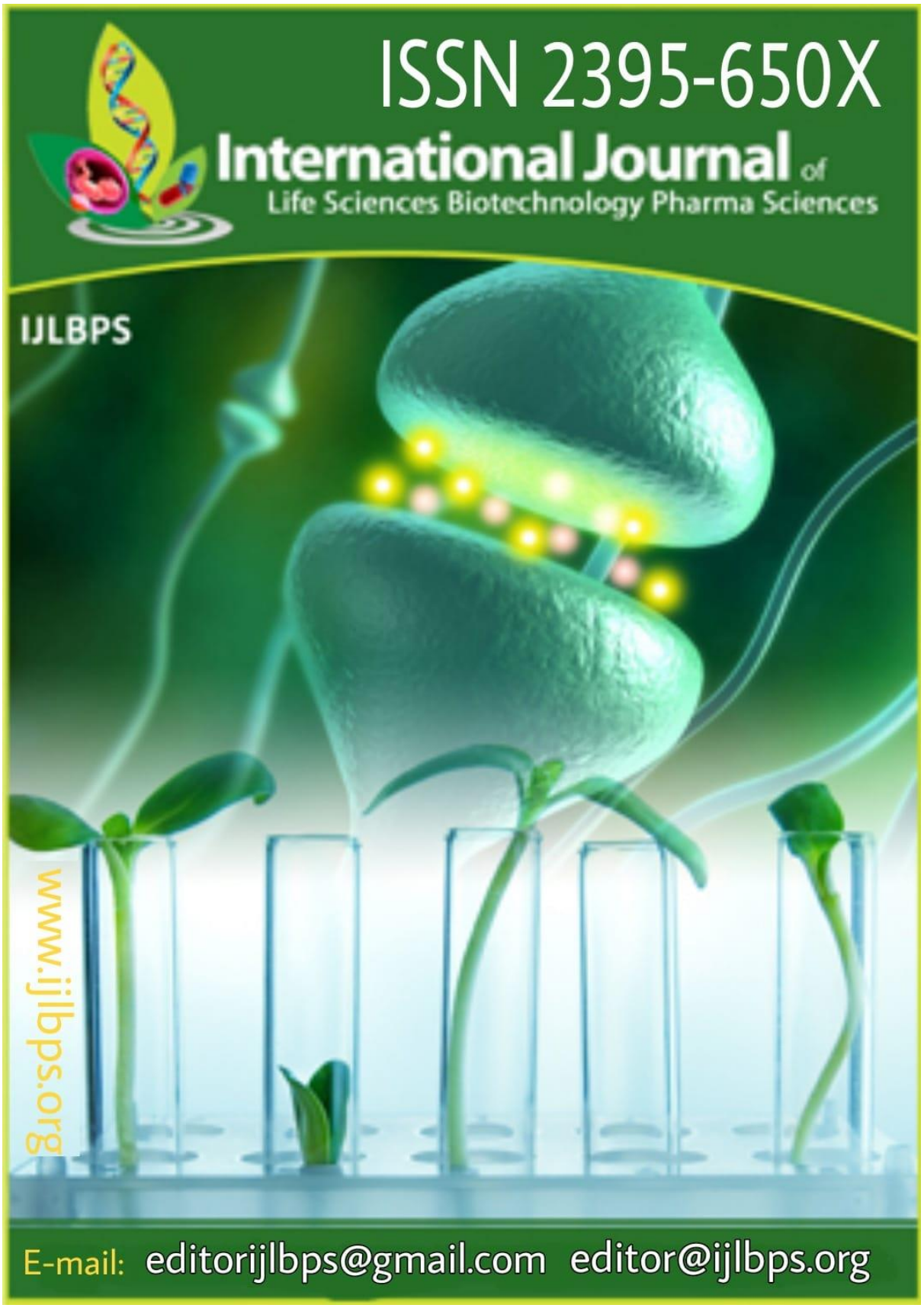
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Measurement Uncertainty Calculation for Twenty Clinical Chemistry Analytes Using the Real-World ISO Method

