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St. Joseph Health
Santa Rosa Memorial

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

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.

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. Standard precautions are observed during specimen collection, testing and disposal of lancets and strips.
3. A lockout system is in place that only allows certified users to perform testing using the ACCU-CHEK Inform II meter. An additional lockout system is in place for the mandated performance of the two levels (high and low) of quality control solutions **once each day of use.** The required QC tests must pass in order to proceed to patient testing.
4. 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.
5. Patient and QC results are downloaded to the Alere RALS middle ware program 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.
6. The ACCU-CHEK instrument may not be used to test for glucose on critically ill patients. On April 12, 2016 the medical executive committee defined a critically ill patients 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.

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.

COMPETENCY / 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 Nurse 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 Alere RALS software system. Individuals are 'locked out' if not current.

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)
    - Expire three months after opening. Date with new expiration date when new vial is opened. Do not use after expiration.
- ACCU-CHEK Inform II test strips
    - Obtain from Central Supply
    - Store at room temperature (39-86 °F)
    - Keep test strips in tightly capped container at all times. Replace cap immediately after use
    - Strips are stable until the expiration date on the container. Do not use after expiration

- Single patient use disposable lancets
- 10% bleach wipes: Wipes must not contain hydrogen peroxide or detergent additive
- 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.

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, it is 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.

QUALITY CONTROL TESTING POLICY

- 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 of use. Additional quality control testing is performed:
  - When test results contradict clinical symptoms
  - With each new vial of testing strips
  - If a meter has been dropped or damaged
- If quality control testing has not been performed in 24 hours, the meter 'locks out' for patient testing until quality control has been completed.
- Quality control testing is performed using high and low control solutions.
- Control solutions are not used past their expiration date. Solutions out date 3 months from opening or the date printed on the strip vial label, whichever comes first.
- Quality control results are reviewed at least monthly by the laboratory Point of Care Coordinator or designee and archived for 2 years.

Steps:

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.
    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 call ACCU-CHEK Customer Care 1-800-440-3638. If the problem cannot be resolved, return the meter to the laboratory where a loaner meter can be issued. Advanced troubleshooting will be conducted by the laboratory Point of Care Coordinator or designee.

BLOOD SPECIMEN COLLECTION /HANDLING

Acceptable Samples:

1. The following fresh whole blood sample types may be used:
    a. Fresh capillary whole blood from non-neonates. Test immediately as the sample is collected. Assure fingers are warm.
    b. Venous or arterial whole blood. Test as soon as possible and not later than 15 minutes following collection. Be sure sample is well mixed. For line draw samples such as arterial lines, make sure the line is thoroughly clear of fluids before drawing blood sample. Do not allow bubbles to enter the test strip-sampling chamber.
    c. Neonate <3 days old heel stick.
    d. Cord blood samples **cannot** be used.
2. The following anticoagulants are acceptable (do not use any other anticoagulants for meter testing): Lithium or Sodium Heparin; EDTA
3. Sample Size is 0.6 ul.

PATIENT TESTING POLICY

Patient testing with the ACCU-CHEK INFORM II system quantitatively measures glucose in fresh venous,

arterial, neonatal heel stick and capillary whole blood from the finger and is used as an aid in monitoring the effectiveness of glucose control.

- 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 critical ill patient.**
- 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 a leading SV00 at Santa Rosa Memorial Hospital and PV00 at Petaluma Valley Hospital.
- Scanned ID'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.
- **Reportable/linearity limits** are between 10 mg/dL and 600 mg/dL. Results outside range display as Hi (above meter range) or Low (below meter range).

Steps:

Prepare Patient:

1. Wash your hands, don 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 (SV00#) or Petaluma Valley Hospital (PH00#) 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, gently insert the test strip into the meter with the silver bar tip first.
13. When the flashing droplet icon appears on the screen, the strip is ready to be dosed.
14. For venous or arterial specimens proceed to step 26.

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. **NURSE ALERT:** test **results do NOT flow to the EMR** when the comment **'PROCEDURE ERROR'** is entered.
23. Turn meter off.
24. Remove test strip. Discard test strip and lancet according to infection prevention policy.
25. Clean meter with bleach.
26. Dock the meter. All patient results will automatically flow into the Alere RALS middleware system and then into EMR after docking the meter.

Venous or Arterial blood Specimens

27. 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. Test within 15 minutes.
28. 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.
29. An hourglass icon is displayed while waiting for the result. You will get an error message if the sample is insufficient.
    NURSE ALERT: test results do NOT flow to the EMR when the comment 'PROCEDURE ERROR' is entered.
30. Turn meter off.
31. Remove test strip. Discard test strip and lancet according to infection prevention policy.
32. Clean meter.
33. Dock the meter.
34. All patient results automatically flow into the AlereRALS middleware system and then into EMR after docking the meter.

INTERPRETATION OF RESULTS

- **Normal Values**

- Fasting Adults: 65 – 99 mg/dL (plasma/serum)
- Neonate: <3 days: 40 – 90 mg/dL (plasma/serum)
  Caution is advised in the interpretation of neonatal glucose values below 30 mg/dL.

- **Critical Values:**
  - Definitions:
    - **Adults:** less than **50 mg/dL** or greater than 400 mg/dL
    - **Newborns <3 days:** less than 30 mg/dL or greater 400 mg/dL.
  - Action to Take:
    - Repeat the test if result is unexpected.
    - Order a STAT Laboratory glucose within 2 hours after an Accu-chek critical value was obtained, to verify the glucose result. A glucose repeated in the lab **within 15 minutes** of bedside testing and without any treatment intervention should fall within +/-20% of the bedside glucose if the result is greater than 75 mg/dL or if below 75 mg/dL, the variation should be +/- 15 mg/dL.
    - Promptly notify physician, obtain verbal read back of critical value and document per hospital critical value policy.
    - Follow physician order for treatment.
- **Results Outside Reportable Limits:**
  - **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).
  - **Action To Take:**
    - A STAT laboratory blood glucose test is ordered to obtain a numerical result.

REPORTING RESULTS

Results are downloaded to the hospital information system via the Alere RALS middle ware system when meters are returned to their docking station.

Wired Data Transfer: Results are transferred to EMR by placing the meter into a base unit that is connected to the hospital network. When properly docked, the meter will automatically transfer test results. A series of screen displays, 'Connecting', 'Synchronizing Database' and 'Idle' confirm the data transfer is occurring.

The meter can be removed and used any time during the transfer of information. Any information not completed will be transferred the next time the meter is docked. When properly docked, the meter will communicate every 10 minutes. This provides up to date ADT information. If the meter does not recognize your patient, it may need to be freshly downloaded to receive the most current patient information.

METER CLEANING/DISINFECTION POLICY

- Meter is cleaned and disinfected after each patient using 10% 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 a one minute dwell time (three minutes only if a suspect tuberculosis patient in airborne isolation).**
5. Always dry thoroughly before putting back into use or placing into the base unit.

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

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Lab Medical Director	Paul Wasserstein	11/2020

Step Description	Approver	Date
	Wanhua Yang	10/2020
	Karla Gonzalez Anchondo: Point of Care Coordinator - NE	10/2020

Applicability

CA - Santa Rosa Memorial Hospital