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Providence Santa Rosa Memorial Hospital

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Owner	Karla Gonzalez Anchondo: Point of Care Coordinator
Area	Laboratory - Point-of-Care
Applicability	CA - Santa Rosa Memorial Hospital
References	GACRLS

Accu-Chek Whole Blood Glucose Testing Policy

PURPOSE

Whole blood glucose is a definitive test performed at the 'point of care'" by certified staff for the purpose of assessment and/or treatment of patients.

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.

The system 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 NIST standard.

PERSONNEL

Licensed staff may perform blood glucose testing if trained and passed competency. Individuals must meet California state requirements to perform patient testing.

POLICY

1. The laboratory Point of Care Coordinator oversees the whole blood glucose point of care testing with direct supervision from the Laboratory Medical Director.
2. A lockout system is in place that only allows certified users to perform testing using the ACCU-CHEK Inform II meter.
3. The Point of Care Coordinator or designee ensures the accuracy of meter performance throughout the reportable range by performing a linearity evaluation on each new meter. Meter linearity is repeated if there is a major repair or if there is an unusual occurrence of a trend or if the QC is consistently out of range.
4. Patient and QC results are downloaded to the middleware program wirelessly or when the meter is 'docked'. Patient results automatically flow to the patient EMR unless a comment stating **'PROCEDURE ERROR"** is added by the nurse. The laboratory Point of Care Coordinator or other designated staff review flagged results and monitor quality control values.
5. The ACCU-CHEK instrument has not received FDA clearance for use with patients receiving intensive medical intervention or therapy. This device may not be used to test for glucose on patients receiving intensive medical intervention or therapy. On November 17, 2022 the Medical Director defined patients receiving intensive medical intervention or therapy as any patient:
    a. That is in the ICU and is on a pressor
    b. A patients in the OR and is on a pressor and is from the ICU

This policy follows manufacturer's instructions.

COMPETENCY AND CERTIFICATION

1. Each user must successfully complete initial and annual competency training to perform blood glucose testing using the ACCU-CHEK Inform System:
    a. A certified ACCU-CHECK Inform instructor is a designated individual who is trained in the use of the meter, authorized to teach others.
    b. Initial training and competency assessment is done by Nursing Education.
    c. Initial training includes: operation, use and troubleshooting of the glucose meter, quality control testing, patient testing, critical value follow up, and cleaning. Competency is validated through post test and performance of accurate testing using quality control samples.
    d. Annual competency validation requires performance of accurate testing using 2 levels of quality control samples and health stream module that includes a written test.
2. Initial training and annual competency is tracked in the middleware. Individuals are 'locked out' if the certification is not completed.

This program follows the manufacturer's instructions.

EQUIPMENT AND MATERIALS

- ACCU-CHEK Inform II Meter
    - Uses laser light to scan operator ID, test strip and control solution bar codes.
    - Caution: Because laser light can damage vision, always avoid staring directly into the laser light or shining the laser light into anyone's eye while scanning a barcode.
- ACCU-CHEK Inform II Controls (high and low levels)
    - Obtain from Central Supply
    - Store at room temperature (39-86 °F)

Solutions out date 3 months from opening or the date printed on the strip vial label, whichever comes first. Date with new expiration date when new vial is opened. Do not use after expiration. Discard vials with expired, missing or illegible expiration dates.

- ACCU-CHEK Inform II test strips
    - Obtain from Central Supply
    - Store at room temperature (39-86 °F) and 10%-80% humidity.
    - Test strips are sensitive to heat, light and moisture. Keep the bottle tightly sealed. Use test strips immediately upon removing them from the bottle. Never return test strips to the bottle after taking them out.
    - Strips are stable until the expiration date on the container. Do not use after expiration.
- Single patient use disposable lancets
- Clorox Germicidal Wipes
- Alcohol wipe
- Gauze/cotton ball for cleaning and wiping finger
- Disposable gloves

Coding of Test Strips: The properties of each lot number of test strips are downloaded (as a code file) from the code key into the ACCU-CHEK Inform II system by means of the code key reader. A code file is uploaded into the ACCU-CHEK Inform II system for every test strip lot that is received. The laboratory Point of Care Coordinator is responsible for doing this for each lot of test strips received by the hospital.

