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Roche Accu-Chek Inform II Glucose Meter

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.

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.

PURPOSE

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

ACCU-CHEK INFORM II SYSTEM

The Accu-Chek Inform II Blood Glucose Monitoring System will consist of:

- Accu-Chek Inform II Meter
- Base Unit (docking station)
- Code Key Reader
- Test Strips
- Control Solutions
- Linearity Kit
- Accessory Box
- Cobas IT 1000 Data Management System

TEST STRIP, METER STORAGE AND HANDLING

- Use the test strips at temperatures between 61-95°F (16-35°C).
- Store the test strips at temperatures between 39–86°F (4–30°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 37-108°F (3-42°C).

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.

Only a certified operator may perform a blood glucose test on the Accu-Chek Inform System. The Point of Care Coordinator will provide staff Operator ID barcode card to access the meter. The Operator ID barcode card will contain a six-digit prefix number to identify HHCC Service Unit, followed by the operator's internal number that is generated by RPMS, thus is at least 9 to 10 digits in length.

The Accu-Chek Inform II System stores the following information with each patient, control, linearity, and proficiency test:

- Test Result
- Operator ID
- Patient ID/Sample ID

- Lot number of the test strips
- Date and time of test
- Comment(s)
- Meter Serial Number

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.

SPECIMEN COLLECTION AND HANDLING

- Capillary, venous (lithium heparin, sodium heparin or EDTA), neonatal heel stick 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.

PATIENT GLUCOSE TEST PROCEDURE

Create a Patient Visit for the Clinic and/or Inpatient

A. Use the Electronic Health Record and create an outpatient clinic visit by selecting the appropriate Clinic and selecting the ordering medical provider.

B. It is important that this step is completed before performing the whole blood glucose test.

C. For Inpatients, check the Electronic Health Record to ensure that the patient is admitted and there is an admitting or ordering medical provider assigned to the patient.

D. **NOTE**: For unknown patients such as emergency and/or John or Jane Doe, enter the chart number **999999** into the meter. This will send an error code to the POC Coordinator and the result can later be transmitted once the patient is identified through the Cobas IT 1000 interface software. It is mandatory that any employee using the "999999" number to submit a glucose correction form. See Point of Care Testing Correction Form (attached below).

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 thoroughly before and after patient 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). Obtain capillary blood from the side of the fingertip which is least sensitive to pain.
- 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.

Patient Testing 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. Press the forward arrow button.
2. Press barcode icon. Scan (or enter) your operator ID barcode.
3. Select Patient Test.
4. Scan (or enter) the patient's medical record number (MRN), then verify and confirm it is the correct MRN.
    - **Note**: If manually entering patient MRN it must contain 6 digits. Add leading zeros if MRN is less than 6 digits (Example: If patient's MRN is 1234, enter "001234").

5. Scan the barcode on the on the test strip vial ensure the strip lot number corresponds to the lot number on the Accu-Chek Inform II System.
    - Select green (√) if the lot number corresponds, or
    - Select red (X) to verify the correct test strip 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: A glucose control test must be always be performed before using a lot for the first time.
6. Remove a test strip from the vial. Immediately replace the cap on the vial.
7. When a flashing green arrow 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. The meter beeps. The hourglass icon appears and indicates the meter is checking the test strip.
    - 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 heel stick procedure as this ensures that the cleansing agent is dry, it stimulates blood flow and clears interstitial fluid from the sample.
9. Apply the drop of blood to the front edge (yellow dosing area) of the test strip. The blood is drawn into the test strip by capillary action. No-redosing is allowed. If sufficient blood is not collected to fill the yellow target area the first time, testing will have to be repeated using a new strip.
10. An hourglass will appear while the test is running. When test is completed, the meter beeps again.
11. Enter up to three preprogrammed comments and one custom comment, as necessary. Enter comment "Cleaned Meter" to indicate cleaning was or will be performed after patient testing. 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 below.
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 the Electronic Health Record or document the blood glucose result according to the facility policy in the patient's chart.

