Title: Accu-Chek II Glucose Monitoring System Document No. POC 4 113 Rev. No. 2.3

POC 4 113 Accu-Chek II Glucose Monitoring System

Copy of version 2.3 (approved and current)

Last Approval or Periodic Review Completed	9/2/2020
Next Periodic Review Needed On or Before	9/2/2022
Effective Date	1/31/2022

Uncontrolled Copy printed on 3/17/2022 1:11 PM

Printed By Kimberly Ballard

Organization VA Memphis - Shequita Banks

Comments for version 2.0 (last major revision)

REVISED TO REFLECT QUALITY MANAGEMENT TO ANOTHER SOP

reviewed, REVISED FOR QUALITY MANAGEMENT TO ANOTHER SOPConcurconcurReviewed by A. Hankerson

Comments for version 2.3 (this revision)
revised for quality control update//kabquality control revisionFormat changes only.concurREVIEWED BY A. HANKERSON

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	9/2/2020	2.0	Eugene Pearlman	
Approval	Lab Director	12/6/2019	1.0	Eugene Pearlman	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.3	Approved and Current	Minor revision	11/3/2021	1/31/2022	Indefinite
2.2	Retired	Minor revision	5/17/2021	7/1/2021	1/31/2022
2.1	Retired	Minor revision	12/6/2020	2/22/2021	7/1/2021
2.0	Retired	Major revision	4/9/2020	9/2/2020	2/22/2021
1.0	Retired	Initial version	11/7/2019	12/6/2019	9/2/2020

ACCU-CHEK INFORM II GLUCOSE MONITORING SYSTEM

POC 4 113

Memphis VA Medical Center
Memphis, TN 38104

Service Line(s):
Pathology and Laboratory Medicine Service- Ancillary Testing Department

Signatory Authority:
Chief, Pathology and Laboratory Medicine Service

Effective Date:
February 4, 2021

Responsible Owner:
Kimberly Ballard, MHA, MLS (ASCP)
Ancillary Testing Coordinator

Recertification Date:
February 28, 2026

1. PURPOSE AND AUTHORITY

a. The purpose of this standard operating procedure (SOP) contains the policies and procedure to be followed when performing tests for the use of the ACCU-Chek Inform II System for capillary, venous or arterial blood glucose monitoring in the Memphis VA Medical Center and associated VA Community Based Outpatient Clinics (CBOCs). This SOP must be followed by users who utilized the ACCU-Chek Inform II instrument.

b. Substantial improvement in diabetic control can be achieved with point-of-care (POC) glucose monitoring. Therapeutic decisions are based on results from whole blood glucose's POC testing. Urgent use is necessary with patients found in a stupor, unconscious, or known to be a diabetic with clinical symptoms suggesting hypoglycemia. Routine use is beneficial for monitoring patient on sliding scale regular insulin, with labile blood sugars, with a recent onset of treatment with insulin or oral hypoglycemic agents, after surgery until glucose is stable, or with total parenteral nutrition (TPN).

c. 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, covets the glucose in the blood sample to gluconolactone. This reaction creates a harmless electrical direct current (DC) signal that the meter interprets for a glucose result. The sample and environmental conditions are also evaluated using a small alternating current (AC) signal.

d. 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 a National Institute of Standards and Technology (NIST) standard.

e. This SOP sets fourth mandatory procedures and processes to ensure compliance with VA/VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, Joint Commission, the Food and Drug Administration (FDA), and College of American Pathology.

2. ASSIGNMENT OF RESPONSIBILITIES

a. **Laboratory Director.** Has the overall responsibility for ensuring that the provisions of this SOP are followed by all personnel involved in the use of the ACCU- Chek Inform II System in the Memphis VA Medical Center and/or associated VA CBOCs.

b. **Ancillary Testing Coordinator.** Responsible for assisting the Laboratory Director and the Clinical Pathology Director, for the training and competency assessment of testing personnel, and for monitoring quality control and proficiency testing performance.

c. **Ancillary Testing Program Specialist.** Will assist the Ancillary Testing Coordinator in the performance of his/her duties.

d. **Testing Personnel.** Will be responsible for the proper performance and documentation of all procedures as described in the "Procedures" of this Standard Operating Procedure (SOP). Testing personnel includes Licensed Practical Nurses (LPN), Registered Nurses (RN), Respiratory Therapists, and Medical Technologists assigned to locations that perform ancillary testing.

