STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE: Nova Biomedical Glucose / Ketone Meter Linearity Test	**Revision Date:** 07-July-2016	**Issue Date:** 07-July-2014
Document Number: POC20601	**Status: Approved**	
Distribution: Point of Care Testing Manual	**Page:** 1 of 5	
Approved by: C. Case, Manager Diagnostic Services	**Signed by:** Cheryl Case	

PURPOSE:

Linearity testing is performed on a bi-annual basis to ensure that results generated are accurate and precise by testing samples with known analyte concentrations and evaluating the line of best fit when those results are plotted on a line graph.

POLICY:

See Quality Manual Section 6. Process Control

REAGENTS and/or MEDIA:

- Nova Biomedical StatStrip® GLU Test Strips
- Nova Biomedical StatStrip® KET Test Strips
- Nova Biomedical StatStrip® GLU KET Linearity Kit

SUPPLIES:

- Nova Biomedical StatStrip® Glucose / Ketone Hospital Meter
  OR
- Nova Biomedical StatStrip® Glucose Hospital Meter

SPECIAL SAFETY PRECAUTIONS:

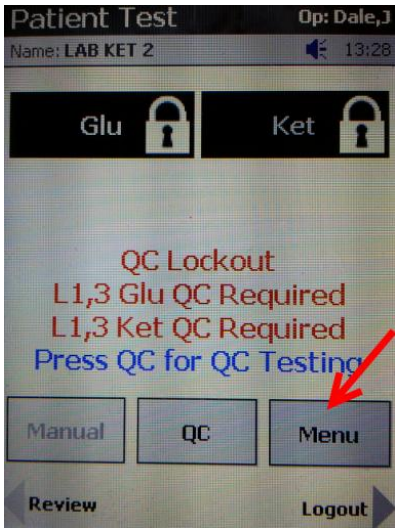
- Handle all patient samples and testing sera using “Routine Practices”.
- Please refer to the Northwest Territories Infection Prevention and Control Manual, March 2012.

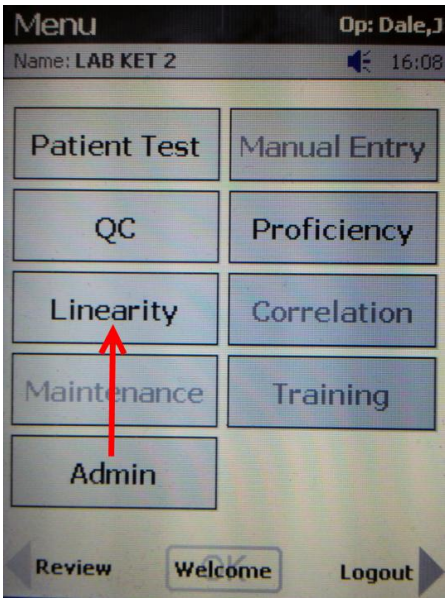
QUALITY CONTROL:

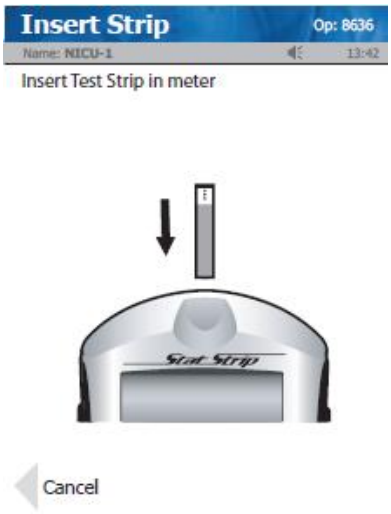
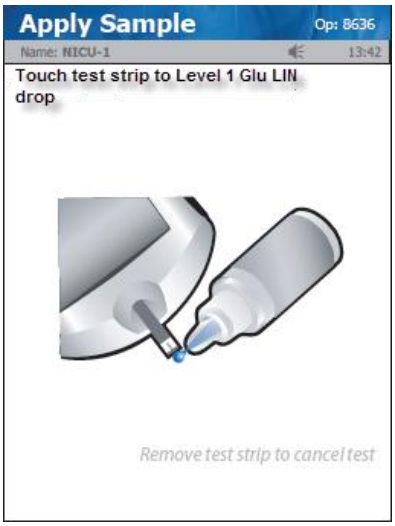
See POC20701 Nova Biomedical Glucose / Ketone Meter Quality Control Test

PROCEDURE INSTRUCTIONS:

Follow the steps in the table below to perform a linearity test.

Step	Action
1	Turn on by pressing the **Sleep Mode** button. 
2	Press the **OK/Enter** button to begin testing.
3	Enter your Operator ID number manually or scan your barcode.
4	Press the **OK/Enter** button to accept your Operator ID number.
5	Touch the **Menu** soft key on the instrument screen. 

6	Touch the **Linearity** soft key on the instrument screen. 
7	Scan the barcode on the side of the vial for the lot number of the test strips you are using. Press **OK/Enter**.
8	Linearity reagents are received in a kit from Nova Biomedical. These reagents are ordered directly from the manufacturer. The same linearity kit is used for both whole blood glucose and ketone linearity testing. Scan the barcode of the linearity solution you will be testing by pressing and holding the **OK/Enter** button and passing the scanner over the barcode on the side of the dropper bottle.
9	Press the **OK/Enter** button to accept the proficiency test reagent number.

10	Insert a test strip into the top of the testing meter as shown on the screen. 
11	Gently mix the Linearity Solution before each use
12	With the test strip correctly inserted, the Apply Sample screen will display. 
13	Discard the first drop of control solution from the bottle to avoid contamination.
14	With the meter placed on a flat level surface, place a drop of linearity solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. When sample has been drawn into the strip, an audible beep is sounded by the meter.
15	Wipe the applicator tip of the bottle and recap the linearity solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.

16	The test result will appear in 6 or 10 seconds depending on which test is being performed. Do not remove the test strip until the countdown is complete. Meter results range from 0.6 – 33.3 mmol/L for glucose and <0.1 to 7.0 mmol/L for Ketones.
17	Run each level in duplicate.
18	Repeat steps 8 to 17 for the all other levels in the linearity kit.
19	Dock the meter into a connected docking station to transmit the result to the NovaNet. Results will be compiled and analyzed by the Technologist II.

RELATED DOCUMENTS:

- POC20801 Nova Biomedical Glucose / Ketone Meter Patient Test
- POC20401 Nova Biomedical Glucometer Basic Maintenance

REFERENCES:

Nova Biomedical, StatStrip® Glucose Hospital Meter, Instructions for Use Manual, Nova Biomedical Corporation, Waltham, MA, 2011

Nova Biomedical, StatStrip™ Glucose and β-Ketone Control Solution Package Insert, Nova Biomedical UK, Cheshire, UK, 2011

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	23 Dec 2013	Initial Release	JGD Bernier
2.0	15 May 2014	Updated to include reference to: NWT Infection Prevention & Control Manual	JGD Bernier