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**PURPOSE:**

Point of Care glucose monitoring allows for the rapid evaluation and monitoring of patient whole blood glucose at the bed side for patient with glycemic disorders.

**PRINCIPLE:**

The ACCU-CHEK Inform II system quantitatively measures glucose in whole blood. The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase from Acinetobacter calcoaceticus, recombinant in E. coli, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless electrical DC current that the meter interprets for a glucose result. The sample and environmental conditions are also evaluated using a small AC signal.

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

**POLICY:**

The ACCU-CHEK Inform II system is used within its limitations as describes by the manufacturer’s most current literature in interference and limitations – See list below and manufacturer’s ACCU-CHEK Inform II test strip package insert and literature.

The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.

\*Hematocrit should be between 10-65%.

\*Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.

\* Blood concentrations of galactose>15mg/dL will cause overestimation of blood glucose results.

\*Intravenous administration of ascorbic acid which results on blood concentration 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.

* **Result Ranges:** The normal, critical and reportable ranges of the ACCU-CHEK Inform II system are established as described in the table below, Results that exceed the reportable and critical range of the system require follow up as described in the *Patient Testing* section if this manual,
* **Reportable Range:** The meter is configured to display a non-numeric result (RR LO/RR HI or LO/HI; measurement range default) for tests that exceed the established reportable range 28-550 mg/dL.
* **Critical Range:** The meter is configured to display a result (CR LO or CR HI) for test that exceed the established critical range of <40 mg/dL and >450 mg/dL.

**A venous blood sample will be obtained and sent to the laboratory to confirm all glucometer results <40 mg/dL and >400 mg/dL and also any patient the glucometer is unable to give a result for.**

Patient testing with the ACCU-CHEK Inform II system quantitatively measures glucose in fresh venous, arterial, neonatal heel stick and capillary whole blood from the finger and is used as an aid in monitoring the effectiveness of glucose control. The procedure below describes the steps taken to perform patient testing on the ACCU-CHEK Inform II system; General patient testing policies are as follows:

1. Patient testing must be ordered according to established test ordering policies and procedures.
2. Patient samples are collected according to established phlebotomy procedures.
3. Patients are identified for testing by means of medical record number. Patient identifiers are entered into the ACCU-CHEK Inform II system when prompted by the meter.
4. Patient identification numbers are entered into the ACCU-CHEK Inform II system by means of the numeric key pad.

**Acceptable Samples:**

1. The following fresh whole blood samples types may be used:
2. Venous whole blood
3. Arterial whole blood
4. Capillary (non-neonate fingerstick and neonate heelstick) whole blood
5. The following anticoagulants are acceptable (do not use any other anticoagulants for meter testing):
6. Lithium or Sodium Heparin
7. EDTA

**PROCEDURE:**

1. Performing the Test:
2. Place the meter on a level surface free from vibration.
3. Press the **ON/OFF** button to power on the meter.
4. **Performing self-check…**displays as meter performs self checks.
5. The **Power Up** screen briefly displays.
6. If QC Lockout has activated:
7. QC Due: immediately displays.
8. Operator must perform QC to proceed with testing.
9. The **Operator ID** screen displays after 5 seconds, or touch to advance to the **Operator ID** screen.
10. Scan the **Operator ID**
11. Hold your employee ID barcode parallel to and approximately 4 to 8 inches from the scanner port on the top edge of the meter.
12. **Touch & release** the **SCAN** icon on the screen.
13. The barcode scanner icon will turn darker while scanning.
14. Do NOT press and hold the icon. The scanner activates **after** you release the icon, not when you are touching it.
15. After a successful scan the meter beeps and the main menu appears.
16. Select the **Patient Test** icon from the menu.
17. Scan the **Patient ID** and confirm the meter identified the correct patient.
18. **In-Patients:** Verbally verify patient identity, (i.e. full name, DOB, etc.) and compare with wristband. Scan the patient’s wristband barcode identification number (account number).
19. If the patient ID cannot be read, print a new armband or admission document. Additionally, refer to the Unregistered Patient Procedure.
20. **Strip Lots** entry screen displays.
21. Scan the barcode from the test strip vial.
22. **“Please wait I-304: Performing Code Key Checks”** displays.
23. Available lots and code key data may only be assigned and entered by the POCT department.
24. If the scanned test strip lot is not recognized by the meter:
25. **Patient ID** and **Strip Lot** are displayed with a prompt to insert a test strip.
26. A **Moving Arrow** displays next to a **Test Strip** icon.
27. Insert the test strip at the top edge of the meter with the gold bars (strip electrodes) facing upward on the end to be inserted.
28. The test strip protrudes from the meter with the yellow sample window facing upwards in the outer tip of the test strip.
29. Display prompts operator to apply sample.
30. **Test Strip** icon displays with a flashing blood drop.
31. Touch a drop of blood to the yellow sample window at the end of the test strip.
32. Test begins automatically when adequate sample volume is added.
33. A flashing **Hourglass** icon displays while the test is being completed.
34. The test result displays and the meter beeps when test is complete.
35. Press to save the selected comments and the result.
36. Press return to the **Main Menu**.
37. Remove the test strip and dispose of appropriately.
38. Clean the meter as described in the Instrument Maintenance section.
39. Document patient test results on log sheets according to nursing policy.

