White paper

epoc Blood Analysis System: Summary of Analytical Methods and Performance

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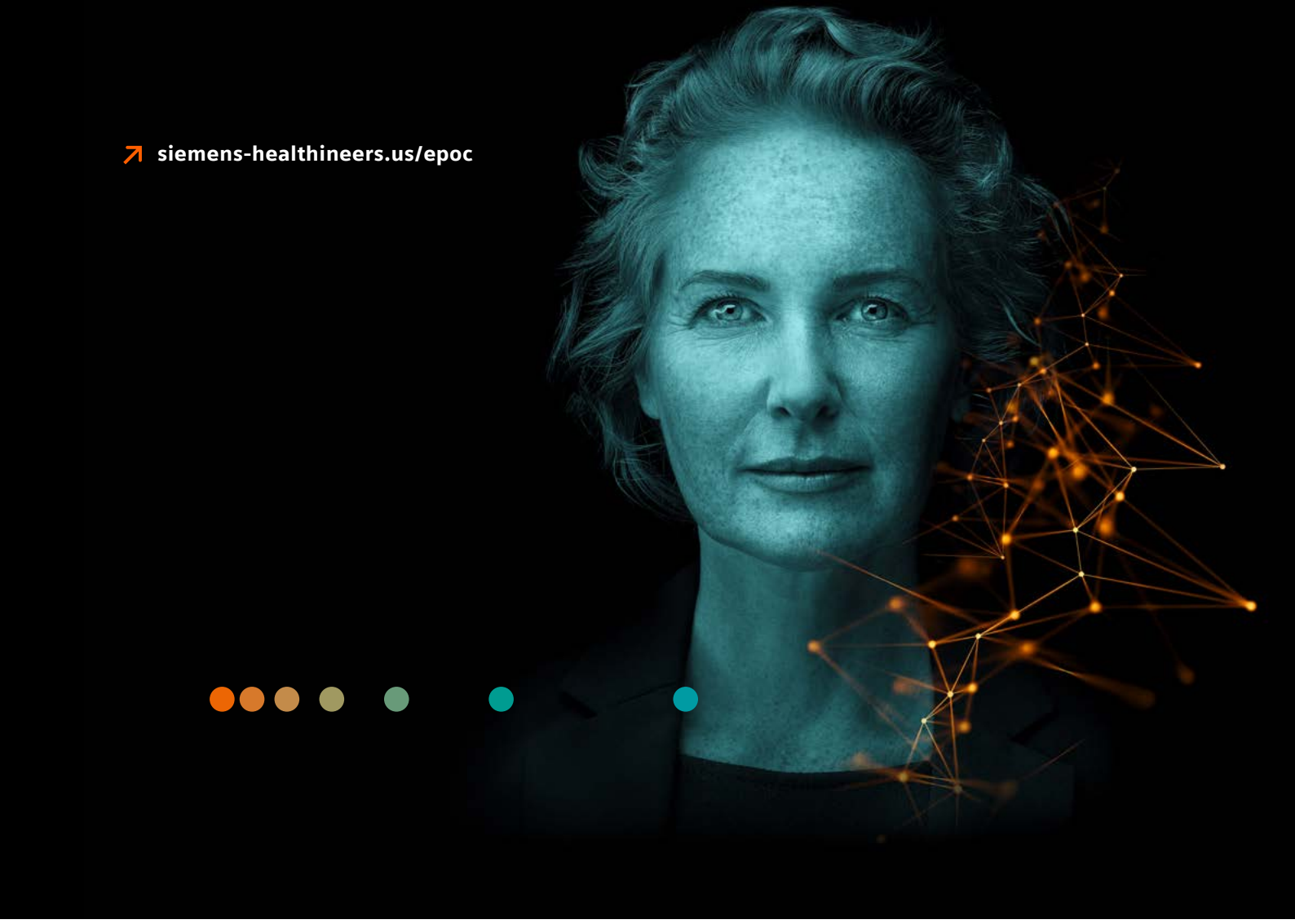

SIEMENS Healthineers

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BLOOD ANALYSIS
REF 10736515
pH Na+ Glu
pCO2 K+ Lac
pO2 Ca++ Crea
TCO2 Cl− BUN
Hct
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siemens.com/epoc

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]

$S_{y.x}$ 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 effects 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 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.

***p*CO₂** 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.

***p*O₂** 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,[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 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:

$$\text{ß-D-glucose} + O_2 + H_2O \xrightarrow{\text{Glucose Oxidase}} \text{D-gluconic acid} + H_2O_2$$

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

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

$$HRP^{ox} + Red \longrightarrow Ox + HRP^{red}$$

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

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:

$$\text{ß-D-lactate} + O_2 + H_2O \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvic acid} + H_2O_2$$

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.

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

$$HRP^{ox} + Red \longrightarrow Ox + HRP^{red}$$

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

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:

$$\text{Urea} + H_2O + 2H^+ + \text{Urease} \rightarrow 2NH_4^+ + CO_2$$

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:

$$\text{Creatinine} + H_2O \xrightleftharpoons{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

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.

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

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

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

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:

[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.*

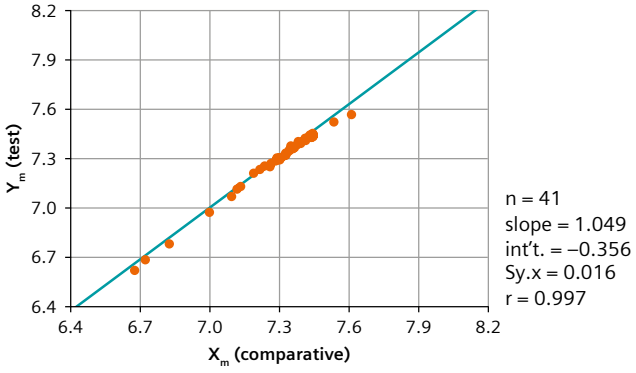
[3]*IFCC 2001/3. Reference measurement procedure for substance concentration determination of total carbon dioxide in blood, plasma or serum. Clin Chem Lab Med. 2001;39(3).*

pH Method Comparison

pH

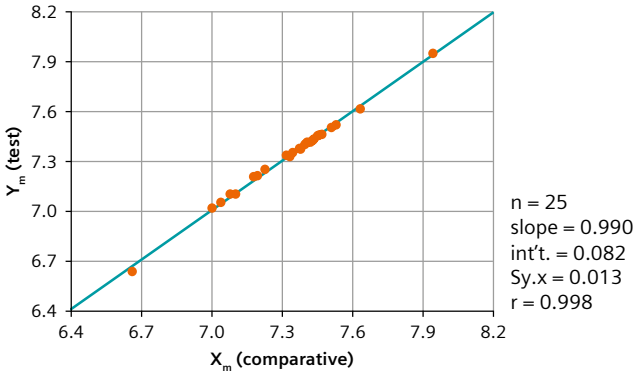
Precision	n	Mean	SD	%CV
Level 1	24	7.052	0.009	0.13%
Level 3	25	7.646	0.007	0.09%

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



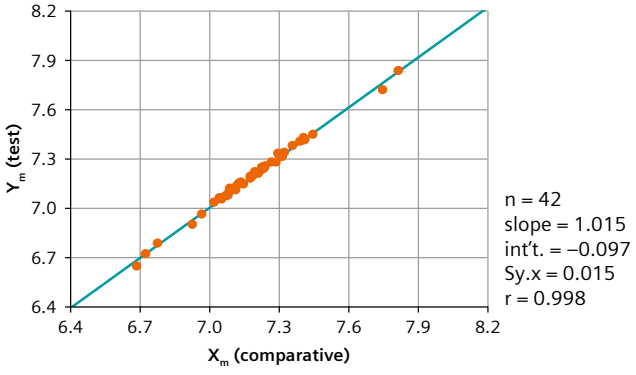
n = 41
slope = 1.049
int't. = –0.356
Sy.x = 0.016
r = 0.997

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



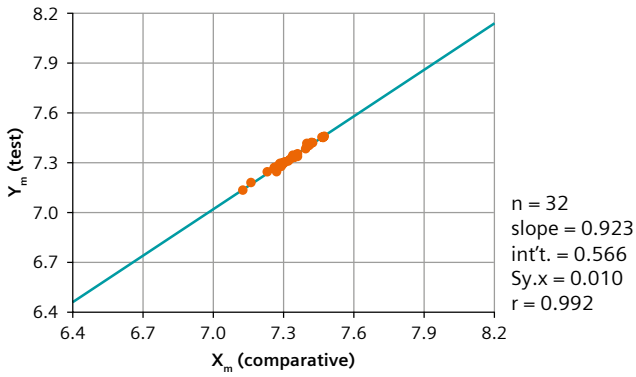
n = 25
slope = 0.990
int't. = 0.082
Sy.x = 0.013
r = 0.998

pH
X: Radiometer ABL 700 System
Y: epoc System



n = 42
slope = 1.015
int't. = –0.097
Sy.x = 0.015
r = 0.998

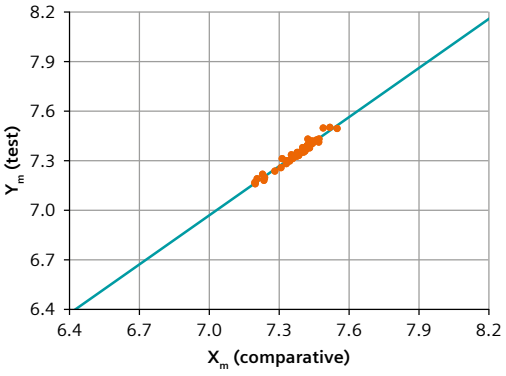
pH
X: IL GEM PREMIER 3000 System
Y: epoc System



