Accu-Chek Inform II CBG Procedure

I. PRINCIPLE/PURPOSE

Any patient requiring blood glucose levels for the purpose of monitoring and managing diabetes control or glucose levels. A review of glucose metabolism is essential in order to appreciate blood glucose concentration variations that may reflect primary abnormalities of carbohydrate metabolism as well as secondary abnormalities accompanying other diseases.

The Inform II use in a rapid response situation, before the patient can be evaluated for the "Limitations" criteria, is as an aid in determining treatment, NOT as a means of diagnosis. It is recommended to follow-up with a laboratory draw and monitor patient for any adverse events.

II. MATERIALS

A. Gloves
B. Accu-Chek Safety Pro Lancets (One time use device to be stored in primary box)
C. Alcohol pads
D. Gauze or cotton balls
E. Accu-Chek Inform II test strips (Stored in Lab)
F. Accu-Chek Inform II Control Levels 1 & 2 (Stored in Lab)
G. Super Sani-Cloth (EPA reg. no. 9480-4)

III. EQUIPMENT

A. Accu-Chek Inform II CBG Meter
B. Computer with access to LIS

IV. QUALITY CONTROL

A. Purpose
   1. Quality control testing validates the integrity of the strips, the correct coding and calibration of the meter, and operator technique.
   2. QC should be done on a routine basis and whenever there is a change in the meter, strips or with questionable test results.
   3. The meter will alert the user when the QC testing is due.

B. Material Stability
   1. Accu-Chek Inform II control levels 1 and 2 are stable for 90 days once opened at temperatures between 4 to 30°C.
      a. A new expiration date must be written on the bottles once they have been opened.
      b. The expiration date will be the shortest, the open 90 expiration or the manufacture expiration.
   2. Accu-Chek Inform II strips are stable at 4 to 30°C until the expiration date on the test strip bottle.
      a. The test strips must be used immediately after being removed from the bottle.

   b. Tightly close the lid immediately after removing strips.
   c. Do not return strips to the bottle.
3. No "open" dates are necessary on strips, but the control material MUST have the written expiration date clearly indicating that it is the expiration date. Use "exp." or an "X" before the date **(example: exp 01-01-18).**

C. Frequency

1. Control Levels 1 (low) and 2 (high) will be run once in a 24 hour period. The meter will lock-out further patient testing until QC is performed and an acceptable result is obtained.
2. QC will also be performed in the following situations:
   a. Each time new control lot is put into use
   b. Each time a new lot of tests strips is opened
   c. Each time a new vial of test strips is opened
   d. When a vial of strips has been left opened more than 60 seconds
   e. If the Accu-Chek Inform II™ System has been dropped
   f. When test results contradict clinical symptoms
   g. If questionable test results are displayed repeatedly
   h. If you wish to test the performance of the sytem.
3. Patient testing may only proceed when quality control results are within the acceptable control range.
   a. This is indicated as PASS or FAIL.
   b. If the QC results FAIL, the problem must be corrected before any patient testing is performed.

D. Quality Control Procedure

1. Put on disposable gloves.
2. Press power ON button.
3. Enter your operator ID and then press the forward arrow button.
4. Select Control Test.
5. Press the Barcode button and scan the barcode for either one of the control solutions bottles: Level 1 (Low) or Level 2 (High).
   a. Ensure the solution has not expired by viewing manufacturer's expiration date on the bottles and the hand written expiration date (90 days from date first opened).
6. Scan the test strip vial barcode.
   a. Check manufacturer expiration date on bottle and discard if expired.
7. Remove a test strip from the vial and immediately recap the vial.
8. Wait for the flashing strip icon to appear on the meter display, gently hold test strip with the yellow target area or test window facing up and insert the end with the gold bars.
9. When prompted, mix well and touch a bead of the control solution to the end of the test strip while holding or placing the meter horizontally.
   a. Do not hold the meter upright to run controls.
10. Repeat steps 5-9 to run the other control level.

