

1 Quality assessment of the creatinine and electrolytes measurement in the emergency
2 department

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18 **Running title:** POCT in emergency department

19 **Keywords:** point-of-care testing, blood gas analyzer, creatinine, electrolyte, emergency
20 department, central laboratory.

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23 **ABSTRACT**

24 **Background & Aims:** The study aim was to validate the usability of a blood gas analyzer for
25 the measurement of creatinine and electrolytes.

26 **Methods:** A total of 190 patients were retrospectively investigated. Creatinine, sodium,
27 potassium, and chloride concentrations in heparinized whole blood samples taken from an
28 artery (103 patients) and vein (117 patients) measured with the blood gas analyzer and in
29 serum measured in the laboratory were compared.

30 **Results:** The bias and coefficient values for the measured concentrations between serum and
31 heparinized whole blood taken from an artery were as follows: creatinine, -0.089 mg/dL,
32 0.966; sodium, 0.214 mEq/L, 0.906; potassium, 0.234 mEq/L, 0.860; chloride, -1.874 mEq/L,
33 0.924, respectively. The bias and coefficient values for the measured concentrations between
34 serum and heparinized whole blood taken from a vein were as follows: creatinine: -0.12 mg/dL,
35 0.992; sodium: -0.829 mEq/L, 0.953; potassium: 0.132 mEq/L, 0.969; and chloride: -0.744
36 mEq/L, 0.951, respectively. Compared with the concentrations measured in the laboratory,

37 the blood gas analyzer concentrations for creatinine and chloride were slightly higher, but that
38 for potassium was slightly lower.

39 **Conclusion:** Acceptable agreement was obtained between the blood gas analysis and the
40 laboratory analysis of creatinine and electrolytes for use in time-critical clinical decision-
41 making in the emergency department.

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43

44 **Introduction**

45 Exposure of patients with reduced renal function to contrast media increases their risk of a
46 contrast-induced acute kidney injury (CI-AKI) known as contrast-induced nephropathy
47 (CIN).^{1,2} A rapid kidney function assessment at point-of-care testing (POCT) improved
48 waiting times before computed tomography (CT) examination in an emergency department
49 and imaging department.³⁻⁵ POCT, such as blood gas analysis, helps reduce delays in real-
50 time contrast-enhanced diagnostic imaging studies, requires only a low blood volume, and
51 potentially enables more rapid and efficient clinical decision-making.³⁻⁶ Furthermore, in
52 intensive care units (ICUs), episodes of small creatinine (Cr) increases, as observed from
53 frequent POCT Cr measurements, are common among critically ill patients and are early and
54 sensitive indicators of illness severity.⁷ Frequent measurement of Cr by POCT has been

55 suggested as a simple, inexpensive, and easy predictive test for diagnosis of AKI in ICUs⁸ and
56 nephrology departments.⁹ These measurements require the use of a blood gas analyzer to
57 measure circulating Cr concentrations for rapid kidney function assessment. Since whole-
58 blood samples are used for blood gas analysis, as a POCT, it can be analyzed immediately
59 after blood collection. In contrast, it takes $\cong 20$ minutes to separate serum from whole blood
60 for laboratory testing. Therefore, it takes approximately 30–40 minutes to determine Cr
61 concentrations in a central hospital laboratory. Although a blood gas analyzer enables rapid
62 measurement of Cr concentrations, the reliability and agreement between blood gas analysis
63 and laboratory measurements of Cr should be established at each medical institution. The
64 Clinical Laboratory Center of Gunma University Hospital is ISO 15189 certified, which
65 specifies requirements for quality and competence in medical laboratories and can be used by
66 medical laboratories to develop their quality management systems and assess their
67 competence.¹⁰ However, POCT based on a blood gas analyzer in an emergency department
68 is not covered by ISO 15189. The study aim was to determine the agreement between the
69 data measured by POCT by blood gas analysis and by laboratory testing, especially for Cr and
70 electrolytes in our emergency department. The Cr and electrolyte concentrations in serum
71 measured in the central laboratory were compared with those in heparinized whole blood
72 taken from an artery and a vein measured by a blood gas analyzer.

73

74 **Methods**

75 **Study design and participants**

76 From January 2020 to March 2020, a total of 1215 patients were treated at the Emergency
77 Department of Gunma University Hospital. Of these 1215 patients, we retrospectively
78 investigated 190 consecutive Japanese patients aged ≥ 20 years whose blood Cr levels were
79 measured both by a blood gas analyzer using heparinized whole blood taken from an artery or
80 vein and by the central laboratory using serum (Figure 1A). Laboratory data and other
81 information were obtained from the medical records for all subjects.

82 **Laboratory analyses**

83 Heparinized whole-blood samples were collected in standard, prepared, heparinized blood gas
84 syringes, and measurements using a blood gas analyzer (model ABL800, Radiometer Co.,
85 Tokyo, Japan) were taken without delay. The ABL800 is constantly maintained by emergency
86 department staff according to the manufacturer's recommendations. All testing was
87 performed on the ABL800 that was routinely maintained, which included quality control
88 checks and calibration by the emergency department staff. In this study, samples taken from
89 an artery of heparinized whole blood and of serum from 73 patients, samples taken from a
90 vein of heparinized whole blood and of serum from 87 patients, and heparinized whole blood

91 samples taken from both an artery and a vein and of serum from 30 patients were tested
92 (Figure 1A). The analyzer measured pH, partial pressures of O₂ (PaO₂) and carbon dioxide
93 (PaCO₂), and concentrations of bicarbonate (HCO₃⁺), sodium (Na⁺), potassium (K⁺),
94 chloride (Cl⁻), Cr, and lactate using whole blood samples at 37° C. The analyzer requires at
95 least 400μL of heparinized whole blood for measurement. The hospital's central laboratory,
96 named the Clinical Laboratory Center of Gunma University Hospital, complies with standards
97 of the National Association of Testing Authorities. The measurement of Cr concentration by
98 the blood gas analyzer is based on an enzymatic method using an amperometric biosensor.¹¹
99 Cr measurement by the central laboratory is based on an enzymatic method using the
100 peroxidase activity of copper-creatinine complexes (Cygnus Auto CRE, Shino-Test
101 Corporation, Kanagawa, Japan). At least 100μL of serum is required for measurement in
102 central laboratory. During the study period, blood gas analyses were performed by a trained
103 medical doctor or nurse at the emergency department. Blood samples were also taken and
104 sent to the laboratory within 5 minutes for immediate analysis. Cr concentrations were
105 measured by enzymatic method, whereas Na⁺, K⁺, and Cl⁻ concentrations were measured by
106 using an ion-selective electrode method and an automatic analyzer (LABOSPECT 008;
107 Hitachi, Tokyo, Japan).

108 **Statistical analysis**

109 Linear regression analysis was performed to compare data from the two methods used for
110 determining Cr, Na⁺, K⁺, and Cl⁻, and the scatter of differences was visualized by generating
111 a Bland-Altman plot.¹² Pearson's correlation analyses were performed to determine the
112 relationships between the concentrations of Cr, Na⁺, K⁺, and Cl⁻. Correlations were
113 considered significant for p values < 0.05 . Because almost all variables were not normally
114 distributed, data are expressed as median values with a 25th–75th percentile range. Unpaired
115 Student's t -tests or Mann–Whitney U tests were used, as appropriate, to identify statistically
116 significant differences between the two study groups. Kruskal–Wallis tests with Bonferroni
117 multiple comparison tests were performed to compare the two groups classified by quartile.
118 Differences and correlations were considered significant when $p < 0.05$. SPSS Statistics
119 version 25.0 (IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY, USA) was used to
120 perform all statistical analyses.

121

122 **Results**

123 The age distribution of the study subjects is shown in Figure 1. More than 50% of the study
124 subjects, both males and females, were over 70 years of age. (Figure 1B and C). In all, 103
125 patients were assessed by analyzing both heparinized whole blood samples taken from an
126 artery and serum samples, the results of which showed good agreement for Cr, Na⁺, K⁺, and

127 Cl⁻ (Figures 2 and 3). The serum Cr and Cl⁻ concentrations measured by laboratory testing
128 were slightly lower than those measured in heparinized whole blood taken from an artery and
129 measured by blood gas analysis (Figures 2 and 3). In heparinized whole blood taken from
130 artery, when the Cr \geq 4.0mg/dL, there is a significant discrepancy with the serum Cr
131 concentration. The serum K⁺ concentrations measured by laboratory testing were slightly
132 higher than those in heparinized whole blood taken from an artery measured by blood gas
133 analysis (Figure 3).

134 Heparinized whole blood samples taken from a vein and serum samples were
135 analyzed in 117 patients and were in good agreement for Cr, Na⁺, K⁺, and Cl⁻ concentrations
136 (Figures 2 and 4). The serum Cr and Cl⁻ concentrations in serum measured by laboratory
137 testing were slightly lower than those in heparinized whole blood taken from a vein measured
138 by blood gas analysis (Figures 2 and 4). The K⁺ concentrations in serum measured by
139 laboratory testing were significantly higher than those in heparinized whole blood taken from
140 a vein and measured by blood gas analysis (Figure 4). The serum Na⁺ concentrations
141 measured by laboratory testing and those measured in heparinized whole blood taken from an
142 artery or a vein measured by blood gas analysis were the same (Figure 3 and 4).

143

144 **Discussion**

145 This study was conducted because the management of the ABL800 blood gas analyzer is not
146 covered by ISO 15189, so it was necessary to confirm the reliability of the ABL800 operation
147 in our hospital. We validated the usability of the blood gas analyzer installed in our emergency
148 department for the measurement of Cr, Na⁺, K⁺, and Cl⁻ concentrations. We confirmed that
149 the Cr and electrolyte concentrations in heparinized whole blood samples taken from an artery
150 and a vein and measured by an ABL800 blood gas analyzer were comparable to those in serum
151 measured in the central laboratory. Slight differences were observed between the Cr and
152 electrolyte concentrations measured in serum by laboratory testing and those measured in
153 heparinized whole blood measured by the blood gas analyzer. Based on the data from this
154 study, venous blood was more suitable for measuring Cr and electrolytes than arterial blood
155 in the blood gas analyzer.

156 The correlation coefficient and narrow 95% confidence interval between
157 heparinized whole blood taken from a vein and serum suggested the superiority of heparinized
158 whole blood taken from a vein. In heparinized whole blood taken from artery, when the Cr
159 $\geq 4.0\text{mg/dL}$, there is a significant discrepancy with the serum Cr concentration, so laboratory
160 measurement results should be referred.

161 Our central laboratory is ISO 15189 certified. The laboratory is managed and
162 operated by trained technicians in accordance with ISO 15189. In the laboratory, internal

163 quality control and calibration are routinely performed, and external quality control is
164 performed three times a year. In the emergency department, routine quality control and
165 calibration of the ABL800 are performed by nurses and physicians according to the
166 manufacturer's recommendations.

167 Our results showed that the results obtained from the ABL800 blood gas analyzer
168 with heparinized whole blood were sufficiently similar to those obtained from laboratory
169 analysis of serum samples. The reliability of these results supports the use of this blood gas
170 analyzer (and possibly others) in our emergency departments. Evidence of the potential of
171 point-of-care Cr tests to assess kidney function for patients requiring intravenous contrast-
172 enhanced diagnostic imaging has been increasing.³⁻⁶ Point-of-care Cr testing has been found
173 to be comparable to laboratory testing in terms of analytical performance and turnaround
174 time.³⁻⁶ The present study results are consistent with previous study findings³⁻⁶ showing that
175 rapid kidney function assessment by POCT in an emergency department facilitated imaging
176 examinations and clinical decision-making.

177 Short-term point-of-care Cr testing enables identification and monitoring of
178 critically ill patients with AKI.^{6, 7, 11, 13-16} Moreover, even in patients with normal Cr on
179 admission, small and early elevations in Cr can help detect AKI.⁸ Previous reports suggest that
180 the screening of patients at high risk of AKI is feasible with point-of-care Cr testing in the

181 emergency department or ICU. Moreno and colleagues⁹ described the positive impact of the
182 implementation of point-of-care blood gas analysis in a nephrology department on the clinical,
183 operative, and economic aspects of patient care. However, the same paper reported significant
184 differences in pCO₂ and in Na⁺, glucose, and lactate concentrations between point-of-care
185 blood gas analysis and laboratory testing. Although the K⁺ and Cl⁻, but not Na⁺,
186 concentrations determined by blood gas analysis in our emergency department differed
187 slightly from the laboratory measurements, they were within clinically acceptable limits for
188 use in an emergency department or ICU and consistent with those of previous reports.^{6, 17-21}
189 Most studies comparing blood gas analyzers with laboratory Cr and electrolyte measurements
190 have found blood gas analyzer results to be reliable in emergency department and ICU
191 operations. However, there is also a significant difference between the two, and in non-
192 emergency situations, the central laboratory measurements should be recommended.³⁻²¹
193 Whether the difference between the Cr and electrolyte values measured by the blood gas
194 analyzer and the values measured in the central laboratory is high or low depends on the
195 medical institution.³⁻²¹ This difference is considered to be due to the measurement equipment,
196 reagent, and environment.

197 ISO 22870 provides specific requirements for POCT and is intended for use in
198 conjunction with ISO 15189.²² A recent report showed that accreditation of both ISO 15189

199 and ISO 22870 led to an improved total testing process and good quality assurance of patient
200 results.²³ Although the blood gas analyzer installed in the emergency department is not
201 certified by either ISO 15189 or ISO 22870, the measurements obtained by the ABL800 blood
202 gas analyzer showed acceptable agreement with the laboratory measurements for Cr and
203 electrolytes concentrations for use in Gunma University Hospital. In the emergency
204 department of our hospital, ISO 22870 accreditation may contribute to our continuous
205 improvement of performance verification, staff training, and quality control of POCT.

206 Our study had some limitations. First, this was a retrospective single-center study
207 with a small sample size. Second, the cost and time analyses of the improvement in workflow
208 were not performed. Third, in the emergency department, blood gas analysis is generally used
209 for patients with severe illness or in those with moderate to severe respiratory disease, which
210 potentially adds bias but reflects real-world practice in Japanese emergency departments.
211 Future studies involving a large number of targeted emergency patients, inpatients, and
212 outpatients randomized between the POCT and central laboratory would provide more
213 conclusive findings.

214 **CONCLUSIONS**

215 In conclusion, measurements obtained by POCT by blood gas analysis and laboratory analysis
216 for Na⁺, K⁺, Cl⁻, and Cr concentrations showed acceptable agreement for use in time-critical

217 clinical decision-making in the emergency department of our hospital.

218

219 **ACKNOWLEDGEMENT**

220 We thank Mayumi Nishiyama for their technical assistance and helpful discussion.

221 **DISCLOSURE**

222 This study was approved by the institutional review board of Gunma University Hospital
223 (Protocol number: HS2019-079). All regulations and measures of ethics and confidentiality
224 were handled in accordance with the Declaration of Helsinki.

225 Informed Consent: We conducted retrospective research using an opt out approach.

226 Animal Studies: N/A

227 Conflict of Interest: The authors declare no competing interests.

228 **DATA AVAILABILITY STATEMENT**

229 Data will be made available on reasonable request.

230

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- 293

294 **Figure legends**

295 **Figure 1.** (A) Study protocol. Age distribution of the study participants of 102 males (B) and
296 88 females (C).

297

298 **Figure 2.** Difference in creatinine concentrations between blood gas analysis and laboratory
299 analysis. (A) Bland-Altman plot showing the absolute bias, partitioned bias for different
300 subgroups, and regression line for creatinine in serum measured by laboratory testing and
301 heparinized whole blood taken from an artery and measured by the ABL800 blood gas
302 analyzer (n = 103). The difference between two values in the y axis is plotted against the
303 average of the two measurements in the x axis. The dash-dotted horizontal line represents the
304 mean difference in measured creatinine concentration between the methods, and the dotted
305 lines represent 95% limits of agreement (mean of difference \pm 1.96 standard deviation).
306 The bias is -0.089 mg/dL, and the 95% limits of agreement range from -0.548 to 0.371 mg/dL.

307 (B) Linear regression analysis between heparinized arterial blood creatinine concentrations
308 and serum creatinine concentrations. (C) Comparison of creatinine concentrations using the
309 two methods. (D) Bland-Altman plot showing the absolute bias, partitioned bias for different
310 subgroups, and regression line for creatinine concentrations in serum measured by laboratory
311 testing and heparinized whole blood taken from a vein measured by the ABL800 blood gas

312 analyzer (n = 117). The difference between two values in the y axis is plotted against the
313 average of the two measurements in the x axis. The dash-dotted horizontal line represents the
314 mean difference in measured creatinine concentration between the methods, and the dotted
315 lines represent 95% limits of agreement (mean of difference \pm 1.96 standard deviation). The
316 bias is -0.12 mg/dL, and the 95% limit of agreement range from -0.400 to 0.16 mg/dL. (E)
317 Linear regression analysis between heparinized venous blood creatinine concentrations and
318 serum creatinine concentrations. (F) Comparison of creatinine concentrations measured
319 using the two methods.

320

321 **Figure 3.** Difference in electrolyte concentrations between heparinized whole blood taken
322 from an artery measured by the ABL800 blood gas analyzer and serum measured by laboratory
323 analysis. Bland–Altman plot showing the absolute bias, partitioned bias for different
324 subgroups, and regression line in serum measured by laboratory analysis and in heparinized
325 whole blood taken from an artery measured by the ABL800 blood gas analyzer (n = 103). In
326 Bland-Altman plot, the difference between two values in the y axis is plotted against the
327 average of the two measurements in the x axis. The dash-dotted horizontal line represents the
328 mean difference in measured electrolytes concentration between the methods, and the dotted
329 lines represent 95% limits of agreement (mean of difference \pm 1.96 standard deviation). (A)

330 Bland–Altman plot for sodium, the bias is 0.214 mEq/L, and the 95% limits of agreement
331 range from -4.822 to 5.25 mEq/L. (B) Linear regression analysis between heparinized arterial
332 blood sodium concentrations and serum sodium concentrations. (C) Comparison of sodium
333 concentrations measured using the two methods. (D) Bland–Altman plot for potassium, the
334 bias is 0.234 mEq/L, and the 95% limits of agreement range from -1.355 to 1.823 mEq/L. (E)
335 Linear regression analysis between heparinized arterial blood potassium concentrations and
336 serum potassium concentrations. (F) Comparison of potassium concentrations measured
337 using the two methods. (G) Bland–Altman plot for chloride, the bias is -1.874 mEq/L, and
338 the 95% limits of agreement range from -6.727 to 2.979 mEq/L. (H) Linear regression
339 analysis between heparinized arterial blood chloride concentrations and serum chloride
340 concentrations. (I) Comparison of chloride concentrations measured using the two methods.

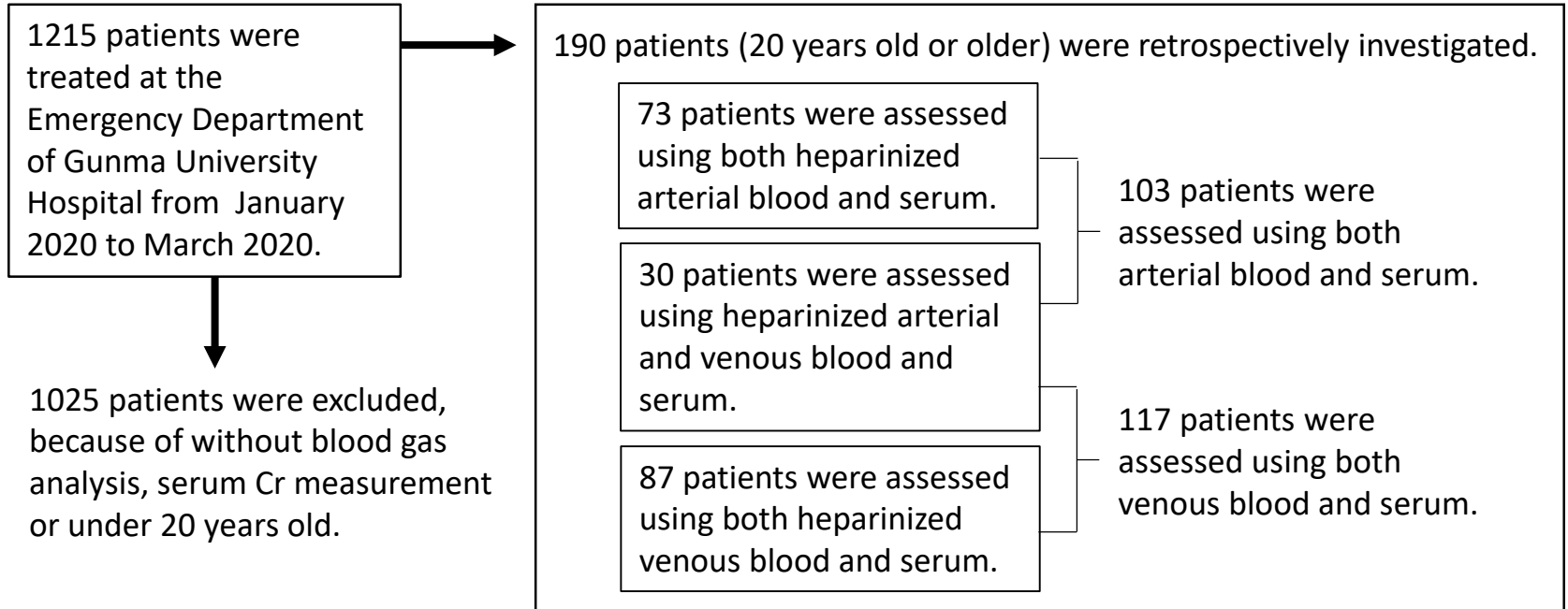
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342 Figure 4. Difference in electrolyte concentrations between heparinized whole blood taken
343 from a vein measured by the ABL800 blood gas analyzer and serum measured by laboratory
344 analysis. Bland-Altman plot showing the absolute bias, partitioned bias for different
345 subgroups, and regression line in serum measured by laboratory analysis and in heparinized
346 whole blood taken from a vein measured by the ABL800 blood gas analyzer (n = 117). The
347 difference between two values in the y axis is plotted against the average of the two

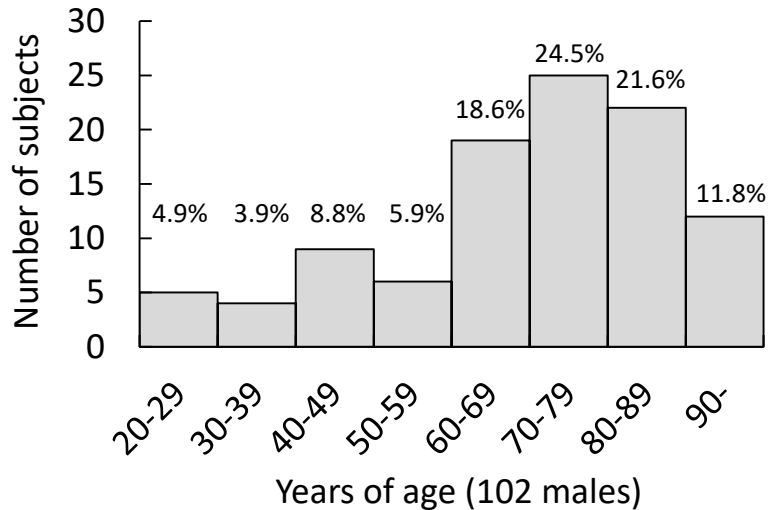
348 measurements in the x axis. The dash-dotted horizontal line represents the mean difference
349 in measured electrolytes concentration between the methods, and the dotted lines represent
350 95% limits of agreement (mean of difference \pm 1.96 standard deviation). (A) Bland-Altman
351 plot for sodium, the bias is -0.829 mEq/L, and the 95% limits of agreement range from -4.957
352 to 3.3 mEq/L. (B) Linear regression analysis between heparinized venous blood sodium
353 concentrations and serum sodium concentrations. (C) Comparison of sodium concentrations
354 measured using the two methods. (D) Bland-Altman plot for potassium, the bias is 0.132,
355 and the 95% limits of agreement range from -4.91 to 0.754 mEq/L. (E) Linear regression
356 analysis between heparinized venous blood potassium concentrations and serum potassium
357 concentrations. (F) Comparison of potassium concentrations measured using the two
358 methods. (G) Bland-Altman plot for chloride, the bias is -0.744 mEq/L and the 95% limits of
359 agreement range from -5.47 to 3.982 mEq/L. (H) Linear regression analysis between
360 heparinized venous blood chloride concentrations and serum chloride concentrations. (I)
361 Comparison of chloride concentrations measured using the two methods.

Figure 1

A



B



C

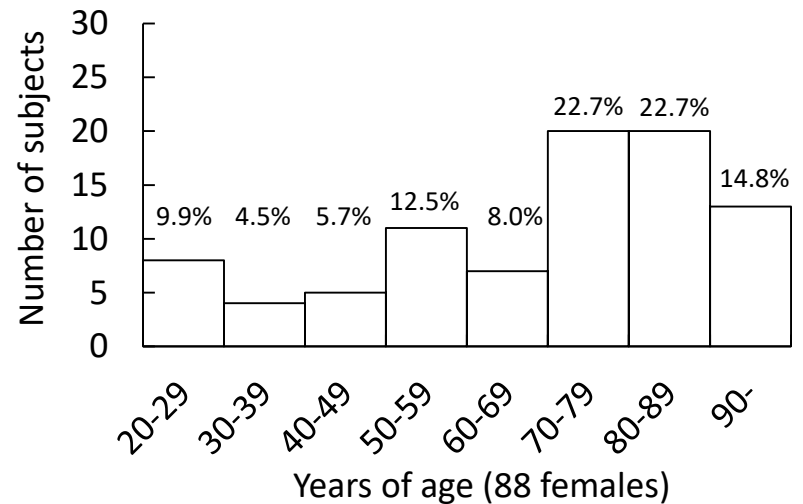


Figure 2

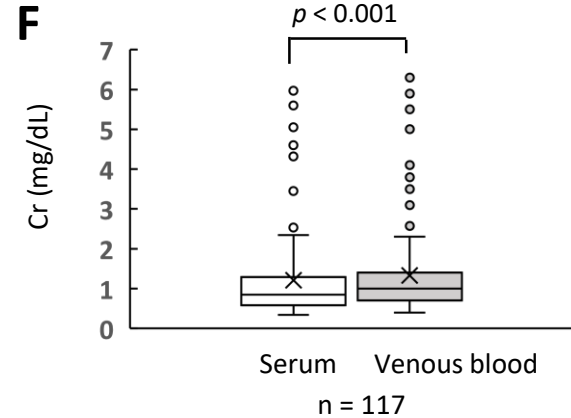
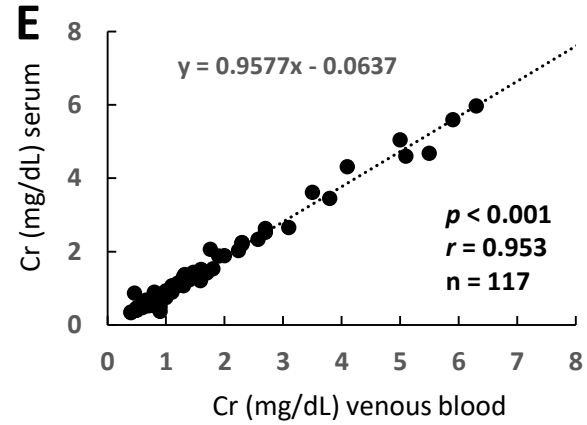
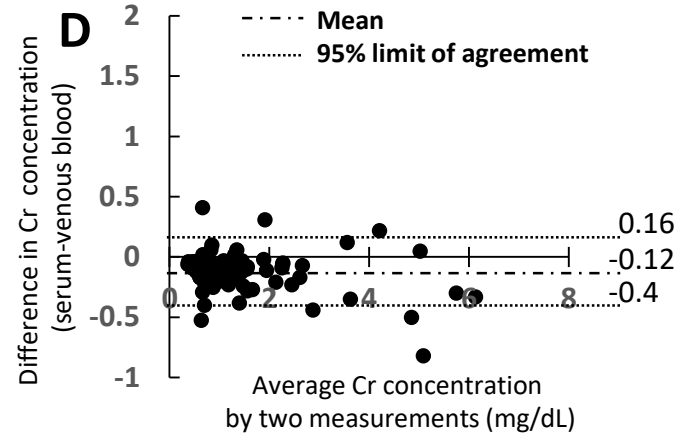
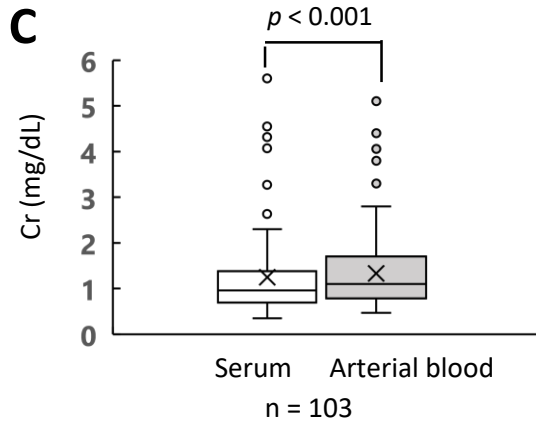
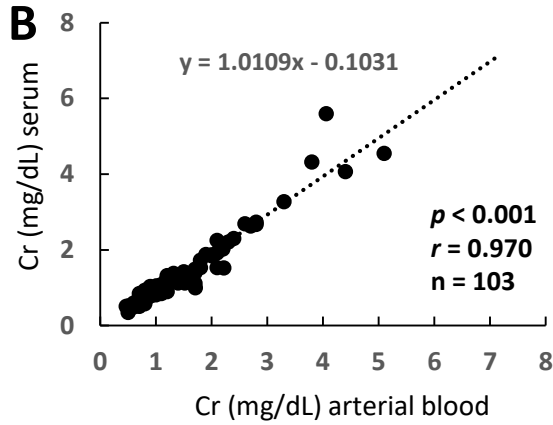
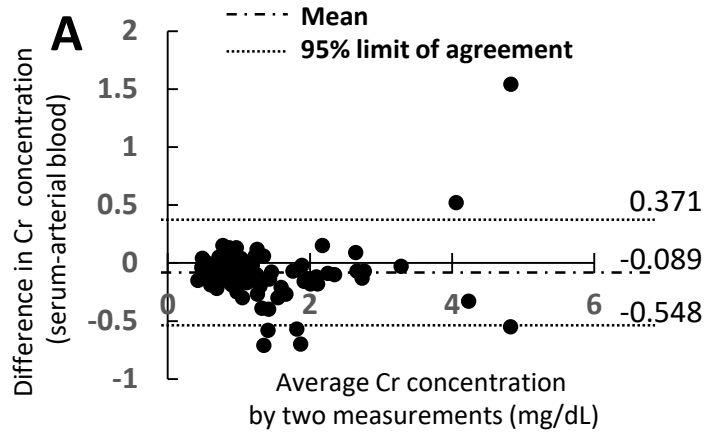


Figure 3

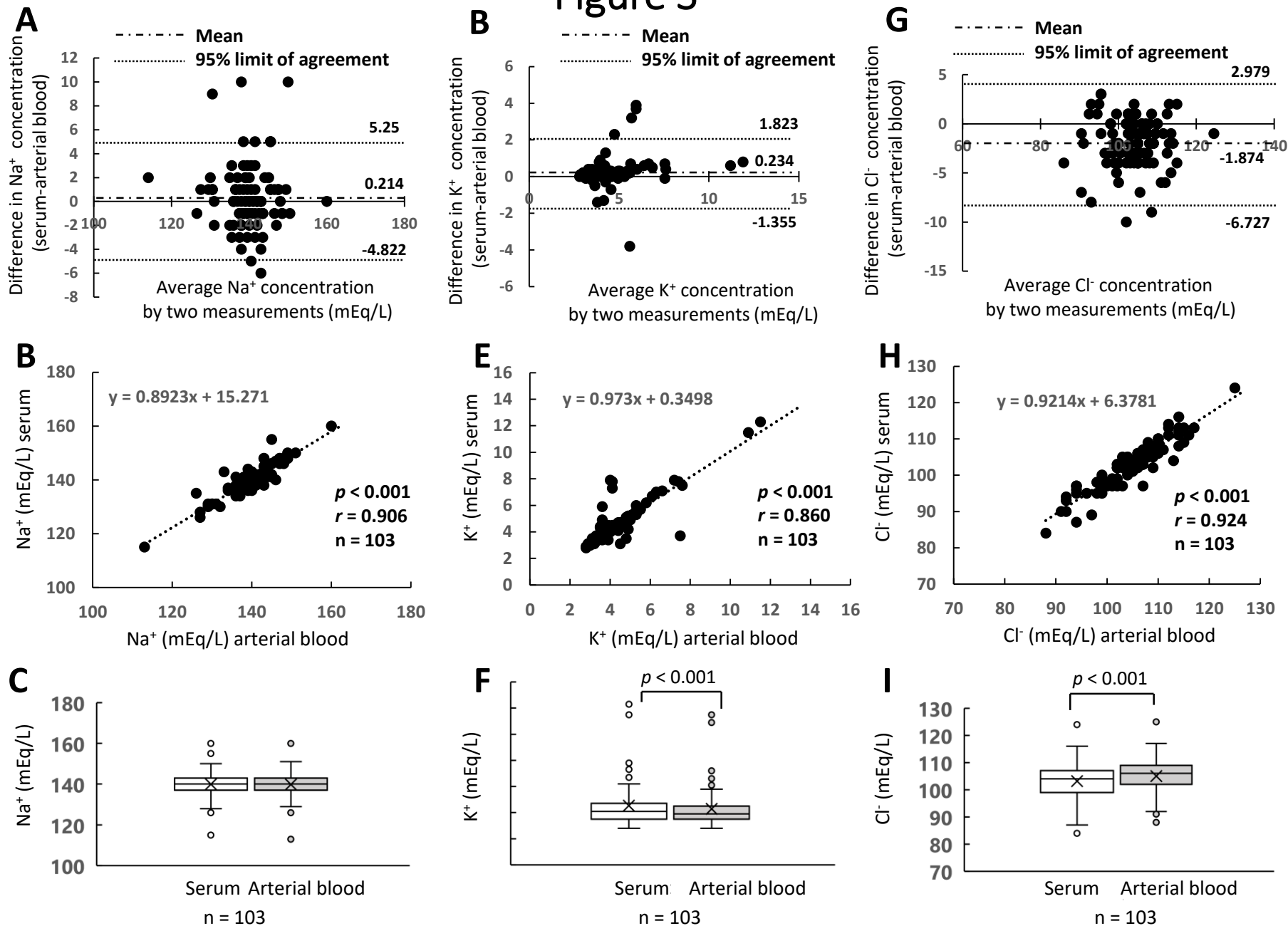


Figure 4

