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Performance evaluation of the i-Smart 300E cartridge for point-of-care electrolyte measurement in serum and plasma

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Abstract

Background: Electrolytes are measured regularly in a variety of clinical settings because electrolyte imbalance can be life-threatening. Although arterial blood-gas analysis reports electrolyte levels, the result often is discrepant with results from serum and plasma samples. Since prompt and accurate measurement of serum electrolyte levels could allow early treatment, point-of-care (POC) electrolyte analyzers would be beneficial. We evaluated a POC electrolyte analyzer cartridge based on the Clinical and Laboratory Standard Institute (CLSI) guidelines.

Methods: Precision and linearity were assessed according to the CLSI EP05-A3 and EP06-A guidelines, respectively. A comparison study was conducted with both serum and plasma samples according to the CLSI EP09-A3. For serum, results from the i-Smart 300E analyzer were compared with results from the Nova 8 and i-Smart 30 analyzers. For plasma, results were compared among the i-Smart 300E, Nova 8, i-Smart 30, and Cobas c702 analyzers.

Results: Coefficients of variation in the precision analysis were all less than 5%. Linearity assessment demonstrated a coefficient of determination between 0.999 and 1.000 for all analytes. The comparison study showed a high Pearson's correlation coefficient greater than 0.9 for all analytes, instruments, and specimens.

Conclusions: The i-Smart 300E demonstrated good analytical performance. Its use could be beneficial in terms of both efficiency and clinical outcome in point-of-care testing (POCT) for electrolyte levels from serum and plasma samples.

KEYWORDS
analytical performance, calcium, chloride, electrolytes, hematocrit, i-Smart 300E, pH, plasma, point-of-care testing, potassium, serum, sodium

1 | INTRODUCTION

Point-of-care testing (POCT) can provide both economic and medical advantages due to faster clinical decisions leading to earlier treatment.[1] There is fair evidence that POCT of arterial blood-gas results obtained in the intensive care unit (ICU) and emergency department (ED) leads to improved clinical outcomes due to reduction in therapeutic turnaround time compared with central laboratory testing.[2] Electrolytes are measured regularly in tertiary hospitals because many critical patients depend on intravenous fluid. Moreover,

electrolyte levels are critical in differential diagnosis of numerous conditions such as diabetic ketoacidosis and renal tubular acidosis. Since electrolyte imbalance can cause devastating results, rapid testing and immediate intervention are warranted. This is why most POCT blood-gas analyzers also report electrolytes including sodium (Na^+), potassium (K^+), chloride (Cl^-), and ionized calcium (iCa^{2+}).[3]

Although arterial blood-gas analysis also provides electrolyte levels, there can be a discrepancy in measured levels compared to those determined with serum using automated chemistry analyzers.[4–7] In addition, there are times when regular follow-up of electrolyte levels is required despite no need for arterial blood-gas analysis. In such cases, a POC device for electrolyte analysis with a short turnaround time would be beneficial. Furthermore, while automatic chemistry analyzers with added modules provide the ability to measure electrolytes, cartridge-type POC devices could be more efficient in terms of quality control and laboratory management. Therefore, use of a cartridge-type POC electrolyte analyzer can provide results with greater precision and ease.

Herein, we evaluated the analytical performance of the i-Smart 300E (i-SENS, Seoul, Korea) electrolyte analysis cartridge for measurement of electrolytes, pH, and hematocrit (Hct) in serum and plasma.

2 | MATERIALS AND METHODS

2.1 | Instruments

The i-Smart 300E is an exchangeable cartridge for electrolyte measurement designed for the i-Smart 300, which is a POC blood-gas analyzer device. Maintenance of the device is convenient since the disposable cartridge contains needed sensors, reagents, waste bag, tubing, and sample probe. The i-Smart 300E measures pH, Na^+, K^+, Cl^-, iCa^{2+}, and Hct in 100 μL of heparinized whole blood. The Nova 8 (NOVA Biomedical, Waltham, MA, USA) is capable of measuring pH, Na^+, K^+, and $iCa^{2+,}$ while the i-Smart 30 (i-SENS, Seoul, Korea) and Cobas 702 (Roche Diagnostics International, Rotkreuz, Switzerland) are capable of measuring Na^+, K^+, and Cl^-.

