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ACCU-CHEK INFORM II BLOOD GLUCOSE DETERMINATION

PURPOSE

The Accu-Chek INFORM II meter is considered a **waived** test by the FDA used to obtain rapid assessment of blood glucose concentration results at the point of care. The test is to be used for monitoring glucose levels and should not be used for diagnosis.

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 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 NIST standard.

TESTING PERSONNEL

Qualified Licensed Registered Nurses (RNs) and approved Health Care Providers

EQUIPMENT AND MATERIALS

Gather the following supplies in preparation for patient testing:
Note: The POCT Service Team provides the meter and test strip and control vials. For all other glucose testing supplies, contact Lab Support Services or CPD.

- ACCU-CHEK Inform II meter – fully charged and coded to the test strip lot you intend to use.
- ACCU-CHEK Inform II test strip vial. Note about reagents: Reagents are not to be used past their expiration date.

- Supplies for collecting a blood sample: cotton balls, alcohol preps, approved auto-disabling single-use lancing device
- Gloves
- Biohazard and sharps container
- Transfer pipette or syringe as needed if testing a venous, arterial or line draw sample.
- Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes for cleaning meters, base units, and base unit hubs. NOTE: When dealing with patients with possible or confirmed infections (e.g., *Clostridium difficile*, Norovirus infections), use PDI Bleach Wipes.

REAGENTS, STORAGE AND HANDLING

A. **Test Strips**
   a. Use the test strips at temperatures between 16 – 35°C.
   b. Use the test strip immediately after removing it from the container.
   c. Use the test strips between 10-80% relative humidity. Humidity is the amount of dampness in the air.
   d. Close the container tightly immediately after removing a test strip to protect the test strips from humidity.
   e. Store test strips at room temperature 15-30°C (59-86°F).
   f. Store unused test strips in the original container with the cap closed. Do not remove test strips from the test strip container and put them into another container such as a plastic bag or pocket, etc.
   g. Discard test strips that are past the expiration date printed on the test strip container. If the expiration date is missing or illegible, do not use the test strips.
   h. Do not use test strips beyond expiration date as printed on the strip vial label.
   i. Quality Control must be performed on all new vials of test strips when first opened.

B. **Quality Control Solutions**
   a. Store the controls at room temperature 15-30°C (59-86°F).
   b. Do not refrigerate or freeze. Unopened control solutions remain stable up to their original expiration date when stored at room temperature.
   c. **Control vials must be dated with MM/DD/YR when opened**.
   d. Opened Control solutions are good for **3 months** from date opened – or the original expiration date – whichever comes first.
   e. **Expiration date MM/DD/YR must be written on the vials when opened**.

C. **Meter Touchscreen**
   a. Use only your finger to touch the screen elements.
   b. Using a sharp-edged object (such as the tip of a pen) can damage the touchscreen.
   c. Do not use the system in direct sunlight.
   d. Direct sunlight may reduce the life expectancy and functionality of the display, as well as, the integrity of the test strips.
   e. Handle the meter and its system components carefully. Avoid dropping or banging it.
   f. Protect the base unit from dripping liquid.
   g. Do not **immerse or drench** the meter and/or base unit in any liquid.
   h. Do not expose the meter to excessive sources of heat for prolonged periods of time when performing a test. Potential sources of heat include, but are not limited to:
      i. Leaving the meter under a bilirubin light or photo therapy light.
      ii. Leaving the meter on a bed warmer.

iii. Leaving the meter in an isolette.
iv. Leaving the meter on a bedside table by the window.

D. **Code Key**
   a. New test strip codes are uploaded into all meters by the Clinical Laboratory when the new lot of strips is validated for use. The properties of the test strips are downloaded as a code file from the Clinical Lab and sent to all meters. The code file is stored in the meter. **The operators will not need to insert a code key.**

E. **Data Management**
   a. Data management is maintained through the RALS system in the Clinical Laboratory by the Point of Care Testing Services Team.

