

THEVALLEY HOSPITAL
Ridgewood, New Jersey

PATIENT CARE SERVICES (PCS) POLICIES AND PROCEDURES

SUBJECT: Whole Blood Glucose

PURPOSE: The Accu-chek Inform II is intended for use to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, heel stick neonatal, or fresh capillary whole blood samples drawn from fingertips as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.

PRINCIPLE:

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

Acceptable Testing personnel:

Waived Blood Glucose Monitoring System: Registered Nurse (RN), Patient Care Associate (PCA) II, Certified Nuclear Medical Technologist (CNMT), Respiratory Therapist (RT), Catherization Laboratory Technologist, Mobile ICU Paramedic (MICP), RN/MICP, RN and Mobile ICU nurses (MICUN) and Medical Technologists.

Non-waived high complexity Blood Glucose Monitoring System designated d for “critically ill patient” areas are restricted to Registered Nurses, Medical Laboratory Techs and Medical Laboratory Scientists testing personnel only.. The following units were determined to be “critically ill”: Intensive Care unit (ICU), Coronary Care unit (CCU), Cardiac Surgery Intensive care unit (CSICU), Intermediate Care unit (IMC), Neonatal Intensive Care unit (NICU), Pediatric Intensive Care unit (PICU), and Emergency Department (ED).

Materials Required:

Accu-Chek Inform II meters with RF card for wireless connectivity.
Base units for connectivity for wire connectivity (LAN), and/or recharge meter’s battery.
Accu-Chek Inform II Test Strips.
Accu-Chek Inform II Quality control (QC) solutions Level 1 and Level 2
Accessory box: Gauze, Alcohol Swabs, Lancet, and Gloves.
Hospital Approved Germicidal Disposable wipes

Specimen Type:

The following fresh whole blood sample types may be used:

- Capillary (non-neonate fingers stick and neonate heel stick) whole blood
- Fresh venous whole blood containing the anti-coagulant: EDTA (Purple top tube), Lithium Heparin (mint top tube), or Sodium Heparin (green top tube), test must be performed within 30 Minutes of sample collection

- Fresh arterial blood, test must be performed within 30 Minutes of sample collection
- Cord blood is not acceptable

Reagent Storage:

- Use the test strips at temperatures between 61 – 95 °F (16 – 35 °C)
- Use the test strips between 10-80 % relative humidity. Humidity is the amount of dampness in the air.
- Store the test strips at temperatures between 39 – 86 °F (4-30 °C). Do not freeze.
- 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.
- Close the container tightly immediately after removing a test strip to protect the test strips from humidity.
- Use the test strip immediately after removing it from the container.
- 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.
- All supplies for Accu-Chek (liquid QC and strips) are stored in Supply Distribution Department SDD

Quality Control:

Run 2 levels (low and High) of controls to be performed at least once every 24 hours, when instrument is in use.

Controls must be acceptable prior to testing patients.

Note: “Critically ill” designated areas- acceptable testing personnel as indicated above must perform quality control.



Other circumstance to run Quality Control:







- When using a new test strip vial for the first time
- When using a new test strip lot for the first time
- If a test strip vial was left open.
- If questionable test results are displayed repeatedly
- If the Inform II meter has been dropped.
- If the test strips have been exposed to extremes of heat, cold and/or humidity.

Performing Quality Control Testing:

When liquid QC is opened, it must be labeled with the open date. Liquid QC will expire 3 months to the day of the open date.

The Accu-Chek Inform II will lock out operators from performing patient tests when the previous 24 hours quality control tests have expired or if QC performed fails acceptability ranges.




1. Press the *On/Off* button to power on the meter.
2. Once the *Power Up* screen appears, touch  to proceed to the *Operator ID* screen, or wait 5 seconds and the meter automatically proceeds to the *Operator ID* screen. Control
3. Barcode scan operator ID, then touch  to display the *Main Menu* screen.




4. Touch *Control Test* to display the *Control Test* screen. Perform Control Testing
5. Touch the control level to be run.
6. Verify the control lot number.
 - If correct, touch . You are prompted to confirm the test strip lot.
 - If incorrect, touch  to barcode scan a different lot number.
7. Verify the test strip lot.
 - If correct, touch . You are prompted to insert the test strip.
 - If incorrect, touch  to select a different test strip lot number.
8. Slide the test strip into the test strip port as far as it will go in the direction indicated by the arrows on the test strip.
9. Wait until the flashing drop appears in the screen before applying the control solution.
10. Apply a drop of glucose control solution to the front edge (yellow dosing area) 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. The meter beeps, and an hourglass appears while the meter completes the test.
11. When the test is completed, the result is displayed. Touch  to enter the “acceptable QC” comment. Touch  to continue with the next level, if necessary, or to return to the *Main Menu*.
12. Remove the test strip and dispose of it in accordance with applicable regulations and directives

Procedure for Finger Stick:


- a. Properly identify patient using name and Account number (V#)
- b. Adhere to standard precautions
- c. Clean fingertip with alcohol. Let the alcohol dry completely.
- d. Hold the single use lancet on outer aspect of finger site with moderate pressure, rotate sites with each stick.
- e. Depress plunger with index finger to make puncture.
- f. Immediately release plunger while holding lancet on site.
- g. Obtain a small drop of blood resting on the finger wiping away the first drop.
- h. Apply second blood drop 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. After sample has been obtained, gently apply pressure with clean gauze to punctured site.
- i. Discard all sample collection and testing material into appropriate containers.
- j. Wash Hands before leaving the patient room.
- k. Clean and disinfect meter after every use. See Cleaning of Meter Section

Performing Patient Testing:

1. Press the *On/Off* button to power on the meter.
2. Once the *Power Up* screen appears, touch  to proceed to the *Operator ID* screen, or wait 5 seconds and the meter automatically proceeds to the *Operator ID* screen.
3. Scan operator barcode ID, then touch  to display the *Main Menu* screen. If operator ID is not accepted, attempt to re-enter your ID. When ID is rejected that operator cannot perform test (locked out). The operator must contact the POC department.
4. Touch *Patient Test* to display the *Patient ID* screen.
5. Scan patient barcode ID, then touch . You are prompted to confirm the test strip lot.
6. Verify the test strip lot.

- If correct, touch . You are prompted to insert the test strip.
 - If incorrect, touch  to select a different test strip lot number.
7. Slide the test strip into the test strip port as far as it will go in the direction indicated by the arrows on the test strip. Wait until the flashing drop appears in the screen before applying the blood.
 8. Apply the drop of blood to the front edge (yellow dosing area) of the test strip. Do not apply the blood to the top of the strip. Blood is pulled into the test strip by capillary action. The meter beeps, and an hourglass appears while the meter completes the test. When the test is completed, the result is displayed.
 9. Touch  to enter the desired comments.


| | |
|--------------------|--------------------------|
| Operator error | Insulin drip protocol |
| Notified physician | Notified nurse |
| Cleaned meter | Sent specimen to the lab |
| Repeated test | Replaced controls |
| Test on Baby | QC acceptable |

10. Touch  to return to the Main Menu.
11. Clean and disinfect the meter following each patient use. See cleaning procedure listed below.
12. Return the meter to docking station to recharge battery. If wireless is not working, dock in a docking station that can transmit results. The docking cradle will be labeled "WIRED"
13. Document results on Electronic Medical Record (EMR) as appropriate. Critical value, treatment and notification of Licensed Independent Practitioner (LIP) are documented in the EMR.

Validity of results: If you get unexpected results:

- a. **Verify by repeating test**
- b. **Collect blood for STAT venous blood glucose test and send it to the laboratory.**

Expected result:

- a. **Reference Range: 74 – 106 mg/dl.**
- b. **Analytical Measurement Ranges:**
 1. **10 - 600 mg/dl**
 2. **Less than 10 reads = LO**
 3. **Greater than 600 reads = HI**
- c. **Critical values**
 1. **Adult and Pediatric: less than 50 mg/dl or greater than 400 mg/dl,**
 2. **Newborn Full term greater than 38 weeks (0-15 days): less than 45 mg/dl or greater than 400 mg/dl (refer to Patient Care Services (PCS) policy 72:28 *Care of the Full Term Newborn*)**
 3. **Newborn less than 38 weeks: Refer to PCS policy 75:46 *Care of the Infant Outside of the NICU with a Gestation less than 38 Weeks.***
 4. **NICU (Neonate Intensive Care Unit): Refer to the most current NICU POC Glucose Testing Protocol available on the unit and in the EMR.**
 5. **If result value is critical you MUST enter a notification comment(s), touch  to enter your comment, you may enter up to 3 comments from the meter available list, or type your own notification comment. In point-of-care settings, the identity of the testing individual and person notified need not be documented**

when the individual performing the test is the same person who treats the patient. Example is: as in insulin protocol.

- 6. Initial results that appear on the meter as LO less than 10 mg/dL) or HI greater than 600 mg/dL) require repeat testing and verification by the main laboratory. Subsequent results exceeding the upper limits of the meter do not require verification if consistent with previous patient results and clinical history.**
- 7. Repeat testing is required of critical results on the glucose meter. If repeat confirms critical result, notify LIP. The attending LIP will determine on a case by case basis if additional diagnostic laboratory tests are warranted. If LIP requests lab confirmation, order a STAT glucose test to be performed by the main laboratory.**

Limitations and Interference:

The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. 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 greater than 15 mg/dL will cause overestimation of blood glucose results
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid greater than 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.

