VA Black Hills HealthCare System **Pathology & Laboratory Medicine Services**			
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AT 5 Inform II Glucometer

Copy of version 3.0 (approved and current)

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Comments for version 3.0
changed glucometer criticals from <40 and >400 to <54 and >400

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	1/16/2025	3.0	Michael Koch. M.D. Michael Koch	
Approval	Lab QA	1/15/2025	3.0	Cole Weaver	
Approval	ATC	1/15/2025	3.0	Lynnette Fletcher	
Approval	Lab QA	10/22/2024	2.1	Cole Weaver	
Approval	ATC	10/22/2024	2.1	Lynnette Fletcher	
Approval	Lab Director	8/12/2024	2.0	Michael Koch. M.D. Michael Koch	
Approval	Lab QA	8/12/2024	2.0	Cole Weaver	
Approval	ATC	8/7/2024	2.0	Lynnette Fletcher	
Approval	Lab Director	7/1/2024	1.2	Michael Koch. M.D. Michael Koch	
Approval	Lab QA	4/5/2024	1.2	Cole Weaver	
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Approval	Lab QA	4/12/2023	1.1	Cole Weaver	
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Approval	Lab Director	6/30/2022	1.0	Justin Peltola Justin Peltola	
Approval	Lab Manager	6/30/2022	1.0	Steven Rizner	
Approval	Lab QA	6/29/2022	1.0	Cole Weaver	
Approval	ATC	6/13/2022	1.0	Lynnette Fletcher	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
3.0	Approved and Current	Major revision	1/15/2025	1/16/2025	Indefinite

2.1	Retired	Minor revision	10/17/2024	10/22/2024	1/16/2025
2.0	Retired	Major revision	7/31/2024	8/12/2024	10/22/2024
1.2	Retired	Minor revision	4/2/2024	4/5/2024	8/12/2024
1.1	Retired	Minor revision	4/10/2023	4/12/2023	4/5/2024
1.0	Retired	Initial version	5/23/2022	6/30/2022	4/12/2023

INFORM II GLUCOMETER POLICY

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PURPOSE

The purpose is to set policy, provide guidance and standardize procedures regarding Inform II Glucometer.

PRINCIPLE

The ACCU-CHEK Inform II system quantitatively measures glucose in whole blood.

POLICY

The procedures and technical information in this policy applies to all personnel assigned to the VA Black Hills Health Care System's Pathology and Laboratory Medicine Service (P&LMS). Personnel assigned to the Fort Meade (FM) Laboratory, Hot Springs (HS) Laboratory and Rapid City (RC) Laboratory belong to the P&LMS.

REAGENTS/SUPPLIES

- Comfort Curve Test Strips (available from LAB). Can use until expiration date on vial. Store at 4°C to 30°C and keep container tightly closed.
- Comfort Curve Control Solution (available from LAB). A new vial will be dated with the “open” date and a 3-month expiration date. Store at 2°C to 30°C.
- Accu-Chek Inform II linearity test kit
- Super Sani-cloth Germicidal wipes.
- Single-Use, retractable needle lancets.
- Alcohol swab, gloves and cotton balls. (available from Logistics)
- Clorox bleach wipes

EQUIPMENT

- Accuchek Inform II Glucometer
- Accuchek Inform II Downloader

SPECIMEN

The following fresh whole blood sample types may be used: Venous and Capillary whole blood

SPECIAL SAFETY PRECAUTIONS

Consider all clinical specimens, controls, and calibrators potentially infectious. When performing testing, personnel must wear Personal Protective Equipment (PPE).

LINEARITY

To be performed with each new change of lot strips to evaluate performance

PROCEDURE

Step	Procedure
1	Power on the meter and enter ID #
2	With main menu displayed, press the arrow in the bottom right corner
3	Press Linearity Lots
4	Highlight the lot by touching the screen and then select “MAKE CURRENT”
5	Verify linearity lot#
6	Scan strip lot #
7	The linearity test screen displays the levels used for testing. Press L1
8	Insert test strip
9	Apply solution #1
10	After the result is displayed, press enter
11	Repeat steps 8,9 and 10 until all 6 solutions have been tested in duplicate.
12	Download data to RALS-Web 3

