Evaluation of the Correlation across Siemens Healthineers Blood Gas and Clinical Chemistry Systems for Electrolytes and Metabolites


Abstract

Objective: The objective of the study is to demonstrate an end-to-end solution across the Siemens Healthineers three blood gas systems and a central laboratory-based analyzer. The epoc® Blood Analysis System for patient-side testing, the RAPIDPoint® 500 Blood Gas System designed for the POC and the RAPIDLAB® 1265 Blood Gas System, the laboratory-based system and the central laboratory-based ADVIA® 1800 Clinical Chemistry system were evaluated for specific critical care analytes to demonstrate harmonization, without the diagnostic product portfolio. The study design and analysis followed CLSI EP09 for the measurement of sodium, potassium, chloride, glucose, lactate, BUN and creatinine, where applicable. Correlation statistics including slopes, intercepts, coefficients of determination (r²) and bias at the medical decision levels were generated.

Methodology: A measurement procedure comparison study was performed on the Siemens blood gas systems (epoc Blood Analysis System, RAPIDPoint 500 and RAPIDLab 1265 Blood Gas Systems) with whole blood versus the ADVIA 1800 Clinical Chemistry System with plasma. The study was performed in accordance with the CLSI EP09 guideline. A minimum of 40 samples were assayed in duplicate on all platforms. Samples were altered as needed to span the reportable ranges for each measurement. Regression type and statistical outliers were determined using the guidance provided in CLSI EP09. Correlation statistics including slope, intercept, coefficient of determination (r²) and bias at the medical decision levels were generated.

Results

Measurement procedure comparison results for the epoc, RAPIDPoint 500 and RAPIDLab 1265 systems versus the ADVIA 1800 system are summarized in Table 1. Measurement procedure comparison results for the epoc system versus the RAPIDPoint 500 and RAPIDLab 1265 systems are summarized in Table 2.

Conclusion: Harmonization at the clinically relevant medical decision levels was demonstrated for a true end-to-end solution across the Siemens Healthineers blood gas and clinical chemistry systems for electrolytes and metabolites.

Background

Healthcare providers expect comparable test results among different measurement procedures for the same patient sample, regardless of where the testing is performed. Siemens Healthineers offers a comprehensive critical care portfolio of patient-side, point of care and central laboratory analyzers for blood gas, electrolyte and metabolite analysis. The company also offers an extensive variety of clinical chemistry systems designed to simplify workflow and deliver consistent, quality results from the central laboratory and the point of care.

A measurement procedure comparison study was conducted to compare results obtained from the epoc® Blood Analysis System to the ADVIA® 1800 Clinical Chemistry System for electrolytes and metabolites, and from the RAPIDPoint® 500 and RAPIDLab® 1265 Blood Gas Systems to the ADVIA 1800 Clinical Chemistry System for blood gases. The objective was to demonstrate an end-to-end solution across three Siemens Healthineers blood gas systems for the blood gas parameters and versus the central laboratory-based analyzer for specific, common analytes in whole blood and plasma.

The epoc blood analysis system is a handheld, wireless solution that provides blood gas, electrolyte, metabolite and hematocrit test results at the patient bedside in less than 1 minute. By incorporating a full critical care menu, including creatinine and BUN, on a single, room temperature stable test card, the epoc system delivers an efficient and easy-to-manage patient-side testing program for the hospital.

The RAPIDPoint 500 system delivers accurate, laboratory-quality test results at the point of care in as little as 60 seconds. The cartridge-based, maintenance-free critical care analyzer provides a comprehensive menu, including pH and blood gases, electrolytes, glucose, lactate and full CO-oximetry. The measurement cartridge resides on the system for up to 28 days, and the variety of cartridge test sizes available accommodates low- to high-volume tests.

making the RAPIDPoint 500 System ideal for both point of care and laboratory settings.

The RAPIDLab 1265 system is a benchtop critical care analyzer that combines the longevity of Ready Sensor® individual sensors with the efficiency and ease of cartridge-based reagents to optimize operational performance in the medium- to high-volume testing sites, such as the laboratory or select point of care settings. Minimal sample volume requirements, advanced automatic quality control, fast calibration times, and hands-free, bio-safe sampling help improve workflow wherever critical care testing is performed.

