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

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

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Method comparison studies were performed at three sites.

epoc Blood Analysis System: Summary of Analytical Methods and Performance

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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.

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.

TCO₂ is measured based on a modified Henderson-Hasselbalch equation, using pH and pCO₂,² 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

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.

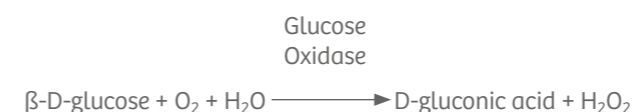
Potassium is measured by potentiometry using an ion-selective membrane electrode. The concentration of potassium ions is obtained from the measured potential using the Nernst equation. The epoc potassium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional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

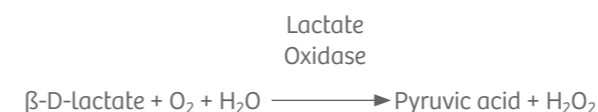


and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox-mediated (ABTS [2,2'-azino-bis 3-ethylbenzothiazoline-6-sulfonic acid] diammonium salt) horseradish peroxidase (HRP)-catalyzed reduction on a gold electrode.

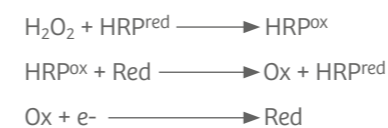


The reduction current is proportional to the concentration of glucose in the test fluid. The epoc glucose result is reported as plasma-equivalent glucose concentration.

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:



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.

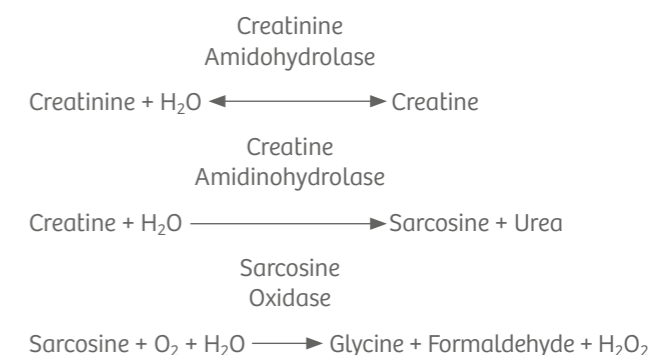
BUN/Urea is measured by potentiometry using an ammonium ion selective electrode coated onto a gold electrode, covered with an enzymatic membrane second layer. The urease enzyme is employed to convert urea to ammonium ions:



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:



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.



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:

- Westgard JO. Basic method evaluation. 3rd ed. Madison, WI (USA): Westgard QC, Inc.; 2008 p. 77–78.
- A.H. Maas, P. Rispens, O. Siggaard-Andersen, W.G. Zijlstra, "On the reliability of Henderson-Hasselbalch equation in routine clinical acid-base chemistry", Ann. Clin. Biochem., 21, 26–39, 1984.
- IFCC 2001/3, "Reference Measurement Procedure for Substance Concentration Determination of Total Carbon Dioxide in Blood, Plasma or Serum," Clin Chem Lab Med, 39(3), 2001.

