

epoc Blood Analysis System with NXS Host Summary of Analytical Methods and Performance

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epoc Blood Analysis System with NXS Host 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.

 ${f x}$ 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.

pCO₂ is measured by potentiometry using a membranecovered 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 membranecovered oxygen-sensing cathode electrode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

TCO₂ is measured based on a modified Henderson-Hasselbalch equation, using pH and $pCO_{2'}^2$ and calibrated to match the International Federation of Clinical Chemistry (IFCC) Reference Measurement Procedure for Total Carbon Dioxide.³ Therefore, it is metrologically traceable to the IFCC TCO₂ reference method.^{2,3}

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:

Glucose Oxidase β-D-glucose + O, + H,O ──► D-gluconic acid + H,O,

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.

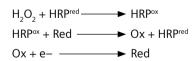
$$\begin{array}{c} H_2O_2 + HRP^{red} \longrightarrow HRP^{ox} \\ HRP^{ox} + Red \longrightarrow Ox + HRP^{red} \\ Ox + e^- \longrightarrow Red \end{array}$$

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:

Lactate
Oxidase
$$\beta$$
-D-lactate + O₂ + H₂O \longrightarrow Pyruvic acid + H₂O₂

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.



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:

 $Urea + H_2O + 2H^+ + Urease -> 2NH_4^+ + CO_2$

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:

Creatinine Amidohydrolase Creatinine + H₂O ◀ ← Creatine

Sarcosine Oxidase

Sarcosine +
$$O_2$$
 + H_2O \longrightarrow Glycine + 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.

$$H_2O_2 + HRP^{red} \longleftarrow HRP^{ox}$$

$$H_2O_2 + HRP^{ox} + Red \longleftarrow HRP^{red} + Ox$$

$$Ox + e^- \longleftarrow Red$$

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

References:

- 1. Westgard JO. Basic method evaluation. 3rd ed. Madison, WI (USA): Westgard QC, Inc.; 2008 p. 77–78.
- 2. Maas AH, Rispens P, Siggaard-Andersen O, Zijlistra WG. On the reliability of Henderson-Hasselbalch equation in routine clinical acid-base chemistry. Ann Clin Biochem. 1984;21:26-39.
- 3. International Federation of Clinical Chemistry and Laboratory Medicine. IFCC reference measurement procedure for substance concentration determination of total carbon dioxide in blood, plasma or serum. Clin Chem Lab Med. 2001;39(3).

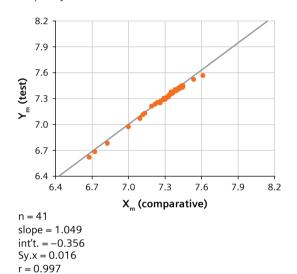


pH Method Comparison

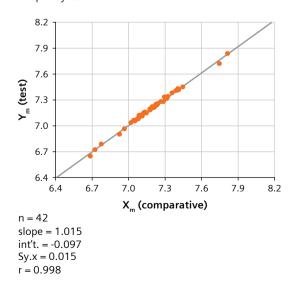
		рН		
Precision	n	Mean	SD	%CV
Level 1	24	7.052	0.009	0.13%
Level 3	25	7.646	0.007	0.09%

pН

X: Abbott I-STAT System Y: epoc System

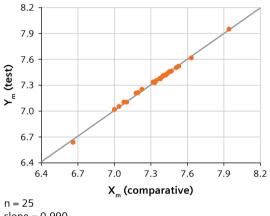


pH X: Radiometer ABL 700 System Y: epoc System



рΗ

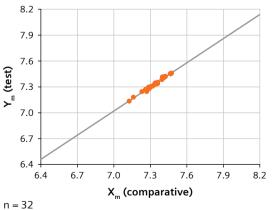
X: RAPIDLab® 1265 Blood Gas System by Siemens Healthineers Y: epoc System



slope = 0.990 int't. = 0.082 Sy.x = 0.013 r = 0.998



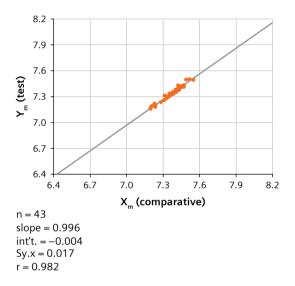
X: GEM PREMIER 3000 System Y: epoc System



slope = 0.923int't. = 0.566Sy.x = 0.010r = 0.992

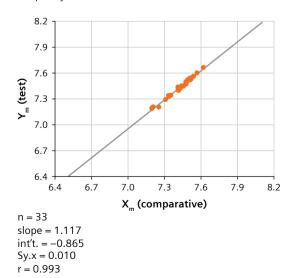


pH X: Nova Biomedical CRITICAL CARE XPRESS System Y: epoc System





X: IRMA TRUPOINT System Y: epoc System

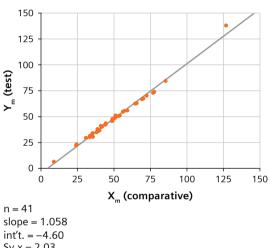




pCO₂ Method Comparison

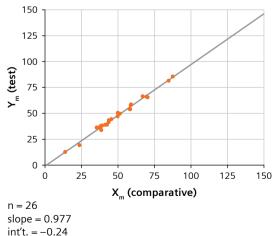
pCO₂ mmHg				
Precision	n	Mean	SD	%CV
Level 1	24	67.2	2.30	3.41%
Level 3	25	20.8	0.68	3.25%

 pCO_2 X: Abbott I-STAT System Y: epoc System



Sy.x = 2.03 r = 0.996

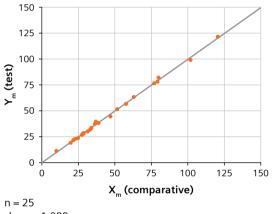
pCO₂ X: Radiometer ABL 700 System Y: epoc System



int't. = -0.24Sy.x = 1.63r = 0.995

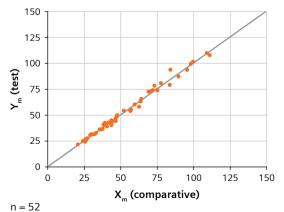
pCO₂

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



slope = 1.000 int't. = -0.91 Sy.x = 1.24 r = 0.999

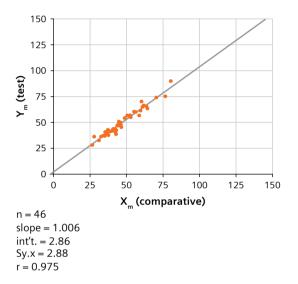
pCO₂ X: IL GEM PREMIER 3000 System Y: epoc System



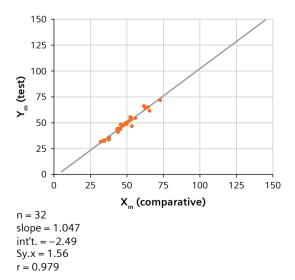
slope = 1.002 int't. = -0.34Sy.x = 2.47r = 0.995



pCO₂ X: Nova Biomedical CRITICAL CARE XPRESS System Y: epoc System



pCO2 X: IRMA TRUPOINT System Y: epoc System

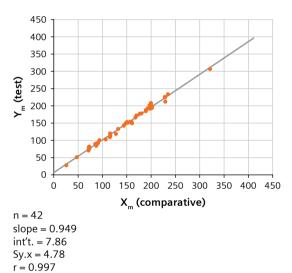




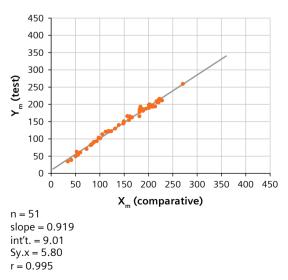
pO₂ Method Comparison

<i>p</i> O₂ mmHg				
Precision	n	Mean	SD	%CV
Level 1	24	63.7	4.46	7.00%
Level 3	25	185.6	6.46	3.48%

