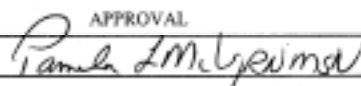
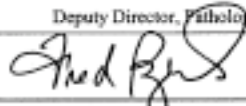


**MEDICAL CENTER OF LOUISIANA AT NEW ORLEANS
DIVISION OF NURSING
STANDARD OF CLINICAL NURSING PRACTICE MANUAL**

UNIVERSAL STANDARD/PROCEDURE	GLUCOSE TESTING WITH THE ROCHE ACCU-CHEK INFORM GLUCOMETER SYSTEM
EFFECTIVE: 10/27/2003 REVISION DATE: 10/27/2003, 10/26/04, 10/28/05, 5/23/06, 6/12/07 REVIEW DATE: 10/27/2003, 5/23/06, 6/12/07 06/25/08	Fred Braza, M.D. Deputy Director, Pathology
APPROVAL 	APPROVAL 
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I. STANDARDS AND SCOPE OF GLUCOSE TEST BY THE ROCHE ACCU-CHEK INFORM SYSTEM

Unit based Glucose testing will be performed to ensure prompt quality care through monitoring of the Glucose level. A Glucose result from this glucometer is not to be used for diagnosis.

II. STANDARD OF PROFESSIONAL PRACTICE

The Point of Care Coordinator (POCC) and/or designated personnel from the Pathology Department are responsible for routine QC and lab proficiency testing. They have the authority to recommend to the Departmental Director the removal of any instrument from an area that does not meet with specific standards of proficiency.

Any competent Medical Laboratory Technologist, Laboratory Technician, RN (Registered Nurse), LPN (Licensed Practical Nurse), NP (Nurse Practitioner) may perform a glucose test to determine a blood glucose level using patient capillary blood. A competent operator is defined as any Medical Laboratory Technologist, Laboratory Technician, RN, LPN, NP whose performance has been verified in the use of the Roche Inform System (ie, through orientation, in-service programs and/or annual competency verification), which includes a satisfactory repeat demonstration of the glucose test procedure by the operator. Competency checks are to be performed once the first year and annually thereafter. Documentation of competency will be filed in the users' personnel folder/POCT binder on the unit. Any operator who does not complete competency on a yearly basis will be locked out from using the Roche Inform System. It is recommended that the competency check be performed at the time of the employees annual PPE. New employees must complete orientation and the skills checklist before being verified as users. Their operator ID and the date of their competency testing must be submitted to the POCC before they are authorized to use the instrument.

Any operator who demonstrates difficulty in performing Glucose testing must complete an additional in service in order to be verified as competent operator.

III. PRINCIPLE OF OPERATION

The enzyme glucose dehydrogenase converts the glucose in the blood sample to gluconolactone. This reaction liberates an electron that reacts with a coenzyme electron acceptor, the oxidized form of the mediator hexacyanoferrate (III), forming the reduced form of the mediator, hexacyanoferrate (II). The Accu-Chek Comfort Curve test strips employ the electrochemical principle of biamperometry. The monitor applies

a voltage between two identical electrodes, which causes the reduced mediator (II) formed during the incubation period to be reconverted to an oxidized mediator (III). This generates a small current that is read by the monitor.

The Accu-Chek Inform Comfort Curve test strips have been calibrated to deliver serum/plasma equivalent values (not whole blood glucose values).

NOTE: Therefore, the glucose values from the Accu-Chek Inform System should be comparable to the main Chemistry analyzer.

IV. REAGENTS AND CONTROLS

- Accu-Chek Comfort Curve Test Strips (50 tests/vial)
- Accu-Chek Comfort Curve Glucose Control Solutions (1 abnormal and 1 normal)

V. CODING (CALIBRATION) OF THE ACCU-CHEK INFORM SYSTEM

A. Policy

1. Coding is always verified by matching the code on the meter display screen with the code number printed on the side of the vial of test strips.
2. 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.
3. It is recommended that the Code Key be changed with each new vial of strips.

B. Procedure

1. Gather the following items for calibration:
 - Accu-Chek Inform System
 - Test strips with appropriate Code Key
2. Remove the Code Key from the test strip box.
3. Compare the 3-digit number on the Code Key with the number on the test strip vial.
4. Snap the new Code Key (slot on the back of the meter) into the Code Key slot with the printed side facing up.
5. When a new box of test strips is opened, discard the Code Key and insert the new Code Key into instrument.

