Summary of Analytical Methods and Performance

The epoc® Blood Analysis System

Data Compilation provided by Alere
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The epoc® Blood Analysis System is a portable blood analyzer comprised of 3 components:

**epoc® Reader**
- Is a battery-powered portable device
- Has an internal barcode scanner
- Has a card slot for accepting Test Cards
- Reads epoc® Test Cards during blood tests
- Has status indicators to inform user of test progress
- Measures electrical signals from Test Card sensors
- Transmits test results wirelessly via Bluetooth to the epoc® Host

**epoc® Host**
- Is a dedicated-use mobile computer with the epoc® Host software application installed
- Communicates wirelessly via Bluetooth with epoc® Reader
- Calculates analytical values from sensor data sent by epoc® Reader
- Displays test results

**epoc® Test Card**
- Is a single-use device with port for blood sample introduction
- Contains an array of sensors on a Sensor Module
- Contains calibration fluid within a sealed reservoir
- Generates electrical signals proportional to analyte concentrations in sample
- Uses a barcode to identify card type, “Use By” date, serial and lot numbers

### 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 at 10 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 a single site 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 or how closely multiple results analyzed on 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’l)** or y-intercept describes where the line of best fit intersects the y-axis. Ideally, the y-intercept should be 0.0. Deviations are an indication of constant systematic error.\(^1\)

\[ S_{y.x} \] 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 effect that vary from one sample to another. \( S_{y.x} \) will never be 0 because both methods have some imprecision.\(^1\)

\[ r \] or correlation coefficient describes how well the results between the two methods change together. The lower the \( r \) values, 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.\(^1\)

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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.

**pCO₂** 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.

**pO₂** is measured by amperometry using a membrane covered oxygen sensing cathode electrode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

**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.
**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,

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

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-sulfonic acid) diammonium salt), horseradish peroxidase (HRP) catalyzed, reduction on a gold electrode.

\[
H_2O_2 + HRP^{red} \rightarrow HRP^{ox}
\]

\[
HRP^{ox} + \text{Red} \rightarrow \text{Ox} + HRP^{red}
\]

\[
\text{Ox} + e^- \rightarrow \text{Red}
\]

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,

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

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.

\[
H_2O_2 + HRP^{red} \rightarrow HRP^{ox}
\]

\[
HRP^{ox} + \text{Red} \rightarrow \text{Ox} + HRP^{red}
\]

\[
\text{Ox} + e^- \rightarrow \text{Red}
\]

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

**Hematocrit** is measured by ac conductometry using two (2) gold electrodes. The conductance of the blood sample in the fluidic path between the two (2) electrodes, after correction for variable plasma conductivity through the measurement of sodium concentration, is inversely proportional to the hematocrit value.
**pH Method Comparison**

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

**Abbott i-STAT® vs. epoc®**

- X: Abbott i-STAT®
- Y: epoc®

**Radiometer ABL® 700 vs. epoc®**

- X: Radiometer ABL® 700
- Y: epoc®
X: Siemens RAPIDLab® 1265
Y: epoc®

\[
r = 0.998
\]
\[
n = 25
\]
\[
slope = 0.990
\]
\[
int't. = 0.082
\]
\[
Sy.x = 0.013
\]
\[
r = 0.992
\]
\[
n = 32
\]
\[
slope = 0.923
\]
\[
int't. = 0.566
\]
\[
Sy.x = 0.010
\]
\[
r = 0.992
\]
pH Method Comparison ...continued

X: Nova® CCX
Y: epoc®

\[
\begin{array}{c|c|c|c|c|c|c}
\text{pH} & 6.4 & 6.7 & 7.0 & 7.3 & 7.6 & 7.9 & 8.2 \\
\hline
Y_m (TEST) & n = 43 & \text{slope} = 0.996 & \text{int'} t. = -0.004 & Sy.x = 0.017 & r = 0.982 \\
\end{array}
\]

X: IRMA TRUpoint®
Y: epoc®

\[
\begin{array}{c|c|c|c|c|c|c}
\text{pH} & 6.4 & 6.7 & 7.0 & 7.3 & 7.6 & 7.9 & 8.2 \\
\hline
Y_m (TEST) & n = 33 & \text{slope} = 1.117 & \text{int'} t. = -0.865 & Sy.x = 0.010 & r = 0.993 \\
\end{array}
\]
pCO₂ Method Comparison

