Glucose, Whole Blood
Accu-Chek® Inform II

Point of Care Testing Education
Regional Laboratory Services
Rev. 03/2013
Objectives:

- Review the use of Accu-Chek Inform II Glucose meter
- Meter Components
- Principles of operation
- Specimen requirements
- Reagent/Supplies/Equipment
- Test Strip & Control Requirements
- Perform and document Quality Control
- Perform and document Patient Results
- Interpret Results/Documentation
- Troubleshooting
- Instrument Maintenance
Meter Components:

The base unit:
• Charges the meter battery pack.
• Communicates with a data management system, if available.

Store the meter on the base unit to:
Charge the battery pack
Download QC & Results
Upload new lot data
Upload patient information
Principles of Operation:

• Test method
  – The meter combines whole blood with chemicals in the test strip.
  – A measured small electrical current is produced proportional to the amount of glucose.

• Regulatory class: This test is CLIA-waived & definitive

• Confirmatory testing is required if unexpected results are achieved. Send a specimen to the laboratory if:
  – Critical values are obtained and they have not been verified previously.
  – No results are obtained (instrument displays a code instead of a value)
  – Repeated results are not confirmed within accepted limits
    • A Glucose result of < 75 mg/dL is confirmed if repeat is ± 15 mg/dL
    • A Glucose result of > 75 mg/dL is confirmed if repeat is ± 20%
  – Confirmed results are inconsistent with the patient’s condition
Specimen Requirements:

• Acceptable specimens
  – Capillary whole blood from a fingerstick or heelstick
  – Venous or arterial fresh whole blood tested immediately
  – Venous or arterial whole blood collected in EDTA or Heparin & tested within 30 minutes.

• Unacceptable specimens
  – Capillary specimens from alternate sites (palm, forearm, etc.)
  – Specimens collected in other anti-coagulants
  – Specimens from patients with Hematocrit < 10% or > 65%
  – Specimens from patients with impaired peripheral blood circulation or dehydration
  – Specimens with marked lipemia (triglycerides > 1800 mg/dL)
  – Cord blood, serum or plasma
Reagents / Supplies / Equipment:

• Reagents
  – Accu-Chek Inform II Test Strips
  – Accu-Chek Inform II Quality Control (2 levels)

• Supplies
  – Routine fingerstick or phlebotomy supplies

• Equipment
  – Accu-Chek Inform II Test Meter & Accessory Tote
  – Accu-Chek Inform II Base Unit / Docking Station
Reagents:

NOTE: New lot numbers are entered by the POCT department. Data will upload when the meter is docked.

- Accu-Chek Inform II Test Strips:
  - Test strips **expire at manufacturers date on bottle**
    - Document “Opened Date” on vial
    - Do NOT insert a test strip until prompted by the meter
    - Do NOT apply specimen to a test strip until prompted by the meter
    - Test strips are sensitive to heat, light and moisture
    - Store sealed in the original bottle at room temperature
    - Use test strips within 3 minutes after removing from the container
    - Do not freeze, or place in direct heat or sunlight

- Accu-Chek Inform II High & Low Control solutions:
  - Controls **expire 3 months after opening**
    - Document “Opened Date” and “Discard Date” (MM/DD/YY)
    - Store at room temperature
  - Discard all expired strips and control solutions
Quality Control:

- Perform 2 levels of Quality Control every 24 hours on each meter

If “QC Due: immediately” displays, the meter locks out until QC testing is performed

1. Press the ON/OFF button to power on the meter
2. Meter performs self checks
3. Wait for Operator ID screen or Press to display the screen
4. Scan “Operator ID” by touching & releasing
5. Select “CONTROL TEST” from the menu
6. Press “LEVEL 1 (Lo)” or “LEVEL 2 (Hi)” to select level to test
7. Scan “CONTROL LOT” barcode on the selected control
8. Scan “STRIP LOT” barcode on the selected test strip vial

NOTE: If Control or Test Strips are not recognized:

- Dock the meter to upload new lot data
- If problems continue, contact POCT department
Quality Control:

10. Insert test strip when prompted
    – Insert at the top edge of the meter
    – Gold electrodes face up and push in to the meter