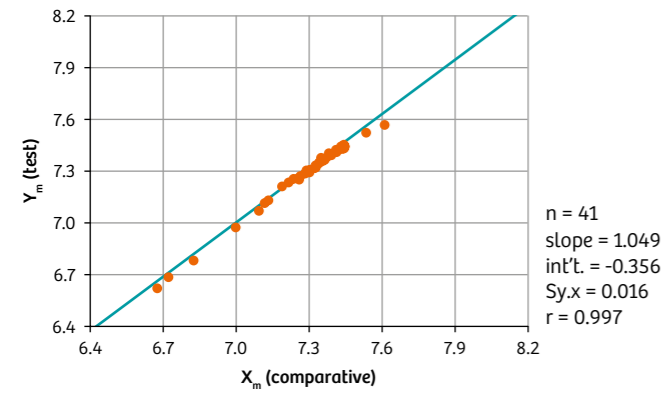
pH Method Comparison

pH

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

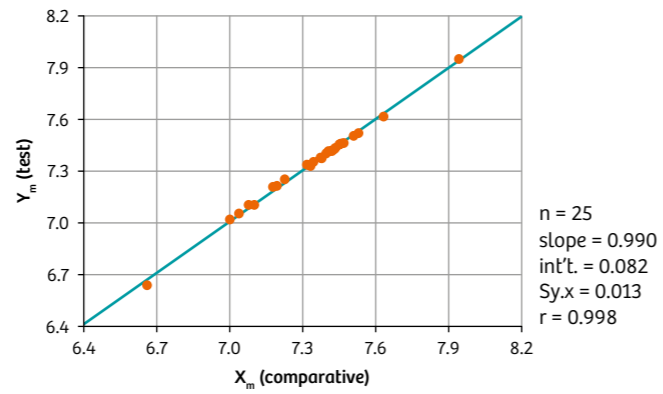
pH

X: Abbott I-STAT System
Y: epoc System



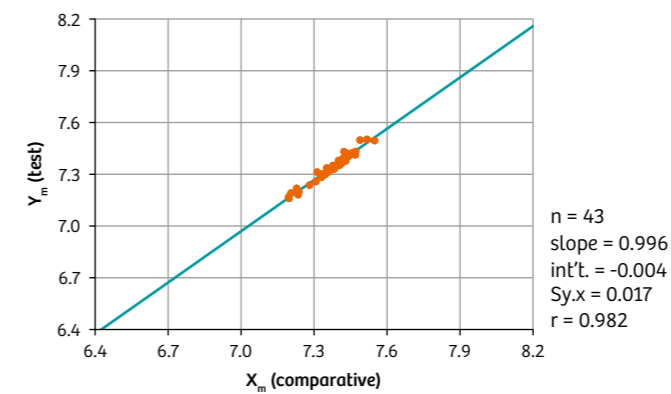
pH

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



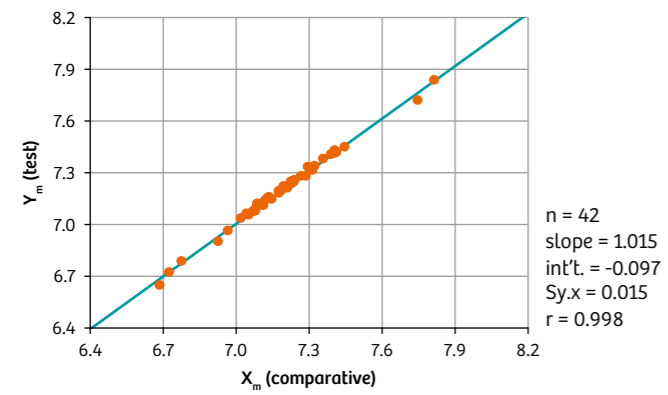
pH

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



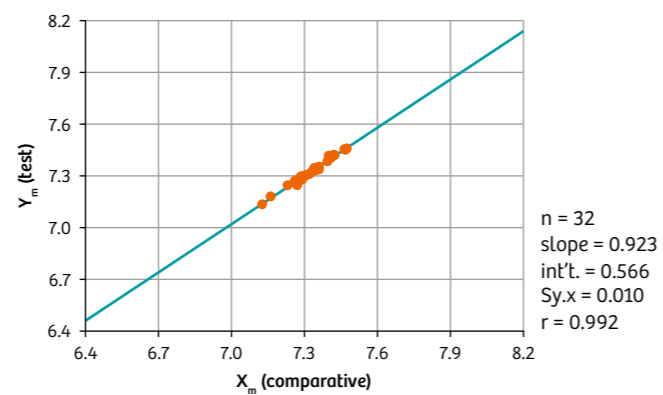
pH

X: Radiometer ABL 700 System
Y: epoc System



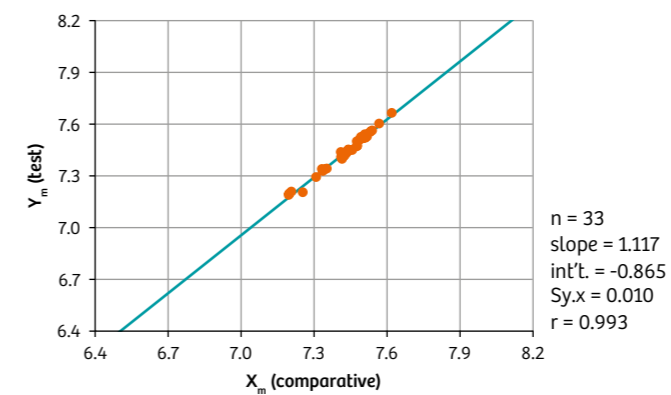
pH

X: IL GEM PREMIER 3000 System
Y: epoc System



pH

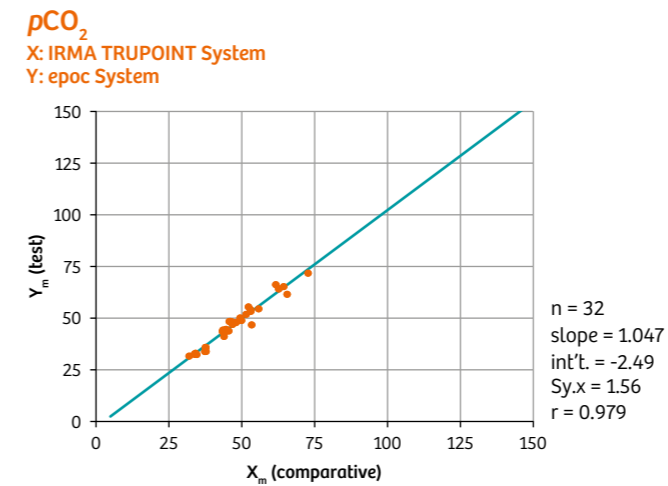
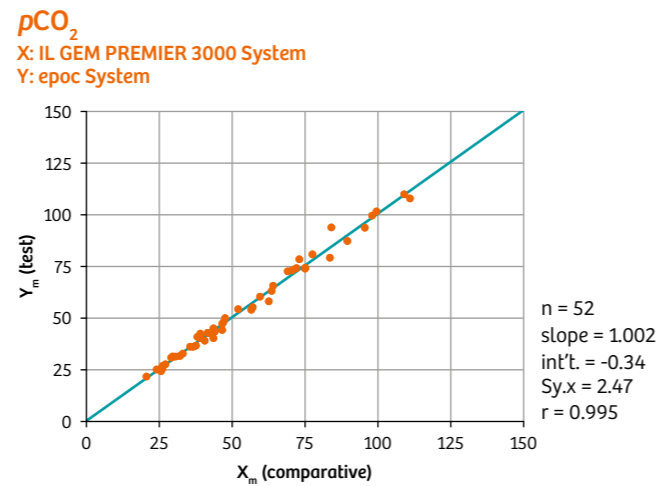
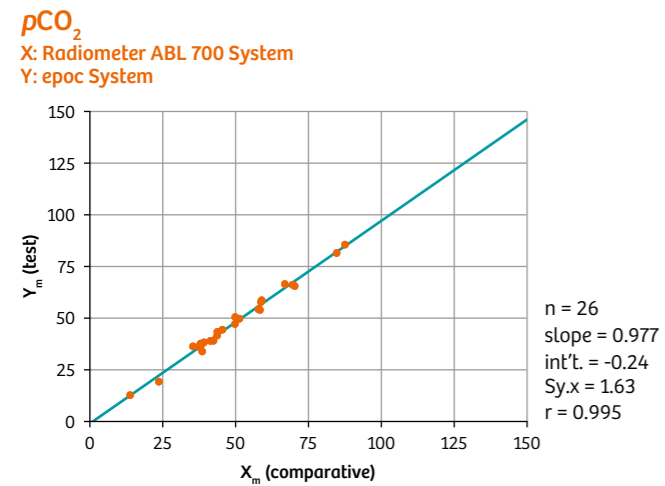
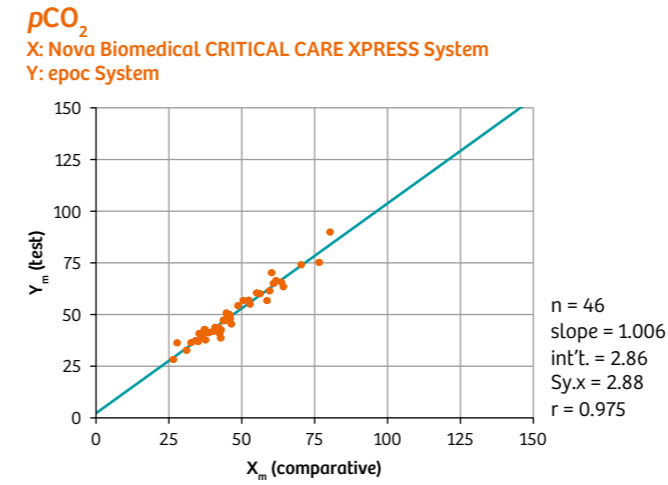
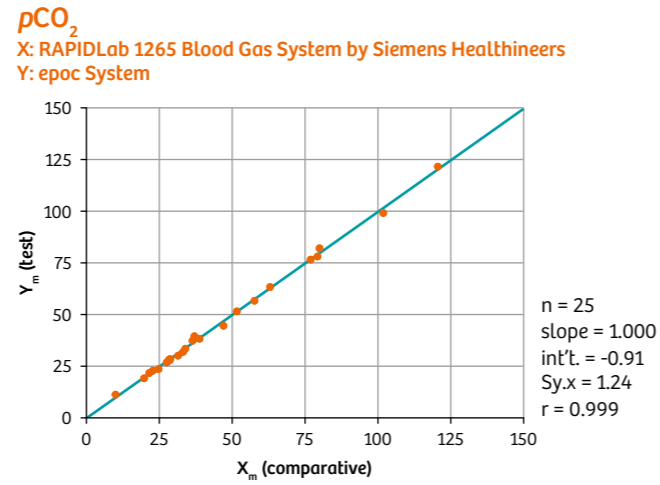
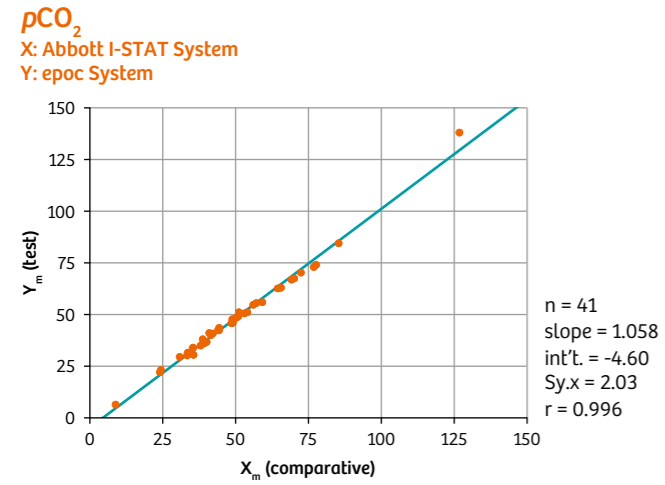
X: IRMA TRUPOINT System
Y: epoc System



