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White Paper | epoc® Blood Analysis System

# 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 at 10 user sites.

### Method comparison

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

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

## Glossary

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

**Precision** is reproducibility—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.<sup>1</sup>

**Intercept (int't)** or y-intercept describes where the line of best fit intersects the y-axis. Ideally, the y-intercept should be 0.0. Deviations are an indication of constant systematic error.<sup>1</sup>

**S<sub>y,x</sub>** 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<sub>y,x</sub> will never be 0 because both methods have some imprecision.<sup>1</sup>

**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.<sup>1</sup>

## Methodologies

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

**pCO<sub>2</sub>** is measured by potentiometry using a membrane-covered pH sensing electrode. The electrode voltage is proportional to the dissolved carbon dioxide concentration through the Nernst equation.

**pO<sub>2</sub>** is measured by amperometry using a membrane-covered oxygen-sensing cathode electrode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

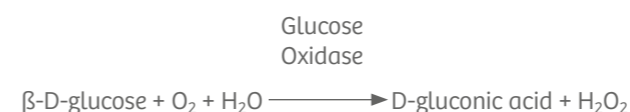
**Sodium** is measured by potentiometry using an ion-selective membrane electrode. The concentration of sodium ions is obtained from the measured potential using the Nernst equation. The epoc sodium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect)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

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

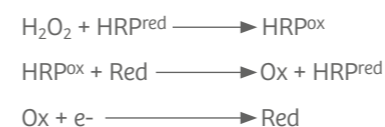
**Ionized calcium** is measured by potentiometry using an ion-selective membrane electrode. The concentration of calcium ions is obtained from the measured potential using the Nernst equation.

**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.

**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:

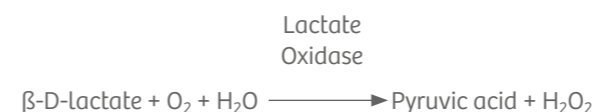


and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox-mediated (ABTS [2,2'-azino-bis 3-ethylbenzothiazoline-6-sulfonic acid] diammonium salt) horseradish peroxidase (HRP)-catalyzed reduction on a gold electrode.

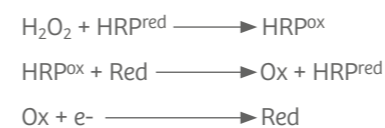


The reduction current is proportional to the concentration of glucose in the test fluid. The epoc glucose result is reported as plasma-equivalent glucose concentration.

**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:



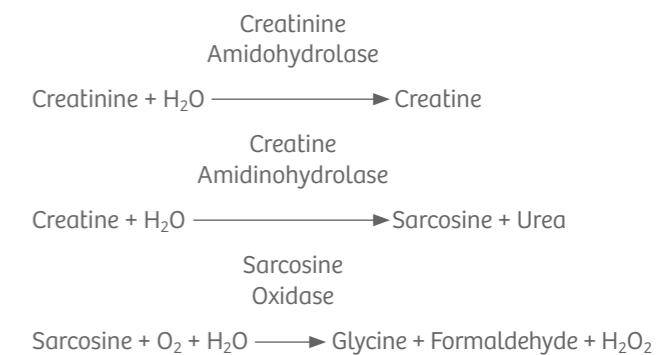
and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox-mediated (ABTS [2,2'-azino-bis 3-ethylbenzothiazoline-6-sulfonic acid] diammonium salt) horseradish peroxidase (HRP)-catalyzed reduction on a gold electrode.



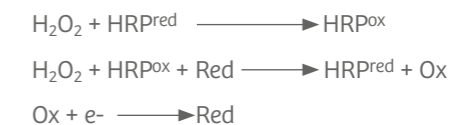
The reduction current is proportional to the concentration of lactate in the test fluid.

**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.

**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 concentration, is inversely proportional to the hematocrit value.

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

### Reference:

- Westgard JO. Basic method evaluation. 3rd ed. Madison, WI (USA): Westgard QC, Inc.; 2008. p. 77-78.

