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Document History:

Title: Validation of New QC and Strip Lots for Nova StatStrip Glucose Meter

Site(s): Quality and Development Technologist

Document #:	**110-130-09**	**Version #:**	**03**
Section:	**Clinical Biochemistry & Genetics**	**Subsection:**	**Point of Care**

Approved by:	L Thorlacius	**Date:**	24-May-2018

Approved by:	L Thorlacius	**Date:**	29 Jan 2021
Signature:	(Signature on File)_		
		Effective Date:	29 Jan 2021

#	Details of Revisions:	Approval:	Date:
1	New document	L Thorlacius	24 May 2018
2	Updated References to include SOP 110-130-07. Removed Roche Result 2 and Mean from Patient Comparison chart in Appendix C (p.6).	A Sokoro	26 Jan 2021
3			
4			

1.0 REFERENCES:

1.1 StatStrip Blood Glucose POC Meter Procedure Manual, SOP # 110-130-01
1.2 Evaluation Protocol of POC Blood Glucose Monitoring Instruments, SOP # 110-130-07
1.3 Nova Biomedical StatStrip Express Glu/Ket Control 1/3 package insert, Ref# 46947/46949 2017-03
1.4 EP Evaluator Software 11.1.0.26, 4161-A6-7B Guide

2.0 PURPOSE:

New lot numbers of Nova quality control material and reagent test strips must be validated in-house prior to provincial distribution.
Nova Biomedical will contact us well in advance indicating there are either new lots of QC or test strips that require validation. The new products are to be sent directly to the Quality and Development Technologist for evaluation. Once validated, Nova Biomedical is notified the product is acceptable for patient testing.

3.0 MATERIALS:

Reagents	Supplies	Equipment
• New or current test strip lots • New or current QC material L1 and L3	• 50% Dextrose IV solution • Roche false bottom tubes	• Nova StatStrip Glucose Meter x2 • Roche Cobas c501 • EP Evaluator • Centrifuge • 37 ° Water or sand bath

4.0 SPECIAL SAFETY PRECAUTIONS:

Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

5.0 PROCEDURE:

5.1. Validation of New Lot of Nova Glucose **Control Material 1 and 3** (day to day precision)

Step	Action
1	Receive new lots of Control Levels 1 and 3 from Nova Biomedical. Prepare an excel spreadsheet similar to the one pictured in Appendix A.
2	Document the new lot numbers, expiry dates and expected ranges (on the front of the vials) on the spreadsheet.
3	Document the lot number and expiry date of the current test strip lot numbers used for testing. Prepare 2 Nova StatStrip Glucose Meters documenting the model numbers used.
4	Test the new levels 1 and 3 once a day on 2 separate meters for 10 days (total of 20 values for each level). Follow doc. #110-130-01 (StatStrip Blood Glucose POC Meter) for correct operation of the meter. QC values MUST fall within the ranges supplied.
5	Plot the data using the EP evaluator Simple Precision Module (see example Appendix B). File pdf in shared drive under “Point of Care Glucose Meters”.
6	If all data fall within the acceptable range on the vials, the new QC lots are validated. If all data does not fall within range contact Clinical Biochemist for review and next steps.

5.2. Validation of New Lot of **Glucose Test strips** (patient comparisons):

Step	Action
1	Receive new lot of glucose test strips from Nova Biomedical. Prepare to do a 10 sample patient correlation (using the new strips) between the Nova StatStrip meter (in duplicate between 2 meters) and the Roche c501 (only run once). This usually takes a day to perform.
2	Obtain a 50% Dextrose IV solution from pharmacy. This will be used as a spiking solution.
3	Prepare an excel spreadsheet to enter all data similar to the one pictured in Appendix C. Document all lot numbers and expiration dates as listed.
4	On the morning of testing turn on the 37 °C heating bath. Run Daily QC on both meters using the new strips.
5	Fresh lithium heparin whole blood is required for the Nova glucose meter which is then immediately centrifuged to obtain plasma to analyze on the Roche c501. The sample values must span the meter's measuring range up to 30 mmol/L with 2 specific target values of 1.7 and 2.2 mmol/L. Fresh specimens can be gathered by removing 1 mL of whole blood from random samples arriving in the lab. Be sure to cap tightly when complete.
6	Aliquot the 1 mL whole blood specimen into a Roche false bottom tube and mix well. Quickly analyze and the whole blood on 1 meter to get a starting baseline value.
7	Specimens can be used as is OR are either spiked with the dextrose solution to increase the values as desired or glycolyzed in the heating bath to lower the values. Lower the values by placing the 1 mL whole blood sample into the 37 ° heating bath. The glucose value will decrease by 0.84 mmol/L for every hour it remains in the bath. Use this information to calculate the approximate amount of time you need to arrive at the target value. Refer to doc# 110-130-07 "Evaluation Protocol for Point of Care (POC) Blood Glucose Monitoring Instruments" section 7 and 8 for information on spiking and glycolyzing whole blood specimens.
8	Continue adding samples so that the entire range is covered. Whole blood samples should be analyzed as soon as possible and the specimens spun immediately for analysis on the c501.
9	Once all data is collected enter the values into the EP Evaluator software "Glucose POC Instrument Evaluation" statistical module. See Appendix D.
10	Forward completed data and EP evaluator pdf report to a Biochemist for sign-off.
11	Notify Nova Biomedical that strip lot is approved.

Appendix A

Nova Biomedical – New QC Evaluation

Site : _____
Analyst: _____
Start Date: _____
Test strip lot: _____ **exp** _____
Statstrip Meter #1 SN# _____
Meter #2 SN# _____

		Meter #1	Meter #2
Nova Low Glucose Control (1)	**Date**	**Value**	**Value**
lot # xxxxxxxxxxx exp xxxxx			
Allowable Range			
xx- xx mmol/L (printed on the vial)			
Nova High Glucose Control (3)	**Date**	**Value**	**Value**
lot # xxxxxxxxxxx exp xxxxx			
Allowable Range			
xx- xx mmol/L (printed on the vial)			

APPENDIX B

EP Evaluator®

Clinical Biochemistry -- St. Boniface Hospital

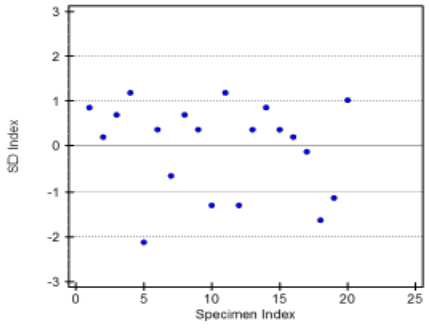
Glucose
Instrument Nova StatStip
Sample Name Nova Level 3

Simple Precision

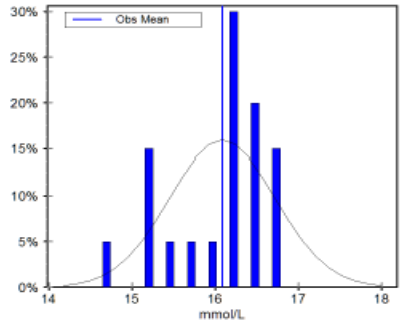
Precision Statistics

Obs Mean	16.09 mmol/L	95% CI for Obs Mean	15.80 to 16.37
Obs Standard Dev (SD)	0.61	Obs 2 SD Range	14.87 to 17.30
95% Confidence for Obs SD	0.46 to 0.88	Number of Specimens (N)	20 of 20
Obs Coef of Variation (CV)	3.8%		

Precision Plot



Histogram



Supporting Data

Analyst	A. Victoruk
Expt Date	26 Mar 2018
Units	mmol/L
Target Mean	–
Target Range	–
Target CV	–
Control Lot	Nova Biomedical 0417346303 exp 12 Jun 2020
Reag Lot	Nova Biomedical Strip 0317129309 exp 30 Nov 2019
Cal Lot	–

Accepted by: _____ _____

	Source	Lot Number	Expiration	Analytes
Controls	Nova Biomedical	0417342301	08 Dec 2020	Glucose
	Nova Biomedical	0417346303	12 Jun 2020	Glucose
Reagents	Nova Biomedical	Strip 0317129309	30 Nov 2019	Glucose

Precision Data

Index	Results	Index	Results	Index	Results	Index	Results
1	2.9	6	3.1	11	3.4	16	3.3
2	3.4	7	3.2	12	2.8	17	3.3
3	3.3	8	3.2	13	3.4	18	3.1
4	3.3	9	3.3	14	3.0	19	3.3
5	3.1	10	3.5	15	2.7	20	3.2

O: outliers X: excluded from calculations

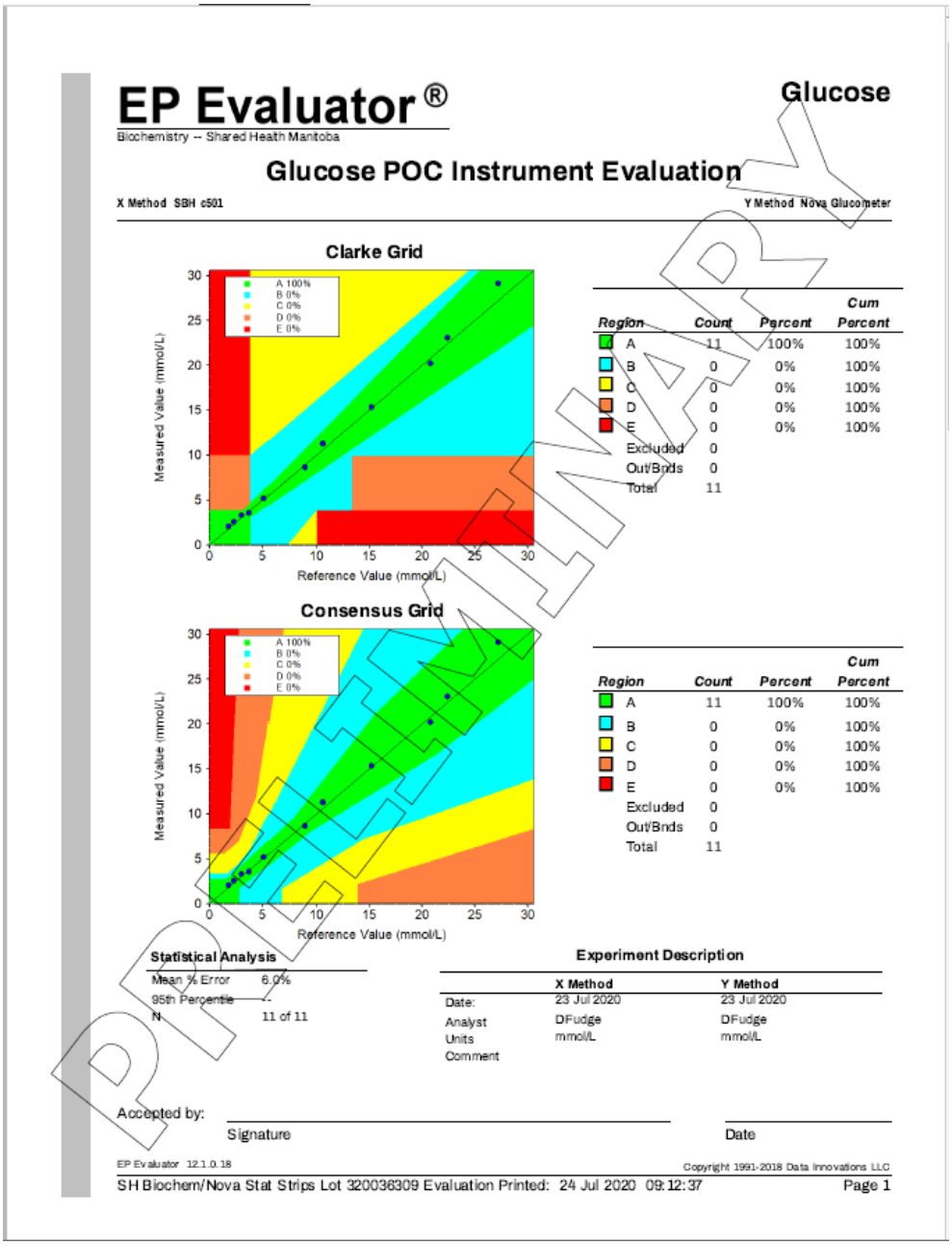
Appendix C

Evaluation of Nova Test strips – Patient correlation vs Roche Cobas			
New test strip Lot #		Exp. date	
Site:			
Analyst:			
Date of correlation:			
Meter Serials #			
Nova Control 1 lot #		Exp. date	
Nova Control 3 lot #		Exp. date	
50% glucose lot #		Exp. date	
Specimen type:			

	Patient Correlation						
		Nova Stat Strip (WB)				Roche Cobas c501 (plasma)	
Spec #	Date	Analysis time	Result 1	Result 2	X	Analysis time	Result 1
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							

mmol/L

APPENDIX D



EP Evaluator®

Biochemistry -- Shared Health Manitoba

Glucose

Glucose POC Instrument Evaluation

X Method SBH c501

Y Method Nova Glucometer

Clarke Grid

Region	Count	Percent	Cum Percent
A	11	100%	100%
B	0	0%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	11		

Consensus Grid

Region	Count	Percent	Cum Percent
A	11	100%	100%
B	0	0%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	11		

Statistical Analysis

Mean % Error	6.0%
95th Percentile	--
N	11 of 11

Experiment Description

	X Method	Y Method
Date:	23 Jul 2020	23 Jul 2020
Analyst	DFudge	DFudge
Units	mmol/L	mmol/L
Comment		

Accepted by:

Signature

Date

EP Evaluator 12.1.0.18

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