CALIBRATION VERIFICATION (LINEARITY TESTING)

A. Linearity solutions (L1-L6) and QC (high and low) are performed on new, replacement, and repaired meters.
B. Linearity testing is performed to validate the reportable range. Level 1 – Level 6 linearity solutions are run in duplicate and results are plotted against reference values. The ideal linearity should be a straight line. Linearity and QC results are acceptable if they fall within the manufacturer's ranges.
C. New and repaired meters must pass linearity and QC testing prior to being used for patient testing.

SPECIMEN REQUIREMENTS

1. The following fresh whole blood sample types may be used:
   a. Venous whole blood
   b. Arterial whole blood
   c. Capillary (non-neonate finger-stick and neonate heel-stick) whole blood

2. The following anticoagulants are acceptable (do not use any other anticoagulants for meter testing):
   a. Lithium Heparin

QUALITY CONTROL

A. **Quality Control (QC) testing must be performed:**
   a. Each day of use (once every 24 hours) **prior to patient testing**.
   b. Before using the meter for patient testing the first time.
   c. When using a new vial for the first time.
   d. When using a new test strip lot for the first time (and as a result a new test strip code).
   e. If a test strip vial was left open.
   f. If questionable test results are displayed repeatedly
   g. If the previous control test is out of range.
   h. If testing the performance of the system is required.
   i. If the meter has been dropped.
   j. When the test strips or QC solutions have been exposed to extreme heat, humidity, or cold (or when the storage conditions are out of range).

B. Results for Low QC (Level 1) and High QC (Level 2) must fall within the acceptable QC ranges. **The meter cannot be used for patient testing if it fails any quality**

control test, in which case, the meter will lock out and not permit patient testing.

C. **Corrective Actions for failed QC:**
   a. If QC fails, select "**SFGH Will Repeat**" in the pre-programmed comments on the meter.
   b. Check expiration date of the control solutions and test strips.
   c. Check the test strip lot number on the meter display and make certain it matches the lot number on the vial of test strips being used.
   d. Repeat QC using the same control solution and test strip vial.
   e. If QC still fails, discard the control solution and open a new bottle of controls.
   f. Repeat QC with the newly opened controls.
   g. If the QC still fails, discard the test strips and open a new vial of test strips.
   h. Repeat QC on the new vial of test strips.
   i. If the QC still fails, remove meter from service and notify POCT Service.

D. The meter will lock down at **0300** each morning and the message "**QC Due: Immediately**" will appear on screen. QC must be performed and successfully passed in order to initiate patient testing for the day.

E. **QC Testing Procedure:**
   a. Press the power ON/OFF button to turn on the meter. The meter will perform self-checks.
   b. Touch the forward icon or wait 5 seconds to automatically proceed to the Operator ID screen.
   c. Press and release the barcode button.
   d. Hold the meter so that the window of the barcode scanner is approximately 4-8 inches above the barcode you wish to read. The meter beeps once the barcode has been read successfully. (Barcode IDs are imbedded with unique identifiers to each operator. They are akin to a computer password and **sharing of barcode IDs is not allowed**.)
   e. From the Main Menu screen, touch Control Test.
   f. Scan the lot number barcode on the control vial Level 1 (low) or Level 2 (high). If the lot number is incorrect, this message appears:

Control lot not found. **Please enter an existing Control lot or** **See your System Administrator**

      i. Make sure you are scanning the control vial and not the test strips.
      ii. Check the expiration date and lot number.
      iii. If the control vial is not expired, but will not work, contact the POCT Service Team.
   g. Touch the check mark button to confirm the selected control solution lot number.
   h. Scan the lot number barcode on the test strip vial when prompted to verify test strip lot number. The meter will perform the code key/code file checks. Make sure the code file displayed in the meter match the lot number of the test strips used.
   i. Touch the check mark button to confirm the selected test strip lot number.
   j. Remove the test strip from the test strip vial and close the vial with the cap immediately.
   k. Hold the test strip so the lettering "Accu-Chek" is **facing upward**.
   l. Slide the test strip into the test strip port as far as it goes in the direction indicated

by the arrows on the test strip. The meter beeps indicating the strip has been detected.

