Hopi Health Care Center
Polacca, AZ
Waived Testing Policy and Procedure

Title: Roche ACCU-CHEK Inform II Glucose Meter			
Responsible Person: Kendrick Fritz, Supervisory Medical Technologist			
Standards/Regulations: WT.01.01.01			
Distribution: ED/UC, OPD, IPU, OB, PHN, Dental, Med Staff			
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HHCC Website: Chapter: Departmental Policies and Procedures Folder: Laboratory Policy & Procedure			

I. POLICY

Hopi Health Care Center (HHCC) certified operators will use the Accu-Chek Inform II Meter to perform point-of-care tests to monitor whole blood from patients with diabetes mellitus within the limitations as described by the manufacturer's most current literature.

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 a NIST (National Institute of Standards and Technology) standard.

III. PURPOSE

- To describe the general steps to take to perform quality control, maintenance, and patient testing.
- To describes the steps to take to transfer patient test results to the Electronic Health Record for proper documentation.

IV. TEST STRIP STORAGE AND HANDLING

- Use the test strips at temperatures between 61-95 °F (16-35 °C).
- Use the test strips between 10-80 % relative humidity. Humidity is the amount of dampness in the air.
- Store the test strips at temperatures between 36–86 °F (2–30 °C). Do not freeze.
- Store unused test strips in the original container with the cap closed. Do not remove test strips from the test strip container and put them into another container such as a plastic bag or pocket, etc.
- Close the container tightly immediately after removing a test strip to protect the test strips from humidity.
- Use the test strip immediately after removing it from the container.
- Discard the test strips that are past the expiration date printed on the test strip container. If the expiration date is missing or illegible, do not use the test strips.
- Do not apply blood or control solution to the test strip before inserting it into the meter. If a result appears before applying blood or control solution, do not act on that result.
- Use the Accu-Chek Inform II Meter in temperatures that range from 61-95°F (16-35 °C). Store the instrument at temperature that ranges between 41-104°F (5-40 °C).

V. ACCU-CHEK INFORM II SYSTEM

The Inform System consists of an Accu-Chek Inform II Meter, an Inform II Base Unit, and the Cobas IT 1000 Data Management System.

A. Accu-Chek Inform II Meter

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

B. Cleaning and maintenance of the Accu-Chek Inform II Meter System

Dos:

- If you notice any signs of deterioration after cleaning and disinfecting a meter system, contact the laboratory for assistance.
- Disposable latex or latex free gloves are worn when performing preventive maintenance and cleaning on the Accu-Chek Inform II Meter and blood glucose testing equipment. Used disposable latex gloves should be discarded in the biohazard waste according the infection control policy.

- Use only the battery pack available from Roche Diagnostics in the Accu-Chek Inform Meter. Using any other type of battery pack may damage the system.
- If the Accu-Chek Inform II Meter 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 appropriately. Incorrect storage or disposal of batteries could result in a hazardous condition.

Dont's:

- **Do Not** clean or disinfect the meter while performing any type of test.
- **Do Not** allow pooling of liquid on the touchscreen.
- **Do Not** spray anything onto the meter or base unit.
- **Do Not** immerse the meter or base unit in liquid.
- **Do Not** get liquid into the 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 quality control testing.
- **Do Not** wipe the electrical connectors on the back of the base unit.
- **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.

1. Accu-Chek Inform II Meter cleaning and disinfection is performed **between testing of each patient** by the certified operator as follows:

   a. Place the meter on a level surface prior to disinfecting.

   b. Power off the meter.

   c. Approved wipes to use for cleaning and disinfection are Super Sani-Cloth® Germicidal Disposable Wipes or Clorox® Germicidal Wipes.

   d. Remove an approved wipe from its packaging. Squeeze the wipe out and blot on a dry paper towel to remove any excess solution from it before disinfecting the surfaces of the meter.

   e. Use an approved wipe to disinfect by gently wiping the surfaces of the meter three times vertically and three times horizontally. Use additional wipes as needed.

      Note: Carefully wipe around the meter test strip port area, making sure that no liquid enters the test strip port.

f. Allow the surfaces of the meter to remain damp with for two full minute when using Super Sani Cloths.

g. Dry the meter surfaces thoroughly with a soft cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the meter at the completion of cleaning.