2.2 | Specimens

For precision analysis, the following quality control (QC) materials from the manufacturer were used: i-Smart QC for electrolytes and pH and i-Smart Hct QC for Hct. For linearity analysis, the following QC materials were used as follows: RNA QC 623 Blood Gas-Electrolyte Control (RNA Medical, Devens, MA, USA) for electrolytes and pH and RNA QC 900 Hematocrit Control for Hct. For comparison analyses, serum samples and plasma samples were collected starting in December 2019 and May 2020, respectively. To include more than 50% of the samples as those beyond the reference range, select samples were incorporated based on the results of ordered electrolyte levels. As a result, a total of 100 tests for each analyte in both serum and plasma were performed using specimens from 240 total subjects. The Institutional Review Board of Samsung Medical Center approved the study for both serum and plasma (reference number: 2019–12–066 and 2020–05–008) and waived the need for informed consent.

2.3 | Precision

The following QC materials from the manufacturer were used for precision analysis: three levels of i-Smart QC for electrolytes and pH and two levels of i-Smart Hct QC for Hct. For 20 days, duplicate runs were performed twice a day. Repeatability and within-laboratory precision were evaluated from the observed measurements based on the Clinical and Laboratory Standards Institute (CLSI) EP05-A3 guidelines.[8]

2.4 | Linearity

Five levels of verification controls were measured in four replicates. For electrolytes and pH, the CVC 123 (RNA Medical, De-vens, MA, USA) reagent was used. For Hct, the CVC 90005 (RNA Medical) reagent was used. Linearity was assessed following the CLSI EP06-A guidelines.[9] For analytes with significant nonlinear coefficients, acceptability criteria were met if the percent deviation of the linear regression model from the nonlinear regression model was less than the total allowable error percentages suggested by Ricos.[10,11] The expected values for verification controls were provided by the manufacturer.

2.5 | Comparison

The i-Smart 300E was compared with the Nova 8, i-Smart 30, and Cobas c702 analyzers according to the CLSI EP09-A3 guidelines.[12] The i-Smart 300E test results using serum were compared with results from the Nova 8 and i-Smart 30 analyzers, and results using plasma were compared with all three instruments. The selected devices for comparison were previously approved for the corresponding specimen type.[13–16] Each sample was tested with all instruments serially in random order to avoid potential bias caused by the tested sequence. The total duration of time taken for a sample to be tested with all instruments was less than 5 min.

For comparisons showing proportional and/or systematic differences, additional analysis was performed to identify significant differences in the medical decision levels based on values suggested by Statland.[17] The cutoffs provided by the manufacturer were applied for pH since medical decision levels were not available. The desirable total allowable error percentages were those suggested by Ricos[10]; those for serum were applied for plasma as well since no separate values were provided for plasma. Since total allowable error of pH was not available for either serum or plasma, the value for whole blood was adopted.

2.6 | Statistical analyses

Data management and basic statistical analysis such as calculation of mean, standard deviation (SD), and coefficient of variation (CV) were conducted using Microsoft Excel (Microsoft, Redmond, WA, USA). Linear regression, polynomial regression, Passing-Bablok regression, and Bland-Altman analyses were performed using R 4.0.5 (R Foundation for Statistical Computing, Vienna, Austria). Plots were illustrated using the ggplot2 3.3.3 package on R 4.0.5. Along with Passing-Bablok regression, the difference between the compared instruments at medical decision levels was determined if the 95% confidence interval (CI) of the slope and intercept did not include 1 and 0, respectively, to evaluate the feasibility of using the i-Smart 300E analyzer in routine clinical practice.

3 | RESULTS

3.1 | Precision

For all analytes, the within-run precision CV ranged from 0.00% to 1.41%, and the within-laboratory precision CV ranged from 0.03% to 4.29%. Detailed results regarding precision analyses of each analyte are described in Table 1.

3.2 | Linearity

While five levels were measured for each analyte, the lowest level was under the reportable range of the iCa^{2+}. Thus, the corresponding measurements were excluded from the linearity assessment. For all analytes, the coefficient of determination (R^2) ranged from 0.999 to 1.000. The 95% CI of slope for K^+, Cl^-, iCa^{2+}, and Hct did not include 1. The best fit by polynomial regression was second order for K^+, iCa^{2+} and Hct and third order for pH, and the differences between the linear and nonlinear models were smaller than the error goal for all analytes except iCa^{2+}. For iCa2+, the lowest level measured showed a percent deviation between the nonlinear model and linear model beyond the total allowable error. Therefore, with the exception of iCa^{2+}, all analytes showed linearity in measurement. Table 2 and Table S1 summarize the results of linearity evaluation, and Figure 1 depicts the regression lines.

