D.11 ACCU-CHEK INFORM II GLUCOSE METER OPERATING PROCEDURE

I. **PRINCIPLE:** The ACCU-CHEK Inform II system is used to quantitatively measure glucose in fresh finger stick 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 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 an NIST standard.

II. SCOPE/RELATED POLICIES:

• Ancillary Testing Policy (113-05)

III. SPECIMEN:

PLEASE NOTE: All laboratory tests, including Point of Care bedside glucose testing require a provider's order. Orders can be placed post testing in emergent situations only.

- Capillary whole blood
- ICU/ER/OR/Nuclear Medicine Patient line Access for Whole Blood POC Glucose

IV. MATERIALS:

- Accu-Chek Inform II Test strips: Store at room temperature (16 30°C).
 - Strips are stable until the expiration date on vial.
 - Lid must always be on tight.
- Accu-Chek Inform II Control Level 1 (LO)
- Accu-Chek Inform II Control Level 2 (HIGH)
 - Controls are *stable for 3 MONTHS* after *opening at room temperature* or until expiration date, whichever comes first.
 - Controls *MUST* have the *date vials were open and expiration written* on label.
 - $\circ~$ ALL reagents and controls are to be used only within their indicated expiration date.
 - ALL reagents and controls must be stored and handled as recommended by the manufacturer.
- 70% Isopropyl Alcohol Prep
- Single -Use Lancet Device
- Gauze or Kim wipes
- Biohazard Container for Lancets
- Specimen Size Biohazard Bag for Isolation C. difficile patients
- Clorox Germicidal Wipes
- Disposable Gloves

V. INSTRUMENTATION:

Accu-Chek Inform II Glucose Meter (Roche)

VI. SAFETY:

Universal blood and body fluid precautions

VII. DOCUMENTS:

- ACCU-chek Inform II meter training checklist
- ACCU-chek Inform II meter annual competency assessment

VIII. QUALITY CONTROL:

- · Hospital Wards: Every 24 HOURS both Level 1 (LO) and Level 2 (HIGH) of ACCU-CHEK Whole Blood Inform II Glucose Controls MUST be run prior to patient testing. Meters will display when QC is needed.
- Hospital Clinics: Level 1 (LO) and Level 2 (HIGH) of ACCU-CHEK Whole Blood Inform II Glucose Controls MUST be run on the day of the hospital clinic prior to patient testing. Meter will display when QC is needed.
- CBOC Outreach Clinics: Level 1 (LO) and Level 2 (HIGH) of ACCU-CHEK Whole Blood Inform II Glucose Controls MUST be run prior to patient testing. Meters will display when QC is needed. QC is to be run at the CBOCS daily when the CBOCS are open even if patients are not tested.
- If the ACCU-CHEK Inform II Meter has been dropped: Both levels of QC 1 and 2 must be rechecked.
- If the ACCU-CHEK Inform II Meter results contradict clinical symptoms, both levels of QC 1 and 2 should be rechecked.
- QC should be rechecked when a vial of test strips has been left opened OR exposed to Extreme heat, cold, or humidity
- TWO levels of control must be tested in acceptable range and PASS to clear the control lockout.
- Technical problems should be directed to the Ancillary Testing Coordinator @ # 626-5771 or ACCU-CHEK Customer Care (#1-800-440-3638)

A. Running Quality Controls:

- 1. Turn on glucometer.
- 2. Enter (or scan) your operator ID.
 - Note to Scan: Press the scan button and immediately scan user barcoded ID.
 - If manually entering, enter the entire operator ID and press the enter

button. Use the "<" key if a number is entered incorrectly.

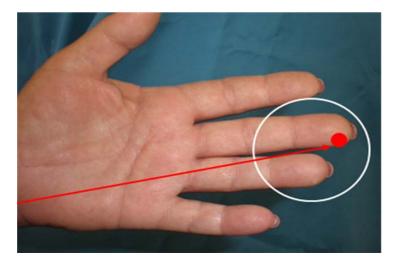
- DO NOT use another operator ID to access the glucometer.
- If your code does not work, contact the Ancillary Testing Coordinator
- 3. From Main Menu, touch Control Test.
- 4. Confirm that the control solutions are not expired. (see Quality Control)
- 5. Scan one of the control bottles.
- 6. Scan the strip bottle.

