PURPOSE

Whole blood glucose testing with Accu-Chek® Inform II monitors is used to monitor blood glucose concentrations for adjustments of insulin dosage in diabetic patients. It is not used for definitive diagnosis (e.g., diabetes, insulinoma). Definitive testing for apparent hypoglycemia (<40 mg/dl) or severe hyperglycemia (> 400 mg/dl) detected by these meters requires sending a sample to the laboratory.

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.

This test is definitive for the purposes of following existing nursing protocols.

NOTE: Complexity is waived.

SPECIMEN

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

- Sample volume 0.6 µL
- Hematocrit should be between 10–65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated 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.
- Store all supplies at room temperature.

SAMPLE COLLECTION AND PREPARATION

Venous or arterial samples

The following criteria need to be met when performing a blood glucose test on venous or arterial samples.

- Caution should be taken to clear arterial lines before blood is drawn.
- To minimize the effect of glycolysis, blood glucose determination with venous or arterial blood must be performed within 30 minutes of sample collection.
- Avoid air bubbles with the use of pipettes.
- Fresh venous and arterial blood samples containing the anticoagulants EDTA, lithium heparin, or sodium heparin are acceptable. *Iodoacetate or fluoride-containing anticoagulants are not recommended.*
- Refrigerated samples should be brought to room temperature slowly prior to testing.

Intereferents

- 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.
- As a matter of good clinical practice, caution is advised in the interpretation of neonate blood glucose values below 50 mg/dL. Follow the unit guidelines for follow-up care that have been set for critical blood glucose values in neonates. Glucose values in neonates suspect for galactosemia should be confirmed by an alternate methodology.

QUALITY CONTROL

Quality control must be performed every day that patient tests are performed. Every twenty-four (24) hours a low and high-level glucose control must be performed prior to testing patient samples. Rotate performance of QC among all operators.

Upon opening the liquid QC is good for 3 months or the printed expiration date on the vial, whichever comes first.
When new vials of liquid QC are opened, document the open date in the "opened" prompt provided on the label to include mm/dd/yy. Count out 3 months and document the expiration date in the "expiration" prompt provided on the label to include mm/dd/yy.

The Accu-Chek® Inform II will lock out operators from performing patient tests when the previous twenty-four hour quality control tests have expired or if QC performed fails acceptability ranges.

1. Turn on the Accu-Chek® Inform II® meter.
2. Enter or your operator ID by means of barcode scanning, or manual entry. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or the Point of Care Testing office at (434) 982-0483.. **DO NOT** attempt to perform tests under another operator's ID.
3. From the *Main Menu*, touch *Control Test*.
4. Select the level of control that you wish to test then scan the barcode on that bottle.
5. Confirm that the meter is coded (calibrated) to the same test strip code that is printed on the test strip vial by scanning the barcode on the bottle of strips you are using. Contact your supervisor, or the Point of Care Testing office if you are unable to confirm the correct test strip code.
6. 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.
7. 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. An error message will display if the sample is insufficient. If this occurs repeat the test.
8. The measurement is complete when the result is displayed on the meter screen.
9. Remove the test strip and dispose of it in a *CMC.*
10. Touch the comment button () to enter an appropriate comment(s) if required.
11. Touch the  button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter

Results do not need to be documented as they will automatically transfer the next time the unit is docked, or if wireless, the results transfer immediately.

In addition to once per 24 hours, two levels of quality control checks must be performed when:

- A new vial of test strips is opened.
- When a vial of strips has been left with the lid off.
- If the Accu-Chek® Inform II® monitor has been dropped.
- When test results contradict the clinical symptoms.

Contact the Point of Care office if QC repeatedly fails. The instrument will be unavailable for patient testing until quality control performance is within acceptable ranges.

