Memorial Surgery Center at Ridgeview Document

ROCHE ACCU-CHEK INFORM II

PURPOSE:

The ACCU-CHEK® Inform II test strips are for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, heel-stick neonatal, or fresh capillary whole blood samples drawn from the fingertips as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.

The ACCU-CHEK Inform II Blood Glucose Monitoring System is intended for testing outside the body (*in vitro* diagnostic use) and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. The multiple-patient use ACCU-CHEK Inform II Blood Glucose Monitoring System will consist of:

- Meter: ACCU-CHEK Inform II Meter
- Test Strip: ACCU-CHEK Inform II Test Strip
- Controls: ACCU-CHEK Inform II Control Solutions
- Linearity: ACCU-CHEK Linearity Kit

POLICY:

Safety Information:

- All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals.
- Follow your facility's infection control procedures when handling blood-contaminated items. Always adhere to the recognized procedures for handling objects that are potentially contaminated with human material. Follow the hygiene and safety policy of your laboratory or institution.
- Disinfect the meter after use on each patient. The ACCU‑CHEK Inform II system may only be used for testing multiple patients when Standard Precautions and the ACCU‑CHEK Inform II system disinfecting procedures are followed.
- Read and follow the ACCU‑CHEK Inform II cleaning and disinfecting instructions found in the ACCU‑CHEK Inform II Operator's Manual.
- Perform thorough hand hygeine before and after testing each patient.
- Always wear a new pair of clean gloves for each patient.
- Never use fingerstick devices for more than one person. Use auto-disabling, single-use fingerstick devices for assisted monitoring of blood glucose.

Meter Cleaning and Disinfection:

Clean the meter to remove visible soil and organic material prior to disinfection. Disinfect the meter to destroy pathogenic and other type of microorganisms. Cleaning and disinfection must be performed between each patient use.

Cleaning

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

3. Use a Super Sani-cloth to clean by gently wiping the outside of the meter and carefully around the test strip port.
4. Dry meter thoroughly with a dry cloth or gauze.

Disinfecting

1. Use a fresh Super Sani-Cloth to disinfect by gently wiping the outside of the meter three times horizontally and three times vertically. Avoid the test strip port.
2. Allow the meter to stay damp the 2 minute contact time suggest by the manufacturer.
3. If the patient is under enteric precautions, prior to step 1 of the disinfection process, the meter must be wiped with a bleach cloth, with a contact time of 1 minute. Then proceed to step 1 above.
4. Dry meter thoroughly with a dry cloth or gauze.

Accu-Chek Operator's Manual pages 125-128

SPECIMEN:

Sample size: 0.6 µL.

Fresh, un-anticoagulated whole blood: venous, arterial, or capillary (fingerstick or neonatal heelstick), used immediately. EDTA or Heparinized anticoagulated samples can be used within 30 minutes of collection.

Reject specimen:

- If clotted
- Greater than 30 minutes from time of draw
- Other anticoagulant used than stated above
- Neonatal Cord Blood
- Specimens with marked lipemia

MATERIALS:

- Meter: ACCU-CHEK Inform II Meter
- Test Strip: ACCU-CHEK Inform II Test Strip (stocked in the department or can be obtained from the purchasing stockroom)
    - 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 39–86 °F (4–30 °C).
    - Do not freeze.
    - Store unused test strips in the original container with the cap closed. Do not remove test strips from the test strip container and put them into another container such as a plastic bag or pocket, etc.
- Controls: ACCU-CHEK Inform II Control Solutions (stocked in the department or can be obtained from the purchasing stockroom)
- Linearity: ACCU-CHEK Linearity Kit
- Adjustable auto-disabling, single-use fingerstick device

QUALITY CONTROL:

Controls: ACCU-CHEK Inform II Control Solutions-

Quality Control materials for 2 levels must be run every 24 hours of use. The device will lock out the user for patient testing until complete. Additional routine QC solution testing should occur when there is a circumstance that could affect the performance of the meter, the strips or the operator such as:

- New Meter
- Meter dropped or exposed to extreme temperatures, humidity, heat, etc.
- Cap left off test strip vial
- When a new vial of strips opened
- Operator wants to confirm technique
- Should questionable patient results be displayed

Control procedure:

1. Turn on the device.
2. Scan operator ID.
3. Select Control test.
4. Select a level (Level 1 Lo or Level 2 Hi).
5. Scan barcode on the selected level.
6. Scan strip lot.
7. Insert a strip, ensuring the canister lid is fully closed after removing a strip.
8. Mix Control material thoroughly, wasting the first drop.
9. When the Accu-Chek prompts to add Control material, hold the QC bottle horizontal while forming a drop on the end and then touching the drop to the end of the strip.
10. Results will appear within 5 seconds. Pass or Fail will display on the screen.
11. If Pass, then repeat steps 4-10 on the other level.
12. If the result is Fail, then a comment must be made by selecting the comment button on the bottom left of the screen. Then select a comment that matches next steps.
13. Controls will need to Pass for both levels prior to running patient testing. Troubleshooting steps could include:
    a. Repeat testing
    b. Ensure the levels were not switched during testing.
    c. Repeat with new or different set of Controls.
    d. Repeat with new box of strips.
14. If troubleshooting fails, the device must be removed from use and the Point of Care department in the lab must be notified. Ext. 5847.

QUALITY ASSURANCE:

Linearity: ACCU-CHEK Linearity Kit-
Linearity testing is performed and verified prior to use of each new device.

Comparison Studies: CAP WBG-Q kit performed on a subset of glucometers two times per year as a quality cross check between devices and with a peer group.

CALIBRATION:

N/A

PROCEDURE:

1. Perform hand hygiene and don personal protective equipment (gloves, gowns, etc.) as required by infection control and isolation policies and procedures.
2. Turn on the device.
3. Scan operator ID.
4. Select Patient test.
5. Scan Patient ID on wristband (can be manually entered if required, be careful to ensure correct entry).
6. Verify the entered number matches the patient ID, perform a two part patient identification.
7. Scan the test strip lot.
8. 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.
9. 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.
10. Have the patient clean their hands with soap and water if available. If not, use an alcohol prep pad ensuring the cleaned finger is fully dry prior to testing. The site can be warmed prior to cleaning, if required.
11. Perform the appropriate phlebotomy procedure dependent on sample type to be used. Fingerstick on the sides of the finger. Heelstick on the sides of the heel. Venous or arterial samples via phlebotomy or line draw. Waste the appropriate volume of sample prior to testing from a line draw.
12. Waste the first drop of sample by either wiping away with gauze or dropping out of syringe.
13. Apply second drop to the end of the test strip (not the top).
14. Results will display within 5 seconds.
15. Touch  to enter up to three appropriate comment(s) as required. Documenting "Meter Cleaned" in the result each time.
16. Touch the  button to confirm the result and send the result from the meter wirelessly.
17. Dispose of auto-disabling, single-use fingerstick device and test strips into a rigid sharps container.
18. Clean and disinfect the meter, using the Meter Cleaning and Disinfection instructions from the Policy section above.
19. Remove required PPE and perform hand hygiene.
20. Return the meter to the docking station.

RESULT REPORTING:

Results are transmitted to the patient's chart in Cerner wirelessly.

REFERENCE RANGES:

Test	Units	Age	Normal Range		Critical Range		Reportable Range	
Glucose	mg/dL	0-30 days old 1 month- Adult	40 60	90 100	30 50	300 500	10 10	600 600

Critical Values must be documented in the meter as "MD/RN notified", and "Lab Glucose Ordered" (if required for confirmation).

Documentation must also be made in the patient's chart that includes the provider notified, date, time, that the result was read back and who performed the notification.

PROCEDURE NOTES:

Only trained healthcare professionals may operate the ACCU-CHEK Inform II system. Operators must also have received comprehensive instruction in the operation, quality control, and care of the ACCU-CHEK Inform II system. Operators are required to complete annual recertification.

LIMITATIONS OF PROCEDURES:

- The ACCU‑CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
- Hematocrit should be between 10–65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce falsely elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- This system has been tested at altitudes up to 10,000 feet.
- ***The performance of this system has not been evaluated in the critically ill. It is the provider's discretion as to which patient meets this category.***

TROUBLESHOOTING:

Refer to the Accu-Chek Inform II Operator's Manual found on the intranet under:
Applications>Lab Test Catalog>Point of Care>Procedures/Manuals
If error cannot be resolved, notify the Point of Care department in the lab, ext: 5847.

REFERENCES:

Accu-Chek Inform II Operator's Manual
Accu-Chek Inform II Test Strips and 1 Code Key Package Insert
Sample Template for Accu-Chek Inform II Glucose Monitoring System

DOCUMENT REVIEW:

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