11. Apply gently mixed control solution when prompted
    – Touch drop of solution to the yellow area at the tip of test strip
    – Test begins automatically when adequate volume is applied
    – A flashing Hourglass displays while the test is being completed

12. The QC test result displays “PASS” or “FAIL” when completed

13. QC Test Comments are required for all QC failures
    – Press COMMENTS to select up to 3 comments
    – Press to record comments and save result

14. Remove the test strip and dispose of appropriately

15. Repeat the same steps for both control solutions
Patient Testing:

1. Press the **ON/OFF** button 🔄 to power on the meter
2. Meter performs self checks
3. Wait for Operator ID screen or Press 📣 to display the screen
4. Scan your **“Operator ID”** by touching and releasing 📨
5. Select **“Patient Test”** from the menu
6. Scan the **“Patient ID”** and confirm the identification is correct
7. Scan the **“STRIP LOT”** barcode from the test strip vial
   - If the scanned barcode isn’t recognized, dock the meter to upload
   - If the barcode still isn’t recognized, contact the POCT department
8. Confirm correct patient identification is displayed
9. Insert test strip when prompted
10. Apply sample when prompted
    - Wipe first drop of blood away to eliminate tissue fluid contamination
    - Touch a drop of blood to the yellow area at the tip of the test strip
    - Test begins automatically when adequate sample volume is applied
11. A flashing Hourglass displays while the test is being completed
Patient Testing:

12. The test result displays and the meter beeps when test is complete

13. Patient Test Comments are required on Critical Values
   – Press COMMENTS 🆙 to enter up to 3 comments
   – Press ✓ or MENU to record comments and save result

12. Remove the test strip and dispose of appropriately

13. Place meter in docking unit to:
   – Download results
   – Upload new reagent lot data
   – Upload new ADT patient information
   – Recharge the
Result Interpretation and Documentation:

 Reference Range
  • 0 – 30 days 45 – 100 mg/dL
  • 30 days – Adult 60 – 99 mg/dL

 Critical Value Range: (Displays CR LO or CR HI)
  • 0 – 30 days < 35 mg/dL or > 200 mg/dL
  • 30 days – Adult < 40 mg/dL or > 400 mg/dL
  • Follow your Critical Value Reporting policy

 Reportable Range: (Displays as RR HI or RR LO)
  • RR HI result > 500 mg/dL
  • RR LO result < 30 mg/dL
  • Follow your Critical Value Reporting policy

 Attach up to 3 comments to critical values
 Document results per your department work flow
Troubleshooting:

• If a result is unexpected or inconsistent with patient condition:
  – Perform QC using the same meter and test strips
    • If QC is acceptable, the meter is performing as expected, REPEAT the patient test
      – If repeat patient test confirms, report the original result. Attach comment to repeat test
      – If repeat patient test does not confirm, refer a blood sample to the lab
    • If QC fails, repeat the QC using new control solutions and/or a new vial of strips
      – If repeat QC is acceptable, the meter is performing as expected, REPEAT the patient test
      – If repeat QC fails:
        » Sequester the meter and the original test strip vial and QC solutions
        » Contact the POCT department
        » Test patient using a different meter, a new test strip vial and new QC solutions
        » Or, refer a venous sample to the lab

• Range limits for acceptable confirmation by repeat:
  – If patient result is \( \leq 75 \text{ mg/dL} \), repeat test must agree within \( \pm 15 \text{ mg/dL} \)
  – If patient result is \( > 75 \text{ mg/dL} \), repeat test must agree within \( \pm 20\% \)
Instrument Maintenance:

• Transport the meter and all accessories in the tote
• Store the meter on the docking station / base unit
• Sanitize the meter and tote between each patient prior to leaving the patient’s room
• Approved sanitizing wipes are:
  – PDI Super Sani-Cloth is approved for routine usage
  – Clorox Germicidal Wipe (EPA 67619-12) is **required** for any patient in Contact Enteric Precautions
• Don’t allow excess liquid to enter or remain on the meter
• Clean the docking station/base as needed
  – Wipe the surfaces with a soft cloth dampened with water (NOT WET)
  – Do NOT get the connector in the base unit wet
  – Dry thoroughly after cleaning