2. Accu-Chek Inform II Base Unit cleaning and disinfection is performed **whenever there is evidance of visable contramination** by the certified operator as follows:

a. Place the base unit on a level surface prior to disinfecting.

b. Unplug the base unit.

c. Approved wipes to use for cleaning and disinfection are Super Sani-Cloth® Germicidal Disposable
Wipes or Clorox® Germicidal Wipes.

d. Remove an approved wipe from its packaging. Squeeze the wipe out and blot on a dry paper towel to remove any excess solution from it.

e. Use an approved wipe to disinfect by gently wiping the surfaces of the base unit. Use additional wipes as needed.

Note: Do not wipe the electrical connectors on the back of the base unit.

f. Allow the surfaces of the meter to remain damp for two full minute when using Super Sani Cloths.

g. Dry the base unit surfaces thoroughly with a soft cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the base unit at the completion of cleaning.

C. Transferring Data from the Accu-Chek Inform II Meter

When properly docked, the meter will automatically transfer test results. The following series of screen displays will appear to confirm that data transfer is occurring:

- "Connecting," (meter is establishing connection)
- "Transferring," (meter is transferring information)
- "Idle" (meter has finished communications and is ready to use)

The meter can be removed and used at any time during the transfer of information. Any information not completed will be transferred the next time the meter is docked.

When properly docked, the meter will communicate every 10 minutes even if the meter is off. This connection gives the meter the most up to date settings.

The meter must be docked every 72 hours.

Transferring data from an Accu-Chek Inform II Meter is the responsibility of each certified operator.

Result information can only be cleared from the Accu-Chek Inform II Meter after results have been transferred.

D. Documentation and Replacement

Any maintenance or repair to an Accu-Chek Inform meter is entered into the Inform II meter and documentation is transferred upon docking to the Cobas IT 1000 Data Management System.

Each certified operator is responsible for the performance and documentation of maintenance or notification of the Hopi Health Care Center laboratory.

If certified operator's are unable to correct a problem with the Accu-Chek Inform meter, call the Hopi Health Care Center Laboratory at 928-737-6220. If the problem is unable to be corrected at that time, then the meter will be removed from service. Call and inform the lab of the need for a replacement. The lab will be in charge of changing the location of the replacement meter in the the Cobas IT 1000 Data Management System. The Accu-Chek Inform meter must be cleaned and disinfected before it is sent out for repair or replacement.

The Hopi Health Care Center Laboratory oversees record keeping for compliance with acceditation standards and laws.

VI. CALIBRATION

The meter is "calibrated" when the instrument is turned on with the Code Key inserted.

The operator must verify test strip code information in the Accu-Chek Inform II System whenever a patient or quality control test is performed. Coding is always verified by matching the code on the Accu-Chek Inform II display screen with the

code number printed on the side of the vial of test strips. The test strip code displayed by the Accu-Chek Inform II System must match the code of the test strips in use. If not, the instrument will not work and the meter must be recoded (recalibrated) and the new code information must be entered in the Accu-Chek Inform II System.

If a new test strip vial is opened and the meter does not recognize the lot, contact the laboratory so that the new lot can be entered into the system.

It is recommended that the Code Key be changed with each new vial of test strips. Place the new Code Key in the meter and discard the old Code Key.

Code Key Procedure:

1. Remove the Code Key from the test strip box.
2. Verify the three-digit number on the Code Key matches the number on the test strip vial.
3. Remove old Code Key from Accu-Chek Inform meter.
4. Snap the new Code Key (slots facing towards the meter) into the Code Key slot with the printed side facing up.
5. Leave the Code Key in the meter.

VII. QUALITY CONTROL

A. Accu-Chek Inform II Control Solutions - 2-levels

Glucose control solutions must be stored at room temperature (<92°F or <32°C). 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 along with the new expiration date. Any outdated glucose control solutions will be discarded. Control solutions should be clear. Do not use if cloudy or shows other evidence of contamination.

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

Control tests are performed at the following times:

- Each time a new vial of test strips is opened.
- When a vial of strips has been left opened.
- If the Accu-Chek Inform System has been dropped.
- Each day of use or every 24 hours.
- When the test strips have been exposed to extreme heat, humidity, or cold.
- When test results contradict clinical symptoms.

- After the battery in the Accu-Chek Inform II System has been replaced or after the Accu-Chek Inform II System has been recoded.
- When the Accu-Chek Inform II System has been reset.