n = 32
slope = 0.923
int't. = 0.566
Sy.x = 0.010
r = 0.992

pH

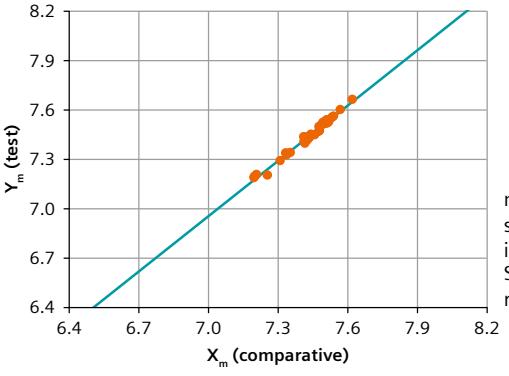
X: Nova Biomedical CRITICAL CARE XPRESS System
Y: epoc System



n = 43
slope = 0.996
int't. = –0.004
Sy.x = 0.017
r = 0.982

pH

X: IRMA TRUPOINT System
Y: epoc System



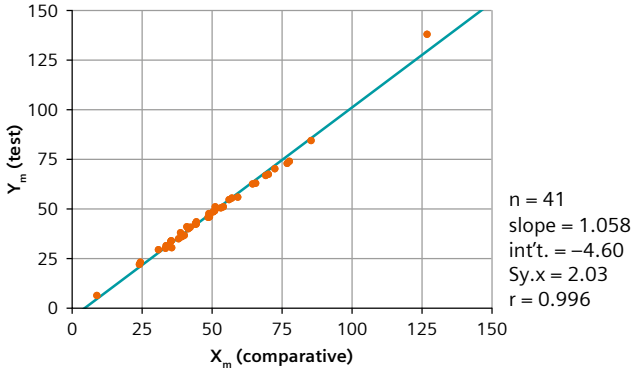
n = 33
slope = 1.117
int't. = –0.865
Sy.x = 0.010
r = 0.993

pCO_2 Method Comparison

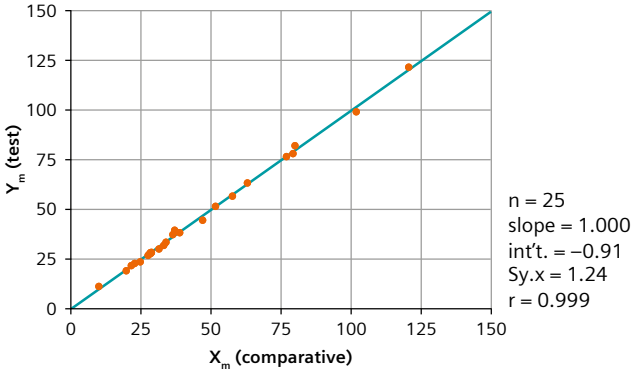
pCO_2 mmHg

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

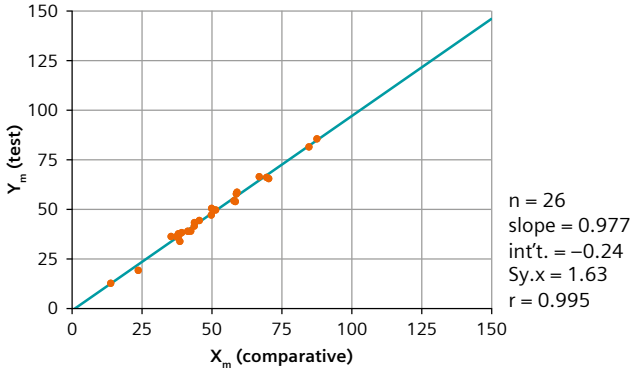
pCO_2
X: Abbott I-STAT System
Y: epoc System



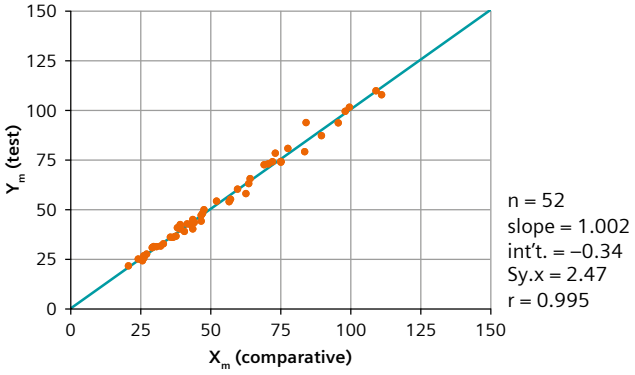
pCO_2
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System



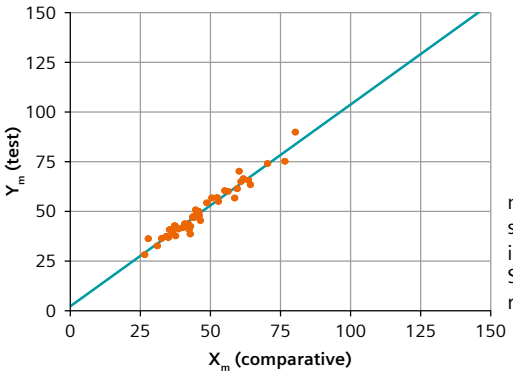
pCO_2
X: Radiometer ABL 700 System
Y: epoc System



pCO_2
X: IL GEM PREMIER 3000 System
Y: epoc System

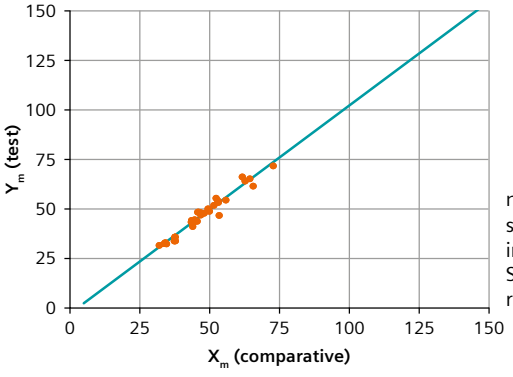


pCO_2
X: Nova Biomedical CRITICAL CARE XPRESS System
Y: epoc System



n = 46
slope = 1.006
int't. = 2.86
Sy.x = 2.88
r = 0.975

pCO_2
X: IRMA TRUPOINT System
Y: epoc System



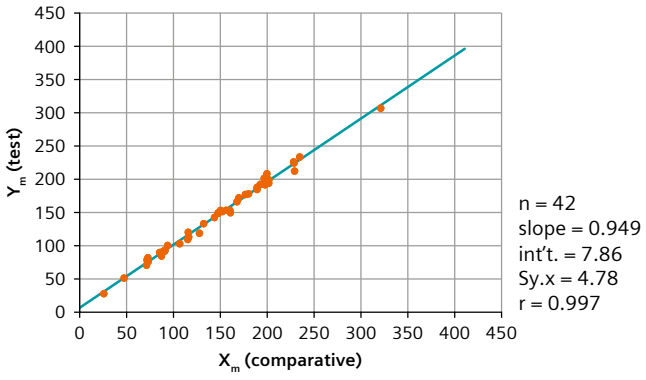
n = 32
slope = 1.047
int't. = –2.49
Sy.x = 1.56
r = 0.979

pO_2 Method Comparison

pO_2 mmHg

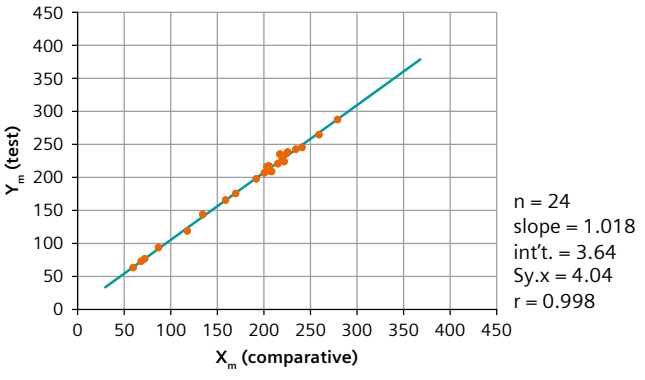
Precision	n	Mean	SD	%CV
Level 1	24	63.7	4.46	7.00%
Level 3	25	185.6	6.46	3.48%

pO_2
X: Abbott I-STAT System
Y: epoc System



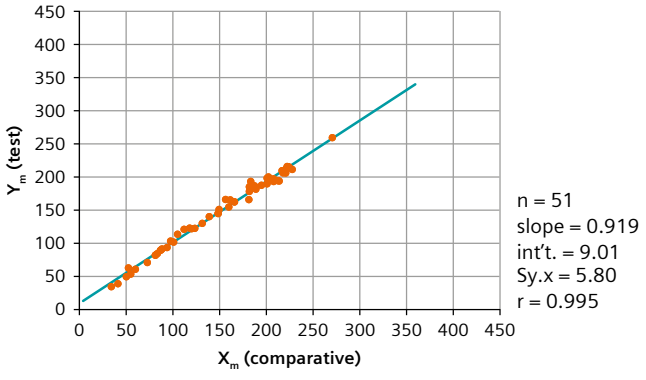
n = 42
slope = 0.949
int't. = 7.86
Sy.x = 4.78
r = 0.997

pO_2
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System



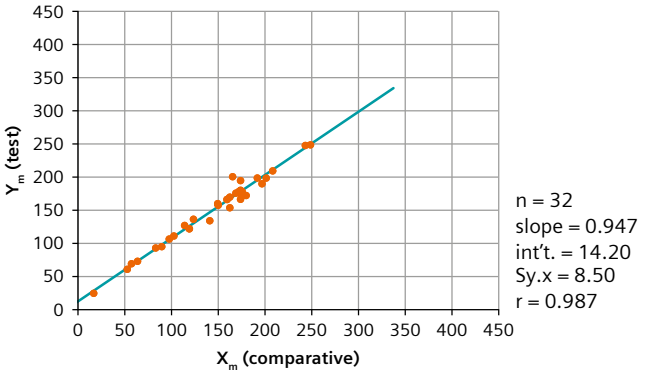
n = 24
slope = 1.018
int't. = 3.64
Sy.x = 4.04
r = 0.998

