POC.18 Whole Blood Glucose

Copy of version 2.1 (approved and current)

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Comments for version 2.0 (last major revision)
Maintenance has been updated to manufacturer's guidelines for both cleaning and disinfecting.

Comments for version 2.1 (this revision)
Changed font color from red to black

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
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Prior History
POC.18.2

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.1	Approved and Current	Minor revision	12/18/2024	12/23/2024	Indefinite
2.0	Retired	Major revision	12/11/2024	12/11/2024	12/23/2024
1.2	Retired	Minor revision	11/14/2023	12/8/2023	12/11/2024
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1.0	Retired	First version in Document Control	7/27/2022	4/11/2022	11/2/2022

Pathology & Laboratory Medicine Service
VA Medical Center, Columbia, MO

Department: POC

POC.18 Whole Blood Glucose

Using The AccuChek® Inform II

INTENDED USE

The AccuChek® Inform II is a portable instrument used to determine whole blood glucose levels. The test system quantitatively measures glucose in venous, arterial, or fresh capillary whole blood samples from the fingertips.

The Whole Blood Glucose is a definitive test and is useful for monitoring the blood glucose levels in diabetic patients.

CAUTION: The Food and Drug Administration (FDA) has enacted labeling changes specific to the use of multi-patient waived whole blood glucose devices. Under the section of "Intended Use" in the 510(k) Summary the limitations clause "The performance of this system has not been evaluated on the critically ill" has been added. The labeling change is specifically intended to alert the end-user that these devices have limitations and are not applicable in some health care settings. The Clinical Laboratory Improvement Amendments (CLIA) regulations specify the use of such devices on critically ill patients as "off-label" application. At this facility, the Harry S Truman Memorial Veteran's Hospital, and its associated clinics, has defined critically ill patients in the Memorandum, Definition of Critically Ill Patient and Use of Roche Accu-Chek Inform II Glucometer for Point of Care Whole Blood Glucose Testing .

It is essential that the provider consider the following when making the decision to monitor the patient glucose using the AccuChek Inform II:

- **Is the patient defined as critically ill, such as the patient is on mechanical ventilation with a mean arterial pressure less than 60 mmHg despite the use of pressors?**
- **Is the patient defined as critically ill, due to decreased peripheral blood flow due to dehydration, hypotension, shock, decompensated heart failure, or peripheral arterial occlusive disease.**

Some facilities may attempt to identify critically ill patients on the basis of their location, such as ICU patients, Emergency Room (ER) patients, and Operating Room (OR) patients. The VA National Enforcement Office does not recommend the identification of critically ill patients solely by location.

SCOPE

This procedure provides instruction on how to perform glucose test directly from patient blood specimens.
Complexity:

- This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Level of Personnel:

- All testing personnel who are qualified to performed waived testing and who have successfully completed initial training and fulfilled the specific competency requirements for the complexity level of this test.

Testing Sites:

- Clinical sites approved and on file with the Pathology service's POC Division.

PRINCIPLE

The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH), from *Acinetobacter calcoaceticus*, recombinant in *E.coli*, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for the blood glucose result. The sample and the environmental conditions are also evaluated using a small AC signal.

SPECIMEN REQUIREMENTS

To perform a whole blood glucose test, a drop of fresh whole blood is necessary. Capillary, venous, or arterial blood may be used. **The same specimen type should be used consistently throughout the patient's care. If a change in whole blood collection site is made, this should be noted on the meter by the use of a comment code in order to be reported with the result. This should be considered when reviewing the results.**

Use standard biohazard precautions when collecting any blood specimen. Wear gloves during specimen collection and while testing. Dispose of lancets and needles in appropriate puncture resistant containers.

Use of whole blood glucose specimens should include establishment of a baseline glucose result by the clinical laboratory method and rechecked periodically thereafter.

Capillary – To obtain a sample of capillary blood, an alcohol wipe must be used, let the finger dry completely before testing. Warming fingers can increase blood. Using a lancet, obtain a drop of fresh capillary blood following nursing guidelines.

Arterial – To obtain a sample of arterial blood, collect the blood in a plain sterile syringe without additives or in a blood gas syringe containing lithium heparin. **Do not use a syringe with sodium heparin.** Caution should be taken to clear arterial lines before blood is drawn. The specimen must be tested immediately to avoid glycolysis.