B. Quality Control Procedure

1. Press power ON button.

2. Enter (or scan) your operator ID, then press the forward arrow button.

3. Select Control Test.

4. Select (or scan) the desired control level: Level 1 or Level 2.

5. Verify (or scan) the lot number of control solution displayed on the Accu-Chek Inform II System,
   - Select (√) if the lot number is correct.

6. Verify (or scan) that the strip code number on the test strip vial matches the code number on the Accu-Chek Inform II System, which has been preprogramed.
   - Select (√) if the code numbers match, or
   - Select (X) and change the code key.

7. Remove a test strip from the vial and replace the vial cap immediately.

8. 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.

9. Using the Accu-Chek Inform II test strip, touch and hold drop of glucose control solution to the edge of the yellow target area.
   - The glucose control solution is drawn into the test strip automatically.
   - Do not allow the tip of the control solution bottle to touch the test strip.

10. An hourglass will be displayed on the Accu-Chek Inform II meter while waiting for the result.

11. Review the result and enter the appropriate comment(s). Then press the forward arrow button to record the test and to test the next level of control (if other levels are required) or to proceed to patient testing.

12. Remove the used test strip(s) and disposable latex or latex free gloves and discard them in the biohazard trash.

13. Document the result(s): The date, time, initials or ID of the operator, meter serial number, and quality control result are transferred into the computer database by docking the Inform meter.

14. Clean the meter according to the "Cleaning and maintenance of the Accu-Chek Inform Meter" section above.

15. If a quality control test result falls within the acceptable control range, meter will display "PASS", it is acceptable to proceed with patient testing.

16. If a quality control test result falls outside of the acceptable control range, meter will display "FAIL", proceed with the following:

    a. Repeat the quality control test. If it still falls outside the acceptable control range,
    b. Retest using strips from a new vial and document that new strips were used in the meter. If it still falls outside the acceptable control range,
    c. Retest using new quality control reagents and document that new controls were used in the meter. If it still falls outside the acceptable control range,
    d. Call the HHCC laboratory.

The meter will not allow you to perform patient testing until it passes quality control testing.

Any quality control result that falls outside the acceptable control range, along with any corrective action to restore that result to acceptable range, is recorded on the troubleshooting log for the individual instrument and entered in the Inform II meter.

Each certified operator is responsible for the performance and documentation of quality control.

The laboratory supervisor or designee will review the quality control records for completion, as well as note any trends that may indicate potential problems. These trends include gradual drifting of values, sudden shifts in glucose control values while using the same lot of strips, and operator

performance. This should be completed at least weekly and QC reports generated monthly. Quality control records will be retained for a minimum of two years.

VIII. Linearity Testing

A. Accu-Chek Linearity Test Kit

Store Glucose Linearity Solutions at room temperature (<92°F or <32°C). Do not freeze. Unopened vials are stable at room temperature (<90°F or <32°C) until the expiration date on the label. The Linearity solutions are stable for **three months** after first opening the bottles, or until the expiration date on the label, whichever comes first.

Control solutions should be clear. Do not use if cloudy or shows other evidence of contamination.

B. Linearity is required

- Before a blood glucose meter is put into use.
- With each new lot of test strips.
- With each new shipment of test strips, even if it is the same lot number as a previous shipment.
- At least every six months.
- Anytime the Accu-Chek Inform II System has been repaired.
- When controls begin to reflect an unusual trend or are consistently out of range.

The manufacturer's stated linear range of each Accu-Chek Inform II System is 10 mg/dL to 600 mg/dL. The reportable range of each instrument is verified by the laboratory POCT coordinator or a qualified operator for each test strip lot number prior to release for patient testing. This verified range only goes from 30 mg/dL to 500 mg/dL.

If a patient test result falls outside of the linear range, it needs to be verified by the laboratory by an alternative method and is reported as less than (<30 mg/dL) or greater than (>500 mg/dL) the linear limits.

The linearity results of each Accu-Chek Inform II System are filed with each instruments records in the laboratory. Linearity records are retained for two years.