Abnormal Values

- Blood glucose tests with the Accu-Chek Inform II System must be ordered by a provider unless the patient is experiencing symptoms of hypoglycemia or hyperglycemia, and quality care

dictates a STAT test per policy.

- A red flashing arrow next to the patient glucose result indicates the result is a critical.
- A provider will be notified of a critical result according to parameters specifically ordered. The 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 400 mg/dL.
- **NOTE: Any patient result that exceeds the critical range established by the facility is followed-up by the operator by repeating the test and notifying the provider. If outside of testing parameters, collect blood to be sent to laboratory for confirmatory testing.**
- The appropriate comment(s) is/are selected in the Accu-Chek Inform II System by the operator: Ordering Medical Provider notified, RN Notified or Will Repeat Test.

CALIBRATION AND QUALITY CONTROL TESTING

Calibration

The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using a validated test method. The test method is referenced to the hexokinase method and is traceable to an NIST standard.

Each box of test strips contains a **code key**. Each code key belongs to a single lot number and provides information about the lot-specific properties of the test strip. The properties of the test strips are downloaded (as a code file) from the code key using the code key reader and sent to the meter. The code key contains the test strip lot number, expiration date and parameters for control solutions.

If a new lot number of test strip vial is opened and the meter does not recognize the lot, contact the POCC or laboratory to enter the new lot into the system.

Code Key Procedure

NOTE: Will only be performed by laboratory staff.

1. Touch the forward button to open the Main Menu 2 screen.
2. Press Strip Lots. Press Add. Password Required. The Add Strip Lot Screen opens.
3. Insert the new code key into the opening of the code key reader. The LED starts flashing green and signals that the reader is ready to transfer data.
    - Note: The code key remains ready to send for a few seconds after it has transmitted data.
4. Hold the meter 4-6 inches above the code reader so a connection can be made between the two infrared windows.
5. Touch the forward button to begin downloading. Once the connection is made, the meter provides status information on the download.
6. Strip Lot Confirmation appears, verify the information and then press the green (√) to confirm

correct information.

7. Press the green (√) to confirm that you want this lot number to be the lot number currently in use.

Accu-Chek Inform II Control Solutions: 2 Levels

Glucose control solutions must be stored at room temperature 39-86°F (4-30°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 must be written on the vial label along with the 3 month expiration date.** Any outdated glucose control solutions must 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 day of use or every 24 hours.
- When a new box of test strips is opened.
- When a vial of strips has been left opened.
- When patient test results contradict clinical symptoms.
- If the Accu-Chek Inform meter was dropped.
- If previous control test results failed or control tests were not run at the proper interval.
- When the Accu-Chek Inform II System has been reset.

Quality Control Procedure

1. Press power ON button. Press the forward arrow button.
2. Press barcode icon. Scan (or enter) your operator ID barcode.
3. Select Control Test.
4. Select (or scan) the desired control level: Level 1 (Lo) or Level 2 (Hi).
5. Scan the lot number of control solution displayed on the Accu-Chek Inform II System.
6. Scan the barcode on the test strip container and compare the number displayed by the meter to the number on the label of the test strip container.
7. Remove a test strip from the vial. Immediately replace the cap on the vial.
8. When a flashing green arrow 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. The meter beeps. The hourglass icon appears and indicates the meter is checking the test strip.
9. Wait until the flashing drop appears before applying the control solution. Apply a drop of glucose control solution to the front edge of the test strip. Do not apply the control solution to the top of the strip. The glucose control solution is drawn into the test strip by capillary action.