3. DEFINITIONS

a. **Waived Tests**. Are laboratory tests that yield of low complexity in operations, interpretation, and treatment of results.

b. **RALS.** Data management system allows all ancillary testing equipment to upload patient results into VISTA/CPRS.

c. **Reference Range.** Means the range of test values expected from 95% of fasting individuals presumed to be healthy.

d. **Reportable Range.** Means the range of test values throughout which the measurement system's results have been shown to be valid.

e. **Critical Results.** Are laboratory test results that fall above or below defined values such that they could pose an immediate risk to the patient.

4. SPECIMEN INFORMATION

a. Fingerstick blood sample is the preferred primary acceptable sample type.

b. Venous, arterial or line draw samples should be tested 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.

5. SPECIAL SAFETY PRECAUTIONS

a. Testing is prohibited on patients on pressors. ACCU-Chek glucose monitoring system is not FDA valid for testing on critically patients. Another method of testing must be done.

b. Venous arterial or line draw samples should be tested 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.

c. Employees are not allowed to perform testing on themselves or on co-workers without proper authorization. Employees must report t their supervisor or employee health prior to testing.

d. Only a certified operator may perform a blood glucose test on the ACCU-Chek Inform II System.

e. Single-use, disposable lancets must be used. Reuse of a disposable lancet is strictly prohibited. Disposable lancets are to be disposed of in a biohazard sharps container.

f. RALS-Plus will flag patient results that are not in VISTA, scheduled for appointments or admitted. Patient ID errors will be corrected at least weekly by laboratory staff. This will be accomplished by printing the “FLAGGED RESULTS” and review of the glucose meter from the same patient location within the same timeframe +/- two days. Patient IDs that have been edited will be documented in the comments. The performing staff member and their supervisor will be notified for corrective action of the Patient IDs who do not meet the editing criteria. If the testing personnel is unable to identify the results, results will be placed in the “DO NOT UPLOAD FILE”. Erroneous patient IDs may only be altered in the following situations:

(1) The ID is missing one number that if added would yield the correct patient ID.

(2) The ID has one extra number that if deleted will yield a correct ID.

(3) The ID has two numbers that are switched that if transposed will yield the correct ID.

(4) When the Operator ID has been entered as the Patient ID and the operator is able to identify the correct patient.

(5) The meter will remain docked on the base unit when not in use and all results will download.

(6) Transferring data from an ACCU-Chek Inform II System is the responsibility of each operator by downloading the meter on the base.

(7) During computer downtimes, results will be documented according to service policy when the system comes back online. The meter can store 2000 results.

6. EQUIPMENT/FORMS

a. ACCU-Chek Inform II meter- Fully charged and coded to the test strip lot you intent to use.

b. RALS Data management System

c. Base/Downloader (including al ethernet cables and power cords)

7. REAGENTS

a. ACCU-Chek Inform II Control Level 1 (Low) and Control Level 2 (High), the lot and range information will be available in meter

b. ACCU-Chek Inform II Test strip vial

c. Single-use, disposable lancets

d. Alcohol swab

e. Cotton Ball, tissue or gauze for wiping finger after alcohol and after stick

f. Personal Protection equipment as required by infection control and isolation policies and procedures

g. Disposable transfer pipette or syringe as needed if testing a venous, arterial or line draw sample

h. Biohazard sharps container

8. QUALITY CONTROL

a. Daily quality controls consist of 2 levels of testing (Level 1 & Level 2) performed under the “CONTROL” pathway from the main menu.

b. Quality control must be performed, and acceptable results must be obtained prior to release and performance of patient testing. Quality control is performed at the beginning of each day starting at 12midnight. In areas where the ACCU-Chek Inform II meter is not being used daily, quality control will be performed each day that testing is performed.

