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ORIGINAL ARTICLE

Standardized Estimation of Measurement Uncertainty in Clinical Chemistry Using ISO 20914

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ABSTRACT

Background: **The degree to which one is certain of results for a particular measurement/testing process is expressed as a confidence level within a range. Measurement uncertainty (MU) is a critical parameter in clinical chemistry, reflecting the degree of confidence in laboratory test results and directly influencing diagnostic accuracy and patient care.**

Methods: **The study calculated MU for 27 general chemistry analytes using the ISO 20914:2019 top-down approach, which uses long-term internal quality control (IQC) data and manufacturer calibrator traceability certificate values. The study was conducted at Nad al Hammar Health Center, Dubai Health, Dubai, using Roche Cobas Pure analyzers. The study compared calculated MU values with maximum allowable uncertainty (MAU) thresholds obtained from the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) biological variation database.**

Results: **The results show that 17 analytes met the desirable MAU criteria at IQC level 1, confirming robust analytical performance. However, 10 analytes - including albumin, alkaline phosphatase, calcium, magnesium, phosphorus, transferrin, troponin T hs, uric acid, urine albumin, and vitamin D - exceeded the desirable MAU limits, suggesting potential areas for method optimization or high signal to noise ratio at quality control level 1.**

Conclusions: **The findings underscore the importance of MU estimation in ensuring metrological traceability, fulfilling ISO 15189 accreditation requirements, and supporting risk-based quality management in clinical laboratories. This study highlights the practicality of ISO 20914 for routine MU assessment and advocates for its broader adoption to enhance result reliability and inter-laboratory comparability.**

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Supplementary Data

Table S1. Characteristics of measuring systems and measurement uncertainty contributions for measurands evaluated in Roche cobas pure analyzer.

Analytes	Method	Calibrator Traceability	QC level	Urw	Ucal	Urel	Urel %	MAU (desirable)	MAU (minimum)
ALBUMIN	bromo-cresol green	ERM9-DA470k/IFCC	level 1	0.14	0.06	0.15	4.64	4.2	6.3
			level 2	0.12	0.06	0.13	2.67	4.2	6.3
ALK- P	IFCC Gen. 2	original formulation IFCC	level 1	7.5	1.6	7.6	7.1	6.0	9
	para nitrophenol phosphate AMP buffer	(Schumann, 2011)	level 2	11.1	1.6	11.2	4.4	6.0	9
AMYLASE	IFCC method, enzymatic colorimetric	roche reagent	level 1	1.51	1.40	2.06	2.53	6.60	9.9
		according to IFCC (1998)	level 2	3.11	1.40	3.41	1.78	6.60	9.9
CALCIUM	5-Nitro-5'-methyl-BAPTA	SRM6 956c L2	level 1	0.54	0.09	0.55	6.07	0.80	1.2
			level 2	0.18	0.09	0.20	1.50	0.80	1.2
T. CHOLES	enzymatic colorimetric method	Abell-Kendall	level 1	2.63	1.40	2.98	2.95	5.20	7.8
			level 2	4.23	1.40	4.45	2.64	5.20	7.8
BICARB	enzymatic method	primary standard	level 1	0.69	0.29	0.75	4.07	4.00	6
		traceable to NIST	level 2	0.90	0.29	0.95	3.14	4.00	6
CREAT	enzymatic method	ID-MS	level 1	0.03	0.03	0.04	4.33	4.40	6.6
			level 2	0.07	0.03	0.07	2.02	4.40	6.6
CRP	immunoturbidimetric method	ERM-DA474k/IFCC	level 1	0.15	2.05	2.06	35.56	58.9	88.3
			level 2	1.89	2.05	2.79	5.27	58.9	88.3
IRON	ferrozine colorimetric method	SRM 937	level 1	2.01	2.57	3.26	2.96	9.6	14.4
			level 2	3.99	2.57	4.74	1.94	9.60	14.4
FERRITIN	particle enhanced	NIBSC Reagent	level 1	3.55	11.60	12.13	9.56	12.90	19.4
	immunoturbidimetric Gen. 4	ferritin (human liver) 80/602	level 2	5.24	11.60	12.73	5.27	12.90	19.4
GGT	glutamyltransferase gamma	original formulation	level 1	1.28	1.60	2.05	5.01	8.30	12.5
	liquid stand. Szasz	Persijn/v.d. Slik (1976)	level 2	3.32	1.60	3.69	2.16	8.30	12.5
GLUCOSE	hexokinase	ID-MS	level 1	1.58	1.60	2.25	2.14	4.60	6.9
			level 2	3.72	1.60	4.04	1.65	4.60	6.9

Table S1. Characteristics of measuring systems and measurement uncertainty contributions for measurands evaluated in Roche cobas pure analyzer (continued).

