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Research Paper

Commutability assessment of NIST SRM 3666 albumin and creatinine in frozen human urine among routine clinical laboratory measurement procedures

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ABSTRACT

The accuracy of urine albumin results is important for healthcare decisions related to kidney disease. A commutable human urine secondary certified reference material (CRM) is needed for metrological traceability of results from clinical laboratory in vitro diagnostics (IVD) measurement procedures (MPs). The commutability of NIST Standard Reference Material® (SRM) 3666, Albumin and Creatinine in Frozen Human Urine, was assessed using the NIST reference measurement procedures (RMPs) and IVD-MPs for urine albumin and creatinine. Fifty single-donor clinical samples and NIST SRM 3666 (Level I to Level IV) were measured using IVD-MPs from Abbott Laboratories, Beckman Coulter, Mindray, QuidelOrtho, Roche Diagnostics, and Siemens Healthcare Diagnostics. Commutability was assessed using the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) approach based on differences in bias between the SRM and clinical samples. For urine creatinine (Enzymatic and Jaffé), all levels of SRM 3666 were commutable with clinical samples on all IVD-MPs, with the exception of 1 IVD-MP for urine creatinine-Jaffé with Level III. For urine albumin, Level I is commutable with clinical samples for use with 5 IVD-MPs; Level II is commutable for use with 6 IVD-MPs; Level III is commutable for use with 6 IVD-MPs; and Level IV is commutable for use with 3 of the 5 IVD-MPs that could measure Level IV. This study demonstrated that NIST SRM 3666 has commutability properties suitable for use on select IVD-MPs for urine albumin, as well as for all examined Enzymatic and Jaffé IVD-MPs for urine creatinine.

1. Introduction

Urine albumin is a major diagnostic and prognostic biomarker for kidney disease. The accuracy and consistency of urine albumin results significantly influence the decisions made by healthcare practitioners regarding the diagnosis and treatment of kidney disease. Therefore, it is crucial for healthcare practitioners to have access to reliable and comparable patient sample results, which can be achieved by having all in-vitro diagnostic measurement procedures (IVD-MPs) adopt the same standardized calibration hierarchy with results metrologically traceable

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to higher-order certified reference materials (CRMs) and reference measurement procedures (RMPs) [1]. When urine albumin results are standardized, the results from all IVD-MPs are equivalent and independent of the methods or laboratories used.

In collaboration with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Laboratory Working Group and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group for the Standardization of Albumin Assays in Urine (WG-SAU), the National Institute of Standards and Technology (NIST) has developed a reference measurement system (RMS) for urine albumin [2,3]. This RMS for urine albumin includes a primary CRM [NIST SRM 2925 [4–6], Recombinant Human Serum Albumin Solution], a secondary RMP [NIST RMP for Urine Albumin [7–10]], and a secondary CRM [NIST SRM 3666 [11,12], Albumin and Creatinine in Frozen Human Urine]. NIST SRM 3666 Albumin and Creatinine in Frozen Human Urine is a four (4)-level (Level I to Level IV) human urine-based CRM with certified values for endogenous urine albumin, creatinine, and the albumin-to-creatinine ratio (ACR). The endogenous levels of urine albumin and urine creatinine were determined using the NIST RMP for Urine Albumin [7–10] and the modified NIST RMP for Serum Creatinine [13,14], respectively. Both RMPs are currently listed in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) Database, an internationally recognized repository of higher-order RMs and RMPs that meet the appropriate International Organization for Standardization (ISO) standards for clinical applications (RMP UA – C21RMP9 [10] and RMP SC – C4RMP1 [14]). NIST SRM 3666 will serve as a secondary measurement standard designed for use at the m.3 position in the calibration hierarchy [1]. It is intended for use in the validation of measurement procedures or as quality control material for the determination of albumin, creatinine, or the ACR in human urine. SRM 3666 will play a critical role in ensuring the accuracy and comparability of clinical results for urine albumin and creatinine.

A key requirement for the inclusion of SRM 3666 in the calibration hierarchy for IVD-MPs for urine albumin and creatinine is its commutability with clinical samples used in routine clinical measurement procedures. Commutability of a CRM is defined as a "*property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures, and the relation obtained among the measurement results for other specified materials*" [15]. In other words, the urine albumin and creatinine results in SRM 3666 and in the clinical human urine samples obtained using different IVD-MPs should exhibit the same bias within a criterion that is consistent with correct medical decisions based on the measurements. Historically, the commutability of CRMs has been evaluated using a linear regression model with prediction intervals used as criteria [16,17]. The main limitations of this approach are the varying statistical acceptance limits among different IVD-MPs, which complicates the comparison of commutability results. Additionally, there is no consideration of uncertainty. The IFCC Working Group for Commutability in Metrological Traceability (WG-CMT) has introduced new guidelines for assessing commutability, which are based on a difference in bias model [18,19]. In the IFCC approach, the difference in bias between the CRM and the clinical samples is determined using two different measurement procedures, as expressed by the difference between the log-transformed results from the two methods $[\ln(y) - \ln(x)]$, where x represents the RMP results and y represents the IVD-MP results [19]. The difference in bias for the CRM and the average bias for the clinical samples is represented by d_{RM}, with an associated expanded uncertainty, $U(d_{RM})$ [19]. This difference in bias is compared with a clinically relevant predefined commutability criterion [19,20]. The commutability criterion is the maximum allowable noncommutability bias (MANCB), which allows the use of the CRM in the calibration hierarchy for an IVD-MP without exceeding the maximum allowable combined standard uncertainty for a clinical patient result ($\mu_{max_{CS}}$) [20]. The IFCC approach presents a significant advantage in that the RMP–IVD-MP pairs are assessed using the same commutability criterion and the uncertainty is considered in the assessment [19,20]. To assess commutability using MANCB, the d_{RM} and the $U(d_{RM})$ for the CRM is compared to the MANCB [19,20]. The CRM is considered "Commutable (C)", or suitable for use in the traceability hierarchy of the IVD-MP, when $d_{RM} \pm U(d_{RM})$ is within the MANCB $(-MANCB, +MANCB)$ [19,20]. The CRM is considered "Noncommutable (NC)", or not suitable for use in the traceability hierarchy of the IVD-MP, when $d_{RM} \pm U(d_{RM})$ exceeds the MANCB [19,20]. However, when $d_{RM} \pm U(d_{RM})$ overlaps the MANCB, the CRM is considered "Inconclusive (I)" [19,20]. For an "inconclusive" determination, further evaluations are required to assess whether the CRM is suitable for use in the traceability hierarchy [19,20]. The objective of this study is to evaluate the commutability of NIST SRM 3666 (Level I to Level IV) with end-user IVD-MPs for urine albumin and creatinine using the IFCC approach.