c. The meter will alert operators that quality controls are due starting at 12m.

d. Quality controls are required to ensure both the strips and the meter are functioning properly and results are reported as “Pass” or “Fail”.

e. If either quality control tests result report as “Fail”, enter an appropriate comment and replace the control solution and repeat test. If the control fails again, replace the test strips, enter appropriate comment and repeat test. If the problem is corrected proceed with patient testing. Contact the Ancillary Testing Coordinator if quality control continues to fail.

f. Instruments where quality controls have “FAILED” should be repeated using a new test strip/ cartridge and control solutions. Failed results could be an indicator of sampling air bubbles, expired reagents/ supplies, or underfilling test strips/ cartridges.

g. Cease patient testing if failed quality controls persist by the third trial. Contact ATC for further troubleshooting instructions, to gain a replacement meter, or other testing supplies.

h. If ATC is unavailable, cease patient testing, remove meter from service (attach a ‘Do Not Use” label or give to charge nurse on duty to arrange return to ATC) collect appropriate patient sample for analysis by the main lab.

i. Quality Control tests are performed at the following times for the Memphis VAMC and CBOCs:

(1) Each time a new vial of test strips is opened.

(2) When a vial of strips has been left opened.

(3) If the ACCU-Chek Infom II meter has been dropped.

(4) Each day as determined in Setup (every 24 hours)

(5) When the test strips have been exposed to extreme heat, humidity, or cold.

(6) When test results contradict clinical symptoms.

(7) After the battery in the ACCU-Chek Inform II system has been replaced or after the ACCU-Chek Inform II system has been recoded.

(8) After software upgrades.

j. College of American Pathologists (CAP) proficiency testing to verify meter accuracy and operator competencies will be performed 2 times a year on each meter.

k. Glucose control solutions must be stored at room temperature. Do not freeze. Glucose control solutions are stable for three months after opening or until the expiration date on the vial, whichever comes first. The open date, the expiration date and the Operator's Initials must be handwritten on the vial label. Any outdated glucose control solutions will be discarded.

l. Test strips must be stored at room temperature. Do not refrigerate or freeze. Test strips are stable until the expiration date on the vial. Test strips must be stored in the same capped vial in which they were packaged, and the vial cap must be immediately replaced after removal of a test strip. Test strips from different bottles (even if they are the same lot) must never be combined.

m. Quality control testing for central laboratories is mandated by TJC and the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88).

n. The product used for cleaning (removal of visible soil and organic material) and disinfecting (destroying pathogenic microorganisms) the ACCU-Chek Inform II meters and system components is Sani-Cloth.

o. Each box of test strips contains a code key. Each code key belongs to a single lot and provides important information about the lot-specific properties of the ACCU-Chek Inform II test strip.

p. A code file is uploaded into the ACCU-Chek Inform II system for every test strip lot that is received by the Ancillary Testing Program Specialist.

9. EQUIPMENT CALIBRATION AND MAINTENANCE

a. The meter is "calibrated" when the instrument is turned on the Code Key (as a code file) information for that particular lot number of test strips. The Code Key Information is entered into the data management system by the Ancillary Testing Program Specialist for each new lot of test strips. The RALS-PLUS data management system centrally stores the Code Key information and can be distributed to all meters or can be configured for individual meters.

b. Each box of test strips contains a code key. Each code key belongs to a single lot and provides important information about the lot-specific properties of the ACCU-Chek Inform II test strip.

c. The purpose of these validation studies are to verify that identical specimens yield comparable results when tested on different ACCU-Chek instruments, or when tested by different methods (generally, core lab vs. ancillary testing instruments). Literature standards, may referable to CUA, are used to determine whether the degree of agreement between instruments or platforms is acceptable. Requirements for these studies as listed by inspecting agencies fall into two categories: Those for non-waived tests and those for waived tests.

d. Correlation studies for both waived and non-waived tests: For instruments at the Memphis VAMC, ACCU-Chek inter-instrument, cross-platform correlations, and AMR must be performed at least twice a year.

e. If the error message “Strip Defect Error” appears on the display, the test strip may be defective, or the blood glucose result may be extremely low and below the meter’s measurement range. Refer to the test strip package insert, perform a quality control test using a new test strip, review proper testing procedure, and repeat the blood glucose test, or follow your facility’s testing policy.

f. If the meter displays “Type Bad Dose,” there may be insufficient amount of blood on the test strip. Repeat the test using a new test strip, ensuring proper sample application, or refer to the test strip package insert.

