283.233 Accuchek Inform II

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Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	1/29/2024	2.0	yahyaelshimali JohnYahya Elshimali	
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2.0	Approved and Current	Major revision	1/28/2024	1/29/2024	Indefinite
1.0	Retired	Initial version	1/12/2023	1/13/2023	1/29/2024

West Texas V A Health Care System
Ancillary Testing

ACCU-CHEK INFORM II GLUCOSE METER

1. **INTENDED USE:**

The ACCU-CHEK Inform II system is used to quantitatively measure glucose in fresh fingerstick capillary whole blood. The system is used as an aid in monitoring the effectiveness of glucose control. The system may be used on multiple patients when compliant with the cleaning and disinfecting recommendations of VA, FDA, CDC, and CMS. The system is not for use in diagnosis or screening of diabetes mellitus.

2. **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 has been calibrated with venous blood containing various glucose concentrations and has been calibrated by the manufacturer 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 an NIST standard.

3. **SPECIMEN REQUIREMENTS:**

A. Patient Preparation

1. Employees MUST wash their hands and wear gloves as per the facilities' Infection Control Policy
2. Capillary whole blood specimens from the fingertip will be used for patient testing on the ACCU-CHEK Inform II System.
3. **Refer to section 10, "LIMITATIONS" for restricted use guidelines on certain patient populations including those that are defined as critically ill and/or have peripheral circulation impairment.**
4. The capillary sample must be tested immediately after collection.
5. Sufficient sample size is required to ensure accurate results.
6. For the most accurate results, the middle and the ring finger are the primary fingers that should be used for testing.
   a. Select a site that does not appear to have been used recently.
   b. Puncture the skin on the side of one of these fingers (this area contains a larger amount of capillaries and less nerve endings)
   c. Avoid using the pinky (more sensitive), thumb (calloused), and index finger (calloused), for testing, as they can lead to inaccurate results.

4. MATERIALS:

A. Taken to the Bedside:

1. ACCU-CHEK Inform II Glucose Monitoring System (kept in docking station and charging when not in use)
2. ACCU-CHEK Inform II Test Strips
3. Alcohol Swabs
4. Disposable Protective gloves
5. Single-Use Lancet Device (testing is limited to use with single use fingerstick devices only)
6. Gauze or tissue
7. Sani-Cloth Plus or Bleach wipes for cleaning/disinfection of the meter after each patient use.
8. Specimen Size Biohazard Bag (Isolation C. difficile patients)

B. Miscellaneous Equipment:

1. ACCU-CHEK Inform II Control Solutions - Level 1 & 2
2. Sharps Container for Lancet Disposal

C. Control Solution and Test Strip Storage and Handling:

1. Test strips are used at temperatures between 16º and 35ºC and between 10-80% humidity.
2. Test strips and control solutions must be stored at temperatures between 4-30 ºC
3. Store unused test strips in the original container with the cap closed. Close the container tightly immediately after removing a test strip to protect the test strips from humidity.
4. Test strips are stable until the expiration date on the vial; Outdated test strips are discarded.
5. 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 a label along with the three month expiration date place the label on the vial so that it is legible.

5. CALIBRATION:

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 the Ancillary Testing Coordinator in the Laboratory or designee once s/he has validated the lot for use. 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.

Coding the Meter (Ancillary Testing Coordinator / Designee Only):

1. ATC/Designee logs into the meter and accesses the Main Menu 2 screen.
2. Select “Strip Lots”
3. Select “Add” if you want to add the information for a new test strip lot from a new code key
4. 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.
5. Place the code key reader on a level surface.
6. 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.
7. Touch the forward arrow key to begin downloading data.
8. Successful transmission will display two progress messages: “Please Wait – Connecting to code key reader and “Please Wait – Receiving Code Key Contents.”
9. A *Strip Lot Confirmation* screen will ask you to confirm use of the suggested values for the test strip lot
10. Touch the ✓ button to store the data for this test strip lot number in the meter without changes, or
    Touch the **X** button to modify the data for this test strip lot number .
11. 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.
12. Touch the ✓ button to confirm that you want this lot number to be the lot number currently in use, or touch the **X** button to store the entries without making the lot number the current lot number.
13. Touch the *Main Menu* icon in the center of the bottom of the screen to return to the *Main Menu*.
14. Dock the meter in the network connected base unit to send the new test strip lot information from the meter into the electronic centralized test strip lot data center (RALS)