VI. ENTERING TEST STRIP CODES

A. Policy

1. The test strip code displayed by the Accu-Chek Inform System must match the code of the test strips in use. If not, the monitor must be recoded (recalibrated) and the new code information must be entered in the system. Refer to Section V.
2. 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.

B. Procedure

1. Press the power ON button.
2. Enter (or scan) the operator ID and press the forward arrow button.
3. 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, and press the forward arrow button.
4. Verify the strip code information.
 - Select “YES” if the code is correct. If selected, the user will be prompted to insert a test strip and begin testing.
 - Select “NO” if the code is incorrect. If selected, the user will be prompted to replace the Code Key. Replace with new Code Key and proceed with testing.
5. Proceed with patient or QC testing.

VII. REAGENT AND CONTROL GUIDELINES

- A. Normal precautions are exercised when handling laboratory reagents. Follow the Infection Control guidelines of MCLNO.

- B. Test strips must be stored at room temperature. Do not refrigerate or freeze.
- C. Test strips are stored in the same tightly capped vial in which they are packaged. The vial cap must be immediately replaced after the removal of a test strip.
- D. Test strips are stable until the expiration date on the vial.
- E. Outdated strips are to be discarded.
- F. Test strips are used at temperatures between 14 and 40 degrees Centigrade (57-104 degrees Fahrenheit) and less than 85% humidity.
- G. Glucose control solutions must be stored at room temperature. Do not refrigerate or freeze.
- H. Glucose control solutions are stable for 3 months after opening or until the expiration date, whichever comes first. The date the vial is opened and the expiration date should be written on the vial label.
- I. Any outdated glucose control solutions should be discarded.
- J. The test strip lot number and the acceptable glucose control ranges are found on the label of each vial of test strips.
- K. All glucose QC must be run at the time set up for lockout. If the QC is run before the lockout time, you will have to run QC again at the lockout time. QC results will be displayed as **PASS** or **FAIL**
- L. All QC must be run once every 24 hours.
- M. All Reagents and QC will be obtained from the Pathology Department, 4th Floor Lab at University Hospital. If you have any questions, call 903-3897.
- N. Supplies will be given out from 0630 to 1530 M-F. They will not be given out on weekends or holidays. Supplies will be given out at the beginning of each month based on the usage of that unit. If you run out of supplies, they may be obtained from the lab.

VIII. QUALITY CONTROL TESTING PROCEDURE

- A. Put on disposable gloves.
- B. Press Power ON button.
- C. Enter your operator ID, then press the forward arrow button.
- D. Select Control Test.
- E. Select desired control level: Level 1, Level 2.
- F. Verify the lot number of control solution displayed:
 - Select YES if correct.
 - Select NO if incorrect. Enter lot number and expiration date from control solution bottle.
- G. Verify that the strip code number on the test strip vial matches the code number on the Accu-Chek Inform System:
 - Select YES if the code numbers match
 - Select NO to enter a new code
- H. Remove a test strip from the vial and replace the vial cap immediately.
- I. 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.
- J. Using the Accu-Chek Comfort Curve Test Strip:
 - Touch and hold drop of glucose control solution to the edge of the comfort curve.
 - The glucose control solution is drawn into the test strip automatically.
- K. An hourglass will flash in the display. In 26 seconds the glucose control result will appear.
- L. Enter comment code, if needed. Then press the forward arrow to record the test and to test the next level of control (if required) or to proceed to patient testing.
- M. Remove the used test strip and disposable latex gloves and discard them according to infection control policy.
- N. If the control results are not within the acceptable range, repeat the QC. If the QC fails again, repeat with new control. If QC fails for a third time, repeat with new bottle of strips. Contact Hotline or POCC if problem persists.
- O. Proceed to patient testing if QC test results fall within the acceptable control range.

IX. SPECIMEN COLLECTION AND HANDLING

- A. Capillary, venous, neonatal (including cord blood) and arterial whole blood specimens may be used for testing.
- B. The capillary sample must be tested immediately after collection.
- C. Blood glucose determinations using venous and arterial blood specimens should be performed within 30

- minutes of specimen collection to avoid glycolysis. Mix samples thoroughly.
- D. For best results with arterial and venous blood, use the following anticoagulant: lithium heparin (green top tube) or EDTA (purple top tube).
 - E. Caution should be taken to clear arterial lines before blood is drawn and dosed on the strip.
 - F. Sufficient sample size (4 ul) is required to ensure valid results.

