epoc Blood Analysis System: Summary of Analytical Methods and Performance

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Performance Data
The data summarized here are compiled from user performance verifications of the epoc® Blood Analysis System, performed as part of the implementation process.

Precision
The precision data provided for each analyte are the pooled averages of the precision data from performance verifications from 1–12 user sites.

Method comparison
Method comparison studies were performed by individuals who were thoroughly familiar with the operation, maintenance, and control of both the epoc system and comparative method systems before starting. Testing was performed at all sites using blood collected in either blood gas syringes or in green-top evacuated tubes.

Some samples were spiked with concentrated solutions to create samples with concentrations throughout the reportable range of each analyte. Each plot included in this summary is from 1–3 sites and is representative of the comparison of the epoc Blood Analysis System to each instrument.

Glossary
Accuracy is how close a result is to its true value.

Precision is reproducibility—how closely multiple results obtained from the same sample agree with each other.

n is the number of data points included in the data set.

x represents the comparison method in regression analysis.

y represents the test method in regression analysis.

Slope describes the angle of the line that provides the best fit of the test and comparison results. A perfect slope would be 1.00. Deviations from 1.00 are an indication of proportional systematic error.\(^1\)

Intercept (int’t) or y-intercept describes where the line of best fit intersects the y-axis. The y-intercept should be an indication of constant systematic error.\(^1\)

Sy.x describes the scatter of the data around the line of best fit. It provides an estimate of the random error between the methods and includes both the imprecision of the test and comparison methods, as well as possible matrix effects that vary from one sample to another. Sy.x will never be 0 because both methods have some imprecision.\(^1\)

r or correlation coefficient describes how closely the results between the two methods change together. The lower the r value, the more scatter there is in the data. The main use of r is to help assess the reliability of the regression data—r should never be used as an indicator of method acceptability.\(^1\)

Methodologies
pH is measured by potentiometry using a pH-selective membrane electrode. The concentration of hydrogen ions is obtained from the measured potential using the Nernst equation.

pCO\(_2\) is measured by potentiometry using a membrane-covered pH sensing electrode. The electrode voltage is proportional to the dissolved carbon dioxide concentration through the Nernst equation.

pO\(_2\) is measured by amperometry using a membrane-covered oxygen-sensing cathode electrode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

TCO\(_2\) is measured based on a modified Henderson-Hasselbalch equation, using pH and pCO\(_2\) and calibrated to match the International Federation of Clinical Chemistry (IFCC) Reference Measurement Procedure for Total Carbon Dioxide.\(^2\) Therefore, it is metrologically traceable to the IFCC TCO\(_2\) reference method.\(^2\)

Sodium is measured by potentiometry using an ion-selective membrane electrode. The concentration of sodium ions is obtained from the measured potential using the Nernst equation. The epoc sodium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect) methods.

Potassium is measured by potentiometry using an ion-selective membrane electrode. The concentration of potassium ions is obtained from the measured potential using the Nernst equation. The epoc potassium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect) methods.

Ionized calcium is measured by potentiometry using an ion-selective membrane electrode. The concentration of calcium ions is obtained from the measured potential using the Nernst equation.

Chloride is measured by potentiometry using an ion-selective membrane electrode. The concentration of chloride ions is obtained from the measured potential using the Nernst equation.

Hematocrit is measured by AC conductometry using two gold electrodes. The conductance of the blood sample in the fluidic path between the two electrodes, after correction for variable plasma conductivity through the measurement of sodium and potassium concentration, is inversely proportional to the hematocrit value.
Glucose is measured by amperometry. The sensor comprises an immobilized enzyme first layer coated onto a gold electrode of the electrode module, with a diffusion barrier second layer. The glucose oxidase enzyme is employed to convert glucose to hydrogen peroxide:

\[
\text{Glucose Oxidase} \\
\beta-\text{D-glucose} + O_2 + H_2O \rightarrow \text{D-gluconic acid} + H_2O_2
\]

and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox-mediated (ABTS [2,2’-azino-bis 3-ethylbenzothiazoline-6-sulfonyl] diammonium salt) horseradish peroxidase (HRP)-catalyzed reduction on a gold electrode.

\[
\text{H}_2\text{O}_2 + \text{HRP}^{\text{red}} \rightarrow \text{HRP}^{\text{ox}} \\
\text{HRP}^{\text{ox}} + \text{Red} \rightarrow \text{Ox} + \text{HRP}^{\text{red}} \\
\text{Ox} + e^- \rightarrow \text{Red}
\]

The reduction current is proportional to the concentration of glucose in the test fluid. The epoc glucose result is reported as plasma-equivalent glucose concentration.

Lactate is measured by amperometry. The sensor comprises an immobilized enzyme first layer coated onto a gold electrode of the electrode module, with a diffusion barrier second layer. The lactate oxidase enzyme is employed to convert lactate to hydrogen peroxide:

\[
\text{Lactate Oxidase} \\
\beta-\text{D-lactate} + O_2 + H_2O \rightarrow \text{Pyruvic acid} + H_2O_2
\]

and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox-mediated (ABTS [2,2’-azino-bis 3-ethylbenzothiazoline-6-sulfonic acid] diammonium salt) horseradish peroxidase (HRP)-catalyzed reduction on a gold electrode.

\[
\text{H}_2\text{O}_2 + \text{HRP}^{\text{red}} \rightarrow \text{HRP}^{\text{ox}} \\
\text{HRP}^{\text{ox}} + \text{Red} \rightarrow \text{Ox} + \text{HRP}^{\text{red}} \\
\text{Ox} + e^- \rightarrow \text{Red}
\]

The reduction current is proportional to the concentration of lactate in the test fluid.

BUN/Urea is measured by potentiometry using an ammonium ion selective electrode coated onto a gold electrode, covered with an enzymatic membrane second layer. The urease enzyme is employed to convert urea to ammonium ions:

\[
\text{Urea} + H_2O + 2H^+ + \text{Urease} \rightarrow 2\text{NH}_4^+ + CO_2
\]

and then uses a potentiometric ion selective electrode to detect the enzymatically produced ammonium ion. The concentration of ammonium ions is obtained from the measured potential using the Nernst equation.

Creatinine is measured by amperometry. Each creatinine sensor is a three-layer enzyme electrode comprising a first immobilized enzyme creatinine-conversion underlayer coated onto a gold electrode, a second immobilized enzyme creatine screening layer, and a third diffusion barrier layer.

The creatinine electrode underlayer contains the enzymes creatinine amidohydrolase, creatine amidinohydrolase, and sarcosine oxidase, which convert creatinine to hydrogen peroxide in an enzyme product cascade:

\[
\text{Creatinine Amidohydrolase} \\
\text{Creatinine} + H_2O \rightarrow \text{Creatine} \\
\text{Creatine Amidinohydrolase} \\
\text{Creatine} + H_2O \rightarrow \text{Sarcosine} + \text{Urea} \\
\text{Sarcosine Oxidase} \\
\text{Sarcosine} + O_2 + H_2O \rightarrow \text{Glycine} + \text{Formaldehyde} + H_2O_2
\]

and then uses the underlying gold electrode to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox-mediated horseradish peroxidase (HRP)-catalyzed reduction.

\[
\text{H}_2\text{O}_2 + \text{HRP}^{\text{red}} \rightarrow \text{HRP}^{\text{ox}} \\
\text{HRP}^{\text{ox}} + \text{Red} \rightarrow \text{Ox} + \text{HRP}^{\text{red}} \\
\text{Ox} + e^- \rightarrow \text{Red}
\]

The reduction current is proportional to the concentration of creatinine in the test fluid.

Please refer to the epoc Blood Analysis System Manual for more information.

References:
pH Method Comparison

<table>
<thead>
<tr>
<th>pH</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean</td>
<td>SD</td>
<td>%CV</td>
</tr>
<tr>
<td><strong>Level 1</strong></td>
<td>24</td>
<td>7.052</td>
<td>0.009</td>
<td>0.13%</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
<td>25</td>
<td>7.646</td>
<td>0.007</td>
<td>0.09%</td>
</tr>
</tbody>
</table>

- **X: Abbott I-STAT System**
  - Y: epoc System
  - $r = 0.997$
  - $n = 41$
  - slope = 1.049
  - int'.' = -0.356
  - $Sy.x = 0.016$

- **X: RAPIDLab® 1265 Blood Gas System by Siemens Healthineers**
  - Y: epoc System
  - $r = 0.998$
  - $n = 25$
  - slope = 0.990
  - int'.' = 0.082
  - $Sy.x = 0.013$

- **X: Radiometer ABL 700 System**
  - Y: epoc System
  - $r = 0.992$
  - $n = 32$
  - slope = 0.923
  - int'.' = 0.566
  - $Sy.x = 0.010$