REAGENT AND MATERIALS (See Addendum I for hospital store-room order information)

- Roche Diagnostics Accu-Chek® Inform II® monitor.
- Accu-Chek® Quality Control Glucose Solutions, Level one (1) and two (2)
  - Must be dated when opened; good for 3 months after opening or until printed expiration date (whichever is earlier). Do not use expired reagents.
- Accu-Chek® Inform II® test strips
  - The strips are good until printed expiration date. Do not use expired strips.
- Alcohol wipes, gauze or cotton balls, small plastic pipettes, bandaids or tape
- Lancets (one time use) or blood drawing devices
- Gloves

PROCEDURE FOR PATIENT TESTING

Adhere to Standard Precautions

1. Turn on the Accu-Chek® Inform II® meter.
2. Enter your operator ID by means of barcode scanning, or manual entry. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or the Point of Care Testing office. **DO NOT** attempt to perform tests under another operator's ID.
3. From the *Main Menu*, touch *Patient Test*.
4. Enter the patient identification in the Accu-Chek® Inform II® system by scanning the armband barcode, or manually enter by using the keypad.
5. Confirm that the meter is coded (calibrated) to the same test strip code that is printed on the test strip vial by scanning the barcode on the bottle of strips you are using. Contact your supervisor or the Point-of-Care Testing office if you are unable to confirm the correct test strip code.
6. The screen will display a picture of a test strip with a downward flashing arrow indicating that you are ready to insert a test strip into the meter.
7. 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.
8. Collect an acceptable blood sample according to your unit's established procedures.

   - **Fingerstick or neonate heelstick samples**: Clean the intended puncture site using an alcohol pad. Allow the area to dry prior to puncture. Test immediately as the sample is collected.
   - **Venous, arterial or line draw samples:** Test as soon as possible and no later than 30 minutes following collection. Be sure they are well mixed and that line draw samples have been thoroughly cleared of line fluids. Do not allow bubbles to enter the test strip-sampling chamber.

9. For capillary sticks be sure to wipe away the 1st drop of blood with dry, clean gauze. Use the 2nd drop of blood for testing.
10. 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.
11. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.
12. 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.
13. 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.
14. Remove the test strip and dispose of it in a CMC.
15. Touch  to enter up to three appropriate comment(s).
16. Touch the  button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.
17. Results may be documented in the patient chart per unit policy. Results will automatically transfer to the electronic medical record when docked or immediately if wireless.
18. Follow up on any results that exceed critical or reportable limits according to policy.
19. Clean and disinfect as necessary following your unit's policy.

REVIEWING RESULTS

The following information is displayed when a test result is reviewed:

- Patient ID, QC level or sample number
- The test result
- The lot number of the reagent(s) used to perform the test
- The date and time the test was performed.
- Comments that were entered at the time the test was performed.

1. With the Main Menu displayed, press **Review Result** button to display the Result screen.
2. The Result screen is displayed and lists all stored results. You can scroll through the results using the arrow keys (▲ ▼) at the bottom of the screen. To view details, select a result by touching the result with your fingertip.
3. Details of the selected results are shown. You can scroll through the results using the arrow keys (▲ ▼) at the bottom of the screen. Select **Back** to return to the result screen.
4. To display patient results only, select the **Patient** button at the bottom of the screen. The Patient ID screen is displayed.

5. Enter the patient ID by pressing the number keys on the touchscreen using your fingertip or by scanning.
   If you need to change your entry when using the manual entry method, press the ← to backspace.
6. The Result screen is displayed listing all stored results for the selected patient. You can scroll through the results using (▲ ▼) at the bottom of the screen. To view details select a result by touching the result with your fingertip.
7. Details of the selected patient results are shown. You can scroll through the results using the arrow keys (▲ ▼) at the bottom of the screen. Select **Back** to return to the Patient Result screen.
8. To display QC results, select the **QC** button at the bottom of the screen. The QC Result screen is displayed.
9. The QC Result screen is displayed listing all stored QC results. You can scroll through the results using the arrow keys (▲ ▼) at the bottom of the screen. To view details select a result by touching the result with your fingertip.
10. Details of the selected QC result are shown. You can scroll though the results using the arrow keys (▲ ▼) at the bottom of the screen. Select **Back** to return to the QC Result screen.

Press (▶) to return to the Main Menu screen.

REPORTING RESULTS

The patient's blood glucose result will be documented by the staff on the General Purpose Flow Sheet, which is a permanent record in the chart. The date, time, results, and name of tester must appear on the Flow Sheet. Additionally, as long as all steps listed above were performed correctly (operator ID, patient ID, etc), the result will be available as part of the electronic medical record.

