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White Paper
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Method Comparison of Critical Analytes on Siemens Blood Gas Systems: RAPIDPoint 500 Point-of-care Analyzers versus RAPIDLab 1265 Laboratory-based Analyzers

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Introduction

Critical care testing may be performed in many different locations throughout a hospital. Some testing may be done close to the patient for immediacy of test results, while other samples may be sent to the central laboratory for evaluation. Siemens Healthcare Diagnostics offers a selection of blood gas analyzers, including the point-of-care (POC) RAPIDPoint® 500 Blood Gas System and the laboratory-based RAPIDLab® 1200 Series Blood Gas Systems. A hospital may have a RAPIDPoint 500 system placed in a decentralized location such as the ICU or ER, while a RAPIDLab 1265 system may be the primary critical care system in the laboratory. It is imperative that harmonization, or the ability to achieve comparable results across different measurement technologies, exist across the Siemens blood gas systems. This helps to ensure that the same clinical decisions are made for the patient, regardless of which Siemens blood gas system performed the test, so that appropriate and consistent therapeutic actions are administered.

The Siemens RAPIDPoint 500 Blood Gas System is a POC analyzer that measures pH, blood gases, electrolytes, glucose, lactate, total hemoglobin, CO-oximetry fractions, and neonatal bilirubin. Results are available in approximately 60 seconds from a single sample of whole blood. With its easy-to-use, completely cartridge-based design that requires minimal operator interaction, this system meets the challenges of the critical care environment. The RAPIDPoint 500 system delivers laboratory-quality results where and when they are needed.

The RAPIDLab 1265 analyzer offers the same test menu and quick turnaround time for the clinician. By combining the longevity of Ready Sensor® electrode technology with the efficiency and ease of cartridge-based reagents, the RAPIDLab 1265 system optimizes operational performance. In medium- to high-volume testing sites such as the laboratory or in POC settings, operators can routinely test a large number of patient samples with minimal interaction.

The principle sensing technologies (for example, potentiometric, amperometric, or optical) used to measure the analytes are consistent across the RAPIDLab and RAPIDPoint systems. The difference is the method of sensor construction. The measurement module in the RAPIDLab 1265 system contains individual sensors developed for selectivity to each analyte. These sensors are robust, highly stable, and have a long onboard use life. Each sensor can easily and independently be replaced as required, and in some cases may last up to a year. Figure 4 shows a view of the Ready Sensor electrodes aligned in the measurement module of the RAPIDLab 1265 analyzer.

The sensors used in the RAPIDPoint 500 analyzer are miniaturized and planar chip in design, utilizing spotting technologies to deposit contact leads and membranes onto ceramic substrates. The RAPIDPoint 1265 system's measurement module opened horizontally. Three planar sensor chips have been removed for easier viewing. Based on typical sampling rates, the measurement cartridge consisting of the sensor measurement module and reagents has a use life of up to 28 days.
Method Comparison of Critical Analytes on Siemens Blood Gas Systems

Relevance

The AACC’s International Consortium for Harmonization of Clinical Laboratory Results has been working with a variety of stakeholders in pursuit of harmonization among results from different methods and labs for the same measurement.1 Malone states, “Harmonization means achieving comparable results among different measurement procedures.” Further, “When lab measurement procedures give different results for the same specimen, patients may get the wrong treatment, because decision criteria are not appropriate for the procedure in use. In order to do this effectively, results need to be harmonized.”

Study Objective

A method comparison of the RAPIDPoint 500 system versus the RAPIDLab 1265 system was performed to establish correlation between the two blood gas analyzers. The objective was to demonstrate that harmonization exists between the Siemens point-of-care and laboratory-based blood gas systems.

Materials and Methods

Fresh whole blood was collected in lithium heparin tubes on each day of the study. Blood samples were either left unaltered, or modified with tonometry for the pH and gases or spiking solutions for the remaining analytes, to cover the measurement range for each analyte tested.

Proper sample handling technique, i.e., expulsion of the air bubble with the appropriate mixing technique both immediately after draw and prior to analysis, was followed. The samples were assayed on two RAPIDPoint 500 and two RAPIDLab 1265 analyzers within 10 minutes of each other in normal syringe mode. The performance of all four systems was verified daily with quality control materials using automatic quality control (AQC) cartridges scheduled to run at regular intervals. The method comparison study was performed in accordance with the CLSI EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples Guideline.1 Correlation statistics including slope (m), intercept (b), and coefficient of determination (r²) were calculated by either ordinary or weighted Deming regression analysis for the following analytes:

- pH, pCO₂, pO₂
- Sodium (Na⁺), potassium (K⁺), ionized calcium (Ca²⁺), chloride (Cl⁻)
- Glucose, lactate
- Total hemoglobin (Hb)
- Neonatal bilirubin (nBili)

CO-oximetry fractions were not evaluated in this study.

Results

Regression statistics for the method comparison between the RAPIDPoint 500 system and the RAPIDLab 1265 system are summarized in Table 1. Note that n refers to the total number of paired samples tested, and the measurement range represents the minimum and maximum levels tested. Regression equation slope results were between 0.90 and 1.01, and r² results were equal to or greater than 0.9732 for the measurement range tested.

![Figure 6. pH method comparison results.](Image)

![Figure 7. Partial pressure carbon dioxide (pCO₂) method comparison results.](Image)

![Figure 8. Partial pressure oxygen (pO₂) method comparison results.](Image)

The results of the RAPIDPoint 500 analyzer comparison to the RAPIDLab 1265 system for the analytes tested are graphically depicted in Figures 6 through 16. In each figure, the x-axis represents the comparative device (RAPIDLab 1265 system) and the y-axis represents the test device (RAPIDPoint 500 system). The linear equation is:

\[ y = mx + b \]

where \( y \) = RAPIDLab 1265 system value, \( m \) = slope, and \( b \) = intercept; r² = coefficient of determination.

![Figure 9. Sodium (Na⁺) method comparison results.](Image)

Conclusions

The RAPIDPoint 500 blood gas analyzer demonstrates good correlation with the RAPIDLab 1265 blood gas analyzer as evidenced by the slopes from the regression analyses (0.90 to 1.01) and coefficients of determination ($r^2 \geq 0.9732$).

Results confirm that harmonization between the RAPIDPoint 500 system and the RAPIDLab 1265 system exists. Regardless if a test is performed on the Siemens point-of-care analyzer with planar sensors or the central laboratory blood gas analyzer using Ready Sensor electrodes, comparable results for the same patient sample will be reported.

For all of the critical care analytes evaluated, both RAPIDPoint and RAPIDLab blood gas systems deliver consistent, high-quality patient results to the clinician when and where they are needed.