**Precision**: Table showing precision data for different levels:

<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>

**Graphical Comparison**:

- **Graph 1**: X: Abbott i-STAT®, Y: epoc®
  - Equation: $Y_m = \text{COMPARATIVE}$
  - Data points: $n = 41$, $\text{slope} = 1.058$, $\text{int}'t. = -4.60$, $\text{Sy}.x = 2.03$, $r = 0.996$

- **Graph 2**: X: Radiometer ABL® 700, Y: epoc®
  - Equation: $Y_m = \text{COMPARATIVE}$
  - Data points: $n = 26$, $\text{slope} = 0.977$, $\text{int}'t. = -0.24$, $\text{Sy}.x = 1.63$, $r = 0.995$
pCO₂ Method Comparison  ...continued

X: Siemens RAPIDLab® 1265
Y: epoc®

n = 25
slope = 1.000
int t. = -0.91
Sy.x = 1.24
r = 0.999

X: IL Gem 3000
Y: epoc®

n = 52
slope = 1.002
int’t. = -0.34
Sy.x = 2.47
r = 0.995
**pCO₂ Method Comparison**  ...continued

**X:** Nova® CCX  
**Y:** epoc®

![Graph](image1.png)

- \( n = 46 \)
- \( \text{slope} = 1.006 \)
- \( \text{int'}t. = 2.86 \)
- \( \text{Sy.x} = 2.88 \)
- \( r = 0.975 \)

**X:** IRMA TRUpoint®  
**Y:** epoc®

![Graph](image2.png)

- \( n = 32 \)
- \( \text{slope} = 1.047 \)
- \( \text{int'}t. = -2.49 \)
- \( \text{Sy.x} = 1.56 \)
- \( r = 0.979 \)
**pO₂ Method Comparison**

X: Abbott i-STAT®
Y: epoc®

*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>

### Precision

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

#### Example Graph

- **X**: Radiometer ABL® 715
- **Y**: epoc®

- **Equation Details**:
  - \( n = 42 \)
  - Slope: 0.949
  - Intercept: 7.86
  - Standard error of the x-variable: 4.78
  - Correlation coefficient: 0.997

- **Graph Details**:
  - Range: 0 to 450
  - Axes: \( X_m \) (COMPARATIVE) vs. \( Y_m \) (TEST)

- **Example Data**:
  - \( pO₂ \) values
  - 42 data points

#### Another Example Graph

- **X**: Radiometer ABL® 715
- **Y**: epoc®

- **Equation Details**:
  - \( n = 51 \)
  - Slope: 0.919
  - Intercept: 9.01
  - Standard error of the x-variable: 5.80
  - Correlation coefficient: 0.995

- **Graph Details**:
  - Range: 0 to 450
  - Axes: \( X_m \) (COMPARATIVE) vs. \( Y_m \) (TEST)

- **Example Data**:
  - \( pO₂ \) values
  - 51 data points
**pO₂ Method Comparison**  …continued

**X:** Siemens RAPIDLab® 1265  
**Y:** epoc®

\[ \text{n} = 24 \]  
\[ \text{slope} = 1.018 \]  
\[ \text{int'} = 3.64 \]  
\[ \text{Sy.x} = 4.04 \]  
\[ r = 0.998 \]

---

**X:** IL Gem 3000  
**Y:** epoc®

\[ \text{n} = 32 \]  
\[ \text{slope} = 0.947 \]  
\[ \text{int'} = 14.20 \]  
\[ \text{Sy.x} = 8.50 \]  
\[ r = 0.987 \]
**pO\textsubscript{2} Method Comparison**  
...continued

**X: Nova\textsuperscript{®} CCX**  
**Y: epoc\textsuperscript{®}**

![Graph](image1)

- \(n = 43\)
- Slope = 0.900
- Int’l. = 11.32
- Sy.x = 7.30
- \(r = 0.997\)

**X: IRMA TRUpoint\textsuperscript{®}**  
**Y: epoc\textsuperscript{®}**

![Graph](image2)

- \(n = 31\)
- Slope = 1.047
- Int’l. = -6.60
- Sy.x = 5.13
- \(r = 0.971\)
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>

**X:** Abbott i-STAT®
**Y:** epoc®

![Graph](image1)