2. Materials and methods

2.1. NIST SRM 3666

NIST SRM 3666 is a four (4)-level (Level I, Level II, Level III, Level IV) human urine-based material composed of endogenous levels of urine albumin and urine creatinine. The pooled human urine materials were prepared from multiple donors with target urine albumin levels, as previously described [12]. The urine albumin certified values were determined using the NIST RMP for Urine Albumin [7–10]: Level I – 8.28 mg/L ± 1.12 mg/L; Level II – 31.11 mg/L ± 2.64,mg/L; Level III – 112.77 mg/L ± 10.79 mg/L; and Level IV – 360.50 mg/L ± 31.11 mg/L, (mass concentration value ± expanded uncertainty) [11]. The urine creatinine certified values were determined using the modified NIST RMP for Serum Creatinine [13]: Level I – 119.69 mg/dL ± 2.63 mg/dL; Level II – 122.65 mg/dL ± 2.73 mg/dL; Level III – 127.19 mg/dL ± 2.78 mg/dL; and Level IV – 130.90 mg/dL ± 2.96 mg/dL, (mass concentration value ± expanded uncertainty) [11]. The certified values are outlined in the Supplemental Information (Section I, Tables S1-S3).

2.2. Single-donor urine samples

For the commutability study, 50 single-donor human urine specimens were acquired by Virginia Commonwealth University (VCU) via a NIST Measurement Science and Engineering (MSE) Research Grant (Cooperative Agreement Grant# 70NANB23H097). An FDA-approved IVD-MP for urine albumin (Abbott Architect c8000 Microalbumin) was used to selectively identify urine specimens with target levels of endogenous urine albumin content near the four levels of SRM 3666. No albumin was spiked in, nor were the high endogenous urine albumin levels diluted to achieve the target urine albumin concentrations. In addition to the target urine albumin levels, the specimens were subjected to a freeze/thaw cycle to assess their suitability for commutability assessment. One aliquot of each specimen was frozen at −70 °C for a minimum 24 h and then thawed, and the urine albumin concentration was compared to that of a non-frozen aliquot. One aliquot of 11 representative specimens with urine albumin from 6.7 to 331 mg/L was frozen at −70 °C for a minimum 24 h and then thawed. The differences in mean urine albumin results between the frozen and non-frozen aliquots were − 3.8 % to 0.5 % for 10 specimens and − 0.8 mg/dL for 1 specimen with urine albumin 6.7 mg/L. These results were considered an acceptable influence of a freeze-thaw cycle and thus the frozen individual samples were suitable for commutability assessment. The selected single-donor human urine specimens were representative of routine patient samples, without restrictions regarding age, gender, body mass index, or health status. The urine was stored at 4 °C to 8 °C for up to 5 days from collection before aliquoting and freezing at −70 °C. Each single-donor sample aliquot contained approximately 1.0 mL of human urine. A full description of the sample acquisition, processing procedure, and suitability assessment is provided in the Supplemental

Information (Section II). For the commutability assessment, the clinical samples were bracketed around the certified values of urine albumin and creatinine in SRM 3666. The total number of clinical samples used for the urine albumin commutability assessment, including overlap: Level I – 14; Level II – 16; Level III – 16; and Level IV – 14 (Supplemental Information, Table S13). A total of 20 clinical samples for all levels (Level I to Level IV) were used for the urine creatinine commutability assessment (Supplemental Information, Table S14).

2.3. Clinical measurement procedures

As recommended in the IFCC guidelines for commutability, selection of the participating IVD-MPs was based on the frequency of their use by participants in several global external quality assessment (EQA) surveys. For urine creatinine, two types of analytical measurement principles were included: Enzymatic and Jaffé. Six IVD manufacturers (Abbott Laboratories, Beckman Coulter, Mindray, QuidelOrtho, Roche Diagnostics, Siemens Healthcare Diagnostics) were included in the study, with a total of eight IVD-MPs for urine albumin, seven IVD-MPs for urine creatinine-Enzymatic, and five IVD-MPs for urine creatinine-Jaffé (Table 1). The IVD manufacturers utilized their IVD-MPs to measure the urine albumin and creatinine concentrations in the clinical samples and in SRM 3666. A detailed list of the IVD-MPs and assay information (i.e., instrument/model, assay type, reagent number) for each analyte is provided in Table 1. Each IVD manufacturer provided additional information regarding the IVD-MP for each analyte (Supplemental Information, Table S10). The results for all measurement procedures for the 50 single-donor clinical samples and SRM 3666 (Level I to Level IV) are provided in Supplemental Information (Section VI). Due to differences in measuring intervals, not all clinical samples and SRM levels were measured by all IVD MPs.

2.4. Commutability study protocol

A commutability sample set, consisting of 50 single-donor clinical human urine samples and SRM 3666 (Level I to Level IV), was shipped to each participating IVD manufacturer. The commutability sample sets were shipped frozen on dry ice. Upon receipt of the study samples, the study participants were requested to store the samples at $\leq -70\ ^{\circ}C$ until analysis. Prior to analyzing the commutability study samples, each participant was requested to conduct a qualification assessment to ensure the IVD-MP was ready for use. A detailed description of the commutability protocol is provided in the Supplemental Information (Section VI).

Table 1
IVD manufacturers (study participants) and clinical IVD-MPs used in the commutability study for SRM 3666 (Level I to Level IV).

