Written By: Point of Care Coordinator	**Distribution:** Laboratory Point of Care Testing Procedure Nursing Policy and Procedure Manual
Approved By: Laboratory Medical Director	**Revised:** E Weilnau 2 /20/2016
	Reviewed: E Weilnau 2/5/2018

PURPOSE

The ACCU-CHEK Inform II system is used at Firelands Regional Medical Center (FRMC) to quantitatively measure glucose in fresh venous, arterial and capillary (fingerstick and neonatal heelstick) whole blood. The system is used as an aid in monitoring the effectiveness of glucose control.

METHOD

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.

SPECIMEN REQUIREMENTS

1. The following fresh blood sample types may be used:
    a. Capillary (non-neonate fingerstick and neonate heelstick) whole blood
    b. Venous blood
    c. Indwelling Lines or VADs (vascular access device)

2. The following anticoagulants are acceptable (do not use any other anticoagulants for meter testing):
    a. Lithium or Sodium Heparin, EDTA

REAGENTS

ACCU-CHECK Inform II Test Strips

The test strips are for use with the ACCU-CHECK Inform II meter to quantitatively measure glucose.
Refer to ACCU-CHECK Inform II Test Strips and 1 Code Key Package Insert for more details.

QUALITY CONTROL

ACCU-CHEK Inform II Control Level 1 (Low) and Control Level 2 (High)

Low and high quality control testing is performed on the following occasions:

1. Once during every 24 hour period of patient testing.
2. When a new test strip vial is opened and placed into service.
3. When the meter is dropped.
4. When unexpected QC results are observed.

Acceptable quality control results are defined as results of **PASS** or **FAIL**. A failed result should be evaluated and documented with appropriate comment. Repeat the failed test x 2. Use the Troubleshooting Guide located on the hospital intranet under Laboratory. LABORATORY→ QUICK REFERENCE → POINT OF CARE → INFORM II → TROUBLESHOOTING GUIDE. Seek assistance if troubleshooting doesn't work. Use an alternate instrument for testing.

The control solution is stable for 3 months from the opened date or until the "use by" date (manufacturer's date printed on the bottle). The control bottle must be labeled with the "Open" date and the "Expiration" date visibly seen.

Refer to package insert for further details on ACCU-CHECK Inform II controls for storage and handling.

Materials for running QC: Gather the following supplies in preparation for quality control testing:

1. ACCU-CHEK Inform II meter – fully charged and coded to the test strip lot you intend to use.

2. ACCU-CHEK Inform II Control Level 1 (Low) and Control Level 2 (High), the lot and range information will be available in meter.

3. ACCU-CHEK Inform II test strip vial

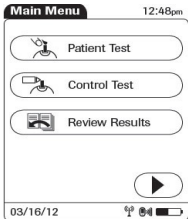
   NOTE about reagents: *Reagents are not to be used past their expiration date. ACCU-CHEK Inform II strips expire on the date printed on the strip vial label.*

Procedure for running QC:

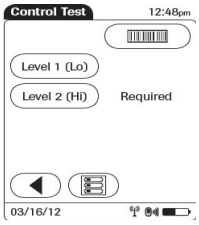
1. Turn on the ACCU-CHEK Inform II meter.

2. Enter your operator ID. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to perform tests under another operator's ID.

3. From the *Main Menu*, touch *Control Test*.



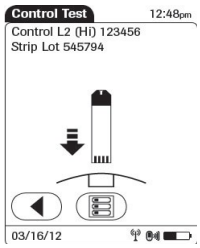
4. Select the level of control that you wish to test.



5. Confirm that the meter is coded (calibrated) to the same test strip code that is printed on the test strip vial. See calibration instructions in this procedure to code the glucometer (To be performed by the Laboratory).

6. Contact your supervisor or Point-of-Care Coordinator if you are unable to confirm the correct test strip code.

7. The meter will display a picture of a test strip with a downward flashing arrow on the meter indicating that you are ready to insert a test strip into the meter. Remove a test strip from the vial and immediately recap the vial. Insert the test strip into the meter in the direction of the arrows and with the "ACCU-CHEK" lettering facing upward. The meter will display a flashing drop above the test strip icon when the test strip is properly inserted indicating that you are ready to apply control solution.



8. Apply control solution to the front edge of the test strip. The solution will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress. You will get an error message if the sample is insufficient. If this occurs, you will need to repeat the test.

9. The measurement is complete when the result is displayed on the meter screen. See the "Interpretation of Results" and "Troubleshooting" sections for guidance on what to do if your result is "Fail" or shows an "out of range" message associated with the result.

10. Remove the test strip and dispose of it in a proper waste container.

11. Touch the comment button ( ) to enter an appropriate comment(s) as required. *Example: QC failed - will re-check.*

12. Touch the button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.

Interpretation of Quality Control Results:

1. Results are displayed on the screen as **Pass** or **Fail**. Any result that shows an "out of range" message or "Fail" is an indication that the system may not be performing correctly for patient testing.

2. Patient testing may not be performed if quality control testing results are not within acceptable limits and the meter will not display the patient testing option if scheduled quality control results exceed acceptable limits.

CALIBRATION (Coding)

Calibration (Coding) will be done in the laboratory by the Point of Care Coordinator or designee. This is done with each new lot of test strips prior to distribution to the floor. Each box of test strips contains a code key. Each code key belongs to a single lot and provides important information about the lot-specific properties of the ACCU-CHEK Inform II test strip. The properties of each lot number of test strips are downloaded (as a code file) from the code key into the ACCU-CHEK Inform II system by means of the code key reader. A code file is uploaded into the ACCU-CHEK Inform II system for every test strip lot that is received by FRMC.
The code file for each in-use test strip lot resides in all meters so that end users on nursing units are able to access and select the correct test strip lot for testing. New test strip codes are uploaded into the system.

Materials to calibrate new lot of strips for meters: Gather the following materials in preparation for uploading a new test strip lot code file into the ACCU-CHEK Inform II system:

1. A single ACCU-CHEK Inform II meter – Fully charged
2. A code key from the new strip lot
3. A code key reader

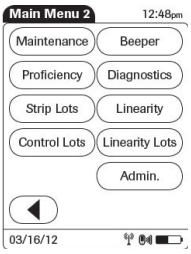
Procedure to calibrate new lot of strips for meters:

1. Turn on the ACCU-CHEK Inform II meter.

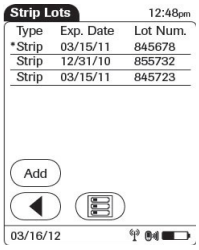
2. Enter or barcode scan your operator ID. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. DO NOT attempt to perform tests under another operator's ID.

3. From the *Main Menu*, touch the forward arrow button to open the *Main Menu 2* screen.

4. Touch *Strip Lots* to open the test strip lot code file menu.



5. Touch *Add* if you want to add the information for a new test strip lot from a new code key. The *Add Strip Lot* screen opens.



6. Insert the new code key in the opening of the code key reader. A LED starts flashing green to signal that the code key reader is ready to transfer data.

7. Place the code key reader on a level surface such as a bench or table.

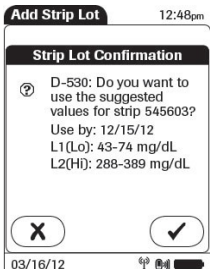
8. Hold the meter 4-6 in (10-15 cm) above the code key reader so that a connection can be made between the infrared window on the bottom of the meter and the infrared window on the top of the code key reader.

9. Touch the forward arrow key to begin downloading data.

10. Successful transmission will display two progress messages: "Please Wait – Connecting to code key reader and "Please Wait – Receiving Code Key Contents."

11. A *Strip Lot Confirmation* screen will ask you to confirm use of the suggested values for the test strip lot.

12. Touch the ✓ button to store the data for this test strip lot number in the meter without changes, or Touch the ✗ button to modify the data for this test strip lot number (see the ACCU-CHEK Inform II Operator's manual for detailed instructions on editing parameters of the test strip lot.)



13. You will then see a *Make 'Current'* screen asking you if you want to make the test strip lot that you are entering the current test strip lot.
14. Touch the ✓ button to confirm that you want this lot number to be the lot number currently in use, or touch the ✗ button to store the entries without making the lot number the current lot number.
15. Touch the *Main Menu* icon in the center of the bottom of the screen to return to the *Main Menu*.
16. Dock the meter in the network connected base unit to send the new test strip lot information from the meter into the data management system for centralized test strip lot distribution.

OPERATION – PATIENT TESTING

Materials:

1. ACCU-CHEK Inform II meter – fully charged and coded to the test strip lot you intend to use.
2. ACCU-CHECK Inform II test strip vial. Reagents are not to be used past their expiration date. date. ACCU-CHEK Inform II strips expire on the date printed on the strip vial label.
3. Supplies for collecting a blood sample as required by established Firelands Regional Medical Center.
4. Biohazard and sharps container
5. Transfer pipette or syringe as needed if testing a venous, arterial or line draw sample.

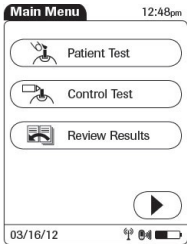
Procedure:

Note: Quality control testing results must be acceptable prior to performing patient testing.
Procedure:

1. Take the meter and testing supplies to the patient location.
2. Wash hands and don personal protective equipment (gloves, gowns, etc.) as required by FRMC infection control and isolation policies and procedures.
3. Greet and identify the patient according to FRMC guidelines.
4. Explain the procedure to the patient.
5. Turn on the ACCU-CHEK Inform II meter.

6. Enter your operator ID. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to perform tests under another operator's ID.

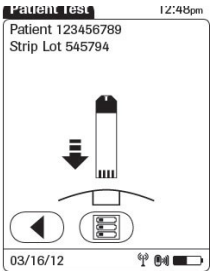
7. From the *Main Menu*, touch *Patient Test*.



8. Enter the patient identification in the ACCU-CHEK Inform II system by scanning the barcode on the patient's wristband.

9. Confirm that the meter is coded (calibrated) to the same test strip code that is printed on the test strip vial. Contact your supervisor or Point-of-Care Coordinator if you are unable to confirm the correct test strip code.

10. You will now see a picture of a test strip with a downward flashing arrow on the screen indicating that you are ready to insert a test strip into the meter.



11. Remove a test strip from the vial and immediately recap the vial. Insert the test strip into the meter in the direction of the arrows and with the "ACCU-CHEK" lettering facing upward. The meter will display a flashing drop above the test strip icon when the test strip is properly inserted indicating that you are ready to apply a blood sample.

12. Collect an acceptable blood sample according to Firelands Regional Medical Center's established procedures.

    A. **Fingerstick samples**: Test immediately as the sample is collected.

        1. Assess the patient for compromised peripheral blood flow. Fingertips should be warm and pinkish when the hand is gently massaged from the palm outward to the fingertips. Fingertips should not appear pale, bluish or mottled. Patients with compromised peripheral blood flow are not good candidates for fingerstick testing.

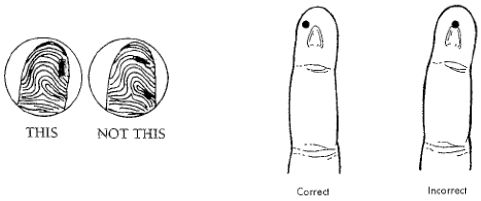
        2. Select the finger site for puncture. It is preferred to select the side of a middle or ring finger that has not been punctured recently.
        3. Enhance blood flow to the selected puncture site by means of:
            a. Warming the intended puncture site
            b. Instructing the patient to flex and move the arm, wrist, hand and fingers while you are assembling your supplies and preparing the system for testing
            c. Positioning the intended puncture site below heart level
            d. Gently massaging in an outward (distal) direction from the palm and the base of the finger to the fingertip.

4. Cleanse the puncture site by means of Firelands Regional Medical Center protocol. With the alcohol swab, cleanse the entire fingertip. Allow the site to air dry. Do not dry by wiping, as disinfection occurs during air drying. Wipe the area with a gauze square to assure the tip of the finger is thoroughly dry. This avoids an unacceptable specimen due to hemolysis and lessens the stinging caused by alcohol.

5. Pick up the sterile retractable lancet which has been selected for finger puncture (Red Trigger).

6. With one hand, firmly grasp the lancet. With your other hand firmly grasp the patient's finger to maintain control and provide the best access to the puncture site.

7. Hold the device firmly against the side of the pad of the finger. Deploy the unit, and then remove the device after deployed. The cut should be across (perpendicular to the lines of) the fingerprint.



The puncture should be performed on the palmar surface of the middle or ring finger, between the side and the center of the finger.

8. Dispose of the lancet in an approved puncture-resistant sharps container.

9. Hold the puncture site downward and gently apply intermittent proximal to distal pressure along the finger toward the puncture site to express a blood drop. Do not apply strong repetitive pressure at the fingertip as it may cause hemolysis or contamination of the sample with tissue fluid and may lead to questionable results.

10. If blood flows freely, take a piece of gauze and wipe away the first drop. Wipe the area dry. Dispose of the gauze. If blood does not flow freely, increase blood flow by holding the finger downward and applying gentle continuous pressure above the puncture site. Do not massage the area since this may contaminate the blood sample with tissue fluid. If blood does not flow easily after gentle pressure, make another puncture using a new sterile lancet.

11. Apply a well-formed drop to the ACCU-CHEK Inform II test strip as described in the patient testing procedure that follows.
12. Apply gentle direct pressure to the puncture site for several minutes and elevate the hand to reduce blood flow to the fingertip. Check the site to ensure that it is no longer bleeding before leaving the patient bedside.

13. Discard all sample collection and testing materials by means of appropriate sharps container and biohazard containers. Note: The single-use fingerstick device(lancet) is used.

14. Wash hands before leaving the patient room.

B. **Heelstick samples:** Test immediately after sample is collected.

1. Wash your hands with either an alcohol-based hand rub (if hands are not visibly soiled) or soap and water (if hands are visibly soiled).

2. If the heel is not already pre-warmed, use the heel warmer provided in the heel puncture collection kit to pre-warm the heel for 3 to 5 minutes.

3. Put on new properly fitting gloves.

4. Choose a puncture site in the fleshy lateral or medial posterior portion of the heel and clean the area with an alcohol sponge. Only this area should be punctured. Using other sites may result in trauma to the bones of the foot.

5. If possible place the baby on its stomach.

6. Thoroughly dry the cleaned area with dry gauze.

7. Hold the foot firmly to avoid sudden movement.

8. Using the retractable lancet selected for heel puncture, oriented so the puncture site is perpendicular to the skin print lines, deploy the device while it is resting firmly against the heel. To avoid infection, do not puncture in the same place as a previous puncture that is not healed.

9. Take piece of clean dry gauze and wipe away the first blood drop. Wipe the area dry and dispose of the gauze.

10. Newborns often do not bleed immediately. If the blood is not freely flowing, use gentle pressure to produce a rounded drop of blood. (Excessive or heavy massaging dilutes the blood with tissue fluids; therefore, use gentle pressure only.)
11. Apply a well-formed drop to the ACCU-CHEK Inform II test strip as described in the patient testing procedure that follows.

12. Dispose of the retractable lancet in the approved puncture-resistant sharps container. Remove your gloves and wash your hands using either an alcohol-based hand rub (if hands are not visibly soiled) or soap and water (if hands are visibly soiled).

Venous or line draw samples: In rarely used situations this sample is acceptable for collection. Test as soon as possible and no later than 30 minutes following collection. Samples are to be kept at room temperature. Be sure they are well mixed and that line draw samples have been thoroughly cleared of line fluids. Do not allow bubbles to enter the test strip-sampling chamber.

1. Collect a full tube to fully ensure an accurate sample for testing.

2. After collecting the sample properly, according to Firelands Regional Medical Center protocol, expel a few drops of blood for waste from the syringe.

3. Holding the syringe allow a full rounded drop to appear at the tip of the needle. Apply the drop to the strip as listed below.

13. Apply a full rounded drop of blood to the front edge of the test strip. The sample will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip.

14. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.

15. After the sample has been obtained, apply gentle pressure to the puncture with a clean gauze square or cotton ball on the site for several minutes.

16. The measurement is complete when the result is displayed on the screen. Depending upon how high or low the result is, it may appear in a numeric or non-numeric format. See *Interpretation of Results* section below for interpretation of each result format.

17. Remove the test strip and dispose of it according to FRMC policy

18. Touch  to enter up to three appropriate comment(s) as required.
19. Touch the  button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.

20. Document the result according to FRMC policy.

21. Follow up on any results that exceed critical or reportable limits according to the *Nursing Critical Tests and Critical Values Reporting* policy.

22. Clean and disinfect the glucometer after each patient use. See Meter and Base Unit Storage, Maintenance, and Handling Section of this procedure.

INTERPRETATION OF PATIENT RESULTS

1. Results may appear in any of the following formats and may require follow-up:
   a. **A numeric value** that may /may not fit the patient's clinical history.
   b. **"HI" or "LO"** indicates the value is above or below the limits of the instrument. The limits are 10-600 mg/dL.
      i. Repeat test if >600 mg/dL or <10 mg/dL within 5 minutes of initial test. If you obtain the same results initiate testing by laboratory method for glucose reporting. These methods allow for accurate results outside the ACC-CHECK Inform II range.
      ii. If the repeated result is between 10-600 mg/dL, then test the patient for a third time for confirmation of accurate results. These results must be within 10% of each to be acceptable. Report out the second result.
   c. **"CR HI" or "CR LO**" indicates the result exceeds Firelands Regional Medical Center's establish critical results. These critical limits are as follows: ≤60 mg/dL and ≥ 400 mg/dL. Patient results of < 70 mg/dL should be treated under the guidelines of Hypoglycemia Protocol for Adults.
      i. REPEAT and NOTIFY THE PHYSICIAN
      ii. Perform repeats within 5 minutes of each other. Repeat testing must be within 10% of the previous result to be accepted. The second result will automatically be reported in Meditech.
      iii. Baby critical is < 40 mg/dl

2. Follow up on results that exceed critical or reportable limits as outlined in the Nursing Manual Critical Tests and Critical Values Reporting.

3. REMINDER: It is important to do any repeat testing within five minutes of each to assure the results will be transferred and reported in the computer system. Results should be within 10% of each other to be acceptable as in the allowable standard error. Results that do not fall within these guidelines automatically transfer into the Telcore Computer program. The Point of Care Coordinator or designee will examine nurse's comments in notes, and Care Trend to see if results were reported based on the patient's clinical condition and history. Any results that were not used are placed in Repository under the Telcore program. Results that were noted will be re-sent to Meditech.

4. Results are reported in the EMR of Meditech.

5. The Exception of the repeat Blood Sugar is in ICU where the Insulin protocol is followed. Blood is drawn every Hour.

REFERENCE RANGE

The EMR results will have the following statement/comment posted in lieu of a reference range:

"*Random glucose reference range is dependent on time and content of last meal. Glucose of more than 200 mg/dl in a non-stressed, ambulatory subject supports the diagnosis of Diabetes Mellitus"*

DOCUMENTATION

Upon any critical glucometer reading, nursing uses clinical decision making skills to prioritize actions to be taken including: performing re-checks, implementing protocols, and/or physician notification. Per policy, documentation of physician notification will include the provider notified, the date, and time of notification. The actual documentation occurs within the patient record. Documentation of physician notification can be found with the blood glucose assessment template or within the narrative notes.

Documentation will occur from all involved in the notification process. As appropriate, documentation will include the date and time of the communication, actions taken, orders received, and any read back that is appropriate.

Notification is not required, when the individual performing the glucose testing is the same person who treats the patient. However, there must be documentation of the critical results, date and time in test report or elsewhere in the medical record. Notification is not required when:

- The physician documented specific notification range values.
- The critical value is improved from a previous value, and/or the patient is under treatment form the critical result.
- A specific treatment protocol has been ordered to address anticipated critical values.

LIMITATIONS OF METHOD

Carefully assess the patient for any indication that bedside glucose testing may not be appropriate (See Procedure notes for patient assessment guidance). Consider the following potential interferences and compromising conditions:

- 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.

- The performance of this system has not been evaluated in the critically ill.
- See nursing procedure "Blood Glucose Testing in Critically Ill Patients"

TROUBLESHOOTING

1. If the meter fails to function at any point in the procedure or if you get an error message associated with the result, make a note of the malfunction or error message and attempt to repeat the test. **See Troubleshooting guide for Nursing personnel located on the intranet.** If the error persists, sequester the meter and test strip vial involved and contact the Point of Care Coordinator, Laboratory Services.

Consult the troubleshooting guide from the ACCU-CHECK Inform II manual, Point of Care Coordinator or call Customer Care at **1-800-440-3638**.

METER AND BASE UNIT STORAGE, MAINTENANCE, AND HANDLING

Meters, system components and reagents are stored, maintained and handled according to manufacturer's instructions and in compliance with all established safety and infection control policies and regulatory guidelines.

- Handle the meter and its system components carefully. Avoid dropping it or banging it.
- Protect the base unit from dripping liquid.
- Do **not** immerse the meter and base unit in any liquid.
- Do not expose the meter to excessive sources of heat for prolonged periods of time when performing a test. Potential sources of heat include but are not limited to:
  – Leaving the meter under a bilirubin light or photo therapy light
  – Leaving the meter on a bed warmer
  – Leaving the meter in an isolette

Specification	Meter	Base Unit	Power Supply
Measurement temperature	61–95 °F (16–35 °C)	N/A	N/A
Storage temperature (long-term storage)	41 to 104 °F (5 to 40 °C) At 10-85% RH (non-condensing)	41 to 104 °F (5 to 40 °C) At 10-85% RH (non-condensing)	41 to 104 °F (5 to 40 °C) At 10-85% RH (non-condensing)

Cleaning the ACCU-CHEK Inform II System Components (meters, base units, accessories boxes) – Procedure

1. Place the meter on a level surface prior to cleaning.

2. Power off the meter.

3. 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 cleaning the surfaces of the meter.

4. Use an approved wipe to clean by gently wiping the surfaces of the meter, bases, and accessories boxes being careful to remove any visible soil or organic material. Use additional wipes as needed. ***Note: Carefully wipe around the test strip port area or electrical connectors (back of base unit) making sure that no liquid enters the test strip port.***

5. Dry the meter surfaces thoroughly with a soft cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the meter, base or accessories boxes at the completion of cleaning. Comment "CLEANED METER" in the glucose meter.

Disinfecting the ACCU-CHEK Inform II System Components (meters, base units, accessories boxes) – Procedure

1. Place the meter on a level surface prior to cleaning.

2. Power off the meter.

3. 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 cleaning the surfaces of the meter.

4. Use an approved wipe to clean by gently wiping the surfaces of the meter, bases, and accessories boxes being careful to remove any visible soil or organic material. Use additional wipes as needed. Note: Carefully wipe around the test strip port area or electrical connectors (back of base unit) making sure that no liquid enters the test strip port. Dry the meter surfaces thoroughly with a soft cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the meter, base or accessories boxes at the completion of cleaning.

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.

GLUCOMETERS TO BE PLACED IN/OUT OF SERVICE

Occasionally glucometers will need to be removed from service and replaced by a new one. The following steps will be taken to ensure quick turnaround time of a meter:

1. The in-operative meter will be tagged and the Point of Care Coordinator will be contacted by the floor.

2. After a meter arrives into the laboratory it will be checked for possible repairs including replacing the battery and checking connections. Basic troubleshooting will first be attempted before contacting Roche Diagnostics for a troubleshooting suggestions/replacement.

3. Contact number for Roche Diagnostics on the Inform II is **1-800-440-3638**.

4. The Laboratory has several back-up units available for use to replace the meter that is defected.

5. Select a backup meter to be used in the nursing unit. Point of Care Coordinator or designee will run QC to assure the instrument is functioning properly.

6. Prior to distribution to the floor, the location code of the meter must be changed. This will be under the Cobas IT 1000 application program.

7. To remove the existing defected meter from service goes to: Instrument Assignment →Double click the instrument being removed.

8. To change location of a backup meter to the floor assignment location go to: Instrument Assignment → double click the instrument being changed → Select the location of the floor from the drop-down box → OK

9. Changes are also made to the Telcore Computer program in un-assigning and assigning new meters. Go to device configuration → devices → click on the appropriate devices to activate and deactivate → save.

10. When a new meter is brought into the lab a six point linearity calibration is performed along with running both levels of QC x 10. In addition, a patient samples (x10) are run.

NEW LOTS OF QC AND REAGENTS

QC: Both levels (Low & High) are run on 10% of the meters in operation on the same strip lot number.

TEST STRIPS: Both levels of QC (Low & High) x 10 compare new lot versus old lot of reagent strips. Linearity (6 levels).

PROFIECINCY TESTING

CLIA regulation Subpart H – Participation in Proficiency testing requires a laboratory to enroll in a proficiency testing program approved by CMS for its primary test system. The ACT proficiency test from CAP is shipped three times a year with five samples rotated through the operators.

BLOOD SUGAR TESTING ON THE CRITICALLY ILL PATIENT

Firelands Regional Medical Center follows manufacturer's instructions on the critical ill patient. The hospital as defined the critical ill patient and along with nursing protocol. Detailed information is found in the Quality Department procedure "Blood Glucose Testing in the Critically Ill".
When the specimen is drawn and sent to the lab, it is treated as a STAT with immediate spinning/running of the specimen. Blood sugar results are called to the attending nurse.

REFERENCES

1. ACCU-CHECK Inform II Glucose Monitoring System, Comprehensive Policies, Processes and Procedure Manual, 4302-02-0713, Roche 2013
2. ACCU-CHECK Inform II Test Strip and 1 code Key Package Insert, Cat. No. 05942861001, Roche Diagnostics 2013
3. ACCU-CHECK Inform II Controls Package Insert, Cat. No. 05213509001 ,Roche Diagnostics 2012
4. Nursing Manual - Critical Tests and Critical Values Reporting, Quality and Patient Satisfaction Department. pg. 3 2012
5. Nursing Manual - Hypoglycemic Protocol for Adults, Jean Feick MSN, CNP, CDE 2011
6. Infection Control Manual - Hand Hygiene, Director of Infection Control and Safety 2012
7. Infection Control Manual - Waste Management: Sharps Handling and Disposal, Director of Infection Control and Safety 2012
8. Laboratory Manual - Point of Care Safety Procedure for both Patient and Operator, Patrick Collins 2012
9. ACCU-CHECK Inform II Glucose Monitoring System Operator's Manual, Roche Diagnostics 2012