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ABSTRACT

The diagnosis, treatment, monitoring, and risk assessment of patients rely heavily on the findings of laboratory tests conducted in clinical labs. Therefore, Reliability of measurement results and proper patient treatment are dependent on precise and accurate regular measurements (1). The reliability and accuracy of measurements are first assessed using total error (TE). When the measured value deviates from the precise value, it is indicated by TE, which is a mix of random and systematic mistakes (2). In order to account for these sources of error, Westgard et al. (3) defined TE as the sum of the observed bias plus two standard deviations. In order to compute the TE, one must be aware of the precise value of the measurement data. The idea of measurement uncertainty (MU) is another way to evaluate the precision of a measurement. It's a non-negative parameter linked to the measurement's outcome that defines the range of values that can be rationally attributed to the measurement (2). The absence of a completely correct value of the findings is emphasised by MU, which operates on the assumption that the precise value of the test results cannot be known (1). Measurement uncertainty (MU) is the range of possible measurable values for a given analyte, and the equal likelihood of obtaining values within this range (4). If a result considerably differs from accuracy, it may be determined by comparing it with permissible analytical performance standards (APS), much as with the TE concept (5). There should be proper evaluation of MU values of test results in routine laboratory practices, according to international accreditation bodies like JCGM, ISO, and ILAC (6-8).

There are a lot of variables that might affect the MU value, such as matrix effects, interferences, environmental factors, reference material uncertainties, commercial system calibrator uncertainties, and measurement technique and method uncertainties (9). In order to estimate measurement uncertainty, two models have been identified in the literature. A bottom-up model put forward by JCGM is the first (6). All possible unknowns that have a major impact on the result of a particular measurement technique (such as calibration, identifying a large number of sources and using sophisticated mathematical models, this methodology is not suited for routine laboratory medicine (1). Data from both internal and external quality control or technique verification is used to determine measurement uncertainty in the other model, the top-down approach (10). Together with the ISO/TS 20914:2019 standard, we provide a workable method for MU computation. Following this protocol, while determining the MU value, it is advised to primarily consider long-term imprecision (uRw) and calibrator uncertainty (ucal). The bias (ubias) should only be included in the MU calculation when it leads to a significant difference in medical outcomes

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The purpose of this study was to assess the potential impact of the results on clinical decision-making by comparing the MU values of the biochemical parameters examined in two identical devices of the same brand and model in our lab. We used the ISO/TS 20914:2019 guideline as our basis for comparison, along with the allowable analytical performance specifications.

MATERIAL

Table 1. Measurands Definitions

Test (Abbreviations)	Method	Sample type
Albumin (Alb)	Bromocresol green colorimetric method	Serum
Alanine aminotransferase (ALT)	IFCC method without pyridoxal phosphate activation	Serum
Amylase (Amy)	IFCC method, enzymatic colorimetric	Serum
Aspartate aminotransferase (AST)	IFCC method without pyridoxal phosphate activation	Serum
C-reactive protein (CRP)	Immunoturbidimetric method with expanded particle surface	Serum
Iron (Fe)	Ferrozine colorimetric method	Serum
Ethanol (EtOH)	Enzymatic method with alcohol dehydrogenase	Serum
Glucose (Glu)	Enzymatic hexokinase, colorimetric method	Serum
HDL - Cholesterol (HDL-C)	Homogeneous enzymatic colorimetric method	Serum
Calcium (Ca)	Colorimetric method, o-cresolphthalein complex	Serum
Chloride (Cl)	Indirect method using ion-selective electrodes	Serum
Creatinine (Crea)	Jaffe kinetic colorimetric method	Serum
Potassium (K)	Indirect method using ion-selective electrodes	Serum
Sodium (Na)	Indirect method using ion-selective electrodes	Serum
Total Bilirubin (T.Bil)	Diazo method	Serum
Total Cholesterol (Cholesterol)	Enzymatic colorimetric method	Serum
Total Protein (TP)	Colorimetric	Serum
Triglyceride (TG)	Enzymatic colorimetric	Serum
Blood urea nitrogen (BUN)	Kinetic test with urease and glutamate dehydrogenase	Serum
LDL- Cholesterol (LDL-C)	Homogeneous enzymatic colorimetric method	Serum