pO_2
X: Radiometer ABL 700 System
Y: epoc System



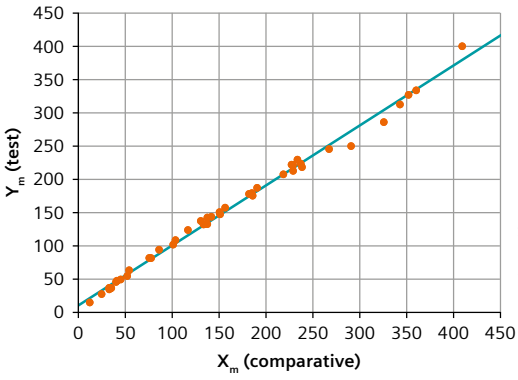
n = 51
slope = 0.919
int't. = 9.01
Sy.x = 5.80
r = 0.995

pO_2
X: IL GEM PREMIER 3000 System
Y: epoc System



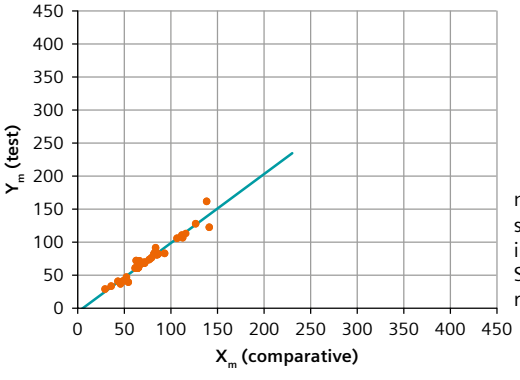
n = 32
slope = 0.947
int't. = 14.20
Sy.x = 8.50
r = 0.987

pO_2
X: Nova Biomedical CRITICAL CARE XPRESS System
Y: epoc System



n = 43
slope = 0.900
int't. = 11.32
Sy.x = 7.30
r = 0.997

pO_2
X: IRMA TRUPOINT System
Y: epoc System



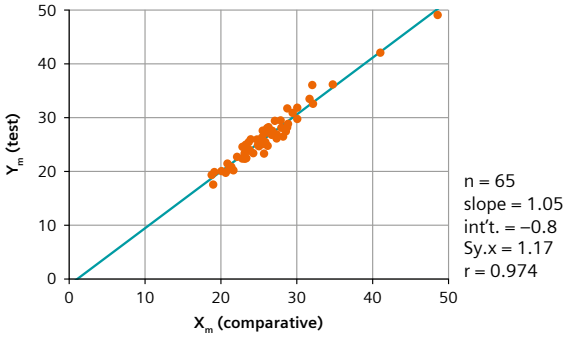
n = 31
slope = 1.047
int't. = –6.60
Sy.x = 5.13
r = 0.971

TCO_2 Method Comparison

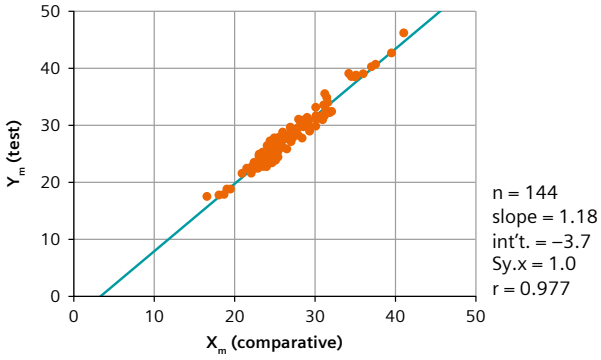
TCO_2 mmol/L

Precision	n	Mean	SD	%CV
Level 1	136	18.7	0.23	1.2%
Level 3	132	30.8	0.54	1.7%

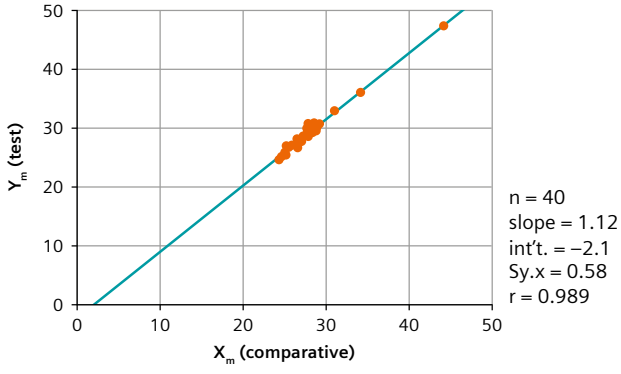
TCO_2
X: Dimension® EXL Integrated Chemistry System by Siemens Healthineers
Y: epoc System



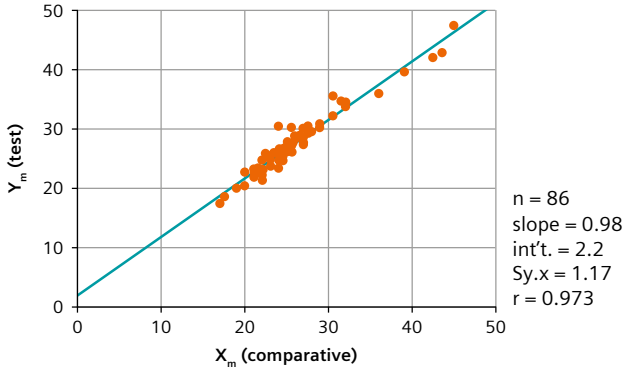
TCO_2
X: Dimension Vista® Intelligent Lab System by Siemens Healthineers
Y: epoc System



TCO_2
X: Beckman Coulter DXC System
Y: epoc System

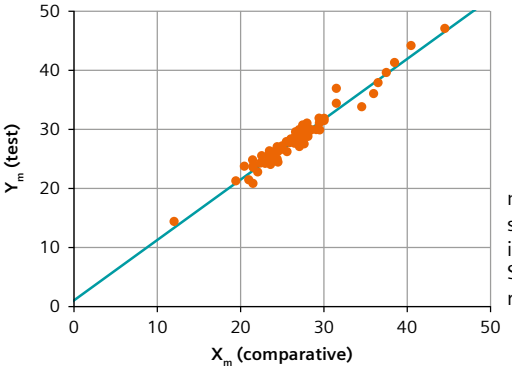


TCO_2
X: Abbott ARCHITECT System
Y: epoc System



TCO_2

X: ROCHE COBAS System
Y: epoc System



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

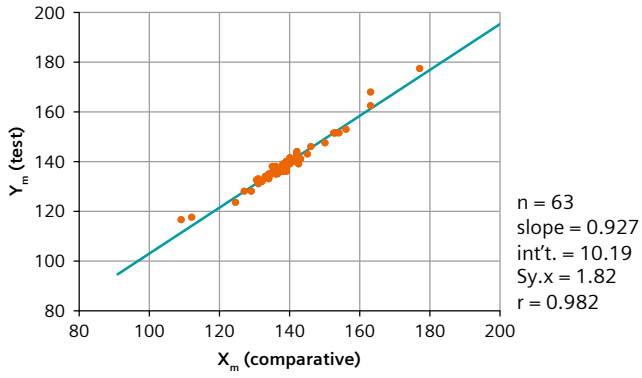
Sodium Method Comparison

Sodium mmol/L

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

Na^+

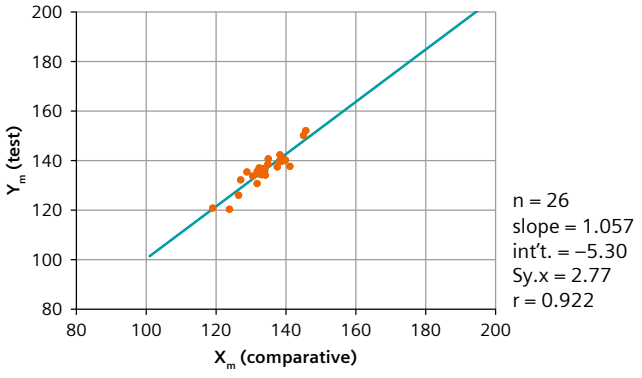
X: Abbott I-STAT System
Y: epoc System



n = 63
slope = 0.927
int't. = 10.19
Sy.x = 1.82
r = 0.982

Na^+

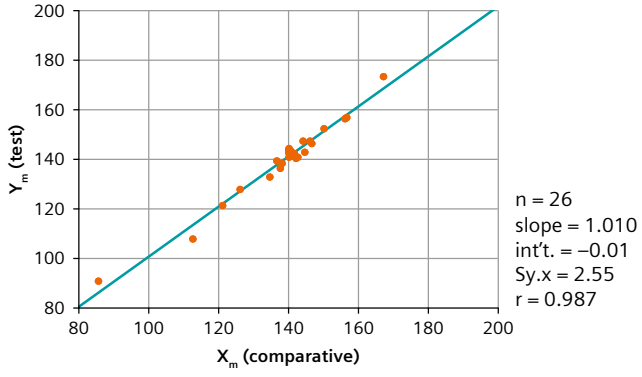
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System