Venous – To obtain a sample of venous blood, collect the blood using a syringe and needle. The specimen must be tested immediately to avoid glycolysis and clotting of the specimen

REAGENTS – SUPPLIES – EQUIPMENT

1. Accu-Chek Inform™ II Glucose Meter

2. AccuChek Inform II Test Strips (supplied by the laboratory via pneumatic tube system by calling extension 53006).

    - Use test strips temperatures between 61–95 °F or (16-35 °C) and between 10-80% relative humidity.
    - Store test strips at temperatures between 39-86 °F (4-30 °C).
    - Keep the test strips in the original container with the cap closed. Do not remove test strips from the container and put them into another container such as a plastic bag or pocket. Exposure to moisture may cause the monitor to reject the strip. Moisture will cause a deterioration of the test strip reagents.
    - Reagent composition:
        - Nitrosoaniline Mediator 6.72%
        - Quinoprotein glucose dehydrogenase 15.27%
        - Pyrroloquinoline quinone 0.14%
        - Buffer 34.66%
        - Stabilizer 0.54%
        - Non-reactive ingredients 42.66%

3. AccuChek Inform II Control Solutions (supplied by the laboratory via pneumatic tube system by calling extension 53006)

    - Store control solutions at 39-86 °F (4-30 °C).

    - The glucose control solutions are stable for three months after first opening the bottles, or until the expiration date, whichever comes first. **Date the bottles when first opened and with the open date and new expiration date.**
    - Reagent composition: Glucose, Buffer, Biological Salt, Preservative, , Nonreactive Ingredients, and FD&C Blue #1.

4. Other supplies to perform whole blood glucose testing.

    - **Capillary** collections –alcohol swabs, cotton balls or **gauze, lancets-disposable single use only.**
    - **Arterial** – plain sterile syringes or blood gas syringe containing lithium heparin **(do not use blood from syringes containing sodium heparin)**.
    - **Venous** – sterile syringe and needle.

CALIBRATION (Coding)

1. Each code key belongs to a single lot number and provides important information about the lot-specific properties of the test strip. The properties of the test strips are downloaded (as a code file) from the code key using the code key reader and sent to the meter.

    This procedure allows the code key information to be stored centrally in the data management system, from where it can be sent to all the meters in the facility.

2. Refer to the Accu-Chek Inform II Operator's Manual for further directions.

QUALITY CONTROL

- QC is good for 3 Months from the open date. If no date is on vial one must be put on the vial when opened and the expiration 3 months from the open date.

    Example: Date Opened 06/29 Discard 09/29

- Two levels of Accu-Chek Control. (Control 1 and Control 2) of quality control will be tested at the following times:
    - At a minimum of every 24 hours of Accu-Chek Inform II use. The Accu-Chek Inform II is preset to "lockout" patient testing at 0200 in all whole blood glucose testing areas. Control tests (Level 1 and 2) must PASS before further patient testing may commence.
    - If the Accu-Chek Inform II has been dropped.
    - Immediately after a new lot number of test strips has been put into use.
    - The battery has been replaced or other maintenance has taken place.
    - When the test results contradict the patient's clinical symptoms and the accuracy of the Accu-Chek Inform II is in doubt.

  - Any time a test strip vial has been left open. Even short periods of exposure to humidity can affect the test strips and cause false results.

- Acceptable ranges and mean values for the glucose control solutions are entered into the AccuChek via the RALS*Web*-3. The operator testing the quality controls will only see a PASS or FAIL result. All FAIL results require a repeat of the failed QC and or the entry of a comment code and further investigation.
- If the quality control results exceed the acceptable range, repeat the test after checking to ensure that neither the test strips nor the control solution are outdated. If the controls are still not within limits, use a test strip from an unopened vial and repeat the test. Refer to the troubleshooting section for further actions to be taken and/or contact the Ancillary Testing Coordinator for assistance.
- Each operator performing patient testing must be trained and authorized for the meter usage. The Ancillary Testing Coordinator will maintain a copy of a list of all authorized operators. Operator competency testing will be maintained on a regular basis by the Ancillary Testing Coordinator reviewing the quality control tests of each operator to verify that their results are within acceptable range. **CAP proficiency testing** (performed on each meter 2 times per year) will be coordinated by the Ancillary Testing Coordinator and will be performed by randomly chosen authorized operators who normally perform patient testing. All CAP proficiency testing records will be retained by the Ancillary Testing Coordinator for a minimum of 2 years.
- Quality control records will be kept for a minimum of two years.
- **Procedure for Testing Quality Controls**
  - Power Inform II on
  - Scan operator ID
  - At the main menu tap on Control Test.
  - Tap on the barcode icon and scan the vial of quality control solution.
  - Tap the barcode icon and scan the vial of test strips.

    Remove one test strip from the vial, close the lid, and at the prompt (green downward moving arrow), place the test strip into the Test Strip Port.
  - At the prompt (flashing red blood drop) introduce a drop of the control solution to the end of the test strip.
  - With the resulting PASS on the screen, tap on the green check mark in the lower right corner of the screen and continue with the other level of control solution.

- Remove the test strip and discard into regular trash.
- With the FAIL result on the screen, Repeat QC to troubleshoot until a PASS is shown upon testing. Possible solutions include:
  - Check to see that the yellow reagent area has air bubbles and repeat testing if they are present.
  - Repeat testing using a newly opened vial of strips.
  - Repeat testing with a newly opened vial of control solution.
  - Contact the Ancillary Testing Coordinator for assistance.

PROCEDURE

1. Gather and organize the necessary equipment and supplies at the test site.

2. Prior to collecting the specimen, identify the patient by the wristband ID, patient VA photo ID card, or by having the patient state their full name and SSN or date of Birth. Two identifiers are to be used every time.

CAUTION: Be sure to wear exam gloves while performing testing on the patient and to follow all precautions for bloodborne pathogens.

3. The patient's hands should be warm. This increases the circulation of the hands and fingers and will facilitate good blood flow.
4. Turn on the AccuChek Inform II glucose meter.

5. After the meter performs a self-check, it will proceed to the operator ID menu. Enter the operator ID by tapping the barcode icon and laying the red laser line on the barcode area of your hospital ID badge or by manually entering your ID on the keypad, then pressing the green √.. Your ID number must be recognized as an authorized operator before any further steps may be taken.

6. Tap the Patient Test icon.

7. Enter the patient ID by tapping the barcode icon and laying the red laser line on the patient ID barcode of their wristband. The outpatient will need to have their ID manually entered on the keypad, pressing the green √**.**

8. Scan the barcode on the vial of test strips being used. If the code chip entry does not match the scanned entry, an error message will appear. Refer to the trouble shooting section of the operator's manual to resolve this problem.

9. Remove a test strip from the vial and replace the cap on the vial immediately.
10. When the flashing strip icon appears on the meter display, gently insert the test strip with the yellow test window facing up and the electrodes in first.

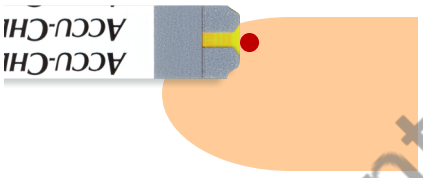
11. Once the meter has detected the test strip, the flashing red drop is the prompt to apply blood to the end of the test strip.

12. After ensuring the patient's finger is clean and dry, use a new lancet to puncture the fleshy side area of the finger (See Figure A) and wipe away the first drop of blood.

Figure A.

NOTE: Puncture only the side area of the patient fingertips. Long term use may cause callouses and hamper the ability to use braille if needed at some point of a diabetic patient's lifetime.

13. Dose the strip at the front edge, not on top of the strip.



14. Once a sufficient blood sample has been detected, the meter beeps and the measurement begins.

15. When the result is displayed, a message or warning may also appear fortifying you if the result exceeds the specified limit values. A message may indicate that a result is out of range. All criticals must be documented using the CPRS template.

    ↑ The value is above the normal/critical upper range

    ↓ The value is below the normal/critical lower range.

16. Remove the test strip and dispose of it in (regular trash is allowed). **Used lancets must be discarded into a sharps container.**

17. Press the ON/OFF button to turn the meter off.
18. Remove gloves and dispose of (regular trash is allowed).

INTERPRETATION

When results are higher or lower than the reportable range of the test it is necessary to repeat the test either with a whole blood glucose or with a plasma glucose sent to the laboratory.