m. Wipe the tip of the control solution bottle with gauze before and after use.
n. When flashing drop appears in the display, apply a drop of glucose control solution to the front **edge** of the test strip. (Do not apply the control solution to the top of the strip.) The control solution is pulled into the test strip by capillary action. Tightly close the cap of the control solution after use.
o. The meter beeps when an adequate sample is applied and an hourglass is displayed while the test is running.
p. The test takes 5 seconds to complete, an audible beep is heard and the quantitative result is displayed.
q. If the result is out of range, you will be required to enter a comment.
    i. Touch the comment bubble icon to display the pre-programmed and custom comment options. Up to three comments can be entered.
    ii. Select "**SFGH Will Repeat**" as one of your comments.
    iii. For a custom comment, press the double lined comment bubble icon to enter other or additional pertinent customized comment(s).
    iv. Once the selected or custom comment(s) are entered, press the check mark icon to return to the Results Screen.
r. Remove the test strip and discard in a biohazard waste container.
s. Repeat all steps to run the second level of QC.
t. Proceed to patient testing or Power OFF button to turn the meter off.
u. Placing the meter in the docking station ensures downloading of QC information to the POCT Services Team and charges the battery simultaneously.

BLOOD SAMPLE COLLECTION

A. **Patient Preparation:**

NOTE: Observe universal precautions; wash hands thoroughly with soap and water (or with hand sanitizer) before and after testing each patient, wear new clean gloves and other personal protective equipment as appropriate. **Never** use finger-stick devices for more than one person. Use auto-disabling, single-use finger-stick devices for assisted monitoring of blood glucose.

a. For **Capillary** Glucose Testing:
    i. Only finger-stick and heel-stick for infants are approved test sites. The site must be cleaned, dried, and punctured via **a single use lancet**. (**One Lancet: One Patient: One Time Use**)
    ii. Discard lancet in biohazard sharps container.
    iii. Wipe the first drop of blood with gauze and use the second free flowing drop of blood for testing.
    iv. Do not squeeze the puncture site too hard as it may result in tissue fluid contamination.
    v. Alcohol used to cleanse the puncture site for capillary samples must be thoroughly dry or an error code / inaccurate result may occur.

b. For **Venous, Arterial, or Neonatal** blood collection in Lithium Heparin:
    i. Use only the blood drawing syringe assigned to the patient. Do not share blood drawing syringes between patients. (**One Syringe: One Patient: One Time Use**)
    ii. Discard blood drawing syringe in biohazard sharps container.
    iii. Caution should be taken to clear arterial lines before blood is drawn.
    iv. To minimize the effect of glycolysis, blood glucose determination with

venous or arterial blood must be performed within 30 minutes of sample collection.

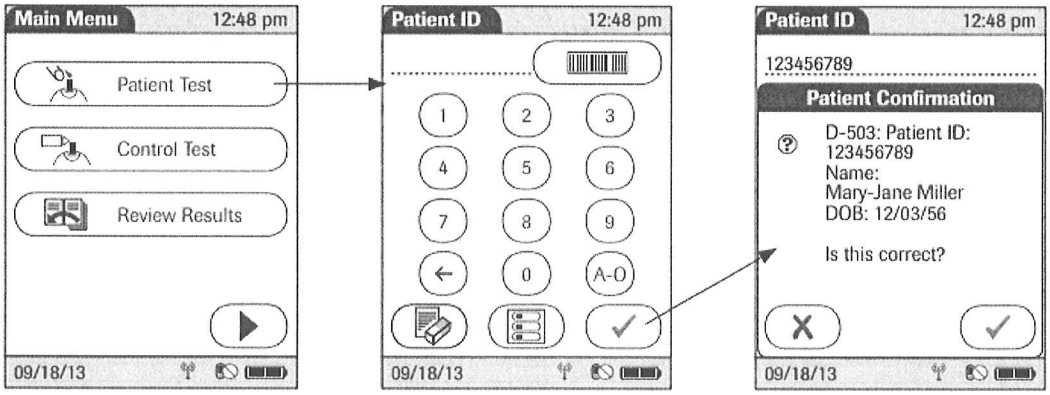
v. Avoid air bubbles with the use of pipettes.

Neonate Samples

As a matter of good clinical practice, caution is advised in the interpretation of neonate blood glucose values below 50 mg/dL. Critical blood glucose values always require follow up. Glucose values in neonates suspect for galactosemia must be confirmed by an alternate glucose methodology. Refer to your location's IDA (Indications, Documentation, and Action) page for appropriate documentation and actions indicated.