- **X: IL GEM PREMIER 3000 System**
  - Y: epoc System
  - $r = 0.998$
  - $n = 32$
  - slope = 0.923
  - int'.' = 0.566
  - $Sy.x = 0.010$
**pH**

*X:* Nova Biomedical CRITICAL CARE XPRESS System
*Y:* epoc System

\[ r = 0.982 \]

\[ n = 43 \]
\[ \text{slope} = 0.996 \]
\[ \text{int'lt} = -0.004 \]
\[ \text{Sy.x} = 0.017 \]
\[ r = 0.982 \]

---

**pH**

*X:* IRMA TRUPOINT System
*Y:* epoc System

\[ r = 0.993 \]

\[ n = 33 \]
\[ \text{slope} = 1.117 \]
\[ \text{int'lt} = -0.865 \]
\[ \text{Sy.x} = 0.010 \]
\[ r = 0.993 \]
**pCO₂ Method Comparison**

**pCO₂ mmHg**

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>24</td>
<td>67.2</td>
<td>2.30</td>
<td>3.41%</td>
</tr>
<tr>
<td>Level 3</td>
<td>25</td>
<td>20.8</td>
<td>0.68</td>
<td>3.25%</td>
</tr>
</tbody>
</table>

**pCO₂**

- **X:** Abbott I-STAT System  
  **Y:** epoc System

\[r = 0.996\]

- **n:** 41  
  **slope:** 1.058  
  **int.:** -4.60  
  **Sy.x:** 2.03

**pCO₂**

- **X:** RAPIDLab 1265 Blood Gas System by Siemens Healthineers  
  **Y:** epoc System

\[r = 0.999\]

- **n:** 25  
  **slope:** 1.000  
  **int.:** -0.91  
  **Sy.x:** 1.24

**pCO₂**

- **X:** Radiometer ABL 700 System  
  **Y:** epoc System

\[r = 0.995\]

- **n:** 26  
  **slope:** 0.977  
  **int.:** -0.24  
  **Sy.x:** 1.63

**pCO₂**

- **X:** IL GEM PREMIER 3000 System  
  **Y:** epoc System

\[r = 0.995\]

- **n:** 52  
  **slope:** 1.002  
  **int.:** -0.34  
  **Sy.x:** 2.47
$pCO_2$

X: Nova Biomedical CRITICAL CARE XPRESS System
Y: epoc System

$n = 46$
slope = 1.006
int'l. = 2.86
$Sy.x = 2.88$
$r = 0.975$

$pCO_2$

X: IRMA TRUPOINT System
Y: epoc System

$n = 32$
slope = 1.047
int'l. = -2.49
$Sy.x = 1.56$
$r = 0.979$
**pO₂ Method Comparison**

**pO₂ mmHg**

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>24</td>
<td>63.7</td>
<td>4.46</td>
<td>7.00%</td>
</tr>
<tr>
<td>Level 3</td>
<td>25</td>
<td>185.6</td>
<td>6.46</td>
<td>3.48%</td>
</tr>
</tbody>
</table>

- \( pO₂ \) X: Abbott I-STAT System  
  Y: epoc System  
  \( r = 0.997 \)

- \( pO₂ \) X: Radiometer ABL 700 System  
  Y: epoc System  
  \( r = 0.998 \)

- \( pO₂ \) X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers  
  Y: epoc System  
  \( r = 0.987 \)

- \( pO₂ \) X: IL GEM PREMIER 3000 System  
  Y: epoc System  
  \( r = 0.987 \)
**pO₂**

X: Nova Biomedical CRITICAL CARE XPRESS System

Y: epoc System

- \( n = 43 \)
- slope = 0.900
- int'lt. = 11.32
- \( Sy.x = 7.30 \)
- \( r = 0.997 \)

**pO₂**

X: IRMA TRUPOINT System

Y: epoc System

- \( n = 31 \)
- slope = 1.047
- int'lt. = -6.60
- \( Sy.x = 5.13 \)
- \( r = 0.971 \)
**TCO₂ Method Comparison**

**TCO₂ mmol/L**

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
<td>136</td>
<td>18.7</td>
<td>0.23</td>
<td>1.2%</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
<td>132</td>
<td>30.8</td>
<td>0.54</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