11. If you receive a "PASS" on both levels of control, proceed with patient testing.
    a. If QC receives a "FAIL," choose a comment from below and proceed with corrective action. See section E below.

Quality Control Comments

Invalid, Will Repeat
Switched QC vial
Replaced test strips
Replaced QC solution

E. Corrective Action for QC Failure
1. Verify that the strips and control material are not expired.
2. Ensure that the correct level is being tested. Repeat QC, if the result is still "FAIL" continue to step 3.
3. Run QC with a new bottle of strips, continue to step 4 if not resolved.
4. Run QC with new control solutions.
5. If QC is still failing, contact the Ancillary Testing Coordinator in the laboratory.

F. QC Review
1. The laboratory Ancillary Testing Coordinator (ATC) will review QC on a monthly basis, and notify the Section Manager when corrective action is needed for identified problems.
2. The ATC will oversee performance quality related to glucose testing. This includes checking dating of control solutions, review of QC results and monthly error reports, operator certification/recertification, as well as acting on QC results which identify trends that may indicate potential problems.

V. SAMPLE/SPECIMEN

*Refer to the test strip package insert f*or the most current information

A. Capillary, venous and arterial whole blood specimens may be used for testing on the Accu-Chek Inform II™ System with Accu-Chek Inform II test strips.
B. Point of care testing staff will use only the capillary specimen.
C. The capillary fingertip sample must be tested at the time of collection. Sufficient sample size is required to ensure accurate results.
Do not "Milk" fingers for sample.

VI. TESTING PROCEDURE

A. Orders
1. POC testing is performed under verbal order and signed off by the provider, per service line protocol or standing order, or per facility protocol and details can be found in the specific service line policies and procedure.

B. Patient Testing

1. Put on disposable gloves (Refer to MCM for proper hand hygiene).
2. Identify the patient.
    a. The operator must view the patient's ID Badge and verify Date of Birth or Name. (The Joint Commission National Patient Safety Goal, the use of two patient identifiers).
3. Turn on the meter and scan your operator ID
4. Choose *Patient test* from the Main Menu
5. Enter the patient identification by barcode scanning of the patient's badge (FIN).
    a. Manual input of FIN should be used **only** in situations where scanning is not available or feasible or during downtime (see below).
    b. Every effort should be made to wait for FIN to be created or downtime to be resolved prior to running patient test.
6. Confirm the patient name and DOB on the screen
    a. If the name and DOB is not listed then check you have the correct FIN
    b. If you have the correct FIN, proceed with testing.
7. Wait for the 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.
8. Remove a test strip from the vial and immediately recap the vial.
9. Insert the test strip into the meter. Wait for the meter to display a flashing drop above the test strip icon indicating that you are ready to apply a blood sample.
10. Cleanse the puncture site (the side of the fingertip) with an alcohol swab and allow it to thoroughly dry.
    a. Alcohol at the puncture site must be dry or an error code/inaccurate result may occur.
11. Perform a fingerstick using a single use lancet device. With a cotton ball, wipe the first drop of blood from the finger.
12. Apply next drop of blood to the front edge of the test strip.
    a. The sample will fill the yellow sample chamber by capillary action.
    b. Do not apply sample to the top of the test strip.
13. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.
14. After the sample has been obtained, apply gentle pressure to the puncture with a clean gauze square or cotton ball site for several minutes.
    a. If the patient is conscious and capable, enlist the patient's assistance with applying pressure.
15. The measurement is complete when the result is displayed on the screen.
    a. Depending upon how high or low the result is, it may appear in a numeric or non-numeric format.
    b. See *Interpretation of Results* section below for interpretation of each result format.
16. Click the comment bubble in the bottom left corner, select the **Clean Meter** comment and select the green check mark
    a. You may add up to three comments to the results (example: add Clean Meter and RN repeat required for critical results).

17. Review the results and comment on the screen then click the green check mark in the bottom right corner to accept.
    a. Comment is required to accept results. Complete step 15 if you receive an error message.
18. Remove the test strip and dispose of it in the trash receptacle.
19. Check EHR to verify results crossed to the patient chart.