Patient values less the 40 mg/dl or greater than 400 mg/dl (flagged results) should be repeated to ensure accuracy and called to the physician in charge of the patient. The physician will decide if a STAT venous sample for glucose testing should be sent to the Core Lab.

REFERENCE RANGES

Adult Fasting ($\geq$ 14 yr): 74 – 99 mg/dl
Child Fasting (0-13 yr): 60 – 99 mg/dl

MAINTENANCE AND HANDLING

Proper handling practices of the Accu-Chek Inform II Meter are:

- Handle the meter carefully; avoid dropping or banging it.
- Store the meter away from direct sunlight and extreme temperatures.
- Avoid spilling liquids on the meter.
- When preparing to clean the meter, read and follow the next section: **How To Clean the System.**

If the meter must be stored for an extended period of time, perform the following:

- Remove the Accu-Chek® Inform II® Meter batteries.

Note: Always download the Meter prior to removing the battery to avoid loss of data.

HOW TO CLEAN THE SYSTEM

- Health care professionals should wear gloves and follow UVa's Infection Control procedures when handling blood glucose testing equipment. It is important to keep the system clean and disinfected. The Accu-Chek® Inform II® meter should be cleaned and disinfected between each patient use.
- Any time a meter is found in an isolation room, it should be cleaned thoroughly.

I. ***METER, ACCSSORY BOX, AND BASE UNIT CLEANING PROCEDURE***

Use the following procedure to clean all the components of the Accu-Chek® Inform II® glucose testing system.

- **For C. diff patients always use bleach wipes to clean and disinfect the meter and base unit. Remove the bleach wipe and squeeze out the excess solution over a trash can or in a sink. The bleach wipes require a 4 minute contact time**. **Allow bleach to dry. Follow with a Sani-wipe to remove film from meter and base unit. Allow the meter and base unit to completely dry before returning the meter to the base unit.**

For all other patients use Sani-wipes to clean and disinfect the meter and base unit. Remove the Sani-wipe and squeeze out the excess solution over a trash can or in a sink. Sani-wipes require a 2 minute contact time. Allow the meter and base unit to completely dry before returning the meter to the base unit.

II. ***SCANNER WINDOW***

The scanner window on the bottom side of the Accu-Chek® Inform II® meter should be cleaned periodically Use a clean dry cloth to wipe the scanner; taking care to remove bleach residue that may accumulate and cloud the window which can affect the laser's ability to scan barcodes.

TECHNIQUE TIPS

1. Ensure the patient's fingers are sufficiently warm before performing capillary puncture.
2. Allow finger to completely air dry after cleaning with an alcohol pad.
3. Do not touch puncture site prior to performing puncture once area has been cleansed.
4. Avoid excessive squeezing or "milking" of finger when obtaining patient's blood.
5. Be sure to wipe away the 1st drop of blood with dry, clean gauze. Use the 2nd drop of blood for testing.
6. Do not smear the sample drop on the yellow target area of the glucose strip.
7. If an insufficient drop is initially placed to edge of yellow target area, additional sample may be added within 15 seconds to completely fill the yellow target area.
8. Apply pressure to the puncture site with dry, clean gauze. Dispose of lancet device in Sharps container.
9. Write your initials and opened/expiration date on QC solution & strip vial upon first opening. Follow these requirements:
    a. Test strips - Expiration date is printed on vial label by manufacturer.
    b. QC solution – Record your initials, open date, and expiration date in the spaces provided on the QC bottles (3 months from the date the bottle is first opened or the manufacturer's expiration date **whichever comes first.**)
10. Keep unit and monitor touchscreen clean by following the directions on page 8 of this procedure: How To Clean The System.
11. Replace the cap on the strip bottle immediately after removing strip for testing.
12. Store test strips at room temperature, protected from heat and light.
13. When scanning, **do not stare into the laser light beam**.
14. Dispose of one-time use lancets in a Sharps container. Dispose used glucose strips and bloody gauze in a contaminated materials container.
15. If the meter is not working, take it to the Medical Laboratories Blood Bank Laboratory located on the 2nd floor of UH, room 2621, and obtain a "Loaner" meter.
    on the 2nd floor UH, Room 2621, to obtain a "Loaner" meter.