3.3 | Comparison

Both serum and plasma demonstrated a very high positive correlation, greater than 0.9 for all analytes and instruments compared. The Pearson's correlation coefficients were 0.979 and 0.919 for serum and plasma, respectively. The results of the comparison study are listed in Table 3.

3.4 | Comparison using serum

Compared with Nova 8, all analytes demonstrated a high Pearson's correlation coefficient of at least 0.979. However, pH and K^+ demonstrated both proportional difference and systematic difference between the two instruments. Compared with i-Smart 30, all analytes

TABLE 1 Precision of the i-Smart 300E for pH and electrolyte measurement at three levels and for hematocrit at two levels

				CV(%)	
Analyte	**Level**	**Mean**	**SD**	**Repeatability**	**Within-laboratory**
pH	Low	7.13	0.01	0.04	0.07
	Middle	7.37	0.00	0.03	0.03
	High	7.53	0.01	0.02	0.07
Na^+ (mmol/L)	Low	109.08	0.44	0.32	0.41
	Middle	131.11	0.45	0.26	0.35
	High	156.44	0.64	0.28	0.41
K^+ (mmol/L)	Low	1.95	0.07	1.41	3.41
	Middle	4.32	0.04	0.00	0.89
	High	6.12	0.07	0.45	1.10
Cl^- (mmol/L)	Low	71.78	0.56	0.49	0.77
	Middle	93.38	0.54	0.34	0.58
	High	119.40	0.57	0.42	0.47
iCa^{2+} (mmol/L)	Low	0.47	0.01	0.98	2.36
	Middle	1.20	0.01	0.43	0.88
	High	1.57	0.03	0.99	1.58
Hct (%)	Low	28.23	1.21	0.56	4.29
	High	53.86	1.20	0.21	2.23

Abbreviations: CV, coefficient of variation; Hct, hematocrit; SD, standard deviation.

TABLE 2 Summary of linearity of pH, electrolyte, and hematocrit measurements with the i-Smart 300E analyzer

Analyte	Test range	Manufacturer AMR	R^2	Slope (95% CI)
pH	6.87–7.73	6.50–7.80	0.999	1.001 (0.986–1.017)
Na^+ (mmol/L)	83.0–162.0	80.0–200.0	1.000	1.002 (0.994–1.010)
K^+ (mmol/L)	1.5–10.5	1.0–20.0	1.000	**1.020 (1.014–1.025)**
Cl^- (mmol/L)	61.0–130.0	50.0–150.0	1.000	**1.014 (1.008–1.020)**
iCa^{2+} (mmol/L)	0.52–3.44	0.25–5.0	0.999	**1.104 (1.088–1.120)**
Hct (%)	24.0–69.0	10.0–70.0	0.999	**1.050 (1.032–1.068)**

Abbreviations: AMR, analytical measurement range; CI, confidence interval; Hct, hematocrit.
The bold font means that 95% CI of the slope does not contain 1.

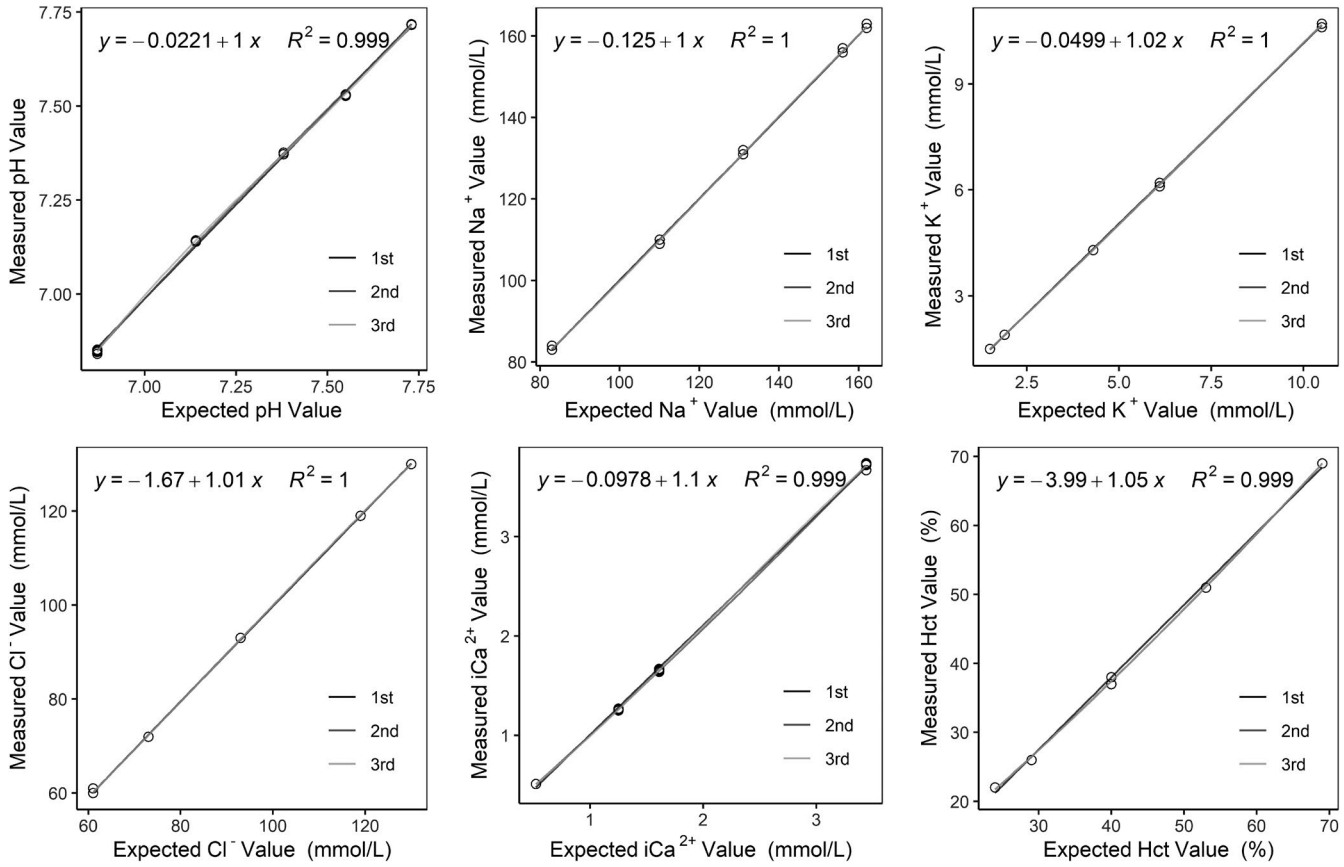

FIGURE 1 Linear and polynomial regression plots of pH, electrolyte, and hematocrit from the i-Smart 300E analyzer

demonstrated a high Pearson's correlation coefficient of at least 0.986. However, Cl^- demonstrated both proportional and systematic differences between the two instruments. The Passing-Bablok regression and Bland-Altman plots of comparison using serum with Nova 8 and i-Smart 30 are presented in Figure S1 and Figure S2, respectively.

3.5 | Comparison using plasma

Compared with Nova 8, all analytes demonstrated a high Pearson's correlation coefficient of at least 0.951. However, pH exhibited both proportional and systematic differences, and Na^+ showed a systematic difference. Compared with i-Smart 30, the regression model showed an excellent fit, with a slope of 1.000 and an intercept of 0.000. Compared with Cobas c702, K^+ and Cl^- showed both proportional and systematic differences. The Passing-Bablok regression and Bland-Altman plots of comparison using plasma with Nova 8, i-Smart 30, and Cobas c702 are presented in Figure S3, Figure S4 and Figure S5, respectively.

3.6 | Comparison in medical decision levels

For comparisons that did not include either 1 in 95% CI of slope or 0 in 95% CI of intercept, predicted values for i-Smart 300E at medical

TABLE 3 Comparison summary using serum (Nova 8 and i-Smart 30) and plasma (Nova 8, i-Smart 30, and Cobas c702)