6. QUALITY CONTROL:

A. Control tests are performed at the following times in this facility:

1. Every 24 hrs. of Patient testing. The meter displays when Quality Control is due.
2. When a vial of strips has been left opened or has been exposed to extreme heat, humidity, or cold, or may otherwise appear to be compromised.
3. If the ACCU-CHEK Inform II System has been dropped.
4. When test results contradict clinical symptoms.

B. Quality Control Instructions:

1. Turn on meter.
2. Verify the temperature and humidity are in range. There should be a meter next to the base unit.
3. Enter (or scan) your operator ID. Note: To Scan, press the scan button and immediately scan user bar-coded ID. If manually entering, enter the entire operator ID and press the enter✓ button. Use the "<" key if a number is entered incorrectly. If your operator ID is rejected, DO NOT attempt to perform tests under another operator ID.
4. From Main Menu, touch Control Test.
5. Confirm that the control solutions are not expired (See "Quality Control Notes" below)
6. .Scan one of the control bottles.
7. Scan the strip bottle.
8. 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.
9. 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.
10. The measurement is complete when the result is displayed on the meter screen.
11. The meter will display **PASS** or **FAIL** for control results. Enter the appropriate comment(s), if needed. Press the enter✓ button forward arrow button to record the test and to test the next level of control before proceeding to patient testing.
12. Before removing strip press the comment icon. From the list of messages picked **cleaned meter**, and **temp and humidity messages**. SEE SECTION ON CLEANING THE METER.
13. Remove and discard the used test strip(s).

C. Quality Control Notes And Troubleshooting:

1. Patient testing cannot be performed if both levels are not successful. Repeat any failed control results. If a quality control test result falls outside of the acceptable control range, the test is repeated and the problem must be corrected before proceeding with patient testing. Any problems should be directed to the ATC or designee or ACCU-CHEK customer Care (800-440-3638). **Remember, TWO levels of control must be tested in acceptable range to clear the control lockout.**
2. In areas where the ACCU-CHEK Inform II meters are not being used daily, quality control will be performed each day of use and operators will be locked out every 24 hours per instrument set-up.
3. There should never be more than 1 strip vial open per glucose meter.

4. Troubleshooting during hours the lab is staffed will be done over the phone with laboratory staff. If the meter does not perform properly following easy to do at site procedures such as turn off and one, or place in charger, it will be returned to the laboratory and backup meter sent to the clinic.
5. For Community Living Center (nursing home) a minimum of two meters will be on the floor for off shifts if a meter goes down. During the day while the lab is open call the main lab and work with the lab staff on troubleshooting.
6. Clinics are closed at 1630 pm. The lab is closed from 22:00 to 0600. The nursing home floor may contact Roche directly at 1-800-440-3638 for assistance. However the presence of 2 meters should not make this necessary.
7. If a lab draw for glucose is needed during the hours the lab is open call the main lab for a stat draw. Between the hours of 2200 and 0600 there is no lab testing available.
8. Troubleshooting internally to the laboratory will be done following guidelines in the instrument manual and phone contact with Roche technical service.

7. PROCEDURE:

A. PATIENT TESTING:

1. Employees MUST wash their hands and wear gloves as per the facilities' Infection Control Policy. Observe Standard Precautions for handling blood.

2. Press power ON button.

3. Enter (or scan) your operator ID. Note: To scan, tap the scan button and immediately scan user bar-coded ID. If manually entering, enter your operator ID and press the enter button. Use the "<" key if a number is entered incorrectly. If your operator ID is rejected, DO NOT attempt to perform tests under another operator ID.
From Main Menu, touch Patient Test.