** For questions, contact the Point of Care Testing Office at (434) 982-0483. **

SCANNING TIPS

The following tips will help you successfully use the barcode scanner:

- When scanning, hold the scanning window steady approximately four to eight inches from the barcode until you hear the beep indicating a successful scan (approximately 3 seconds). Make sure the laser beam covers the length of the barcode that is being scanned.
- If the attempted scan is unsuccessful (no beep is heard and the information does not appear on the screen), reposition the scanner, press the scan button, and try again.
- Clean the scanner window by wiping it periodically with a clean soft, dry cloth.

METHOD NOTES

Glucose quality control solutions are stable for three months after opening or until the expiration date, whichever comes first. Write the open and expiration dates on the new bottles and initial.

The test strips are good until the stated expiration provided they are capped after use and stored with the cap on. Always recap after removing a strip.

You must use the test strip immediately after removing it from the container.
Avoid air bubbles if dosing the strip from a plastic pipette.

Insufficient sample can cause erroneous results. Repeat the test using a new strip.

LINEARITY

The instrument reports values between 10 and 600 mg/dl. Lower values reported as "LO" and higher values as "HI".

CLINICAL SIGNIFICANCE

Causes of hyperglycemia include:

1. Diabetes mellitus
2. Hemochromatosis
3. Cushing's Syndrome
4. Acromegaly
5. Adrenalin injection
6. Pheochromocytoma
7. Stress (emotional, burns, shock, etc.)
8. Acute pancreatitis
9. ACTH administration

Causes of hypoglycemia include:

1. Hyperinsulinism
   - Islet cell tumor
   - Exogenous insulin
   - Non-pancreatic insulin secreting tumors
2. Early stage of diabetes mellitus
3. Hepatic disease
   - Toxic liver disease
   - Cirrhosis
   - Hepatoma
   - Reye's Syndrome
   - Hepatitis
4. Hypopituitarism
5. Addison's disease
6. Adrenal medullary unresponsiveness
7. Postgastrectomy syndrome
8. Malnutrition
9. Pediatric anomalies
   - Prematurity
   - Infant of diabetic mother
10. Inherited enzyme defects
    - VonGierke's disease (glycogen storage I disease)
    - Galactosemia
11. Hypothyroidism
12. In vitro glycolysis

** For questions, contact the Point of Care Testing Office at (434) 982-0483. **

REFERENCES

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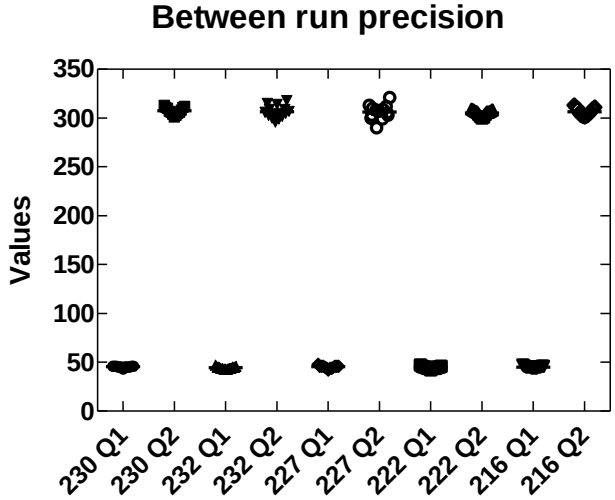
2. Ellenberg, M., and Rifkin H., et al., Diabetes mellitus Theory and Practice, 3rd Edition, p. 928 (1983)
3. Roche Diagnostics, Accu-Chek™ Inform II Blood Glucose Monitoring Systme Operator's Manual for Healthcare Professionals Version 1.0 October 2012 (05234646001 2012-10 USA)
4. Tietz, N.W., Textbook of Clinical Chemistry, p. 2112 (1994)
5. Roche Diagnosstics Accu-Chek™ Inform II Test Strips Package Insert Cat. No. 05942861001 ©2012 Roche Diagnostics 05942934001-1012

