**PROCEDURE:** Glucose, Whole Blood by *Roche ACCU-CHEK Inform II meter®*

**ISSUE DATE:** August 2013

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**REVIEW DATE: MAY 2018**

## AUTHORIZATION

Testing is only granted to nursing and staff personnel who have received appropriate instruction and have completed competency testing for this procedure within the past 12 months. Instruction and testing must be documented. Operators may perform tests only after entering their own ID and must under no circumstances provide their ID to enable another operator to perform testing. To maintain certification, each operator must run both a low and high QC under their operator ID, and semi-annually thereafter.

## PURPOSE:

Persons with diabetes who are hospitalized often have fluctuations in blood glucose levels due to illness, stress, changes in diet and activity, and changes in medications and treatments. These changes require frequent testing so that the blood glucose can be as tightly controlled as possible. The American Diabetes Association[1] recommends Point of Care Testing (POCT), or bedside glucose monitoring, for persons with diabetes who are hospitalized.
Critically ill patients including those with and without diabetes, receiving hyperalimentation therapy, or exhibiting diabetes-like symptoms brought on by certain drug treatments, typically require more frequent monitoring of their blood glucose concentrations. Testing at the bedside may therefore be an important aspect of immediate care.

## PRINCIPLE:

The ACCU-CHEK Inform II system quantitatively measures glucose in whole blood. The enzyme on the test strip, a mutant variant of quinoprotein glucose dehydrogenase (GDH) from Acinetobacter calcoaceticus, recombinant in E. coli, converts the glucose in the blood sample to gluconolactone. The recombint GDH does not react with maltose. This reaction creates a harmless electrical DC current that is proportional to the glucose concentration producing a glucose result. The sample and environmental conditions such as hematocrit and presence of reducing substances 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 an NIST standard.

## REAGENTS & MEDIA:

1. ACCU-CHEK INFORM II TEST STRIPS & CODE KEY – Cat No.= 05942861001. Manufactured by Roche Diagnositcs, Indianapolis, IN 46256.

    - REAGENTS & PREPARATION – No preparation needed. Remove strip from bottle immediately before testing is performed and do not return unused strips to the original container.

    - STORAGE & STABILITY - Store at room temperature (2-30 $^{o}$C) and away from heat and humidity. Use the test strips at temperature between 16-35 $^{o}$C. Keep vial capped when not in use. Do not put strips into a plastic bag, pocket or any other secondary container. Test strips are stable until expiration (use by) date printed on the vial.



2. ACCU-CHEK INFORM II CONTROL SOLUTIONS – Cat. No = 05213509001. Manufactured by Roche Diagnostics, Indianapolis, IN 46256.

   - REAGENTS & PREPARATION – No preparation needed. Buffered stabilized solutions of glucose, preservative and FD&C Blue #1 dye. Mix well before use. Do not shake. The introduction of bubbles into the test solution may cause inaccurate results. Wipe tip before and after use.

   - STORAGE & STABILITY - Store at room temperature (4-30 °C). Keep vial tightly capped. Do not use the solutions after 3 months from date opened or after the expiration date printed on bottles, whichever comes first. Document new expiration date when opened.

3. ACCU-CHEK INFORM II Linearity Test Kit – Cat No. = 05871166. Six (6) vials of glucose solutions of varying concentration for verifying method/meter linearity.

   - INGREDIENTS & PREPARATION – No preparation needed. Buffered stabilized solutions of glucose, preservative and FD&C Blue #1 dye. Mix well before use. Do not shake. The introduction of bubbles into the test solution may cause inaccurate results. Wipe tip before and after use.

   - STORAGE & STABILITY - Store at room temperature (4-30 °C). Keep vial tightly capped. Do not use the solutions after 3 months from date opened or after the expiration date printed on bottles, whichever comes first. Document new expiration date when opened.

**SUPPLIES & MATERIAL:**

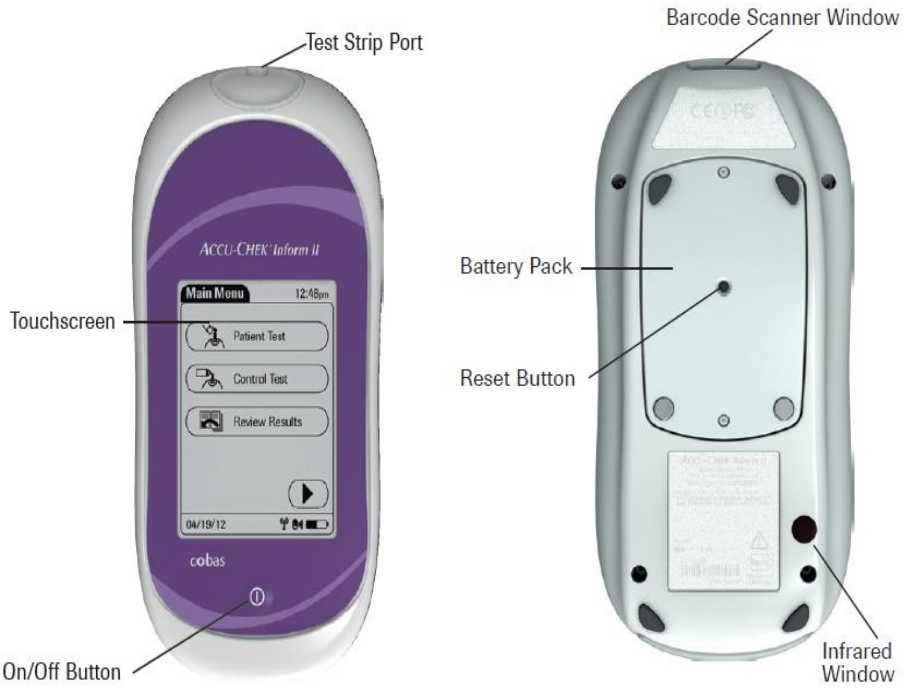
1. Super Sani-Cloth® – PDI, Inc, Orageburg, NY 10954. Cat. No. H04082

**EQUIPMENT**:

1. BASE UNIT – Cat No. = 0588876001. Data transfer and recharger unit. Manufactured by Roche Diagnositcs, Indianapolis, IN 46256.


BASE UNIT

2. Roche Inform II METER – Glucose meter for semi-quantitative analysis of glucose in untreated whole blood. Manufactured by Roche Diagnositcs, Indianapolis, IN 46256.




**SAFETY PRECAUTION:**

| | |
|---|---|
| **BIOHAZARD** | All products or objects that come in contact with or contain human or animal body fluids or tissue should be handled at all times as if capable of transmitting infectious diseases. |

**SAMPLE REQUIREMENT:**

SPECIMEN TYPE –

- Whole Blood: Capillary, venous, arterial or neonatal whole blood may be used. Whole blood collected in tubes containing anticoagulants such as Lithium or Sodium heparin and EDTA may be used but should be tested within 15 min. to minimize glycolysis.

**QUALITY CONTROL PROCEDURE:**

Low and high glucose control solutions must be performed every 24 hours to verify the Inform II system performance. Certain designated low volume areas have been approved to perform QC weekly and on days of patient testing. Quality control is also performed whenever you observe unexpected results of any kind or when a meter is dropped.

1. Turn on the glucose meter.

2. Enter your operator ID by scanning the bar code on your employee badge. If the operator ID you enter is not accepted contact your supervisor or Point of Care Coordinator. **DO NOT** perform tests under another operator's ID.

3. From the Main Menu, touch Control Test.

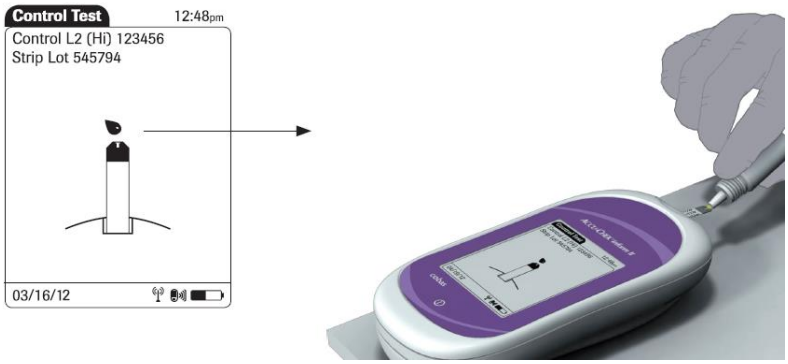

4. Select the control level you wish to run.

5. Confirm QC lot number by pressing ✓

6. The strip lot screen will appear. Scan reagent strip vial to enter correct strip lot number into the meter.

7. Insert the strip when prompted. Scan reagent strip vial to enter correct strip lot number into the meter.

8. Once the flashing blood drop icon appears, apply control solution to the front edge of the test strip. The solution will fill the yellow sample chamber by capillary action. Do not apply sample to the top of the test strip. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress. You will get an error message if the sample is insufficient. If this occurs, you will need to repeat the test.




9. The measurement is complete when the meter displays “PASS” or “FAIL”

10. If PASS, proceed with the other level of QC

11. If FAIL is displayed you must select a comment that pertains to why the QC failed. Press the comment icon 💬 to display the preprogrammed comments. Enter comment code which best describes QC failure. If multiple QC failures occur, contact laboratory Point of Care Testing office.

12. Touch the ✓ button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.

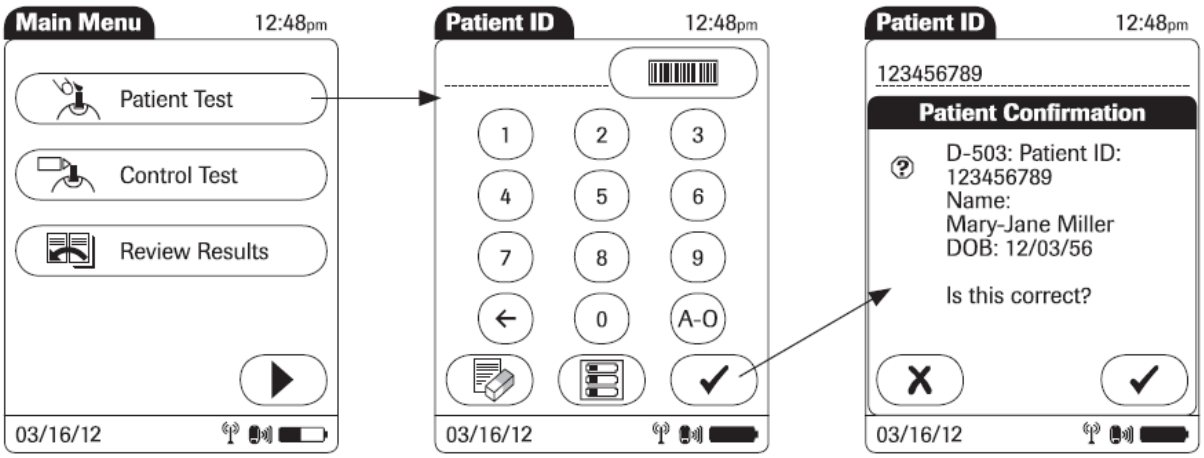
**CALIBRATION:**

Each box of test strips contains a code key. Each code key belongs to a single lot and provides important information about the lot-specific properties of the ACCU-CHEK Inform II test strip. 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 by the laboratory POCT technologist for every test strip lot that is received by the BJC Healthcare System. The code file for each in-use test strip lot resides in all meters so that end users on nursing units are able to access and select the correct test strip lot for testing. Calibration by the operator is not required. The chip contained in each strip container can be discarded.