B. **Patient Testing Procedure:**

1. Observe universal precautions; wash hands (or use hand sanitizer), wear new clean gloves and other personal protective equipment as appropriate.
2. Using two patient identifiers, verify patient identification, and explain procedure to patient and/or family. NOTE: Carefully assess the patient for any indication that bedside glucose testing may not be appropriate. Consider the potential interferences and compromising conditions listed in the LIMITATIONS section.
3. identify the patient using two patient identifiers (e.g., full name and date of birth or medical record number or CSN number)
4. Explain the procedure to the patient.
5. Turn on the ACCU-CHEK Inform II meter.
6. Enter your operator ID by scanning your barcode ID. **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to perform tests under another operator's ID. **Sharing barcode IDs is strictly prohibited.**
7. From the *Main Menu*, touch *Patient Test.*
8. Enter the patient identification in the ACCU-CHEK Inform II system by scanning the patient's CSN barcode ID. If the scanner is inoperable, manually enter the CSN number.



Follow the appropriate steps:

A. After scanning the patient ID barcode:	B. Actions to take:
Demographics display on the screen	1. Verify that the demographics displayed on the screen is correct. 2. If so, then touch the check mark icon. 3. If not, then touch the X mark icon and start over.
Demographics do not display on the screen	1. Verify the scanned CSN is correct, checking it against the patient label or patient wristband.

	2. If not correct, then touch the X mark icon and start over. 3. If it is correct, then run the test and wait for the result to display. Add the comment  , PATIENT ID VERIFIED and touch the check mark icon.

9. Confirm that the meter is coded (calibrated) to the same test strip code that is printed on the test strip vial by scanning the lot number barcode on the test strip vial. Contact your supervisor or Point-of-Care Service Team if you are unable to confirm the correct test strip code.
10. You will now see a picture of a test strip with a downward flashing arrow on the screen indicating that you are ready to insert a test strip into the meter.
11. 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 a blood sample.
12. Collect an acceptable blood sample according to your facility's established procedures (See the "Patient Testing Procedure Notes" section below for tips on optimizing sample quality)
    - **Finger-stick or neonate heel-stick samples**: Test immediately as the sample is collected.
    - **Venous, arterial or line draw samples:** Test 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.
13. Wipe away the first drop of blood with gauze and use the second free-flowing drop of blood from the finger-stick site for testing.
14. Apply blood to the front edge of the test strip. The sample will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip.
15. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.
16. After the sample has been obtained, apply gentle pressure to the puncture with a clean gauze square or cotton ball site 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 screen. Depending upon how high or low the result is, it may appear in a numeric or non-numeric format. See "Interpretation and Reporting of Patient Results" section below for interpretation of each result format.
18. Remove the test strip and dispose of it in a biohazard container.
    b. Make note of the result. If result is in the critical range or outside of the reportable range, the following message will appear:

REPEAT TEST and CONSIDER sending a STAT specimen to the lab.

    c. If a result is in the critical range, a comment **must** be entered to continue meter use.
        i. Touch the comment bubble icon to display the pre-programmed and custom comment options:

1. **SFGH WILL REPEAT**
2. **SFGH NOTIFY MD**
3. **SFGH REFER TO CHART**

d. Touch the ✓ button to confirm the result and send the result from the meter by placing the meter in the base unit and/or record the result into the electronic data management system. The base unit also charges the meter.
e. Follow up on any results that exceed critical or reportable limits according to policy.
f. Clean and disinfect in accordance with the CLEANING / PREVENTIVE MAINTENANCE section.
g. Discard gloves and wash hands or use hand sanitizer.
h. Place meter in docking station to ensure downloading of QC and patient result information and to keep the meter battery charged.