To perform a linearity test in the Accu-Chek Inform II System:

1. Press power ON button.
2. Enter (or scan) your operator ID, then press the forward arrow button.

3. From the Main Menu screen, press the forward arrow button.
4. Select Linearity, this will bring up the current lot number. Check the lot number and select the (√) if correct. To use a different number than the lot number displayed, touch the (X) to open the keypad and enter the new number manually.
5. Once you have entered and confirmed the lot number of the linearity test kit, you are asked to choose the test strip lot number.
6. Scan in the strip code number from the vial or answer "YES" after verifying the strip lot number.
7. Select the linearity solution lot number for the first test, starting with level 1.
8. When the test strip symbol flashes on the display, the meter is ready to accept the test strip.
9. Remove a new test strip from the vial. Tightly replace the vial cap.
10. Insert the test strip into the meter.
11. Hold the Level 1 bottle horizontally with the tip pointed directly at the right hand edge of the strip in line with the comfort curve. Gently squeeze the bottle to form one small drop.
12. Bring the tip of the bottle to the edge of the strip and allow the strip to automatically draw the solution into the yellow window until it is completely covered.
13. After reviewing the results, select the appropriate comments and press the forward arrow button to return to the linearity test screen.
14. Press the forward arrow button to record the test.
15. Remove the test strip from the meter and discard.
16. Repeat steps 7-15 using Level 1 solution (each level of linearity solution is run twice).
17. Repeat steps 7-16 for each of the remaining linearity solutions (levels 2 – 6).
18. Dock the Inform II meter to download the data for graphing, printing and supervisory (or designee) review.

IX. Proficiency Testing

The Accu-Chek Inform II System stores the following information about each proficiency test:

- Test Result
- Operator ID
- Sample ID
- Test Time and Date
- Strip Information
- Comment(s)
- Meter Serial Number

This facility is enrolled in an external proficiency program through American Proficiency Institute (API). Proficiency tests are performed 2-3 times per year, by a qualified operator.

To record a proficiency test in the Accu-Chek Inform II System:

1. Press the power ON button.
2. Enter (or scan) your operator ID, then press the forward arrow button.
3. Press the forward arrow button to display the Main Menu 2 screen.
4. Select "Proficiency".
5. Enter (or scan) the sample ID and press the forward arrow button.
6. Barcode scan the strip lot information.
7. Perform the proficiency test.
8. Enter comment(s), if necessary.
9. Press the forward arrow button to return to the Main Menu 2 screen to run the next sample.
10. Remove the strip and discard it according to your CRSU's infection control policy.
11. Press the power OFF button to turn the Accu-Chek Inform II System off.

X. PERSONAL PROTECTIVE EQUIPMENT

Because of the hazardous nature of handling blood products, it is recommended that disposable latex or latex free gloves be used when collecting specimens, performing test procedures, and cleaning blood glucose meter equipment.

Gloves are to be removed and hands washed thoroughly with soap and water after completing the test procedure and prior to handling equipment not related to the procedure. Used disposable latex or latex free gloves should be discarded according to HHCC's infection control policy.

Universal precautions should be observed for all blood specimens. They should be handled at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control/National Institutes of Health manual, *Biosafety in Microbiological and Biomedical Laboratories*, 1988 or in the National Committee for Clinical Laboratory Standard Document M29, *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*, 1991.

XI. SPECIMEN COLLECTION AND HANDLING

- Capillary, venous (lithium heparin, sodium heparin of EDTA), neonatal heelstick and arterial whole blood specimens may be used for testing on the Accu-Chek Inform II System.
- The capillary sample must be tested immediately after collection.

- Blood glucose determinations using venous and arterial blood specimens should be performed within 30 minutes of specimen collection to avoid glycolysis. Mix samples thoroughly.
- 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.
- Follow HHCC's policy and procedures for blood collection by capillary, venous or arterial methods.

XII. TEST PROCEDURE

The Accu-Chek Inform II System is set up to store the following information about each patient test:

- Test Result
- Operator ID
- Patient ID
- Test Strip Information
- Test Time and Date
- Comment(s)
- Meter Serial Number

Blood glucose tests with the Accu-Chek Inform II System must be ordered by a credentialed medical provider unless the patient is experiencing symptoms of hypoglycemia or hyperglycemia, and quality care dictates a STAT test per policy.

A medical provider will be notified according to parameters specifically ordered.

The medical provider determines what test(s) performed by the laboratory is ordered whenever the blood glucose result is less than 60 mg/dL or greater than 300 mg/dL, the critical values.

Only a certified operator may perform a blood glucose test on the Accu-Chek Inform System.