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:

- Leaving the meter under a bilirubin light or photo therapy light
- Leaving the meter on a bed warmer
- Leaving the meter in an isolette

CLEANING OF ACCU-CHEK INFORM II AND ACCESSORY BOX

Clean and disinfect meter and accessory box:

1. Place the meter on a level surface prior to disinfecting.
2. Power off the meter.
3. Remove Hospital Approved Germicidal Disposable Wipes. Squeeze the wipe to remove any excess solution from it before disinfecting the surface of the meter.
4. Wipe to disinfect by gently wiping the surfaces of the meter three times vertically and three times horizontally. Use additional wipes as needed.
Note: Carefully wipe around the meter test strip port area, making sure that no liquid enters the test strip port.
5. *Allow the surfaces of the meter to remain damp with the disinfecting solution as indicated on the germicidal wipe container for hard surface disinfection.*
6. Dry the meter surfaces thoroughly with a soft cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the meter at the completion of cleaning.

7. Return the meter to docking station.

***NOTE:** Refer to Infection Control Policy # 1.03 *Contact Precautions* for handling of the meter for patients on isolation precautions.

TROUBLESHOOTING

- 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, or follow your facility’s testing policy.
- 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.
- If the meter became inoperable or unable to trouble shoot the problem, send meter to the laboratory, and document the problem in the log book located in the main laboratory. Loaners are available for use.

FINGERSTICK SITE SELECTION

The recommended site for capillary collection on adults and children over one year of age is the palmar surface of the distal (end) segment of the third (middle) or fourth (ring) finger, ideally of the non-dominant hand. Fingers on the nondominant hand are generally less calloused. The puncture should be made slightly off center from the central, fleshy portion of the fingertip and if using a blade-type puncture device, perpendicular to the fingerprint whorls. Puncturing along or parallel to the whorls may cause the blood to follow the pattern of the fingerprint, redirecting the flow and making it more difficult to collect. The index finger is often calloused and potentially more sensitive to pain due to additional nerve endings. The thumb also may be calloused and has a pulse, indicating arterial presence, and, therefore, should be avoided. The distance between the skin surface and the bone in the fifth finger also makes it unsuitable for puncture. The side and tip of the finger should be avoided, as the tissue is about half as thick as the central portion of the fingertip.



HEELSTICK SITE SELECTION

The recommended site for heel punctures is the lateral (outside) or medial (inside) plantar surface of the heel. In small or premature infants, the heel bone (calcaneus) may be no more than 2.0 mm beneath the skin surface and no more than half this distance at the posterior curvature of the heel. Puncturing deeper than 2.0 mm on the plantar surface of the heel of small infants may, therefore, risk bone damage. When using incision devices, puncturing the heel at a 90° angle to the length of the foot is recommended. 5 Such incisions create a 'gap' puncture (one which opens when pressure is applied) and further enhance blood flow.



For infants, punctures must not be performed on:

- The posterior curvature of the heel.
- The central area of an infant's foot (area of the arch).
- Punctures to this area may result in injury to nerves, tendons, and cartilage.
- The fingers of a newborn or infant less than one year old.

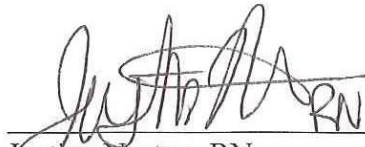
RESPONSIBILITY:

It is the responsibility of Nursing leadership and the Medical director of the laboratory to implement, maintain, evaluate and revise this policy.

APPROVED DATE:

Nurse Practice Council: May 10, 2002, June 14, 2002; January 14, 2005, February 11, 2005, July 8, 2005, April 14, 2006, May 11, 2007, November 14, 2008, December 11, 2009, March 12, 2010, January 14, 2011, May 11, 2012, April 12, 2013, October 11, 2013, February 14, 2014, January 9, 2015, September 11, 2015.

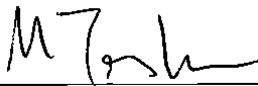
Nurse Practice Council, January 3, 2018



Justine Norton, RN
Chairperson, Nurse Practice Council



Ann Marie Leichman, RN
Sr. Vice President/CNO, Patient Care Services



Metin Taskin, MD, FCAP
Director, Department of Pathology and Laboratory Medicine

REVIEWED/REVISED DATE:

East 4 Practice Education Committee, March 2002

Medical Surgical Leadership, April 2002

Department of Pathology and Laboratory Medicine, March 17, 2015, June 2017

Beth Benjamin, MD, Pediatrics, November 2017

Metin Taskin, MD, FCAP, Director, Department of Pathology and Laboratory Medicine, June 2017

Women and Children's Services, 2017

REFERENCES:

1. Roche Accu-Chek Inform II Operator's manual 03/2015
2. Roche Accu-Chek Inform II Quick Reference Guide for Healthcare professionals 10/2012
3. Roche Accu-Chek Inform II package insert.
4. CLSI H4-A6. Procedures and Devices for the Collection of Diagnostic Blood Specimen by Skin Puncture; Approved Standard Sixth Edition, Vol. 24, No. 21, 2008.
5. Adamkin, D. H. (2011). Clinical Report--Postnatal Glucose Homeostasis in Late-Preterm and Term Infants. Pediatrics, 127(3), 575-579. doi:10.1542/peds.2010-3851

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