Analytes	Method	Calibrator / Traceability	QC level	Urw	Ucal	Urel	Urel %	MAU (desirable)	MAU (minimum)
SGPT/ALT	IFCC with pyridoxal	original formulation	level 1	1.85	0.86	2.04	4.41	8.60	17.1
	phosphate Gen.2	IFCC (2002)	level 2	3.20	0.86	3.31	2.31	8.60	17.1
SGOT/AST	IFCC with pyridoxal	original formulation	level 1	2.32	0.69	2.42	4.71	11.40	12.9
	phosphate Gen.2	IFCC (2002)	level 2	5.51	0.69	5.55	4.33	11.40	12.9
HDL	homogenous	according to the CDC reference method	level 1	0.89	1.16	1.18	3.91	5.70	8.6
	enzymatic colorimetric method	(ultracentrifugation method)	level 2	1.44	1.16	1.85	3.46	5.70	8.6
LDL CHOL	homogenous	according to CDC	level 1	1.86	1.54	1.54	2.57	7.80	11.7
	enzymatic colorimetric method	beta quantification method	level 2	2.43	1.54	2.88	2.84	7.80	11.7
MAGNESIUM	xylidyl blue method serum, plasma	atomic absorption	level 1	0.06	0.02	1.86	94.67	2.70	4.1
			level 2	0.05	0.02	0.05	1.60	2.70	4.1
PHOSPHORUS	molybdate	primary reference material (NERL)	level 1	0.09	0.03	2.08	50.49	7.70	11.6
	UV ver. 2 serum, plasma	(weighed in purified material)	level 2	0.12	0.03	0.12	1.40	7.70	11.6
TOTAL BILIRUBIN	diazo method	acc. to Doumas	level 1	0.06	0.03	0.09	10.25	20.20	30.3
			level 2	0.20	0.03	0.20	5.86	20.20	30.3
TOTAL PROTEIN	Biuret Gen. 2	SRM 927d	level 1	0.08	0.03	0.06	1.28	2.60	3.9
			level 2	0.10	0.03	0.10	1.34	2.60	3.9
TRANSFERIN	transferrin	CRM 470	level 1	0.05	0.04	0.09	4.51	3.90	5.8
	immunoturbidimetric ver. 2		level 2	0.10	0.04	0.11	3.07	3.90	5.8
TRI-GLYCERIDES	enzymatic	ID-MS	level 1	2.44	1.60	1.60	1.37	19.80	29.7
	GPO-PAP		level 2	3.33	1.60	3.70	1.73	19.80	29.7
TROPONIN hs	troponin T Gen. 5 STAT	inhouse reference system	level 1	1.18	58.22	58.27	197.94	11.40	17.1
		(Elecsys Troponin T hs)	level 2	63.00	58.22	85.78	4.35	11.40	17.1
URIC ACID	uric acid	ID-MS	level 1	0.10	0.04	1.18	25.01	8.10	12.1
	enzymatic colorimetric test		level 2	0.13	0.04	0.14	1.43	8.10	12.1
	ver. 2								
ALBU URINE	immunoturbidimetric	ERM-DA470k/IFCC	level 1	2.69	14.90	15.40	47.46	12.40	15.5
	Gen. 2 urine		level 2	6.92	14.90	16.43	3.82	12.40	15.5
UREA	urease/GLDH serum, plasma	ID-MS	level 1	1.70	1.89	1.89	4.73	13.10	19.2

Table S1. Characteristics of measuring systems and measurement uncertainty contributions for measurands evaluated in Roche cobas pure analyzer (continued).

