Measurement Uncertainty in Princess Iman Center Chemistry Department

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DOI: 10.29322/IJSRP.10.04.2020.p10090
http://dx.doi.org/10.29322/IJSRP.10.04.2020.p10090

***Abstract*-** The approach described in this paper using the (top down) method, Bias should be eliminated, and we use QC results using third part control from BIO-RAD, to estimate the MU for the Haemoglobin A1C.

***Index Terms*-** Coverage factor (k), Combined standard measurement uncertainty (uc)
Expanded Measurement Uncertainty (U)

I. INTRODUCTION

The aim of this study is to estimate the measurement uncertainty for a HA1C results, according to internal quality control (Third part control), expressed as a confidence level within a range,for the test results , so we can have a Confirmation that patients' results meet the quality goals set by our laboratory.

Concept

Measurement uncertainty expresses the level of confidence a laboratory has of a test result.

It's a requirement in **ISO 15189:2012** Medical laboratories: requirements for quality and competence (**clause 5.5.1.4**)

ISO 15189:2012 states that measurement uncertainty applies to each measurement procedure used to report measurement uncertainty for those falling into the quantitative and semi-quantitative category.

Definitions of measurement uncertainty :-

1. The degree to which one is certain of results for a particular Measurement, Expressed as a confidence level within a range.

3. Parameter, associated with the result of a measurement that characterized the dispersion of the values that could reasonably be attributed to the measurand.

(Source: National Pathology Accreditation Advisory Council Requirements for estimation measurements Uncertainty). the

USES

Measurement uncertainty is useful because:

- It provides quantitative evidence that measurement results meet the lab requirements .
- It can be used to compare results with previous results using the same measurement procedure.
- It can be used as evidence for improvement, and for achieving standardized measurements.

Measurement uncertainty does not necessarily need to be reported to users of the laboratory, but shall be available if requested.

II. IDENTIFY,REASEARCH AND COLLECT IDEA

- How to calculate Measurement Uncertainty in medical Laboratory.

Our lab use the top-down approach , using available laboratory test performance information ,such as Quality control (QC) DATA ,to calculate estimate of the standard uncertainty associated with the result produced by the overall testing procedure.

Determining Measurement Uncertainty by the top-Down Approach Using Interlaboratory Data.

1-The preferred method is that we use performance data from the (QC)

Programs our centre have a (unity Real time) program from BIO-RAD Company .

2-The lab (**PISC**) Use a **QC materials** from (BIO-RAD) a third part control that behaves a similar way to that of patient samples.

3-Imprecision is equivalent to the standard measurement uncertainty, assuming negligible or no bias.

4-A minimum of six months data is recommended (in order to ensure that variations due to multiple users, reagents and calibrator lots are captured).

5-The Mean Value and SD is calculated for each level of QC used in our chemistry Lab., (BIO-RAD) over 6 MONTH to encompass as many routine procedure changes as possible.

6-The parameter of **MU is 1 SD** (Standard measurement uncertainty, symbol **μ** because the SD of the (QC) reflect the combined effect of all the individual uncertainties arising within the measuring system.)

7-To Define intervals that enclose larger fractions of expected dispersions of results, coverage factors (k) applied to (μ) to provide expanded measurement uncertainties (U).Usually k=2 is chosen .So the result could be in the form x±y (95%confidence) Where y=2SD ,U=(2*μc) .

8-For each level of **QC MU** should be calculated for each level.

III. RESULTS

We use a **BIO-RAD** Control for Haemoglobin HA1c ,**two levels** were examined for **lot no: 33980Exp Date:31/3/2021FROM (4-2-2019 until 16-9-2019)**covering at least six month , the **number of control reading were :136point** ,which is sufficient to do the calculation, as un the table below:

QC	4-2-2019/16-9-2019	Mean (%)	SD(µc)	2SD(U)(U=2*µc)
Level 1	**N=136**	**4.84**	**0.08**	**0.16**
Level 2	**N=138**	**9.67**	**0.14**	**0.28**

For our laboratory test performance for release the HA1C result to doctors we must calculate the MU for each level (Normal/Abnormal) and decide that our test result have an MU as mention in the table above.

For Example:

Patient 1: result: 4.20±0.16

(the 95% confidance level for this result is (4.04-4.36)%

Patient 2: result: 8.00±0.28

(the 95% confidance level for this result is (7.72-8.28)%

IV. CONCLUSION

1- In order to comply with accreditation requirements, medical laboratories must Estimate the measurement uncertainty associated with all quantitative measurement results.

2-Measurement uncertainty is to be expressed in this form: Measurand (result of laboratory test or examination): Value+/- U units

U is the expand uncertainty and units are typically SI or internationally accepted non-SI units.

Abbreviations

ISO: International Organization for Standardization, Geneva, Switzerland.

MU: measurement uncertainty

SD: standard deviation

PISC: Princess Iman for Research and Laboratory Science Center

REFERENCES

[1] International Organization of Standardization ISO15189:2012 Medical Laboratories Requirements for Quality and Competence.

[2] Joint Committee for Guides in Metrology. JCGM 200:2012,

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