- Note: 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 test is running.
11. The result will be displayed as PASS or FAIL. Then press the green (√) button to record the test. Then repeat test with the next level of control before proceeding with patient testing.
12. Remove the used test strip(s) and disposable latex or latex free gloves and discard them.
13. Clean the meter according to the "Cleaning and maintenance of the Accu-Chek Inform Meter" section above.
14. If a quality control test result falls within the acceptable control range, meter will display "PASS". It is acceptable to proceed with patient testing.
15. If a quality control test result falls outside of the acceptable control range, meter will display "FAIL". Proceed with the following steps until QC passes:
    a. Repeat the quality control test.
    b. Retest using test strips from a new vial and document that new strips were used in the meter.
    c. Retest using new quality control reagents and document that new controls were used in the meter.
    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 is stored in the Inform II meter.

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

The point of care coordinator or 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. QC reports will be reviewed monthly. Quality control records will be retained for a minimum of two years.

LINEARITY

Accu-Chek Linearity Test Kit

Store unopened Glucose Linearity Solutions at room temperature 39-86°F (4-30°C). Do not freeze. Unopened vials are stable 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.

Linearity tests help check the function and accuracy of the entire system over the full range of specified values.

Linearity is required:

- Before a blood glucose meter is put into use.
- At least every six months.
- 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.

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 (<10 mg/dL) or greater than (>600 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.

Linearity Testing Procedure:

1. Press power ON button. Press the forward arrow button.
2. Press barcode icon. Scan (or enter) your operator ID barcode.
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 green (√) if correct. To use a different number than the lot number displayed, touch the red (X) to open the keypad and enter the new number manually.
5. Scan in the test strip barcode number from the vial or answer "YES" after verifying the strip lot number.
6. Select the linearity solution lot number for the first test, starting with level 1 (L1).
7. When the flashing green arrow appears on the display, the meter is ready to accept the test strip.
8. Remove a new test strip from the vial. Tightly replace the vial cap.
9. Insert the test strip into the meter.
10. Hold the linearity solution 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.
11. 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.
12. After reviewing the results, select the appropriate comments and press the green (√) button to return to the linearity test screen.
13. Remove the test strip from the meter and discard.
14. Repeat steps 6-13 using Level 1 solution (each level of linearity solution is run twice).
15. Repeat steps 7-14 for each of the remaining linearity solutions (levels 2 - 6).
16. Dock the Inform II meter to download the data for graphing, printing and supervisory (or designee) review.

PROFICIENCY TESTING

HHCC 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.

Proficiency Testing Procedure:

1. Press power ON button. Press the forward arrow button.
2. Press barcode icon. Scan (or enter) your operator ID barcode.
3. From the Main Menu screen, press the forward arrow button.
4. Select Proficiency.
5. Enter the sample ID (example: GLU 01) and green (√) button.
6. Scan the barcode on the test strip container and compare the number displayed by the meter to the number on the label of the test strip container.
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 HHCC's infection control policy.
11. Press the power OFF button to turn the Accu-Chek Inform II System off.

REPORTING RESULTS

The date and time of test, operator ID and name, patient name/patient ID number, and glucose value are recorded 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 will be manually documented into RPMS or use the Electronic Health Record notes section to eliminate duplicate results. All results will be uploaded into the patient's chart once interface issues have been resolved.

If both the Cobas IT 1000 Data Management System and EHR are 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 for result retrieval.

Expected Values

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

One to two hours after meals, normal blood glucose levels for a non-diabetic adult should be less than 140 mg/dL.

Abnormal Results

The Nursing staff should notify the requesting provider if the patient's whole blood glucose is:

- Less than 60 mg/dL or
- Greater than 400 mg/dL.

Notify the provider immediately of any patient result that exceeds the critical range and follow-up by repeating the test. If outside of testing parameters, collect blood to be sent to laboratory for confirmatory testing. The Inform meter and Accu-Chek Inform II test strip combination have been found to lose 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.

TRANSFERRING DATA

Transferring data from an Accu-Chek Inform II Meter is the responsibility of each certified operator. Every patient tested for glucose will need an EHR visit created with a clinical provider before docking the 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)
- "Synchronizing Database..."
- "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 24 hours.