ADDENDUM I

GLUCOSE MONITORING SUPPLIES FROM THE STOREROOM

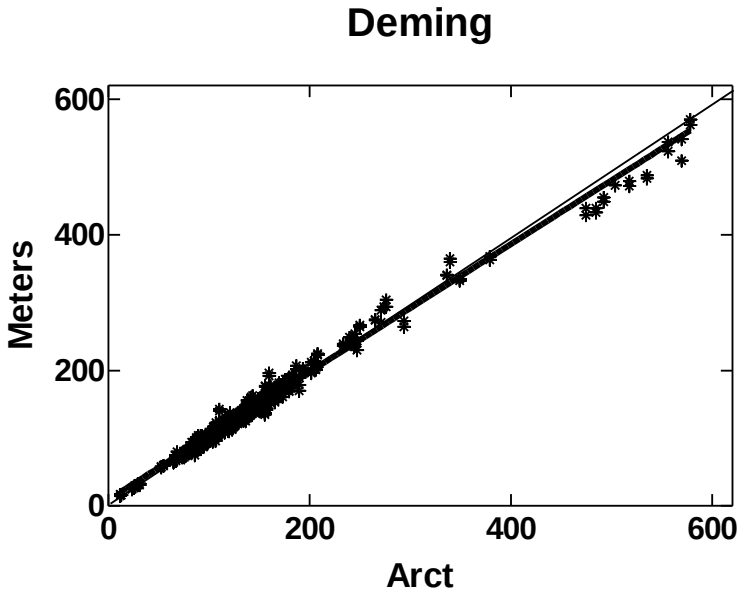
ACCU-CHEK® INFORM II QUALITY CONTROL SOLUTION	**BIN 92414**
ACCU-CHEK® INFORM II STRIPS	**BIN 92416**
TRANSFER BULB PIPETTES	**BIN 92517**
LANCETS (one time use)	**BIN 94002**
GREEN QC LABELS	**BIN 92417**
SUPERSANI GERMICICAL WIPES	**BIN 90603**

Validation data: Between run precision and Deming regression of patient comparisons (to Abbott Architect C16000®)



230 Q1	230 Q2	232 Q1	232 Q2	227 Q1	227 Q2	222 Q1	222 Q2	216 Q1	216 Q2
46	306	43	299	42	290	44	301	44	307
45	301	44	296	45	309	44	306	44	302
45	307	44	303	46	305	44	307	45	310
46	303	45	300	46	303	44	304	46	305
45	311	44	305	46	308	44	306	46	303
43	306	43	306	44	303	42	300	44	301
45	305	45	309	46	312	46	307	47	311
45	310	46	314	45	310	45	306	46	302
45	313	47	318	46	313	46	308	44	310
46	311	45	315	48	321	47	309	45	311
45	308	44	302	44	299	45	302	45	303
46	304	45	309	46	300	45	304	45	305
46	312	43	307	44	307	45	308	45	313

	230 Q1	230 Q2	232 Q1	232 Q2	227 Q1	227 Q2	222 Q1	222 Q2	216 Q1	216 Q2
Number of values	13	13	13	13	13	13	13	13	13	13
Mean	45.23	307.5	44.46	306.4	45.23	306.2	44.69	305.2	45.08	306.4
Std. Deviation	0.8321	3.733	1.198	6.564	1.481	7.636	1.251	2.833	0.9541	4.154
Std. Error	0.2308	1.035	0.3323	1.821	0.4107	2.118	0.3469	0.7857	0.2646	1.152
Coefficient of variation	1.84%	1.21%	2.70%	2.14%	3.27%	2.49%	2.80%	0.93%	2.12%	1.36%



	Meters
Best-fit values	
Slope	0.9422 ± 0.004167
Y-intercept when X=0.0	9.301 ± 0.6769
X-intercept	-9.872
1/slope	1.061
95% Confidence Intervals	
Slope	0.9341 to 0.9504
Y-intercept when X=0.0	7.972 to 10.63

	Meters
Number of XY Pairs	321
Pearson r	0.9943
95% confidence interval	0.9929 to 0.9954
P value (two-tailed)	< 0.0001
P value summary	****
Is the correlation significant? (alpha=0.05)	Yes
R square	0.9887