**TCO₂**

X: Dimension® EXL Integrated Chemistry System by Siemens Healthineers  
Y: epoc System

\[ r = 0.974 \]

\( n = 65 \)

slope = 1.05  
\( \text{int.} = -0.8 \)  
\( S_y.x = 1.17 \)  
\( r = 0.974 \)

---

**TCO₂**

X: Dimension Vista® Intelligent Lab System by Siemens Healthineers  
Y: epoc System

\[ r = 0.973 \]

\( n = 144 \)

slope = 1.18  
\( \text{int.} = -3.7 \)  
\( S_y.x = 1.0 \)  
\( r = 0.977 \)

---

**TCO₂**

X: Beckman DXC System  
Y: epoc System

\[ r = 0.989 \]

\( n = 40 \)

slope = 1.12  
\( \text{int.} = -2.1 \)  
\( S_y.x = 0.58 \)  
\( r = 0.989 \)

---

**TCO₂**

X: Abbott ARCHITECT System  
Y: epoc System

\[ r = 0.977 \]

\( n = 86 \)

slope = 0.98  
\( \text{int.} = 2.2 \)  
\( S_y.x = 1.17 \)  
\( r = 0.973 \)
TCO₂
X: ROCHE COBAS
Y: epoc System

n = 80
slope = 1.02
int't. = 1.2
Sy.x = 1.04
r = 0.981
Sodium Method Comparison

Sodium mmol/L

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>27</td>
<td>113</td>
<td>0.82</td>
<td>0.73%</td>
</tr>
<tr>
<td>Level 3</td>
<td>27</td>
<td>166</td>
<td>1.07</td>
<td>0.64%</td>
</tr>
</tbody>
</table>

Na⁺
X: Abbott I-STAT System
Y: epoc System

\[ r = 0.982 \]
\[ n = 63 \]
\[ \text{slope} = 0.927 \]
\[ \text{in't.} = 10.19 \]
\[ \text{Sy.x} = 1.82 \]

Na⁺
X: Radiometer ABL 700 System
Y: epoc System

\[ r = 0.919 \]
\[ n = 26 \]
\[ \text{slope} = 1.010 \]
\[ \text{in't.} = -0.01 \]
\[ \text{Sy.x} = 2.55 \]

Na⁺
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System

\[ r = 0.922 \]
\[ n = 26 \]
\[ \text{slope} = 1.057 \]
\[ \text{in't.} = -5.30 \]
\[ \text{Sy.x} = 2.77 \]

Na⁺
X: IL GEM PREMIER 3000 System
Y: epoc System

\[ r = 0.987 \]
\[ n = 58 \]
\[ \text{slope} = 1.000 \]
\[ \text{in't.} = 1.42 \]
\[ \text{Sy.x} = 1.05 \]
**Na**

**X:** Nova Biomedical PHOX System  
**Y:** epoc System

- $r = 0.939$
- $n = 43$
- slope = 0.944
- $\text{int}.' = 8.38$
- $\text{Sy}.x = 2.18$
- $r = 0.939$

**Na**

**X:** Ortho Clinical Laboratories VITROS System  
**Y:** epoc System

- $r = 0.981$
- $n = 35$
- slope = 0.947
- $\text{int}.' = 6.70$
- $\text{Sy}.x = 1.25$
- $r = 0.871$

**Na**

**X:** Beckman Coulter  
**Y:** epoc System

- $n = 25$
- slope = 0.975
- $\text{int}.' = 4.49$
- $\text{Sy}.x = 2.00$
- $r = 0.981$

**Na**

**X:** Dimension Integrated Chemistry System by Siemens Healthineers  
**Y:** epoc System

- $n = 36$
- slope = 1.043
- $\text{int}.' = -4.15$
- $\text{Sy}.x = 0.77$
- $r = 0.994$
Potassium Method Comparison

Potassium mmol/L

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>27</td>
<td>2.1</td>
<td>0.043</td>
<td>2.04%</td>
</tr>
<tr>
<td>Level 3</td>
<td>27</td>
<td>6.3</td>
<td>0.075</td>
<td>1.20%</td>
</tr>
</tbody>
</table>

K⁺

X: Abbott I-STAT System
Y: epoc System

\[
r = 0.997
\]
\[
n = 38
\]
\[
slope = 0.980
\]
\[
int'. = 0.07
\]
\[
Sy.x = 0.099
\]

\[
r = 0.999
\]
\[
n = 31
\]
\[
slope = 0.959
\]
\[
int'. = 0.13
\]
\[
Sy.x = 0.090
\]

K⁺

X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System

\[
r = 0.995
\]
\[
n = 26
\]
\[
slope = 1.019
\]
\[
int'. = -0.08
\]
\[
Sy.x = 0.141
\]

K⁺

X: Radiometer ABL 700 System
Y: epoc System

\[
r = 0.995
\]
\[
n = 26
\]
\[
slope = 1.023
\]
\[
int'. = -0.11
\]
\[
Sy.x = 0.082
\]

K⁺

X: IL GEM PREMIER 3000 System
Y: epoc System

\[
r = 0.995
\]
\[
n = 31
\]
\[
slope = 0.959
\]
\[
int'. = 0.13
\]
\[
Sy.x = 0.090
\]
K+  
X: Nova Biomedical PHOX System  
Y: epoc System  
n = 43  
slope = 1.042  
int’l. = -0.18  
Sy.x = 0.122  
r = 0.995

K+  
X: Beckman Coulter  
Y: epoc System  
n = 26  
slope = 0.991  
int’l. = 0.19  
Sy.x = 0.063  
r = 0.998

K+  
X: Ortho Clinical Laboratories VITROS System  
Y: epoc System  
n = 54  
slope = 0.965  
int’l. = -0.07  
Sy.x = 0.072  
r = 0.985

K+  
X: Dimension Integrated Chemistry System by Siemens Healthineers  
Y: epoc System  
n = 43  
slope = 0.948  
int’l. = 0.13  
Sy.x = 0.101  
r = 0.997
Ionized Calcium Method Comparison

### Ionized Calcium mmol/L

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
<td>26</td>
<td>1.53</td>
<td>0.019</td>
<td>1.25%</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
<td>27</td>
<td>0.67</td>
<td>0.009</td>
<td>1.40%</td>
</tr>
</tbody>
</table>

**Ca++**

X: Abbott I-STAT System  
Y: epoc System

\[
\begin{align*}
& n = 39  \\
& \text{slope} = 0.997  \\
& \text{int'}. = 0.00  \\
& \text{Sy.x} = 0.025  \\
& r = 0.991
\end{align*}
\]

**Ca++**

X: Radiometer ABL 700 System  
Y: epoc System

\[
\begin{align*}
& n = 25  \\
& \text{slope} = 1.004  \\
& \text{int’}. = -0.05  \\
& \text{Sy.x} = 0.035  \\
& r = 0.997
\end{align*}
\]

**Ca++**

X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers  
Y: epoc System

\[
\begin{align*}
& n = 44  \\
& \text{slope} = 1.004  \\
& \text{int’}. = -0.05  \\
& \text{Sy.x} = 0.035  \\
& r = 0.997
\end{align*}
\]

**Ca++**

X: IL GEM PREMIER 3000 System  
Y: epoc System

\[
\begin{align*}
& n = 31  \\
& \text{slope} = 0.979  \\
& \text{int’}. = 0.06  \\
& \text{Sy.x} = 0.027  \\
& r = 0.979
\end{align*}
\]
**Ca**

X: Nova Biomedical PHOX System  
Y: epoc System

- $r = 0.994$
- Slope = 0.986
- Int. = 0.00
- $S_{YX} = 0.039$
- $r = 0.994$
- $n = 43$
Chloride Method Comparison

**Chloride mmol/L**

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level 1</strong></td>
<td>20</td>
<td>76</td>
<td>0.53</td>
<td>0.69%</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
<td>20</td>
<td>125</td>
<td>0.94</td>
<td>0.76%</td>
</tr>
</tbody>
</table>

**Chloride**

X: Abbott I-STAT System  
Y: epoc System

\[ Y_m = 0.989X_m + 0.525 \]

\[ r = 0.995 \]

**Chloride**

X: ADVIA® Clinical Chemistry System by Siemens Healthineers  
Y: epoc System

\[ Y_m = 0.981X_m + 1.084 \]

\[ r = 0.985 \]

**Chloride**

X: ROCHE COBAS 6000 System  
Y: epoc System

\[ Y_m = 0.982X_m + 5.032 \]

\[ r = 0.990 \]

**Chloride**

X: Beckman Coulter DXC System  
Y: epoc System

\[ Y_m = 0.990X_m + 1.611 \]

\[ r = 0.982 \]
Chloride
X: Radiometer ABL 800 System
Y: epoc System

- $n = 56$
- slope = 1.040
- int'l. = -4.866
- $Sy.x = 0.545$
- $r = 0.995$
Hematocrit Method Comparison