Analytes	Method	Calibrator Traceability	QC level	Urw	Ucal	U rel	Urel %	MAU (desirable)	MAU (minimum)
UREA	urease/GLDH serum, plasma	ID-MS	level 2	4.47	1.89	4.85	4.07	13.10	19.2
VITAMIN D	vitamin D total G3	LC-MS/MS	level 1	2.05	5.34	5.60	26.82	6.80	10.2
			level 2	2.94	5.34	6.10	14.42	6.80	10.2

uRw: standard uncertainty component for the long-term precision obtained from twelve months' internal quality control; ucal2: 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.
CRM: certified reference material; ERM: European reference material; SRM: standard reference material; IFCC: International Federation of Clinical Chemistry; ID-MS: Isotope Dilution Mass Spectrometry; NIST: National Institute of Standard Technology.

Table S2. Analytical performance specifications and maximum allowable measurement uncertainty as per biological variation EFLM.

ANALYTE	Specification	MAU	Total error
ALBUMIN	minimum	6.3	7.5
	desirable	4.2	5
	optimal	2.1	2.5
ALKP	minimum	9	15.6
	desirable	6	10.4
	optimal	3	5.2
AMYLASE	minimum	9.9	17.6
	desirable	6.6	11.7
	optimal	3.3	5.9
CALCIUM	minimum	1.2	2.7
	desirable	0.8	1.8
	optimal	0.4	0.9
CHOLESTEROL	minimum	7.8	12.5
	desirable	5.2	8.3
	optimal	2.6	4.2
BICARBONATES	minimum	6	7.3
	desirable	4	4.9
	optimal	2	2.4
CREATININE	minimum	6.6	11.7
	desirable	4.4	7.8
	optimal	2.2	3.9
CRP	minimum	88.3	109.4
	desirable	58.9	72.9
	optimal	29.4	36.5
IRON	minimum	14.4	41.4
	desirable	9.6	27.6
	optimal	4.8	13.8

Table S2. Analytical performance specifications and maximum allowable measurement uncertainty as per biological variation EFLM (continued).

ANALYTE	Specification	MAU	Total error
FERRITIN	minimum	19.4	20.8
	desirable	12.9	13.9
	optimal	6.5	6.9
GGT	minimum	12.5	27.5
	desirable	8.3	18.3
	optimal	4.2	9.2
GLUCOSE	minimum	6.9	9.2
	desirable	4.6	6.1
	optimal	2.3	3.1
ALT/SGPT	minimum	17.1	28
	desirable	11.4	18.7
	optimal	5.7	9.3
AST/ SGOT	minimum	12.9	18.6
	desirable	8.6	12.4
	optimal	4.3	6.2
HDL cholesterol	minimum	8.6	14.9
	desirable	5.7	9.9
	optimal	2.9	5
LDL cholesterol	minimum	11.7	18.1
	desirable	7.8	12
	optimal	3.9	6
MAGNESIUM	minimum	4.1	5.8
	desirable	2.7	3.8
	optimal	1.4	1.9
PHOSPHATE	minimum	11.6	14.5
	desirable	7.7	9.6
	optimal	3.9	4.8
BILIRUBIN	minimum	30.3	37
	desirable	20.2	24.7
	optimal	10.1	12.3
TOTAL PROTEIN	minimum	3.9	5.1
	desirable	2.6	3.4
	optimal	1.3	1.7
TRANSFERRIN	minimum	5.8	10.2
	desirable	3.9	6.8
	optimal	1.9	3.4
TRIGLYCERIDES	minimum	29.7	39.4
	desirable	19.8	26.2
	optimal	9.9	13.1
TROPONIN T hs	minimum	17.1	26.5
	desirable	11.4	17.6
	optimal	5.7	8.8

Table S2. Analytical performance specifications and maximum allowable measurement uncertainty as per biological variation EFLM (continued).

ANALYTE	Specification	MAU	Total error
URATE	minimum	12.1	19
	desirable	8.1	12.6
	optimal	4	6.3
UREA	minimum	19.6	25.3
	desirable	13.1	16.8
	optimal	6.5	8.4
VITAMIN D	minimum	10.2	20
	desirable	6.8	13.3
	optimal	3.4	6.7