IVD Manufacturer (Study Participant)	IVD-MP (Instrument/Model)	Analyte	Analytical Method	Assay Kit Name	Analytical Measuring Interval (AMI)	Assay Calibration Kit
Abbott Laboratories	Alinity c	Urine Albumin	Immunoturbidimetric	Microalbumin Reagent Kit (uAlb)	5.0 mg/L to 500.0 mg/L	Microalbumin Calibrator Kit
		Urine Creatinine	Enzymatic	Alinity c Creatinine (Enzymatic) Reagent Kit	2.50 mg/dL to 400.00 mg/dL	Alinity c Clinical Chemistry Calibrator Kit
		Urine Creatinine	Jaffé	Creatinine2 Reagent Kit (Crea2)	2.56 mg/dL to 740.00 mg/dL	Consolidated Chemistry Calibrator Kit
Beckman Coulter, Inc.	Beckman Coulter DxC 700 AU	Urine Albumin	Immunoturbidimetric	Urine/CSF Albumin Reagent (UALB)	7 mg/L to 450 mg/L	Urine/CSF Albumin Calibrator (UALB CAL)
		Urine Creatinine	Enzymatic	Creatinine (Enzymatic) Reagent Kit (CREA)	1 mg/dL to 500 mg/dL	Urine Creatinine Calibrator Kit
		Urine Creatinine	Jaffé	Urine Creatinine Reagent Kit (CRE1N)	1 mg/dL to 400 mg/dL	Urine Creatinine Calibrator Kit
Mindray	Mindray BS-800 M Autoanalyzer	Urine Albumin	Immunoturbidimetric	Mindray Urine Albumin Reagent Kit (MALB)	4 mg/L to 300 mg/L	MALB Control
		Urine Creatinine	Enzymatic	Mindray Creatinine Reagent Kit (Sarcosine Oxidase Method)	1.13 mg/dL to 791 mg/dL	Multi Sera Calibrator Kit
QuidelOrtho	QuidelOrtho VITROS 5600	Urine Albumin	Immunoturbidimetric	mALB Reagent Kit	6.0 mg/L to 190.0 mg/L	Calibrator Kit 24
		Urine Creatinine	Enzymatic	Creatinine	3.2 mg/dL to 346.5 mg/dL	VITROS Chemistry Products Calibrator Kit 1
Roche Diagnostics	Roche Cobas Pro c 503	Urine Albumin	Immunoturbidimetric	ALBT2	3 mg/L to 400 mg/L	C.f.a.s. Calibrator Kit
		Urine Creatinine	Enzymatic	CREP2	1.1 mg/dL to 610 mg/dL	C.f.a.s. Calibrator Kit
		Urine Creatinine	Jaffé	CREJ2	4.2 mg/dL to 622 mg/dL	C.f.a.s. Calibrator Kit
Siemens Healthcare Diagnostics	Siemens Atellica CH	Urine Albumin	Immunoturbidimetric	Atellica CH Microalbumin_2 (μALB_2) Assay	5 mg/L to 400 mg/L	μALB_2 CAL
		Urine Albumin	Immunoturbidimetric	Atellica CH Microalbumin (UAlb) Assay	5 mg/L to 400 mg/L	UAlb Calibrator
		Urine Creatinine	Enzymatic	Atellica CH Enzymatic Creatinine_3 (ECre3)	2.0 mg/dL to 245.00 mg/dL	Atellica CH Chemistry Calibrator
		Urine Creatinine	Jaffé	Atellica CH Creatinine_2 (Crea_2)	3.00 mg/dL to 245.00 mg/dL	Atellica CH Chemistry Calibrator
		Urine Creatinine	Jaffé	Atellica CH Creatinine_3 (Crea3)	3.00 mg/dL to 245.00 mg/dL	Atellica CH Chemistry Calibrator
	Siemens Dimension EXL	Urine Albumin	Immunoturbidimetric	Dimension MALB	1.3 mg/L to 100 mg/L	Dimension MALB Calibrator
		Urine Creatinine	Enzymatic	Dimension EZCR Reagent	0.03 mg/dL to 20.0 mg/dL	Dimension Chem 1 Calibrator
		Urine Creatinine	Jaffé	Dimension CRE2 Reagent	0.15 mg/dL to 20.00 mg/dL	Dimension Chem 1 Calibrator
	Siemens BN ProSpec	Urine Albumin	Immunoturbidimetric	N Antiserum to Human Albumin	2.2 mg/L to 340 mg/L	N PROT STANDARD

2.5. NIST Value assignment of clinical samples and SRM 3666

NIST assigned target concentrations for urine albumin and creatinine in each of the 50 single-donor samples and SRM 3666 (Level I to Level IV) using the NIST RMPs for the commutability assessment [7–10,13,14]. For value-assignment of urine albumin, three [3] aliquots (process replicates) of each sample (50 single-donor samples and SRM 3666) were processed and analyzed in triplicate via LC-MS/MS. For value-assignment of urine creatinine, three [3] aliquots (process replicates) of each sample (50 single-donor samples and SRM 3666) were processed and analyzed in triplicate via LC-MS. The RMP for urine albumin and modified-RMP for serum creatinine, validated internally for urine measurements, were used to generate a reference value and associated expanded uncertainty value for each of the 50 single-donor samples and SRM 3666 (Level I to Level IV) (Supplemental Information, Table S7). To align with the study protocol used by IVD manufacturers and apply the IFCC statistical approach, the results obtained from the RMPs have been designated as reference values (Supplemental Information, Tables S8-S9). Instead of generating a single consensus value with associated uncertainty, the technical replicates were averaged, and each process replicate was treated as a reference value. Three [3] independent reference values for urine albumin and urine creatinine were used as the NIST RMP results for the commutability assessment (Supplemental Information, Tables S8-S9).