REFERENCE RANGES

Test	Reference Ranges	Reportable Ranges Analytical Measurable Range (AMR)	Critical Ranges
Glucose	72.0 – 100.0 mg/dL	10 – 600 mg/dL	< 45 mg/dL - > 500 mg/dL

REPORTING OF RESULTS

A normal fasting plasma or whole blood glucose for a normal healthy patient is 72-100 mg/dL at all VISN 15 hospitals and clinics. Diabetic patient glucose results will vary depending upon the physician's recommended choice of therapy, i.e. diet control or insulin control. Therefore, any action based upon the whole blood glucose results of an individual patient is solely at the discretion of the provider in charge of the patient's diabetic or other medical care. The results will be entered in the lab report section of the patient electronic medical record (EMR) via the RALS-Web3 interface.
Automatic entry of the results into the hospital computer system (CPRS), is done by placing glucometer into base. Results post via our middleware RALS into CPRS. Results will be reported with the normal range for healthy patients.

1. **Values <45 mg/dL or >500 mg/dL are considered critical.** The test must be validated by the testing personnel by repeat testing, comparison testing with a plasma glucose by the laboratory, or comparison with the patient symptoms and previously recorded results to verify result reproducibility prior to any patient intervention. This validation should follow nursing protocols for patient care.

2. Upon obtaining a critical result, the provider must be notified immediately. It is a Joint Commission Patient Safety Goal to "measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the provider, of critical values." To comply, sixty (60) minutes after test completion has been established as the allowable time to notify the provider of a critical glucose result. Accreditation standards require there be documentation that the provider was notified of critical glucose results. This notification must be documented using the CO-CRITICAL GLUCOSE POC TEST RESULT (T) template (See attachment 1) or charted in CPRS under the patient's notes. If charted in the patient's notes, then documentation must follow Joint Commission guidelines and must include the

following elements to comply with policy: **date and time of notification, responsible testing individual, person notified (the person's first name alone is not adequate documentation), and test results**. Documentation of action taken (i.e. juice given, insulin, etc) must also be included in the patient's notes or on the CO-CRITICAL GLUCOSE TEST RESULT template. Associate Chief Nurses (ACN) are expected to use this information to monitor and enforce staff's compliance with policy.

3. A result indicated by "RR LO" means the result may be below 30 mg/dL or a technical error may have taken place. A result indicated by "RR HI" means the result may be above 600 mg/dL or a technical error has taken place. When either of these codes is obtained, the test will be repeated unless clinical symptoms are comparable and the repeat test would delay emergent patient care. Upon validation of the result, and "RR LO" or "RR HI" will be treated the same as a critical test result which will require immediate provider notification and critical result documentation in CPRS.

4. When multiple critical glucose results occur within an hour timeframe, it will be considered one event. Critical glucose documentation will be recorded once per hour. All subsequent critical glucose results will be considered repeat testing. Notification to the provider must occur with each critical glucose result, but only one documented notification is required in CPRS per event. CPRS documentation, either using the CO-CRITICAL GLUCOSE POC TEST RESULT (T) template (See attachment 1) or charted in CPRS under the patient's notes must occur. Associate Chief Nurses (ACN) are expected to use this information to monitor and enforce staff's compliance with policy.

5. Ancillary Testing Coordinators (ATC) are responsible for sending critical glucose results to the ACNs in a timely manner. ACNs are responsible for checking the patient's chart for the CO-CRITICAL GLUCOSE POC TEST or patient's notes for critical documentation compliance. When testing operators fail to comply with policy, it is the responsibility of the ACNs to notify the operator and their nurse manager(s). ACNs are expected to use this information to monitor and enforce staff's compliance with policy.

6. It is the responsibility of the ACNs to audit and track a monthly report showing critical glucose documentation compliance.

7. It is the responsibility of the Ancillary Testing Coordinators to track noncompliant testing operators. The ACNs will alert the ATCs of noncompliant testing operators. When an operator fails to document a critical glucose result up to three times per fiscal year, the operator's ID will be suspended. If an operator's ID is suspended, their glucometer access will be deactivated. The operator will have to attend a re-training before their ID will be reactivated.

LIMITATIONS OF PROCEDURE

1. The Accu-Chek Inform II test strips are for testing fresh capillary, venous, and arterial samples. Do not use for testing body fluids of any type.

2. Hematocrit should be between 10-65%.

3. Lipemic samples with triglycerides in excess of 1800 mg/dL may produce elevate results.

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

5. Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
6. 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.

7. The performance of this system has not been evaluated in the critically ill. Please note cautions regarding this.

PROCEDURAL NOTES:

No Patient testing is done without QC being within limits. QC performed every 24 hours. Operators are removed from testing if annual competencies are not performed. Not to be used on critically ill patients.

MAINTENANCE

1. Please observe the following points to ensure the reliable operation of the system over the long term**. Avoid getting liquid into test strip port! Failure to follow these instructions may damage the meter.**
    - Handle the meter and its system components carefully. Avoid dropping it or banging it.
    - Protect the base unit from dripping liquid.
    - Do **not** immerse the meter or base unit in any liquid.
    - Do **not** spray anything onto the meter.

- DO **not** clean or disinfect the meter while performing a blood glucose or control test.
- Do **not** expose the meter to excessive sources of heat for prolonged periods.
- Store the system and test strips in the same environment in which they are used.
- Do **not** store the meter in direct sunlight or under extreme temperature conditions.

2. Cleaning the Accu-Chek Inform II system.

    - All blood and other body fluids must be thoroughly cleaned from the meter before disinfection by the germicidal wipe.
    - The meter must be cleaned after each patient test.
    - Wear gloves when cleaning the meter.
    - The gloves worn during cleaning and disinfecting should be removed and hands washed thoroughly with soap and water before performing the next patient test.
    - Prior to cleaning, place meter on level surface. Power off meter
    - Use the **first** Super Sani-Cloth® Germicidal Disposable Wipe to remove visible soil. Squeeze excess liquid from the wipe before using.
    - Clean by gently wiping outside of meter and carefully around test strip port.
    - Dry the meter thoroughly after cleaning.
    - Dispose of used wipe according to local regulations for infectious waste disposal.
    - **Isolation patients:** Use a pre-moistened bleach disinfecting wipe provided on the cart by the patient room doorway. Squeeze excess liquid from the wipe. Dry the meter thoroughly after the disinfection time listed on the packet of wipes.

3. Disinfecting the Accu-Chek Inform II system

    - Prior to disinfecting, place meter on level surface. Power off meter.

- Use **second** germicidal wipe to disinfect by gently wiping outside of meter three times horizontally and then three times vertically and carefully around the test strip port.
- Allow meter surface to remain damp for the entire required contact time of the germicidal wipe; 2 minutes with sani-cloth and 3 minutes with bleach wipe.
- After cleaning and disinfecting, be sure the meter is dry and remember to replace the meter in the base unit to charge.

Maintenance Documentation

a) Scan in operator ID or manually type it in meter
b) Press the arrow in bottom right corner
c) Press the maintenance button
d) Press the speech bubble button
e) Choose from the list or type in cleaned and press green arrow
f) Return to base

TRANSMITTING INFORMATION

1. All meters should be returned to the base unit upon completion of quality control and patient testing. **This includes isolation areas and meters at bedsides in ICU.**
2. Place the meter back in the base unit and verify that the touchscreen moves to the Connecting, Busy, Synchronizing Database screens. This verifies patient results are transmitting to the computer network server and information from the RALSWeb3 database is being returned to the meter.

3. All critical results will be held in RALS until the ATC has reviewed the result and then uploads the results in CPRS.

TROUBLESHOOTING

If unable to resolve a problem with the glucose meter, please contact the Ancillary Testing Office at 53026 or 53034. A “Loaner” meter may be obtained by taking a non-working meter to the laboratory and filling out the Accu-Chek Inform II Meter Problem form. All areas must be filled out in order to obtain another meter.

RELATED DOCUMENTS:

Accu-Chek Inform Meter Problem Log
Critical Whole Blood Glucose Documentation CPRS Template

REFERENCES

1. Accu-Chek® Inform II Operator's Manual
2. RALSWeb3, software version 4.0, Online Help Manual
3. Accu-Chek® Inform II Test Strips package insert
4. Accu-Chek® Inform II Control package insert
5. College of American Pathologists Checklists: Point-of- Care-Testing, All Common, and Laboratory General.
6. HPM 589A4-10, Bloodborne Pathogens Exposure Control Plan.
7. HPM 589A4-299, Personal Protective Equipment.
8. HPM589A4-368, Cleaning, Disinfection, and Sterilization Guidelines.
9. McPherson MD MSc, R; Pincus MD PhD, M. 2017. *Henry's Clinical Diagnosis and Management of by Laboratory Methods 23rd Edition*. Pages 481-508. St Louis, MO: Elsevier Inc.
10. Digital Copy link: https://www.clinicalkey.com/#!/browse/book/3-s2.0-C20130143425