T-099

Measurement Procedure Comparison between the RAPIDPoint 500 Blood Gas System and the ABL90 FLEX Blood Gas Analyzer

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Abstract

Background: Although it is most common for laboratories to standardize on a single brand and model of blood gas analyzer, there are also instances where a variety of systems may be in operation within one hospital network. Therefore, with testing performed on different systems, chances of precision and bias variations between systems for critical care measurements are likely to occur. Harmonization is generating comparable test results across different instrument platforms and technologies. It is significant for proper clinical decision-making and the administration of appropriate medicines and therapies for patients. This measurement comparison study assesses harmonization for blood gas, electrolytes, and metabolites between two popular blood gas analyzers: the Siemens' RAPIDPoint® 500 system and Radiometer's ABL90 Flex system. Harmonization of critical care analyte measurements is significant in assuring proper clinical decision-making and the administration of appropriate medicines and therapies is being made by doctors for patients.

Methodology: A measurement procedure comparison study was performed with heparinized whole blood on the Siemens RAPIDPoint 500 Blood Gas System and the Radiometer ABL90 Flex blood gas system for each parameter, in accordance with the CLSI EP09-A3 guideline. Forty samples were assayed in duplicate on one RAPIDPoint 500 System and one ABL90 Flex Analyzer. Correlation statistics including regression types (ordinary Deming, weighted Deming, or Passing-Bablok), slopes, intercepts, and coefficients of determination (r^2) were generated for pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{2+}, glucose and lactate.

Conclusion: The measurement procedure comparison proved equivalence between the ABL90 FLEX analyzer and RAPIDPoint 500 System.

Background

The RAPIDPoint 500 Blood Gas System is an entirely cartridge-based system including a measurement cartridge, wash/waste cartridge, and a separate automatic quality control cartridge. The sensor module on the measurement cartridge contains miniaturized planar chip sensors that utilize automated spotting technologies to deposit small contact leads and membranes onto ceramic substrates. This module is offered in various test sizes that last up to 28 days on the system to accommodate low- to high-volume test sites. With its easy-to-use cartridge technology, minimal operator interaction, essentially no maintenance, and portable size, the RAPIDPoint 500 system is ideal for both the point-of-care settings and the central laboratory.

RAPIDPoint 500 Blood Gas System

The ABL90 FLEX system is a compact blood gas analyzer comprising a solution pack and a separate sensor cassette. The solution pack contains eight foil pouches for calibrators, gas mixture, quality control, and waste. The individual sensor cassette is offered in a variety of sizes and lasts up to 30 days once installed on the system.

ABL90 FLEX blood gas analyzer

An overview of the methodologies employed on the RAPIDPoint 500 system and the ABL90 FLEX analyzer for the critical care parameters evaluated in this study is provided in Table 1.

Table 1. Methodology comparison.

Measurand	RAPIDPoint 500 System	ABL90 FLEX Analyzer
pH	Potentiometric	Potentiometric
pCO_2	Potentiometric	Potentiometric
pO_2	Amperometric	Optical
Na^+	Potentiometric	Potentiometric
K^+	Potentiometric	Potentiometric
Ca^{2+}	Potentiometric	Potentiometric
Cl^-	Potentiometric	Potentiometric
Glucose	Amperometric	Amperometric
Lactate	Amperometric	Amperometric

Method

A measurement procedure comparison study was performed for pH, gases, electrolytes, and metabolites in accordance with the CLSI EP09-A3 guideline. A minimum of 40 whole blood samples were assayed in duplicate on each platform. Samples were modified to encompass the analytical measurement range for each measurand. Measurement procedure comparisons were completed using Analyse-it® software to generate slope, intercept, and coefficient of determination statistics.

Results

Regression and medical decision statistics for each measurement procedure comparison are displayed in Tables 2 and 3. Outliers were excluded for measurands where n< 40. The mean of duplicate samples, identity lines, and equations are illustrated in Figures 1 through 9.

Table 2. Measurement procedure comparison statistics for the RAPIDPoint 500 system vs. ABL90 FLEX analyzer.

Measurand	n	Regression Type	Slope	Intercept	r^2	Measurement Interval
pH (units)	39	Ordinary Deming	0.963	0.2717	0.999	6.952–7.702
pCO_2 (mmHg)	40	Passing- Bablok	1.050	0.4039	0.989	14.1–153.1
pO_2 (mmHg)	39	Weighted Deming	0.994	-0.5232	0.999	27.0–393.7
Na^+ (mmol/L)	38	Ordinary Deming	1.064	-8.367	0.999	100.7–180.5
K^+ (mmol/L)	38	Weighted Deming	1.045	-0.22	0.998	1.17–13.79
Ca^{2+} (mmol/L)	40	Passing- Bablok	1.096	-0.1237	0.997	1.11–4.48
Cl^- (mmol/L)	40	Ordinary Deming	1.189	-16.46	0.995	65.0–138.5
Glucose (mg/dL)	40	Weighted Deming	1.036	-3.797	0.995	41.5–711.0
Lactate (mmol/L)	46	Weighted Deming	1.071	-0.4708	0.991	0.82–17.43

Table 3. Measurement procedure comparison statistics at medical decision levels.

Measurand	Medical Decision Level RAPIDPoint 500 System	ABL90 FLEX Analyzer Result	Reporting Unit Bias	% Bias
pH (units)	7.300	7.304	0.004	N/A
	7.500	7.496	-0.004	N/A
pCO_2 (mmHg)	30.0	31.9	1.9	6.3%
	50.0	52.9	2.9	5.8%
pO_2 (mmHg)	55.0	54.1	-0.9	-1.6%
	200.0	198.2	-1.8	-0.9%
Na^+ (mmol/L)	130.0	129.9	-0.1	-0.1%
	150.0	151.2	1.2	0.8%
K^+ (mmol/L)	3.00	2.91	-0.09	-2.9%
	6.00	6.05	0.05	0.8%
Ca^{2+} (mmol/L)	1.10	1.08	-0.02	-1.6%
	1.30	1.30	0.00	0.1%
Cl^- (mmol/L)	90	90.6	0.6	0.6%
	110	114.4	4.4	4%
Glucose (mg/dL)	50.0	48.0	-2.0	-4.0%
	200.0	203.4	3.4	1.7%
Lactate (mmol/L)	1.30	0.92	-0.38	-29.1%
	2.70	2.42	-0.28	-10.3%

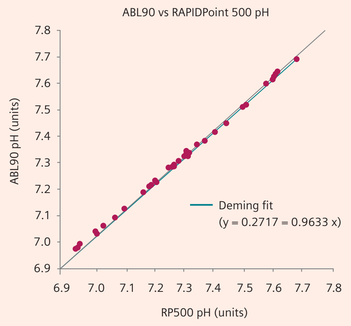

Figure 1. pH measurement procedure comparison.

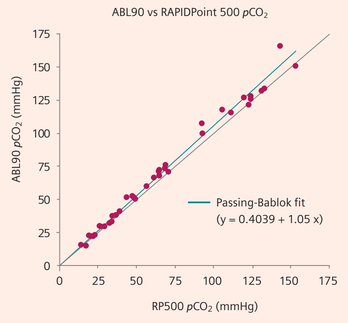

Figure 2. pCO_2 measurement procedure comparison.

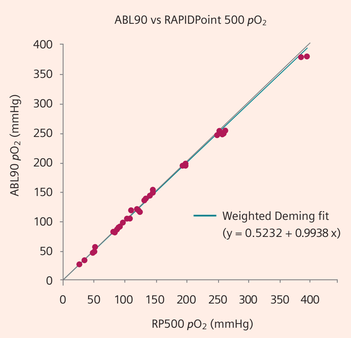

Figure 3. pO_2 measurement procedure comparison.

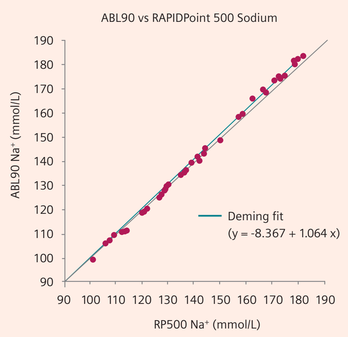

Figure 4. Na^+ measurement procedure comparison.

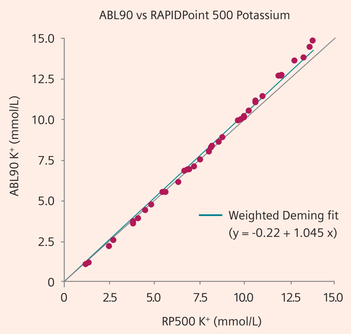

Figure 5. K^+ measurement procedure comparison.

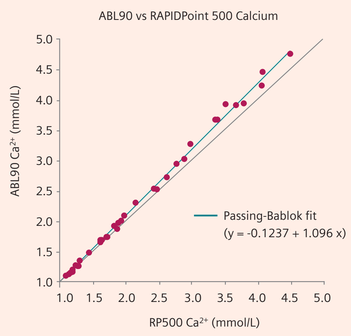

Figure 6. Ca^{2+} measurement procedure comparison.

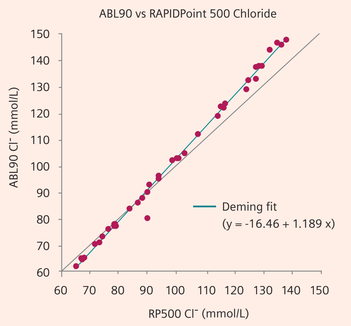

Figure 7. Cl^- measurement procedure comparison.

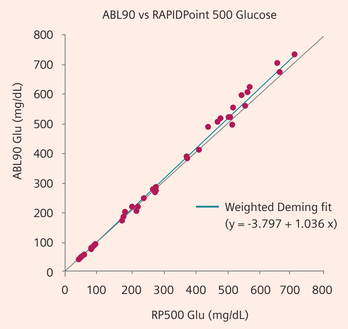

Figure 8. Glucose measurement procedure comparison.

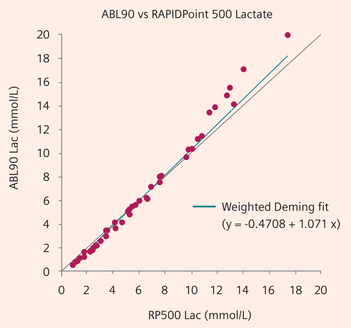

Figure 9. Lactate measurement procedure comparison.

Conclusion

The measurement procedure comparison demonstrated equivalency for the two critical care instruments. Slopes for each measurand were all within 10% (0.90 to 1.10) with the exception of chloride, which recovered with a slope of 1.189. The coefficient of determination for chloride was 0.995, indicating a strong linear relationship between both measurement procedures. A bias equation can be entered into a ABL90 FLEX analyzer to achieve a comparable result to the RAPIDPoint 500 system. Coefficients of determination for all measurands were ≥0.99, showing a strong linear relationship between the ABL90 FLEX analyzer and the RAPIDPoint 500 system.

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