- 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.
- 8. Remove a test strip from the vial and immediately recap the vial.
- 9. Insert the test strip into the meter in the direction of the arrows and with the "ACCU-CHEK" lettering facing upward.
- 10. The meter (depending on the software up date) will display either a flashing drop OR a bottle tilting a drop of liquid above a test strip icon when the test strip is inserted properly.
- 11. Apply control solution to the front edge of the test strip. The solution will fill the yellow sample chamber by capillary action.
- 12. Once sufficient sample has been detected, the measurement begins.
 - An hourglass icon indicates that the measurement is in progress.
- 13. The measurement is complete when the result is displayed on the meter screen.
- 14. You will get an error message if the sample is insufficient.
- 15. If error message occurs, you will need to repeat the test.
- 16. The measurement is complete when the result is displayed on the meter screen.
- 17. The meter will display PASS or FAIL for control results.
- 18. You **MUST** enter the appropriate quality control comment at this time into the meter. These comments include:
 - Wrong QC used
 - Replaced test strip
 - QC good
- 19. Press the enter button forward arrow button to record the test and to test the next level of control before proceeding to patient testing.
- 20. Remove and discard the used test strip(s).
- 21. If ALL control results have PASSED; the meter is now ready to use for patient testing.
- 22. TWO levels of control must be tested in acceptable range and PASS to clear the control lockout and proceed with patient testing.
- 23. If any control has not passed see <u>Accu-Chek Inform II Quality Control Chart</u> for Quality Control troubleshooting help.
- Technical problems should be directed to the Ancillary Testing Coordinator @ # 626- 5771 or the ACCU-CHEK Customer Care (#1-800-440-3638)*

IX. PROCEDURE:

- 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. Only ICU/ER/OR/Nuclear Medicine may test blood accessed from a line.
 - 4. Refer to section "LIMITATIONS" of this procedure for restricted use guidelines on certain patient populations including those that are defined as critically ill and/or have peripheral circulation impairment.
 - 5. The capillary sample must be tested immediately after collection.
 - 6. Sufficient sample size is required to ensure accurate results.
 - 7. To achieve the most accurate results:
 - Middle and ring finger are primary fingers 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 the fingers with a **single-use lancet device** (the side of the finger contains more capillaries and less nerve endings)
- c. Always wipe away the first drop of blood
- d. Avoid using the pinky finger (sensitive), thumb (calloused), and index finger. Calloused finger sticks may lead to inaccurate results.



B. <u>Running Patient Samples:</u>

Employees MUST wash their hands and wear gloves as per the facilities' Infection Control Policy.

- 1. Press **power ON** button.
- 2. Enter (or scan) your operator ID into the glucometer.
 - 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
 - DO NOT attempt to perform tests under another operator ID.
 - Contact the Ancillary Testing Coordinator if operator ID code does not work.
- 3. From Main Menu, touch Patient Test.
- 4. Ask the patient for their name and social security number, and verify this information with patient's wristband (inpatients). In outpatient settings, verbal SSN by the patient must be confirmed by VIC card, CPRS, or other permanent. The patient must repeat their entire social security number as second identifier.
- 5. Explain both the purpose of the test and the steps of the testing procedure to reassure the patient.
- 6. 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.
 - Allow the site to dry thoroughly (30 seconds).
 - Alcohol or water at the puncture site may result in inaccurate results.
- 7. Enter the patient's SSN into the glucometer:
 - a. Wrist-Banded Patient.