n = 26
slope = 1.057
int't. = –5.30
Sy.x = 2.77
r = 0.922

Na^+

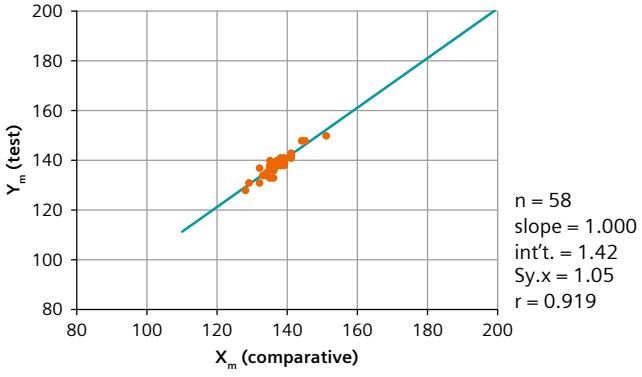
X: Radiometer ABL 700 System
Y: epoc System



n = 26
slope = 1.010
int't. = –0.01
Sy.x = 2.55
r = 0.987

Na^+

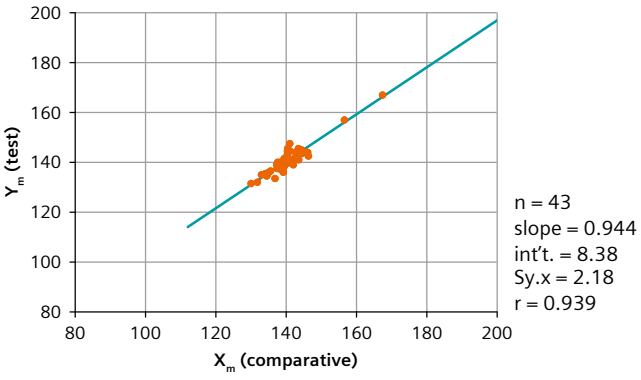
X: IL GEM PREMIER 3000 System
Y: epoc System



n = 58
slope = 1.000
int't. = 1.42
Sy.x = 1.05
r = 0.919

Na^+

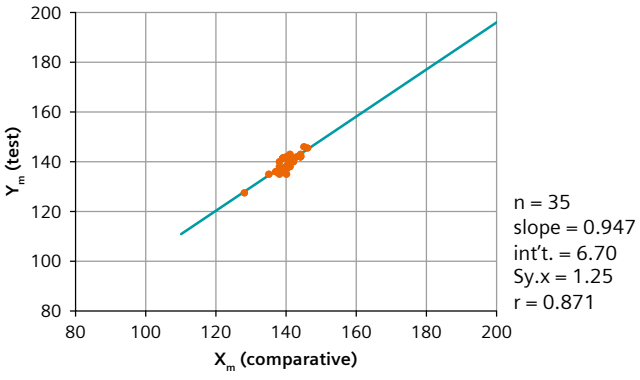
X: Nova Biomedical PHOX System
Y: epoc System



n = 43
slope = 0.944
int't. = 8.38
Sy.x = 2.18
r = 0.939

Na^+

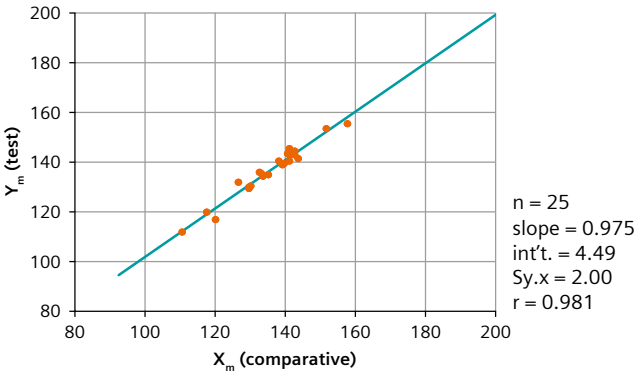
X: Ortho Clinical Laboratories VITROS System
Y: epoc System



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

Na^+

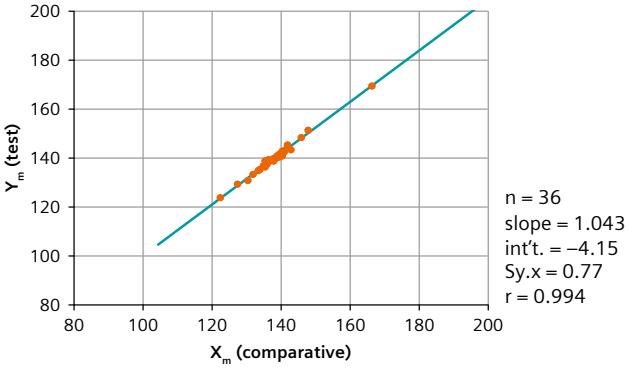
X: Beckman Coulter DXC System
Y: epoc System



n = 25
slope = 0.975
int't. = 4.49
Sy.x = 2.00
r = 0.981

Na^+

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



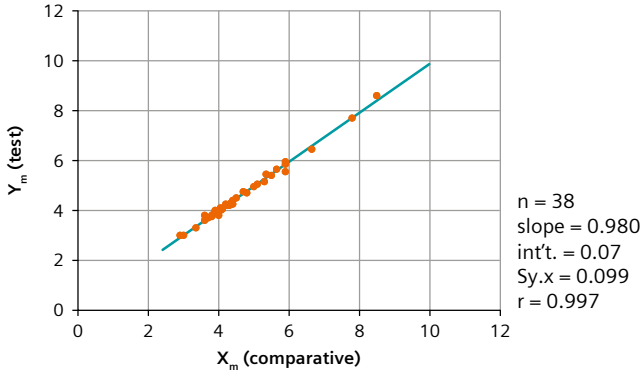
n = 36
slope = 1.043
int't. = –4.15
Sy.x = 0.77
r = 0.994

Potassium Method Comparison

Potassium mmol/L

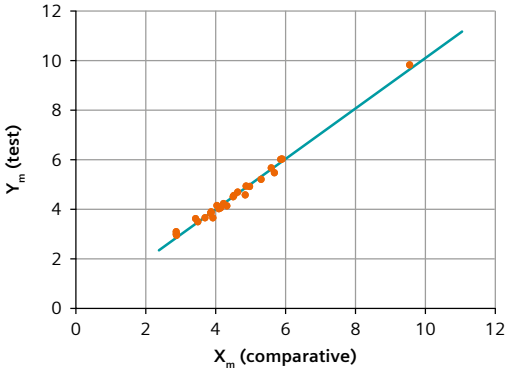
Precision	n	Mean	SD	%CV
Level 1	27	2.1	0.043	2.04%
Level 3	27	6.3	0.075	1.20%

K^+
X: Abbott I-STAT System
Y: epoc System



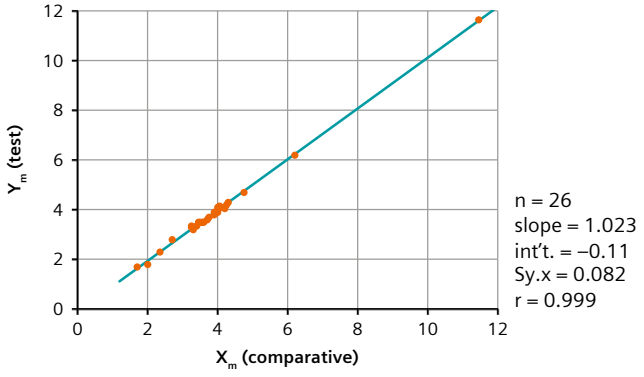
n = 38
slope = 0.980
int't. = 0.07
Sy.x = 0.099
r = 0.997

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



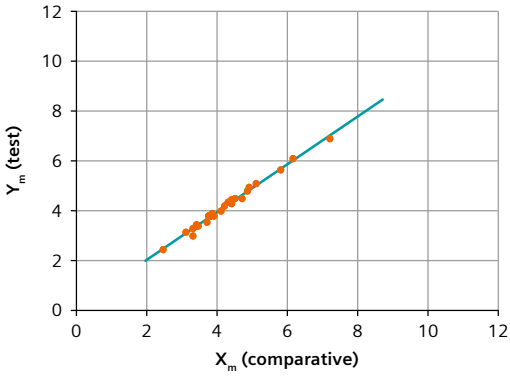
n = 26
slope = 1.019
int't. = –0.08
Sy.x = 0.141
r = 0.995

K^+
X: Radiometer ABL 700 System
Y: epoc System



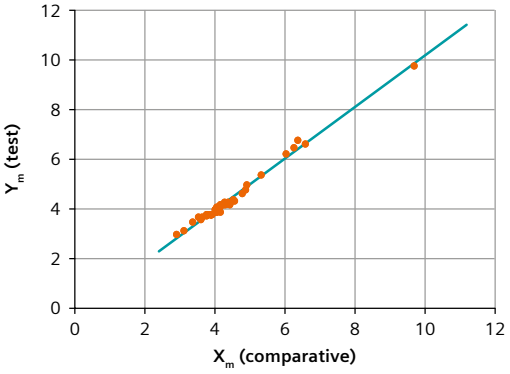
n = 26
slope = 1.023
int't. = –0.11
Sy.x = 0.082
r = 0.999

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



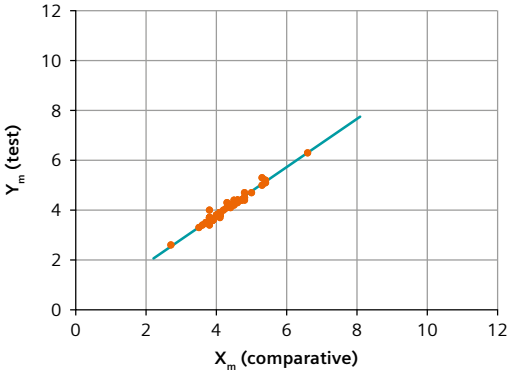
n = 31
slope = 0.959
int't. = 0.13
Sy.x = 0.090
r = 0.995