4. Ask the patient for their name, date of birth, and/or social security number,(two identifiers must be used with one being the full name). Verify this information with patient's wristband, or verbal communication. The patients identification must be confirmed by ID card, CPRS, or other permanent record. The patient must repeat their entire social security number or date of birth as a second identifier. Explain both the purpose of the test and the steps of the testing procedure to reassure the patient.
5. 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, thoroughly cleanse the puncture site with an alcohol swab and allow it to thoroughly dry (30 seconds). Alcohol or water at the puncture site must be dry or an error code/inaccurate result may occur.
6. Enter the patient's SSN into the glucometer
   a. **Wrist-banded Patients**: Scan the patient armband. To scan, press the scan button and immediately scan the patient's wristband. IF wristband does not scan, reprint the patient armband. To prevent ID entry errors, only in emergency situations can the patient's ID be entered manually (see instructions under "Outpatients" below). Entering an incorrect SSN can cause the glucose result to go into the wrong patient's chart and may lead to treatment errors and other patient safety issues.
   b. **Outpatients** (Primary Care, CBOCs, etc) ***Carefully*** manually enter the patient's SSN using the keypad. Verify that what you have entered is correctly by comparing the information in CPRS or with the patient. Press the enter button ✓. (Use the "<" key if a number is entered incorrectly). Entering an incorrect SSN can cause the glucose result to go into the wrong patient's chart and may lead to treatment errors and other patient safety issues.

7. Scan the strip bottle – the glucose meter will not continue with testing if the strip bottle lot does not match the code key information in the meter.
8. From this point on throughout testing, the patient ID appears at the top of the screen. Confirm that this ID matches the patient you are testing. ***If ID scanned or manually entered does not match the patient ID, DO NOT CONTINUE WITH TESTING. Select the "menu" button and reenter/rescan the patient ID.*** Entering an incorrect SSN can cause the glucose result to go into the wrong patient's chart and may lead to treatment errors and other patient safety issues.
9. 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.
10. 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.
11. Collect blood sample as stated in the Specimen Requirements section above.
12. Apply 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.
13. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.
14. After the sample has been obtained, apply gentle pressure to the puncture site with a clean gauze square or cotton ball for several minutes. If the patient is conscious and capable, enlist the patient's assistance with applying pressure.
15. 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 *Reporting of Results* section below for interpretation of each result.
16. Remove the test strip and dispose of it in the trash. Used lancets are discarded in a sharps container.
17. Touch to enter up to three appropriate comment(s) if needed. **Note: Comments MUST be entered for any critical values and repeated test. Refer to Section 8 "Reporting Results, Guidelines/Comments" section for additional instructions and examples.**
18. Touch ✓ the button to confirm the result,

Cleaning and disinfection of meter:

19. Wipe meter with Sani-Cloth wipes, bleach wipes, or another facility approved disinfectant with a similar profile to the named wipes after each patient test as part of the FDA requirements for Reusable Medical Equipment. Avoid getting liquid in the ports or the charging contacts on the back. Refer to **Section 9** below **"Procedural Notes, Infection Control Guidelines and Cleaning of the ACCU-CHEK Inform II" for detailed cleaning instructions.**

19A Using a second wipe of SaniWipe or Bleach disinfect the meter by wiping it down again.

20. Remove and dispose gloves. Wash hands thoroughly with soap and water.
21. Place the meter in the base unit to record the result into CPRS.
22. RN will document the blood glucose by reviewing data in CPRS or viewing result directly from the glucose meter.

Writing patient results on a piece of paper is NOT *acceptable due to potential human/clerical error.*
Results being used for patient treatment MUST be viewed in CPRS (test name fingerstick glucose), the glucometer's "Review Result Screen" or read directly from the glucometer screen at time of patient testing. Refer to the "Reviewing Results" section below on how to view these results using the meter.
Treating a patient based on verbal or paper communication is FORBIDDEN as POSITIVE PATIENT ID CANNOT BE ESTABLISED IN THIS CASE.

However, critical values MUST be communicated to the primary caregiver (i.e. RN or provider) IMMEDIATELY after appropriate repeat testing is performed. The meter can be shown DIRECTLY to the RN or Provider after applicable repeat testing, who can verify the result and patient ID as displayed on the screen and immediately action can be taken.

8. REPORTING RESULTS:

A. Interpretation of Results

Reportable Range: The reportable range for the ACCU-CHEK Inform is 10-600mg/dl. If a patient result falls outside of this range, the meter will display an "HI" or "LO" for the result.

Normal Values: The normal fasting blood glucose range for a non-diabetic adult is 70-110 mg/dl

Critical Values: Critical values are less than 55 mg/dl or greater than 400 mg/dl.
CRITICAL VALUES MUST BE GIVEN TO THE RN ASSIGNED TO THE PATIENT IMMEDIATELY AFTER APPROPRIATE REPEAT TESTING TAKES PLACE.

B. Auto-Documentation and Communication of Results for Patient Treatment

1. Once meter is docked, if the patient ID entered matches a patient in CPRS, and the patient has an assigned provider and location, the system orders and results the test in Vista/CPRS. Along with the patient's test result, the operator's name and the glucometer serial number used will appear in the comments section under the patient's result.
2. The system reviews results for repeated patient test, valid patient ID, Critical Values, and comments entered. Most results cross readily into CPRS. Those that do not cross into CPRS can be viewed using the meter's "Review Results" screen.
3. Examples of results that are "held" from CPRS until they are reviewed by the POCT Coordinator or designee:
   a. Repeated tests within 6 minutes of the previous test
   b. Some tests with comments entered
   c. Incorrect SSN manual entry or miss-scan
   d. Patients without a location or provider assigned to them
   e. Some Critical Values
   f. VistA/CPRS Computer or Server Downtime

Writing patient results on a piece of paper is NOT *acceptable due to potential human/clerical error*.

Results being used for patient treatment MUST be viewed in CPRS (test name fingerstick glucose), the glucometer's "Review Result Screen" or read directly from the glucometer screen at time of patient testing. Refer to the "Reviewing Results" section below on how to view these results using the meter.

Treating a patient based on verbal or paper communication is FORBIDDEN as POSITIVE PATIENT ID CANNOT BE ESTABLISED IN THIS CASE.

However, critical values MUST be communicated to the primary caregiver (i.e. RN or provider) IMMEDIATELY after appropriate repeat testing is performed. The meter can be shown DIRECTLY to the RN or Provider after applicable repeat testing, who can verify the result and patient ID as displayed on the screen and immediately action can be taken

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C. Reviewing results: For each meter, all Patient and Control Test performed on that meter can be viewed using the meter's "Review Result" screen, and can be viewed for 7 days.

1. Press power ON button
2. Enter (or scan) your operator ID. Note: To scan, press the scan button and immediately scan user bar-coded ID. If manually entering, enter your operator ID and touch. Use the < key if a number is entered incorrectly.
3. Select "Review Results"
4. All results are listed according to day.
5. To find a specific patient result, select "Patient"
6. Scan (or enter) the patient's SSN
7. All results performed on that specific meter during the last 7 days will appear. Press the down arrow to get the previous day's results.

D. Guidelines/comments

1. All result should have a comment on temperature and Humidity attached..
2. Any corrective action must be recorded as a comment that explains what occurred and documents any possible discrepancies in result. This includes but is not limited to repeated tests and critical values.
3. Critical values must be repeated immediately, EXCEPT in cases of DOCUMENTED patient history or symptoms. It is understood that these patients should be closely monitored to prevent over/under treating/medicating.
4. **Repeat tests must agree within +/-15% of one another (+/-20 mg/dL for results <75mg/dL) except in cases where there is explanation for the discrepancy AND the appropriate comment is entered.**
5. **If two results do not agree within the above criteria and there is no documented explanation for this (see comment below for examples), testing should be completed a third time or a lab draw should be obtained to determine the correct value.**

6. Examples of comments and appropriate action and documentation are as follows:

   a. **PROCESS ERROR:** This code is used if the test performed is believed to be flawed. This code simply states "Do not use this result for treatment; something went wrong." This documents the reason why the second result may not be consistent with the first value. Examples of this include but are not limited to:

   i. Test strip did not fill all the way / patient did not bleed adequately
   ii. Cleaned / tested wrong finger
   iii. Squeezing the patient's finger too much for blood flow

   Instructions:
   a) Operator realizes result is flawed and enters this comment under the first result
   b) Operator repeats testing.

   b. **WASHED PATIENTS HANDS-REPEATED TEST:** This code/action is used if a patient's test is unexpectedly high, and may be the result of residual sugar on the patient's hands.

   Instructions:
   i. Meter result is unusually high and not consistent with patient history / symptoms
   ii. Operator enters comment code "Repeat Washed Hands.
   iii. Operator washes and thoroughly dries the patient's hands with soap and water.
   iv. Patient test is then repeated –the comment code documents corrective action and explains discrepancy between the first and second result (if any).

E. Other comments –

1. Lab Draw – Instead of results, meter reading is "HI","LO", or patient results are questionable. Enter this comment and request a lab draw.
2. RN Notified – The responsible RN was notified of a critical or discrepant result.
3. Cleaned meter – This is done after every test (QC or Patient)
4. Temp 3 to 42C
5. Humidity 10 to 90

9. PROCEDURAL NOTES:

1. Infection Control Guidelines and Cleaning of the ACCU-CHEK Inform II

A. Due to the hazardous nature of handling blood and control reagents, disposable gloves must be used when performing any type of testing on the meter (Patient Test, Control Test, Proficiency Testing, etc). Gloves are to be removed and hands washed thoroughly with soap and water or antibacterial hand gel (as appropriate) both before and after completing the test procedure. Lancets must be disposed of in sharps containers.

B. DO NOT clean the meter while performing a patient or control test

C. DO NOT allow cleaning solution to enter the test strip port or allow pooling of liquid on the touchscreen. If liquid does get into the test strip port, immediately dry the components with a dry cloth or gauze.

Cleaning is required after each patient test as part of the FDA's requirements for Reusable Medical Equipment, whether or not the meter appears contaminated with blood.

D. **For Routine Patients** (excluding C. difficile and other isolation patients)

i. Power off the meter and place meter on a level surface
ii. Squeeze out excess solution and wipe the surface of the meter with Sani-Cloth wipes, Cavi-wipes, bleach wipes or a facility approved disinfection wipe that meets similar disinfection criteria to the named wipes.
iii. Using the wipe, gently wipe the outside of the meter and carefully wipe around the test strip port area, making sure no liquid enters the test strip port. **Allow a minimum contact time of 2 minutes.**
iv. Visually verify that no solution is seen anywhere on the meter at the completion of the cleaning/disinfecting process

E. For Isolation Patients (excluding C. difficile)

i. Minimal supplies should be brought into the room. Strip can be inserted into the meter PRIOR to scanning the patient. Accessory box should be left outside the room. Strip vial (required for scanning) can be kept outside the room as well, keeping the barcode visible for scanning after the patient ID is scanned
ii. Meter MUST be inserted into a specimen size laboratory biohazard bag, with the opening of the bag allowing for strip insertion in the top of the meter, and the meter placed so the clear back of the bag allows for viewing of the screen
iii. Scan your operator ID or manually enter first, then scan the patient ID, then scan the vial of strips (kept outside the room as noted in step i.)
iv. After testing, remove biohazard bag and wipe down meter as in "D" above.

F. **For C. difficile Isolation Patients:** Sani-Cloth Wipes, or bleach wipes may not destroy the bacterial spores. For these patients:

i. Minimal supplies should be brought into the room. Strip can be inserted into the meter PRIOR to scanning the patient. Accessory box should be left outside the room. Strip vial (required for scanning) can be kept outside the room as well, keeping the barcode visible for scanning after the patient ID is scanned

ii. Meter MUST be inserted into a specimen size laboratory biohazard bag, with the opening of the bag allowing for strip insertion in the top of the meter, and the meter placed so the clear back of the bag allows for viewing of the screen

iii. Scan the patient first, then scan the vial of strips (kept outside the room as noted in step i.)

iv. After testing, remove biohazard bag and wipe down meter as in "D" above.

2. Operator Competency: Several factors may be used in order to determine operator's initial and annual competency. **Failure to comply with competency requirements will result in operator lockout of glucometer use**. Some of the competency requirements may include but are not limited to:

A. Initial training by the POCT Coordinator or designee
B. Performance of Quality Control minimally once per year.
C. Performance of Proficiency Samples
D. Quality Assurance review of patient tests, control tests and proficiency testing
E. Review of Flagged Results using the RALS middleware.
F. Direct observation of testing
G. Use of Medtraining.org competency exams
H. Each ACCU-CHEK Inform II Operator is given a unique user ID during their initial training. If you feel your operator ID has been compromised, please let the POCT Coordinator know. Because your ID is directly tied to your CPRS account it is not possible to change your ID number.

3. Proficiency Testing: This facility if enrolled in an external proficiency program provided by the College of American Pathologists (CAP). Proficiency tests are received three times per year and testing is rotated among qualified operators as part of competency. Proficiency testing samples MUST be mixed per the instructions that come with the proficiency test kit. Failure to mix the samples properly may cause failure of the survey. Failing a survey can cause the National Compliance Office to order glucometer use by stopped at a location until 2 proficiency surveys in a row have passed.
A. Press power ON button ((1)).
B. Enter (or scan) your operator ID.
C. Press the forward arrow button to get to the secondary menu.
D. Select Patient testing.
E. Enter the sample ID (exp. 000000001 or 111111111) and press the forward arrow button. You may also use barcodes issued by the ancillary testing coordinator.
F. Scan the strip bottle
G. Remove a test strip from the vial and replace the vial cap immediately.
H. When the flashing strip icon appears on the meter display, gently insert test strip with the yellow target area or test window facing up into the end of the meter. (Insert the end with the silver bars.) **Note:** Insert test strip BEFORE dosing.
I. Hold the proficiency sample next to (but without touching) the edge of the yellow target area. The Proficiency specimen is drawn into the test strip automatically.
J. Remove the strip and discard it according to your facility's infection control policy.
K. Press the forward arrow button to return to the Main Menu 2 screen to run the next sample. Or press the power OFF button to turn off the ACCU-CHEK Inform II System.

4. Troubleshooting

A. During routine business hours, contact the Point of Care Testing Coordinator x7232 or the Lab Manager x7230.
B. For instrument troubleshooting off hours (24/7), contact ACCU-CHEK Customer Care, 800-440-3638

10. LIMITATIONS

1. The ACCU-CHEK Inform II test strips are for testing fresh capillary whole blood.
2. Hematocrit should be between 10–65 %.
3. Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
4. Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
5. Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
6. **This system is NOT to be used on "Critically Ill". WTVAHCS defines Critically Ill as the following and a lab draw is required in these cases:**
   i. Mean Arterial Pressure (MAP) of <65mmHg
   ii. Use of IV vasopressors to maintain blood pressure such as dopamine.
7. **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. Lab draw is recommended. This may apply in the following circumstances:

   a. Severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome,
   b. Hypotension
   c. Shock
   d. Decompensated heart failure
   e. Peripheral arterial occlusive disease.
8. **In acute cases, POC glucose monitoring via capillary sample may occur before the patient can be evaluated for the "Limitations" criteria. If this discovered, switch to the lab draw protocol as required/recommended above and monitor patient for any adverse events.**

11. REFERENCES:

Comprehensive Policies, Processes and Procedures Manual For use with the ACCU-CHEK Inform II Glucose Monitoring System, Roche Diagnostics, 2021.

ACCU-CHEK Inform II Test Strips Package Insert, Roche Diagnostics, 2016

ACCU-CHEK Inform II Control Solutions Package Insert, Roche Diagnostics,.