- n = 63
- slope = 0.927
- int’l. = 10.19
- Sy.x = 1.82
- r = 0.982

**X:** Radiometer ABL® 700
**Y:** epoc®

![Graph](image2)

- n = 26
- slope = 1.010
- int’l. = -0.01
- Sy.x = 2.55
- r = 0.987
Sodium Method Comparison

X: Siemens RAPIDLab® 1265
Y: epoc®

Na+

\[ n = 26 \]
\[ \text{slope} = 1.057 \]
\[ \text{int’l.} = -5.30 \]
\[ \text{Sy.x} = 2.77 \]
\[ r = 0.922 \]

X: IL Gem 3000
Y: epoc®

Na+

\[ n = 58 \]
\[ \text{slope} = 1.000 \]
\[ \text{int’l.} = 1.42 \]
\[ \text{Sy.x} = 1.05 \]
\[ r = 0.919 \]
Sodium Method Comparison ...continued

X: Nova® pHox
Y: epoc®

\[
\begin{align*}
\text{Na}^+ \\
\text{Xm (COMPARATIVE)}
\end{align*}
\]

\[
\begin{array}{c}
Y_m \text{ (TEST)} \\
80 \\
100 \\
120 \\
140 \\
160 \\
180 \\
200 \\
80 \\
100 \\
120 \\
140 \\
160 \\
180 \\
200 \\
\end{array}
\]

- \( n = 43 \)
- slope = 0.944
- int’l. = 8.38
- Sy.x = 2.18
- \( r = 0.939 \)

X: Beckman Coulter®
Y: epoc®

\[
\begin{align*}
\text{Na}^+ \\
\text{Xm (COMPARATIVE)}
\end{align*}
\]

\[
\begin{array}{c}
Y_m \text{ (TEST)} \\
80 \\
100 \\
120 \\
140 \\
160 \\
180 \\
200 \\
80 \\
100 \\
120 \\
140 \\
160 \\
180 \\
200 \\
\end{array}
\]

- \( n = 25 \)
- slope = 0.975
- int’l. = 4.49
- Sy.x = 2.00
- \( r = 0.981 \)
Sodium Method Comparison …continued

X: Ortho Vitros®
Y: epoc®

X: Siemens Dimension®
Y: epoc®

n = 35
slope = 0.947
int’t. = 6.70
Sy.x = 1.25
r = 0.871

n = 36
slope = 1.043
int’t. = -4.15
Sy.x = 0.77
r = 0.994
Potassium Method Comparison

<table>
<thead>
<tr>
<th>Potassium mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision</td>
</tr>
<tr>
<td>Level 1</td>
</tr>
<tr>
<td>Level 3</td>
</tr>
</tbody>
</table>

**Potassium Method Comparison**

X: Abbott i-STAT®
Y: epoc®

- **n = 38**
- **slope = 0.980**
- **int’t. = 0.07**
- **Sy.x = 0.099**
- **r = 0.997**

X: Radiometer ABL® 700
Y: epoc®

- **n = 26**
- **slope = 1.023**
- **int’t. = -0.11**
- **Sy.x = 0.082**
- **r = 0.999**
Potassium Method Comparison …continued

X: Siemens RAPIDLab® 1265
Y: epoc®

\[ Y_m \text{ (TEST)} = 1.019 X_m \text{ (COMPARATIVE)} - 0.08 \]

\[ n = 26 \]
\[ \text{slope} = 1.019 \]
\[ \text{int’l.} = -0.08 \]
\[ \text{Sy.x} = 0.141 \]
\[ r = 0.995 \]

X: IL Gem 3000
Y: epoc®

\[ Y_m \text{ (TEST)} = 0.959 X_m \text{ (COMPARATIVE)} + 0.13 \]

\[ n = 31 \]
\[ \text{slope} = 0.959 \]
\[ \text{int’l.} = 0.13 \]
\[ \text{Sy.x} = 0.090 \]
\[ r = 0.995 \]
Potassium Method Comparison  ...continued

X: Nova® pHOx
Y: epoc®

Yₘ (TEST)
Xₘ (COMPARATIVE)

K+
n = 43
slope = 1.042
int’t. = -0.18
Sy.x = 0.122
r = 0.995

X: Beckman Coulter®
Y: epoc®

Yₘ (TEST)
Xₘ (COMPARATIVE)

K+
n = 26
slope = 0.991
int’t. = 0.19
Sy.x = 0.063
r = 0.998
Potassium Method Comparison  ...continued