K^+
X: Nova Biomedical PHOX System
Y: epoc System



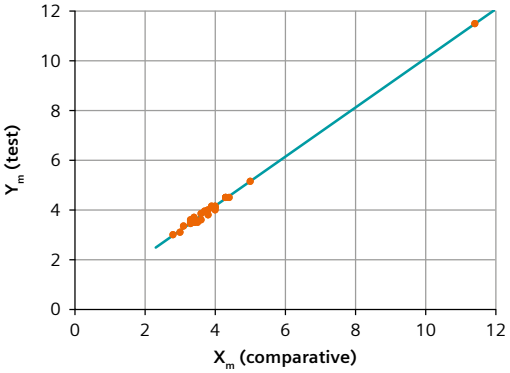
n = 43
slope = 1.042
int't. = –0.18
Sy.x = 0.122
r = 0.995

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



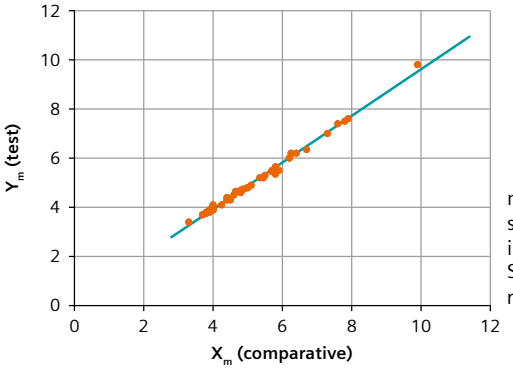
n = 54
slope = 0.965
int't. = –0.07
Sy.x = 0.072
r = 0.985

K^+
X: Beckman Coulter DXC System
Y: epoc System



n = 26
slope = 0.991
int't. = 0.19
Sy.x = 0.063
r = 0.998

K^+
X: Dimension Integrated Chemistry System by Siemens Healthineers
Y: epoc System



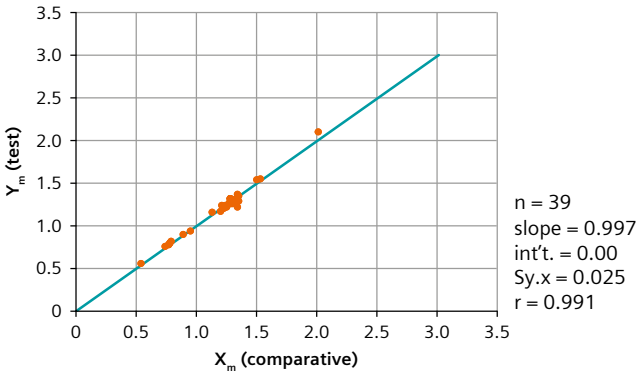
n = 43
slope = 0.948
int't. = 0.13
Sy.x = 0.101
r = 0.997

Ionized Calcium Method Comparison

Ionized Calcium mmol/L

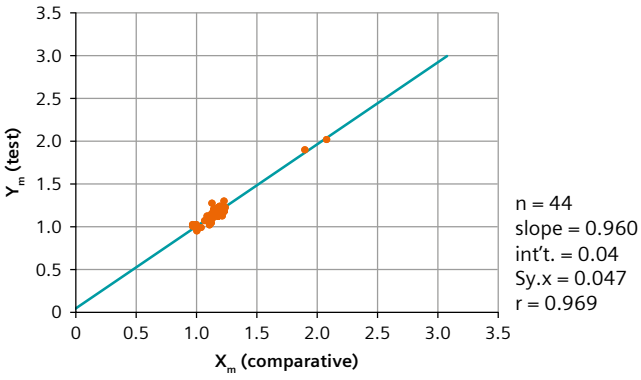
Precision	n	Mean	SD	%CV
Level 1	26	1.53	0.019	1.25%
Level 3	27	0.67	0.009	1.40%

Ca^{++}
X: Abbott I-STAT System
Y: epoc System



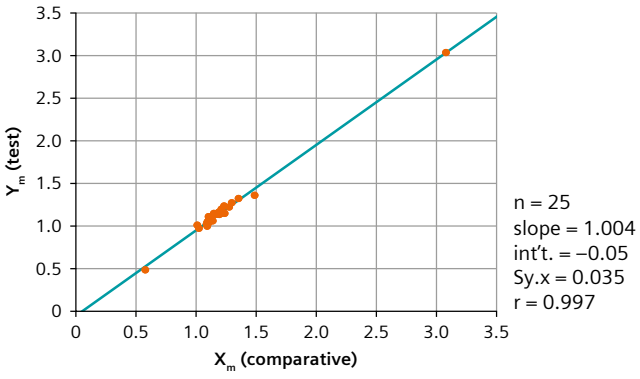
n = 39
slope = 0.997
int't. = 0.00
Sy.x = 0.025
r = 0.991

Ca^{++}
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System



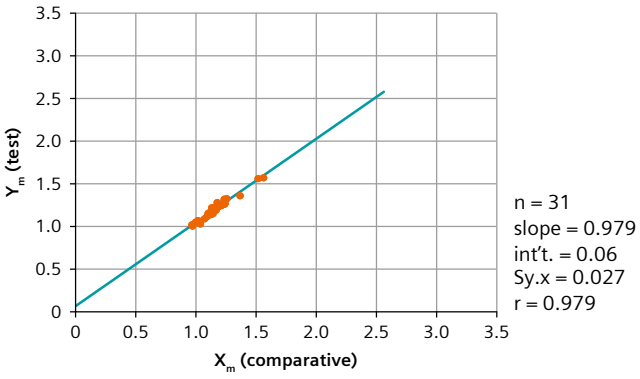
n = 44
slope = 0.960
int't. = 0.04
Sy.x = 0.047
r = 0.969

Ca^{++}
X: Radiometer ABL 700 System
Y: epoc System



n = 25
slope = 1.004
int't. = –0.05
Sy.x = 0.035
r = 0.997

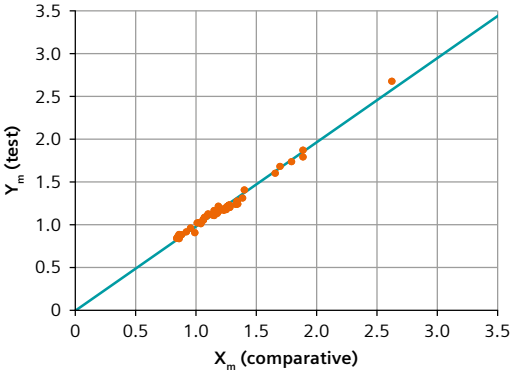
Ca^{++}
X: IL GEM PREMIER 3000 System
Y: epoc System