X. PATIENT PREPARATION

- A. The purpose of the test and the steps of the procedure will be explained to the patient prior to performing the test.
- B. The operator's hands must be washed before and after testing.
- C. Universal precautions must be observed.
- D. If the patient is able, the patient should wash his/her hands prior to testing when capillary samples from the fingertip are to be taken.
- E. Fresh capillary whole blood samples are to be taken from the fingertip or heel (neonates).
- F. Venous, neonatal and arterial blood samples may also be used.
- G. For isolation patients, the Accu-Chek Inform should be enclosed in a powder-free glove or zip-lock bag with just the strip exposed. This prevents the decontamination of the meter each time it is used.

XI. EQUIPMENT AND SUPPLIES

- Accu-Chek Inform System
- Accu-Chek Comfort Curve Test Strips
- Single use disposable lancets
- Alcohol swab
- Cotton ball, tissue or gauze for wiping finger after stick
- Disposable latex gloves

XII. PATIENT TESTING

A. Policy

NOTE: The physician's order is to be checked prior to the performance of the whole blood glucose test. The nurse may use discretion in obtaining a sample in emergency situations if signs and symptoms of a diabetic coma or insulin shock are present and documented.

1. Under normal conditions, the concentration of Glucose in the blood is usually between 65 mg/dl and 100 mg/dl before eating in the morning. After a meal it usually rises to between 110 mg/dl and 145 mg/dl. If concentrations are higher, please chart and treat accordingly.
2. **NO PATIENT TESTING SHOULD BE PERFORMED UNLESS THE QUALITY CONTROL RESULTS ARE WITHIN RANGE.**
3. Refer problems to charge nurse or manager. The charge nurse or manager will attempt to correct any problems. If problem continues, contact the POCC (903-3897) during routine hours (M-F 0630-1500). After hours and on weekends, contact the Roche Hotline for assistance.(1-800-440-3638)
4. If an instrument needs to be replaced, contact the POCC and instructions will be given on obtaining a new instrument. If it is after hours or on the weekend and the instrument needs to be replaced, you may obtain the spare instrument from the 4th Floor Lab at University Hospital. Have the charge nurse notify the POCC on the next working day so that replacement instruments may be obtained. **DO NOT CONTACT BIOMED**, they will be unable to assist you.

B. Procedure for Glucose Testing

1. Appropriate universal precautions during testing procedure (i.e., gloves, handwashing, etc.) must be strictly adhered to.
2. The equipment should be at the patient's bedside prior to testing. Refer to the Equipment and Supplies section.
3. Press power ON button.
4. Enter your operator ID. Press the forward arrow button.
5. Select Patient Test.
6. Enter the patient ID. Press the forward arrow button.
7. Verify that the code number on the test strip vial corresponds to the code number on the Accu-Chek Inform System.
 - Select YES if the code numbers correspond.

- Select NO if the code numbers do not correspond. (contact POCC or the Roche hotline for assistance).
- 8. Remove a test strip from the vial. Immediately replace the cap on the vial.
- 9. When the flashing strip 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.
- 10. When the flashing drop icon appears on the meter, obtain a capillary blood sample:
 - a. It is recommended that the middle or ring finger be used. Avoid using fingers which have rings so that the blood can circulate freely in the sampling finger. The finger should be straight but not tense.
 - b. Clean site with disinfectant; dry with gauze or tissue.
 - c. Using thumb in a gentle rocking movement, lightly press patient's finger from the top knuckle to the tip in order to stimulate the flow of blood to the sampling point.
 - d. Using gentle pressure, hold the patient's finger at the top knuckle with thumb. Utilizing a lancet, perform puncture at the side of the fingertip.
 - e. Using a dry gauze or tissue, wipe away the first two or three good size drops of blood in order to stimulate spontaneous blood flow. If necessary, apply light pressure again, until another drop of blood appears. Avoid "milking".
 To obtain a Venous or Arterial Sample (from a Syringe).
 - a. Obtain a specimen according to established procedure. A fresh specimen of blood should be used.
 - b. Pull back the plunger slightly.
 - c. Mix the blood thoroughly by inverting the syringe several times.
 - d. Follow the procedure in steps 1-9 and steps 11-16.
- 11. Using the Accu-Chek Comfort Curve test strip:
 - Touch and hold drop of blood to edge of the comfort strip.
 - The blood is drawn into the test strip automatically.
- 12. A small hourglass will flash on the display. In 26 seconds the blood glucose value will appear. Verify results on both displays.
- 13. Enter up to 3 comment codes, if necessary. Then press the forward arrow button to record return to the Main Menu screen in order to run the next test.
- 14. Remove the test strip from the monitor and discard it according to the infection control policy. Record the patient result into the patient's chart. If a critical value is obtained, follow the proper procedure for repeating critical values. Contact the physician and record into the patient's chart: the name of the physician contacted, the time, your name and the result.
- 15. Press the power OFF button to turn the Accu-Chek Inform System off. Return to base for charging.