NOTE: Any patient result that exceeds the critical ranges of <60 mg/dL or >300 mg/dL must be confirmed by lab testing, notifying the ordering medical provider, and documenting in the Electronic Health Record (EHR) or on a flowsheet.

The appropriate comment(s) is/are entered in the Accu-Chek Inform II System by the operator.

A. Patient Preparation

- The purpose of the test and the steps of the procedure will be explained to the patient prior to performing the test.
- The operator's hands must be washed before and after testing.
- Universal precautions must be observed and disposable latex or latex free gloves must be worn when the operator is handling blood products.
- Fresh capillary whole blood samples for use with the Accu-Chek Inform II System are to be taken from the fingertip or heel (neonates).
- Wash your hands and put on disposable latex gloves prior to testing.
- If the patient is able, ask the patient to wash his/her hands with warm water and soap, rinse and dry well 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.)

NOTE: Unused supplies and medications taken to a patient's bedside during fingerstick monitoring or insulin administration should be discarded and not used for another patient because of possible inadvertent contamination.

B. Patient Test Procedure

The following equipment should be at the patient's bedside prior to testing:

- Accu-Chek Inform II System Meter
- Accu-Chek test strips
- Accu-Chek, single-use, disposable lancets
- Alcohol swab
- Gauze for wiping finger after stick
- Disposable latex or latex free gloves

1. Press power ON button.
2. Enter (or scan) your operator ID. Press the forward arrow button.
3. Select Patient Test.
4. Enter (or scan) the patient ID, then verify it is the correct chart number. Press the forward arrow button.
5. Verify that the code number on the test strip vial corresponds to the code number on the Accu-Chek Inform II System
    - Select YES if the code numbers correspond, or
    - Select NO and verify the correct vial and code chip combination. If incorrect start over after opening a new strip vial and enter the new code chip. QC will be required and the comment of "New Quality Control Opened".

6. Remove a test strip from the vial. Immediately replace the cap on the vial.
7. When the flashing strip icon appears on the meter display, gently insert test strip with the yellow target area, "ACCU-CHEK" lettering, and test strip window facing up. (Insert the end with the silver bars.)

   Note: Insert test strip BEFORE dosing.
8. When the flashing drop icon appears on the meter display, obtain a blood sample. You may use a whole blood capillary, venous, arterial or neonatal (heel) blood sample. Wipe the first drop of blood away when performing a capillary of heelstick procedure as this ensures that the cleansing agent is dry, it stimulates blood flow and clears interstitial fluid from the sample.
9. Touch and hold drop of blood to the yellow target area. The blood is drawn into the test strip automatically. **No-redosing is allowed**. If sufficient blood is not collected to fill the yellow target area the first time, testing will have to restart using a new strip.
10. An hourglass will appear on the display while waiting for the result.
11. Enter up to three preprogrammed comments and one custom comment, as 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.
12. Remove the test strip from the meter and discard it according to HHCC's infection control policy.
13. Press the power OFF button to turn the Accu-Chek Inform II System off.
14. Clean the meter according to the "Cleaning and maintenance of the Accu-Chek Inform II Meter" section above.
15. Remove gloves and dispose of them according to HHCC's infection control policy. Wash hands thoroughly with soap and water.
16. Dock the Accu-Chek Inform II meter onto the Inform II Base Unit to transmit the test result into EHR or document the blood glucose result according to facility policy on patient chart or flowsheet.

XIII. REPORTING RESULTS

The date, time, initials or ID of the operator, patient name/patient ID number, meter serial number, and glucose value are recorded on/in:

- Accu-Chek Inform II System
- Cobas IT 1000 Data Management System
- Patient's chart
- Flow Sheet (in inpatient when EHR is down)

When the Cobas IT 1000 Data Management System interface is down, results must be entered into E.H.R. using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

If both the Cobas IT 1000 Data Management System and EHR is down, document results in the patient's chart or flowsheet by writing the result, include the reporting units (i.e. mg/dL) and reference range. The test result must be documented along with the initials of the personnel performing the test and date the test was performed.

This process allows a functional audit trail which allows result retrieval.

A. Expected Values

The normal fasting blood glucose range for a non-diabetic adult is 70-110 mg/dL.