QUALITY CONTROL

CODE KEY /CALIBRATION

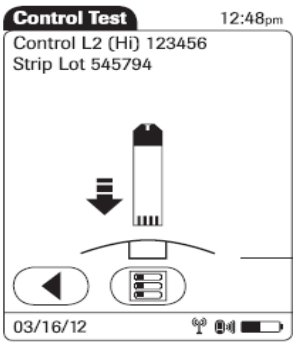
The LAB will be responsible for Coding of the meters. This only needs to be done when lot numbers are switched. Each vial of strips comes with a code key. Each code key belongs to a single lot number and provides the lot-specific properties of the test strip. When opening a new box of test strips, dispose of the code key. It will not be loaded into the meter

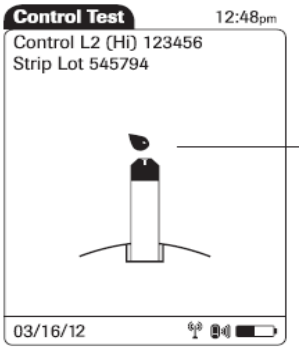
QUALITY CONTROL TESTING

Quality control needs to be run daily/every 24 hours when patient testing is requested, or if questionable test results are displayed repeatedly. DO NOT SHAKE QC MATERIAL!

Step	Procedure
1	Turn on meter by pressing the Power ON/Off button.
2	Scan or enter operator ID
3	Press the Control Test button
4	Scan the bar code on the QC vial of the control level you want to run.
5	Scan the bar code on strip vial
6	When prompted insert a test strip.
7	Apply correct control solution when prompted. An hourglass appears while the instrument performs the test.
8	When the test is complete, the result is displayed either as PASS or FAIL.
9	If the test result is PASS, no comment needed and proceed to next test.
10	If the test result is FAIL, add the necessary comment and repeat. If a test fails twice, try opening a new control solution or new strips.
11	If results continue to FAIL – take meter and strips out of service
12	QC comments: QC Failed Repeat

Control testing on the meter: Power on meter and enter operator





PERFORMANCE OF A FINGERSTICK

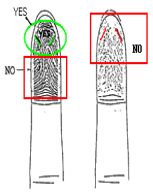
Step	Procedure
1	Positively identify the patient by SS number and full name. Position the patient. The patient should either sit in a chair, lie down or sit up in bed. Hyperextend the patient's arm.
2	Position the patient. The patient should either sit in a chair, lie down or sit up in bed. Hyper-extend the patient's arm.
3	**Gloves must be worn during testing, hand hygiene performed, and gloves changed between patients.**
4	The best locations for a fingerstick is the 3rd and 4th fingers of the non-dominant hand. Do not use the tip of the finger or the center of the finger. Avoid the side of the finger where there is less soft tissue, where vessels and nerves are located, and where the bone is closer to the surface. The 2nd (index) finger tends to have thicker, callused skin. The fifth finger tends to have less soft tissue overlying the bone. Avoid puncturing a finger that is cold or cyanotic, swollen, scarred, or covered with a rash.
5	Clean the patient's fingertip with alcohol and let dry or have patient was hands with soap and water.
6	Using the lancet, make a skin puncture just off center of the finger pad. The puncture should be made perpendicular to the ridges of the fingerprint so the drop of blood does not run down the ridges.
7	Lower the hand below the heart. After poking the finger, massage from above the wrist down to the fingertip.
8	If performing Glucometer testing, wipe away the first drop of blood, which tends to contain excess tissue fluid. Again, massage from above the wrist down to the fingertip.
9	If performing CoaguChek testing, DO NOT wipe away the first drop of blood. Use the first drop for testing.
10	Collect drops of blood into the collection device or apply to glucometer/coag strip by gently massaging the finger. Avoid excessive pressure that may squeeze tissue fluid into the drop of blood.
11	Have the patient hold a small gauze pad or cotton ball over the puncture site for a couple of minutes to stop the bleeding.
12	Dispose of contaminated materials/supplies in designated containers. Lancets must be discarded into the sharps containers per facility policy.