**PATIENT TEST PROCEDURE:**

Use the following procedure to perform patient analysis

1. Take the meter and testing supplies to the patient location.
2. Wash hands and don personal protective equipment (gloves, gowns, etc.) as required by infection prevention and isolation policies and procedures.
3. Explain the procedure to the patient.
4. Identify patient.
5. Turn on the ACCU-CHEK Inform II meter.
6. Enter your operator ID by scanning the bar code on your employee badge. **NOTE:** If the operator ID you enter is not accepted contact your supervisor or Point of Care Coordinator. **DO NOT** perform test under another operator's ID.
7. From the Main Menu, touch Patient Test.
8. Enter the patient identification number in the ACCU-CHEK Inform II system by scanning the barcoded wrist band. In some authorized locations you may manually enter patient ID via key pad.
9. If the patient number is not available, please use the emergency identification number [note 1]. This should only be used in rare circumstances in which an ID cannot be obtained. If the emergency ID is used, notification will be sent to the nurse manager or designee to correctly identify the sample.



10. Confirm the positive patient information by asking the patient (or nurse if the patient is unable to answer) name and date of birth while looking at the meter and confirming that this truly is the patient you are testing by pressing✓. confirm correct patient ID was used. SLCH meters will show the name and DOB when scanning the patient's armband or luggage tag.

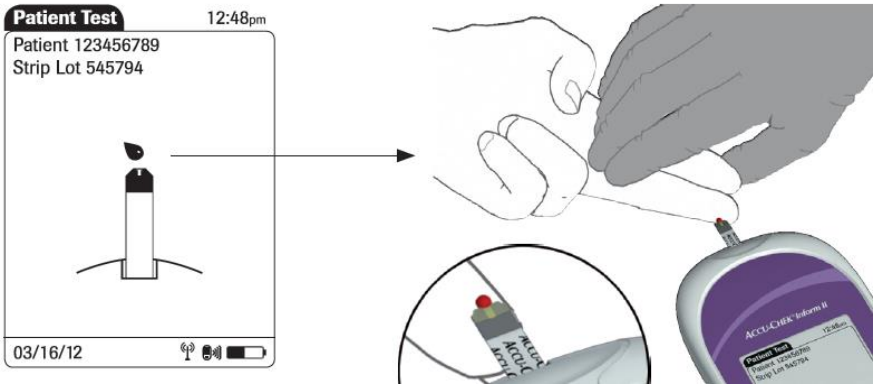
11. The strip lot screen will appear. Scan reagent strip vial to enter correct strip lot number into the meter. You will now see a picture of a test strip with a downward flashing arrow on the screen indicating that you are ready to insert a test strip into the meter.

12. A picture of a test strip with a downward flashing arrow on the screen will appear, indicating that the strip is ready to be inserted into the meter.

13. 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.

14. Collect an acceptable blood sample.

15. Wipe away the first drop of blood with gauze or tissue – not an alcohol prep pad.




16. Once the flashing blood drop icon appears, apply second drop of 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.

17. Once sufficient sample has been detected, the measurement begins. An hourglass icon indicates that the measurement is in progress.

18. 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 Reference Interval and Critical value sections below for interpretation of results.

19. Touch 💬 to enter up a comment. SLCH enters the following comment for a critical value "Critical Value Noted."

20. If result is questionable and repeat testing will be performed, touch 💬 and add "Repeat Test" comment to the questionable result.

21. Remove the test strip and dispose of all testing materials using universal precautions. Dispose of lancet in sharps container.

22. Touch the ✓ button to confirm the result and send the result from the meter wirelessly or place the meter in the base unit to send the result and record the result into the electronic data management system. The base unit also charges the meter.

23. Disinfect the meter and tote with Super Sani-Cloth® according to manufacturer's directions. Wipe down the entire meter and allow to dry for 2 minutes.

**CRITICAL VALUES FOR BARNES-JEWISH, ST. LOUIS CHILDRENS, PARKLAND, BOONE, MISSOURI BAPTIST SULLIVAN, MISSOURI BAPTIST, BARNES-ST. PETERS, PROGRESS WEST, BARNES-JEWISH WEST CO**

| AGE | LOW | HIGH |
|---|---|---|
| 0 - 18 Years | ≤ 40 mg/dL | ≥ 400 Mg/dL |
| >18 Years | ≤ 50 mg/dL | ≥ 450 Mg/dL |

**CRITICAL VALUES FOR ALTON MEMORIAL**

| AGE | LOW | HIGH |
|---|---|---|
| 0 – 1 Month | ≤ 40 mg/dL | ≥ 500 Mg/dL |
| >1 Month | ≤ 40 mg/dL | ≥ 500 Mg/dL |

- Check patient chart for special orders regarding critical values
- Critical values are reported to a Physician or licensed care giver immediately and follow-up testing should be considered. SLCH documents the reporting in the electronic medical record. There must be a comment attached to all critical values of notification, the AccuChek meter will force the user to enter a comment for a critical value. SLCH uses the "Critical Value Noted" in the AccuChek Glucose meter.
- Critically ill patients at SLCH are identified as patients in the 5NICU, CICU and PICU.
- SLCH CSCC has no critically ill patients.

**RESULT REPORTING:**

Patient results will be wirelessly entered into the Laboratory Information System via interface and available to all downstream systems.

In the case of a wireless network down and the glucose results will not transfer to the medical record, please take the meter to the base unit on your floor that is attached to a computer or Ethernet port. This base unit is not only charging station, but it is also a wired download station to transfer results to the computer. Set the meter into the docking station. It will then begin to download all glucose results.

**REFERENCE INTERVAL:**

- RANDOM REFERENCE INTERVALS[2] BARNES-JEWISH, ST. LOUIS CHILDRENS, PARKLAND, BOONE, MISSOURI BAPTIST SULLIVAN, MISSOURI BAPTIST, BARNES-ST. PETERS, PROGRESS WEST, BARNES-JEWISH WEST CO

| AGE RANGE | | | | | CONCENTRATION RANGE | | | |
|---|---|---|---|---|---|---|---|---|
| 0 | Days | To | 3 | Days | 50 | to | 110 | mg/dL |
| 3 | days | To | Adult | & Up | 70 | to | 199 | mg/dL |

- RANDOM REFERENCE INTERVALS[2] ALTON MEMORIAL

| AGE RANGE | | | | | CONCENTRATION RANGE | | | |
|---|---|---|---|---|---|---|---|---|
| 0 | Days | To | 1 | Month | 40 | to | 100 | mg/dL |
| 1 | Month | To | 18 | Years | 65 | to | 199 | mg/dL |
| 18 | Years | To | Adult | & Up | 70 | to | 199 | mg/dL |

- FASTING REFERENCE INTERVALS - BARNES-JEWISH, ST. LOUIS CHILDRENS, PARKLAND, BOONE, MISSOURI BAPTIST SULLIVAN, MISSOURI BAPTIST, BARNES-ST. PETERS, PROGRESS WEST, BARNES-JEWISH WEST CO

| AGE RANGE | | | | | CONCENTRATION RANGE | | | |
|---|---|---|---|---|---|---|---|---|
| 0 | Days | To | 3 | days | 50 | to | 99 | mg/dL |
| 3 | days | To | Adult | & Up | 70 | to | 99 | mg/dL |

- FASTING REFERENCE INTERVALS – ALTON MEMORIAL

| AGE RANGE | | | | | CONCENTRATION RANGE | | | |
|---|---|---|---|---|---|---|---|---|
| 0 | Days | To | 1 | Month | 40 | to | 100 | mg/dL |
| 1 | Month | To | Adult | & Up | 70 | to | 99 | mg/dL |

**MAINTENANCE:**

- Disinfect the entire surface area of the meter and tote after every patient with Super Sani-Cloth® according to directions.. The whole meter is water tight, with the exception of the port. Wring out disinfectant cloth prior to cleaning around test strip port. Wipe down and allow to dry for two minutes.
- Place meter on charging base when not in use.

**METER REPLACEMENT**:

The clinical area using the meter will have the responsibility of troubleshooting any meter that is suspected to be defective. Once the meter has been determined to be defective, it can be exchanged for a new meter in the laboratory. Contact your laboratory POCT technologist for assistance.

**AMR VALIDATION:**

Calibration verification is accomplished using three steps.