NOTE: PLEASE TURN OFF THE INFORM BEFORE RETURNING IT TO THE BASE TO PREVENT IT FROM POSSIBLY FREEZING UP.

XIII. GUIDELINES

1. **When you obtain the following Glucose results on the Roche Inform instrument, you must repeat the test within 15 minutes:**

For an adult or neonate (greater than 15 days): less than or equal to 40 mg/dl or greater than or equal to 500 mg/dl.

For a neonate (0-15 days): less than or equal to 30 mg/dl or greater than or equal 300 mg/dl.

The Shift Supervisor or Charge Nurse should be notified. The physician should be notified to determine a course of action. The Pathology Department is available to assist in patient management by performing a confirmatory specimen in the laboratory at the request of the attending physician.

2. If **HI** is displayed, the blood glucose result may be higher than 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 check. 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, follow hospital policy.
3. 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 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 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, follow your facility's policy. If the control result is not within the acceptable range, refer to the *Accu-Chek Inform System Operator's Manual* before proceeding with patient testing.
4. 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, perform a quality control check. 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, follow hospital policy. If the control result is not within acceptable range, refer to Step 3.
5. 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 test strip. If this display appears before blood is placed on the strip, remove the test strip and reinsert. If the error display remains, repeat the test with a new strip.
6. 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.
7. If the temperature warning message appears on the display, the temperature is above or below the operating range of the test strips. Move to a testing area that is between 57 and 104 degrees F. (14 and 40 degrees C) and wait 5 minutes before repeating the test. Do not artificially heat or cool the meter.

XIV. MAINTENANCE

A. Policy

1. The Accu-Chek Inform System should be handled with care. Sudden shocks caused by dropping or rough treatment may affect performance. If the system is dropped, performance is verified by quality control testing.
2. The Accu-Chek Inform System should be stored away from direct sunlight, extreme temperatures, and humidity.
3. Cleaning and maintenance of the Accu-Chek Inform System should be performed on a weekly basis. Disposable latex gloves should be worn when performing preventive maintenance and cleaning on the Accu-Chek Inform System and blood glucose equipment. Cleaning and maintenance of the Accu-Chek Inform System can be performed by a qualified operator.
4. If personnel are unable to correct a problem with the Accu-Chek Inform System, it is removed from service and sent to W1127 for repair/replacement. The Accu-Chek Inform System must be cleaned and disinfected before it is sent out for repair or replacement.
5. Use only the battery pack available from Roche Diagnostics in the Accu-Chek Inform System. Using any other type of battery pack may damage the 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. When storing or disposing of batteries, keep or replace in manufacturer's packing material. Dispose of used batteries according to your institution's battery disposal policy. Incorrect storage or disposal of batteries could result in a hazardous condition.

B. Procedure

Cleaning the outside of the Accu-Chek Inform System:

- a. Gloves should be worn when performing preventive maintenance.
- b. Be sure the Accu-Chek Inform System is turned off.
- c. Clean the outside of the Accu-Chek Inform System, including the communication window, with a soft cloth slightly dampened with a fresh solution of 1:10 bleach in water or 70% isopropyl alcohol. Never spray directly on the instrument.

XV. DOCUMENTATION

- A. Record any maintenance performed on Accu-Chek Inform System in the instrument maintenance screen.
- B. Report any discrepancies/problems with the unit as well as with the quality control to the POCC.
- C. Record results on appropriate patient care flow sheet.

XVI. REFERENCES

Policies and Procedures for use with the Accu-Chek Inform System

XVII. DISTRIBUTION

Division of Nursing Standards of Clinical Nurse Practice Manual, all patient care areas, Pathology and Anesthesia.

XVIII. Standard Basis

Quality Improvement _____
Ethical Issues _____
Legal Issues _____
Current Nursing Practice _____
Nursing Research _____