C. Clean/Disinfect
1. Clean and disinfect the meter with manufacturer approved antimicrobial wipes,
    a. Cleaning must take place after each patient test.
2. Power off the meter and place on a level surface
3. Get approved wipe and squeeze excess liquid from the wipe
4. Gently wipe the outside of the meter and carefully wipe around the test strip port ensuring no liquid enters the strip port.
    a. If liquid does get into the test strip port, immediately dry the components
5. Dry the meter thoroughly with dry cloth
6. Get a new wipe and squeeze excess liquid from wipe
7. Gently wipe the meter horizontally and vertically and around the test strip port ensuring no liquid enters the strip port.
8. Ensure the surface remains damp for the recommended time (2 minutes).
9. Dry the the meter thoroughly with a dry cloth and place the meter back on the docking station.
10. If you suspect that moisture may have entered the test strip port, perform a glucose control test.
    a. Notify ATC of any issues

D. Downtime
1. FIN IS available however there is no EHR access or you are in downtime
    a. Use FIN for the current visit
    b. Perform testing as normal
    c. Results will transmit to EHR after downtime is resolved.
2. FIN is NOT available due to downtime or veteran is unable to be identified
    a. Test is NOT urgent
        i. Wait for FIN to be created then perform testing as normal
        ii. Results will transmit to EHR as normal
    b. If test is urgent or patient condition is life threating
        i. Use the Sample ID 00000000.
        ii. Perform testing as normal
        iii. Complete and submit the downtime form to ATC
        iv. Results will NOT transmit to EHR until ATC reviews and releases results

Cerner Point of Care Downtime Form

Date:_____ Time:_____ Test:_____

Full name of patient:_____ DOB:_____

Name of staff member who performed the test:_____

Downtime number used as Specimen ID: _____

Correct FIN for the visit: _____

VII. INTERPRETATION OF RESULTS

A. Expected Values

1. The normal fasting blood glucose range in this facility for a non-diabetic adult is **71-109 mg/dL**.
2. One to two hours after meals, normal blood glucose levels for a non-diabetic adult should be less than 145 mg/dL.
3. The recommended level for a diabetic patient is a peak postprandial glucose less than 180 mg/dL. Peak level blood glucose values depend on many factors including: age, stress, current overall control of blood sugars, insulin timing/administration, and medications.
4. All patient results should have the Clean Meter comment added to document the cleaning/disinfection process after each patient test.

B. Critical Results

1. A critical result is **<50 mg/dL or > 400 mg/dL.**
2. The following steps **MUST** be taken when dealing with a critical value:
   a. **Mark first result with comment "RN repeat required".**
   b. All critical results MUST be repeated within 5 minutes by an RN.
   c. **Mark the second result with comment "MD Notified".** All RN repeats for critical values need this comment, even if it is the same patient on the same day. Only charting this in a note in the patient's chart is not sufficient.
3. Provider must be notified of critical result within 30 minutes of testing. Ensure provider acknowledes the notification by affirmative read-back.
4. Document critical result notification using the Message center (See help guide *Entering Critical POC Result Comments*).

C. Results Outside of Reportable Range

1. The Accu-Chek Inform II meters have a validated reportable range from **30 mg/dL to 600 mg/dL.**
2. This means that any result below 30 or greater than 600 will be reported in the following manner**: <30 mg/dL or >600 mg/dL.**
3. The meters are programmed to give a flag of OR HI or OR LO in the event the result is outside the reportable range.
4. It is recommended that a glucose test be performed by the laboratory via venipuncture sample to verify the patient's glucose value. Orders should be placed by appropriate provider.