Gaziosmanpaşa Training and Research Hospital Clinical Research Ethics Committee gave its approval for this retrospective, single-

center investigation (Decree Date and No: 22 December 2021/393), and it was carried out in accordance with the principles outlined in the Declaration of Helsinki.

The MU values were computed according to the "Combined standard uncertainties and expanded uncertainties ISO/ TS 20914:2019" standard (9). For 20 analytes used in clinical chemistry, we defined the amounts that would be used to derive MU values (Table 1). The analysis was conducted at the Medical

Calculations

Standard deviation (SD), which measures the distribution of values obtained from precision studies under long-term precision conditions, is called standard uncertainty

(u) in measurement uncertainty calculations (SD = u). To estimate the overall (combined) uncertainty of the re- sult, it is necessary to combine values from different un- certainty sources. According to the ISO/TS 20914:2019 guideline, under long-term precision conditions, which contribute to uncertainty in the calculation of u(y) of the Y analyte measured in the laboratory, the uncertainty of

Variance $SD^2(A, B) = u^2(A, B) = [\sum \dot{X}- \dot{X} (A, B)]/(n-1)$ (Formula 3).

$u(\text{pooled}) = \sqrt{(u2(A, B)_w + uR^2(A, B))}$ (Formula 4).

We calculated the expanded uncertainty (U) by multipl- ying the calculated u(y) value for each analyte with k (coverage factor) and the percentage relative expanded uncertainty value ($\%U_{rel}$) according to the mean value (Formulas 5 and 6). We set the k value as 2 to represent the 95% confidence interval.

$U(y)= 2x\ u(y)$ (Formula 5).

$$\%U(y)\ rel= \frac{(U(y))}{\text{mean}} \times 100 \text{ (Formula 6).}$$

We obtained maximum expanded allowable measure- ment uncertainty (MAU) targets by selecting desirable tar- gets from The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Biological Variation da- tabase for tests other than ethanol (11). We determined the MAU value for ethanol as 20%, which is the current acceptance limit of Clinical Laboratory Improvement Amendments (CLIA) (12). Microsoft Office 365 (Microsoft Excel Software, Microsoft Corporation, US) was used to perform the calculations and create the tables.

RESULTS

Keeping MU values within as a narrow range as possible means producing quality and reliable test results suitable for patient care. Although it is not obligatory to present MU values in laboratory result reports, laboratories must have MU information about the tests to inform clinicians upon their request. For example, if the clinician has a re- quest for MU for a patient with a glucose value of 120 mg/ dl (U_{rel}=10%), the possible options for reporting MU wo- uld be 120±12 mg/dl, 120 mg/dl ±10% or 120 mg/dl (108 – 132 mg/dl) (k=2, 95% CI) (9,14).

The MU calculation we made for glucose in our study re- vealed the $\%U_{rel}$ (pooled) values, including identical A and B measurement systems in our laboratory, as 10.4% and 4.2% for IQC-1 and 2, respectively. We determined that the MU we calculated for the IQC-2 met the targeted quality specification (5%), but the MU value for the IQC-1 material exceeded the allowable targets. Measurement of blood