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%



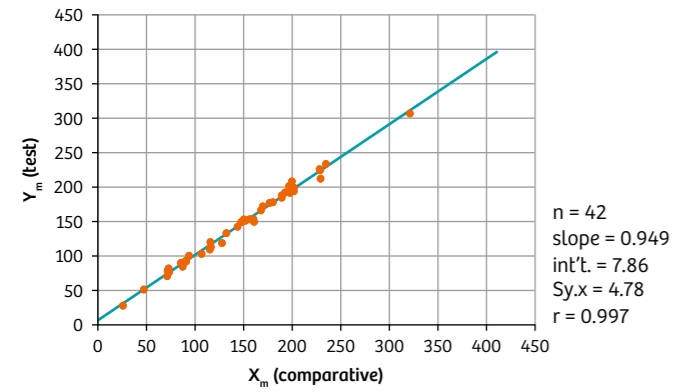
pO₂ Method Comparison

pO₂ mmHg

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

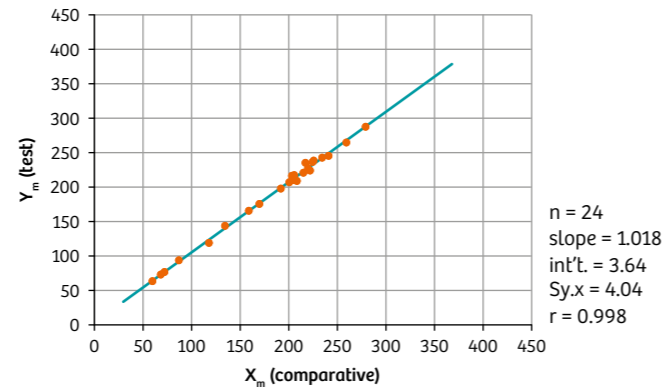
pO₂

X: Abbott I-STAT System
Y: epoc System



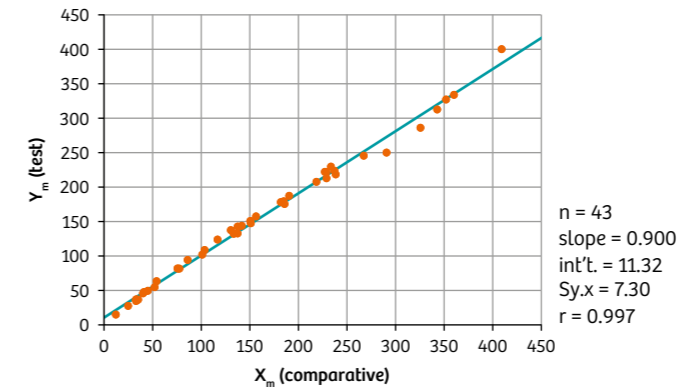
pO₂

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



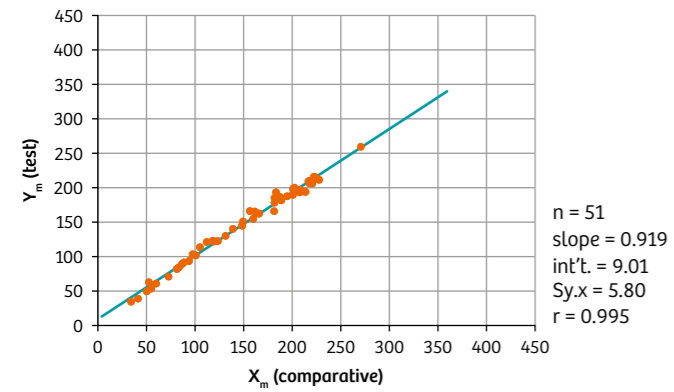
pO₂

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



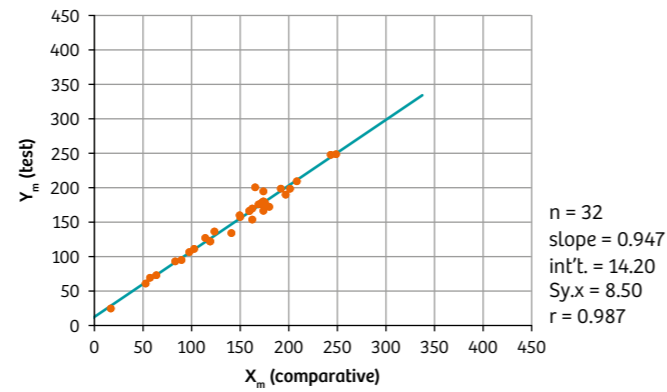
pO₂

X: Radiometer ABL 700 System
Y: epoc System



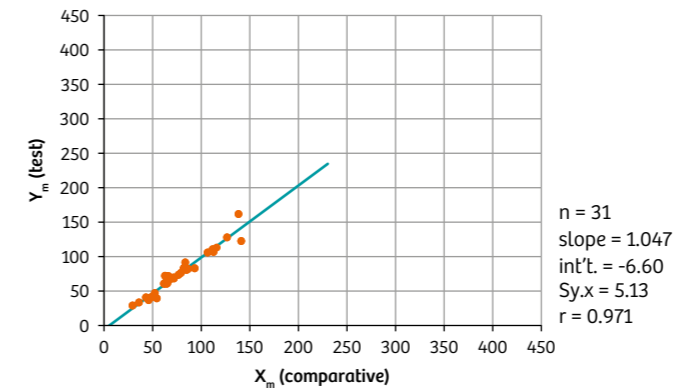
pO₂

X: IL GEM PREMIER 3000 System
Y: epoc System



pO₂

X: IRMA TRUPOINT System
Y: epoc System



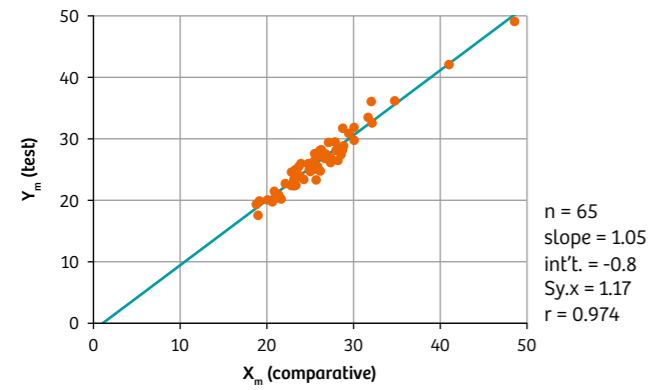
TCO₂ Method Comparison

TCO₂ 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%

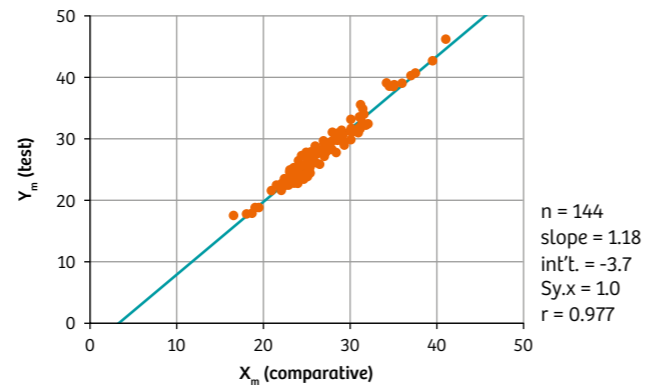
TCO₂

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



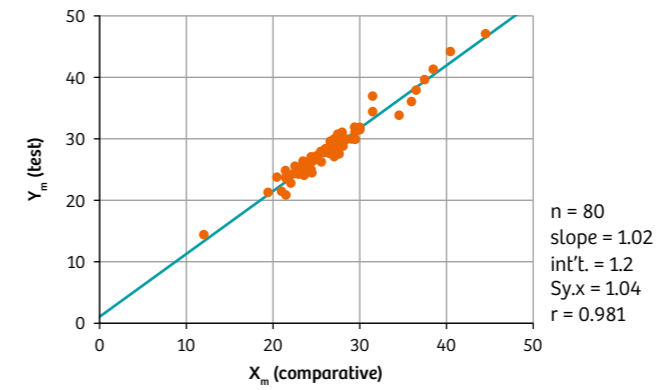
TCO₂

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



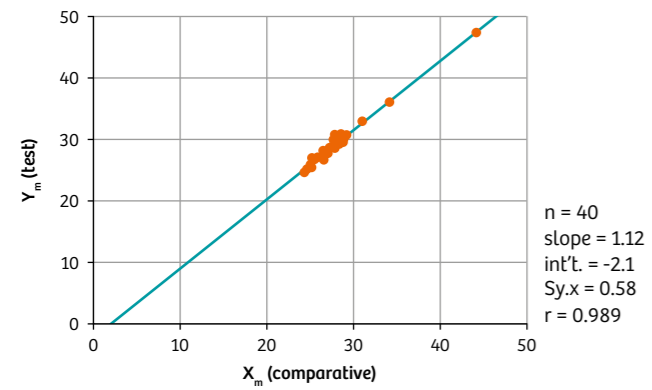
TCO₂

X: ROCHE COBAS
Y: epoc System



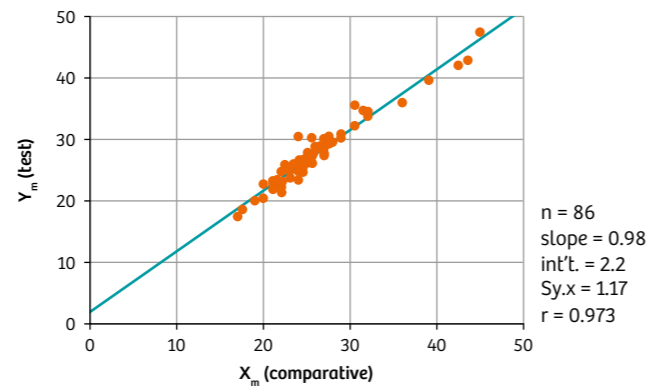
TCO₂

X: Beckman DXC System
Y: epoc System



TCO₂

X: Abbott ARCHITECT System
Y: epoc System



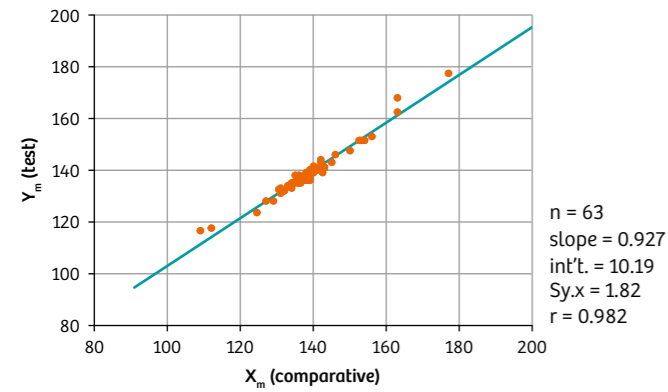
Sodium Method Comparison

Sodium mmol/L

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

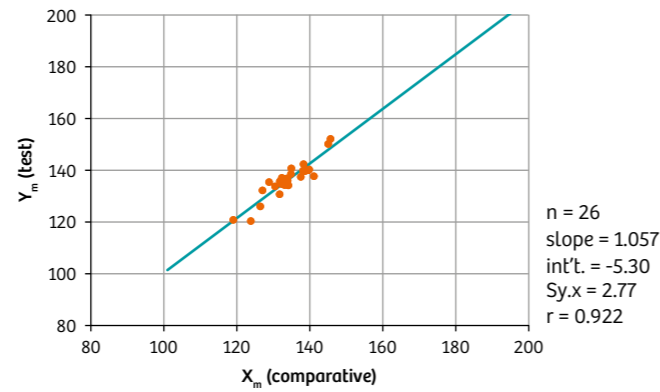
Na⁺

X: Abbott I-STAT System
Y: epoc System



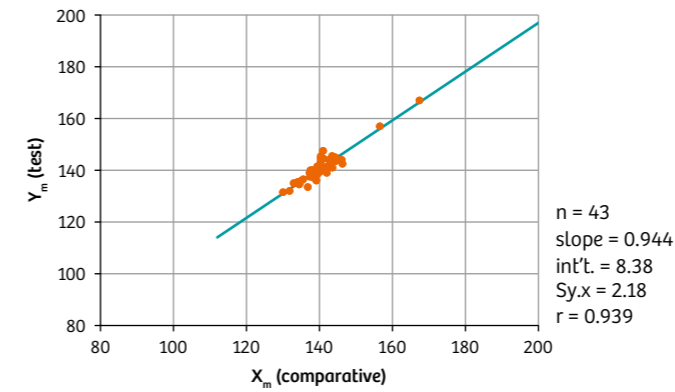
Na⁺

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



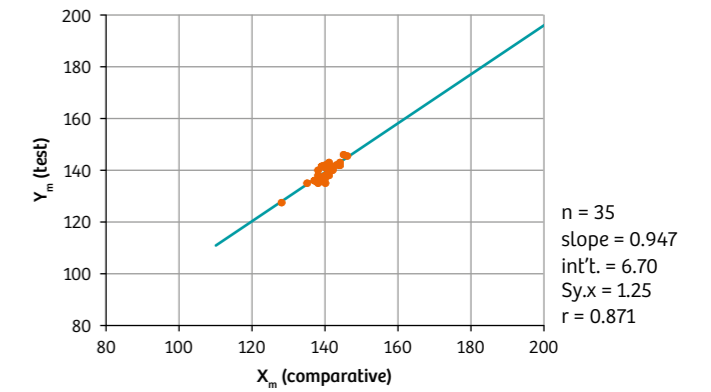
Na⁺

X: Nova Biomedical PHOX System
Y: epoc System



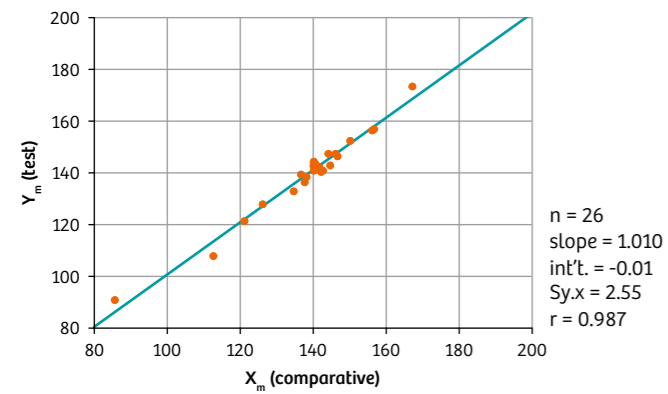
Na⁺

X: Ortho Clinical Laboratories VITROS System
Y: epoc System



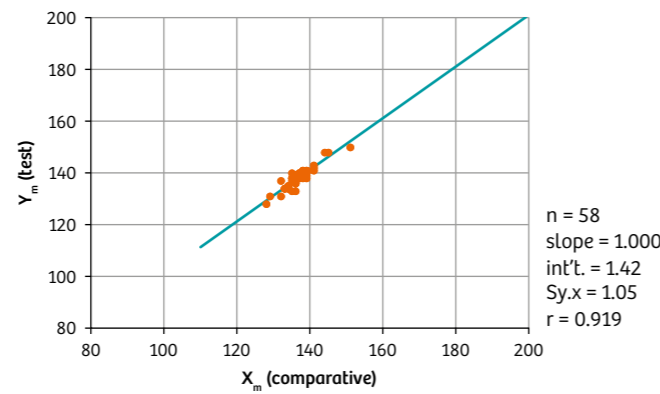
Na⁺

X: Radiometer ABL 700 System
Y: epoc System



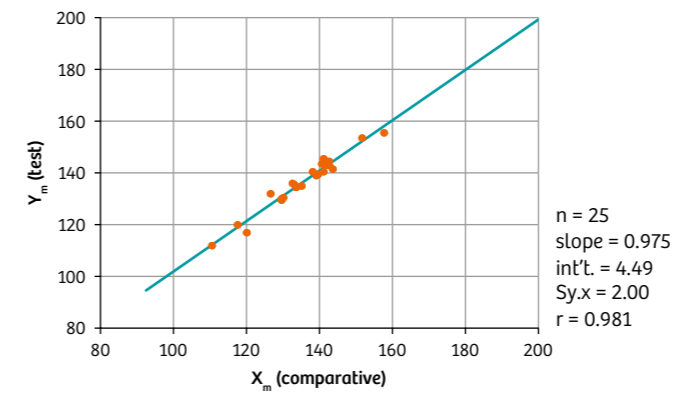
Na⁺

X: IL GEM PREMIER 3000 System
Y: epoc System



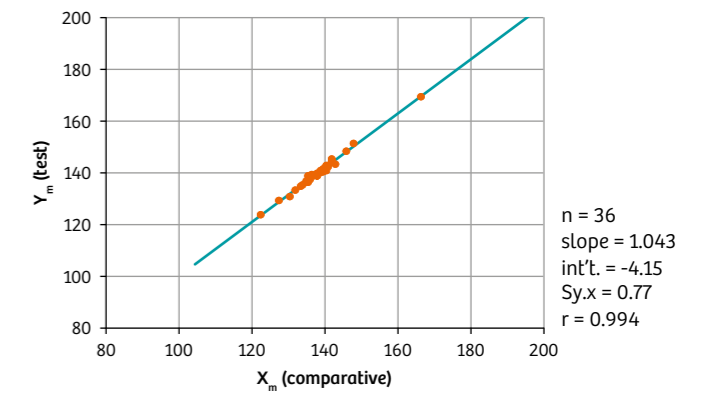
Na⁺

X: Beckman Coulter
Y: epoc System



Na⁺

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



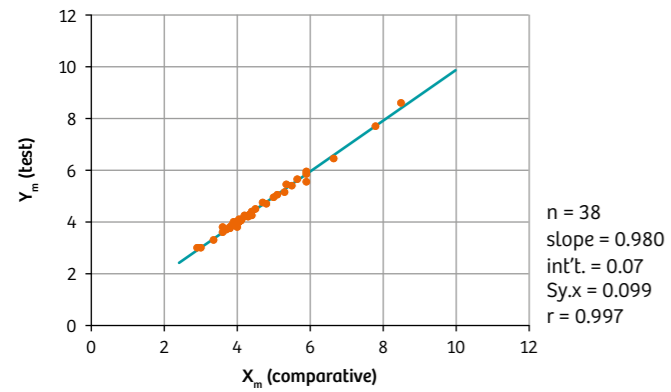
Potassium Method Comparison

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%

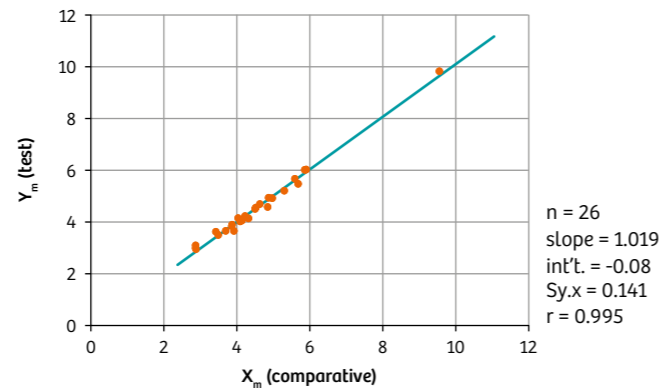
K⁺

X: Abbott I-STAT System
Y: epoc System



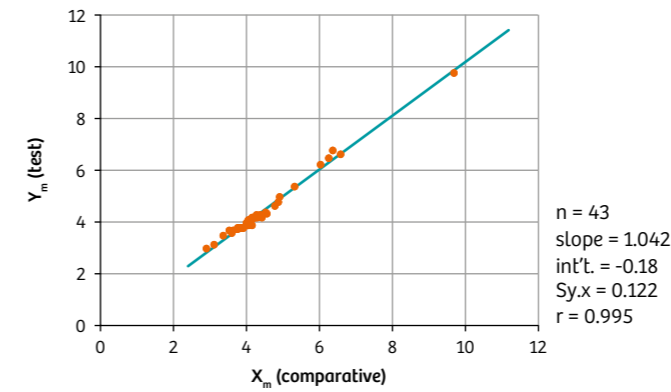
K⁺

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



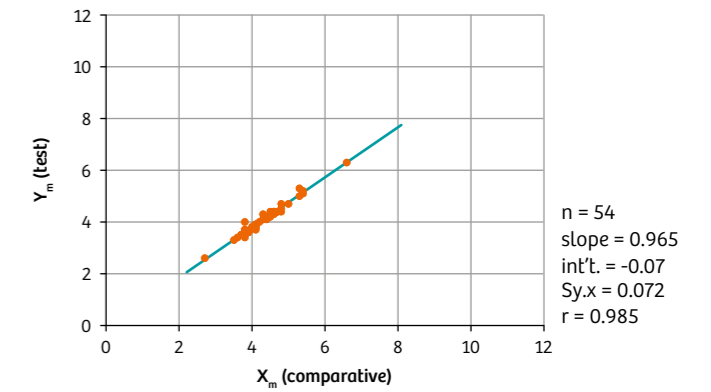
K⁺

X: Nova Biomedical PHOX System
Y: epoc System



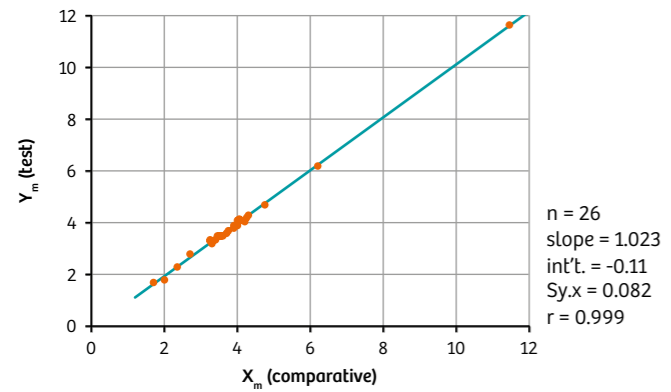
K⁺

X: Ortho Clinical Laboratories VITROS System
Y: epoc System



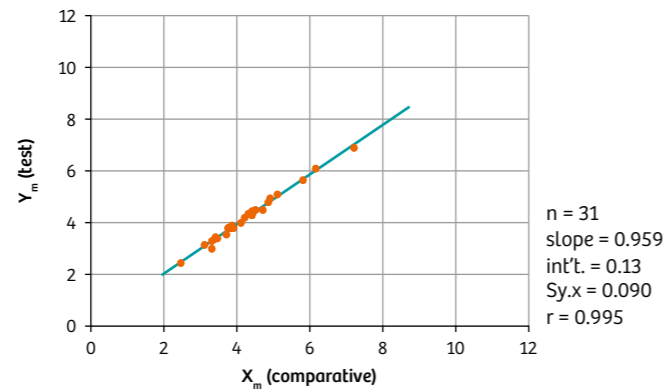
K⁺

X: Radiometer ABL 700 System
Y: epoc System



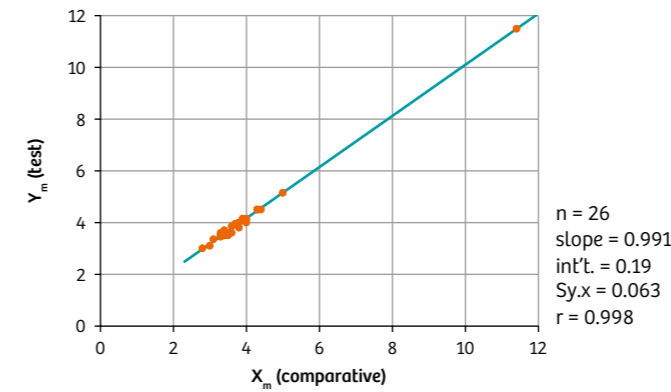
K⁺

X: IL GEM PREMIER 3000 System
Y: epoc System



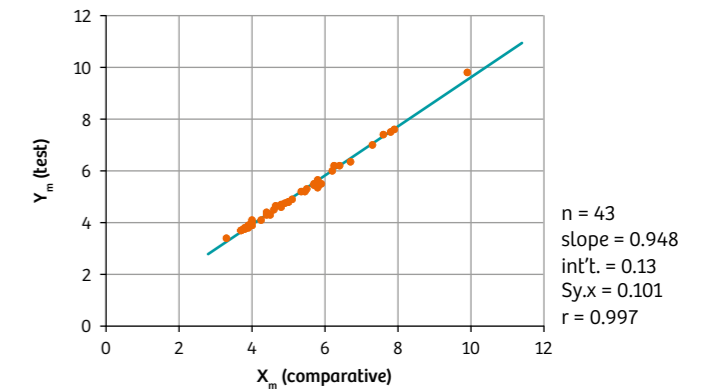
K⁺

X: Beckman Coulter
Y: epoc System



K⁺

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



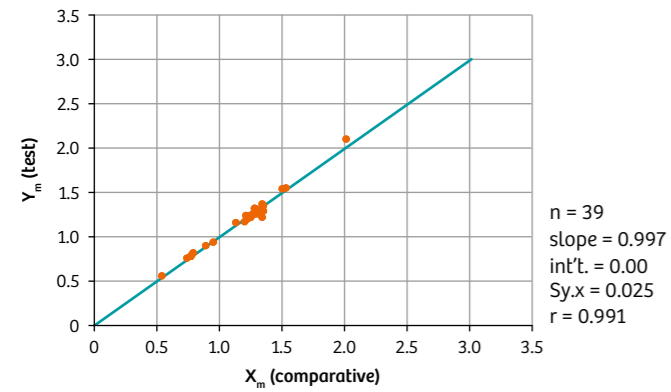
Ionized Calcium Method Comparison

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%

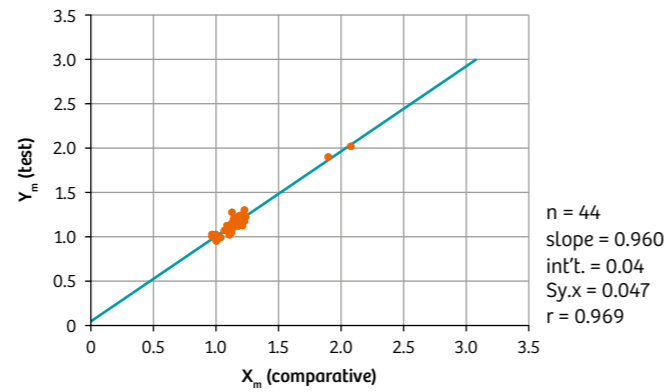
Ca⁺⁺

X: Abbott I-STAT System
Y: epoc System



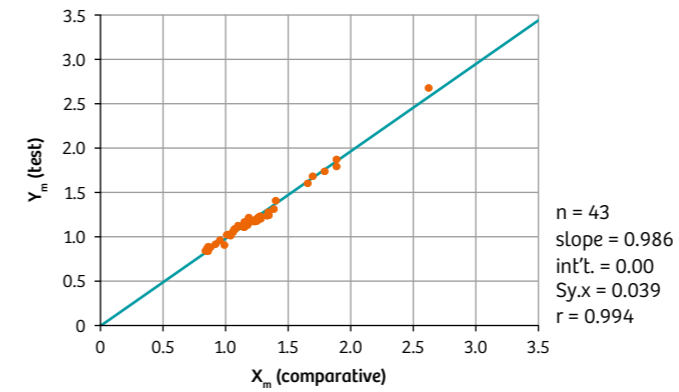
Ca⁺⁺

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



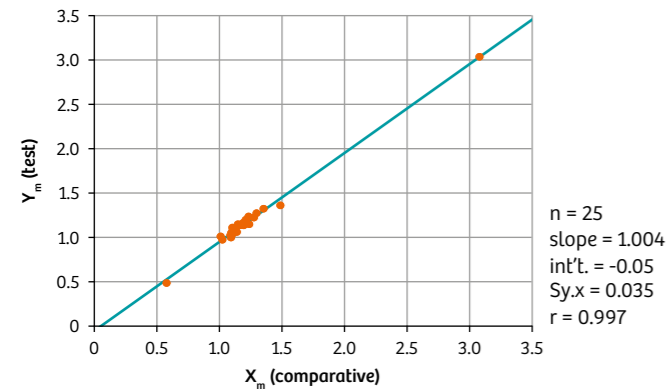
Ca⁺⁺

X: Nova Biomedical PHOX System
Y: epoc System



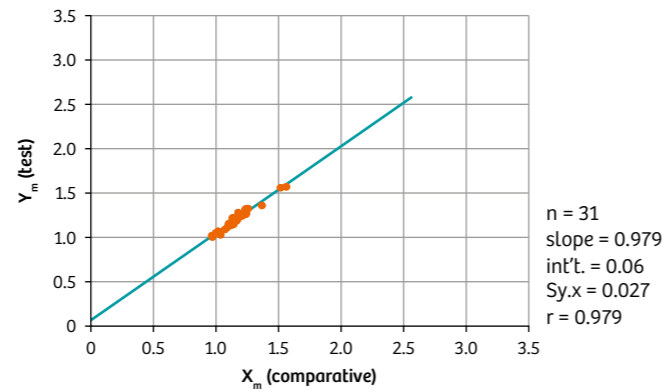
Ca⁺⁺

X: Radiometer ABL 700 System
Y: epoc System



Ca⁺⁺

X: IL GEM PREMIER 3000 System
Y: epoc System



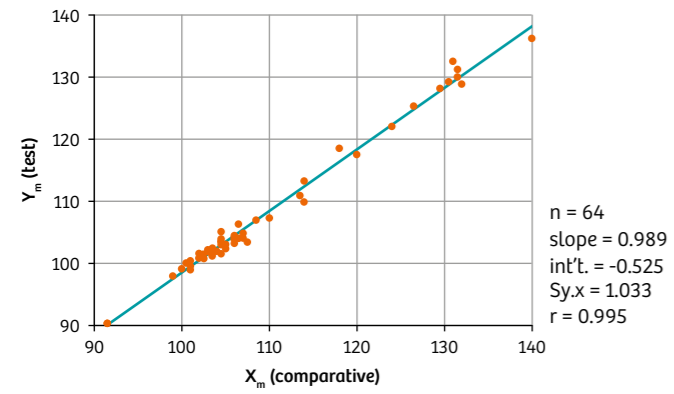
Chloride Method Comparison

Chloride mmol/L

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

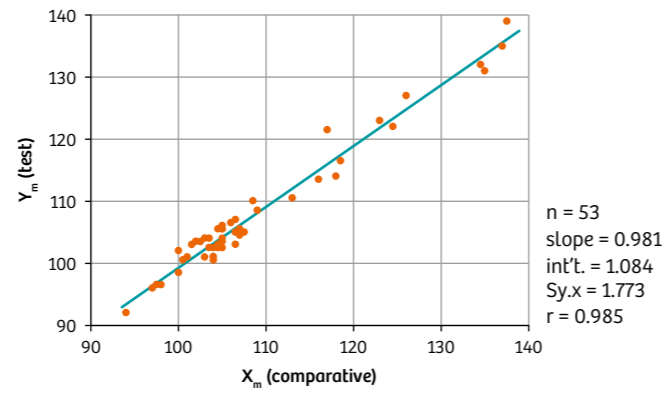
Chloride

X: Abbott I-STAT System
Y: epoc System



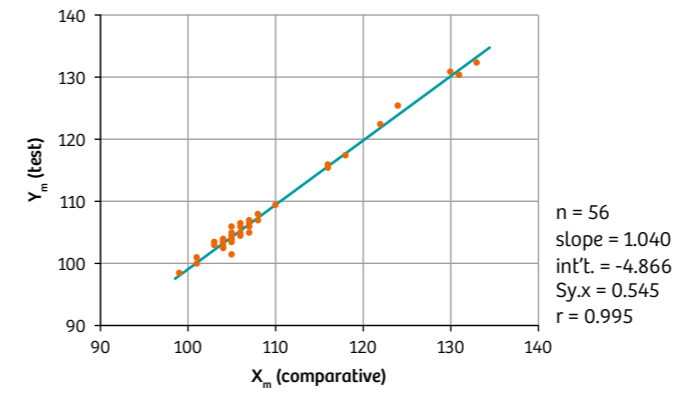
Chloride

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



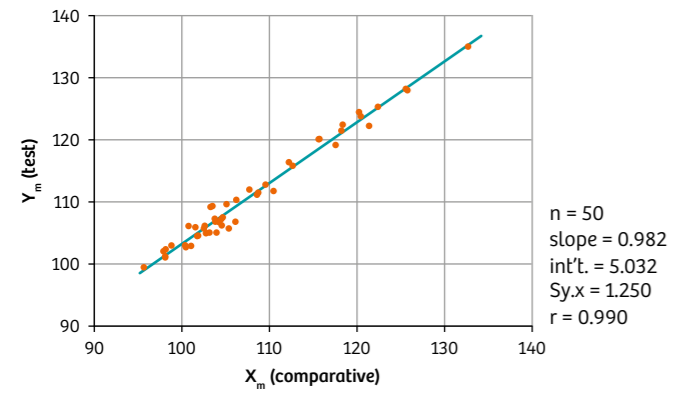
Chloride

X: Radiometer ABL 800 System
Y: epoc System



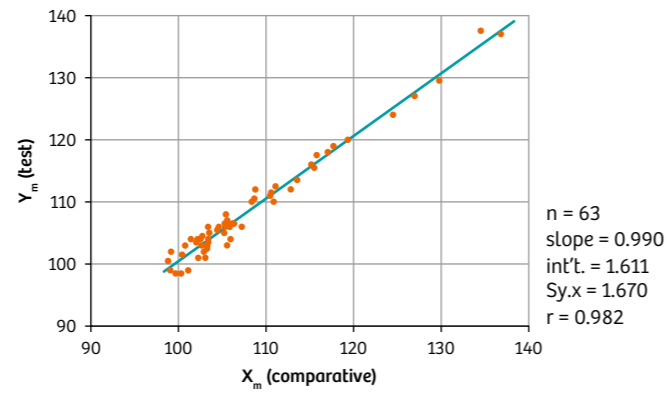
Chloride

X: ROCHE COBAS 6000 System
Y: epoc System



Chloride

X: Beckman Coulter DXC System
Y: epoc System



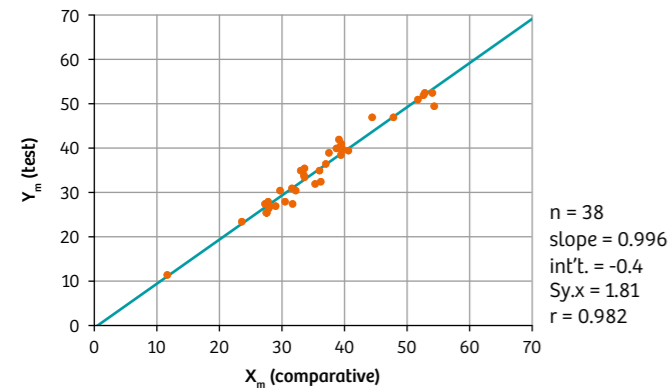
Hematocrit Method Comparison

Hematocrit %PCV

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

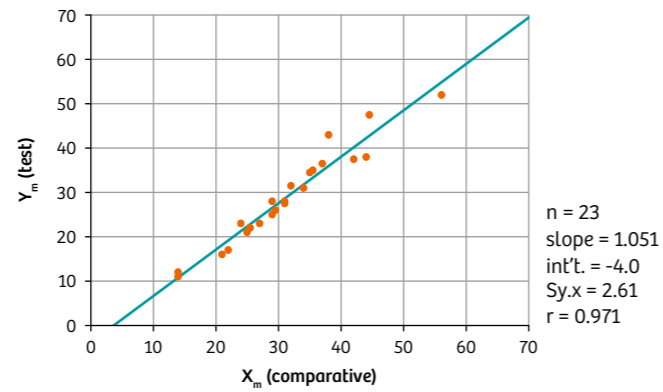
Hct

X: Radiometer ABL 825 System
Y: epoc System



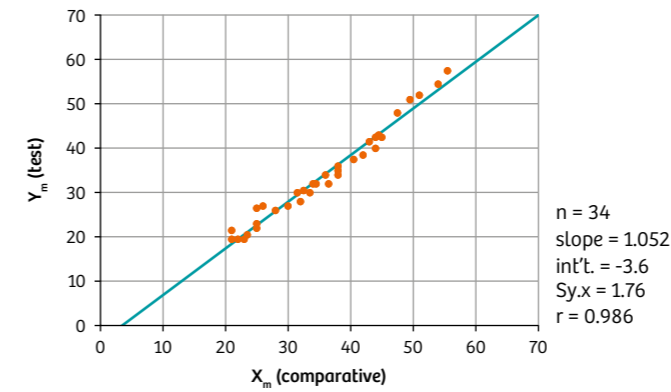
Hct

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



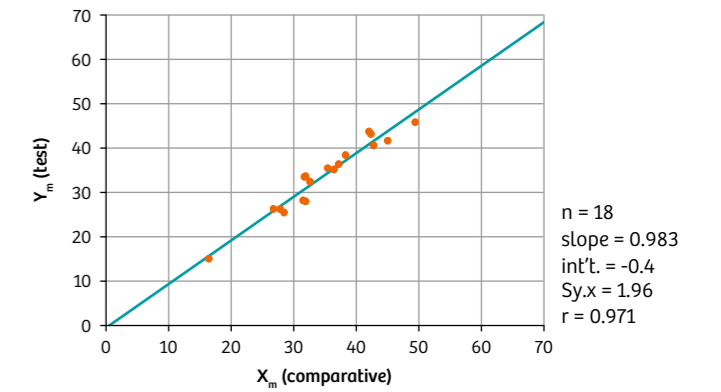
Hct

X: Nova Biomedical PHOX System
Y: epoc System



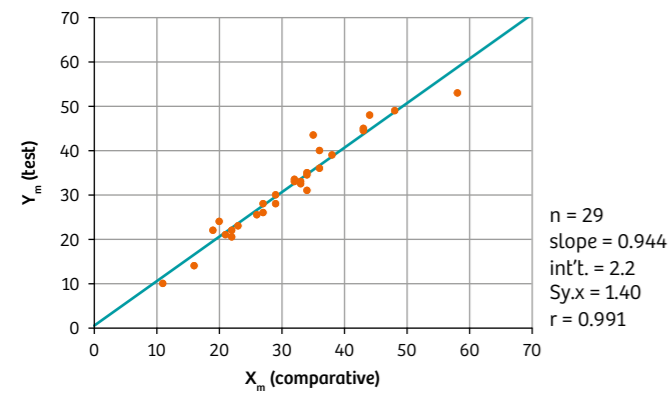
Hct

X: Sysmex XE System
Y: epoc System



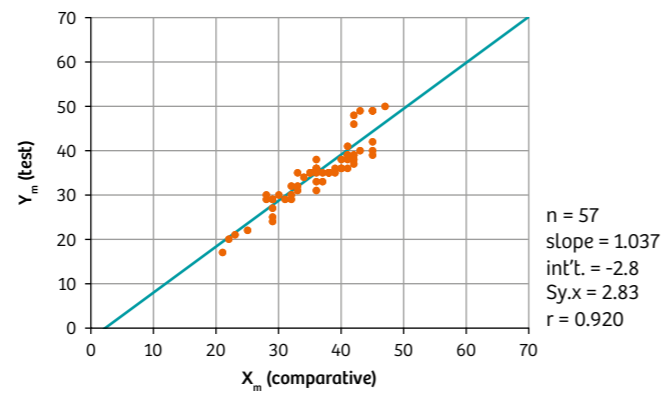
Hct

X: Abbott I-STAT System
Y: epoc System



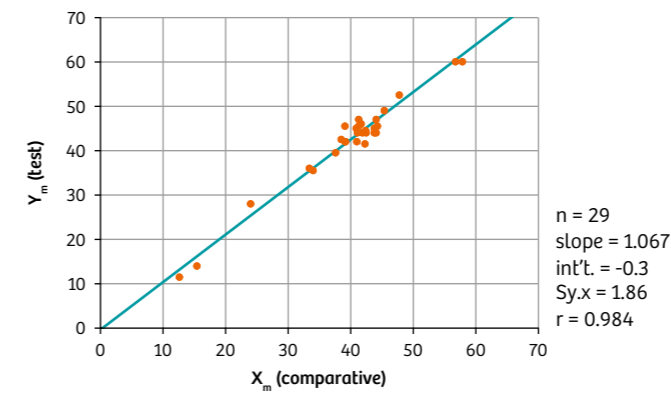
Hct

X: IL GEM PREMIER 3000 System
Y: epoc System



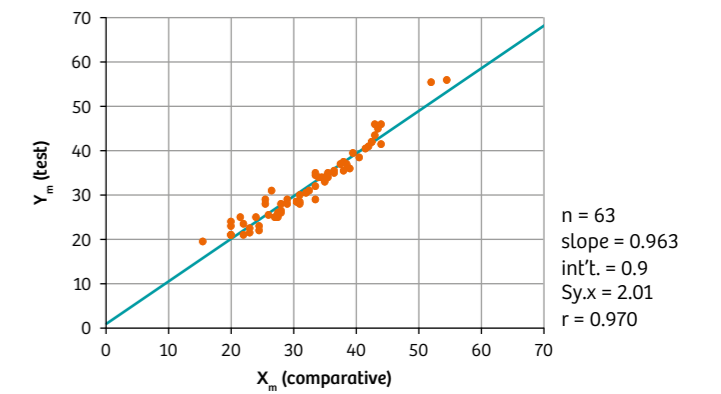
Hct

X: Beckman Coulter LH System
Y: epoc System



Hct

X: Microcentrifugation (spun)
Y: epoc System



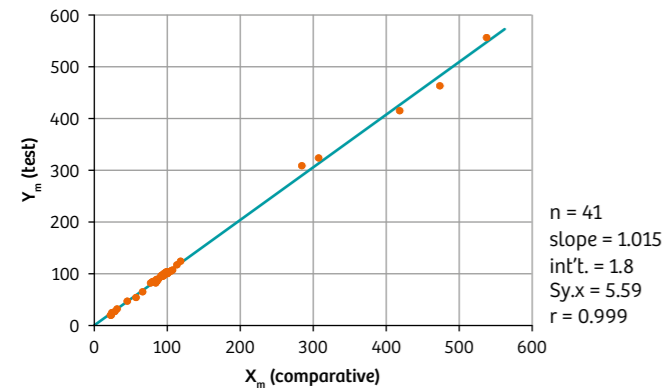
Glucose Method Comparison

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%

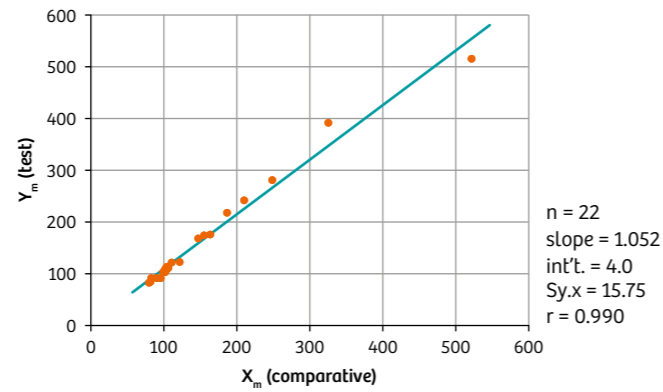
Glucose

X: Abbott I-STAT System
Y: epoc System



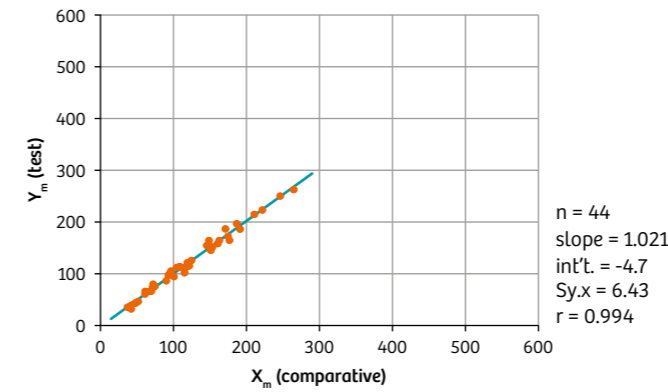
Glucose

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



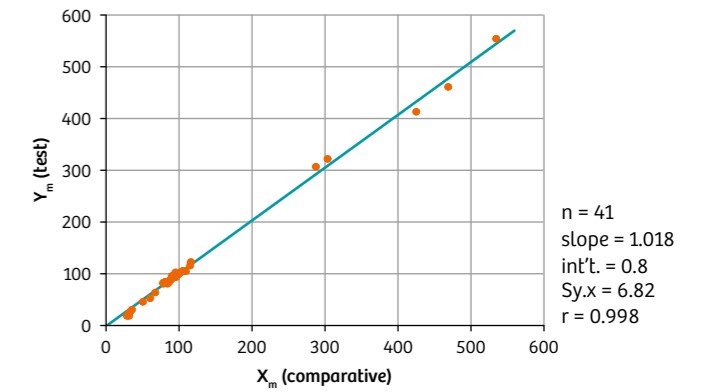
Glucose

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



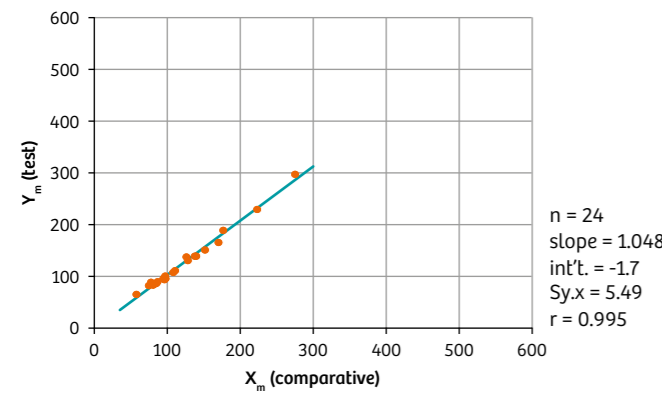
Glucose

X: Ortho Clinical Laboratories VITROS System
Y: epoc System



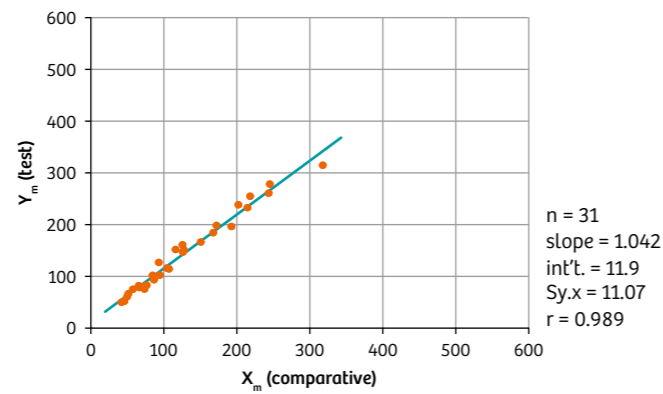
Glucose

X: Radiometer ABL 700 System
Y: epoc System



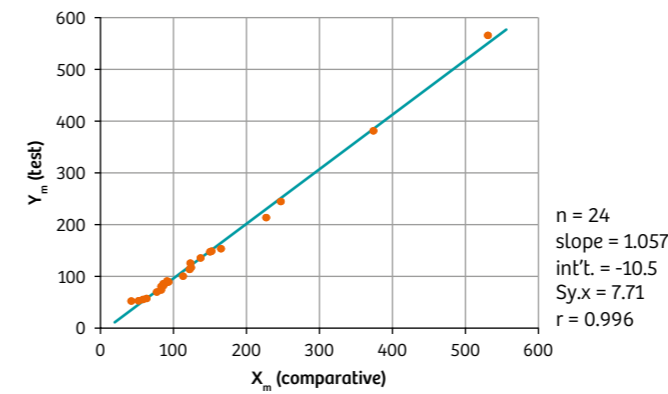
Glucose

X: IL GEM PREMIER 3000 System
Y: epoc System



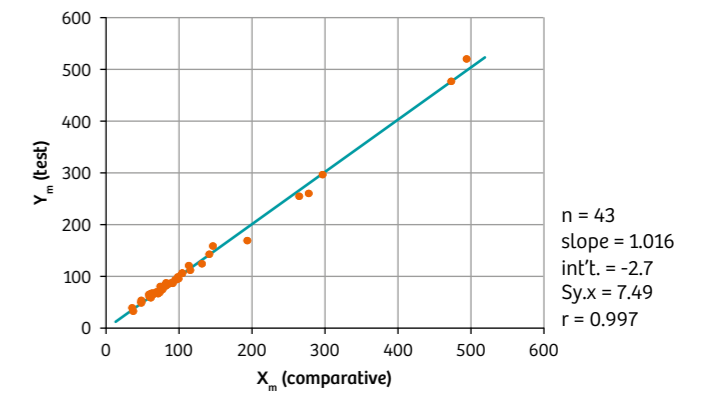
Glucose

X: Beckman Coulter DXC System
Y: epoc System



Glucose

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



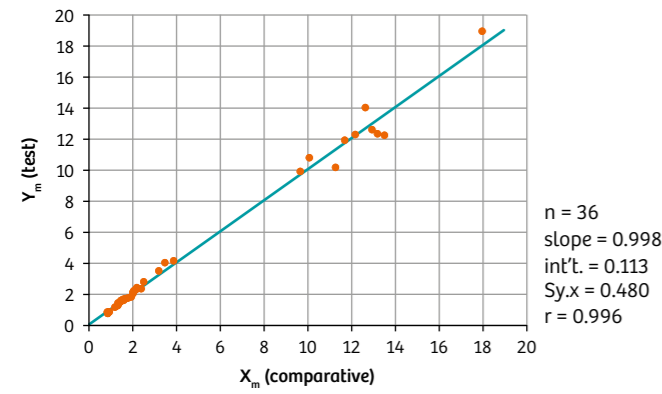
Lactate Method Comparison

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%

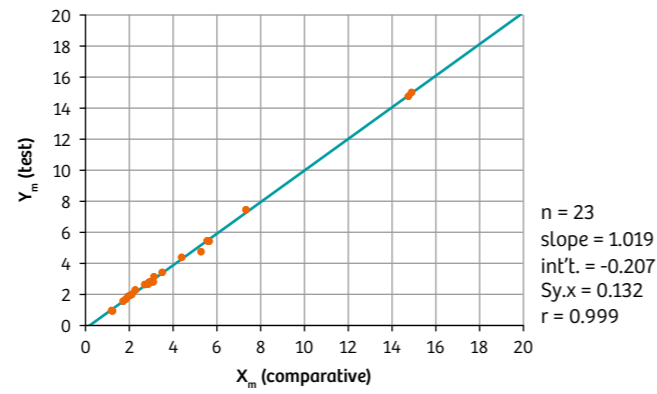
Lactate

X: Abbott I-STAT System
Y: epoc System



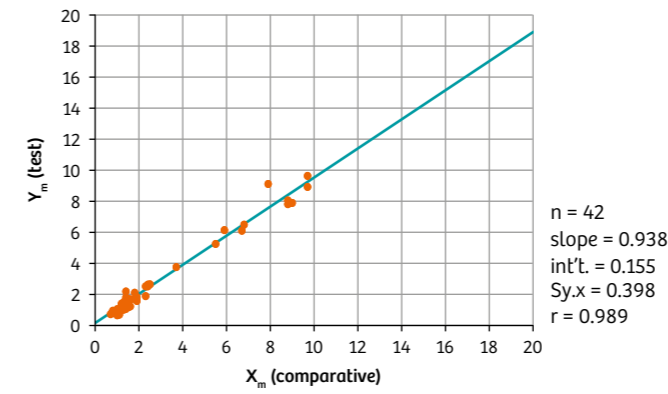
Lactate

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



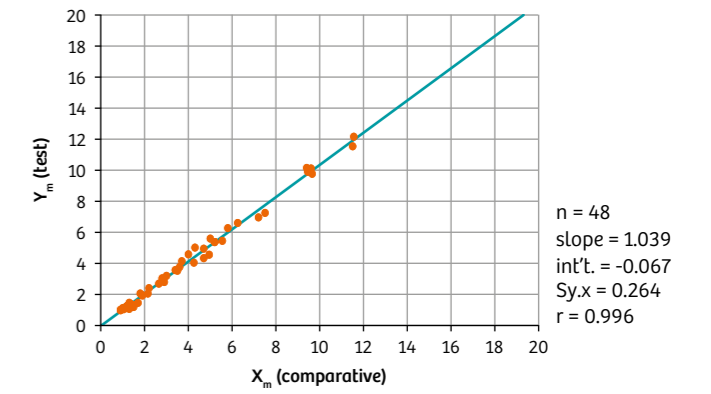
Lactate

X: Ortho Clinical Laboratories VITROS System
Y: epoc System



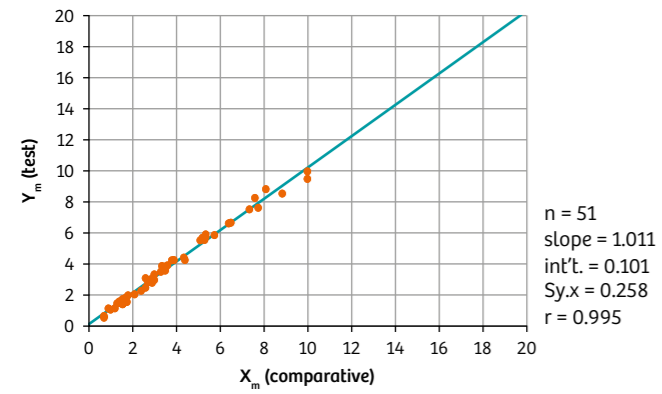
Lactate

X: Roche MODULAR System