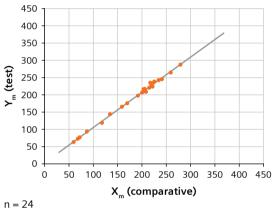
ρO₂ X: Abbott I-STAT System Y: epoc System



pO₂ X: Radiometer ABL 700 System Y: epoc System

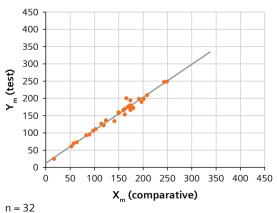


pO₂ X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers Y: epoc System



slope = 1.018 int't. = 3.64 Sy.x = 4.04 r = 0.998

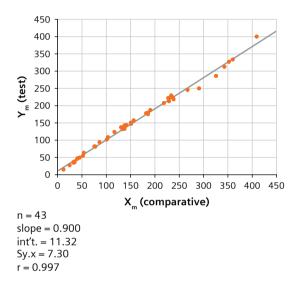
pO₂ X: IL GEM PREMIER 3000 System Y: epoc System

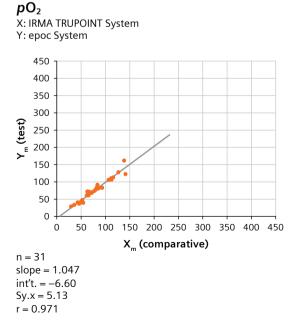


slope = 0.947 int't. = 14.20 Sy.x = 8.50 r = 0.987



ρO₂ X: Nova Biomedical CRITICAL CARE XPRESS System Y: epoc System





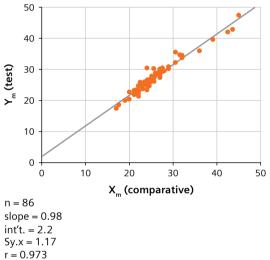


TCO₂ Method Comparison

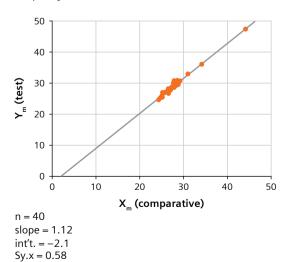
TCO ₂ mmol/L				
Precision	n	Mean	SD	%CV
Level 1	136	18.7	0.23	1.2%
Level 3	132	30.8	0.54	1.7%



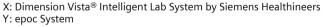


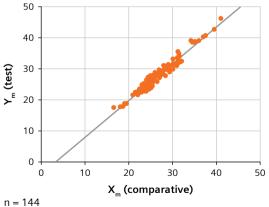


TCO₂ X: Beckman Coulter DxC System Y: epoc System





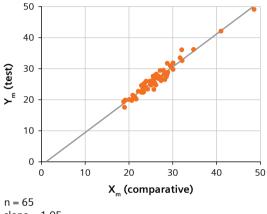




slope = 1.18int't. = -3.7Sy.x = 1.0r = 0.977

TCO₂

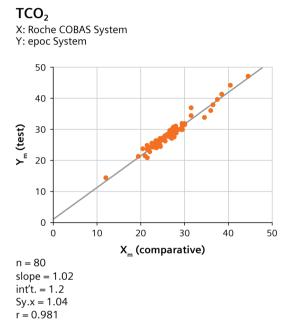
X: Dimension[®] EXL[™] Integrated Chemistry System by Siemens Healthineers Y: epoc System



slope = 1.05int't. = -0.8Sy.x = 1.17 r = 0.974

r = 0.989



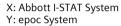


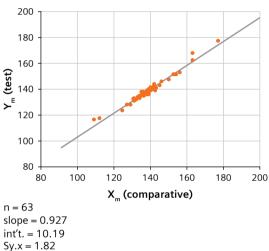


Sodium Method Comparison

Sodium mmol/L				
Precision n Mean SD %CV				
Level 1	27	113	0.82	0.73%
Level 3	27	166	1.07	0.64%