10. PROCEDURES

a. **General Procedure.**

(1) Take the meter and testing supplies to the patient location.

(2) Wash hands and don personal protective equipment (gloves, gowns, etc.) as required by infection control and isolation policies and procedures. Universal precautions should be observed for all blood specimens.

(3) Greet and identify the patient using the prescribed two patient identifiers or armbands.

(4) Explain the procedure to the patient.

(5) Turn on the ACCU-Chek Inform II meter.

(6) Scan your Operator ID to login to the meter. **NOTE**: If the Operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Ancillary Testing Coordinator. **DO NOT** attempt to perform tests under another operator’s ID.

(7) From the Main Menu, touch Patient Test or Control

(8) When the screen for entering the patient ID is displayed, press and release barcode symbol. The button now appears with a black background (during the barcode scan.). Hold the meter so that the window of the barcode scanner is approximately 4-8 inches above the barcode you wish to read. Enter the patient identification (entire 9 digits Social Security number) in the ACCU-Chek Inform II System manually or by scanning the armband. The meter beeps once the barcode has been read successfully. The barcode information appears in the patient ID field. The barcode scanner turns off after 10 seconds, if a barcode is not scanned.

(9) Carefully assess the patient for any indication that POC glucose testing may not be appropriate.

(10) Always take basic steps to stimulate blood flow to the intended puncture site. Even if the patient's peripheral circulation is not impaired this will help you to procure a sufficient and free flowing sample, especially in patients who are sedentary.

(11) Once you have entered and confirmed the patient ID or scanned in the barcode from the vial of quality control, you must select the current lot number for test strips.

(12) 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 strip vial. To read the lot number of test strip vial via barcode scanner, press and release the barcode symbol. Follow the instructions for scanning IDs. To use the preselected lot number displayed by the meter, touch the button to confirm. To use a different lot number than the one displayed for the test strips touch the ✗ button to display a list of stored lot numbers. Select the desired lot number from the list.

(13) 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 the patient sample.

(14) Collect an acceptable fingerstick blood sample. Always wipe the first drop of patient blood away when testing capillary samples-this is advantageous because it ensures that the cleaning agent is dry and clears interstitial fluid from the sample.

(15) Apply patient's sample to the front edge of the test strip. The blood 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. You will get an error message if the sample is insufficient. If this occurs, you will need to repeat the test.

(16) After the sample has been obtained, apply gentle pressure to the puncture site with a clean gauze square or cotton ball for several minutes. If the patient is conscious and capable, enlist the patient's assistance with applying pressure.

(17) The measurement is complete when the result is displayed on the meter screen. Depending upon how high or low the result is, it may appear in a

numeric or non-numeric format. See “Interpretation of Results” section below for interpretation of each result format.

(18) Remove the test strip and dispose of it in the regular trash.

(19) Touch the comment button to enter an appropriate comment (s) as required.

(20) Touch the button to confirm the result and 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. The patient results will transfer into VISTA/CPRS through the RALS-PLUS data management system.

(21) Follow up on any results that exceed critical or reportable limits according to policy by completing a critical value template after reporting to the patient’s provider.

(22) Clean and disinfect the ACCU-Chek Inform II meter after each use.

b. **Limitations.**

(1) Employees are not allowed to perform testing on themselves or on co-workers without proper authorization. Employees must report to their supervisor or employee health prior to testing.

(2) Only a certified operator may perform a blood glucose test on the ACCU-Chek Inform II System.