<table>
<thead>
<tr>
<th>Hematocrit %PCV</th>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td></td>
<td>26</td>
<td>25</td>
<td>0.56</td>
<td>2.28%</td>
</tr>
<tr>
<td>Level 3</td>
<td></td>
<td>26</td>
<td>44</td>
<td>1.16</td>
<td>2.61%</td>
</tr>
</tbody>
</table>

**Hct**

X: Radiometer ABL 825 System  
Y: epoc System

![](chart1.png)

- \( r = 0.982 \)
- \( n = 38 \)
- slope = 0.996
- int'l. = -0.4
- \( Sy.x = 1.81 \)
- \( r = 0.982 \)

**Hct**

X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers  
Y: epoc System

![](chart2.png)

- \( r = 0.991 \)
- \( n = 23 \)
- slope = 1.051
- int'l. = -4.0
- \( Sy.x = 2.61 \)
- \( r = 0.971 \)

**Hct**

X: Abbott I-STAT System  
Y: epoc System

![](chart3.png)

- \( r = 0.971 \)
- \( n = 29 \)
- slope = 0.944
- int'l. = 2.2
- \( Sy.x = 1.60 \)
- \( r = 0.991 \)

**Hct**

X: IL GEM PREMIER 3000 System  
Y: epoc System

![](chart4.png)

- \( r = 0.920 \)
- \( n = 57 \)
- slope = 1.037
- int'l. = -2.8
- \( Sy.x = 2.83 \)
- \( r = 0.920 \)
**Hct**

**X: Nova Biomedical PHOX System**

**Y: epoc System**

- \( r = 0.986 \)
- \( n = 34 \)
- slope = 1.052
- int' = -3.6
- Sy.x = 1.76
- \( r = 0.986 \)

**Hct**

**X: Beckman Coulter LH System**

**Y: epoc System**

- \( r = 0.971 \)
- \( n = 29 \)
- slope = 1.067
- int' = -0.3
- Sy.x = 1.86
- \( r = 0.971 \)

**Hct**

**X: Sysmex XE System**

**Y: epoc System**

- \( r = 0.970 \)
- \( n = 18 \)
- slope = 0.983
- int' = -0.4
- Sy.x = 1.96
- \( r = 0.970 \)

**Hct**

**X: Microcentrifugation (spun)**

**Y: epoc System**

- \( r = 0.970 \)
- \( n = 63 \)
- slope = 0.963
- int' = 0.9
- Sy.x = 2.01
- \( r = 0.970 \)
Glucose Method Comparison

<table>
<thead>
<tr>
<th>Glucose mg/dL</th>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td></td>
<td>27</td>
<td>41.9</td>
<td>1.24</td>
<td>2.96%</td>
</tr>
<tr>
<td>Level 3</td>
<td></td>
<td>27</td>
<td>278</td>
<td>6.84</td>
<td>2.46%</td>
</tr>
</tbody>
</table>

**Glucose**

X: Abbott I-STAT System  
Y: epoc System

- n = 41  
- slope = 1.015  
- int’l. = 1.8  
- Sy.x = 5.59  
- r = 0.999

**Glucose**

X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers  
Y: epoc System

- n = 22  
- slope = 1.052  
- int’l. = 4.0  
- Sy.x = 15.75  
- r = 0.990

**Glucose**

X: Radiometer ABL 700 System  
Y: epoc System

- n = 24  
- slope = 1.048  
- int’l. = 1.7  
- Sy.x = 5.69  
- r = 0.995

**Glucose**

X: IL GEM PREMIER 3000 System  
Y: epoc System

- n = 31  
- slope = 1.042  
- int’l. = 11.9  
- Sy.x = 11.07  
- r = 0.989
Glucose
X: Nova Biomedical CRITICAL CARE XPRESS System
Y: epoc System

- $n = 44$
- Slope = 1.021
- Intercept = -4.7
- $r = 0.994$

Glucose
X: Beckman Coulter DXC System
Y: epoc System

- $n = 24$
- Slope = 1.057
- Intercept = -10.5
- $r = 0.996$

Glucose
X: Ortho Clinical Laboratories VITROS System
Y: epoc System

- $n = 41$
- Slope = 1.018
- Intercept = 0.8
- $r = 0.998$

Glucose
X: Dimension Integrated Chemistry System by Siemens Healthineers
Y: epoc System

