مركز الجودة للمختبرات الطبية
Center for Quality in Medical Laboratories

Uncertainty in Proficiency Testing Schemes: Center for Quality in Medical Laboratories (CQML) Study

An Overview
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Outline

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Introduction:

- Eurachem / CITAC Guide CG4: Uncertainty: “a parameter associated with the result of a measurement that characterizes the dispersion of the values attributed to the measurand”.
- In CQML: values are based on the robust consensus mean of the participants. As a result, robust consensus mean have an uncertainty originating from the testing conditions of laboratories and other factors.

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Introduction cont.,

- MU is not yet included in CQML report for participating lab.
- Lab Performance is based on comparing values for all methods not method groups.
- Future Plan: Lab Performance will be according to method groups.

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Study design:

In this study, the uncertainty of the robust mean of Glucose(mg/dl) and Alkaline phosphatase(U/l) results was checked during the year 2019. (8 samples)

- Calculation is based on ISO 13528

- Uncertainty = MU = $1.25 \times SD / \sqrt{n}$

- $0.3 \times SD$ was used for comparison with MU

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Values of uncertainty for all methods

Sample #	Uncertainty Glucose	Uncertainty Alkaline Phosphatase
73	0.5	2.9
74	0.7	3.1
75	0.7	3.5
76	0.5	2.8
77	0.5	3.1
78	0.4	2.7
79	0.7	6.5
80	0.5	2.5
Average	**0.6**	**3.4**

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MU for Alkaline phosphatase/method

Method	Uncertainty	0.3×SD
Colorimetric	9.5	12.7
AMP, optimized to IFCC	7.8	11.9
Diethanolamine buffer, DEA	4.4	8.9
Tris/carbonate buffer	**26**	7.3
Ortho Vitros Microslide Systems	-	-
AMPD optimized to JSCC	**15.9**	11.9
Siemens/Dade Dimension, AMP buffer	**13.9**	7
AMP, reduced interference	**20.3**	9.8
AMP, non-optimized	**19.6**	12.1
Dry Chemistry	**8.2**	6
Other	5.9	12.3

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MU for Glucose / method

Method	Uncertainty	0.3 × SD
Oxidase/Peroxidase	0.8	2.5
Hexokinase	1.6	2.2
Glucose dehydrogenase	**5.3**	3.9
Other	1.4	2.3
GOD/02-Beckman method	**5.5**	3.4
Oxygen electrode	-	-
Agappe - GOD-PAP	1	2.6

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Interpretation :

- According to ISO/IEC 13528, if the uncertainty of the assigned value is smaller than the 0.3 × SD of the scheme, there is no need to include the uncertainty in the interpretation of the results of the proficiency scheme.
- Glucose and Alkaline phosphatase MU (averages) is less than 0.3 × SD
- Uncertainty for some methods is larger than the 0.3 × SD for method.

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Advantage of reporting MU:

- Lab Accreditation (ISO 15189 & 17025).
- Laboratories can compare their (MU) with other laboratories using the same method and other methods.

Problems:

- The lack of knowledge of the concept of uncertainty and its calculation by laboratories.
- Method Groups for some measurands is less than 5.
- Failure to choose the correct method for examination test by laboratories.

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Conclusion and Recommendation

- Training is required for participating labs on the use and calculation of Uncertainty
- Eliminating methods with high uncertainty

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