X: Ortho Vitros®
Y: epoc®

X: Siemens Dimension®
Y: epoc®

**Graph 1:**
- Equation: \( Y_m = 0.965X_m - 0.07 \)
- \( n = 54 \)
- \( r = 0.985 \)
- \( Sy.x = 0.072 \)

**Graph 2:**
- Equation: \( Y_m = 0.948X_m + 0.13 \)
- \( n = 43 \)
- \( r = 0.997 \)
- \( Sy.x = 0.101 \)
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>Level 1</td>
<td>26</td>
<td>1.53</td>
<td>0.019</td>
<td>1.25%</td>
</tr>
<tr>
<td>Level 3</td>
<td>27</td>
<td>0.67</td>
<td>0.009</td>
<td>1.40%</td>
</tr>
</tbody>
</table>

**X:** Abbott i-STAT®

**Y:** epoc®

---

**X:** Radiometer ABL® 700

**Y:** epoc®

---

**Graph 1:**
- Ym (TEST)
- Xm (COMPARATIVE)
- Ca++
- n = 39
- slope = 0.997
- int’t. = 0.00
- Sy.x = 0.025
- r = 0.991

**Graph 2:**
- Ym (TEST)
- Xm (COMPARATIVE)
- Ca++
- n = 25
- slope = 1.004
- int’t. = -0.05
- Sy.x = 0.035
- r = 0.997
Ionized Calcium Method Comparison

X: Siemens RAPIDLab® 1265
Y: epoc®

\[ Y_m (TEST) \]
\[ X_m (COMPARATIVE) \]

<table>
<thead>
<tr>
<th>n</th>
<th>slope</th>
<th>int’t.</th>
<th>Sy.x</th>
<th>r</th>
</tr>
</thead>
<tbody>
<tr>
<td>44</td>
<td>0.960</td>
<td>0.04</td>
<td>0.047</td>
<td>0.969</td>
</tr>
</tbody>
</table>

X: IL Gem 3000
Y: epoc®

\[ Y_m (TEST) \]
\[ X_m (COMPARATIVE) \]

<table>
<thead>
<tr>
<th>n</th>
<th>slope</th>
<th>int’t.</th>
<th>Sy.x</th>
<th>r</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>0.979</td>
<td>0.06</td>
<td>0.027</td>
<td>0.979</td>
</tr>
</tbody>
</table>
Ionized Calcium Method Comparison  ...continued

X: Nova® pHOx
Y: epoc®

Ca++

$Y_m = 0.986X_m + 0.00$

$n = 43$
slope = 0.986
int’t. = 0.00
Sy.x = 0.039
$r = 0.994$
Glucose Method Comparison

**X**: Abbott i-STAT®
**Y**: epoc®

**X**: Radiometer ABL® 700
**Y**: epoc®

### Glucose 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>27</td>
<td>41.9</td>
<td>1.24</td>
<td>2.96%</td>
</tr>
<tr>
<td>Level 3</td>
<td>27</td>
<td>278</td>
<td>6.84</td>
<td>2.46%</td>
</tr>
</tbody>
</table>

**Glucose Method Comparison**

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

- **n = 24**
- slope = 1.048
- int’. = -1.7
- Sy.x = 5.49
- r = 0.995
Glucose Method Comparison

X: Siemens RAPIDLab® 1265
Y: epoc®

n = 22
slope = 1.052
int't. = 4.0
Sy.x = 15.75
r = 0.990

X: IL Gem 3000
Y: epoc®

n = 31
slope = 1.042
int't. = 11.9
Sy.x = 11.07
r = 0.989
Glucose Method Comparison

X: Nova CCX
Y: epoc®

- $n = 44$
- slope = 1.021
- int’l. = -4.7
- $Sy.x = 6.43$
- $r = 0.994$

X: Beckman Coulter DxC®
Y: epoc®

- $n = 24$
- slope = 1.057
- int’l. = -10.5
- $Sy.x = 7.71$
- $r = 0.996$
Glucose Method Comparison ...continued

**Graph 1:**
- X: Ortho Vitros®
- Y: epoc®
- n = 41
- slope = 1.018
- int't. = 0.8
- Sy.x = 6.82
- r = 0.998

**Graph 2:**
- X: Siemens Dimension®
- Y: epoc®
- n = 43
- slope = 1.016
- int't. = -2.7
- Sy.x = 7.49
- r = 0.997
Lactate Method Comparison