Y: epoc System



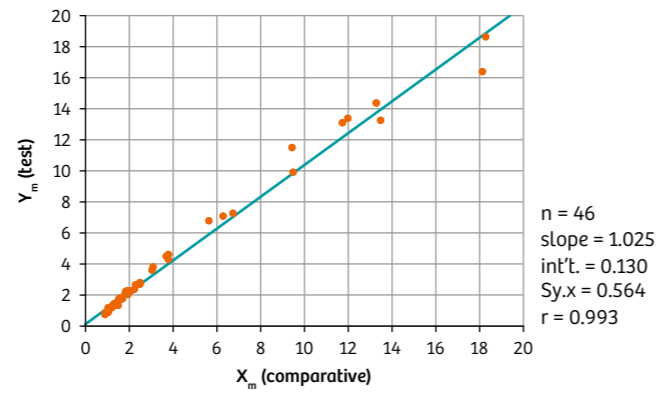
Lactate

X: Radiometer ABL 700 System
Y: epoc System



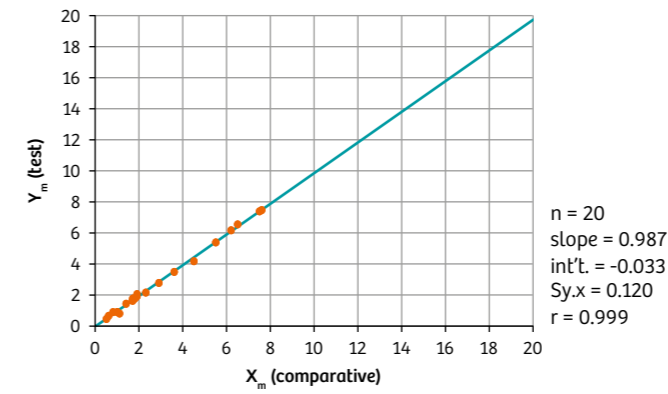
Lactate

X: IL GEM PREMIER 4000 System
Y: epoc System



Lactate

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



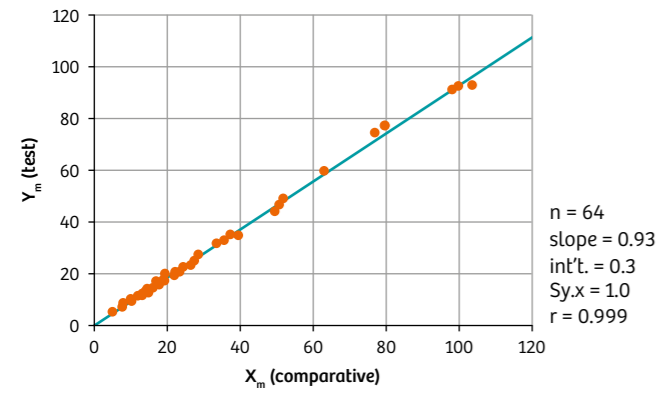
BUN Method Comparison

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%

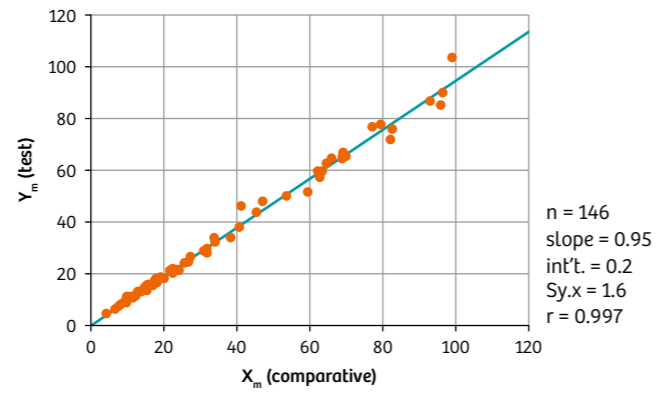
BUN

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



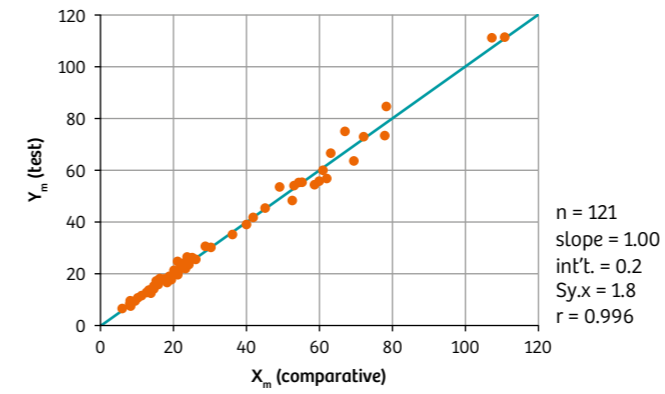
BUN

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



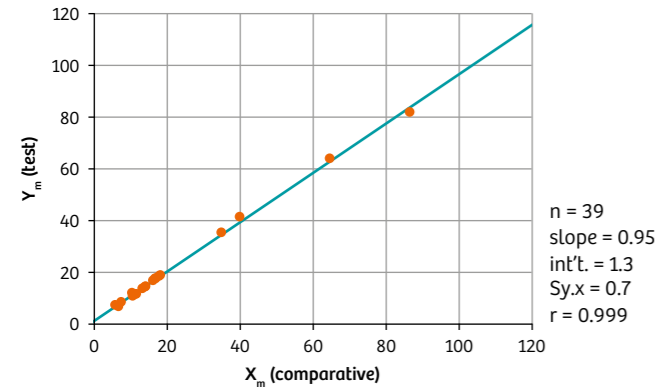
BUN

X: ROCHE COBAS
Y: epoc System



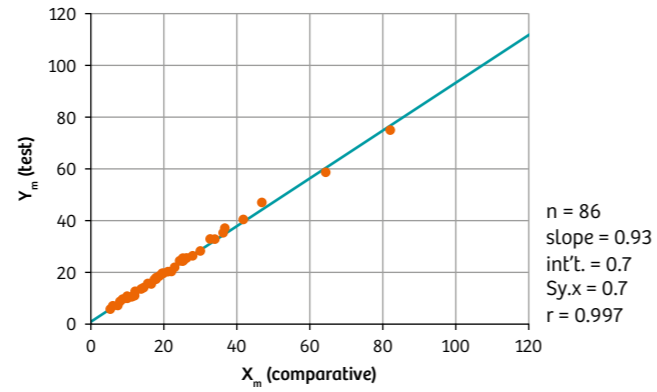
BUN

X: Beckman DXC System
Y: epoc System



BUN

X: Abbott ARCHITECT System
Y: epoc System



Creatinine Method Comparison

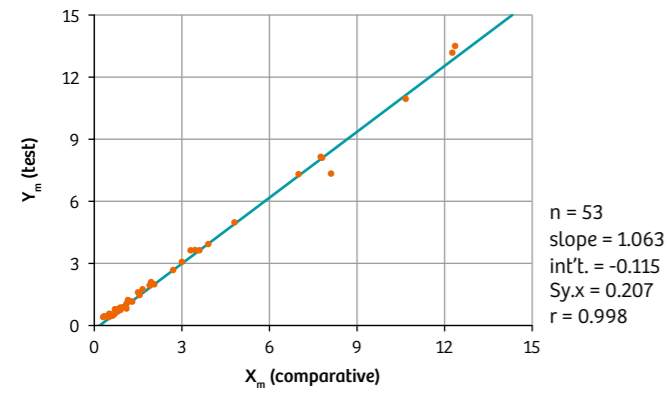
Notes

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%

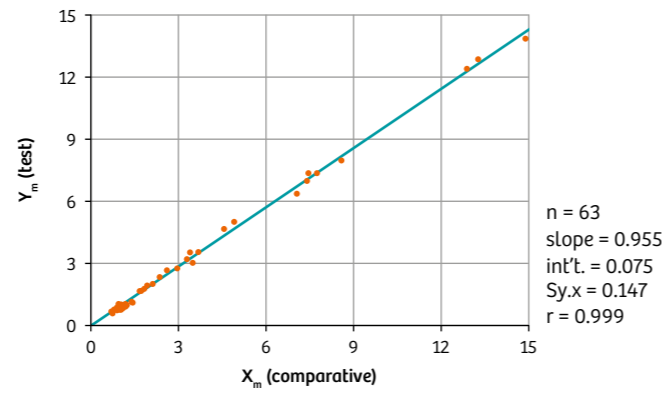
Creatinine

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



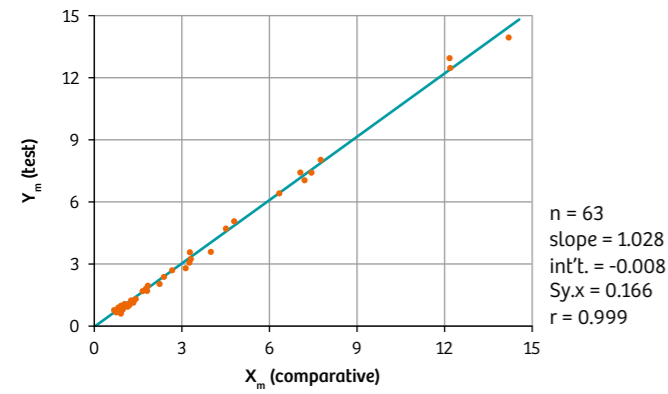
Creatinine

X: Abbott I-STAT System
Y: epoc System



Creatinine

X: Beckman Coulter AU680 System
Y: epoc System



Creatinine

X: ROCHE COBAS 6000 System
Y: epoc System