1. All new meters, upon receipt will have the calibration verification performed. Six vials of glucose solutions at varying concentrations will be analyzed in duplicate. Value assignment is test strip lot number dependent. After data is transmitted to COBAS IT1000 Software in the laboratory POCT office, a report in EP evaluator that consists of a linearity plot, regression statistics summary table, a level statistics summary table and a linearity-listing table are printed. The POCT technologist reviews the report for acceptability of the slope (0.90 to 1.10) and % difference of mean analyzed value from reference value (<10%) for Levels 2 through 6 and +/- 8mg/dL for Level 1. Meters are then rotated for the AMR/Linearity checks over a period of two years.

2. Calibration is verified by analyzing in duplicate six (6) vials of glucose solutions of varying concentrations on a representative sample of meters. Value assignment is test strip lot number dependent. After data is transmitted to COBAS IT1000 and then entered into an EP report that consists of a linearity plot, regression statistics summary table, a level statistics summary table and a linearity-listing table are printed. The POCT technologist reviews the report for acceptability of the slope (0.90 to 1.10) and % difference of mean analyzed value from reference value (<10%) for Levels 2 through 6 and +/- 8mg/dL for Level 1.

3. With each new strip lot at least 20 patient samples are run on two meters with values throughout the reportable range of 20 mg/dL to 600 mg/dL. Whole blood glucose values from the meters should agree ± 12mg/dl for values <100 mg/dl or ±12.5% for values >100mg/dL.[1] Patient comparisons are only performed when a new strip lot is received which is about every 6 months.

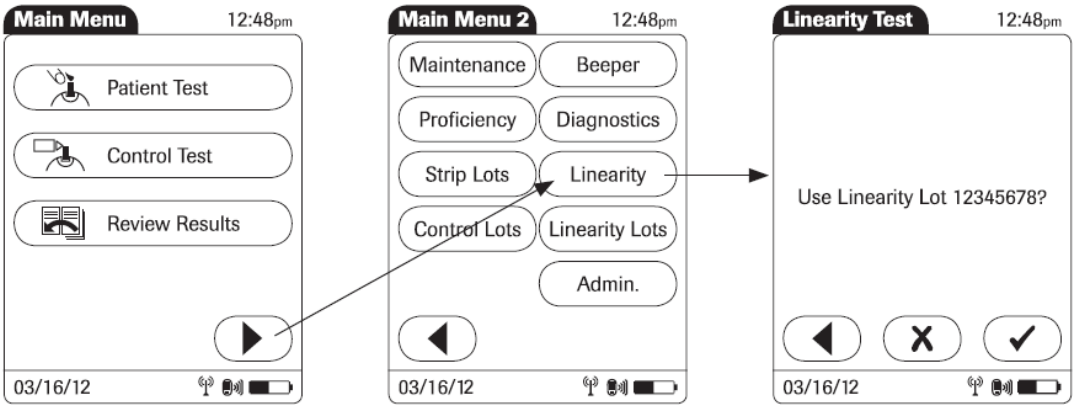
   Note: Some BJC hospitals may require additional patient correlation data for new meters.

Procedure to run AMR

1. Turn on the glucose meter.

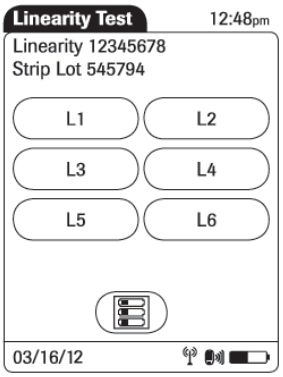
2. Enter your operator ID by scanning the bar code on your employee badge.

3. From the Main Menu, touch key to see additional menu. Press Linearity, then confirm lot number




4. The strip lot screen will appear. Scan reagent strip vial to enter correct strip lot number into the meter. 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.