QUALITY CONTROL

1. Frequency

- Quality control testing is performed as a primary means of ensuring on-going proper performance of the ACCU-CHECK Inform II system. Quality control is required every 24 hours for each meter on each day using high and low control solutions. If quality control testing has not been performed in 24 hours, the meter 'locks out' for patient testing until quality control has been completed. Additional quality control testing is performed:

- When test results contradict clinical symptoms
- With each new bottle of test strips
- If a meter has been dropped or damaged.

Quality control results are reviewed at least monthly by the laboratory Point of Care Coordinator or designee and archived for 2 years.

2. Procedure

1. Put on gloves due to potential for non visible contamination on the meter.
2. Turn on the meter. Press forward **(>)** button to continue.
3. Scan operator bar code on your ID badge.
4. From the main menu, tap **"Control Test"**.
5. Scan the bar code on control solution vial.
6. Scan the test strip vial.
7. Remove test strip from container and immediately recap.
8. When the flashing strip icon appears on the screen, gently insert the test strip into the meter with the silver bar tip first.
9. When the flashing droplet icon appears on the screen, apply control solution to the front edge of the strip. An hourglass icon is displayed while waiting for the result. You will get an error message if the sample volume is insufficient.
10. Results display as a "PASS" or "FAIL". **Both QC levels must pass to proceed to patient testing.**
11. For control "FAILS":
    a. Add a comment(s) to the out-of-control result indicating that the test will be repeated. Up to three comments can be attached to each result.
    b. Repeat the test **one** time using the **same test strip vial, control solution(s) and meter**. If the repeat result is in range, you may proceed to patient testing.
    c. If the repeat test remains out of range, repeat the test using a **new vial of control solution**. If the repeat result is in range, proceed to patient testing using the new control solution. Discard the control vial that failed quality control testing.
    d. If the repeat test using the new vial of control is still out of range, repeat the test using a **different test strip vial**. If the repeat result is in range, proceed to patient testing **using the new test strip vial**. Discard the vial that failed quality control testing.
12. Remove and discard used test strip in appropriate biohazard bins.
13. If further assistance is required because QC is failing, sequester the meter and follow steps from troubleshooting section.

Suggested comments for QC results

1. **Procedure Error:** Known error in procedure occurred, like wrong QC, expired solutions, etc.

2. **QC OK New bottle:** This comment is used when a new bottle of strips is opened and QC is performed.
3. **Will repeat test**: Use when QC failed.

SPECIMEN

Acceptable specimens:

The following fresh whole blood sample types may be used:

1. Fresh capillary whole blood from non-neonates. or heel-stick dor neonate <3 days old. Test immediately as the sample is collected. Assure fingers and/or heel are warm.

   Note: Do not perform capillary (Finger-stick or heel-stick) glucose testing on patients with impaired peripheral circulation. Results may not be a true reflexion of the physiological blood glucose level. Venipuncture or line draws are the only acceptable samples when impaired peripheral circulation conditions are present. See limitations section.
2. Venous or arterial whole blood. Specimens collected in a plain syringe without anticoagulant must be tested immediately. Specimens collected with anticoagulant, may be used if tested within 30 min of collection. Be sure sample is well mixed. Samples collected when IV is being started prior to any fluids given, can be treated as venous or arterial, following the guidelines plain syringe or with anticoagulant.
3. IV lines. For line draw samples such as arterial lines, when the patient is receiving fluids, make sure the line is thoroughly clear of fluids before drawing blood sample by discarding the first 2-3 times the dead space (5cc minimum.) Do not allow bubbles to enter the test strip-sampling chamber.

Unacceptable specimens:

- Cord blood samples
- Specimens from critical ill patients.
- Clotted specimens.
- If testing is not performed at the patient bedside: Unlabeled specimens are unacceptable.
- Specimens collected with anticoagulants other than Lithium or Sodium Heparin; EDTA
- Required sample Size is 0.6 ul. Make sure to fill the tubes up to the manufacturer's mark.

PATIENT TESTING

- A physician order is required for routine testing.
- Patients taking vasopressors and/or hypothermic patients (≤ 36°C) and/or a systolic blood pressure of less than 90 mmHg must have whole blood glucose testing done by another method, send directly to the laboratory. **No patient**

testing can be done in any patients receiving intensive medical intervention or therapy.

- Patients are identified for testing according to hospital policy. Patient identifiers are scanned or manually entered into the system when prompted by the meter. Manual entry requires entry of CSN.
- Scanned arm band's are encouraged to avoid results failing to get to the EMR.
- **Critical limits** for patient testing are:
    - **Adults:** less than **50 mg/dL** or greater than **400 mg/dL**;
    - **Newborns <3 days old:** less than 30 mg/dL or greater 400 mg/dL
    - See **Interpretations of Results** for actions required when critical values are obtained.

Steps:

Prepare Patient:

1. Wash your hands, use gloves and any other personal protective equipment as required by infection prevention and isolation policy and procedures.
2. Verify patient identification according to hospital policy.
3. Explain the purpose of the test and the steps of the procedure.
4. Assess patient for compromised peripheral blood flow. Fingertips should be warm and pinkish when the hand is gently massaged.
5. Select finger site for puncture. It is preferred to select just off the midline of the middle finger or ring finger that has not been recently punctured.

Prepare Meter:

6. Turn on the meter.
7. Enter your operator ID by scanning the bar code on your ID badge.
8. From the Main Menu, tap Patient Test.
9. Enter patient identification number by scanning patient armband barcode or QR code or manual entry. Santa Rosa Memorial Hospital and Petaluma Valley Hospital (CSN) The QR code works the best.
10. Scan the same test strip code that is printed on the testing strip vial.
11. Remove test strip from vial and immediately recap container.
12. When the flashing strip icon appears on the screen, hold the test strip so the lettering "ACCU-CHEK" is facing upward, gently insert the test strip into the test strip port as far as it goes.
13. When the flashing droplet icon appears on the screen, the strip is ready to be dosed.
14. For venous or arterial specimens review section below .

Collect Finger Stick Blood Specimen/ Perform Test

15. Clean puncture site with alcohol swab. Allow to air dry completely. (Alcohol at the puncture site must be dry or an error code or inaccurate result may occur.)

16. Puncture site using single patient use lancet.
17. Hold the puncture site downward and gently apply intermittent proximal to distal pressure along finger.
18. Wipe away first drop of blood. This is advantageous because it ensures the cleansing agent is dry, it stimulates blood flow and clears interstitial fluid from the sample.
19. Apply a well formed drop of blood to front edge of test strip. Do not apply to top of strip.
20. An hourglass icon is displayed while waiting for the result. You will get an error message if the sample is insufficient.
21. Attach a comment as indicated. The most usual comment would be 'Expected Result'.
22. Remove test strip. Discard test strip and lancet according to infection prevention policy.
23. Clean meter with Clorox Germicidal Wipe.
24. The results will transmit into the EMR automatically, wireless or by docking it into the base.

Venous or Arterial blood Specimens

1. Collect venous or arterial blood using established techniques. If blood is collected using an established venous, central or arterial line, a 5 cc discard must be done prior to collecting a blood specimen for testing. Fresh samples containing anticoagulants like EDTA, Lithium Heparin are accepted.Test within 15 minutes.
2. Carefully apply a drop of blood to front edge of test strip. Do not apply to top of strip. Do not overload or squirt into meter.
3. An hourglass icon is displayed while waiting for the result. You will get an error message if the sample is insufficient.
4. **After obtaining a result press the check mark to send the results.** By not pressing the check mark the results transmission into the EMR will be delayed.
5. Turn meter off.
6. Remove test strip. Discard test strip and lancet according to infection prevention policy.
7. Clean meter.
8. When the wireless connectivity is affected, docking the meter into the base will also transmit the results into the EMR.
9. If the result is critical, a warning displays on the meter stating that a comment code is required.See Interpretation of results to address reporting requirements.

NURSE ALERT: test **results do NOT flow to the EMR** when the comment **'PROCEDURE ERROR'** is entered.

INTERPRETATION OF RESULTS

- **Normal Values**
    A. Fasting Adults: 65 – 99 mg/dL (plasma/serum)
    B. Neonate: <3 days: 40 – 90 mg/dL (plasma/serum)

Caution is advised in the interpretation of neonatal glucose values below 50 mg/dL.Glucose values in neonates suspect for galactosemia should be confirmed by alternate laboratory method.

- **Critical Values**:
    A. **Adults:** less than **50 mg/dL** or greater than 400 mg/dL
    B. **Newborns <3 days:** less than 30 mg/dL or greater 400 mg/dL.

Action to Take:

Repeat test to confirm critical value is recommended. Add comment on the meter "Notify Provider" and follow your department's policy

- **Results Outside Reportable Limits:**
  For patient testing are between 10 mg/dL and 600 mg/dL. Results outside range display as"Hi" (above meter range) or "Low" (below meter range). This results should be considered critical values.

Action To Take:

A STAT laboratory blood glucose test is ordered in order to obtain a numerical result.

Confirmation by repeat or comparison of values from different meters or methods may be misleading if specimens are not collected within 15 minutes of each other and tested immediately.

Patient Result Comments:

All **critical results** must have an attached comment. Up to three comments may be attached to each patient result. In addition, operators must follow their department's critical result reporting policy.

- Press **"Comments"** and choose the appropriate comment:

A. **Notify Provider:** Must be added in each critical value obtained. Satisfies regulatory requirement for Point of Care Critical value reporting. Operators must follow their department's critical value reporting policy.
B. **Order labs:** Use when specimen is sent to the lab for verification.
C. **Repeat test:** Use when testing is repeated using an Inform II meter to confirm or verify a result.
D. **Expected Result:** Use when result agrees with previous value and additional testing is not required.
E. **Procedure error:** Known error in procedure occurred. Includes incorrect patient, sample or collection. When using this comment the results will not cross into the EMR.

Note: It is not possible to attach a comment to a result once the meter has timed out or the result has been transmitted.

Confirmatory testing requirements:

Confirmatory testing is required if unexpected results are obtained. Send a venous specimen for confirmation by alternate laboratory method if:

1. Critical values are obtained and they have not been previously verified (unless provider deems results are consistent with clinical picture)
2. No results are obtained, Hi-LO (the instrument displays a code rather than a numerical value).
3. Repeated results are confirmed, but inconsistent with the patient's condition.

REPORTING RESULTS

Results are downloaded into the EMR wireless or when meters are returned to their docking station, in this last case, a series of screen displays, 'Connecting', 'Synchronizing Database' and 'Idle' confirm the data transfer is occurring.

In case of a downtime, nurses will document the Glucose result into nursing notes in the EMR. When the system is restored, all the results contained in each meter will automatically upload into the EMR

METER CLEANING/DISINFECTION

- Meter is cleaned and disinfected after each patient using Clorox Bleach Germicidal Wipes.

Steps:

1. Put on gloves.
2. Remove germicidal wipe, squeeze out excess fluid.
3. Gently wipe meter/base unit with disinfectant wipes. Avoid contact with meter/base unit connectors and base unit circuitry.
4. **Allow three minutes wet time.**
5. Always dry thoroughly before putting back into use or placing into the base unit.

TROUBLESHOOTING

Meter Malfunctions: Most malfunctions can be avoided if the meter is kept charged. It only charges in the download base. It cannot charge if left on a counter top or in the carry case. If a meter malfunctions, or keeps failing QC, must be taken to the laboratory where a loaner meter is issued. Meters are NOT sent to the lab via the pneumatic tube system.

A note is left with the 'broken' meter indicating the specific problem. There is a clip board near the meters in Point of Care to track meters received and meters given out.

The Point of Care Coordinator or designee attempts to correct the problem, consulting with ROCHE Customer Care support team as needed at (1-800-440-3638). If correction is not possible, the meter is sent to the manufacturer for repair or replacement by the Point of Care Coordinator.

PROFICIENCY TESTING

Internal Proficiency Testing (Correlations):

Whenever there is a question of accuracy of meter results, the laboratory can perform a split sample comparison with the meter in question.

A laboratory analysis is performed within 15 minutes of the blood glucose testing on the meter. The expected variation of results is +/- 15 mg/dL for glucose values **below** 75 mg/dL and +/- 20% for levels **above** 75 mg/dL. (Source: NCCLS).

The meters are calibrated to deliver plasma-like results.

LIMITATIONS

- Hematocrit should be between 10 – 65%
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- 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.
- 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, shock hypotension, decompensated heart failure or peripheral arterial occlusive disease. A venous or arterial sample is then recommended.
- Intravenous administration of N-acetylcysteine which results in blood concentrations > 5mg/dL will cause overestimation of blood glucose results. Do not use during intravenous infusion of N-acetylcisteine.

References:

Accu-Chek Inform II System Operator's Manual, Roche Diagnostics Corporation, July 2013

Approval Signatures

Step Description	Approver	Date
	Wanhua Yang: MD	11/2022

Karla Gonzalez Anchondo: 11/2022
Point of Care Coordinator