PATIENT TESTING PROCEDURE NOTES

1. Good sample quality is essential for reliable results. The following tips will help you to optimize the quality of a finger-stick capillary sample:
    a. Assess the patient for signs of reduced peripheral circulation such as cold hands, pale, mottled or bluish nailbeds and administration of vasopressor medications. If peripheral circulation is impaired, collection of capillary blood from approved sites is not recommended, as the results might not be a true reflection of the physiologic 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.
    b. 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. Common methods for stimulating blood flow include:
        i. Warming the site
        ii. Positioning the hand below the heart
        iii. Gently massaging the hand by stroking from the palm outward to the fingertip
        iv. Asking the patient to move and flex his/her arm, wrist, hand and fingers while you are gathering supplies and preparing the system for testing
    c. Be sure to allow the cleansing agent to completely dry before puncturing the intended site.
    d. Wipe away the first drop of blood with gauze and use the second free-flowing drop of blood from the fingerstick site for testing.
    e. Do not attempt to express blood from a previous puncture site even if it still appears to be bleeding because it is likely that the clotting process has begun and may alter the sample matrix. A fresh puncture should be made for every test.

2. Do not place the meter on bedding after applying blood to the test strip. This can cause the blood to be wicked out of the test strip by the bedding.
3. Recap the test strip vial immediately after you remove the test strip you plan to use. Never use test strips found loose outside the vial. Discard any vial of strips that you find uncapped. Discard any reagent strip vials where the cap was NOT left securely in place.

REFERENCE RANGES

Fasting:

Normal	70-99 mg/dL
Impaired Fasting Glucose (Pre-diabetes)	100-125 mg/dL
Diabetes	≥ 126 mg/dL

Random:

Normal per Age	0 – 1 year	50-150 mg/dL
	≥ 1 year	70-199 mg/dL

Impaired Glucose Tolerance	140-199 mg/dL
Diabetes	≥ 200 mg/dL

Critical Values:

Glucose	< 50 or > 500 mg/dL
Neonates (<30 days)	< 50 or > 200 mg/dL

ADDITIONAL INFORMATION

These test strips deliver results that correspond to the blood glucose concentrations in plasma as per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Therefore, the meter displays blood glucose concentrations that refer to plasma although you always apply whole blood to the test strip.

If the blood glucose result does not reflect the patient's clinical symptoms, or seems unusually high or low, perform a control test. If the control test confirms that the system is working properly, repeat the blood glucose test. If the repeated blood glucose result still seems unusual, send a sample to the Clinical Laboratory for blood plasma glucose testing.

INTERPRETATION AND REPORTING OF PATIENT RESULTS

1. Results may appear in any of the following formats and may require follow-up:
    a. A numeric value
    b. "LO" meaning that the result is below the lower reading limits of the ACCU-CHEK Inform II system (<10 mg/dL). "LO" results will not transmit to the EMR (e.g., Epic).
    c. "RR LO" meaning that the result is below your facility's established reportable limits (10-24 mg/dL). "RR LO" results will transmit as its numerical value to the EMR.
    d. "HI" meaning that the result is above the upper reading limits of the ACCU-CHEK Inform II system (>600 mg/dL) "HI" results will transmit as ">600 mg/dL" to the EMR.
2. Critical Results exceeding the critical range of the system require follow up and documentation of this follow up.

    3. For critical results or results outside of the reportable range (LO, RRLO, HI), the meter will prompt the operator to repeat the test; if again obtained on a repeated test **and the** result does not reflect the patient's clinical symptoms ***send a STAT specimen to the Clinical Laboratory prior to treating the patient.*** (Waiting for the STAT results is not necessary before treating the patient, but the specimen must be drawn/sent prior to treating the patient in order to gain a comparable/accurate/real-time test result.)
4. Individual patient results are documented in the patient's medical record by downloading the meter. If for some reason the results do not download, it is the testing employee's responsibility to manually enter the test results into the patient's medical record – ensuring

test result documentation.

5. If an incorrect medical record number has been used or the patient has been misidentified, notify the POCT staff and complete an unusual occurrence report.

CLEANING / PREVENTIVE MAINTENANCE

A. For efficiency, daily cleaning and disinfecting are companion procedures and should be done when QC is performed.
    a. Cleaning removes visible soil and organic material prior to disinfecting.
    b. Disinfecting destroys most pathogenic organisms.