2.6. Selection of commutability criterion (C)

The commutability criterion (C), represented by MANCB, is used to establish the difference in bias limits for the commutability assessment. The analytical performance specifications (APS) for each measurand (urine albumin and creatinine) were used to define the MANCB for the commutability assessment. The APS for urine albumin was previously reported, and the desirable total allowable error (TEa) for the clinical sample result was defined as 30 % [21,22]. An alternative approach to determine the maximum allowable uncertainty (MAU) for a clinical sample result was based on a simulated outcomes assessment of misclassifications of urine albumin to creatinine ratio at the decision values 30 mg/g and 300 mg/g based on measurements using one clinical laboratory analyzer [23]. Based on these data, minimum and desirable expanded MAU of 34 % and 18 %, respectively, were proposed for the urine albumin to creatinine ratio. Considering that the uncertainty for urine creatinine measurement is smaller than that for urine albumin, the alternative approach is consistent with the TEa of 30 % for urine albumin measurements by IVD-MPs developed by the NIDDK/IFCC working group [21,22]. Using the equations outlined by Miller et al. [20], the MANCB for urine albumin was calculated as 9.9 % [24,25]. The TEa 30 % value is applicable to urine albumin concentrations 15 mg/L and higher [21]; however, the SRM 3666 Level I urine albumin concentration is 8.28 mg/L. Using the % CV vs. urine albumin concentration profiles, the ratio of the median % CV for CS values <15 mg/L to CS values ≥15 mg/L was 2.1 (Supplemental Information, Section VII-A). This factor of 2.1 was used to expand the CV_a (between-day analytical measurement repeatability for an IVD-MP) presented in Ref. 22 from 6 % to 12.6 %. Using the expanded CV_a (12.6 %) and the published CV values [22], the new expanded TEa, applicable for urine albumin concentrations <15 mg/L, was 38.9 % for this study. As a result, an expanded MANCB 12.9 % ($MANCB_I$) was derived for concentrations near SRM 3666 Level I (< 15 mg/L) and the MANCB 9.9 % is applicable for Level II to Level IV ($MANCB_{II\ to\ IV}$) (Supplemental Information, Section VII-A).

The TEa (desirable) for urine creatinine of 28 % was acquired from the APS of urine creatinine 24 h and first morning collection using the European Federation of Clinical Chemistry and Laboratory Medicine Biological Variation Database [26]. Using the equations outlined by Miller et al. [20], the MANCB for urine creatinine was calculated as 9.3 %. Calculation of the MANCB for urine albumin and creatinine is outlined in the Supplemental Information (Section VII-A).

3. Results and discussion

3.1. Commutability assessment

For the IFCC approach, Nilsson et al. [19] provided an Excel template with example calculations and detailed instructions for determining $d_{RM} \pm U(d_{RM})$ for a commutability assessment. The template was applied in this study using the following modifications: 1) a bracketed approach was applied, where the clinical sample concentrations for both urine albumin and creatinine were bracketed around each level of SRM 3666 (Level I to Level IV), instead of using the non-bracketed approach; 2) SRM 3666 was measured in three (3) positions within the sequence of clinical samples instead of five (5) positions; 3) the RMP values were treated as reference values to align with the IFCC approach; and 4) the RMP reference values were used on the x-axis instead of using the averaged results of the measurement procedures $[(x+y)/2]$ because the RMP results are taken as true values.

The observed bias in the clinical samples for both analytes, albumin and creatinine, when using all IVD-MPs, demonstrated variability across the full concentration range of SRM 3666 (Level I to Level IV). This trend in the bias is also emphasized by the test statistic and the precision profiles of the non-bracketed data (Supplemental Information, Section VII-D). When the bias is not constant over the interval needed for all four levels of SRM 3666, a bracketed approach is recommended [19]. The figures in the Supplemental Information (Section VII – D1 to D9) compare the commutability assessment for urine albumin and urine creatinine using the non-bracketed and bracketed clinical sample results for the IVD-MPs. The figures illustrate that the concentration-dependent bias for the clinical samples in the non-bracketed panel prevents a suitable commutability assessment across the four levels of SRM 3666. A concentration-dependent bias was also observed in an assessment of performance for 16 IVD-MPs compared to a candidate RMP [27].

Consequently, the bracketed approach was applied for both urine albumin and creatinine commutability assessments for all IVD-MPs paired with the NIST RMPs. For urine albumin, each level of SRM 3666 was evaluated independently, and the number of clinical samples for each assessment ranged from 13 to 16. For urine creatinine, the concentration of creatinine in the clinical samples (total of 20) bracketed the four [4] levels of SRM 3666. The bracketed commutability plots of d_{RM} versus the RMP concentration for urine albumin ($MANCB_I = 12.9$ %; $MANCB_{II\ to\ IV} = 9.9$ %), urine creatinine–Enzymatic (MANCB = 9.3 %), and urine creatinine–Jaffé (MANCB = 9.3 %) are shown in Figs. 1, 2, and 3, respectively.

The trends observed in the difference plots for urine albumin and creatinine were consistent with Options B and C as outlined in Nilsson et al. [19]. Specifically, Option B states that *"the bias function b(μ) is approximately constant in a concentration interval enclosing the reference mean (RM),"* and Option C states that *"the bias function b(μ) has an approximately linear trend in an interval where there are q/2 CSs on each side of the RM"* [19]. Therefore, the standard deviation (SD) estimated from the successive differences (s_{MSSD}) was utilized instead of the SD of the differences (s_b) to determine $u(B_{CS})$ and no correction factor was applied to the results [19]. In addition to the observed trends in the data, the sample-specific differences contributed to the uncertainty of the commutability results for both urine albumin and creatinine (Enzymatic and Jaffé). This information is detailed in the Supplemental Information (Section VII-D, Tables S27 to S29).

It is important to note that two data sets for urine albumin and creatinine were submitted for Roche Cobas Pro c503 due to variations in processing of the clinical samples. Centrifugation of the clinical samples, as listed in the commutability protocol (Supplemental Information, Section VI), was omitted in the first analysis, but included in the second analysis. The results of the second analysis (with centrifugation) were used in the commutability assessment. The commutability results of

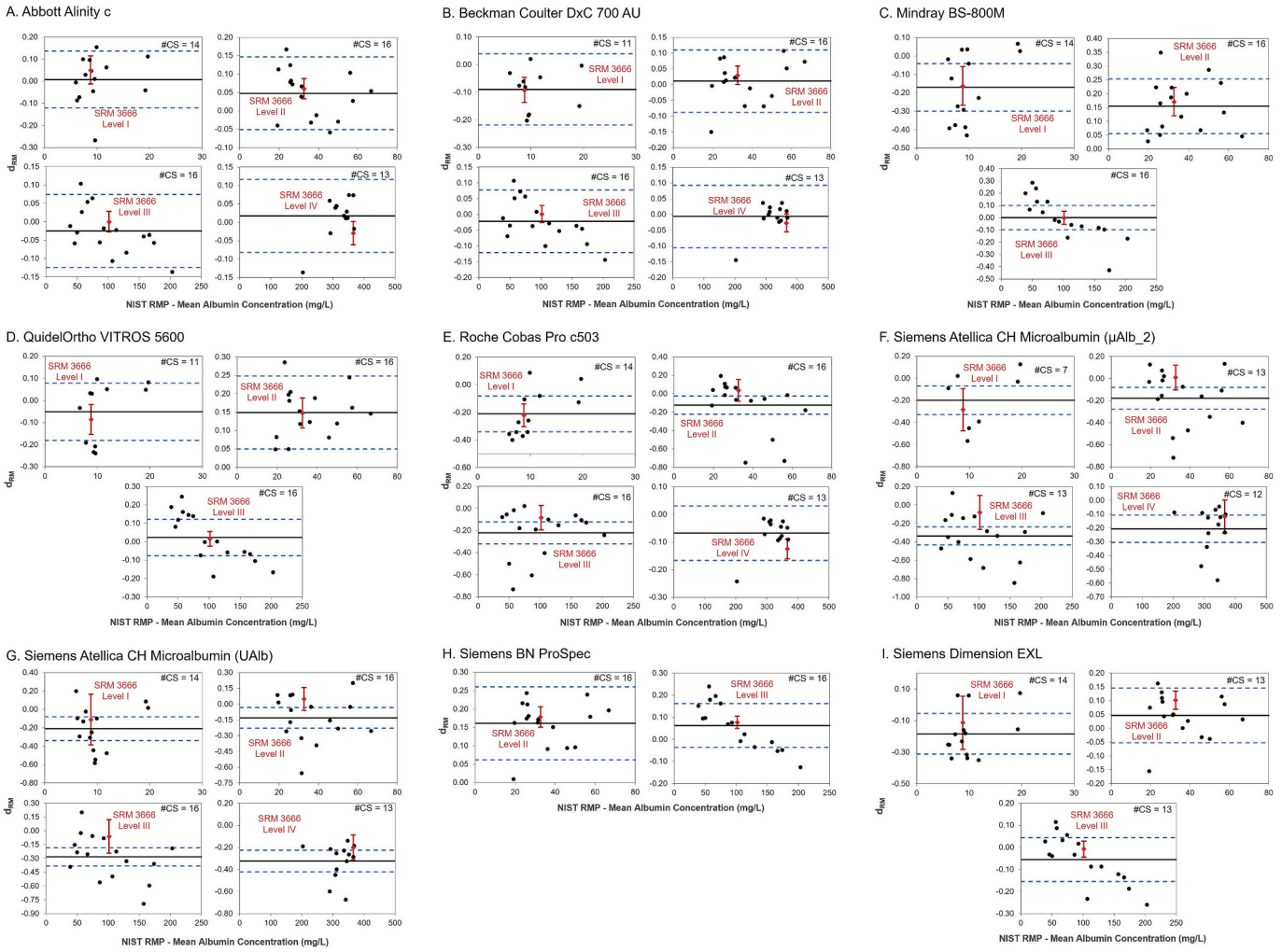

Fig. 1. Bracketed difference in bias plots of SRM 3666 Level I to Level IV for urine albumin evaluated by the NIST RMP for Urine Albumin [7–10] and the IVD-MPs: Abbott Alinity c (a), Beckman Coulter DxC 700 AU (b), Mindray BS-800 M (c), QuidelOrtho VITROS 5600 (d), Roche Cobas Pro c503 (e), Siemens Atellica CH Microalbumin_2 (µALB_2) (f), Siemens Atellica CH Microalbumin (UAlb) (g), Siemens BN ProSpec (h), and Siemens Dimension EXL (i). The solid line (black) indicates the mean bias for the clinical samples (CS), the dashed lines (blue) indicate the commutability criterion (± $MANCB_I$ = 12.9 %; ± $MANCB_{II\text{-}IV}$ = 9.9 %), and #CS indicates the number of clinical samples used in the commutability analysis. The black-filled circles denote the difference in bias for the clinical samples and the red-filled diamonds denote the d_{RM} values and expanded uncertainty [U(d_{RM})], which is a 90 % confidence interval for the d_{RM} values.

both data sets (centrifuged and non-centrifuged) for the Roche Cobas Pro c503 IVD-MP are presented in the Supplemental Materials (Sections VII-D5 and VII-D6).

3.2. Commutability of SRM 3666 for albumin

The commutability of SRM 3666 (Level I to Level IV) for urine albumin ($MANCB_I$ = 12.9 %; $MANCB_{II\ to\ IV}$ = 9.9 %) evaluated using the IFCC approach is shown in Table 2. SRM 3666 Level I, which represents the normal clinical level of urine albumin, is fully commutable with clinical samples when measured using five IVD-MPs (Abbott Alinity c, Beckman Coulter DxC 700 AU, Mindray BS-800 M, QuidelOrtho VITROS 5600, and Roche Cobas Pro c503). Level II is fully commutable with clinical samples when measured using six IVD-MPs (Abbott Alinity c, Beckman Coulter DxC 700 AU, Mindray BS-800 M, Ortho VITROS 5600, Siemens BN ProSpec, Siemens Dimension EXL). Level III is fully commutable with clinical samples when measured using six IVD-MPs (Abbott Alinity c, Beckman Coulter DxC 700 AU, Mindray BS-800 M, QuidelOrtho VITROS 5600, Siemens BN ProSpec, Siemens Dimension EXL). Although the Level III certified urine albumin value (112.77 mg/L ± 10.79 mg/L) [11] is slightly above the upper limit of the analytical measurement range (AMR) for Siemens Dimension EXL, Level III is fully commutable with the IVD-MP (Table 2, Fig. 1i). Level IV, which represents an elevated clinical level of urine albumin (macroalbuminuria), is fully commutable with clinical samples when measured using three IVD-MPs (Abbott Alinity c, Beckman Coulter DxC 700 AU, Roche Cobas Pro c503). It is important to note that Level IV was outside the AMR for four of the nine IVD-MPs for urine albumin.

The Level II and Level III commutability results for Roche Cobas Pro c503 are inconclusive (I). A significant percentage (> 25 %) of the

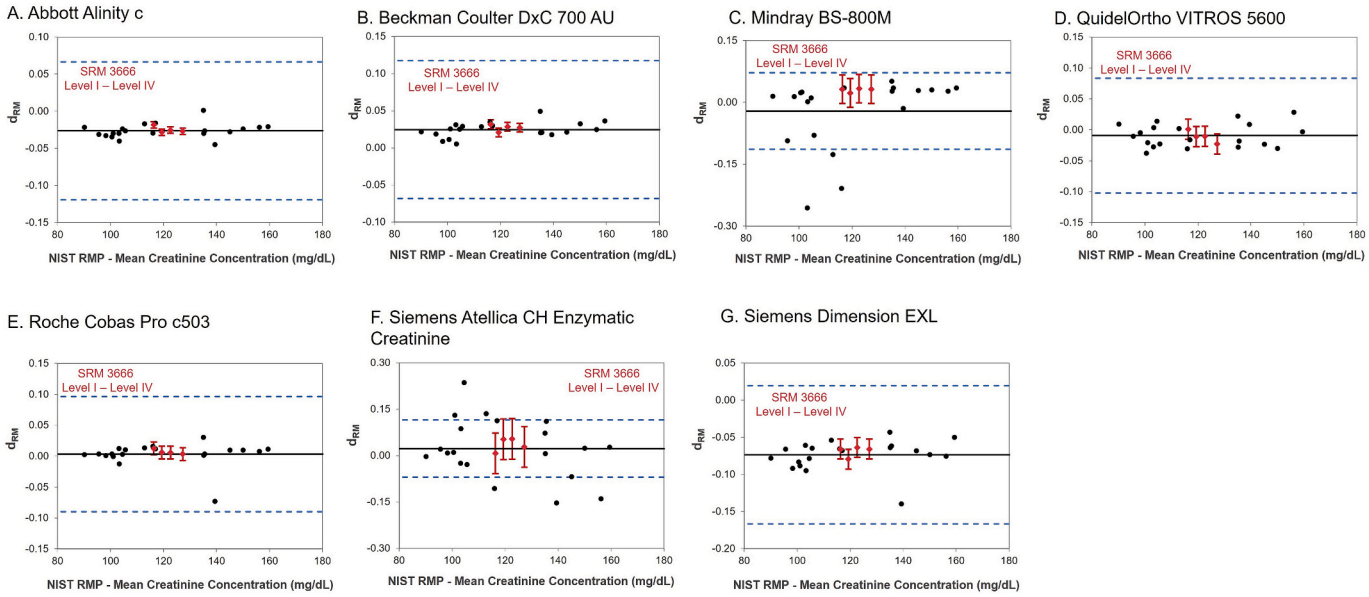

Fig. 2. Bracketed (#CS = 20) difference in bias plots of SRM 3666 Level I to Level IV for urine creatinine evaluated by the NIST modified-RMP for Urine Creatinine [13,14] and the Creatinine-Enzymatic IVD-MPs: Abbott Alinity c (a), Beckman Coulter DxC 700 AU (b), Mindray BS-800 M (c), QuidelOrtho VITROS 5600 (d), Roche Cobas Pro c503 (e), Siemens Atellica CH Enzymatic Creatinine_3 (f), and Siemens Dimension EXL (g). The solid line (black) indicates the mean bias for the clinical samples (CS), the dashed lines (blue) indicate the commutability criterion (± MANCB = 9.3 %), and #CS indicates the number of clinical samples used in the commutability analysis. The black-filled circles denote the difference in bias for the clinical samples, and the red-filled diamonds denote the d_{RM} values and expanded uncertainty [$U(d_{RM})$], which is a 90 % confidence interval for the d_{RM} values.

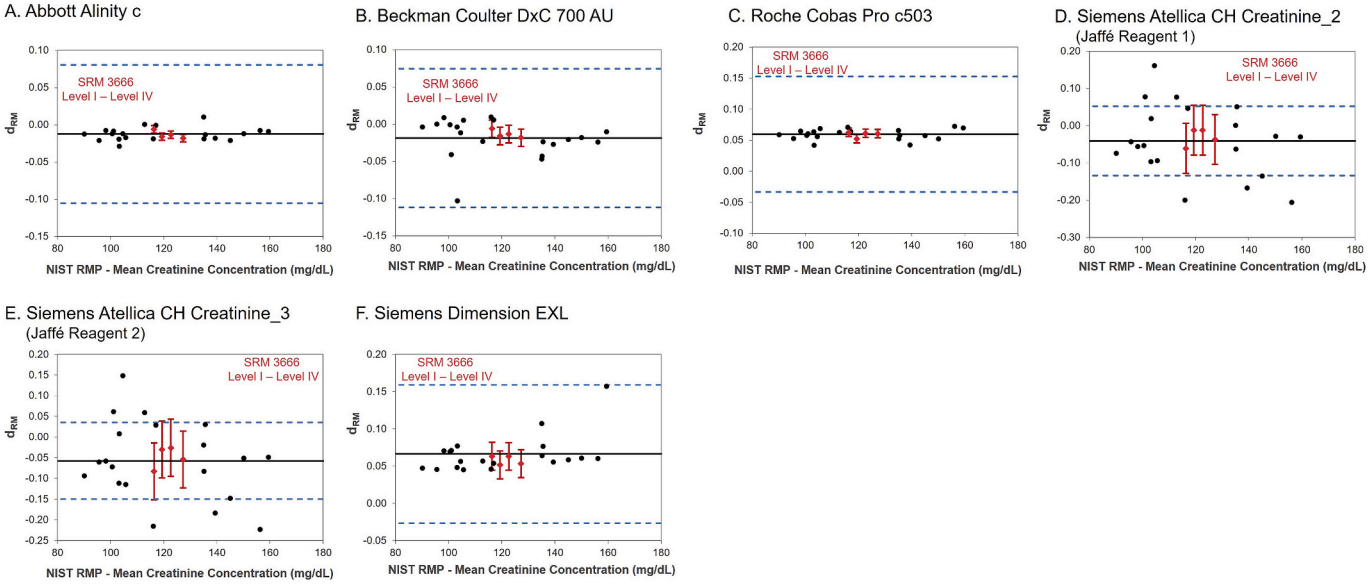

Fig. 3. Bracketed (#CS = 20) difference in bias plots of SRM 3666 Level I to Level IV for urine creatinine evaluated by the NIST modified-RMP for Urine Creatinine [13,14] and the Creatinine-Jaffé IVD-MPs: Abbott Alinity c (a), Beckman Coulter DxC 700 AU (b), Roche Cobas Pro c503 (c), Siemens Atellica CH Creatinine_2 (Jaffé Reagent 1) (d), Siemens Atellica CH Creatinine_3 (Jaffé Reagent 2) (e), and Siemens Dimension EXL (f). The solid line (black) indicates the mean bias for the clinical samples (CS), the dashed lines (blue) indicate the commutability criterion (± MANCB = 9.3 %), and #CS indicates the number of clinical samples used in the commutability analysis. The black-filled circles denote the difference in bias for the clinical samples and the red-filled diamonds denote the d_{RM} values and expanded uncertainty [$U(d_{RM})$], which is a 90 % confidence interval for the d_{RM} values.