D. Reporting in LIS

1. All valid results on the meters will be uploaded to RALS when the meter is docked. RALS will then upload results into the patient's chart via LIS.
2. Verification of results crossing over to the patient's chart from the meters needs to occur at the end of each shift. This can be achieved by checking the laboratory results in EHR.
3. If the results do not appear to be crossing over, contact the ATC in the lab.
4. In the event of downtime related to network failure or inability to upload data to LIS, glucose testing information may be recalled from each meter for up to 10 days or 4000 tests, whichever occurs first.
    a. DO NOT manually enter results into EHR, results will automatically cross when the system is available.
5. All results are reviewed for accurate reporting by the ATC.

VIII. LIMITATIONS

A. *Test strips give dependable test results if the following limitations are understood:*

1. The Accu-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
2. Hematocrit should be between 10-65%
3. Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
4. Blood concentrations of galactose >15mg/dL will cause overestimation of blood glucose results.
5. IV administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
6. IV administration of N-acetylcysteine resulting in >5 mg/dL (may cause overestimation of results).
7. 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 to the following circumstances: severe dehydration as a result of diabetic detoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock,

decomepensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
8. This system has been tested at altitudes up to 10,000 feet.
9. The performance of this system has not been evaluated in the critically ill.
10. Definition of critically ill patient: A patient with a mean arterial pressure of less than 60 mmHg or systolic pressure less than 90 mmHg or patient on vasopressors, patient with mottling of skin, patient with end stage congestive heart failure (CHF) (as defined by ejection fraction less than 15% mmHg), patient with hypothermia (body core temp less than 95 degrees Fahrenheit (F)), or patient with lactic acid of over 4.0 mmol/L. Note: if a patient present meeting the criically ill criteeria and glucose testing is needed a lab draw for testing on lab instrumentaion is required.
11. The Inform II use in a rapid response situation, before the patient can be evaluated for the "Limitations" criteria, is as an aid in determining treatment, NOT as a means of diagnosis. It is recommended to follow-up with a laboratory draw and monitor patient for any adverse events.

IX. MAINTENANCE AND TROUBLESHOOTING

A. Calibration and Calibration Verification
1. Calibration is not required by the manufacturer, however it may be performed as necessary for accuracy of the test method.
2. Refer to the *CBG Instrument Correlation and Verification* procedure for details.
3. Calibration is performed by laboratory ATC.

B. New lot numbers
1. When new lot number of test strip or QC reagents are put into use, ATC will input lot numbers in RALS, rotate stock, and test reagents for use as appropriate.
2. Any reagents not acceptable will be sequestered and technical support contacted for troubleshooting.
3. Reagents will be release to testing staff after testing.

C. Maintenance
1. Meters will be cleaned and disinfected with manufacturer approved wipes using manufacturer approved process.
2. Firmware and software updates are scheduled and performed by the ATC.
3. Each meter is evaluated at least annually for proper functioning and damage by the ATC.

D. Troubleshooting
1. The following are the most common issues encountered with the glucose meters at this facility:

a. **Meters not charging properly or not turning on at all.**
Resolution: Check power supply to the meter docking station to make sure it hasn't becom unplugged. Improper docking of the meter is usually the issue though. Make sure meter is properly docked and confirm that it is charging. Clean contacts with a soft tissue and alcohol if needed, making sure to dry them.

b. **Meters frozen or not very responsive to touch**.
Resolution: This requires a power down. Press and hold the power button for about 20 seconds. The meter will shut off and cycle on. Once the meter comes back on, dock the meter and try logging on. If not resolved, contact the ATC.

c. **Invalid strip or invalid control error message**.
Resolution: This can only be resolved by the ATC in the lab; contact the laboratory.

d. **Inability to log on with user ID.**
Resolution: Your certification has expired or your user ID has not been activated. Contact the ATC to become re-certified.

e. **Results not crossing over to LIS**.
Resolution: This is most likely due to the RALS server or EHR being offline or interface issues. Contact the ATC.

f. **Base units blinking red.**
Resolution: Make sure the data ports are connected to the meter. They will also blink red when RALS is down. Contact ATC.

2. If the above issues continue to be a problem or can't be resolved you can contact the ATC in the lab or via email.
3. See appendix A for troubleshooting other issues and error alarms that may occur.