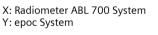
Na⁺

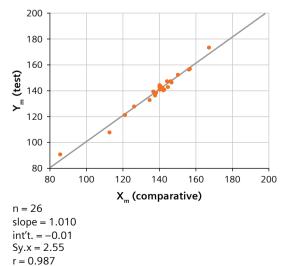




Na⁺

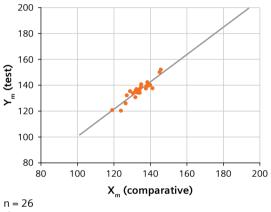
r = 0.982





Na⁺

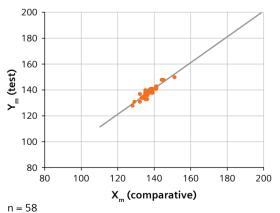
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers Y: epoc System



slope = 1.057 int't. = -5.30 Sy.x = 2.77r = 0.922



X: IL GEM PREMIER 3000 System Y: epoc System

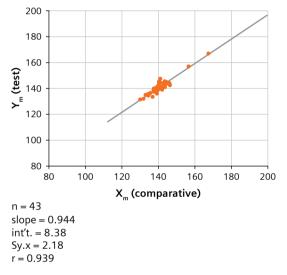


slope = 1.000 int't. = 1.42 Sy.x = 1.05 r = 0.919

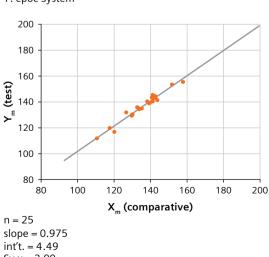


Na⁺ X: Nova Biomedical PHOX System

Y: epoc System



Na⁺

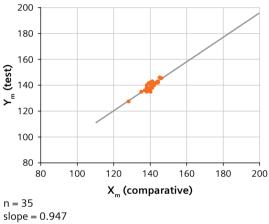


X: Beckman Coulter DxC System Y: epoc System

int't. = 4.49 Sy.x = 2.00 r = 0.981

Na⁺

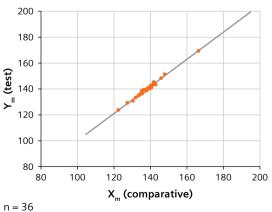
X: Ortho Clinical Laboratories VITROS System Y: epoc System



int't. = 6.70 Sy.x = 1.25r = 0.871

Na⁺

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



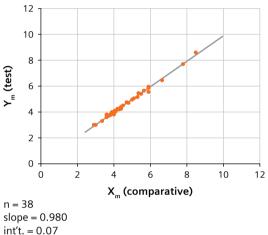
slope = 1.043 int't. = -4.15 Sy.x = 0.77 r = 0.994



Potassium Method Comparison

Potassium mmol/L				
Precision	n	Mean	SD	%CV
Level 1	27	2.1	0.043	2.04%
Level 3	27	6.3	0.075	1.20%

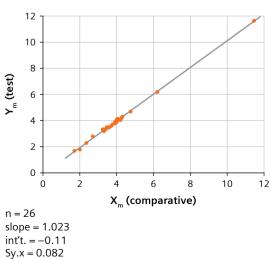




int't. = 0.07 Sy.x = 0.099r = 0.997



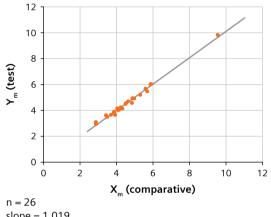
X: Radiometer ABL 700 System Y: epoc System



r = 0.999

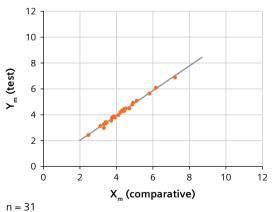
K⁺

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



slope = 1.019 int't. = -0.08Sy.x = 0.141r = 0.995

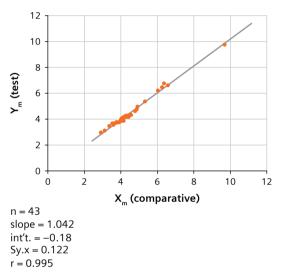
K⁺ X: IL GEM PREMIER 3000 System Y: epoc System