- $n = 43$
- Slope = 1.016
- Intercept = -2.7
- $r = 0.997$
Lactate Method Comparison

<table>
<thead>
<tr>
<th>Lactate mmol/L</th>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td></td>
<td>27</td>
<td>0.97</td>
<td>0.045</td>
<td>4.67%</td>
</tr>
<tr>
<td>Level 3</td>
<td></td>
<td>28</td>
<td>5.96</td>
<td>0.225</td>
<td>3.77%</td>
</tr>
</tbody>
</table>

Lactate
X: Abbott I-STAT System
Y: epoc System

Lactate
X: Radiometer ABL 700 System
Y: epoc System

Lactate
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System

Lactate
X: IL GEM PREMIER 4000 System
Y: epoc System
Lactate
X: Ortho Clinical Laboratories VITROS System
Y: epoc System

n = 42
slope = 0.938
int'l. = 0.155
Sy.x = 0.398
r = 0.989

Lactate
X: Dimension Integrated Chemistry System by Siemens Healthineers
Y: epoc System

n = 20
slope = 0.987
int'l. = -0.033
Sy.x = 0.120
r = 0.999

Lactate
X: Roche MODULAR System
Y: epoc System

n = 48
slope = 1.039
int'l. = -0.067
Sy.x = 0.264
r = 0.996
## BUN Method Comparison

### BUN mg/dL

<table>
<thead>
<tr>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>137</td>
<td>49.9</td>
<td>1.12</td>
<td>2.2%</td>
</tr>
<tr>
<td>Level 3</td>
<td>132</td>
<td>4.9</td>
<td>0.13</td>
<td>2.7%</td>
</tr>
</tbody>
</table>

### BUN

- **X:** Dimension Integrated Chemistry System by Siemens Healthineers
- **Y:** epoc System
- \( n = 64 \)
- \( \text{slope} = 0.93 \)
- \( \text{int'} = 0.3 \)
- \( \text{Sy.x} = 1.0 \)
- \( r = 0.999 \)

### BUN

- **X:** Dimension Vista Intelligent Lab System by Siemens Healthineers
- **Y:** epoc System
- \( n = 146 \)
- \( \text{slope} = 0.95 \)
- \( \text{int'} = 0.2 \)
- \( \text{Sy.x} = 1.6 \)
- \( r = 0.997 \)

### BUN

- **X:** Beckman DXC System
- **Y:** epoc System
- \( n = 39 \)
- \( \text{slope} = 0.95 \)
- \( \text{int'} = 1.3 \)
- \( \text{Sy.x} = 0.7 \)
- \( r = 0.999 \)

### BUN

- **X:** Abbott ARCHITECT System
- **Y:** epoc System
- \( n = 86 \)
- \( \text{slope} = 0.93 \)
- \( \text{int'} = 0.7 \)
- \( \text{Sy.x} = 0.7 \)
- \( r = 0.997 \)
BUN
X: ROCHE COBAS
Y: epoc System

n = 121
slope = 1.00
inf't. = 0.2
Sy.x = 1.8
r = 0.996
Creatinine Method Comparison

<table>
<thead>
<tr>
<th>Creatinine mg/dL</th>
<th>Precision</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>20</td>
<td>0.91</td>
<td>0.045</td>
<td>4.93%</td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>20</td>
<td>4.54</td>
<td>0.191</td>
<td>4.21%</td>
<td></td>
</tr>
</tbody>
</table>

Creatinine

X: ADVIA Clinical Chemistry System by Siemens Healthineers
Y: epoc System

n = 53
slope = 1.063
int'. = -0.115
Sy.x = 0.207
r = 0.998

Creatinine

X: Beckman Coulter AU680 System
Y: epoc System

n = 63
slope = 0.955
int'. = 0.008
Sy.x = 0.166
r = 0.999

Creatinine

X: Abbott I-STAT System
Y: epoc System

n = 63
slope = 1.028
int'. = 0.075
Sy.x = 0.147
r = 0.999

Creatinine

X: ROCHE COBAS 6000 System
Y: epoc System

n = 50
slope = 1.069
int'. = -0.089
Sy.x = 0.201
r = 0.996
Notes
At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 170 years of experience and 18,000 patents globally. With more than 48,000 dedicated colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

Method comparison studies were performed at three sites.