DISCUSSION

The current research showed that out of twenty clinical biochemistry analytes, only seven had MU values that were within the MAU range: ALT, CRP, Fe, EtOH, T. Bil, TG, and BUN. After looking over the MU parts, we found that the combined standard uncertainty was most affected by the uRw values that came from the internal quality control investigations. It seems that uRw is a fundamental part of present MU methods, which is in line with our work (9,13). Thus, assessing the IQC, investigating incorrect findings, and implementing preventative and remedial measures are of utmost significance. physicians can better comprehend if a patient's glucose level significantly surpasses the medical decision limit with the aid of her test findings. The current investigation determined that IQC-1 had a creatinine %Urel (pooled) value of 11.9% and that IQC-2 had a value of 7.6%. After reviewing the data, we concluded that the MU values were below the acceptable quality standard of 4.5%. The severity of acute renal damage is strongly connected to extremely minor variations in serum creatinine concentrati-ons, which are commonly employed for detecting and treating kidney diseases (16,17). Thus, it is important to know the degree of ambiguity in the creatinine test result in order to properly treat acute renal damage. In addition, we saw that the %Urel (pooled) values for Na, K, and Cl were still outside the MAU; for Na, it was 0.5%, for K, it was 4.1%, and for Cl, it was 1.1%. The kidneys and metabolism work in tandem to regulate these ions (5). Specifically, the K value might alter as a result of the medications employed; hence, it is advised to closely monitor its effects on the heart system and evaluate renal functioning (15). Health care providers may find it easier to manage patients' conditions if these tests' MU results remain within the acceptable range.

Table 2. Within-laboratory precision, calibration uncertainty and percent relative expanded uncertainty values of two identical devices calculated according to ISO guideline

Test	Material	u^2(A,B)	u^2R_w(A,B)	u^2cal	U(y) (A,B)	U_{rel}% (pooled) (k=2)	MAU(%)
Alb	IQC-1 (A,B)	0,02	1,8939	0,0882	1,42	**8,65**	2,5
	IQC-2 (A,B)	0	3,0553	0,0882	1,77	**7,01**	
ALT	IQC-1 (A,B)	0,005	3,7445	0,1018	1,96	8,29	10,1
	IQC-2 (A,B)	0,08	15,2767	0,1018	3,93	6,36	
Amy	IQC-1 (A,B)	0,845	40,639	0,49	6,48	**16,15**	6,6
	IQC-2 (A,B)	0,5	84,013	0,49	9,22	**9,78**	
AST	IQC-1 (A,B)	0,02	4,9199	0,1845	2,26	**9,74**	9,6
	IQC-2 (A,B)	0,08	25,1047	0,1845	5,04	7,03	
CRP	IQC-1 (A,B)	0,005	0,1229	1,051	1,09	22,98	34,1
	IQC-2 (A,B)	0,002	5,5586	1,051	2,57	10,04	
Fe	IQC-1 (A,B)	64,98	3007	164,4	56,89	10,33	20,7
	IQC-2 (A,B)	320	8008,86	164,4	92,16	7,71	
EtOH	IQC-1 (A,B)	0,13	6,6218	1,452	2,86	11,3	20*
	IQC-2 (A,B)	0,18	23,231	1,452	4,99	6,7	
Glu	IQC-1 (A,B)	0,08	27,5749	0,637	5,32	**10,4**	5
	IQC-2 (A,B)	1,445	21,7093	0,637	4,88	4,2	
	IQC-1 (A,B)	0,32	1,625	0,3399	1,51	**9,5**	

