Calculation Of Measurement Uncertainty Of Three Different Biochemistry Parameters

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Uncertainty

Accuracy of measurement results depends on precision, sensitive and reliability of results.

Measurement uncertainty is a quality indicator which is used to show the distribution level of the test result.

It also shows to what extent the result represents the actual value. So uncertainty value is a parameter that increases confidence in the accuracy of measurement results.

Uncertainty

Measurement uncertainty is particularly important for parameters with lower and upper reference limits important, especially at medical decision points and when determining the direction of treatment.

In principle, two approaches can be used to calculate measurement uncertainty: “bottom-top” and “top-bottom”

Calculation Of Uncertainty

The “ bottom –top” approach the possible sources of variability affecting the results are listed separately and the contribution of each resource to the measurement uncertainty is determined.

The “top-bottom” approach uses laboratory test performance information, such as intra- and inter-laboratory quality control data to estimate uncertainty associated with the test results.

Guide to the expression of uncertainty in measurement (GUM)

The GUM guide calculates uncertainty according to the bottom-top approach.

It will be a time consuming and costly process.

This method is interpreted by Westgard as difficult and complex to understand.

Nordtest (Handbook For Calculation of Measurement Uncertainty in Environmental Laboratories):

The Nordtest guideline aims to provide a comprehensible and practical application in the measurement uncertainty calculation. The Nordtest guideline calculates uncertainty according to the top-bottom approach.

The disadvantage of this approach is that the contribution of all uncertainty components to combined uncertainty cannot be assessed in detail.

The advantage of this method is that it is practical and easy to apply.

Therefore, this method seems more practical for clinical laboratories.

Material and Methods

In this study, the measurement uncertainty of serum Alkaline Phosphatase (ALP), Creatine Kinase (CK) and Gamma-glutamyltransferase (GGT) levels based on the “top-bottom” approach defined in the Nordtest guideline was estimated.

The measurement uncertainty values of 3 biochemistry parameters are calculated by using internal and external quality control data and these values are compared with total permissible error (TEa%) of 2019 CLIA.

The tests were performed by enzymatic method on Beckman Coulter AU5800 analyzer.

Results

CV% values of level 1 and level 2 were calculated from 50-day internal quality control results.

Bias% values were calculated from 2018 12-month external quality evaluation results.

TEST	LEVEL 1 %CV	LEVEL 2 %CV	%bias
ALP	7,07	5,36	0,6
CK	5,58	2,9	4,79
GGT	2,36	3,45	2,8

Results

Serum ALP CK and GGT analysis measurement uncertainty was 18.8%, 17.7% ,13.3% respectively in the 95% confidence interval, and these values did not exceed the 2019 CLIA% total permissible error values.

TEST	RMS bias	u(cref)	u (bias)	u(Rw)	uc	U(%)	CLIA %Tea
ALP	6,37	3	7,04	6,27	9,43	18,87	20
CK	6,37	5	8,1	3,71	8,875	17,75	20
GGT	5,88	2	6,19	2,5	6,68	13,37	15

2019 CLIA Proposed Acceptance Limits for Proficiency Testing

Routine Chemistry CLIA 2019		
Analyte or Test	**NEW Criteria for AP**	**OLD AP**
Alanine aminotransferase (ALT/SGPT)	TV ± 15%	TV ± 20%
Albumin	TV ± 8%	TV ± 10%
Alkaline Phosphatase	TV ± 20%	TV ± 30%
Amylase	TV ± 10%	TV ± 30%
Bilirubin, total	TV ±20%	TV ± 20% or 0.4 mg/dL (greater)
Blood gas pCO2	TV ± 5mm Hg or ± 8% (greater)	Same
Blood gas pO2	TV ± 15 mm Hg or ± 15% (greater)	TV ± 3SD
Blood gas pH	TV ± 0.04	Same
B-natriuretic peptide (BNP)	TV ± 30%	None
Pro B-natriuetic peptide (proBNP)	TV ± 30%	None
Calcium, total	TV ± 1.0 mg/dL	Same
Carbon dioxide	TV ± 20%	None
Chloride	TV ± 5%	Same
Cholesterol, total	TV ± 10%	Same
Cholesterol, high density liprotein	TV ± 20%	TV ± 30%
Cholesterol, low density lipoprotein (direct)	TV ± 20%	None
Creatine kinase (CK)	TV ± 20%	TV ± 30%
CK-MB isoenzymes	MB elevated (presence or absence)	Same
	or TV ± 25% (greater)	or TV ± 3SD
Creatinine	TV ± 0.2 mg/dL or ± 10% (greater)	TV ± 0.2 mg/dL or ± 15% (greater)
Ferritin	TV ± 20%	None
Gamma glutamyl transferase	TV ± 5 U/L or ±15% (greater)	None
Glucose (excluding FDA home use)	TV ± 8%	TV ± 6 mg/dL or ± 10% (greater)
Hemoglobin A1c	TV ± 10%	None
Iron, total	TV ± 15%	TV ± 20%
Lactate dehydrogenase (LDH)	TV ± 15%	TV ± 20%
Magnesium	TV ± 15%	TV ± 25%
Phosphorus	TV ± 0.3 mg/dL or 10% (greater)	None
Potassium	TV ± 0.3 mmol/L	TV ± 0.5 mmol/L
Prostate Specific Antigen, total	TV ± 0.2 ng/dL or 20% (greater)	None
Sodium	TV ± 4 mmol/L	Same
Total Iron Binding Capacity (direct)	TV ± 20%	None
Total Protein	TV ± 8%	TV ± 10%
Triglycerides	TV ± 15%	TV ± 25%
Troponin I	TV ± 0.9 ng/mL or 30% (greater)	None
Troponin T	TV ± 0.2 ng/ML or 30% (greater)	None
Urea Nitrogen	TV ± 2 mg/dL or ± 9% (greater)	Same
Uric Acid	TV ± 10%	TV ± 17%

Conclusion

Clinical laboratories providing medical services should be able to provide quality, accurate and reproducible results with a valid method in order to be sufficiently beneficial to the patient.

Therefore, laboratories should provide results that do not exceed the target measurement uncertainty values.

Clinicians should also consider uncertainty of measurement when evaluating test results.

Thank you..