Fingerstick Blood Collection

Single-use: No arming is required, and single-use lancing device cannot be used again after activation
Retractable lancing needles: Each are retracted and concealed, before and after use
Efficient: High-speed delivery and penetration method minimizes patient pain .....
Latex-free: Hypo-allergenic
Blade Depth: 2.2

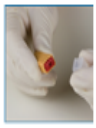
Proper Fingerstick Location:

Best locations for a finger stick is the 3rd and 4th fingers of the hand. Perform the stick off to side of the center of the finger. NEVER use the tip or center of the finger.

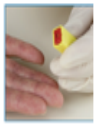


Fingerstick Procedure

1. Clean test site with isopropyl alcohol or soap and water – dry completely.



2. Remove protective pin from the safety lancet. Lancet may vary.



3. Place platform end of safety lancet on the test site.

4. Gently push the safety lancet down against test site to activate the lancet mechanism

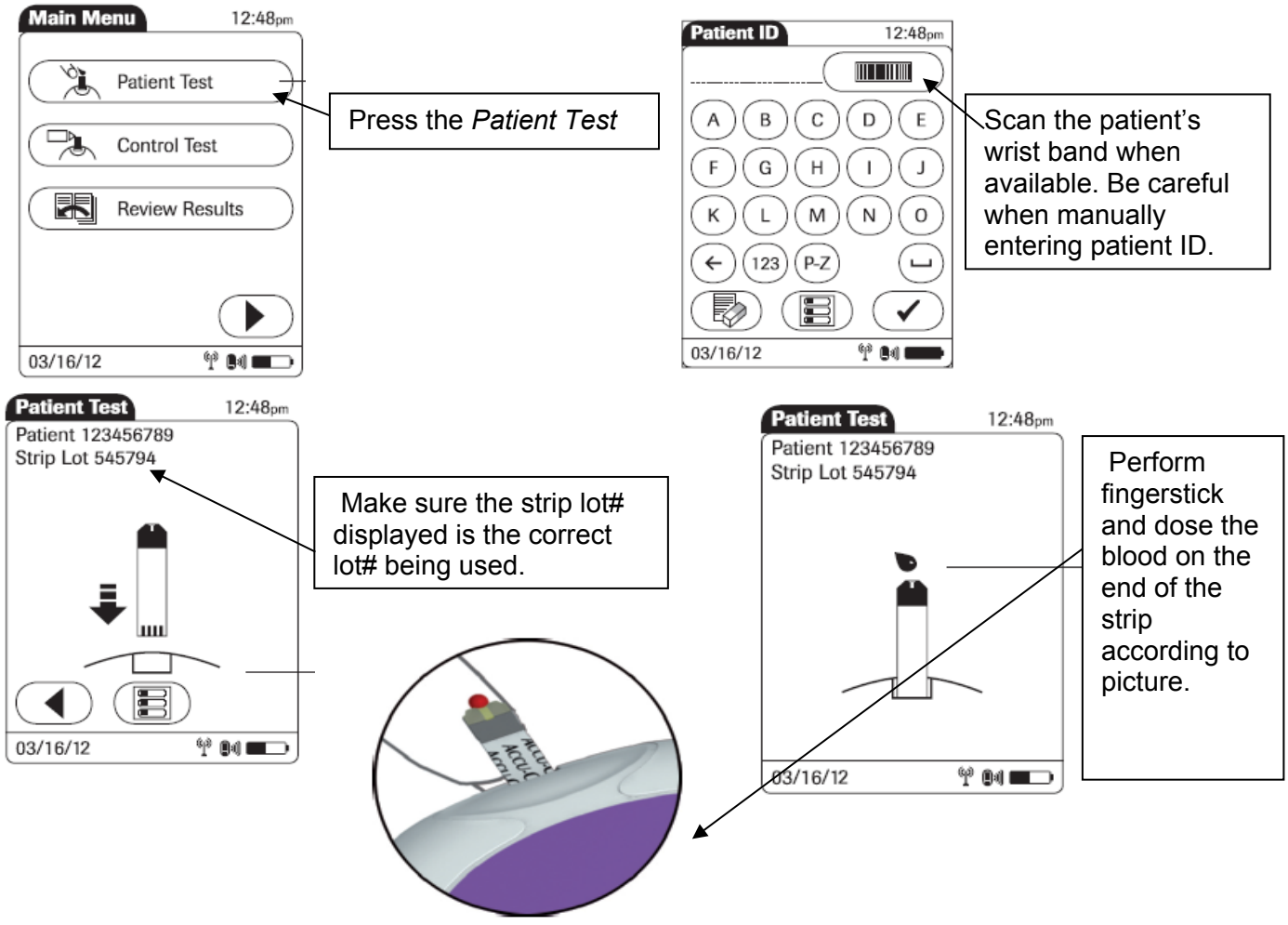
5. Dispose of lancet in biohazard sharps container

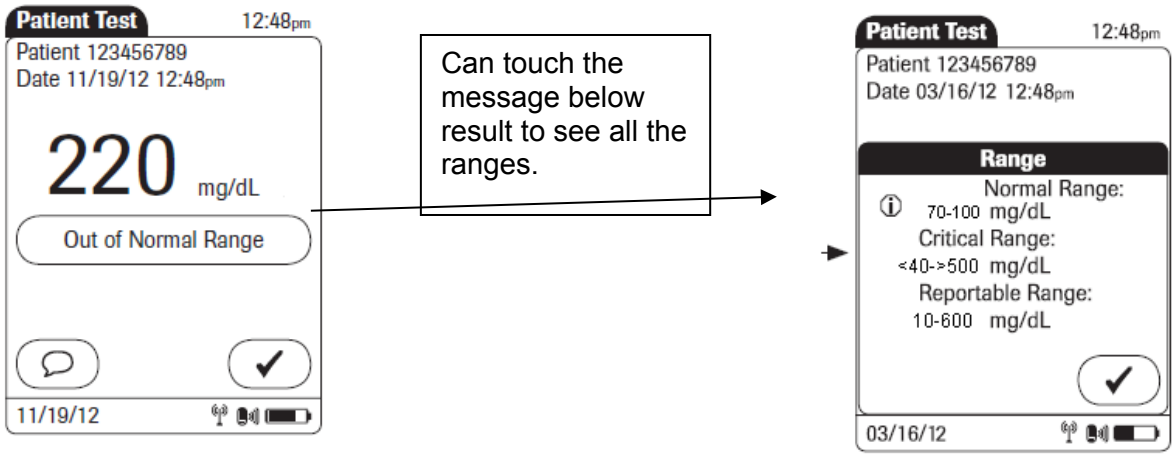
PERFORMING A PATIENT TEST

Step	Procedure
1	Perform Hand Hygiene before and after patient testing
2	Properly identify the patient with two identifiers.
3	Turn on meter by pressing the Power ON/Off button - press the ►.
4	Scan or enter operator ID
5	From the Main Menu screen touch Patient Test
6	Scan (preferable) or enter the patient identification.
7	Scan the bar code on strip vial
8	**STOP!!** Patient identification will be at the top of the screen with the strip lot# being used below. Verify displayed SS# on glucometer screen against patient armband. If the patient is an outpatient with no armband, ask patient to state full SS# and verify it against the displayed SS# on the screen.
9	Insert a test strip- now ready to collect patient sample.
10	Clean the patient's finger with soap and water or use an alcohol pad. Make sure the finger is dry. **Cleaning the finger properly is the most important step in ensuring that the patient result is accurate – if the patient's finger is not prepped properly, you will get erroneous results (usually inaccurate high results)
11	Lance the finger following steps following the finger stick procedure below.
12	Squeeze gently – WIPE THE FIRST DROP OF BLOOD AWAY WITH GAUZE PAD OR COTTON BALL!! (may get erroneous results if the first drop of blood not wiped away – from residual alcohol, tissue fluid or soap/water)

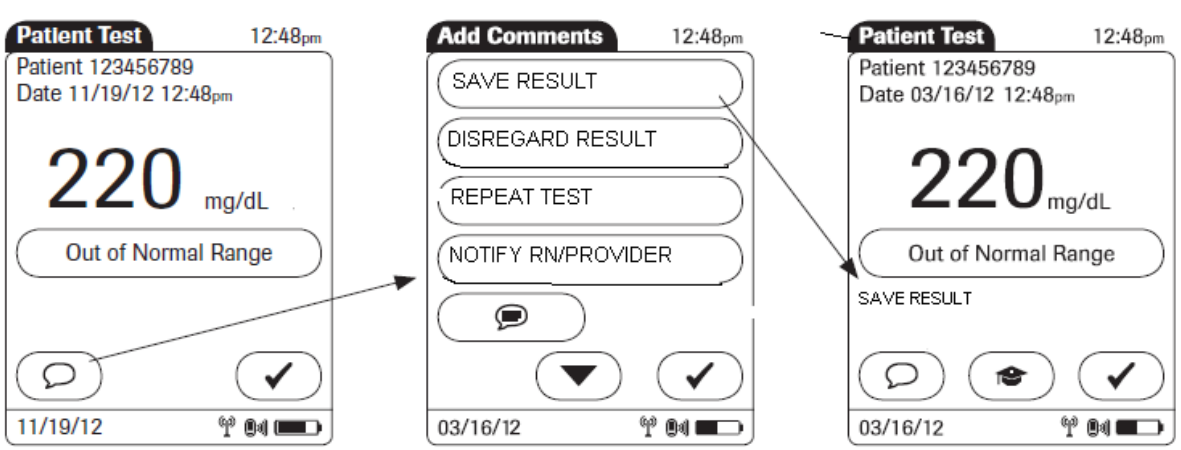
Step	Procedure
13	Apply a drop of blood to the front edge of the strip – blood is pulled into the test strip by capillary action. Once a sufficient blood sample has been detected, the meter beeps and measurement begins. The system will detect if there is enough sample.
14	When testing is complete, the result will be displayed
15	When testing is complete, the result will be displayed
16	Dispose of strip in red biohazard bag
17	Dispose of lancet in Biohazard Sharps Container.
18	***FIRST STEP: Clean*** the meter using a Super Sani-cloth germicidal wipe.
19	***SECOND STEP: Disinfect*** the meter using a second Super Sani-cloth germicidal wipe
20	If the patient has infectious Diarrhea such as Clostridium Difficile, Norovirus etc., ***Disinfect using the Clorox Bleach Germicidal wipes*** provided by lab to each glucometer testing site.
21	Remove gloves and wash hands.

PATIENT TESTING ON THE METER: POWER ON METER AND ENTER OPERATOR ID.



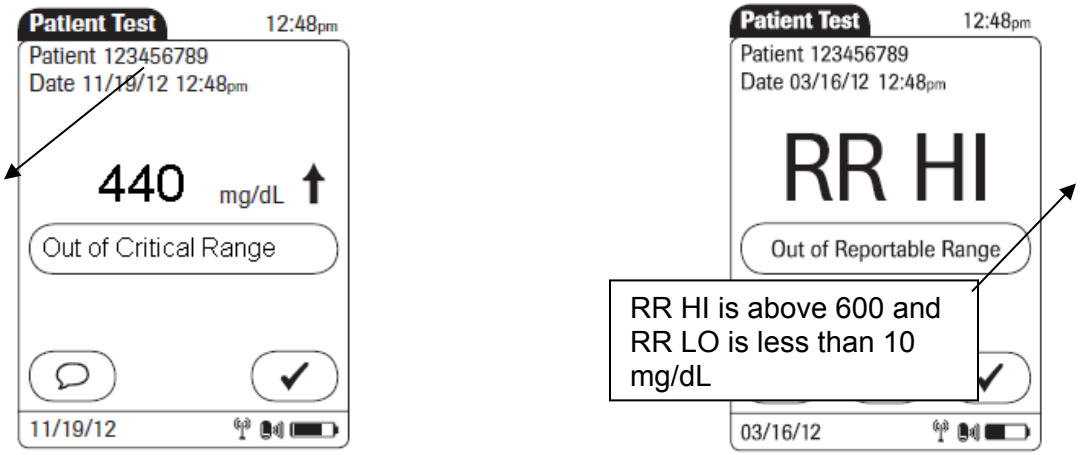


ADD COMMENTS:



MESSAGES THAT MAY BE ENCOUNTERED:

Out of critical range – RED FLASHING ARROW



REVIEW RESULTS

Results can be reviewed by Patient or QC results. The default is all results shown with the most current test on top.

INTERPRETATION/RESULTS

REFERENCE VALUES

Ranges adopted by this facility are from the American Diabetes Association published guidelines:

Fasting: *70-100 mg/dL*

REPORTABLE RANGE OF METER

The meter will read values between *10 and 600 mg/dL*. If patient results are outside this range, the meter will give a RRLO or RRHI result. If a quantitative glucose value is needed, laboratory would need to be notified for blood draw.

CRITICAL VALUES

Critical glucose values are: *<54 mg/dl or >400 mg/dl*

- All critical values must be rechecked immediately to verify result. The meter will display a message when the value is critical stating:

  > Repeat all critical results <54 or >400. Complete critical results notification template if required.

  Critical glucose results should be verified by the laboratory via venous blood draw when clinically indicated, however, it is the provider's discretion whether or not to request a laboratory glucose value.

- **There must be documentation of action taken for patients with critical whole blood glucoses**.
  Notification and documentation of critical results need to follow COS -74. RN needs to fill out the "Critical Lab Value" in CPRS.

- Due to procedural limitations of the meter, all values <54 mg/dl or >400 mg/dl must be rechecked, called to the appropriate provider, and documented in CPRS using the "Critical Lab Value" note.

METHOD LIMITATIONS

Glucose meters cannot be used in the measurement of serial glucose measurements to maintain tight glycemic control in critically ill patients as the accuracy of the glucose meters at this time is not adequate in the critically ill patient. Use in critically ill patients is not approved by the FDA and furthermore violates manufacturer's guidelines on the use of these devices. Until these devices are approved by the FDA for use in critically ill patients, you should utilize glucose testing in the main laboratory. Confirm all normal and high glucose levels by central laboratory testing periodically, or if the clinical picture is inconsistent with the Accuchek II glucose level.
Per BHHCS, any patient whose peripheral circulation is severely compromised (i.e. code blues, shock, sever dehydration) SHOULD NOT have glucometer testing utilized.

If any of the below limitations occur or are suspected, the glucometer result should not be used for patient treatment and a venous blood draw for testing in the main lab should be ordered.

- 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 not been evaluated in the critically ill.
- Hemodynamic, unstable patients.
- It is the provider's discretion whether or not to request a laboratory glucose value in patients with blood glucose <40 mg/dl or >400 mg/dl,

Example 1:
- Mean Arterial Pressure (MAP) of <60 mmHg
- Use of IV vasopressors to maintain blood pressure such as dopamine.

Example 2:
- A patient on mechanical ventilation with a mean arterial pressure less than 60mmHg despite the use of pressors

Example 3:
It is the provider's discretion whether or not to request a laboratory glucose value in:
- A patient that is hemodynamically unstable
- A patient with a blood glucose <40 mg/dl or >400 mg/dl

TROUBLESHOOTING

The Accu-Chek Inform II meter continually checks its systems for unexpected and unwanted conditions. If after troubleshooting there are still having problems, contact the Ancillary Testing Coordinator.
Ft Meade: Ex 7721 or main lab at Ex 7715
Hot Springs: Ex 2970 or the main lab at Ex 2012.
Loaner meters are located in the lab.

- Battery is rechargeable and should not need replacing. Meter should be stored in the base unit to keep the battery charges. If the meter has no power, check that the green light is on in the front of the base unit. If the green light is off, check that the power cord is connected to the base unit and to the wall outlet.
- Results not downloading: Most likely reason is the interface cord has come loose either on the base unit or wall outlet.

Some error codes that can be displayed on meter:

- Strip Defect Error: The strip being used is defective – repeat with a new strip.
- Type Bad Dose: Insufficient amount of blood dosed on the strip. Repeat test with a new strip.

REFERENCES

- Accu-Chek Inform II Operator's Manual Version 8, Roche Diagnostics 4-2022
- Accu-Chek Inform II test strips package insert, Roche Diagnostics 5-2020
- Accu-Chek Inform II controls package insert, Roche Diagnostics, 5-2020
- CLSI Document POCT12-A3, Point -of -Care Blood Glucose Testing in Acute and Chronic Facilities; Approved Guideline – Third Edition, Vol 33 No. 2, January 2013.
- Joint Commision Standards 1-2025
- VHA Handbook 1106.1 Ancillary Testing, January 2024