Specimen	Instrument	Analyte	Pearson's r	Slope (95% CI)	Intercept (95% CI)	% Mean difference (95% CI)
Serum	Nova 8	pH	0.979	**0.887 (0.850 to 0.927)**	**0.795 (0.492 to 1.081)**	0.858 (0.138 to 1.578)
		Na^+ (mmol/L)	0.993	1.000 (1.000 to 1.000)	**−2.000 (−3.000 to −2.000)**	1.645 (0.005 to 3.285)
		K^+ (mmol/L)	0.989	**0.917 (0.889 to 0.938)**	**0.154 (0.062 to 0.267)**	4.942 (0.362 to 9.521)
		iCa^{2+} (mmol/L)	0.980	1.000 (1.000 to 1.083)	0.000 (−0.092 to 0.010)	0.324 (−4.722 to 5.370)
	i-Smart 30	Na^+ (mmol/L)	0.986	1.000 (1.000 to 1.072)	0.000 (−9.859 to 1.000)	−0.159 (−2.492 to 2.173)
		K^+ (mmol/L)	0.995	1.000 (1.000 to 1.000)	−0.100 (−0.100 to 0.000)	1.190 (−1.558 to 3.938)
		Cl^- (mmol/L)	0.991	**1.118 (1.066 to 1.154)**	**−12.235 (−16.089 to −6.984)**	0.191 (−2.365 to 2.747)
Plasma	Nova 8	pH	0.972	**0.857 (0.813 to 0.900)**	**1.046 (0.717 to 1.388)**	0.745 (0.095 to 1.395)
		Na^+ (mmol/L)	0.951	1.000 (1.000 to 1.125)	**−4 (−21.131 to −3.000)**	2.582 (0.823 to 4.340)
		K^+ (mmol/L)	0.982	0.889 (0.857 to 1.000)	0.294 (−0.200 to 0.457)	4.711 (0.332 to 9.089)
		iCa^{2+} (mmol/L)	0.964	1.056 (1.000 to 1.143)	−0.069 (−0.168 to 0.000)	0.716 (−2.759 to 4.191)
	i-Smart 30	Na^+ (mmol/L)	0.932	1.000 (1.000 to 1.000)	0.000 (0.000 to 0.000)	0.392 (−1.591 to 2.375)
		K^+ (mmol/L)	0.987	1.000 (1.000 to 1.000)	0.000 (0.000 to 0.000)	0.202 (−3.218 to 3.623)
		Cl^- (mmol/L)	0.967	1.000 (1.000 to 1.000)	0.000 (0.000 to 0.000)	0.451 (−1.392 to 2.293)
	Cobas c702	Na^+ (mmol/L)	0.919	1.000 (0.909 to 1.111)	−1.2 (−16.781 to 11.732)	0.895 (−1.306 to 3.096)
		K^+ (mmol/L)	0.970	**0.923 (0.893 to 0.962)**	**0.215 (0.047 to 0.350)**	2.576 (−2.541 to 7.693)
		Cl^- (mmol/L)	0.929	**0.909 (0.833 to 0.990)**	**11.727 (3.251 to 19.841)**	−2.326 (−5.151 to 0.498)

Note: Abbreviation: CI, confidence interval.

Bold values significantly differ from the desired value: either 95% CI of slope not including 1 or 95% CI of intercept not including 0.

TABLE 4 Predicted values in medical decision levels and allowable total error analytes showing proportional and/or systematic differences in the comparison analysis

Specimen	Instrument	Analyte	MDL*	Predicted value (95% CI)	TEa (%)**
Serum	Nova 8	pH	7.35	**7.317 (7.304–7.331)**	3.90
			7.45	**7.406 (7.396–7.416)**	3.90
		Na^+ (mmol/L)	115	**113 (112–113)**	**0.73**
			135	**133 (132–133)**	**0.73**
			150	**148 (147–148)**	**0.73**
		K^+ (mmol/L)	3.0	**2.9 (2.9–2.9)**	5.61
			5.8	**5.5 (5.4–5.5)**	5.61
			7.5	**7.0 (6.9–7.1)**	5.61
	i-Smart 30	Cl^- (mmol/L)	90	**88.4 (87.8–88.9)**	1.50
			112	112.9 (112.4–113.3)	1.50
Plasma	Nova 8	pH	7.35	7.346 (7.332–7.361)	3.90
			7.45	**7.432 (7.421–7.442)**	3.90
		Na^+ (mmol/L)	115	**111 (107.9–112.0)**	**0.73**
			135	**131 (130.2–132.0)**	**0.73**
			150	**146 (146.0–147.2)**	**0.73**
	Cobas c702	K^+ (mmol/L)	3.0	3.0 (2.9–3.0)	5.61
			5.8	**5.6 (5.5–5.6)**	5.61
			7.5	**7.1 (7.0–7.3)**	5.61
		Cl^- (mmol/L)	90	**93.5 (92.2–94.8)**	**1.50**
			112	**113.5 (112.7–114.4)**	**1.50**

Note: Predicted value and 95% CI are in bold if the MDL is beyond the 95% CI. TEa(%) is in bold if the difference is beyond the total allowable error.

Abbreviations: CI, confidence interval; MDL, medical decision level; NA: not available; TEa, desirable total allowable error.

*Medical decision levels were adopted from the values suggested by Statland.[17] Since medical decision levels were not available for pH, the cutoffs provided by the manufacturer were adopted.; **TEa values were adopted from the values suggested by Ricos.[10,11] Since TEa for analytes tested with plasma were not available, the values for serum were adopted. Since the TEa of pH was not available for either serum or plasma, the value for whole blood was adopted.

decision levels were obtained. The i-Smart 300E demonstrated lower level of Na^+ compared to that of the Nova 8 and was beyond the total allowable error in both serum and plasma for all levels. The i-Smart 300E showed higher level of plasma Cl^- compared to Cobas c702 and was beyond the total allowable error. The results are described in Table 4.

4 | DISCUSSION

Disturbances in electrolyte levels are among the most common and critical problems encountered in intensive care settings.[18] For prompt clinical decisions, measurement of electrolytes using POC arterial blood-gas analyzers has been common. However, there have been several previous reports demonstrating a significant difference in electrolyte levels measured between arterial blood-gas analyzers and chemistry auto-analyzers.[4–7] Suggested theoretical explanations for this phenomenon are as follows: (1) heparin dilution of the sample to lower the electrolyte concentrations and (2) heparin itself binding to the electrolytes, thereby lowering the electrolyte levels.[5,19] Since central laboratories usually use serum for measurement of electrolytes, the discrepancy in electrolyte levels among specimens could complicate the assessment of patient status. Therefore, to overcome this limitation, POC devices that measure electrolytes from serum or plasma could be beneficial. Hence, we evaluated the analytical performance of the i-Smart 300E analyzer, which is the only cartridge-type POC electrolyte analyzer developed in Korea.

In our study, favorable results were demonstrated in assessment of the i-Smart 300E. Precision analysis showed within-run CV less than 1.5% and total CV less than 4.5% for all analytes. Linearity analysis demonstrated a coefficient of determination (R^2) greater than 0.99 and a slope between 1.0 and 1.2, establishing linearity for all analytes except iCa^{2+}. Moreover, a comparison study demonstrated comparable results, with high Pearson's correlation coefficients greater than 0.91 for all analytes in both serum and plasma. Nonetheless, even though the correlation coefficients were high, some of the analytes exhibited proportional and/or systematic differences in the comparison analysis; among them, some showed differences exceeding the total allowable error. Thus, it is

recommended that measurement of pH and electrolytes be performed using a single instrument during follow-up to avoid misinterpretation of the clinical status. Furthermore, cutoffs should be validated for all analytes when introducing a new instrument. In addition, should an institute use various POC devices from different manufacturers, cutoffs for each instrument must be implemented in the laboratory information system (LIS).

There are several limitations to our study that deserve acknowledgment. First, the lowest level measured in the linearity evaluation was excluded in iCa^{2+} as it was beyond the reportable range of the i-Smart 300E. As a result, our study could not satisfy the CLSI EP06-A guidelines that require measuring five to nine samples multiple times.[9] This might contribute to a linear regression model not being the best fit, with significant deviation from the nonlinear regression model. However, the comparison study showed that iCa^{2+} measured with the i-Smart 300E was comparable to that of the Nova 8 in both serum and plasma. In the linearity evaluation, the greatest deviation in iCa^{2+} level from the expected value (0.52 mmol/L) was smaller than the lowest medical decision level (1.75 mmol/L)[17]; linearity was demonstrated from 1.25 mmol/L to 3.44 mmol/L, within total allowable error in this interval. Thus, we believe iCa^{2+} measurement with i-Smart 300E is feasible for clinical practice. Second, auto-analyzers were not incorporated in the comparative analysis of serum. Nevertheless, since electrolyte levels measured with blood-gas analyzers are not affected by protein levels,[5,20,21] they might better represent the true values compared to those of auto-analyzers.

In conclusion, considering the ease of management and high analytical performance, the i-Smart 300E can be used as a POC electrolyte analyzer in the ED and ICU settings and in clinical laboratories. Introduction of a POC electrolyte analyzer could be beneficial in terms of both efficiency and clinical outcome.

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CONFLICT OF INTEREST

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

AUTHOR CONTRIBUTIONS

HP conceived and designed the study, reviewed and modified the study. BL and HP performed the experiments and analyzed the data. BL wrote the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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