X: Abbott i-STAT®
Y: epoc®

Lactate 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>0.97</td>
<td>0.045</td>
<td>4.67%</td>
</tr>
<tr>
<td>Level 3</td>
<td>28</td>
<td>5.96</td>
<td>0.225</td>
<td>3.77%</td>
</tr>
</tbody>
</table>

Lactate

X: Radiometer ABL® 700 series
Y: epoc®

Lactate

n = 36
slope = 0.998
int’l. = 0.113
Sy.x = 0.480
r = 0.996

Lactate

n = 51
slope = 1.011
int’l. = 0.101
Sy.x = 0.258
r = 0.995
Lactate Method Comparison ...continued

X: Siemens RAPIDLab® 1265
Y: epoc®

Ym (TEST) vs Xm (COMPARATIVE)

n = 23
slope = 1.019
int't. = -0.207
Sy.x = 0.132
r = 0.999

X: IL Gem 4000
Y: epoc®

Ym (TEST) vs Xm (COMPARATIVE)

n = 46
slope = 1.025
int't. = 0.130
Sy.x = 0.564
r = 0.993
Lactate Method Comparison

X: Siemens Dimension®
Y: epoc®

Lactate

\[
\begin{align*}
Y_m \text{ (TEST)} &= 0.938X_m \text{ (COMPARATIVE)} + 0.155 \\
&\quad \text{for } n = 42 \\
\text{Slope} &= 0.938 \\
\text{Intercept} &= 0.155 \\
\text{Sy}.x &= 0.398 \\
\text{r} &= 0.989
\end{align*}
\]

X: Ortho Vitros®
Y: epoc®

Lactate

\[
\begin{align*}
Y_m \text{ (TEST)} &= 0.987X_m \text{ (COMPARATIVE)} - 0.033 \\
&\quad \text{for } n = 20 \\
\text{Slope} &= 0.987 \\
\text{Intercept} &= -0.033 \\
\text{Sy}.x &= 0.120 \\
\text{r} &= 0.999
\end{align*}
\]
Lactate Method Comparison  …continued

X: Roche Modular®  
Y: epoc®

Lactate

\[ Y_m = 1.039X_m - 0.067 \]

- \( n = 48 \)
- \( \text{slope} = 1.039 \)
- \( \text{int’l.} = -0.067 \)
- \( Sy.x = 0.264 \)
- \( r = 0.996 \)
Hematocrit Method Comparison

Hematocrit %PCV

<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>26</td>
<td>25</td>
<td>0.56</td>
<td>2.28%</td>
</tr>
<tr>
<td>Level 3</td>
<td>26</td>
<td>44</td>
<td>1.16</td>
<td>2.61%</td>
</tr>
</tbody>
</table>

**Radiometer ABL® 825 vs. epoc®**

- n = 29
- slope = 0.944
- int’l. = 2.2
- Sy.x = 1.40
- r = 0.991

**Abbott i-STAT® vs. epoc®**

- n = 38
- slope = 0.996
- int’l. = -0.4
- Sy.x = 1.81
- r = 0.982
Hematocrit Method Comparison …continued

X: Siemens RAPIDLab® 1265
Y: epoc®

![Graph 1]

- n = 23
- slope = 1.051
- int't. = -4.0
- Sy.x = 2.61
- r = 0.971

X: IL Gem 3000
Y: epoc®

![Graph 2]

- n = 57
- slope = 1.037
- int't. = -2.8
- Sy.x = 2.83
- r = 0.920
Hematocrit Method Comparison

---

X: Nova® pH Ox
Y: epoc®

---

X: Beckman Coulter® LH
Y: epoc®

---

n = 34
slope = 1.052
int’. = -3.6
Sy.x = 1.76
r = 0.986

---

n = 29
slope = 1.067
int’. = -0.3
Sy.x = 1.86
r = 0.984
Hematocrit Method Comparison …continued

X: Sysmex® XE
Y: epoc®

n = 18
slope = 0.983
int.t. = -0.4
Sy.x = 1.96
r = 0.971

X: microcentrifugation (spun)
Y: epoc®

n = 63
slope = 0.963
int.t. = 0.9
Sy.x = 2.01
r = 0.970
Notes: