MEASUREMENT OF UNCERTAINTY CAPT_QUA_0800

PUPROSE

Measurement Uncertainty (MU) relates to the margin of doubt that exists for the result of any measurement, as well as how significant the doubt is. For example, a piece of string may measure 20 cm plus or minus 1 cm, at the 95% confidence level. As a result, this could be written: 20 cm ±1 cm, with a confidence of 95%. Therefore, we are 95% sure that the piece of string is between 19 cm and 21 cm long.

Standards such as ISO 15189 require that the laboratory must determine uncertainty for each test (glucometers only).

Employing your QC data to calculate uncertainty makes several assumptions; your test system is under control, the patient samples are treated in the same manner as your controls and gross outliers have been removed. If you choose to use your QC data to calculate this you should ensure that you use a commutable control with a matrix similar to that of a patient sample, with analytes present at clinically relevant levels

As uncertainty is calculated as SD and 1SD is equal to 68% confidence on a standard Gaussian curve, we can conclude that if we multiply using a coverage factor of 2, we can attain 2SD confidence of 95%. This is known as the Expanded Uncertainty (U): $U = 2 \times u$

What is the Advantage of Measurement Uncertainty for a lab?

Labs need to carry out MU as it is a requirement of ISO 15189. It states: “The laboratory shall determine measurement uncertainty for each measurement procedure, in the examination phases used to report measured quantity values on patients’ samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty”.

MU also helps determine whether the difference between two results is negligible due to uncertainty or significant due to a genuine change in condition of the patient; giving labs a greater confidence in reported results.

Lab performs calculations every 6 months (using 6 months’ worth of data from 14 glucometers)

Measurement uncertainty is considered when interpreting measured quantitative values.

PROCEDURE

1. Open Measurement of Uncertainty Spreadsheet, found at H:\Lab_Medicine\POCT - Point of Care\Measurement of Uncertainty\!Measurement of Uncertainty V.2. Enter:
    a. In Aegis run QC Statistics Report:

i. Year

ii. Month

iii. Location: BC Cancer

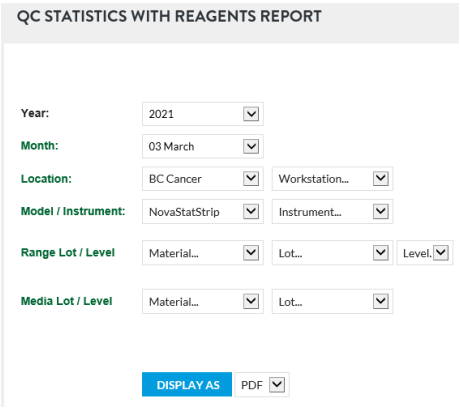
iv. Workstation: don't change

v. Model: NovaStatStrip

vi. Instrument: don't change

vii. Range Lot/Level – don't change

viii. Media Lot/Level – don't change



ix. Display as – PDF

1. Print QC Summary
2. Use data for measurement of uncertainty
3. Store digital copy: H:\Lab_Medicine\POCT - Point of Care\Quality Control & Validation\Quality Reports. Store paper copy in binder.

b. QC 1 Target – 3.4 mmol/L (TRUE VALUE)

c. QC 3 Target – 16.7 mmol/L (TRUE VALUE)

2. Using the QC statistics report, at the bottom of the pages for each level of QC, look for the facility summary, enter into spreadsheet for each level of QC each month:

Analyte	Instrument	Month Year / Lot to Date	Single Instrument Mean	Std.Dev.	Co/Var	N
Facility Summary		3 / 2022	3.29	0.15	4.51	371
BC Cancer						
Glucose		*Lot to Date:*	*3.30*	*0.19*	*5.72*	*3,190*

a. N = Number of tests performed

b. M = Mean or Average

c. SD = Standard Deviation

d. CV = Coefficient of Variation

e. Bias = (mean – true value)/true value x 100

i. TVL1 = 3.4

ii. TVL2 = 16.7

3. Determine whether or not each MU is “acceptable” or not.

a. Optimal/desirable/minimal goals, which are based on biological variation

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		1.0 mmol/L
	≥5.0 mmol/L		20%

4. Medical director reviews and signs every 6 months (January – June)/ (July – December)

REFERENCES

1. https://www.randox.com/what-is-measurement-uncertainty/
2. https://www.westgard.com/biodatabase1.htm