$U(d_{RM})$ upper limit and the d_{RM} value fall outside the boundaries of ±MANCB. In these cases, the $u_{max_{CS}}$ is likely to be exceeded, indicating that SRM 3666 Level II and Level III are "likely to be noncommutable" with clinical samples when measured using the Roche Cobas Pro c503, according to the IFCC guidelines [20,24,25]. However, further evaluation is needed to assess the measurand selectivity and suitability of SRM 3666 Level II and Level III with Roche Cobas Pro c503.

This situation is also observed across all four levels with Siemens Atellica CH Microalbumin, with reagent kit lots (μAlb_2 or UAlb). As illustrated in Fig. 1g, a larger portion of $U(d_{RM})$ (> 25 %) and/or the d_{RM} value fall outside the boundaries of ±MANCB, indicating that SRM 3666 (Level I to Level IV) is "likely to be noncommutable" with clinical samples when measured using the Siemens Atellica CH Microalbumin, according to the IFCC guidelines [20,24,25]. Moreover, this is the only instance observed for urine albumin where consistent results were noted across all four levels, which may suggest a selectivity issue. Further

Table 2
Summary commutability matrix (bracketed results) for SRM 3666 (Level I to Level IV) for urine albumin IVD-MPs with $MANCB_{I} = 12.9$ % (Level I) and $MANCB_{II\ to\ IV} = 9.9$ % (Level II to Level IV).

Analyzer	Analytical Measuring Interval (AMI)	NIST RMP for Urine Albumin - Bracketed[a]			
		SRM 3666 (Level I to Level IV) - Urine Albumin			
		Level I	Level II	Level III	Level IV
Abbott Alinity c	5.0 mg/L to 500.0 mg/L	C	C	C	C
Beckman Coulter DxC 700 AU	7 mg/L to 450 mg/L	C	C	C	C
Mindray BS-800M	4 mg/L to 300 mg/L	C	C	C	
QuidelOrtho VITROS 5600	6.0 mg/L to 190.0 mg/L	C	C	C	
Roche Cobas Pro c503	3 mg/L to 400 mg/L	C	I	I	C
Siemens Atellica CH Microalbumin – µALB_2 (Reagent 1)	5 mg/L to 400 mg/L	I	I	I	I
Siemens Atellica CH Microalbumin – UAlb (Reagent 2)	5 mg/L to 400 mg/L	I	I	I	I
Siemens BN ProSpec	2.2 mg/L to 340 mg/L		C	C	
Siemens Dimension EXL	1.3 mg/L to 100 mg/L	I	C	C	

[a]C, Commutable (green); I, Inconclusive (yellow and orange). For an Inconclusive (I) commutability conclusion: Yellow indicates that the d_{RM} value is within ± MANCB (± 12.9 %; ± 9.9 %) and $U(d_{RM})$ overlaps ± MANCB by more than 25 %; Orange indicates that the d_{RM} value is outside ± MANCB (± 12.9 %; ± 9.9 %) and $U(d_{RM})$ overlaps ± MANCB. Blank white cells indicate that the level and associated clinical samples were not analyzed because the concentration in the SRM Level was outside the measuring interval for the analyzer.

evaluation is needed to assess the measurand selectivity and suitability of SRM 3666 (Level I to Level IV) with Siemens Atellica CH Microalbumin.

To illustrate the spectrum of inconclusive (I) outcomes in the tables, the color-coded results indicate whether an inconclusive result is "likely to be commutable or noncommutable." Light Green indicates that the d_{RM} value is within ±MANCB and $U(d_{RM})$ overlaps ±MANCB by less than 25 %. Yellow indicates that the d_{RM} value is within ±MANCB and $U(d_{RM})$ overlaps ±MANCB by more than 25 %. Orange indicates that the d_{RM} value is outside ±MANCB and $U(d_{RM})$ overlaps ±MANCB.

Additional evaluation by the user may be needed to determine suitability of using an SRM level with an inconclusive commutability conclusion. When commutability is inconclusive, one option for using that SRM level is applying a correction for noncommutability bias in the calibration hierarchy of a specific IVD-MP [28].

3.3. Commutability of SRM 3666 for urine creatinine

The bracketed commutability plots of SRM 3666 (Level I to Level IV) for urine creatinine–Enzymatic and –Jaffé (MANCB = 9.3 %) are shown in Figs. 2 and 3, respectively. For urine creatinine–Enzymatic, SRM 3666 (Level I to Level IV) is fully commutable with clinical samples when measured using all seven IVD-MPs (Abbott Alinity c, Beckman Coulter DxC 700 AU, Mindray BS-800 M, QuidelOrtho VITROS 5600, Roche Cobas c503, Siemens Atellica CH Enzymatic Creatinine_3, Siemens Dimension EXL) (Table 3). For urine creatinine–Jaffé, Levels I, II, and IV are fully commutable with clinical samples when measured using all six IVD-MPs (Abbott Alinity c, Beckman Coulter DxC 700 AU, Roche Cobas Pro c503, Siemens Atellica CH Creatinine_2, Siemens Atellica CH Creatinine_3, Siemens Dimension EXL), and Level III is fully commutable when measured using five IVD-MPs (Abbott Alinity c, Beckman Coulter DxC 700 AU, Roche Cobas Pro c503, Siemens Atellica CH Creatinine_2, Siemens Dimension EXL) (Table 3). Moreover, Level III is "likely to be commutable" when measured using the Siemens Atellica CH Creatinine_3 because the small overlap (less than 25 %) in $U(d_{RM})$ with ± MANCB would probably not cause the $\mu_{max_{CS}}$ to be exceeded. Additional evaluations are needed to determine the suitability of Level III with Siemens Atellica CH Creatinine_3.

4. Limitation

The conclusions regarding commutability of SRM 3666 with clinical samples only apply to the IVD-MPs included and not to other IVD-MPs not examined in this study.

5. Conclusion

NIST SRM 3666 provides four [4] concentration levels that can be selected to cover the measuring interval of specific IVD MPs. The

Table 3
Summary commutability matrix (bracketed results, CS# = 20) for SRM 3666 (Level I to Level IV) for urine creatinine (Enzymatic and Jaffé) clinical measurement procedures with MANCB = 9.3 %.

Analyzer	Analytical Measuring Interval (AMI)[a]	NIST modified-RMP for Serum Creatinine - Bracketed[b] (CS# = 20)				NIST modified-RMP for Serum Creatinine - Bracketed[b] (CS# = 20)			
		SRM 3666 (Level I to Level IV) – Urine Creatinine - Enzymatic				SRM 3666 (Level I to Level IV) – Urine Creatinine - Jaffé			
		Level I	Level II	Level III	Level IV	Level I	Level II	Level III	Level IV
Abbott Alinity c	(E) 2.50 mg/dL to 400.00 mg/dL (J) 2.56 mg/dL to 740.00 mg/dL	C	C	C	C	C	C	C	C
Beckman Coulter DxC 700 AU	(E) 1 mg/dL to 500 mg/dL (J) 1 mg/dL to 400 mg/dL	C	C	C	C	C	C	C	C
Mindray BS-800M	(E) 1.13 mg/dL to 791 mg/dL	C	C	C	C				
QuidelOrtho VITROS 5600	(E) 3.2 mg/dL to 346.5 mg/dL	C	C	C	C				
Roche Cobas Pro c503	(E) 1.1 mg/dL to 610 mg/dL (J) 4.2 mg/dL to 622 mg/dL	C	C	C	C	C	C	C	C
Siemens Atellica CH Enzymatic Creatinine	(E) 2.0 mg/dL to 245.00 mg/dL	C	C	C	C				
Siemens Atellica CH Creatinine_2 (Jaffé Reagent 1)	(J) 3.00 mg/dL to 245.00 mg/dL					C	C	C	C
Siemens Atellica CH Creatinine_3 (Jaffé Reagent 2)	(J) 3.00 mg/dL to 245.00 mg/dL					C	C	I	C
Siemens Dimension EXL	(E) 0.03 mg/dL to 20.0 mg/dL (J) 0.15 mg/dL to 20.00 mg/dL	C	C	C	C	C	C	C	C

[a] (E) indicates Creatinine-Enzymatic and (J) indicates Creatinine-Jaffé.
[b] C, Commutable (green); I, Inconclusive (light green). For an Inconclusive (I) commutability conclusion: Light Green indicates that the d_{RM} value is within MANCB confidence interval (± MANCB = ± 9.3 %) and $U(d_{RM})$ overlaps ± MANCB by less than 25 %. Blank white cells indicate that the MPs were not applicable to the analyzers. No urine creatinine-Jaffé MP is available for the Mindray BS-800 M and Ortho VITROS 5600 analyzers.

commutability of NIST SRM 3666 (Level I to Level IV) with clinical samples for urine albumin and creatinine (Enzymatic and Jaffé) was assessed using the IFCC difference in bias approach for IVD-MPs from five major IVD manufacturers. Overall, NIST SRM 3666 is suitable for use as a secondary commutable CRM in the calibration hierarchies for urine albumin and creatinine for most IVD-MPs. In cases where commutability was inconclusive, a correction can be applied in the calibration hierarchy. This SRM provides a valuable resource supporting the international effort for standardizing urine albumin and creatinine measurements.

NIST Disclaimer

Certain commercial equipment, instruments, and materials are identified in this paper to adequately specify the experimental procedure. Such identification does not imply recommendation or endorsement by NIST, nor does it imply that the equipment, instruments, or materials are necessarily the best available for the purpose.

Research involving human participants and/or animals

The commutability study was determined "not human subjects research" as defined in 15 CFR 27 by the NIST Institutional Review Board (IRB). The acquisition of the human urine specimens was determined "not research involving human subjects" as defined by DHHS and FDA regulations by the VCU IRB.

CRediT authorship contribution statement

Ashley Beasley-Green: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Johanna E. Camara:** Writing – review & editing, Methodology, Investigation, Formal analysis, Conceptualization. **Elena S.C. Wood:** Writing – review & editing, Investigation. **N. Alan Heckert:** Visualization, Formal analysis. **W. Greg Miller:** Writing – review & editing, Methodology, Investigation, Formal analysis, Conceptualization. **Lorin M. Bachmann:** Writing – review & editing, Methodology, Investigation, Formal analysis, Conceptualization. **Laura Ruvuna:** Writing – review & editing, Investigation. **Salman Ali:** Writing – review & editing, Investigation. **Randy Schneider:** Writing – review & editing, Investigation. **Sean O'Donnell:** Writing – review & editing, Investigation. **Liam Murrell:** Writing – review & editing, Investigation. **Jian Dai:** Writing – review & editing, Investigation. **Yeng Xiong:** Writing – review & editing, Investigation. **Soha Mahmoud:** Writing – review & editing, Investigation. **Patti Fanto-Holdaway:** Investigation. **Kristin Eichler:** Writing – review & editing, Investigation. **Achim Grebe:** Writing – review & editing, Investigation. **Jason Snyder:** Writing – review & editing, Investigation. **Jared O'Brien:** Writing – review & editing, Investigation. **Karen Phinney:** Writing – review & editing, Methodology, Conceptualization.

Compliance with ethical standards

The corresponding author has no competing interests to declare that are relevant to the content of this article. Several of the co-authors on the manuscript are employees of companies that produced the assays evaluated in this study [L Ruvuna, S Ali and R Schneider are employees of Abbott; S O'Donnell and L Murrell are employees of Beckman Coulter; J Dai and Y Xiong are employees of Mindray; P Fanto-Holdaway and L Li are employees of Ortho-Clinical Diagnostics; K Eichler and A Grebe are employees of Roche Diagnostics; and J Snyder and J O'Brien are employees of Siemens Healthcare Diagnostics]. The remaining co-authors have no competing interests to declare that are relevant to the content of this article.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cca.2025.120760.

Data availability

Data provided in Supplemental Information.

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