B. Abnormal Results

The Nursing staff should notify the requesting Provider if the patient's Whole Blood Glucose is consider **"Critical" if the glucose test is**:

- **Less than 60 mg/dL.**
- **Greater than 300 mg/dL.**

Notify the ordering medical provider immediately of the need to order a glucose test from the laboratory to validate the results and document the notification in EHR or on the PCC. The Inform meter and Accu-Chek Inform II test strip combination have been found to loose accuracy at values less than 30mg/dL and greater than 500 mg/dL.

For all Inpatient abnormal results, follow medical orders for instituting appropriate therapy.

XIV. PROCEDURE NOTES

1. If **"HI"** is displayed, the blood glucose result may be higher than the reading limits of the meter. If this contradicts the patient's condition, perform a quality control check with glucose control solution and a new test strip.
   a. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip.
   b. If "HI" still appears on the patient test, notify the ordering medical provider for specific follow up laboratory testing.
   c. If the control result is not within the acceptable range, refer to the *Accu-Chek Inform II System Operator's Manual* before proceeding with patient testing.

2. If **"LO"** is displayed, the blood glucose result may be lower than the reading limit of the meter. If this contradicts the patient's condition, perform a quality control check with glucose control solution and a new test strip.
   a. If the control result is within the acceptable range, review proper testing procedure and repeat the blood glucose test with a new test strip.
   b. If "LO" still appears on the patient test, notify the ordering medical provider for specific follow up laboratory testing.
   c. If the control result is not within the acceptable range, refer to *the Accu-Chek Inform II System Operator's Manual* before proceeding with patient testing.

3. If a **"Strip Defect Error"** message appears on the display, the test strip may be defective or the blood glucose result may be extremely low and below the meter's measurement range. Refer to the test strip package insert.
   a. Repeat testing using a new strip, if the error repeats,
   b. Perform QC. If error persists call the laboratory.

4. If the meter displays **"Type Bad Dose"**, there may be insufficient amount of blood on the test strip. Repeat the test using a new test strip, ensuring proper sample application. If this does not resolve the error, call the laboratory.

XV. LIMITATIONS OF PROCEDURE

The ACCU-CHEK Inform II system is used within its limitations as described by the manufacturer's most current literature on interference and limitations - See list below and manufacturer's ACCU-CHEK Inform II test strip package insert and literature attached as an appendix to this procedure.

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

1. Hematocrit should be between 10–65 %.

2. Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.

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

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

5. 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, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.

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

7. The performance of this system has not been evaluated in the critically ill.

XVI. OPERATOR CERTIFICATION/RECERTIFICATION

A certified Accu-Chek Inform II System Instructor will be a POCT Coordinator, Medical Laboratory Technologist/Technician, Nurse Educator or another designated individual who is trained in the use of the Accu-Chek Inform II System and designated by the Hopi Health Care Center Laboratory Supervisor to perform training and certification.

Each operator will be appropriately in-serviced to perform blood glucose testing on the Accu-Chek Inform II System.

Each operator must be certified to perform blood glucose testing on the Accu-Chek Inform II System by successfully completing the:

1. HHCC specific "Accu-Chek Inform II Glucose Meter" procedure on-line on the MTS (medtraing.org) website, and
2. The laboratory's hands-on CLIA Point of Care Testing Competency Training with quiz and completion of the Competency Assessment form.

A certification roster is maintained within the Cobas IT 1000 Data Management System.

A roster of all designated Accu-Chek Inform II system instructors will be maintained within the Cobas IT 1000 Data Management System.

A roster reports of all certified operators and instructors will be generated after addition or removal of any operators and kept by the POCT Coordinator.

Each operator will be evaluated for competency, initially, after 6 months and annually thereafter according to CLIA requirements.

The operator will learn the policies and procedures for:

- Performing blood glucose testing on the AccuChek Inform II System in HHCC.
- Proper coding of the AccuChek Inform II System, patient testing, and documentation of results.

- Proper specimen collection and infection control per HHCC guidelines.
- Proper test performance with the AccuChek Inform System
- Proper documentation of patient blood glucose results and follow-up of critical test results.
- Proper quality control testing.
- Proper cleaning and maintenance.
- Learning the meaning of display codes and proper troubleshooting procedures.

XVII. **REFERENCES**

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THE POLICY AND PROCEDURE HAS BEEN REVIEWED AND APPROVED BY THE FOLLOWING:

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