The ADVIA 1800 Clinical Chemistry System is the ideal solution for mid- to high-volume sample analysis in the central laboratory, with the ability to perform up to 1800 tests per hour. The fully automated system offers an extensive menu and can perform up to 200 basic metabolite panels per hour to meet the turnaround-time requirements of the busiest labs.

The AACC’s International Consortium for Harmonization of Clinical Laboratory Results continues in the effort to manage harmonization activities worldwide. The potential importance of harmonization test results lies in the ability to obtain a result that leads to the same interpretation regardless of the measurement procedure, where and when the testing was done, or the units of measure. Harmonization assists in minimizing the misinterpretation of test results and the potential for adverse patient outcomes.

Methodology: A method comparison study was performed on the Siemens blood gas systems (epoc Blood Analysis System, RAPIDPoint 500 and RAPIDLab 1265 Blood Gas Systems) with whole blood versus the ADVIA 1800 Clinical Chemistry System with plasma. The study design and analysis followed CLSI EP09 for the measurement of sodium, potassium, chloride, glucose, lactate, BUN and creatinine, where applicable. Correlation statistics including slopes, intercepts, coefficients of determination (r²) and bias at the medical decision levels were generated.

Validation/Results: Correlation statistics for glucose are represented in Table 1.

Table 1. Method Comparison Statistics for Glucose Analyte: Siemens Healthineers Blood Gas Systems vs. ADVIA 1800 Clinical Chemistry System

<table>
<thead>
<tr>
<th>Component</th>
<th>epoc vs. ADVIA</th>
<th>RAPIDPoint vs. ADVIA</th>
<th>RAPIDLab vs. ADVIA</th>
<th>Bland-Altman</th>
<th>CLD %</th>
<th>CV</th>
<th>r²</th>
<th>Bias</th>
<th>MDL 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>epoc vs. ADVIA 1800 Average Glucose (mg/dL)</td>
<td>0.996</td>
<td>0.983</td>
<td>0.991</td>
<td>0.991</td>
<td>0.993</td>
<td>0.993</td>
<td>0.993</td>
<td>0.993</td>
<td></td>
</tr>
<tr>
<td>RAPIDPoint vs. ADVIA 1800 Average Glucose (mg/dL)</td>
<td>0.983</td>
<td>0.994</td>
<td>1.000</td>
<td>0.994</td>
<td>0.994</td>
<td>0.994</td>
<td>0.994</td>
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</tr>
<tr>
<td>RAPIDLab vs. ADVIA 1800 Average Glucose (mg/dL)</td>
<td>0.991</td>
<td>0.994</td>
<td>1.000</td>
<td>0.994</td>
<td>0.994</td>
<td>0.994</td>
<td></td>
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</tr>
</tbody>
</table>

Note that “n” refers to the total number of paired samples tested. For the wide range of analytical concentrations tested, including low, normal, and high levels, regression equation slopes for all the critical care parameters were between 0.90 and 1.10. The r² values were equal to or greater than 0.97. The method comparison results for the epoc, RAPIDPoint 500, and RAPIDLab 1265 blood gas systems versus the ADVIA 1800 Clinical Chemistry System for the electrolyte and metabolite concentrations tested and for the epoc versus RAPIDPoint 500 and RAPIDLab 1265 blood gas systems are graphically depicted in Figures 1 through 17.

Conclusion: The method comparison study demonstrates comparable patient results among the Siemens Healthineers critical care product portfolio, specifically the epoc Blood Analysis System, the RAPIDPoint 500 and RAPIDLab 1265 Blood Gas Systems, and the central laboratory ADVIA 1800 Clinical Chemistry System. Siemens Healthineers offers a true end-to-end solution for the critical analytes pHe, blood gas, electrolytes and metabolites regardless of whether the testing is performed at the patient bedside, or in the point of care or laboratory setting. Clinicians can be confident that the Siemens Healthineers analyzers deliver consistent, high-quality patient results when and where they are needed.


Recognition: Additional contributors to this poster include Leonard C. Saagman, C. Shain, V. Tuck, J. Linscheid T. and Mazzarini, M.