HDL-C	IQC-2 (A,B)	1,125	17,1055	0,3399	4,31	**14,2**	5,8
Ca	IQC-1 (A,B)	0,02	0,0901	0,00188	0,34	**7,52**	1,8
	IQC-2 (A,B)	0,045	0,1093	0,00188	0,4	**5,83**	
Cl	IQC-1 (A,B)	0,245	6,9892	0,16	2,72	**6,41**	1,1
	IQC-2 (A,B)	0,125	5,1305	0,0625	2,31	**4,52**	
Crea	IQC-1 (A,B)	0,00005	0,0031	0,00083	0,06	**11,9**	4,5
	IQC-2 (A,B)	0,00005	0,0226	0,00083	0,15	**7,6**	
K	IQC-1 (A,B)	0	0,0111	0,000625	0,11	**6,02**	4,1
	IQC-2 (A,B)	0	0,0157	0,0001	0,13	3,7	
Na	IQC-1 (A,B)	0,02	7,5145	0,16	2,77	**4,92**	0,5
	IQC-2 (A,B)	0,005	5,7189	0,0625	2,401	**3,58**	
T.Bil	IQC-1 (A,B)	0,005	0,0049	0,000337	0,1	19,27	20
	IQC-2 (A,B)	0,02	0,0651	0,000337	0,29	15,8	
Cholesterol	IQC-1 (A,B)	4,81	10,6041	0,4563	3,98	**7,9**	5,3
	IQC-2 (A,B)	12	30,3426	0,4563	6,54	**7,8**	
TP	IQC-1 (A,B)	1,125	4,4217	0,0181	2,36	**9,7**	2,6
	IQC-2 (A,B)	2,645	8,1977	0,0181	3,3	**8,5**	
TG	IQC-1 (A,B)	0,72	12,8189	0,64	3,77	6,3	20
	IQC-2 (A,B)	1,28	34,3906	0,64	6,03	5,7	
BUN	IQC-1 (A,B)	0,5	1,825	0,194	1,59	8,06	13,9
	IQC-2 (A,B)	4,205	11,2289	0,194	3,95	6,9	
LDL-C	IQC-1 (A,B)	2,38	4,41	0,596	2,72	**8,9**	8,3
	IQC-2 (A,B)	3	41,37	0,596	6,71	**13,7**	

Alb - Albumin, ALT - Alanine aminotransferase, Amy - Amylase, AST - Aspartate aminotransferase, CRP - C-reactive protein, Fe - Iron, EtOH - Ethanol, Glu - Glucose, HDL-C - HDL Cholesterol, Ca - Calcium, Cl - Chloride, Crea - Creatinine, K - Potassium, Na - Sodium, T.Bil - Total Bilirubin, Cholesterol - Total Cholesterol, TP - Total Protein, TG - Triglyceride, BUN - Blood Urea Nitrogen, LDL-C - LDL Cholesterol.

Mean (A, B) - Mean of two measurement systems mean values, u^2 (A, B) - variance of two mean values between two measurement systems, u^2Rw (A, B) - standard uncertainty component for the long-term precision obtained from six months' internal quality control, u^2cal - uncertainty of calibrator values provided by manufacturer, U(y) - expanded uncertainty, %Urel (pooled) - percent relative expanded uncertainty, MAU - Maximum expanded allowable measurement uncertainty.

*%Urel (pooled) values exceeding the MAU are indicated in bold. All MAU values obtained from The EFLM Biological Variation Database (11), except EtOH. *The MAU value of EtOH obtained from updated CLIA (Clinical Laboratory Improvement Amendments) Proposed Acceptance Limits (12).*

Supplemental Table 1. MEASUREMENT UNCERTAINTY COMPONENTS OF CLINICAL CHEMISTRY ANALYTES IN ANALYZER A

Analyte	Material	n	%CV	u^2R_w	u^2cal	u (y)	$\%U_{rel}$ (k=2)	MAU
Alb	IQC-1	177	3,61	1,42	0,0882	1,23	**7,48**	2,5
	IQC-2	175	2,6	1,74	0,0882	1,35	**5,35**	
ALT	IQC-1	175	4,01	3,69	0,1018	1,95	8,23	10,1
	IQC-2	175	3,37	17,81	0,1018	4,23	6,86	
Amy	IQC-1	169	6,83	31,25	0,49	5,63	**13,93**	6,6
	IQC-2	189	4,25	69,22	0,49	8,35	**8,83**	
	IQC-1	176	3,73	3,03	0,1845	1,79	7,73	

AST	IQC-2	175	3,05	19,18	0,1845	4,4	6,15	9,6
CRP	IQC-1	175	3,56	0,11	1,051	1,08	22,91	34,1
	IQC-2	174	4,22	4,67	1,051	2,39	9,32	
Fe	IQC-1	197	4,88	2917,08	164,4	55,5	10,02	20,7
	IQC-2	187	3,7	7896,1	164,4	89,8	7,47	
EtOH	IQC-1	173	5,03	6,55	1,452	2,83	11,1	20*
	IQC-2	175	3,03	2,37	1,452	1,96	2,6	
Glu	IQC-1	176	2,53	6,71	0,637	2,71	**5,3**	5
	IQC-2	175	1,85	18,32	0,637	4,35	3,8	
HDL - C	IQC-1	175	3,17	1	0,3399	1,16	**7,4**	5,8
	IQC-2	173	7,31	17,81	0,3399	4,26	**14,2**	
Ca	IQC-1	180	3,39	0,096	0,00188	0,31	**6,96**	1,8
	IQC-2	177	2,3	0,096	0,00188	0,31	**4,57**	
Cl	IQC-1	414	2,93	6,25	0,16	2,53	**5,94**	1,1
	IQC-2	407	2,2	5,06	0,0625	2,26	**4,42**	
Crea	IQC-1	187	4,52	0,0025	0,00083	0,058	**10,8**	4,5
	IQC-2	183	3,42	0,0196	0,00083	0,143	**7,1**	
K	IQC-1	430	3,18	0,0121	0,000625	0,113	**6,27**	4,1
	IQC-2	416	1,87	0,0169	0,0001	0,13	3,83	
Na	IQC-1	425	2,59	8,53	0,16	2,95	**5,22**	0,5
	IQC-2	411	1,91	6,55	0,0625	2,57	**3,83**	
T.Bil	IQC-1	193	6,46	0,005	0,000337	0,07	13,16	20
	IQC-2	189	6,9	0,068	0,000337	0,26	13,72	
Cholesterol	IQC-1	178	3,06	9,99	0,4563	3,23	**6,3**	5,3
	IQC-2	177	2,95	25,4	0,4563	5,09	**6**	
TP	IQC-1	177	3,09	2,34	0,0181	1,54	**6,22**	2,6
	IQC-2	176	2,63	4,29	0,0181	2,07	**5,27**	
TG	IQC-1	175	3,05	13,18	0,64	3,72	6,3	20
	IQC-2	173	2,56	29,59	0,64	5,5	5,2	
BUN	IQC-1	180	3,52	1,96	0,194	1,47	7,36	13,9
	IQC-2	177	2,96	11,77	0,194	3,46	5,96	
LDL-C	IQC-1	192	4,3	7,07	0,596	2,77	**9**	8,3
	IQC-2	195	5,25	27,23	0,596	5,28	**10,6**	

Supplemental Table-2: MEASUREMENT UNCERTAINTY COMPONENTS OF CLINICAL CHEMISTRY ANALYTES IN ANALYZER B								
Analyte	Material	n	%CV	u^2R_w	u^2cal	u (y)	$\%U_{rel}$ (k=2)	MAU
Alb	IQC-1	177	4,73	2,37	0,0882	1,57	**9,62**	2,5
	IQC-2	178	4,17	4,37	0,0882	2,117	**8,34**	
ALT	IQC-1	176	4,13	3,8	0,1018	1,98	8,34	10,1
	IQC-2	177	2,88	12,75	0,1018	3,58	5,79	
Amy	IQC-1	175	8,44	47,06	0,49	6,9	**17,33**	6,6
	IQC-2	182	5,25	98,8	0,49	9,97	**10,6**	
AST	IQC-1	177	5,52	6,81	0,1845	2,65	**11,35**	9,6
	IQC-2	178	3,85	31,03	0,1845	5,59	7,78	
CRP	IQC-1	178	3,81	0,14	1,051	1,09	22,94	34,1
	IQC-2	179	4,91	6,45	1,051	2,74	10,72	
Fe	IQC-1	211	5,08	3097	164,4	57,11	10,42	20,7
	IQC-2	208	3,79	8122	164,4	91,03	7,66	
EtOH	IQC-1	176	5,37	7,29	1,452	2,96	11,7	20*
	IQC-2	167	4,47	44,09	1,452	6,75	9,1	
Glu	IQC-1	177	6,99	48,44	0,637	7,01	**13,7**	5
	IQC-2	187	2,16	25,1	0,637	5,07	4,4	
HDL - C	IQC-1	174	4,63	2,25	0,3399	1,61	**10**	5,8
	IQC-2	176	6,55	16,4	0,3399	4,09	**13,3**	
Ca	IQC-1	178	3,31	0,08	0,00188	0,29	**6,66**	1,8
	IQC-2	178	2,63	0,12	0,00188	0,35	**5,26**	
Cl	IQC-1	392	3,3	7,73	0,16	2,81	**6,65**	1,1
	IQC-2	374	2,24	5,2	0,0625	2,29	**4,5**	
Crea	IQC-1	194	5,76	0,0036	0,00083	0,07	**12,6**	4,5
	IQC-2	190	4,04	0,0256	0,00083	0,16	**8,1**	
K	IQC-1	400	2,81	0,01	0,000625	0,1	**5,73**	4,1
	IQC-2	383	1,7	0,0144	0,0001	0,12	3,54	
Na	IQC-1	393	2,28	6,5	0,16	2,58	**4,58**	0,5
	IQC-2	379	1,64	4,88	0,0625	2,22	**3,31**	
T.Bil	IQC-1	193	7,3	0,0049	0,000337	0,07	14,47	20
	IQC-2	194	6,88	0,0625	0,000337	0,25	13,93	
Cholesterol	IQC-1	182	3,32	11,22	0,4563	3,42	**6,8**	5,3
	IQC-2	184	3,51	35,28	0,4563	5,98	**7,2**	
TP	IQC-1	189	5,28	6,5	0,0181	2,55	**10,66**	2,6
	IQC-2	190	4,52	12,11	0,0181	3,48	**9,12**	
TG	IQC-1	174	2,95	12,46	0,64	3,62	6,1	20*
	IQC-2	176	2,96	39,18	0,64	6,31	6	
BUN	IQC-1	177	3,34	1,69	0,194	1,37	7,06	13,9
	IQC-2	180	2,88	10,69	0,194	3,3	5,84	
LDL-C	IQC-1	194	2,22	1,752	0,596	1,53	5,1	8,3
	IQC-2	195	7,68	55,5	0,596	7,49	**15,4**	

Alb - Albumin, ALT - Alanine aminotransferase, Amy - Amylase, AST - Aspartate aminotransferase, CRP - C-reactive protein, Fe - Iron, EtOH - Ethanol, Glu - Glucose, HDL-C - HDL Cholesterol, Ca - Calcium, Cl - Chloride, Crea - Creatinine, K - Potassium, Na - Sodium, T.Bil - Total Bilirubin, Cholesterol - Total Cholesterol, TP - Total Protein, TG - Triglyceride, BUN - Blood Urea Nitrogen, LDL-C - LDL Cholesterol. u^2Rw - standard uncertainty component for the long-term precision obtained from six months internal quality control, u^2cal - uncertainty of calibrator values provided by manufacturer, U(y) - expanded uncertainty, %Urel (y) - percent relative expanded uncertainty, MAU - Maximum expanded allowable measurement uncertainty.
*%Urel values exceeding the MAU are indicated in bold. All MAU values obtained from The EFLM Biological Variation Database, except EtOH. *The MAU value of EtOH obtained from updated CLIA (Clinical Laboratory Improvement Amendments) Proposed Acceptance Limits.*

Atherosclerotic cardiovascular illnesses are more likely to occur in patients with lipid metabolic problems (18). Hence, if the patient's lip profile is at the medical decision levels, MU consideration

may alter the method of diagnosis and therapy. The %Urel(pooled) values for LDL-C in our research were 8.9% for IQC-1 and 13.7% for IQC-2. By pooling the results, we found that IQC-1 and 2 had%Urel values of 9.5% and 14.2% for HDL-C, respectively.

as well as %Urel (pooled) triglyceride levels of 6.3% for IQC-1 and 5.7% for IQC-2. Total cholesterol %Urel (pooled) readings for IQC-1 were 7.9% and for IQC-2, 7.8%. There was a triglyceride MU value that was 20% over the quality target. The permissible quality goals for HDL-C, LDL-C, and total cholesterol were 5.8%, 8.3%, and 5.3%, respectively, and none of the MU values for any of these parameters reached these levels.

The results of forensic toxicological tests, such as ethanol analysis, have far-reaching consequences for people's legal and medical standing (19). The %Urel (pooled) readings for ethanol were found to be 11.3% for IQC-1 and 6.7% for IQC-2, respectively. We were able to meet the quality standard of 20%. It is possible to alter the course of action by combining the test result with MU to guarantee the accuracy and reliability of an ethanol measurement from a laboratory, which is particularly important when making medical or forensic choices.

When testing the same analyte in clinical labs, several MU models might provide different findings. The glucose MU calculation methods used by Chen et al. yielded results of 7.38 and 13.58%, respectively (20). Consequently, laboratories should establish uniform procedures for calculating MU. The use of only the u (SD) value for MU calculation is sufficient for regular clinical laboratory procedures, according to a recent publication by Coskun et al. (13). Laboratory MU calculations and evaluations are much simplified by this new model, MU for practical use (MUPU). As our research shows, the writers believe that u value is the most important part of MU. On the other hand, the MUPU method still has some room for improvement in its disregard for ucal value and its reliance on a single level of IQC material, particularly normal level IQC (21). Additionally, MU values may be compared with a variety of APS settings (22). In recent times, EFLM has released MAU values based on BV (11). We used the most current suggested MAU values in our investigation, with the exception of the EtOH test, from the EFLM BV database. On the other hand, APS choices could vary by lab and analyte (23). Hence, labs are believed to be able to choose APS by ranking their priorities and taking Milan models into account (24).

For labs that use several devices, it is important that the MU values for the same analyte do not go over the permissible APS values individually. This will ensure that the analytical difference between the devices stays within acceptable limits. Nonetheless, it is well-known that many devices may provide the same laboratory result. Therefore, the u (pooled) calculation proposed by the ISO/TS 20914:2019 guidance is seen to be more practical for assessing the impact of MU on the stated outcomes. The sum of the devices' u-values, however, will be more or lesser than their individual u-values. One issue with include MU in results reports is that the MU value, when computed across u (pooled), does not accurately represent the instruments' analytical performance. It should not be overlooked that we computed the u (pooled) value while evaluating the findings of this research, since there are two identical devices in our laboratory. This was done in accordance with the

recommendation of the ISO standard. In our investigation, for instance, we found that the MU value of the LDL-C test was 5.1% in the first device and 9% in the second. According to Supplemental Tables 1-2, the two devices had a MU value of 8.9%, which was found to be higher than the MAU value of 8%. Given these considerations, we believe that the primary utility of MU and MAU evaluations is to assess the analytical capabilities of the devices, and that we are only in the early stages of including MU values computed from similar devices into the final reports.

CONCLUSION

According to this research, the uRw value was the most important factor influencing the MU value. Altering the calibration frequency and paying closer attention to the IQC results of the applicable technique might be proposed as solutions to this issue. Laboratories are able to consistently track their analytical performance with the support of MU. Clinicians can reliably care for patients by understanding the MU concept, which allows them to appropriately interpret measurement results. Consequently, we postulate that familiarity with the MU idea and its application to standard laboratory procedures may lead to more trustworthy findings.

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