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

CLEANING AND MAINTENANCE

Do:

- 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 needs to be 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.

Do Not:

- 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 port, 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.

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

1. Place the meter on a level surface prior to disinfecting.
2. Power off the meter.
3. Approved wipes to use for cleaning and disinfection are Super Sani-Cloth® Germicidal Disposable Wipes or Clorox® Germicidal Wipes.
4. 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.

5. 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.
6. Allow the surfaces of the meter to remain damp with for two full minutes when using Super Sani Cloths.
7. 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.
8. Enter comment "Cleaned Meter" to indicate cleaning was or will be performed after each patient test.

Accu-Chek Inform II Base Unit cleaning and disinfection is performed whenever there is evidence of visible contamination by the certified operator as follows:

1. Place the base unit on a level surface prior to disinfecting.
2. Unplug the base unit.
3. Approved wipes to use for cleaning and disinfection are Super Sani-Cloth® Germicidal Disposable Wipes or Clorox® Germicidal Wipes.
4. 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.
5. 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.
6. Allow the surfaces of the meter to remain damp for two full minutes when using Super Sani Cloths.
7. 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.

Documentation and Replacement

If certified operator is 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. Inform the POCC or lab to replace the meter. The laboratory will be in charge of changing the location of the replacement meter in 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 accreditation standards and laws.

OPERATOR CERTIFICATION/RECERTICATION

A certified Accu-Chek Inform II System Instructor will be a POC Coordinator, Clinical 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 to perform training and certification.

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

- "Roche Accu-Chek Inform II" procedure on-line on the MTS (www.medtraing.org) website.
- The laboratory's hands-on Roche Accu-Chek Inform II Training Checklist.
- 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 POC Coordinator.

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

PROCEDURE NOTES

If "HI" is displayed, the blood glucose result may be over 600 mg/dL or if "LO" is displayed, the blood glucose result may be below 10 mg/dL. If this contradicts the patient's condition:

- Perform quality control check with glucose control solutions.
- 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" or "LO" still appears on the patient test, notify the ordering medical provider for specific follow up laboratory testing.
- If the control result is not within the acceptable range, refer to the Accu-Chek Inform II Operator's Manual before proceeding with patient testing.

If a "Strip Defect Error" message appears on the display, the test strip is defective. Refer to the test strip package insert.

- Run a glucose control test with a new test strip.
- Repeat test using a new strip.
- If error persists, call the laboratory.

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.

LIMITATIONS

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 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.

- Hematocrit should be between 10–65%.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- 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.
- This system has been tested at altitudes up to 10,000 feet.
- The performance of this system has not been evaluated in the critically ill.

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with the ACCU-CHEK® Inform II Glucose Monitoring System, (version: 4302-02-0713), Roche Diagnostics.

10. Accu-Chek Inform II Operator's Manual, 2021-11 USA, Roche Diagnostics.
11. Roche Diagnostics. (2021). Accu-Chek Inform II Test Strips and 1 Code Key package insert. Indianapolis, IN. 07981554003-0721.
12. Roche Diagnostics. (2016). Accu-Chek Inform II Controls package insert. Indianapolis, IN. 07981503001-0316.
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Attachments

Accu-chek Inform II Operator's Manual.pdf

Accu-chek Inform II Test Strips Package Insert.pdf

Point of Care Testing Correction and Rejection Form.pdf

Approval Signatures

Step Description	Approver	Date
Medical Officer Pathologist	Noelle Blue Arm: Medical Officer Pathologist	02/2024
Chief Nurse Executive	Rachel Hamblin: Chief Nurse Executive	02/2024
Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	02/2024
Director of Quality Management	Jose Burgos: Public Health Nurse Director	02/2024
Medical Technologist	Jeanna Begay	02/2024
	Jeanna Begay	02/2024

Applicability

Hopi Health Center