(3) Single-use, disposable lancets must be used. Reuse of a disposable lancet is strictly prohibited. Disposable lancets are to be disposed of in a biohazard sharps container.

(4) RALS-Plus will flag patient results that are not in VISTA, scheduled for appointments or admitted. Patient ID errors will be corrected at least weekly by laboratory staff. This will be accomplished by printing the “FLAGGED RESULTS” and review of the glucose meter form the same patient location within the same timeframe +/- two days. Patient IDs that have been edited will be documented in the comments. The performing staff member and their supervisor will be notified for corrective action of the Patient IDs who do not meet the editing criteria. If the testing personnel is unable to identify the results, results will be placed in the “DO NOT UPLOADFILE”. Erroneous patient IDs may only be altered in the following situations

(a) The ID is missing one number that if added would yield the correct patient ID.

(b) The ID has one extra number that if deleted will yield a correct ID.

(c) The ID has two numbers that are switched that if transposed will yield the correct ID.

(d) When the Operator ID has been entered as the Patient ID and the operator is able to identify the correct patient.

c. **Transferring Data.** Date from an ACCU-Chek Inform II System is the responsibility of each operator by downloading the meter on the base.

d. **Computer Downtime.** Results will be documented according to service policy. The meter will remain docked on the base unit when not in use and all results will download when the system comes back online. The meter can store 2000 results.

11. ENTRY OF RESULTS

a. The patient results will transfer into VISTA/CPRS through the RALS-PLUS data management system by downloading the meter to the base unit.

b. Reference Range & Reportable Range

c. Meters' Reportable Range: 10-600 mg/dL

d. VAMC Memphis' Reference Range: 70-110 mg/dL

e. Critical Results: < 40 mg/dL or > 450 mg/dL.

f. "HI" or "LO" meaning that the result is above or below the upper or lower reading limits of the ACCU-Chek Inform II System (>600 mg/dL or <10 mg/dL).

g. "RR HI" or "RR LO" meaning that the result is above or below your facility's established reportable limits which are: 70-110 mg/dL.

h. "CR HI" or "CR LO" meaning that the result exceeds your established critical limits which are: <50 mg/dL or > 450 mg/dL.

12. NOTIFICATION

a. The provider will be notified if the blood glucose value is: <40 mg/dL or >450 mg/dL after verification by the operator.

b. The nurse must document reporting of critical values in CPRS using the Critical Lab Value Template.

c. Verification can be done by the following:

(1) Repeating the test within 10%. If the test does not repeat within 10% of initial results, the result must not be reported.

(2) By nursing assessment of the patient. (See note below).

(3) By ordering a STAT glucose to be drawn and sent to the main clinical laboratory. The provider must be notified that reported results could not be obtained and that a STAT glucose is being sent to the main clinical laboraroty.

13. REFERENCES

a. VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, http://vaww.lab.med.va.gov/References_Directives_and Regulations_P.asp

b. Roche Corporation ACCU-Chek Inform II website: (http://www.accuchekinformii.com/)

c. College of American Pathologist (CAP) Laboratory Accreditation Program (LAP) Laboratory General and Point of Care Checklists, 08.17.16.

d. The Joint Commission 2014 Hospital Accreditation Standards

e. National Institutes of Health manual, Biosafety in Microbiological and Biomedical Laboratories, 1988

f. The National Committee for Clinical Laboratory Standard Document M29, Protection of Laboratory Workers form Infectious Disease Transmitted by Blood, Body Fluids, and Tissue, 1991.

14. APPENDICES

None

15. REVIEW

This SOP will be reviewed at least every 2 years, when there are changes to the government document that need to be made and any regulatory requirement for frequent review.

16. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of February 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

17. SIGNATORY AUTHORITY

Dr. Eugene Pearlman
Pathology and Laboratory Medicine Service, Chief

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This SOP is available in Media Lab at: https://www.medialab.com/lms/admin/ad_tab_doc_frameset.aspx?oid=46099748&o=3b129473bf03e0f60788450ba245204a