



STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE: Nova Biomedical Glucose / Ketone Meter Quality Control Test	Revision Date: 07-July-2016	Issue Date: 07-July-2014
Document Number: POC20701	Status: Approved	
Distribution: Point of Care Testing Manual	Page: 1 of 6	
Approved by: C. Case, Manager Diagnostic Services	Signed by: <i>Cheryl Case</i>	

PURPOSE:

The quality control test is performed to ensure that the Nova Biomedical StatStrip® Glucose / Ketone Hospital Meter and the StatStrip® Test Strips are functioning properly.

POLICY:

See Hospital Wide Policy L-1040 Point of Care Testing (Laboratory Testing).

REAGENTS and/or MEDIA:

- Nova Biomedical StatStrip® GLU Test Strips
- Nova Biomedical StatStrip® KET Test Strips
- Nova Biomedical StatStrip® GLU KET Control Solutions 1 & 3

SUPPLIES:

- Nova Biomedical StatStrip® Glucose / Ketone 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.
- Gently shake each vial of control solution before use.
- Do not use a control solution after the expiration date printed on the vial label.
- Discard any unused portion 3 months after opening. Write the opened date on the vial when you first open it.

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- Store the control solution(s) at room temperature, below 30°C. Do not refrigerate or freeze.
- The control solutions contain dye that stains clothing.
- The control solutions are not for human consumption.


QUALITY CONTROL:

When to Perform a Quality Control Test:

- Minimum of once every 24 hours.
- When you open a new bottle of test strips.
- If a patient test has been repeated and the analysis results are still lower or higher than expected.
- After cleaning the meter.
- If there are other indications that the system is not working properly.
- Whenever problems are identified or any time the accuracy of the meter may have been affected by rough handling (such as dropping the meter).

PROCEDURE INSTRUCTIONS:

Follow the steps in the table below to perform a quality control test.

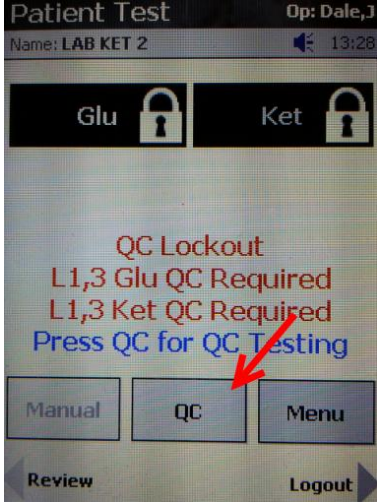
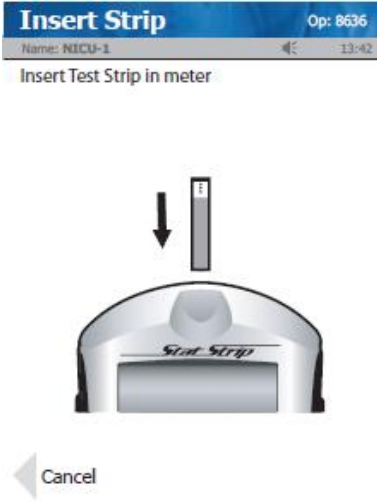
Step	Action
1	Turn on by pressing the Sleep Mode button. 
2	Press the OK/Enter button to begin testing.

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3	Enter your Operator ID number manually or scan your barcode.
4	Press the OK/Enter button to accept your Operator ID number.
5	<p>Touch the QC soft key on the instrument screen.</p> 
6	Scan the barcode on the side of the vial for the lot number of the test strips you are using. Press OK/Enter .
7	Scan the lot number of the control solution you will be testing pressing and holding the OK/Enter button and passing the scanner over the barcode on the side of the dropper bottle.
8	Press the OK/Enter button to accept the lot number of the control solution.
9	<p>Insert a test strip into the top of the testing meter as shown on the screen.</p> 

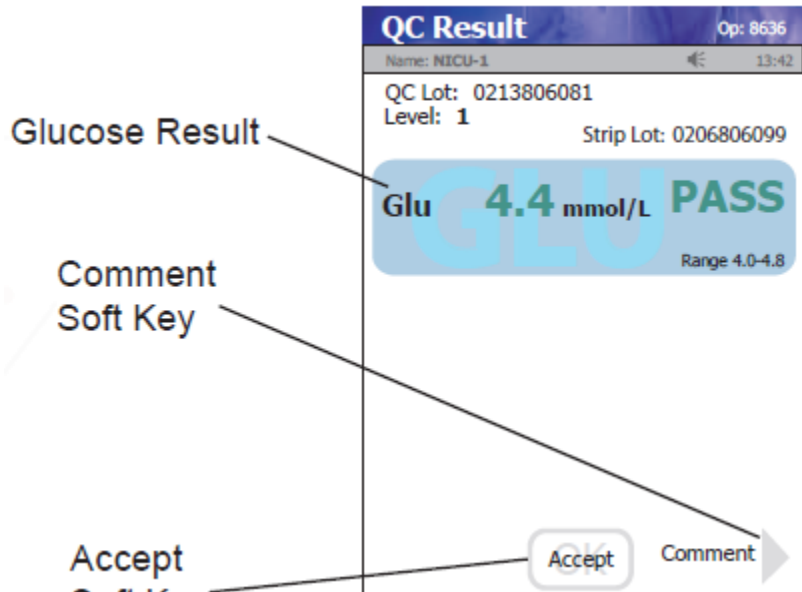
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10	Gently mix the StatStrip® Glucose Control Solution before each use
11	<p>With the test strip correctly inserted, the Apply Sample screen will display.</p>  <p style="text-align: center;">Touch test strip to Level 1 QC drop</p>  <p style="text-align: center;"><i>Remove test strip to cancel test</i></p>
12	Discard the first drop of control solution from the bottle to avoid contamination.
13	With the meter placed on a flat level surface, place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. When enough blood has been drawn into the strip, an audible beep is sounded by the meter.
14	Wipe the applicator tip of the bottle and recap the control solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.

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15	<p>When the meter completes the test, the QC Result screen displays with the results in mmol/L.</p>  <p>The screenshot shows a mobile device screen titled 'QC Result'. At the top right, it says 'Op: 8636'. Below that, it says 'Name: NICU-1' and '13:42'. The main content area shows 'QC Lot: 0213806081', 'Level: 1', and 'Strip Lot: 0206806099'. A large blue box displays 'Glu 4.4 mmol/L PASS' with 'Range 4.0-4.8' below it. At the bottom, there are two soft keys: 'Accept' and 'Comment'.</p>	
	If	Then
	<p>The results are PASS</p> <p>The results are FAIL</p>	<p>You may accept the results by pressing the Accept soft key.</p> <ol style="list-style-type: none"> i. Verify that the test strips and control solutions are not past their expiration dates ii. Repeat the Quality Control check using a new test strip iii. If the second test fails, inspect and clean the meter iv. If the third test fails, contact Nova Biomedical Technical Support toll free at 1-800-345-NOVA.
16	Repeat steps 7 to 15 for the other level of control solution.	

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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 Guidelines; Simplified lot number entry instructions.	JGD Bernier

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