X. CERTIFICATION AND PROFICIENCY TESTING

A. Certification
1. Initial certification, training, and competency records will be maintained in the laboratory.
2. Only personnel whose certification and competency can be tracked in the laboratory glucose database are permitted to perform patient testing independently.
3. To become a certified operator of the Accu-Chek Inform II™ System the first time, each operator will demonstrate the following:
   a. Achievement of the knowledge and skills to perform blood glucose testing as defined in this policy/procedure.

b. Achieve a PASS on a complete Quality Control (QC) routine.
c. Be observed by a certified trainer performing a test
d. The meter will not allow a new operator access to perform testing until the certification information has been entered into the Lab Information Management System by the ATC.

4. Operators must maintain certification to perform glucose testing and be proficient in the use of the Accu-Chek Inform II™ System.
   a. Meters will not work for the operator after certification has expired. It is unacceptable to use another person's user ID for testing.
5. Recertification requires 2 of the following:
   a. A passing score of 80% on the knowledge-based quiz.
   b. Perform a successful QC routine (both levels of controls).
   c. Successful performance of blind specimen (proficiency test).
   d. Observation of testing or cleaning the meter.
6. Each operator will also be assessed for ongoing competency based on:
   a. Monthly unit-based review of quality control and statistical reports.
   b. Individualized findings from ongoing review of flagged results and errors by the Ancillary Testing Coordinator.
7. Retraining and reassessment will occur if problems are identified with user performance.

B. Proficiency Testing
1. Selected operators will be requested to run tests on unknown samples according to the College of American Pathology (CAP) proficiency testing methodology or other provider to verify meter accuracy and operator competency.
   a. There will be no interdepartmental communication about proficiency testing samples until after the deadline for submission of the data to the proficiency testing provider.
   b. Referral of proficiency testing samples to another laboratory is prohibited.
2. The test sample may be a blood product or derivative; therefore, standard precautions, including glove use must be observed.
3. Proficiency testing will be performed according the the instructions provided with the sample.

XI. REFERENCES

A. Roche Diagnostics. Accu-Chek Inform II Test Strips and 1 Code Key Package Insert. 2016. 07981554001-0516
B. Roche Diagnostics. Accu-Chek Inform II Controls Package Insert. 2016. 07981503001-0316.
C. Roche Diagnostics. Accu-Check Inform II Operator's Manual Version 7.1 2020.
D. The Joint Commission E-dition. Waived Testing. Effective Date: July 1, 2023

Appendix A

Error Code/Message	Interpretation	Operator Action(s)
OR LO/OR HI	Test result may be below/above the reportable range set by the system administrator.	**Report to an RN to rerun and verify the result and report to MD. Confirmation glucose should be performed by the laboratory. QC should also be done on the meter.** If control result is not within acceptable range, do not perform any further patient testing with that meter.
CR LO/CR HI	Test result may be below/above the critical range set by the system administrator.	**Report to an RN to rerun and verify the result and report to MD.**
Strip Defect Error	Test strip may be damaged or the test result is extremely low and below the meter's measurement range.	The test strip should be inserted into the meter prior to applying blood to the test strip. If this display appears *before* blood is placed on the strip, remove the test strip and reinsert. If the error display remains, repeat the test with a new strip.
Type Bad Dose	Insufficient amount of blood on the test strip.	Discard test strip and repeat the test. If the error persists, contact the ATC in the lab.
(QC) Fail or Out of Range	Failed QC test as it was out of range for the test strip lot.	Repeat control test with a new test strip. If the error persists, contact the ATC in the lab.
Glucose Error	Detection of an unexpected hardware error	Repeat the test, Run a control test with a new test strip. Reset the meter by following steps in IX. Maintenance and Troubleshooting section D. If the error persists, contact the ATC in the lab.
Unexpected SW Error	Detection of an unexpected software error	Repeat the test. Place the meter into a connected base unit to synchronize. Reset the meter by following steps in IX. Maintenance and Troubleshooting section D. If the error persists, contact the ATC in the lab.