B. Do not clean or disinfect meter while performing any test.
- Remove the meter from the base unit and turn it OFF prior to cleaning and disinfecting. **At a minimum, clean and disinfect the meter between each new patient use and when soiled** with a Hydrogen Peroxide cleaner disinfectant wipe. NOTE: When dealing with patients with possible or confirmed infections (e.g., *Clostridium difficile*, Norovirus infections), use PDI Bleach Wipes.
- Always follow the hospital policy for wet contact time.
- If the reagent strip case was carried into the patient room, disinfect the case as well.

C. The towelette should only be **slightly damp, NEVER dripping wet (wring it out)**.

D. If it is suspected that moisture has entered the strip port, attempt a QC test. If test fails, remove meter from service and notify the POCT Service Team Monday-Friday 0800-1600.

E. The accessory box and docking station base can be cleaned with the same cleaning products. Unplug docking station from electrical power prior to cleaning.

F. Prevent electrical damage. Do not pour or spray solutions directly onto meter or docking stations. Do not immerse in liquids. Do not wet electrical connectors on the back of the base unit.

G. All components must be dry **before** returning meter to docking station.

METER DOCKING AND BATTERY CHARGING

A. The Accu-Chek INFORM II meter contains a rechargeable battery pack that is recharged when connected to the base unit docking station.

B. In order to maintain the battery charge, the Accu-Chek INFORM II **meter should be stored on the docking station when not in use**. (Do not leave meter at bedsides, in hallways, or at nurse's stations in anticipation of next use.)

C. When the meter is in the docking station, the battery with lightning icon is displayed indicating electrical power is available and the meter is charging.

D. The meter must be docked in order to transmit data to and from the Clinical Laboratory and to the patient's electronic medical record.

LIMITATIONS

A. The Accu-Chek INFORM II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.

B. Hematocrit should be between 10-65%.

C. Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.

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

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

F. **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.

G. This system has been tested at altitudes up to 10,000 feet.
H. **The performance of this system has not been evaluated in the critically ill.** Refer to your location's IDA page for appropriate documentation and actions indicated.

ALTERNATIVE TEST METHODS

A. Blood plasma glucose testing is performed in the Clinical Laboratory.
B. Refer to your location's IDA page for appropriate documentation and actions indicated. POCT glucose testing **may not** be performed by the patient or by using the patient's own glucose monitoring device in the hospital setting at SFGH.
C. Alternate site (such as arm or leg) capillary testing is unacceptable in a hospital setting. Due to the potential for less vascular circulation in alternate sites, a 30 minute lag time may occur in detecting hypoglycemia from alternate site capillary samples.

STAFF EDUCATION, ORIENTATION & TRAINING, COMPETENCY, & BARCODE IDs

A. Testing personnel are required to take the initial training and competency assessment. Competency assessment (using two methods) must be completed after initial training and before technical duties are performed, six months after initial competency assessment and annually thereafter. Initial training and competency assessment is documented.
B. Once approved to test, the new operator will be issued a barcode ID with their unique identifiers imbedded within the barcode. Those renewing their annual Competency will not require a new barcode ID; rather, their current barcode ID will be updated via the POCT Service.
C. If an operator's barcode ID is active (is working), it signifies the operator has completed all prerequisites for patient testing and is currently approved to perform this POCT.
D. If an operator's barcode ID is not active (not working), it signifies the lack of approval for performing this POCT and the need to renew their Competency test.
E. If an employee loses or damages their barcode ID, they may request a new barcode ID from the POCT Services.
F. Barcode IDs are to be secured to the employee's hospital or university ID badge.
G. Barcode IDs are to be treated like secure passwords and thus the sharing of barcode IDs in not allowed.
H. All activity occurring under an employee's barcode ID is the responsibility of that employee.
I. Students are not trained, nor approved, to perform this POCT at ZSFG. Their educational experience may be gained only when an employee with an active barcode ID is with them at the patient's bedside supervising and taking full responsibility for the experience, results, documentation, and follow-up actions.

RECORD KEEPING

All records for QC Testing, Patient Testing, Orientation & Training, Competency Testing, Meter Validation, Patient Comparisons, Maintenance, and Testing Issues will be kept on file in the Clinical Laboratory for at least three years. Patient results are documented in their medical record for perpetuity.

RETRIEVAL OF STORED RESULTS FROM THE METER

A. From the **Main Menu**, press **Review Results**.
B. The **Review Results** screen displays the most recent stored results on top. The meter memory stores up to 2,000 results.
C. Select any result to view result details.
    a. The following information will be displayed:
        i. Patient ID (CSN)
        ii. QC level
        iii. The lot number of the reagents used to perform the test, the test result, the date and time the test was performed, and any comments that were entered at the time the test was performed.
D. Press the UP arrow to view most recent tests.
E. Press the DOWN arrow to view previous tests.
F. Select **PATIENT** to view a specific patient's result.
    a. Barcode scan or manually enter the patient's CSN number.
    b. Press the arrow buttons to scroll through the patient results.
    c. Select any result to view patient result details.
    d. Press the back arrow to return to the previous screen.
    e. Select **ALL** to return to viewing ALL RESULTS.
G. Select **QC** to review QC results only:
    a. Use the arrow buttons to scroll through the QC results.
    b. Touch any QC result to view result details.
    c. Touch the back arrow to return to the previous screen.
    d. Press the **Main Menu** icon to return to the Main Menu.

TROUBLESHOOTING GUIDE

Call ACCU-CHEK Customer Care at 1-800-440-3638 for assistance any time you have questions or concerns regarding the ACCU-CHEK Inform II system.

1. **Troubleshooting meter operational issues:** If the meter fails to function at any point in the procedure or if you get an error message associated with the result, make a note of the malfunction or error message and attempt to repeat the test. If the error persists, sequester the meter and test strip vial involved and deliver them to the POCT Service Team.

    - 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. If repeat test still gives "**Strip Defect Error**", consider immediately sending STAT glucose specimen to the Clinical Lab to determine if error message is due to an extremely low glucose result (<10 mg/dL) or some other reason. Do not use the meter (remove from service) and notify the POCT Service Team (not BioMed Services).

Strip Defect Error Extremely Low Blood Glucose Sample, Below the meter's reading range, or a bad strip

- 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.

2. **Troubleshooting questionable results:**
   - Consider whether the result is consistent with the patient's history and clinical presentation. Take the following action if you question the reliability of the result for any reason:
     1. Add a comment(s) to the result indicating that the result is in question.
     2. Perform quality control testing using the same meter and test strips.
     3. If quality control test results are within range, repeat the patient test using the same test strips and meter.
     4. If the quality control tests are not within range, sequester the meter and test strip vial involved and deliver them to the Point of Care Coordinator for advanced troubleshooting.
     5. Repeat patient testing using another meter and test strip vial that have passed routine quality control testing.
3. **Guidance for interpreting on-screen message and error codes:**

You may contact POCT Service Team to attain a meter replacement. During off hours, a meter replacement may be attained from the Clinical Laboratory.

A. **On Screen Messages**

All error messages displayed by the system have a letter identifying the message type, a number and a description of the error to help the operator take action to resolve the problem. The message types are:	
E	Identifies the notification as an **ERROR**. The information notifies the operator that an error has occurred.
W	Identifies the notification as a **WARNING**. The information does not block the operator from continuing, but rather gives the operator information that may suggest an alternate workflow is required.
I	Identifies the notification as **INFORMATIONAL** only. Informational notifications present the operator with contextual information, and allow the operator to proceed after confirming the notification.
D	Identifies the notification of a **DECISION** point. Decision notifications provide the operator with a choice based on contextual information.

B. **Error Codes**

Display Symptom Error Code	POSSIBLE REASON AND SOLUTION
The meter does not power on.	**Battery pack might be dead.** 1. Place meter in the base unit for at least one hour to recharge the battery pack. 2. If error persists, bring meter to the Clinical Laboratory and trade it for a Loaner Meter.