n = 31
slope = 0.979
int't. = 0.06
Sy.x = 0.027
r = 0.979

Ca^{++}

X: Nova Biomedical PHOX System
Y: epoc System



n = 43
slope = 0.986
int't. = 0.00
Sy.x = 0.039
r = 0.994

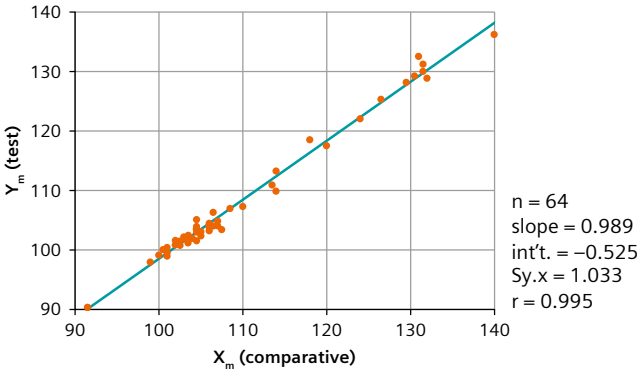
Chloride Method Comparison

Chloride mmol/L

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

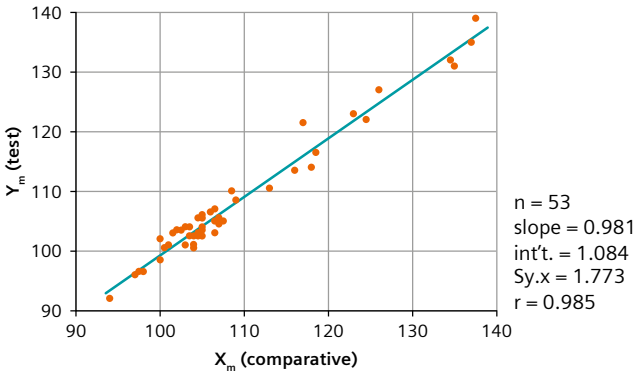
Chloride

X: Abbott I-STAT System
Y: epoc System



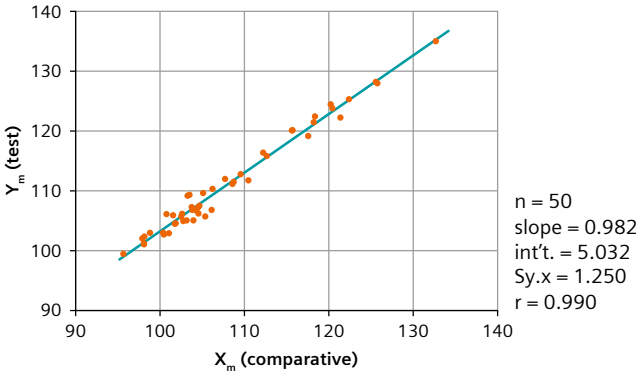
Chloride

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



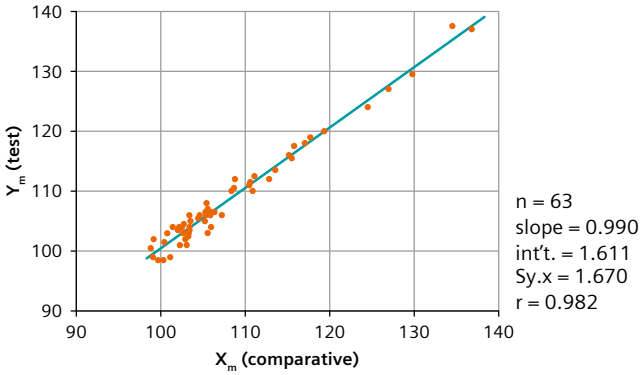
Chloride

X: ROCHE COBAS 6000 System
Y: epoc System



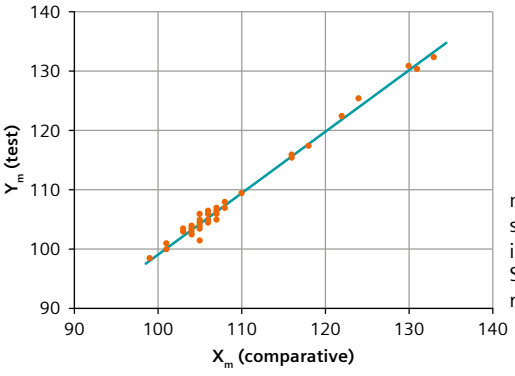
Chloride

X: Beckman Coulter DXC System
Y: epoc System



Chloride

X: Radiometer ABL 800 System
Y: epoc System



n = 56
slope = 1.040
int't. = –4.866
Sy.x = 0.545
r = 0.995

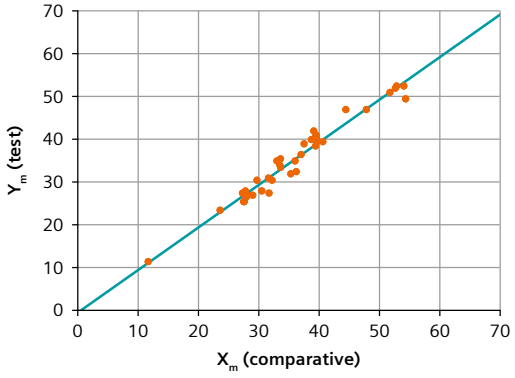
Hematocrit Method Comparison

Hematocrit %PCV

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

Hct

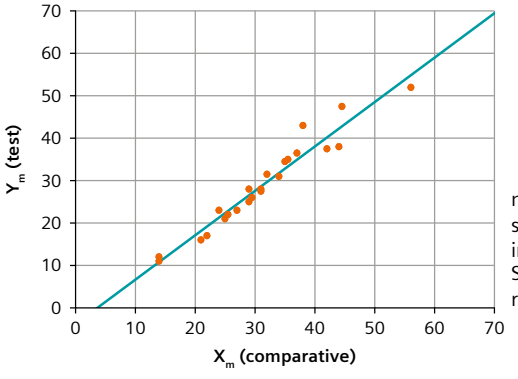
X: Radiometer ABL 825 System
Y: epoc System



n = 38
slope = 0.996
int't. = −0.4
Sy.x = 1.81
r = 0.982

Hct

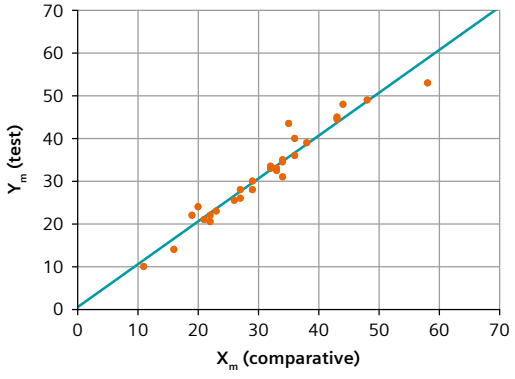
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System



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

Hct

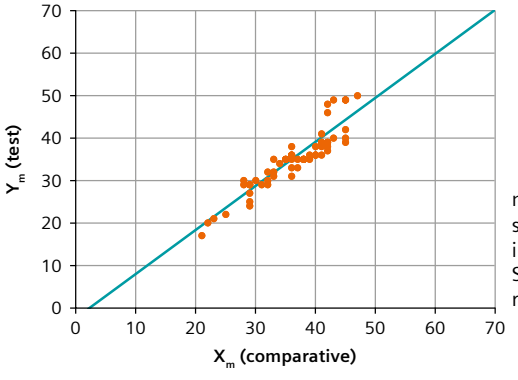
X: Abbott I-STAT System
Y: epoc System



n = 29
slope = 0.944
int't. = 2.2
Sy.x = 1.40
r = 0.991

Hct

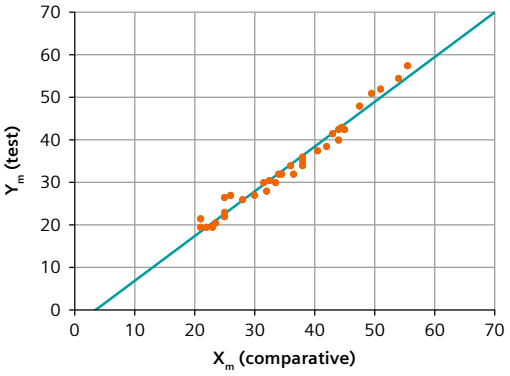
X: IL GEM PREMIER 3000 System
Y: epoc System



n = 57
slope = 1.037
int't. = −2.8
Sy.x = 2.83
r = 0.920

Hct

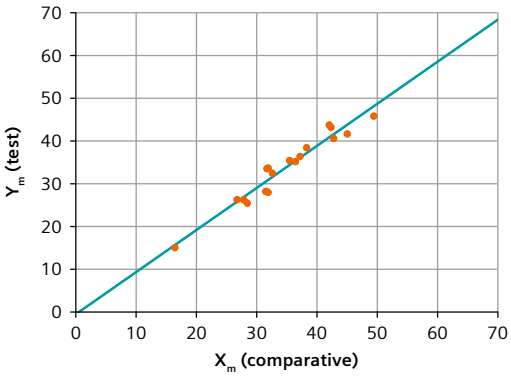
X: Nova Biomedical PHOX System
Y: epoc System



n = 34
slope = 1.052
int't. = –3.6
Sy.x = 1.76
r = 0.986

Hct

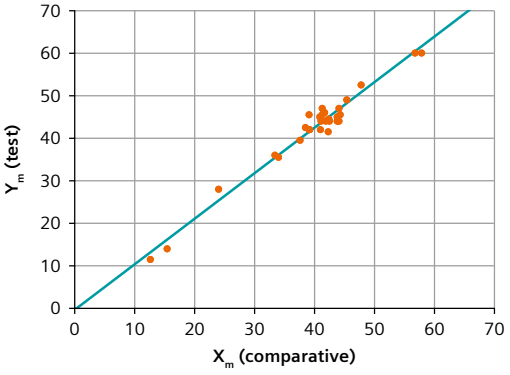
X: Sysmex XE System
Y: epoc System



n = 18
slope = 0.983
int't. = –0.4
Sy.x = 1.96
r = 0.971

Hct

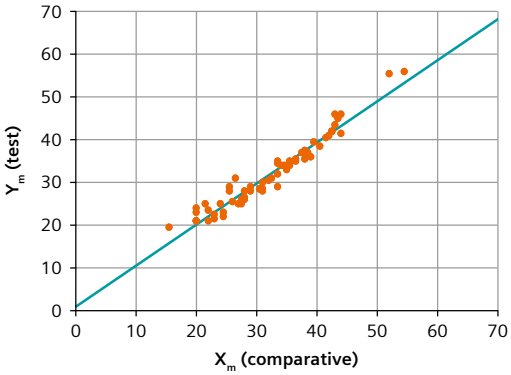
X: Beckman Coulter LH System
Y: epoc System



n = 29
slope = 1.067
int't. = –0.3
Sy.x = 1.86
r = 0.984

Hct

X: Microcentrifugation (spun)
Y: epoc System



n = 63
slope = 0.963
int't. = 0.9
Sy.x = 2.01
r = 0.970

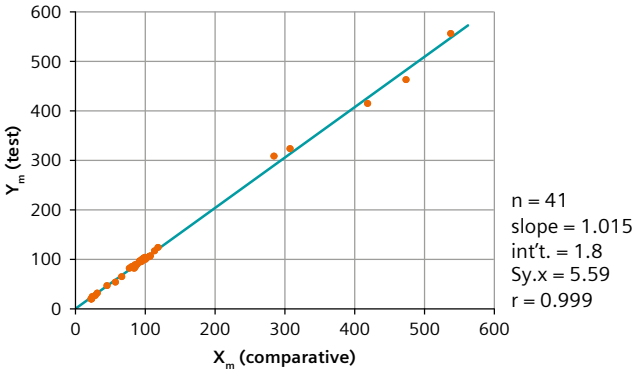
Glucose Method Comparison

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

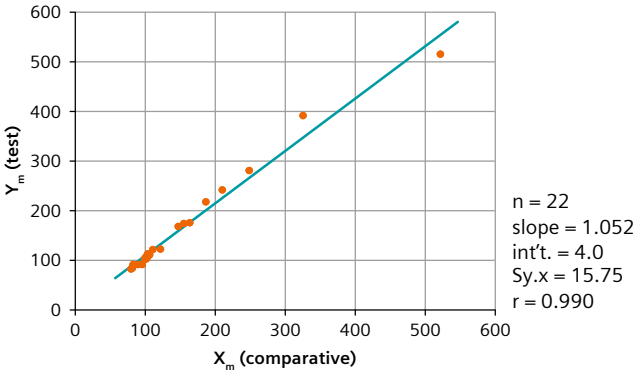
X: Abbott I-STAT System
Y: epoc System



n = 41
slope = 1.015
int't. = 1.8
Sy.x = 5.59
r = 0.999

Glucose

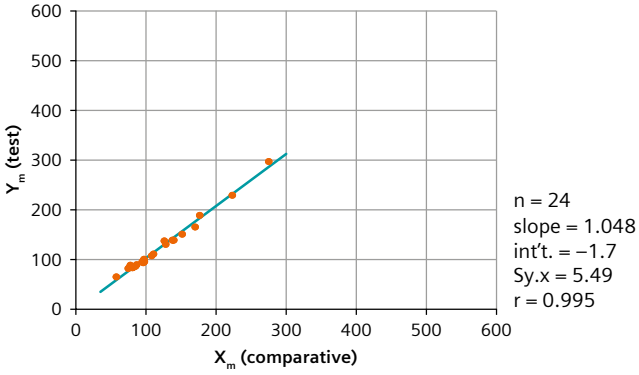
X: RAPIDLab 1265 Blood Gas System by Siemens Healthineers
Y: epoc System