**QUALITY CONTROL MATERIALS:**

1. 2 levels of Accu-Chek Inform II control solutions are run:
2. Each day (24 hours) that the meter is used for patient testing
3. Before a new vial of test strips is put in use
4. When training a new user
5. When the test strip vial has not been kept closed promptly
6. When the meter has been dropped
7. When unusual, unexpected or inconsistent results are determined
8. If meter performance is in question
9. Unopened vial of Quality Control solutions are stable at room temperature 4\*C to 30\*C (39\*F – 86\* F) until the manufacturer outdate.
10. Opened vials of Quality Control solutions are stable at room temperature 4\*C to 30\*C (39\*F – 86\*F) for 3 months.

**QUALITY CONTROL PROCEDURES:**

1. Place the meter on a level surface free from vibration.
2. Press the **ON/OFF** button to power on the meter.
3. **Performing self checks** displays.
4. The Power Up screen briefly displays.
5. If QC Lockout has activated: **QC Due: Immediately** displays.
6. The **Operator ID** screen displays after about 5 seconds, or touch to advance to the **Operator ID** screen.
7. Scan the **Operator ID** as described in Performing the Test (VII.A.4).
8. Select the **Control Test** icon from the **Main Menu.**
9. Select **Level 1 (Lo)** or **Level 2 (Hi).**
10. Control Test entry screen displays and indicates the selected level.
11. Scan the barcode from the selected control vial.
12. Strip Lots entry screen displays.
13. Scan the barcode from the test strip vial.
14. Please Wait I-304: Performing Code Key Checks display.
15. Control Level & Lot and Strip Lot display with a prompt to insert a test strip.
16. Insert a test strip.
17. Display prompts operator to apply control.
18. Touch a drop of control solution to the yellow sample window at the end of the test strip.
19. Test begins automatically when adequate control volume is added.
20. A flashing Hourglass icon displays while the test is being completed.
21. The test result displays a “PASS” or “FAIL” when test is completed.
22. If meter displays “PASS”, proceed to step 16.
23. Patient testing may NOT be performed unless both control levels are acceptable.
24. If meter displays “FAIL”, perform these corrective actions in the following order until an acceptable result is obtained. Enter required QC Test comments to document QC failures.
25. Repeat the procedure.
26. Repeat the procedure using a new vial of test strips.
27. Repeat the procedure using a new vial of control solution.
28. Contact supervisor or POCT department and do not perform patient testing if QC is still unacceptable.
29. Press Comments to select up to 3 comments. See #20, below, for example comment for QC.
30. Press to save the selected comments and QC result. The meter will return to the Control Test menu.
31. Repeat Steps 6 through 16, selecting the other level of control.
32. Press to save the selected comments and QC result. The meter will return to the Main menu.
33. QC Test Comments
34. Required for QC failures
35. Up to 3 comments may be attached to each control result.
36. Press “Comments” and choose appropriate comment:
37. Wrong Level QC Run: Incorrect QC material selected.
38. Procedure Error: Known procedure error occurred.
39. Repeat Control Test: Use when QC test was repeated.
40. Cleaned Meter: Use when troubleshooting requires cleaning the meter.
41. New Vial Strips Used: Use when repeat testing is performed on a new vial of attest strips.
42. New Vial of QC Used: Use when repeat testing is performed with a new vial of QC material.

**Refer to the ACCU-CHEK Inform II Operator’s Manual for system set-up/configuration instructions.**

**REFERENCES:**

1. Roch diagnostics Operator’s Manual: *Accu-Chek Inform II System Operator’s Manual*, Indianapolis, IN: Roche Diagnostics; Roche Diagnostics; Rev. 10/2012
2. Roche Diagnostics Quick Reference Guide: *Accu-Chek Inform II System Quick Reference Guide*, Indianapolis, IN: Roche Diagnostics: Rev. 10/2012
3. Roche Diagnostics Package Insert: *Accu-Chek Inform II Test Strips*, Indianapolis, IN: Roche Diagnostics; Rev. 2012
4. Roche Diagnostics Package Insert: *Accu-Chek Inform II Controls*, Indianapolis, IN: Roche Diagnostics; Rev. 2012.