slope = 0.959 int't. = 0.13 Sy.x = 0.090 r = 0.995

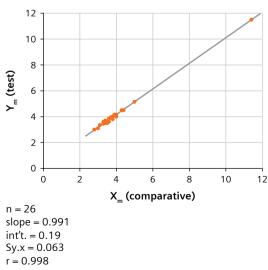




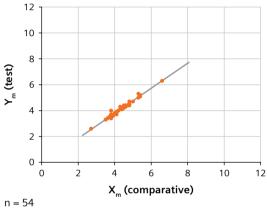




X: Beckman Coulter DxC System Y: epoc System



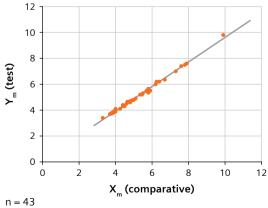
K⁺ X: Ortho Clinical Laboratories VITROS System Y: epoc System



slope = 0.965 int't. = -0.07Sy.x = 0.072 r = 0.985

K⁺

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



slope = 0.948 int't. = 0.13Sy.x = 0.101r = 0.997

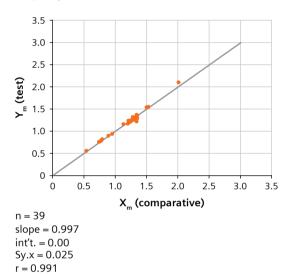


Ionized Calcium Method Comparison

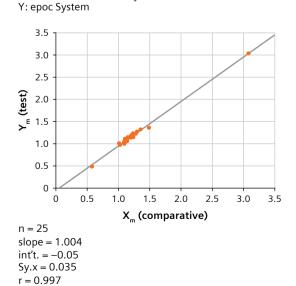
Ionized Calcium mmol/L				
Precision n Mean SD %CV				
Level 1	26	1.53	0.019	1.25%
Level 3	27	0.67	0.009	1.40%

Ca⁺⁺ X: Abbott I-STAT System

Y: epoc System

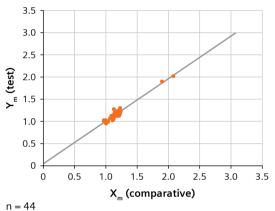


Ca⁺⁺ X: Radiometer ABL 700 System



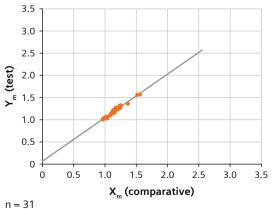
Ca++

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



slope = 0.960int't. = 0.04Sy.x = 0.047r = 0.969

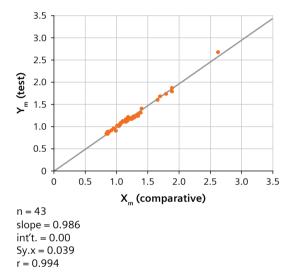
Ca⁺⁺ X: IL GEM PREMIER 3000 System Y: epoc System



slope = 0.979 int't. = 0.06 Sy.x = 0.027 r = 0.979





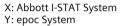


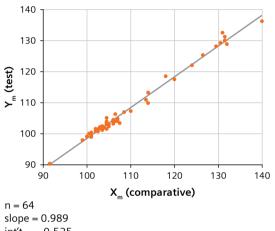


Chloride Method Comparison

Chloride mmol/L				
Precision	n	Mean	SD	%CV
Level 1	20	76	0.53	0.69%
Level 3	20	125	0.94	0.76%

Chloride

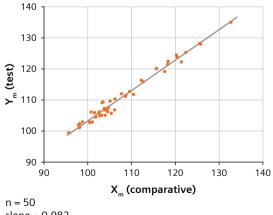




slope = 0.989 int't. = -0.525 Sy.x = 1.033 r = 0.995

Chloride

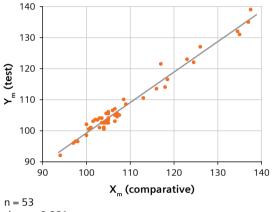
X: Roche COBAS 6000 System Y: epoc System



slope = 0.982 int't. = 5.032 Sy.x = 1.250 r = 0.990

Chloride

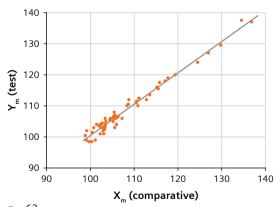
X: ADVIA[®] Clinical Chemistry System by Siemens Healthineers Y: epoc System



