Glucose Correlation between the Point-of-care RAPIDPoint 500 Blood Gas System and Two Central Laboratory Platforms

Poirier D, LaRock K, Hotaling T.
Siemens Healthcare Diagnostics Inc., 2 Edgewater Drive, Norwood, MA, USA

White Paper

Local Contact Information

Siemens Healthcare
Point of Care Diagnostics
2 Edgewater Drive
Norwood, MA 02062-4637
USA
Telephone: +1 781-269-3000
siemens.com/healthcare

Siemens Healthcare Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthcare
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Summary
The accuracy of blood glucose test results is important when monitoring glycemic control and treating patients, especially the critically ill. Glucose measurements may be performed on a number of different test devices in a multitude of hospital settings by a variety of trained personnel. Some reports have suggested that central laboratory analyzers may exhibit "higher accuracy" than point-of-care (POC) systems used to measure patient glucose levels. An internal study conducted by Siemens Healthcare compared the accuracy of the glucose parameter as measured on the RAPIDPoint® 500 Blood Gas System, typically located in the POC setting, to the accuracy of glucose as determined by two hospital main laboratory instruments, the RAPIDLab® 1265 Blood Gas System and the ADVIA® 1800 Clinical Chemistry System.

Results of the study demonstrated good agreement of the POC RAPIDPoint 500 system glucose measurement to those obtained on the laboratory-based RAPIDLab 1265 blood gas as well as the ADVIA 1800 Chemistry analytical systems.

Introduction
Critical care testing, including the measurement of glucose, is routinely performed in many hospital locations. POC analyzers may be used for near-patient testing when immediacy of patient results is required, while other samples may be sent to the central laboratory for analysis.

Regardless of the analytical system, methodology, or test environment, harmonization of critical analyte measurement is essential. The ability to generate comparable results across different testing platforms and technologies helps to ensure appropriate clinical decision making and the administration of proper and consistent therapy.

Blood gas analyzers from Siemens Healthcare Point of Care Diagnostics include the RAPIDPoint 500 system and the RAPIDLab 1265 system. Both systems measure blood glucose in addition to other critical care analytes. Siemens Healthcare's lab-based ADVIA 1800 Clinical Chemistry System integrates general chemistry testing with an extensive menu that includes glucose. All three analyzers are designed to provide equivalency of glucose results.
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Glucose Methodology on Siemens Healthcare Blood Gas Analyzers

Siemens Healthcare offers two blood gas platforms that provide the ability to evaluate glucose. Both the RAPIDPoint 500 and the RAPIDLab 1265 systems measure pH, blood gases, electrolytes, glucose, lactate, total hemoglobin, CO-oximetry, and neonatal total bilirubin in approximately 60 seconds on a single sample of heparinized whole blood. The critical care menu available on the RAPIDLab 1260 model includes most of these parameters except total hemoglobin, CO-oximetry, and neonatal bilirubin. All offer a comprehensive menu and quick turnaround time for busy clinicians.

On the blood gas systems, the glucose assay principle is amperometric technology utilizing a glucose biosensor. The glucose biosensor is a complete electrochemical cell that consists of four internal electrodes. One electrode acts as the reference and a second is the conductor for the polarizing voltage. The remaining two electrodes are the measuring electrode (or active electrode) and the interference measuring electrode (or inactive electrode). Only the active electrode contains the appropriate glucose oxidase enzyme required for the measurement of the glucose metabolite.

Whole blood specimens contain endogenous and/or exogenous substances that can generate an electrochemical signal. Such substances are considered interfering substances because they produce an electrochemical signal that is not related to the concentration of the metabolite being measured. The signal from the inactive electrode is subtracted from the measuring active signal in order to correct for the presence of these interfering substances. In this way, the biosensor accurately measures the actual glucose concentration in the whole blood specimen.

RAPIDPoint 500 Blood Gas System

The RAPIDPoint 500 system is an entirely cartridge-based system comprising of a measurement cartridge and a wash/waste cartridge. The sensors used in the RAPIDPoint 500 system, including the glucose biosensor, are miniaturized and planar chip in design, utilizing automated spotting technologies to deposit small contact leads and membranes onto ceramic substrates.

RAPIDLab 1265 Blood Gas System

The reagents on the RAPIDLab 1265 system are contained within a cartridge, while the measurement module contains individual sensors. These sensors, including the glucose biosensor, utilize Siemens Healthcare’s Ready Sensor Electrode Technology developed for selectivity to the analyte of choice. The Ready Sensor electrodes are aligned in the measurement module of the RAPIDLab 1265 system as shown in the picture below; they are long-lasting and can be replaced independently. By combining the longevity of the Ready Sensor electrodes with the efficiency and ease of cartridge-based reagents, the RAPIDLab 1265 system optimizes operational performance in medium- to high-volume testing sites by providing quick turn-around time for busy clinicians.

RAPIDPoint 500 analyzer sensor module, an integral component of the measurement cartridge

All of the sensors used for the critical care menu on the RAPIDPoint system are incorporated in a single module. The RAPIDPoint 500 system generates lab-quality results wherever needed throughout the hospital. With its easy-to-use cartridge technology, minimal operator interaction and essentially no maintenance and its smaller size, the RAPIDPoint 500 system is ideal for POC settings.

RAPIDLab 1265 Blood Gas System

The ADVIA 1800 Clinical Chemistry System is an automated analyzer that integrates testing for clinical chemistry, drugs of abuse, therapeutic drug monitoring, and specific proteins on human serum, plasma, or urine. It is the ideal solution for high- to very high-volume laboratories, with the capability of measuring over 117 assays and performing up to 1800 tests per hour, including ISE testing.

Two glucose assay methodologies are available on the ADVIA 1800 Chemistry system. This study evaluates the ADVIA 1800 Glucose Hexokinase_3 assay which is a two-step reagent process and optical measurement read from an onboard spectrophotometer. The system draws an appropriate amount of the patient’s plasma sample and adds in the first reagent (Reagent 1). Absorbance readings of the sample in Reagent 1 are taken and are used to correct for interfering substances in the sample. Once a second reagent (Reagent 2) is added, the actual conversion of glucose is initiated. After an incubation period, the absorbance of the resulting final solution is read at 340 and 410 nm wavelengths. The difference between the absorbance in Reagent 1 and Reagent 2 is proportional to the glucose concentration.

ADVIA 1800 Clinical Chemistry System reagent tray

Glucose Methodology on Siemens Healthcare ADVIA Chemistry System

ADVA 1800 Clinical Chemistry System

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Study Purpose

Several factors—including device measurement technology, operator consistency and technique, sample matrix, sample collection, methodology, and the clinical characteristics of the patient—can influence the glucose measurement and affect accuracy.

This study investigated the accuracy of the glucose measurement on Siemens Healthcare’s POC RAPIDPoint 500 Blood Gas System, using whole blood, compared to the accuracy of a laboratory-obtained glucose measurement on:

• RAPIDLab 1265 Blood Gas System, using whole blood
• ADVIA 1800 Clinical Chemistry System, using plasma

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 spiking solutions to cover the glucose measurement range. Each of these samples (total n = 100) were run concurrently on two RAPIDPoint 500 and two RAPIDLab 1265 analyzers in normal syringe arterial patient mode. The remaining volume of each sample was then centrifuged, and the resulting plasma was removed and stored in a ~70°C temperature-controlled device. The frozen prepared plasma samples were subsequently thawed and tested on one ADVIA 1800 Clinical Chemistry System. The performance of each system was verified daily with quality control materials set up to run at regularly scheduled intervals.

Glucose measurement method comparisons were performed in accordance with the CLSI EP09-A3 guideline.2 Correlation statistics, including slope (m), intercept (b), and coefficient of determination (r2) as determined by weighted Deming regression analysis, were calculated for glucose results.

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Results

Glucose analyzer comparisons are shown graphically in Figures 1–3. In each figure, the x-axis represents the comparative device and the y-axis represents the test device.

The linear equation is: $y = mx + b$, where:
- \( y \) = test system value
- \( x \) = comparative system value
- \( m \) = slope
- \( b \) = intercept
- \( r^2 \) = coefficient of determination

Glucose results were evaluated using the weighted Deming regression statistical approach. RAPIDPoint 500 system method comparison versus the RAPIDLab 1265 system and versus the ADVIA 1800 system is summarized in Table 1. RAPIDPoint 500 system method comparison versus the RAPIDLab 1265 and ADVIA 1800 systems, as evidenced by the regression slope values approaching unity (1.01 < m < 1.03) and high coefficient of determination values (\( r^2 \) ≥ 0.9973). This agreement holds true across the wide glucose sample concentrations tested (28–692 mg/dL, 1.6–38.4 mmol/L). The data confirms strong harmonization of glucose measurements between the RAPIDPoint 500 system, RAPIDLab 1265 system, and the ADVIA 1800 analyzer.

Table 1. Method comparisons for glucose between the RAPIDPoint 500 system and central laboratory analyzers.

<table>
<thead>
<tr>
<th>Instrument Comparison</th>
<th>Measurand (unit of measure)</th>
<th>n</th>
<th>Median Bias</th>
<th>Slope</th>
<th>Intercept</th>
<th>( r^2 )</th>
<th>Measurement Range Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAPIDPoint 500 system vs. RAPIDLab 1265 system</td>
<td>mg/dL</td>
<td>100</td>
<td>-2.9%</td>
<td>1.01</td>
<td>-5</td>
<td>0.9981</td>
<td>32 – 674 mg/dL</td>
</tr>
<tr>
<td>RAPIDLab 1265 system vs. ADVIA 1800 system</td>
<td>mg/dL</td>
<td>100</td>
<td>2.1%</td>
<td>1.03</td>
<td>-2</td>
<td>0.9973</td>
<td>28 – 692 mg/dL</td>
</tr>
</tbody>
</table>

Discussion and Conclusions

Designed for easy use in POC environments, the RAPIDPoint 500 system demonstrated excellent glucose correlation with the laboratory RAPIDLab 1265 and ADVIA 1800 systems, as evidenced by the regression slope values approaching unity (1.01 < m < 1.03) and high coefficient of determination values (\( r^2 \) ≥ 0.9973). This agreement holds true across the wide glucose sample concentrations tested (28–692 mg/dL, 1.6–38.4 mmol/L). The data confirms strong harmonization of glucose measurements between the RAPIDPoint 500 system, RAPIDLab 1265 system, and the ADVIA 1800 analyzer.

Glucose measurement on Siemens Healthcare’s POC and laboratory platforms—whether employing planar or Ready Sensor sensors, glucose oxidase or hexokinase methodology, electrochemical or optical measurement, whole blood or plasma matrix—is harmonized across the range. Clinicians can be confident that high-quality glucose results on the same patient sample will be consistently delivered, whether on the RAPIDPoint 500 system, RAPIDLab 1265/1260 system, or ADVIA 1800 Chemistry system.

References