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

Glucose

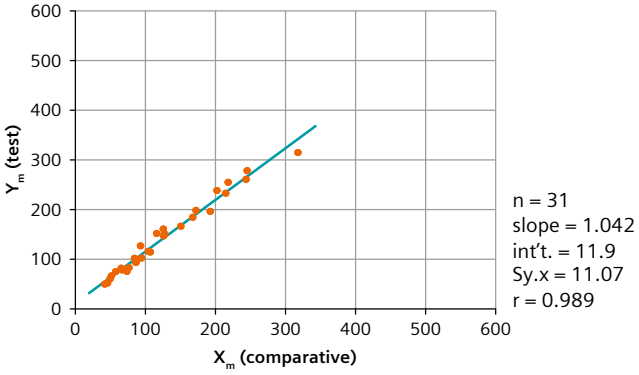
X: Radiometer ABL 700 System
Y: epoc System



n = 24
slope = 1.048
int't. = –1.7
Sy.x = 5.49
r = 0.995

Glucose

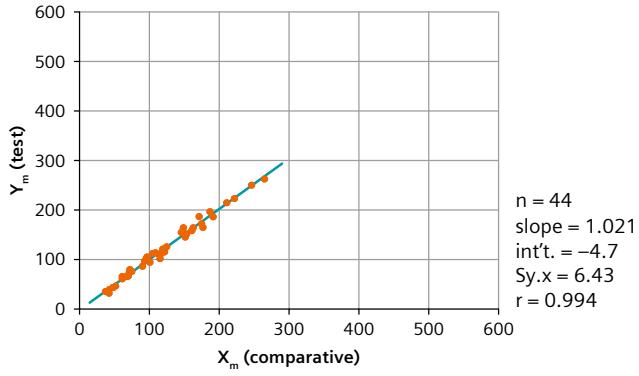
X: IL GEM PREMIER 3000 System
Y: epoc System



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

Glucose

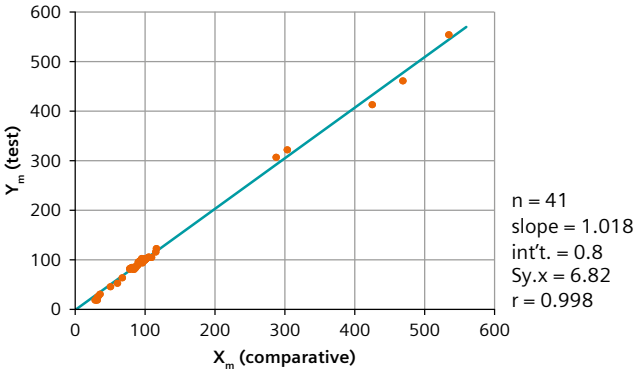
X: Nova Biomedical CRITICAL CARE XPRESS System
Y: epoc System



n = 44
slope = 1.021
int't. = –4.7
Sy.x = 6.43
r = 0.994

Glucose

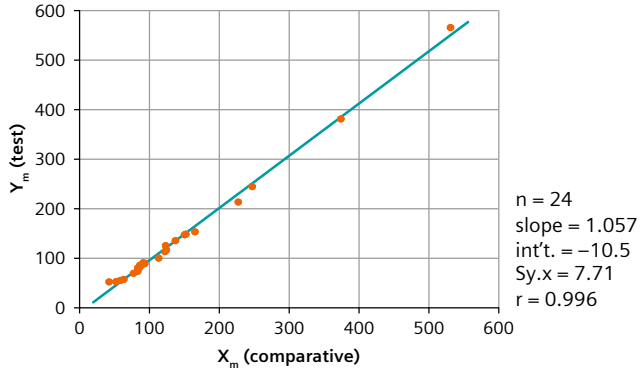
X: Ortho Clinical Laboratories VITROS System
Y: epoc System



n = 41
slope = 1.018
int't. = 0.8
Sy.x = 6.82
r = 0.998

Glucose

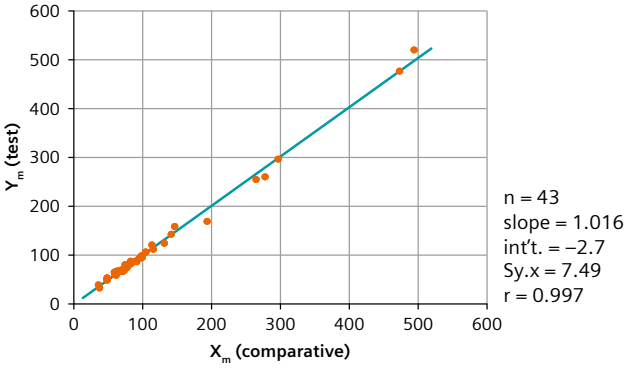
X: Beckman Coulter DXC System
Y: epoc System



n = 24
slope = 1.057
int't. = –10.5
Sy.x = 7.71
r = 0.996

Glucose

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



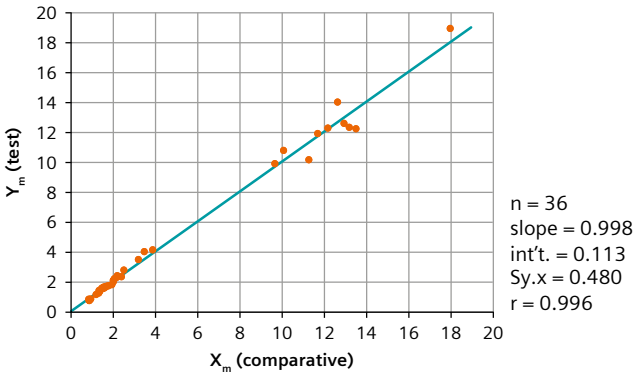
n = 43
slope = 1.016
int't. = –2.7
Sy.x = 7.49
r = 0.997

Lactate Method Comparison

Lactate mmol/L

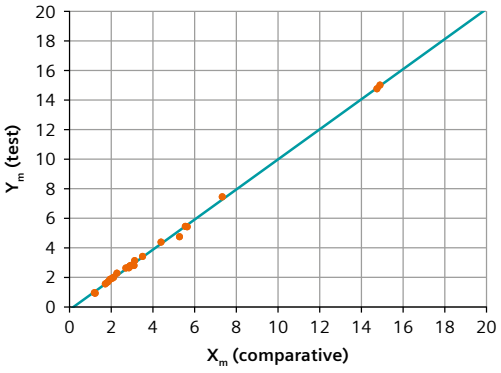
Precision	n	Mean	SD	%CV
Level 1	27	0.97	0.045	4.67%
Level 3	28	5.96	0.225	3.77%

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



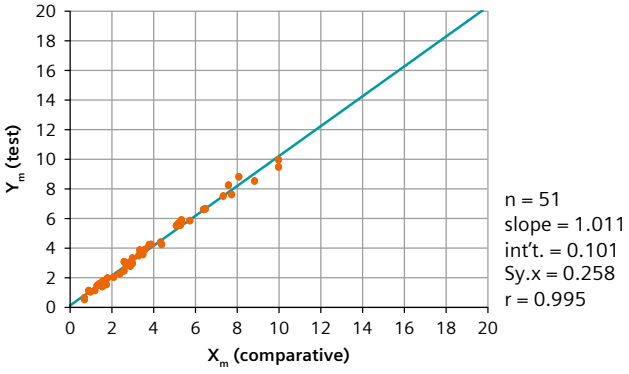
n = 36
slope = 0.998
int't. = 0.113
Sy.x = 0.480
r = 0.996

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



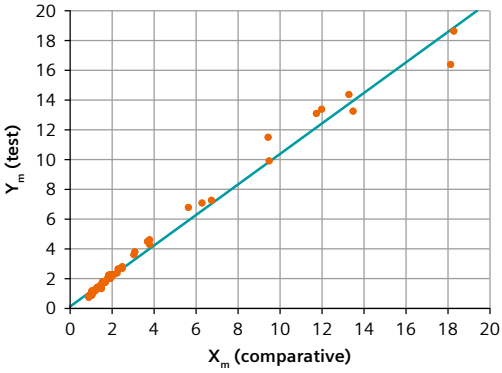
n = 23
slope = 1.019
int't. = –0.207
Sy.x = 0.132
r = 0.999

Lactate
X: Radiometer ABL 700 System
Y: epoc System



n = 51
slope = 1.011
int't. = 0.101
Sy.x = 0.258
r = 0.995

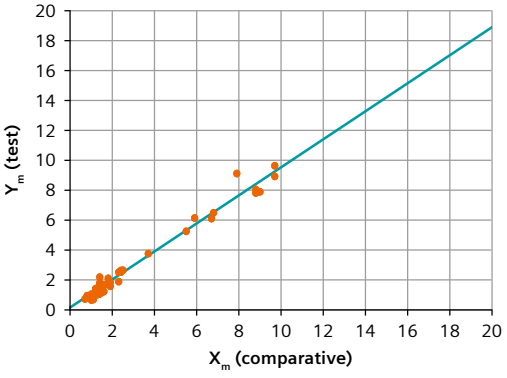
Lactate
X: IL GEM PREMIER 4000 System
Y: epoc System



