

MEASUREMENT OF UNCERTAINTY NOVA GLUCOSE METERS - 2022

	LEVEL 1			
	N	MEAN	ST. DEV	Co/Var
JANUARY	328	3.28	0.16	4.92
FEBRUARY	320	3.26	0.15	4.66
MARCH	371	3.29	0.15	4.51
APRIL	350	3.32	0.17	5.19
MAY	366	3.31	0.17	5.15
JUNE	357	3.33	0.17	5.2
TOTAL/AVERAGE	2092	3.30	0.16	4.94

	LEVEL 3			
	N	MEAN	ST. DEV	Co/Var
JANUARY	325	15.83	0.56	3.52
FEBRUARY	318	15.71	0.55	3.49
MARCH	364	15.85	0.54	3.42
APRIL	338	15.77	0.5	3.16
MAY	358	15.78	0.47	3
JUNE	354	15.79	0.51	3.2
TOTAL/AVERAGE	2057	15.79	0.52	3.30

JULY	357	3.33	0.17	5.2
AUGUST	361	3.38	0.22	6.48
SEPTEMBER*	256	3.41	0.24	6.92
SEPTEMBER**	95	3.41	0.22	6.58
OCTOBER*	21	3.18	0.32	9.95
OCTOBER**	329	3.47	0.17	4.92
NOVEMBER	345	3.41	0.21	6.05
DECEMBER	353	3.43	0.17	5
TOTAL/AVERAGE	2117	3.38	0.22	6.39

JULY	354	15.79	0.51	3.2
AUGUST	355	15.96	0.6	3.75
SEPTEMBER*	252	16.06	0.64	3.98
SEPTEMBER**	94	16.08	0.65	4.06
OCTOBER*	18	15.67	0.49	3.12
OCTOBER**	328	16.32	0.6	3.68
NOVEMBER	342	16.22	0.65	3.99
DECEMBER	345	16.32	0.6	3.7
TOTAL/AVERAGE	2088	16.05	0.59	3.69

QC Data

Test Name	Whole Glucose
Test Units	mmol/L
Number of Decimals for Calculated Results	2
Number of Months of QC Data	6
Number of QC Levels	2
Number of Instruments Running Tests	15

Lot 0420157301*	QC 1 Target	3.4	Bias = (Mean - 3.4)/3.4 x 100
Lot 0420168303*	QC 3 Target	16.7	Bias = (Mean - 16.7)/16.7 x 100
Lot 0421183301**	QC 1 Target	3.3	Bias = (Mean - 3.3)/3.3 x 100
Lot 0421204303**	QC 3 Target	16.7	Bias = (Mean - 16.7)/16.7 x 100

SUMMARY JANUARY - JUNE

SUMMARY: Estimation of MU for a Glucose Measurement Procedure Ignoring Bias

IMPRECISION:

QC LEVEL 1 Date Range

DATA POINTS (N) 2092
 MEAN (mmol/L) 3.30
 SD (ulmp) 0.16
 CV (%) 4.94

QC LEVEL 3 Date Range

DATA POINTS (N) 2057
 MEAN (mmol/L) 15.79
 SD (ulmp) 0.52
 CV (%) 3.30

Bias Not accessed

PLASMA GLUCOSE

3.30 mmol/L, uProc = CV = 4.94
 15.79 mmol/L, uProc = CV = 3.30

EXPANDED UNCERTAINTY (MU) k=1.96

Multiplication of U_{Proc} by a coverage factor of 1.96 provides an interval of values that is believed to include the true value with a coverage probability of 95%.

3.30 mmol/L U = 9.68
 15.79 mmol/L U = 6.46

FINAL MU

MU (%) **8.07**

SUMMARY JULY - DECEMBER

SUMMARY: Estimation of MU for a Glucose Measurement Procedure Ignoring Bias Uncertainty

IMPRECISION:

QC LEVEL 1 Date Range

DATA POINTS (N) 2117
 MEAN (mmol/L) 3.38
 SD (ulmp) 0.22
 CV (%) 6.39

QC LEVEL 3 Date Range

DATA POINTS (N) 2088
 MEAN (mmol/L) 16.05
 SD (ulmp) 0.59
 CV (%) 3.69

Bias Not accessed

PLASMA GLUCOSE

3.38 mmol/L, uProc = CV = 6.39
 16.05 mmol/L, uProc = CV = 3.69

EXPANDED UNCERTAINTY (MU) k=1.96

Multiplication of U_{Proc} by a coverage factor of 1.96 provides an interval of values that is believed to include the true value with a coverage probability of 95%.

3.38 mmol/L U = 12.65
 16.05 mmol/L U = 7.30

FINAL MU

MU (%) **9.97**

IQMH 2021 CRITERIA POC GUIDELINE 20%

Point-of-Care Testing

Analyte	Concentration	Precision	Allowable Limit (Difference from the Instrument Mean Unless Otherwise Stated)
Glucose	<5.0 mmol/L ≥5.0 mmol/L		1.0 mmol/L 20%

Conclusion: 8.07% FALLS UNDER THE 20% THRESHOLD - PASS

Review Date: *Ron Garbuso* July 05, 2022

Reviewed By:

Conclusion: 9.97% FALLS UNDER THE 20% THRESHOLD - PASS

Review Date: *Ron Garbuso* Jan 18, 2023

Reviewed By: