Assessment of Harmonization among Siemens Point-of-care and Central Laboratory Blood Gas Systems

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**Objective**

Determine correlations between Siemens point-of-care (POC) and central lab blood gas systems in order to demonstrate harmonization across the product portfolio.

**Relevance**

AACC’s International Consortium for Harmonization of Clinical Laboratory Results has been working with a variety of stakeholders regarding harmonization among results from different methods and labs for the same measurand.

**Methodology**

Method comparison studies were performed with whole blood among POC (RAPIDPoint®) and central lab (RAPIDLab®) blood gas systems in accordance with the CLSI EP-09 guideline. A minimum of 100 whole blood replicates were assayed on all systems listed below. Samples were stored as needed to span the reportable ranges for each measurand. Correlation statistics including Deming slope, intercepts, and coefficients of determination (r2) were generated for the following comparisons:

- RAPIDPoint 500 Blood Gas System vs. RAPIDPoint 500 Blood Gas System
- RAPIDLab 348EX® Blood Gas System vs. RAPIDPoint 500 Blood Gas System
- RAPIDPoint 405 Blood Gas System vs. RAPIDPoint 500 Blood Gas System

**Validation**

Deming regression statistics for each comparison across intervals for each measurand are shown in Table 1 through Table 3. The mean of the replicates for each measured and the identity line are depicted in Figure 1 through Figure 7. The arrows on each figure indicate clinically relevant decision levels (MDLs) for the following measurements that are available on Siemens blood gas systems:

- pH, pCO2, pO2
- Sodium, potassium, ionized calcium, chloride
- Total hemoglobin, neonatal bilirubin

**Table 1.** Method comparison statistics for RAPIDLab 1265 vs. RAPIDPoint 500 systems.

<table>
<thead>
<tr>
<th>Measurand</th>
<th>RAPIDLab 1265 Mean (mmol/L)</th>
<th>RAPIDPoint 500 Mean (mmol/L)</th>
<th>Bias at MDL 1 (mmol/L)</th>
<th>Bias at MDL 2 (mmol/L)</th>
<th>Deming Mean (mmol/L)</th>
<th>Deming Bias at MDL 1 (mmol/L)</th>
<th>Deming Bias at MDL 2 (mmol/L)</th>
<th>Deming r2</th>
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<tbody>
<tr>
<td>Sodium</td>
<td>142.2</td>
<td>142.0</td>
<td>-0.2</td>
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<td>142.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.998</td>
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<tr>
<td>Potassium</td>
<td>3.6</td>
<td>3.5</td>
<td>0.1</td>
<td>0.1</td>
<td>3.5</td>
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<tr>
<td>Calcium</td>
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<td>2.4</td>
<td>0.0</td>
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**Table 2.** Method comparison statistics for RAPIDLab 348EX® vs. RAPIDPoint 500 systems.

<table>
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**Conclusion**

Harmonization at clinically relevant medical decision levels was demonstrated among Siemens POC and central lab blood gas systems for the measurands evaluated. The slopes for each measured were between 0.96 and 1.02, with r2 = 0.9785.

**References**


*Not available for sale in the U.S. Product availability varies by country.*