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

Lactate

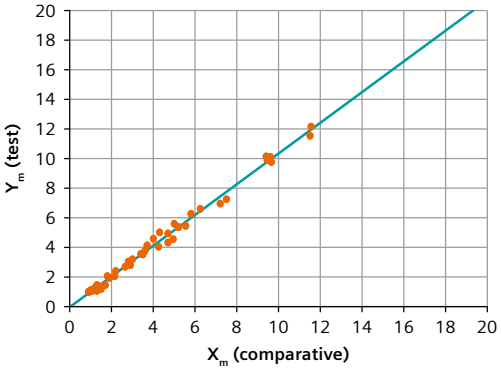
X: Ortho Clinical Laboratories VITROS System
Y: epoc System



n = 42
slope = 0.938
int't. = 0.155
Sy.x = 0.398
r = 0.989

Lactate

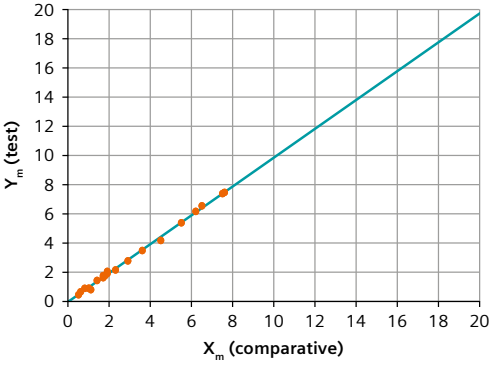
X: Roche MODULAR System
Y: epoc System



n = 48
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



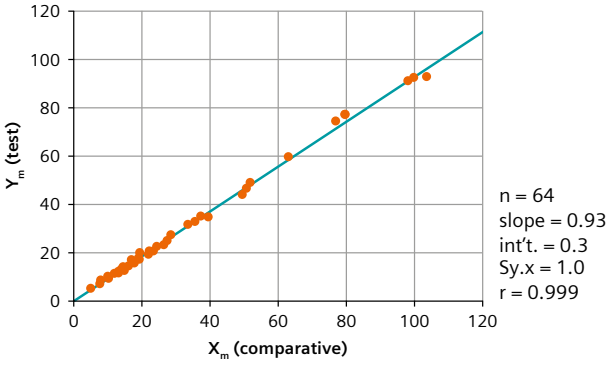
n = 20
slope = 0.987
int't. = –0.033
Sy.x = 0.120
r = 0.999

BUN Method Comparison

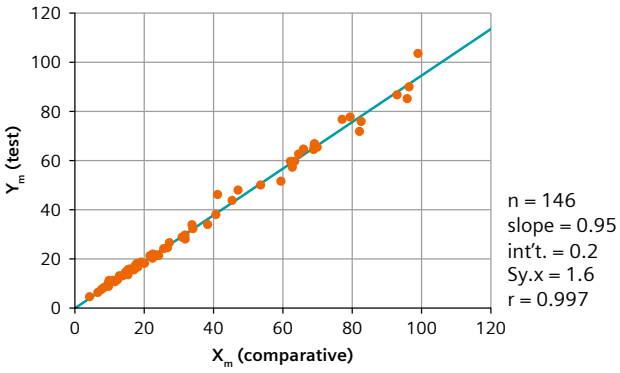
BUN mg/dL

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

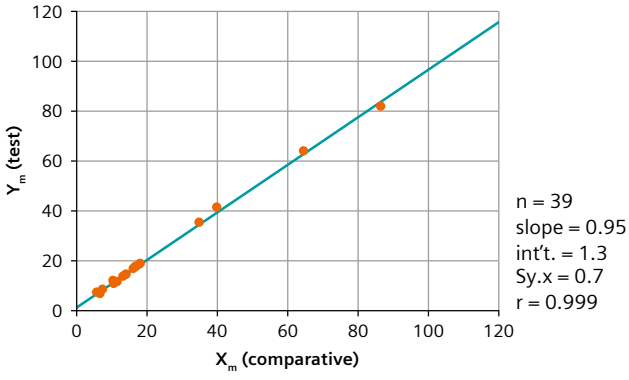
BUN
X: Dimension Integrated Chemistry System by Siemens Healthineers
Y: epoc System



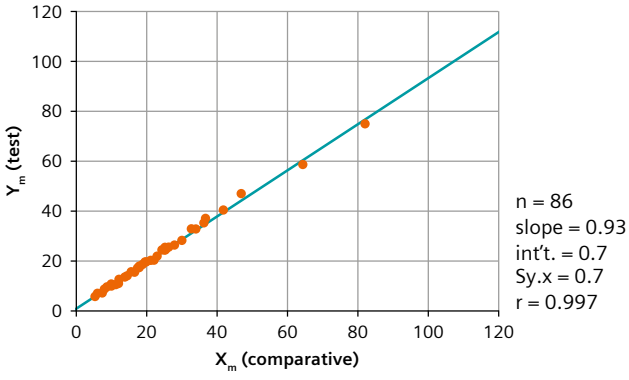
BUN
X: Dimension Vista Intelligent Lab System by Siemens Healthineers
Y: epoc System



BUN
X: Beckman DXC System
Y: epoc System

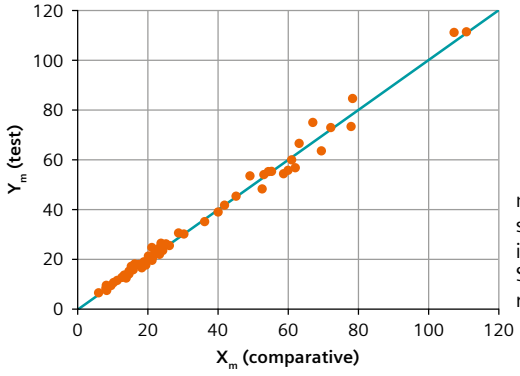


BUN
X: Abbott ARCHITECT System
Y: epoc System



BUN

X: ROCHE COBAS System
Y: epoc System



n = 121
slope = 1.00
int't. = 0.2
Sy.x = 1.8
r = 0.996

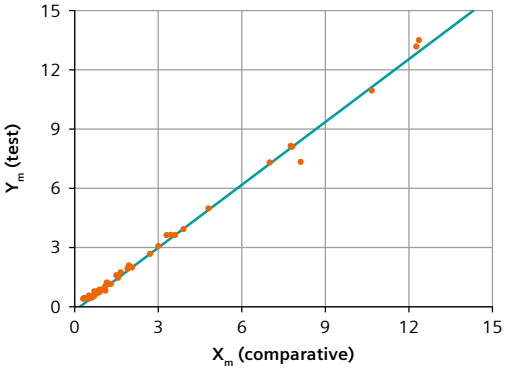
Creatinine Method Comparison

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

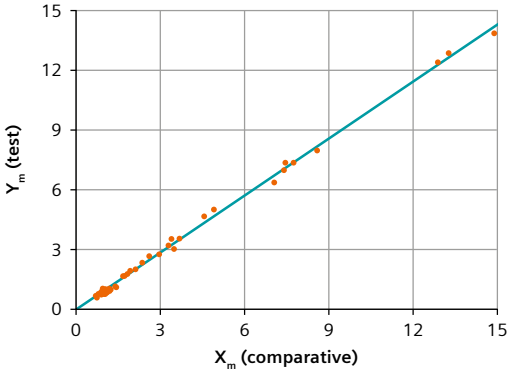
X: ADVIA Clinical Chemistry System by Siemens Healthineers
Y: epoc System



n = 53
slope = 1.063
int't. = –0.115
Sy.x = 0.207
r = 0.998

Creatinine

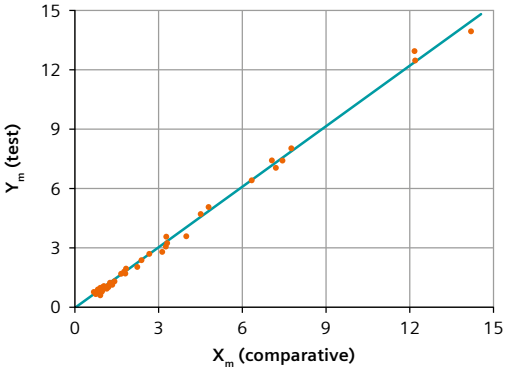
X: Abbott I-STAT System
Y: epoc System



n = 63
slope = 0.955
int't. = 0.075
Sy.x = 0.147
r = 0.999

Creatinine

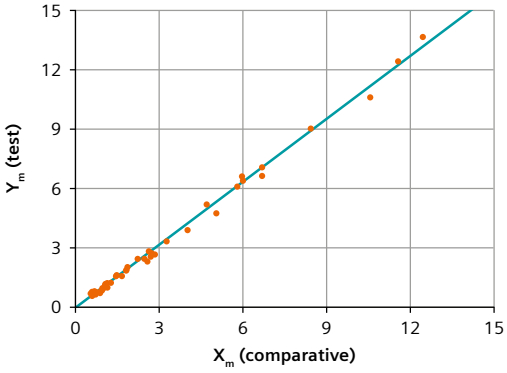
X: Beckman Coulter AU680 System
Y: epoc System



n = 63
slope = 1.028
int't. = –0.008
Sy.x = 0.166
r = 0.999

Creatinine

X: ROCHE COBAS 6000 System
Y: epoc System



n = 50
slope = 1.069
int't. = –0.089
Sy.x = 0.201
r = 0.996

Notes

The outcomes and statements provided by customers of Siemens Healthineers are unique to each customer's setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, and level of service/technology adoption), there can be no guarantee that others will achieve the same results.

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Method comparison studies were performed at three sites.

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