5. Insert the strip when prompted.




6. From the Linearity test menu, press L1.

7. Insert test strip and apply linearity test solution.

8. Touch the ✓ button to confirm the result. Repeat for a total of 2 results for each level.

9. Repeat steps one through eight for remaining Linearity levels L2 – L6.

**LIMITS OF TEST PROCEDURE**:

1. CLINICAL LABORATORY TESTING – Glucose analysis by the central clinical laboratories should be considered for any one or more of the following conditions:

   - Neonatal values not consistent with clinical findings should be confirmed by a clinical laboratory method. Neonates exhibiting hypoglycemic symptoms, regardless of blood glucose monitoring results, should have their glucose tested by a clinical laboratory test method. Use caution when interpreting neonatal blood glucose results that are less than 50 mg/dL
   - Neonatal values greater than 200 mg/dL should be confirmed by an alternate method.
   - Low or High Critical Values are exceeded
   - Low or High Analytical Ranges are exceeded

- Test results, that do not agree with expected values / clinical picture of the patient

2. ANALYTICAL RANGE – results below the limit of sensitivity and above the limit of linearity should be considered for confirmation by the clinical laboratory method.

   - Limit of Sensitivity – varies per BJC hospital. All BJC Hospitals use the sensitivity of 10 mg/dL and report values <10mg/dL except Barnes-Jewish, Children's, and Parkland Hospitals which uses a sensitivity of 20 mg/dL. Values less than 20 are reported as <20 mg/dL.

   - Limit of Linearity - method is linear to 600 mg/dL. Values greater than 600 are reported as > 600 mg/dL.

3. INTERFERING SUBSTANCES & CONDITIONS - the following substances and/or conditions[3] interfere with the glucose measurement. If present, values may be inaccurate and glucose analysis by the clinical laboratory method is warranted.
   - Cord blood samples cannot be used.
   - 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 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.
   - This system has been tested at altitudes up to 10,000 feet.
   - The performance of this system has been evaluated in the critically ill at BJC.
   - SLCH home meter use is limited to education and not for clinical treatment.

**NOTE 1**

Barnes-Jewish Hospital and Christian Northeast Hospital - use 911911911. If the emergency ID is used, notification will be sent to the nurse manager or designee to correctly identify the sample.

Missouri Baptist Sullivan Hospital uses the date of Service (MMDDYYYY)+001 or 002 for the next patient. - If the emergency ID is used, place the identification used on the daily Glucose Monitoring Sheet along with date, time, operator, and glucose result. When available, as much patient information as possible must be added to the sheet. Minimum information required is patient name and date of birth. A registration label is preferred. The sheet will be sent to the laboratory for the POCT person.

Alton Memorial Hospital - If the emergency ID is used in the Emergency Room, place the identification used on the daily Glucose Monitoring Sheet along with date, time, operator, and glucose result. When available, as much patient information as possible must be added to the sheet. Minimum information required is patient name and date of birth. A registration label is preferred. The sheet will be sent to the laboratory for the POCT person.

Barnes St. Peters Hospital – use date of birth MMDDYYYY

Boone Hospital – use emergency barcode ID that is preprinted. Fill out patient information send to the lab.

St. Louis Childrens Hospital – Use Emergency barcode ID that is preprinted. Fill out patient info and send to lab.

**NOTE 2**

SLCH defines critically ill patients as 5NICU, Heart Center and PICU. See attached policy for BJC critically ill patients. 5NICU does not have patients on the epinephrine, norepinephrine and vasopressin at the BJC critically ill defined doses. The Heart Center and PICU does use the 3 above named drugs. When a patient in the Heart Center and PICU is placed on the 3 drugs the pharmacy will notify the Laboratory Medical director who will notify the Medical staff in the unit to not use the AccuChek glucose meter for glucose testing.
See attached BJC HealthCare system definition for the Critically ill patient for glucometer testing.

SLCH CSCC does not see critically ill patients at this site.

SLCH, along with the hospital system, has performed a comparison study of patients from areas of critically ill, correlating glucose results from the Roche AccuChek Inform II and the main Chemistry analyzers.

Training and Competency will be conducted by POC personnel. Testing will be monitored by the Center of Lifelong Learning.

*Operators failing to comply are locked out of the meter for patient testing.*

**REFERENCES:**

1. Standards of Medical Care in Diabetes-2007
2. Diabetes Care 201336(S1) S46-S47.
3. Roche ACCU-CHEK Inform II Operator's Manual
4. CLSI , poc12A Guidelines