Meter displays: "Type Bad Dose"	**Insufficient amount of blood on the test strip.** 1. Repeat the test using a new test strip, ensuring proper sample dosing application (review proper testing procedure). 2. If error persists, bring meter to the Clinical Laboratory and trade it for a Loaner Meter.
Meter displays: "Glucose Error"	**Detection of an unexpected HARDWARE ERROR.** 1. Perform QC on new vial of test strips and repeat patient test with this new vial of test strips. 2. Refresh/Reboot the meter by turning off the meter, wait 10 seconds, then turn on the meter. 3. Reset the meter by following the Meter Reset Procedure. 4. If error persists, bring the meter to the Clinical Laboratory and trade it for a Loaner Meter.
Meter displays: "Unexpected SW Error"	**Detection of an unexpected SOFTWARE ERROR.** 1. Perform QC on new vial of test strips and repeat patient test with this new vial of test strips. 2. Place meter into a connected base unit and let it download completely to synchronize configurations with the data management system. 3. Reset the meter by following the Meter Reset Procedure. 4. If error persists, bring the meter to the Clinical Laboratory and trade it for a Loaner Meter.
Meter displays: "QC Due: Immediately"	**QC needs to be done.** 1. Run controls immediately 2. Patient testing cannot proceed until control tests are successfully run.
Meter displays: "LO" or "HI" or "RR LO"	**Patient's result is possibly critical.** Refer to "**INTERPRETATION AND REPORTING OF PATIENT RESULTS**" section
Meter displays: QC "FAIL" or "Out of Range"	**Quality Control result has failed or is out of range.** 1. Repeat QC. Refer to "**QC Testing Procedure**" for step-by-step instructions.
Battery Low	**Meter left off docking station for too long.** 1. Charge the battery by placing the meter in the docking unit.
Battery Critically Low	**Meter left off docking station for too long.** 1. Charge the battery by placing the meter in the docking unit. 2. If meter does not re-charge, bring to the Clinical Laboratory and trade it for a Loaner Meter.
The Accu-Chek INFORM II meter is unable to communicate with the data management system.	**There is some disconnect in the system.** 1. Reset the meter using the reset button. 2. Ensure all wiring is connected, nothing is unplugged. 3. If meter still will not download results to patient's medical record, notify the POCT Service Team.
Automatic shutdown (powers off)	**To conserve energy the meter may automatically shut down.** 1. Press the ON/OFF button to turn meter back on.

Base Unit LED is not illuminated.	**Base Unit is not connected to power supply unit or power supply unit is defective, or power outlet is not active.** 1. Disconnect the base unit power supply cord from the base unit and electrical outlet and then reconnect it again. Make sure all the cords are tightly connected to the base unit. 2. If error persists, notify the POCT Service Team.
LED flashes red	**Communication or configuration error.** 1. Ensure all cords are plugged in. 2. If problem persists, notify the POCT Service Team.

C. **Meter Reset Procedure**

1. Place the meter face down on a level surface.
2. Press the reset button in the middle of the battery pack using a tool such as a screwdriver or paper clip.
3. Turn the meter over (right side up).
    a. The Roche logo should be displayed.
    b. If the Roche logo does not appear within 60 seconds, place the meter on a base unit for a minimum of 15 minutes to recharge the battery.
    c. Within a short period of time, the meter's version screen will appear, displaying the version numbers of the meter components.
4. To ensure successful troubleshooting, dock the meter in the base unit and let it download completely.
5. Finally, the Power up/Stand By screen and the Main Menu are displayed.

D. **Broken / Inactive Meters**

1. Meters that fail to perform properly or have failed QC cannot be used for patient testing.
2. Meters removed from service must be returned to the Clinical Laboratory for evaluation, inspection, downloading, minor repair and/or meter replacement.
3. Loaner meters are available in the Clinical Laboratory for overnight or over-weekend use or until POCT Services can restore a meter to a unit.

E. **Network Connectivity Problem**

1. Any time data is not communicating between the meter and the Clinical Laboratory or the patient's electronic medical record, be sure all cords are connected and the power supply is working.
2. Be sure the meter is charged.
3. Try to resolve the issue by resetting the meter.
4. If meter will not download, notify Point of Care Testing Services.

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DISTRIBUTION

1. Point of Care Testing Services Master Manual
2. All Testing Sites

REVISION HISTORY

Revision Date	Description:	Director Signoff on:
8/3/2020	Initial version	8/3/2020
3/11/2021	Removed SARS-CoV-2 from cleaning the analyzer section	3/11/2021
6/17/21	Clarified patient ID verification steps	6/17/21