bilirubin light or photo therapy, light during testing
- Leaving the meter on a bed warmer during testing
- Leaving the meter in an isolette during testing
In a situation where the patient is in a bed warmer or isolette, after performing a needle stick, insert the meter into a bed warmer or isolette, no longer than 10 seconds to obtain the sample, then immediately return the meter to ambient temperature. If the meter is in a bed warmer or isolette longer than 10 seconds, allow the meter to return to ambient temperature and repeat the test.

A list of all Accu-Chek Inform System serial numbers, assigned inventory numbers, and locations is maintained in the POCT section in the Department of Pathology. Accu-Chek Inform Meter serial numbers are updated if Accu-Chek Inform Meters are replaced and records are maintained in the POCT section in the Department of Pathology.

Cleaning and maintenance of the Accu-Chek Inform System is performed whenever the meter is soiled with blood. Personal protection equipment by wearing gloves is required whenever performing tests or preventive maintenance and cleaning of the Accu-Chek Inform System and blood glucose testing equipment. Used personal protection equipment should be discarded into biohazard container.

If personnel are unable to correct a problem with the Accu-Chek Inform System, it is removed from service and the Point-of-Care Coordinator/Special Technologist is called where she will investigate the problem. If the problem can not be corrected a replacement will be given to the unit and the damaged instrument will be sent back to company for replacement. The Accu-Chek Inform System must be cleaned and disinfected before it is sent out for replacement.

Only the battery pack available from Roche Diagnostic will be used in the Accu-Chek Inform system. Using any other type of battery pack may damage their system. If the Accu-Chek Inform System is to be stored for a long period of time, the battery is removed to avoid leakage or damage.

1. **Procedure**

   Use the following procedure to clean the Accu-Chek Inform Meter
   a. **DO NOT** clean the meter while performing a patient or control test.
   b. Wipe the surface with Sani Cloth; squeeze off excess cleaning solution or blot on a dry paper towel to remove any excess cleaning solution before cleaning the surface of the meter and base.

   If cleaning fluid is allowed to collect in the meter connector, severe damage can occur to the meter.

2. **Documentation and Replacement**

   Any maintenance or repair to an Accu-Chek Inform Meter is documented by the Team Leader / Technical Specialist of Point-of-Care Testing in Pathology.
All blood glucose monitoring equipment is available from the Point-of-Care Testing section in the Department of Pathology. A replacement will be issued to the unit if a meter continues to malfunction after proper troubleshooting procedures. If nursing personnel are unable to correct a problem with the Accu-Chek Inform Meter, the meter must be removed from service and the Point-of-Care Coordinator/Technical Specialist will attempt to correct the problem or send it back for replacement. All records for maintenance/replacements will be kept by the Point-of-Care Testing Team Leader/Technical Specialist in the Department of Pathology.

Q. Limitations of the Method

Test strips give dependable test results if the following limitations are understood:

a. Use only Accu-Chek Comfort Curve Test Strips for testing capillary, venous, and arterial whole blood samples.

b. Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to minimize the effects of glycolysis. Avoid air bubbles if dosing with pipettes. Air bubbles may cause erroneous results.

c. For best results with arterial and venous blood, the following anticoagulants/preservatives are recommended: heparin and EDTA.

d. Serum separator tubes and red-topped tubes are acceptable if blood is used immediately before the clotting process begins.

e. Iodoacetate or fluoride/oxalate should not be used as a preservative.

f. Caution should be taken to clear arterial lines before blood is drawn and dosed on the test strip.

g. Do not use during xylose absorption testing.

h. No effect was found at 20% to 65% hematocrits and glucose concentrations up to 200 mg/dL.

i. System measurement range is 10-600 mg/dL.

j. The Accu-Chek Inform System has been tested at altitudes ranging from sea level to 10,150 feet.

k. Infusion therapy solutions that contain maltrose concentrations .16 mg/dL (0.467 mmol/L) (such as some human immunoglobulin solutions and peritoneal dialysis solutions containing icodextrin cause overestimation of glucose results.

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galactose</td>
<td>&gt;10 mg/dL</td>
</tr>
<tr>
<td>Maltose</td>
<td>&gt;16 mg/dL</td>
</tr>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>&gt;20 mg/dL</td>
</tr>
<tr>
<td>Lipemic Samples</td>
<td>&gt;5000 mg/dL</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>&gt;8 mg/dL</td>
</tr>
<tr>
<td>Uric Acid</td>
<td></td>
</tr>
</tbody>
</table>

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Hypoglycemic range   >10 mg/dL.
Euglycemic range   >12 mg/dL.
Hyperglycemic range   >16 mg/dL.

k. 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: severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar nonketotic state, hypotension, shock, or peripheral vascular disease.

l. Refer to the test strip package insert for update information.

R. Safety and Infection Control Guidelines

Policy:
1. Hand hygiene must be performed before and after each procedure. (See procedure Hand hygiene and Skin Protection, found in procedure under Infection Prevention and Control Manual)
2. Gloves must be worn when performing test.
3. Meters are to be cleaned with a wipe after each patient test approved by manufacturer. At NW; use PDI Sanicloth and Bleach wipes. Follow instructions for wet and dry times of the wipes (found on product label on container) At Sinai use Sani wipes. Follow instructions for wet and dry times of the wipes (found on product label on container).
4. Refer to POC Safety and Infection Control Plan for NW and SH.
5. Because of the hazardous nature of handling blood products, follow universal blood collection precautions when collecting specimens, performing test procedures, and cleaning blood glucose monitoring equipment.
6. Personal protection equipment should be discarded into biohazard containers.
7. The Accu-Chek Inform meter will be disinfected if contaminated with blood.
8. Only single-use lancets are to be used.

S. Operator Certification / Recertification

Each operator will be trained by a LifeBridge Health certified trainer and follow the policies and procedures of LifeBridge Health.
Certified operator list will be maintained in computer in ERC.
Each operator will be trained when hired and go through re-training yearly.

References