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Global Siemens Headquarters
Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters
Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Telephone: +49 9131 84-0
Germany
www.siemens.com/healthcare

Global Division
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
www.siemens.com/diagnostics

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Assessment of Whole Blood Lactate on the Siemens RAPIDPoint 500 Blood Gas Analyzer

White Paper

Authors: Neal Carpenter, Kaitlyn LaRock, Jeff Tuck

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Introduction

RAPIDPoint® 500 Blood Gas System is the next-generation blood gas analyzer offered by Siemens Healthcare Diagnostics. The system utilizes cartridge-based, no-maintenance technology and is designed for ease of use in the point-of-care setting. The system offers test results for blood gas, electrolytes, metabolites, and CO-oximetry for whole blood.

Abstract

Lactic acid is the endpoint product of the anaerobic metabolism of glucose. Lactate levels can be elevated by strenuous exercise, carbon monoxide poisoning, respiratory failure, alcoholic or diabetic ketoacidosis, as well as numerous other causes. Determining the blood lactate level is helpful in assessing the supply of oxygen at the tissue level. Increased oxygen deprivation causes the normal oxidation of pyruvic acid to lactate and can cause severe acidosis called lactic acidosis.[1] Patients with lactate levels greater than 4 mmol/L have a significant increase in mortality rate.[2]

The RAPIDPoint 500 system provides a stable lactate sensor, with a 28-day use life, enclosed in a maintenance-free cartridge. An internal validation study of whole blood lactate measured on the Siemens RAPIDPoint 500 blood gas analyzer is presented.

Conclusions

Method comparison testing based on Clinical Laboratory Standards Institution Method Comparison and Bias Estimation Using Patient Samples (CLSI EP09-A2-IR) showed that the RAPIDPoint 500 whole blood lactate method provides analytical results substantially equivalent to those of the RAPIDLab® 1265 whole blood lactate method.

Precision testing based on Clinical Laboratory Standards Institution Evaluation of Precision Performance of Quantitative Measurement Methods (CLSI EP05-A2) showed lactate whole blood and aqueous control levels met within laboratory and repeatability guideline criteria for all levels tested.

Linearity testing based on Clinical Laboratory Standards Institution Evaluation of the Linearity of Quantitative Measurement Procedures (CLSI EP06-A) demonstrates that the RAPIDPoint 500 whole blood lactate assay is linear (first order) over the range of 0.3 to 30 mmol/L.

Method Comparison

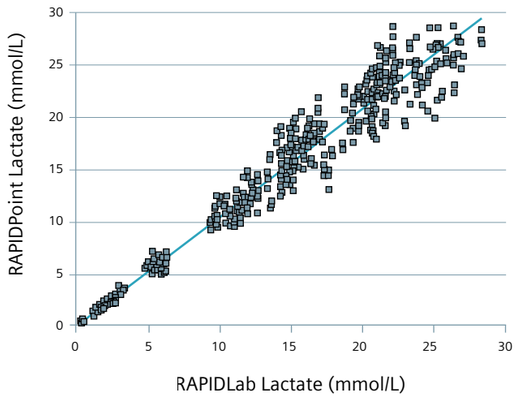
Methods

Test methods were adopted from Clinical Laboratory Standards Institution Guideline Method Comparison and Bias Estimation Using Patient Samples (CLSI EP09-A2-IR). A total of 102 paired lactate whole blood samples (prepared and unaltered) were evaluated on six RAPIDPoint 500 systems and two RAPIDLab 1265 systems. Lactate sample levels that spanned the analytical range of interest (0.2–30 mmol/L) were measured. Regression analysis and bias estimates were performed on the collected data.

Results

Deming regression analysis comparing the test device, the RAPIDPoint 500 system, versus the predicate device, the RAPIDLab 1265 system, yielded a slope of 1.04 and intercept of 0.01, with R^2=0.978 across the lactate range of 0.22–29.56 mmol/L (see Figure 1). No outliers or discordant results were observed.

Figure 1. Mean lactate concentration using the RAPIDPoint 500 system vs. the RAPIDLab 1265 system



The bias of each pair of data points was calculated and summarized (see Table 1).

Table 1 – Bias estimates for lactate levels (mmol/L)

RAPIDLab 1265 Value	Predicted RAPIDPoint 500 Value	Expected Bias	Lower 95% Confidence Limit	Upper 95% Confidence Limit
1.30	1.37	0.07	1.35	1.38
2.00	2.10	0.10	2.10	2.10
2.70	2.82	0.12	2.80	2.85
6.00	6.30	0.30	6.20	6.30
10.00	10.40	0.40	10.30	10.60

Precision

Methods

Test methods were adopted from Clinical Laboratory Standards Institution Evaluation of Precision Performance of Quantitative Measurement Methods (CLSI EP05-A2).

Whole Blood

Lithium heparinized whole blood specimens were collected in-house, prepared for lactate, and measured on the RAPIDPoint 500 system for a total of 20 days. Four levels were run on three systems in duplicate, twice a day, with a minimum of two hours between runs (n=240). Prepared samples were measured in capillary and syringe modes.

Aqueous

Calibration Verification Material (CVM) was measured for lactate on the RAPIDPoint 500 system for a total of 20 days. Four levels were run on three systems in duplicate, twice a day, with a minimum of two hours between runs (n=240). Results were pooled for statistical calculation.

Automatic Quality Control (AQC) was measured for lactate on the RAPIDPoint 500 system for the entire use-life of the AQC cartridge. Imprecision of AQC was monitored on six systems for three levels twice a day (n=336).

Mean lactate concentration (mmol/L), within laboratory standard deviation, and repeatability were calculated.

Results

Table 1. Precision results for prepared whole blood samples

Level	Device	n	Mean[a]	WRSD[b]	WRCV[c]	Total SD[d]	Total CV[e]
1	Syringe	240	0.361	0.03	8.7	0.066	18.2
1	Capillary	240	0.409	0.05	13.3	0.089	21.9
2	Syringe	240	1.337	0.09	6.5	0.135	10.1
2	Capillary	240	1.408	0.10	7.0	0.171	12.2
3	Syringe	240	2.487	0.12	4.7	0.237	9.5
3	Capillary	240	2.516	0.18	7.0	0.265	10.5
4	Syringe	240	22.89	1.83	8.0	2.30	10.0
4	Capillary	240	22.05	1.65	7.5	2.45	11.1

Table 2. Precision results for aqueous material (manual QC)

Level	n	Mean[a]	WRSD[b]	WRCV[c]	Total SD[d]	Total CV[e]
1	240	0.501	0.02	3.5	0.044	8.7
3	240	0.912	0.02	2.3	0.039	4.3
4	240	2.939	0.09	3.0	0.128	4.4
5	240	22.96	1.06	4.6	1.58	6.9

Table 3. Precision results for aqueous material (automatic QC)

Level	n	Mean[a]	WRSD[b]	WRCV[c]	Total SD[d]	Total CV[e]
1	336	12.15	0.26	2.18	0.40	3.30
2	336	0.88	0.02	2.60	0.03	3.27
3	336	2.90	0.09	3.22	0.10	3.33

a. The Mean is expressed in units of mmol/L
b. WRSD = Within-Run Standard Deviation
c. WRCV = Within-Run Coefficient of Variation (%)
d. Total SD = Total Standard Deviation
e. Total CV = Total Coefficient of Variation (%)

Linearity

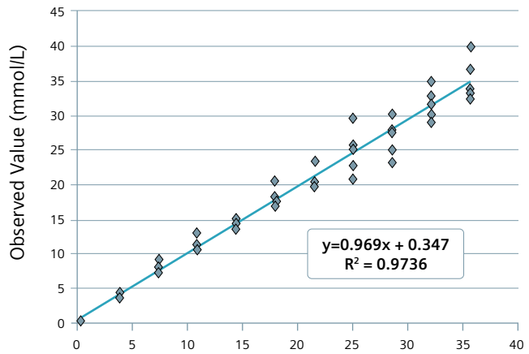
Method

Test methods were adopted from Clinical Laboratory Standards Institution Evaluation of the Linearity of Quantitative Measurement Procedures (CLSI EP06-A). Linearity performance evaluation was carried out on one RAPIDPoint 500 system and one RAPIDLab 1265 system in a single day. A full range experiment used 11 pools ranging from 0.3–30 mmol/L. The pools were run in a randomized fashion with five replicates per concentration (n=55).

Results

The linearity data are graphically presented in Figure 2 which shows the calculated linear regression equation and the coefficient of determination.

Figure 2



Over the range of 0.3–30 mmol/L the linear model was found to be the best mathematical fit for the data yielding a slope of 0.969 and an R^2 of 0.9736.

Summary

Given the value of recognizing sepsis early to reduce mortality and morbidity, lactate testing in critical care settings has become increasingly important. The analytical performance validation based on Clinical Laboratory Standards Institution (CLSI) Guidelines of the RAPIDPoint 500 lactate sensor demonstrates the same accuracy and reliability as the RAPIDLab 1265 lactate sensor.

References:

1. Levinsky NG. Acidosis and alkalosis. Ch 46 in Isselbacher KJ et al. Harrison's Principles of Internal Medicine, 13th Ed. New York: McGraw-Hill, 1994:253-262.
2. Stephen Trzeciak et al. Serum lactate as a predictor of mortality in patients with infection. Intensive Care Medicine. 2007;33:970.