slope = 0.981 int't. = 1.084 Sy.x = 1.773 r = 0.985

Chloride

X: Beckman Coulter DxC System Y: epoc System

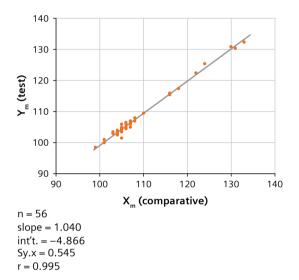


n = 63slope = 0.990 int't. = 1.611 Sy.x = 1.670 r = 0.982



Chloride

X: Radiometer ABL 800 System Y: epoc System



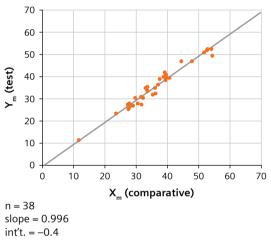


Hematocrit Method Comparison

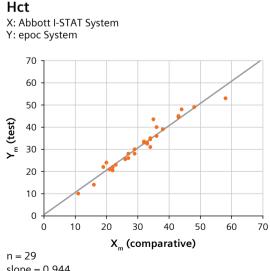
Hematocrit %PCV				
Precision	n	Mean	SD	%CV
Level 1	26	25	0.56	2.28%
Level 3	26	44	1.16	2.61%

Hct

X: Radiometer ABL 825 System Y: epoc System



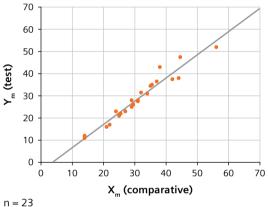
Sy.x = 1.81 r = 0.982



slope = 0.944 int't. = 2.2 Sy.x = 1.40r = 0.991

Hct

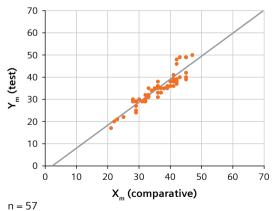
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers Y: epoc System



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



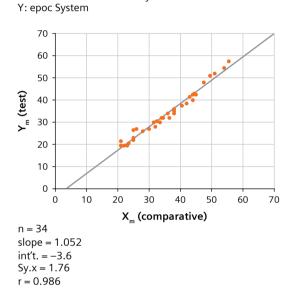
Y: epoc System



slope = 1.037 int't. = −2.8 Sy.x = 2.83 r = 0.920



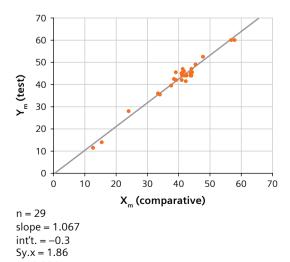
Hct X: Nova Biomedical PHOX System



Hct

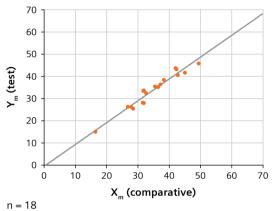
r = 0.984

X: Beckman Coulter LH System Y: epoc System



Hct

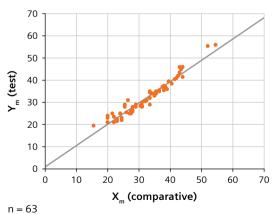
X: Sysmex XE System Y: epoc System



slope = 0.983int't. = -0.4Sy.x = 1.96r = 0.971



X: Microcentrifugation (spun) Y: epoc System



slope = 0.963int't. = 0.9Sy.x = 2.01r = 0.970

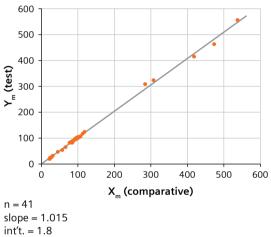


Glucose Method Comparison

Glucose mg/dL				
Precision	n	Mean	SD	%CV
Level 1	27	41.9	1.24	2.96%
Level 3	27	278	6.84	2.46%

Glucose

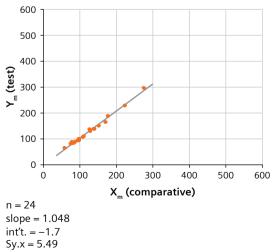
X: Abbott I-STAT System Y: epoc System



Sy.x = 5.59 r = 0.999

Glucose

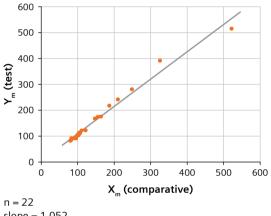
X: Radiometer ABL 700 System Y: epoc System



r = 0.995

Glucose

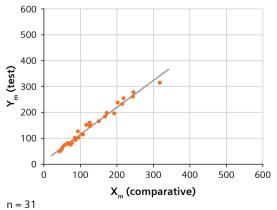
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers Y: epoc System



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

Glucose

X: IL GEM PREMIER 3000 System Y: epoc System

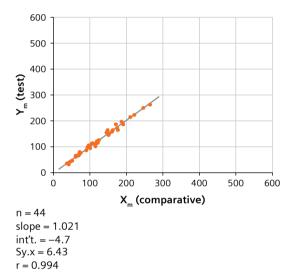


slope = 1.042 int't. = 11.9 Sy.x = 11.07 r = 0.989



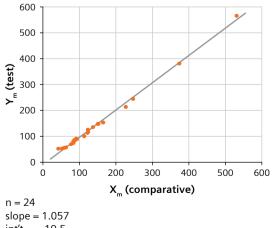
Glucose

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



Glucose

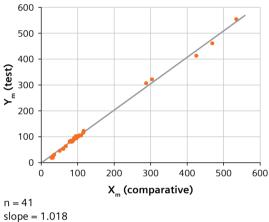
X: Beckman Coulter DxC System Y: epoc System



slope = 1.057int't. = -10.5Sy.x = 7.71r = 0.996

Glucose

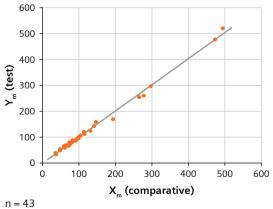
X: Ortho Clinical Laboratories VITROS System Y: epoc System



slope = 1.01int't. = 0.8Sy.x = 6.82r = 0.998

Glucose

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



slope = 1.016 int't. = -2.7 Sy.x = 7.49 r = 0.997

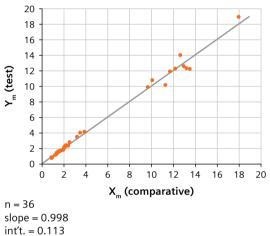


Lactate Method Comparison

Lactate mmol/L				
Precision n Mean SD %CV				
Level 1	27	0.97	0.045	4.67%
Level 3	28	5.96	0.225	3.77%

Lactate

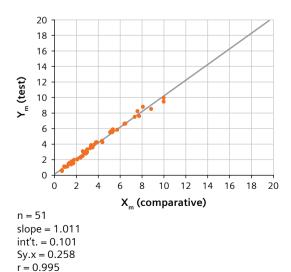
X: Abbott I-STAT System Y: epoc System



slope = 0.998 int't. = 0.113 Sy.x = 0.480 r = 0.996

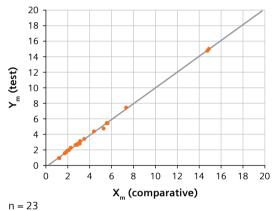
Lactate

X: Radiometer ABL 700 System Y: epoc System



Lactate

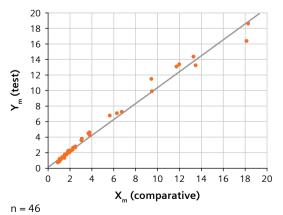
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers Y: epoc System



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



X: IL GEM PREMIER 4000 System Y: epoc System

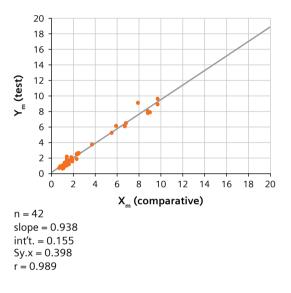


slope = 1.025 int't. = 0.130 Sy.x = 0.564 r = 0.993



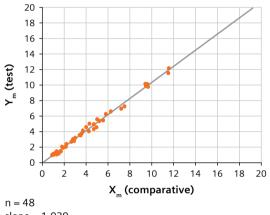
Lactate

X: Ortho Clinical Laboratories VITROS System Y: epoc System



Lactate

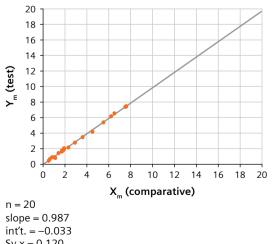
X: Roche MODULAR System Y: epoc System



slope = 1.039 int't. = -0.067 Sy.x = 0.264 r = 0.996

Lactate

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



Sy.x = 0.120 r = 0.999

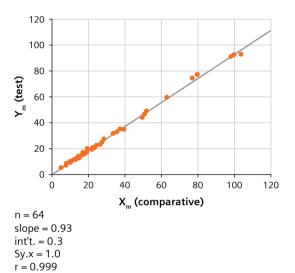


BUN Method Comparison

BUN mg/dL				
Precision	n	Mean	SD	%CV
Level 1	137	49.9	1.12	2.2%
Level 3	132	4.9	0.13	2.7%

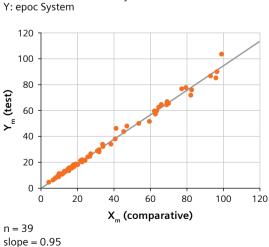
BUN

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



BUN

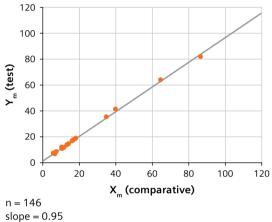
X: Beckman Coulter DxC System



slope = 0.9 int't. = 1.3 Sy.x = 0.7 r = 0.999

BUN

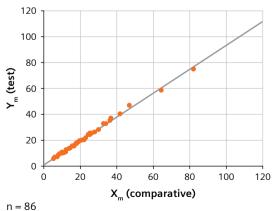
X: Dimension Vista Intelligent Lab System by Siemens Healthineers Y: epoc System



slope = 0.9int't. = 0.2Sy.x = 1.6r = 0.997



X: Abbott ARCHITECT System Y: epoc System



slope = 0.93int't. = 0.7Sy.x = 0.7r = 0.997



X: Roche COBAS System Y: epoc System 120 • 100 80 Y_m (test) 60 • 40 20 0 -0 20 40 60 80 100 X_m (comparative) n = 121

120

slope = 1.00int't. = 0.2Sy.x = 1.8r = 0.996

BUN

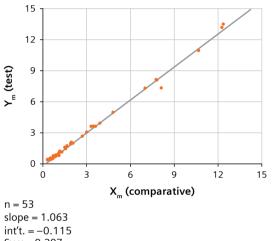


Creatinine Method Comparison

Creatinine mg/dL				
Precision	n	Mean	SD	%CV
Level 1	20	0.91	0.045	4.93%
Level 3	20	4.54	0.191	4.21%

Creatinine

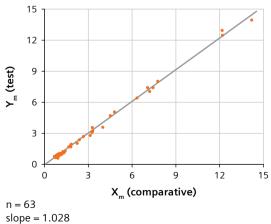
X: ADVIA Clinical Chemistry System by Siemens Healthineers Y: epoc System



int't. = -0.11Sy.x = 0.207 r = 0.998

Creatinine

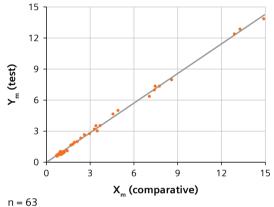
X: Beckman Coulter AU680 System Y: epoc System



stope = 1.028int't. = -0.008Sy.x = 0.166r = 0.999

Creatinine

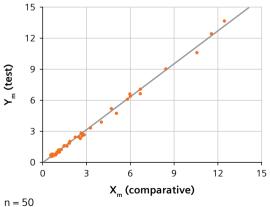
X: Abbott I-STAT System Y: epoc System



slope = 0.955 int't. = 0.075 Sy.x = 0.147 r = 0.999

Creatinine

X: Roche COBAS 6000 System Y: epoc System



slope = 1.069int't. = -0.089Sy.x = 0.201r = 0.996 At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all enabled by digitalizing healthcare.

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