- 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. Outpatient (Primary Care, CBOCs, Etc.):
 - Scan the patient's VIC Card OR Carefully manually enter the patient's SSN using the keypad.
 - Verify that what you have entered is correct either by comparing the information to the VIC card, computer or other document.
 - Press the enter button. (Use the "<" key if a number is entered incorrectly).
- c. When Accurate Patient ID is not easily obtainable:
 - Refer to section below "Procedural Notes, Emergency Patient ID" for the Emergency Patient ID procedure.
- 8. Scan the strip bottle 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 re-enter/rescan the patient ID.
- 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.
- 12. The meter (depending on the software up date) will display either a flashing drop OR a bottle tilting a drop of liquid above a test strip icon when the test strip is inserted properly.
- 13. Collect blood sample as stated in the Specimen Requirements section above, remembering to wipe away the first drop of blood.
- 14. Apply blood to the front edge of the test strip; sample will fill the yellow sample chamber by capillary action.
- 15. Once sufficient sample has been detected, the measurement begins.
 - An hourglass icon indicates that the measurement is in progress.
- 16. After the sample has been obtained, apply gentle pressure to the puncture with a clean gauze square or cotton ball site for several minutes. If the patient is conscious and capable, enlist the patient's assistance with applying pressure.
- 17. The measurement is complete when the result is displayed on the screen. Depending upon how high or low the result is for the glucose, it may appear in a numeric or non-numeric format.
- 18. See Reporting of Results section below for interpretation of each result format.
- 19. Remove the test strip and dispose of it in the trash. Used single-use lancets are discarded into a sharps container.
- 20. Touch 20. to enter up to three appropriate comment(s) at this time
 - Comment codes MUST be entered after ANY patient sample.
 - Cleaned/Disinfected Meter comment MUST be entered at this point by touching the Cleaned/Disinfected Meter icon.

21. Refer to "Reporting Results, Guidelines/Comment Codes" section for additional instructions and examples. Touch the enter \checkmark button to confirm the result.

- 22. Wipe meter with Clorox Germicidal wipes for disinfection after each patient test as part of the Reusable Medical Equipment Policy.
 - Refer to Section below "Infection Control Guidelines and Cleaning of the Meter" for detailed cleaning instructions.
- 23. Remove and dispose gloves. Wash hands thoroughly with soap and water.
- 24. Place the meter in the base unit to send the result and record the result into the electronic data management system.
- 25. RN will document the blood glucose by reviewing data in VISTA/CPRS or viewing result directly from the glucose meter.
- C. STAT Patient Testing (QC Override):
 - Most meters are configured to allow one STAT patient test to be performed in the event that guality control is due, but a stat patient situation arises.
 - Quality Control MUST be performed shortly thereafter to confirm that the instrument and the strips are working properly and that the patient result is accurate.
 - The STAT test has been used up, and will not be available in the event another stat patient situation takes place.
 - 1. STAT Patient Testing Instructions:
 - a. Meter will read "QC Due Immediately" when turned on.
 - b. Enter your operator ID.
 - c. Select "Patient Test"
 - d. The following warning will appear: "Warning! Glucose control is due. Required Controls must be run in order to proceed. 1 STAT test(s) available"
 - e. If Run QC is selected, perform QC as outlined in Quality Control Instructions above.
 - f. If "Run STAT" test is selected, perform routine patient testing as outlined in Patient Testing above. Note: Quality control must be run shortly afterward attending to the stat patient.

Х. INFECTION CONTROL GUIDELINES AND CLEANING OF METER:

- 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 samples, Controls, Proficiency samples, Linearity samples).
- 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.
- DO NOT clean the meter while performing a patient or control test
- 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.
- Document always in the glucometer when you have cleaned/disinfected the meter.

Cleaning/Disinfection is required after each patient test as part of the Reusable Medical Equipment Policy, whether or not the meter appears contaminated with blood.

