

**HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY – POINT OF CARE POLICY MANUAL**

Accucheck Inform Linearity Test

Effective Date: August 7, 2006

Policy No: POC 0010

Cross Referenced:

Origin: Point of Care Tests

Reviewed Date: 1/11; 6/12

Authority: Cristina Hom, MLS (ASCP),
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SCOPE: HRMC Laboratory

PURPOSE:

Linearity test is determined:

1. Before any glucose monitor is placed for service.
2. With each new lot of test strip.
3. At least every 6 months.
4. Anytime the Accucheck has been repaired or the module has been repaired.
5. When controls begin to reflect an unusual trend or been consistently out of range.
6. With the Accucheck Inform, a minimum of three readable points covering the entire linearity range may be required. Draw the best straight line possible through the points. The lower and upper points determine the limits of the linear range.
7. If a result falls outside of the limits of the linear range, repeat the test, calculate the average with the new linearity value and plot accordingly.
8. Occasionally, no code assignment for Level 1 or Level 6 of the lot number you are using is indicated by a dash. This notation indicates that the glucose result may be outside the readable range for the meter. If this occurs, test three of the levels 2, 3, 4, and 5 of your Linearity Test Kit to define the maximum linear range. In the meantime, any meter that has a failed linearity test will not be placed back into service until the linearity test is repeated and ranges are validated.

POLICY:

1. The linearity range for the machine is 10mg/dl or 600mg/dl and this range can be found on each Accucheck meter. Meter will give out a “LO” or “HI” result and no numerical value. If a patient test result falls outside of the linear range, a lab back up test must be ordered for a stat glucose.
2. The linearity graph results of each Accu-Check Inform meters are recorded and kept in the laboratory.

PROCEDURES:

1. Press the button to turn power ON.
2. Scan the operator ID.
3. With the **Main Menu** displayed, press ► to display more options on **Main Menu 2**.
4. Select **ADMIN** to display the Administration Menu.
5. Press **Linearity Lots** to display the Linearity Lots screen.
6. Press Add to display the Linearity Lot screen and add a new lot number to the list (if there are linearity lots already listed, you can scroll up and down the list by using the arrows at the bottom of the screen).
7. Enter a linearity lot number from the linearity kit package by pressing the numbers on the touchscreen. If you need to change your entry, press ◀ key to backspace.
8. Press the large ► button under the touchscreen to go to the Linearity Expiration screen.

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9. Enter the linearity lot expiration date by pressing the number keys on the touchscreen. When ► is pressed, the message box asking if you want to make this the current lot appears. Press **YES** or **NO**.
10. When your entries are complete, press the **MENU** button under the touchscreen to go to the Main Menu or press the large ► button to return to the Administration Menu.
11. Verify the test strip by scanning the test strip vial barcode.
12. Gently insert the test strip into the meter with the electrodes facing up and toward the test strip port.
13. Apply the linearity solution sample to the curved edge of the test strip. Once the test is completed, the Linearity test result screen is displayed.
14. Press the ► button to return to the Linearity Test screen.
15. With the Accucheck Inform, a minimum of three readable points covering the entire linearity range may be required. Occasionally, the code assignment for Level 1 or Level 6 of the lot number you are using is indicated by NA. This notation indicates that the glucose result may be outside the readable range for the monitor. If this occurs, test three of the Levels 2,3,4 and 5 of your Linearity Test Kit to define the maximum linear range.
16. Verify the calibration by running QC.
17. Print the detailed results and the graph for each meter.

REFERENCED:

1. Accucheck Inform Operator's Manual