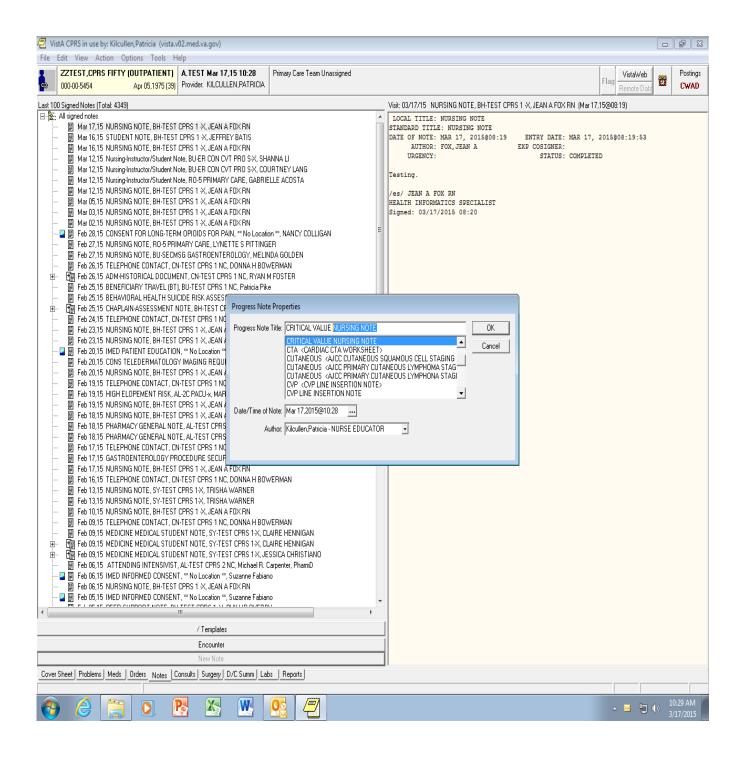
- 1. For Routine Patients (excluding C. difficile and other isolation patients):
 - a. Power off the meter and place meter on a level surface
 - Squeeze of excess solution and wipe the surface of the meter with Clorox Germicidal Wipes. Using the wipe, gently wipe the outside of the meter and carefully wipe around the test strip port area, making sure no liquid enters the test strip port.
 Allow a minimal contact time of 3 minutes.
 - c. Visually verify that no solution is seen anywhere on the meter at the completion of the cleaning/disinfecting process.
- 2. For Isolation Patients (including C. difficile isolation patients):
 - a. **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 also keeping the barcode visible for scanning after the patient ID is scanned
 - b. 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
 - c. Scan the patient first, then scan the vial of strips (kept outside the room as noted in step a.)
 - d. After testing, remove biohazard bag and wipe down meter as done in cleaning/disinfection for routine patients above with Clorox Germicidal Wipes and allow a minimal contact time of 3 minutes.

XI. RESULT REPORTING:

A. Interpretation of Results:

Reportable Range:	The reportable range for the ACCU-CHEK Inform is 20-590 mg/dI . If a patient result falls outside of this range, the meter will display a "HI" or "LO" for the result.
Normal Values:	The normal fasting blood glucose range for a non-diabetic adult is 70-115 mg/dl
Critical Values:	Critical values are less than 50 mg/dl or greater than 450 mg/dl, or display results as "HI' or "LO."

- Critical values must be given to the Provider assigned to the patient IMMEDIATEDLY after appropriate repeat testing is done.
- Please follow the Critical Result Procedures.
- Please document notification of a critical value in CPRS Notes using the "Critical Value Nursing Note" (see template below).



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2 Template: CRITICAL VALUE NURSING NOTE	
CRITICAL VALUE RESULTS:	
Glucose:	
C Provider Notified:	
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of the critical fingerstick result of: *	
Critical Results are: (<50 or >450 mg/dL)	
Provider read back critical result:* 🗐 Yes 🗐 No	
Interventions taken:*	
Additional Medication Ordered and given to patient	
1 Amp D50 given	
1/2 Amp D50 given	
Glucagon given	
Glucose Gel Given	
Insulin Held	
Oral diabetic agents held	
Additional Insulin Given, per order	
No Interventions Ordered	
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Symptoms/Observations:	
Outcomes:	
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- B. Auto-Documentation and Communication of Results for Patient Treatment:
 - Once meter is docked, the majority of results are held for 6 minutes by the RALS Information Management System (IMS) prior to test ordering/resulting in Vista/CPRS.
 - 2. If a 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.
 - 3. The RALS IMS reviews results for repeated patient test, valid patient ID, Critical Values, and comment codes entered. Most results cross readily into the chart after 6 minutes. Those that do not cross into the patient's chart can be viewed using the meter's "Review Results" screen.
 - 4. Examples of results that are "held" from the patient's chart until they are reviewed by the Ancillary Testing Coordinator or designee:
 - a. Incorrect SSN manual entry or miss-scan
 - b. Patients without a location or provider assigned to them

- c. VISTA/CPRS Computer or Server Downtime:
 - Documentation of the 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 (name finger stick 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 established in this case.
 - Critical values MUST be communicated to the primary caregiver IMMEDIATELY after appropriate repeat testing is performed. The meter can be shown DIRECTLY to the provider after applicable repeat testing, who can verify the result and patient ID as displayed on the screen and immediately action can be taken.
- C. Reviewing Results:
 - For each meter, all patient and control tests 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 \bigcirc . 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:
 - 1. Comment codes MUST be entered after ANY quality control, patient, proficiency, and/or linearity sample.
 - 2. Any corrective action must be recorded as a comment code 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 code is entered.
 - 5. If two results do not agree within the above criteria and there is no documented explanation for this (see comment codes below for examples), testing should be completed a third time or a lab draw should be obtained to determine the correct value.
- E. Comment Codes: that can be entered into the glucometer

Codes	Explanation	Cause/Reason/Action
* Process Error -Used if the test performed is believed to have been 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.	 a. Forgetting to wipe away the first drop of blood b. Test strip did not fill all the way/patient did not bleed adequately c. Cleaned /tested wrong finger d. Squeezing the patient's finger too much for blood flow
Repeat Wash Hand- if a patient's glucose test is unexpectedly high, and may be the result of :	Result of residual sugar on the patient's hands	Repeat wash hands- washing and thoroughly dry the patient's hands with soap and water. Patient test is then repeated –the comment code documents corrective action and explain discrepancy between the first and second result (if any).
Expected Results	Patients results are consistent	Documented patient symptoms /history
*Lab Draw	Meter is reading LO or HI and patient results are questionable	Enter this comment and request a venous lab draw
* Provider Notified	Calling a critical glucose value	Used when reporting a critical value
Replaced test strip	New strips	Used when changing test strips
Wrong QC used	Wrong qc used for testing	Repeat with correct qc
**Cleaned Disinfected	Cleaned/disinfected meter	Perform after each patient- clean/disinfect meter
No action needed	No action needed	
*QC okay	Lo & HI QC ran	Both levels with in-limits PASS
Patient treated	Patient treated	Patient treated based on glucometer glucose

F. In emergencies, where barcode scanning or patient ID is not readily available :

- visitor/ employee down, patient's armband was removed, ill patient in an outpatient setting whose ID is not readily available, etc.
- 1. Any operator in an emergency situation can manually type in for the patient ID code: 999999999 OR 123456789
 - a. Perform patient testing as you normally would.
 - b. Phone the Ancillary Testing Coordinator @ extension # 65771 with the person's correct name and SSN.

c. Communication will occur between the Ancillary Testing Coordinator and the Nurse Manager for follow-up as needed.

XII. LIMITATIONS

- A. The ACCU-CHEK Inform II test strips are for testing fresh capillary whole blood. Only ICU/ER/Nuclear Medicine may test blood obtained from a line.
- B. Hematocrit should be between 10–65 %.
- C. Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- D. Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- E. Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.

THIS SYSTEM IS NOT TO BE USED ON "CRITICALLY ILL". THE SYSTEM IS NOT VALIDATED FOR USE ON CRITICALLY ILL PATIENTS AS DEFINED BELOW. A LABORATORY VENOUS DRAW IS REQUIRED ON THESE PATIENTS. STRATTON VAMC (Albany, NY) DEFINES CRITICALLY ILL AS THE FOLLOWING:

- i. Mean Arterial Pressure (MAP) of <65mmHg AND
- ii. Use of IV vasopressors OR inotropes to maintain blood pressure.

Please refer to the Critical Patient ACCU-chek Inform II Glucometer Flowchart.

- F. 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:
 - 1. Severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome (HHNK)
 - 2. Hypotension
 - 3. Shock
 - 4. Decompensated heart failure NYHA Class IV
 - 5. Peripheral arterial occlusive disease.
- G. 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.

XIII. REFERENCES:

- Comprehensive Policies, Processes and Procedures Manual For use with the ACCU-CHEK Inform II Glucose Monitoring System, Roche Diagnostics, 3/2013.
- Accu-Chek Inform II Test Strips Package Insert, Roche Diagnostics, 1/2013.
- Accu-Chek Inform II Control Solutions Package Insert, Roche Diagnostics, 1/2013
- CAP Point of Care Testing Checklist 2015