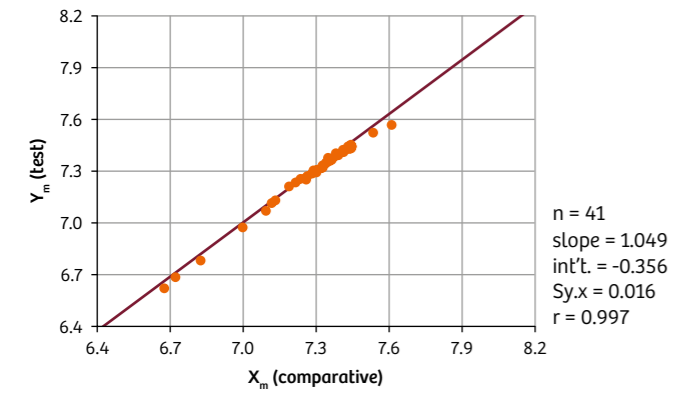
# pH Method Comparison

## pH

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

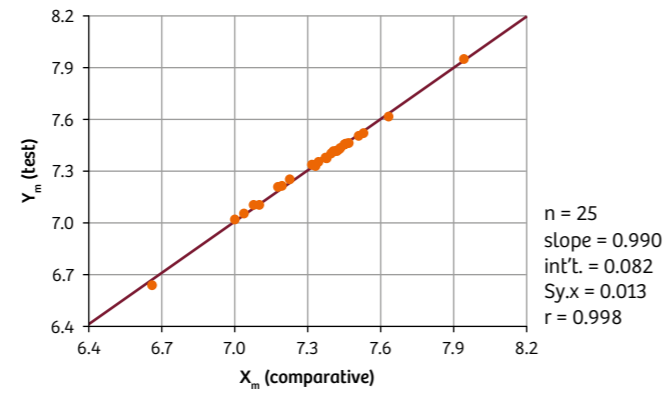
## pH

X: Abbott I-STAT System  
Y: epoc System



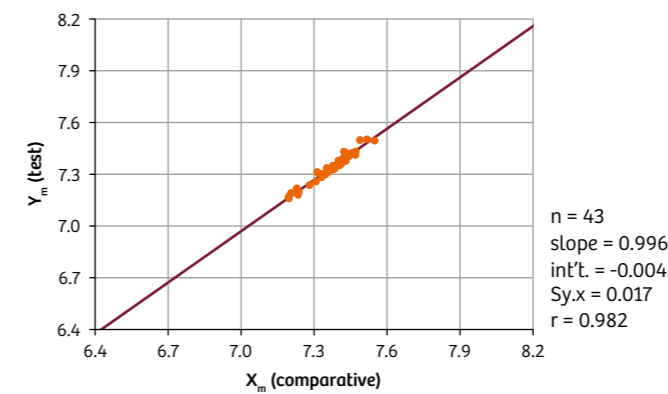
## pH

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



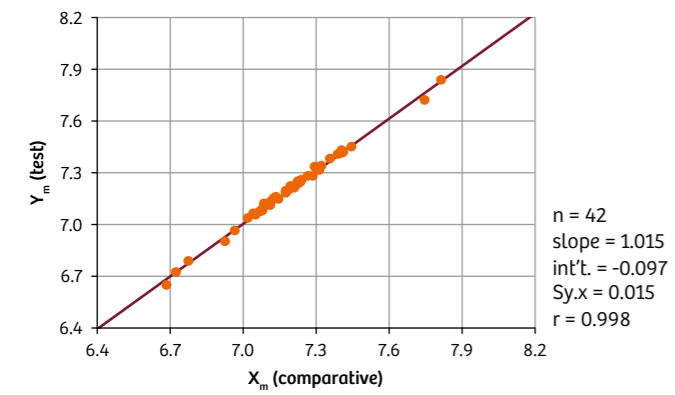
## pH

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



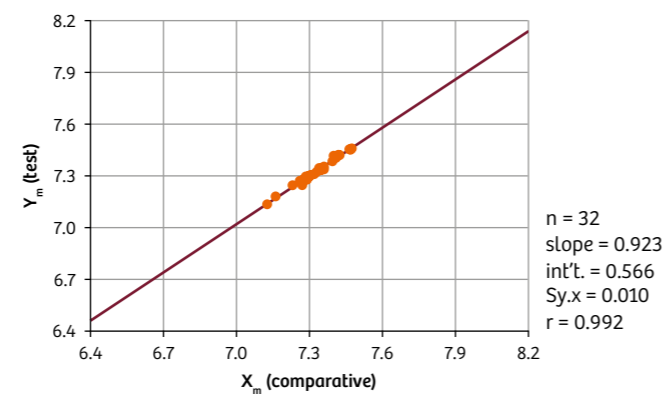
## pH

X: Radiometer ABL 700 System  
Y: epoc System



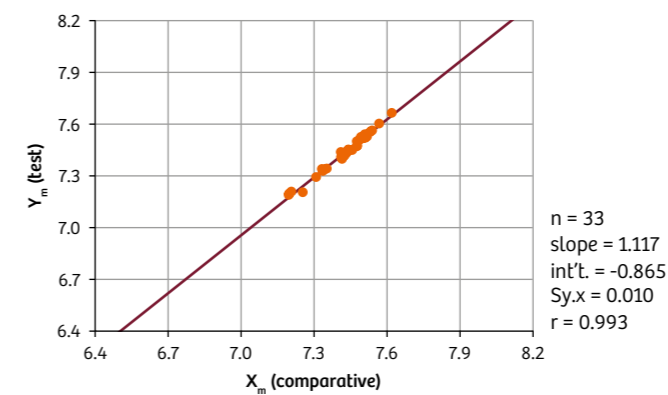
## pH

X: IL GEM PREMIER 3000 System  
Y: epoc System



## pH

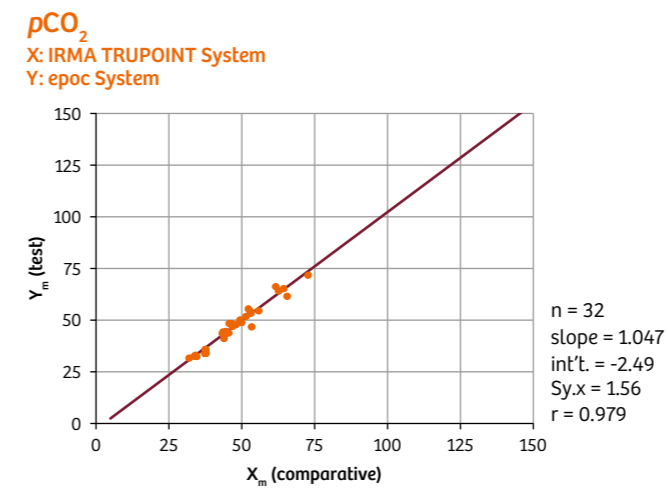
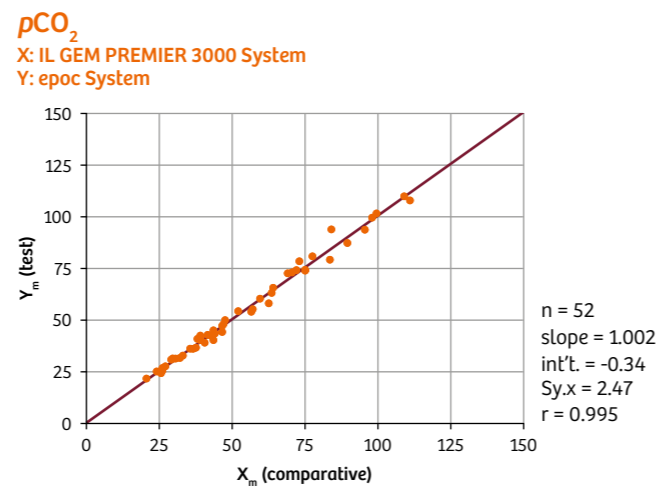
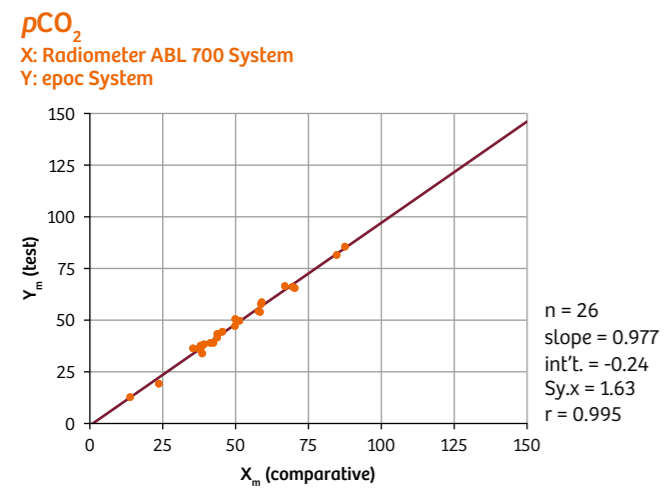
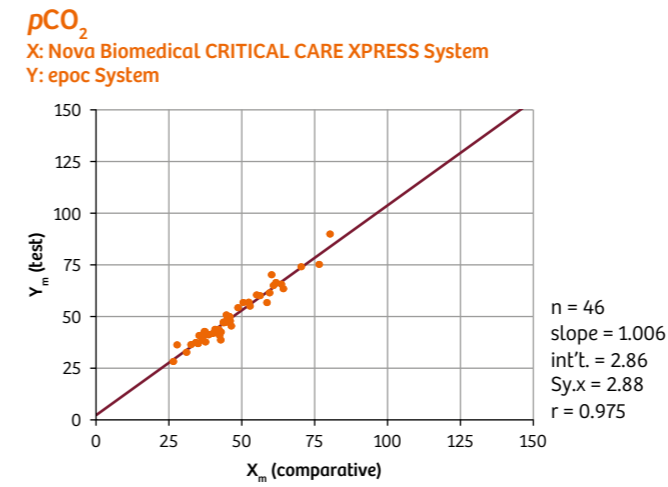
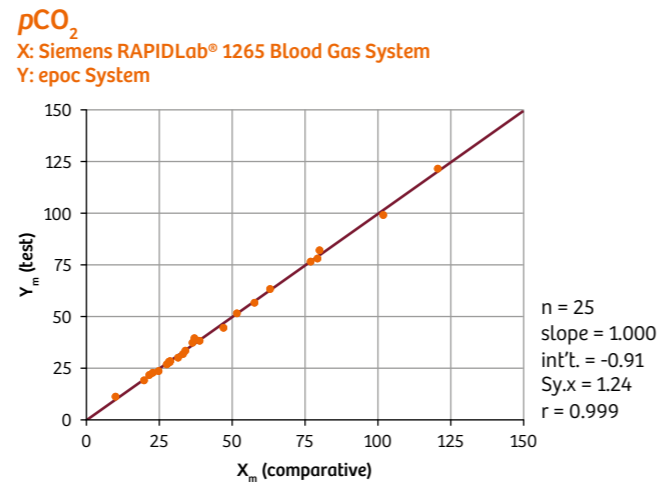
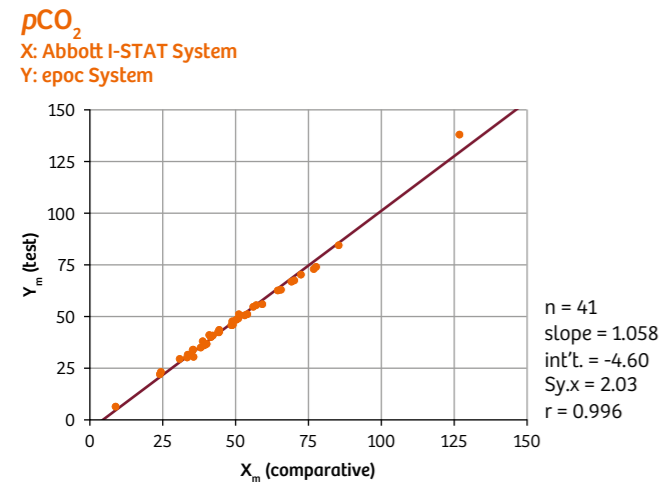
X: IRMA TRUPOINT System  
Y: epoc System



# pCO<sub>2</sub> Method Comparison

**pCO<sub>2</sub>**

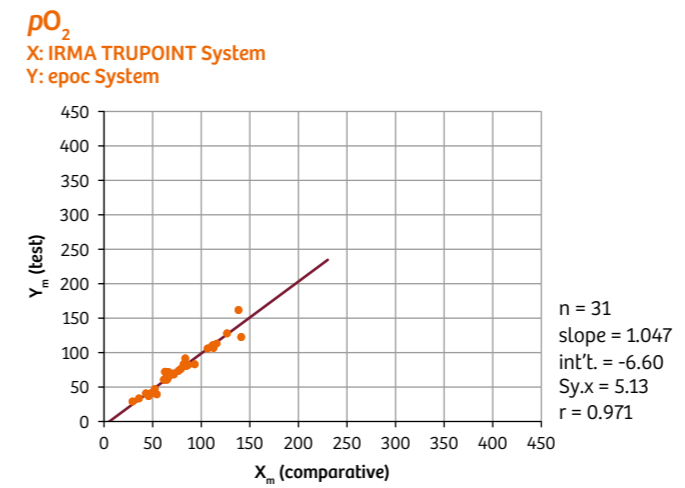
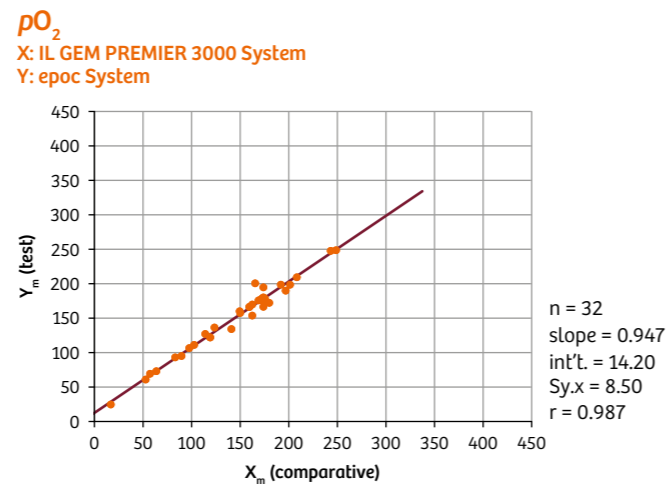
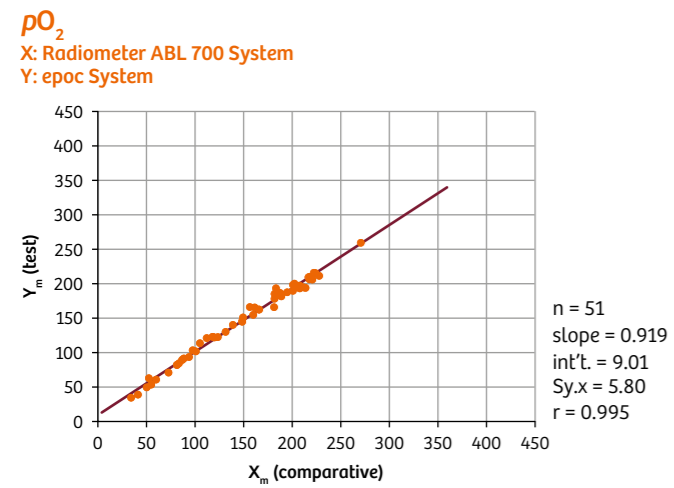
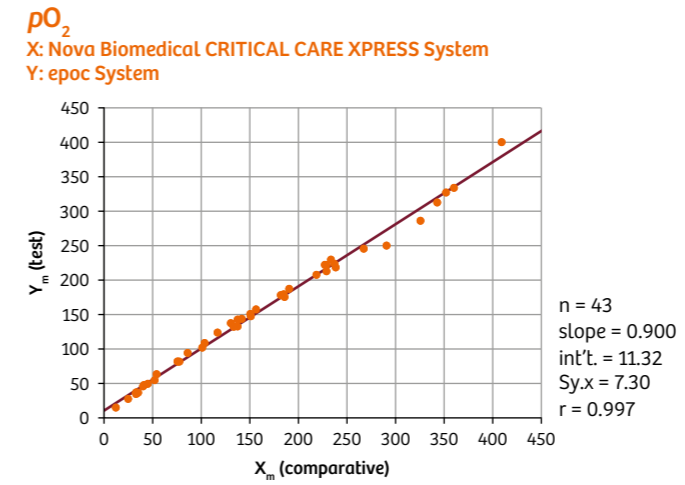
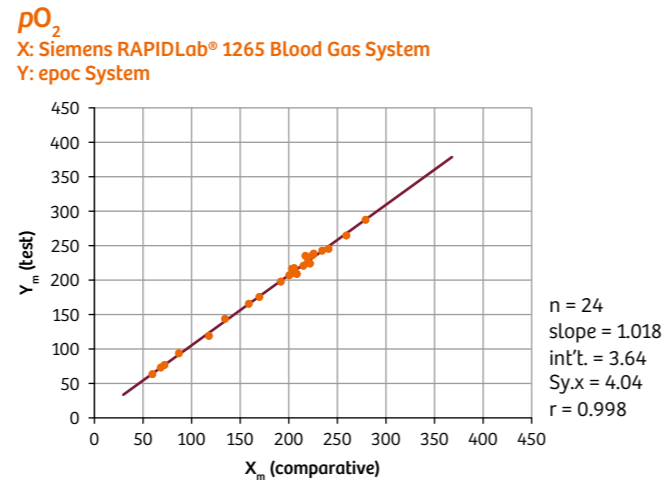
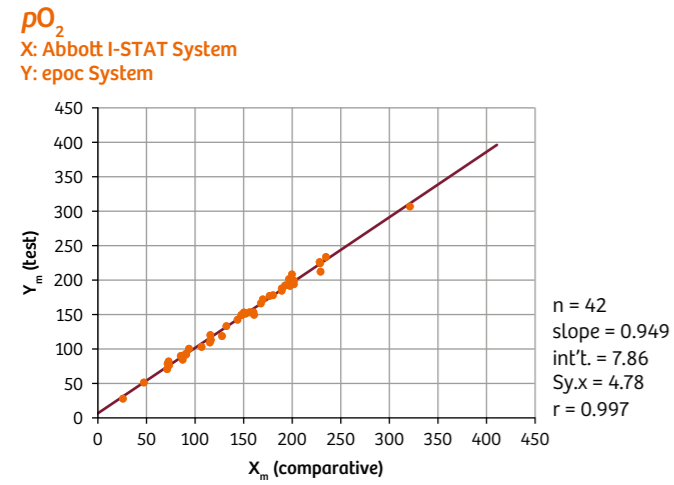
Precision	n	Mean	SD	%CV
<b>Level 1</b>	24	67.2	2.30	3.41%
<b>Level 3</b>	25	20.8	0.68	3.25%



# pO<sub>2</sub> Method Comparison

**pO<sub>2</sub>**

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



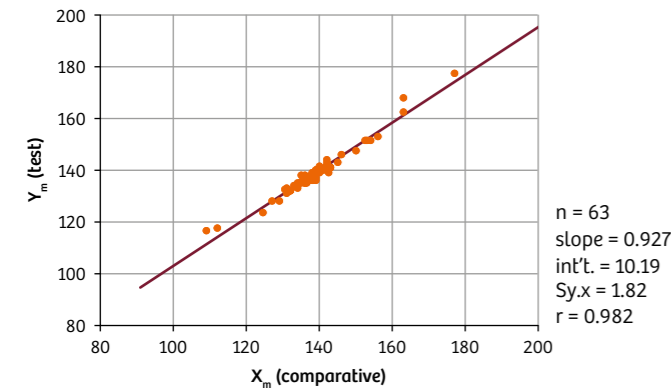
# Sodium Method Comparison

## Sodium mmol/L

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

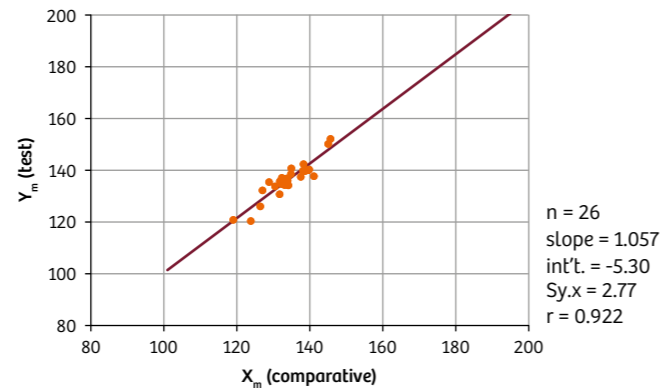
### Na<sup>+</sup>

X: Abbott I-STAT System  
Y: epoc System



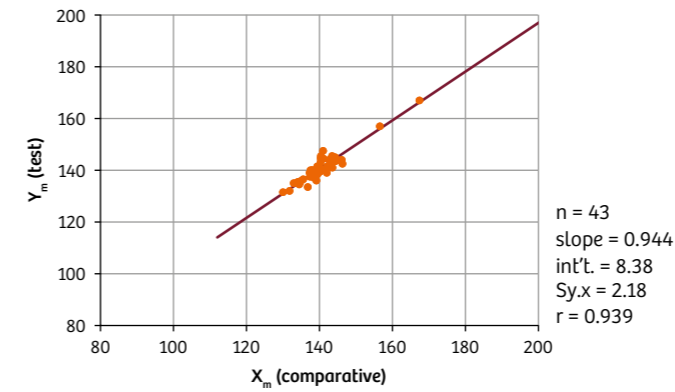
### Na<sup>+</sup>

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



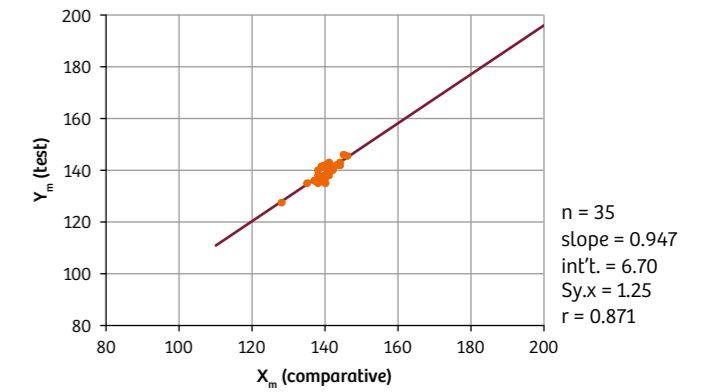
### Na<sup>+</sup>

X: Nova Biomedical PHOX System  
Y: epoc System



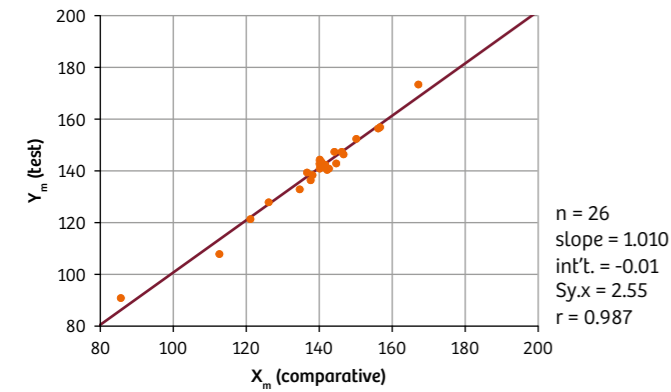
### Na<sup>+</sup>

X: Ortho Clinical Laboratories VITROS System  
Y: epoc System



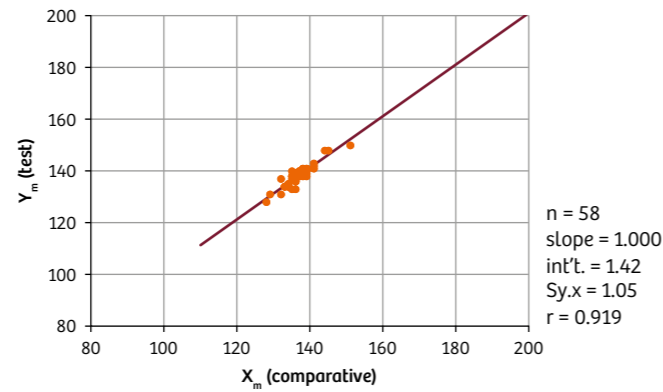
### Na<sup>+</sup>

X: Radiometer ABL 700 System  
Y: epoc System



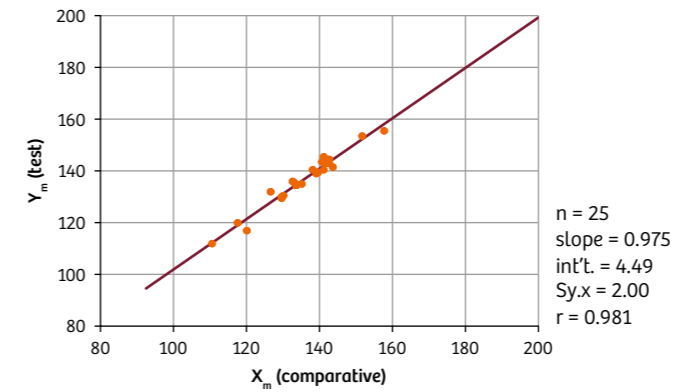
### Na<sup>+</sup>

X: IL GEM PREMIER 3000 System  
Y: epoc System



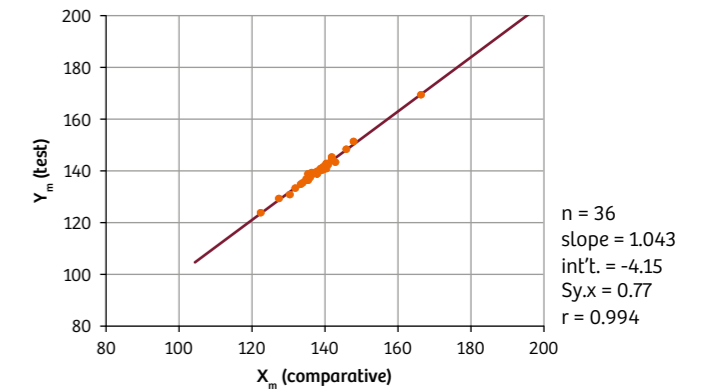
### Na<sup>+</sup>

X: Beckman Coulter  
Y: epoc System



### Na<sup>+</sup>

X: Siemens Dimension® Integrated Chemistry System  
Y: epoc System



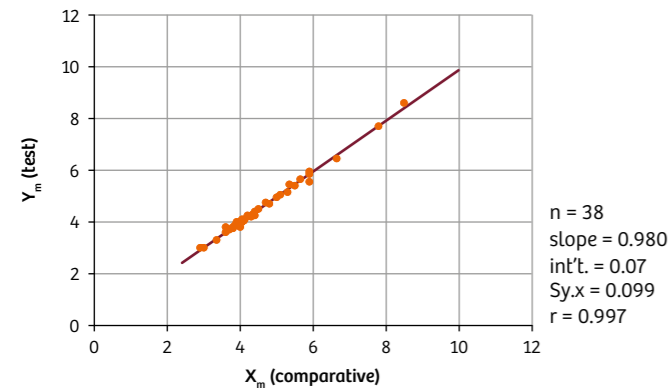
# Potassium Method Comparison

## 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%

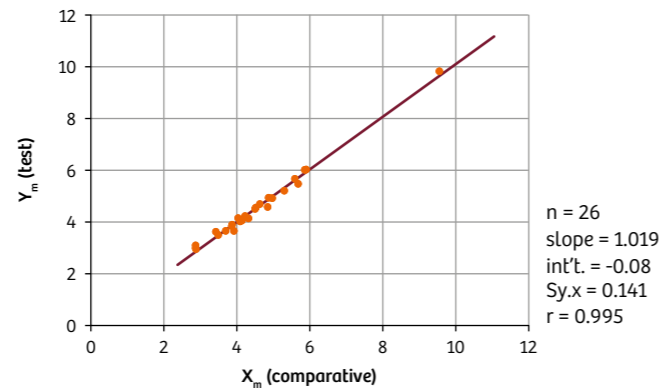
### K<sup>+</sup>

X: Abbott I-STAT System  
Y: epoc System



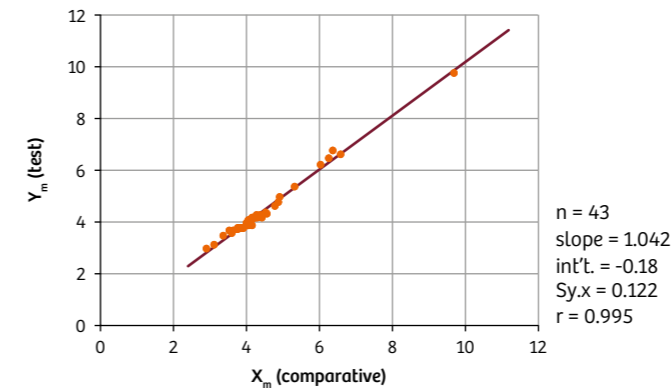
### K<sup>+</sup>

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



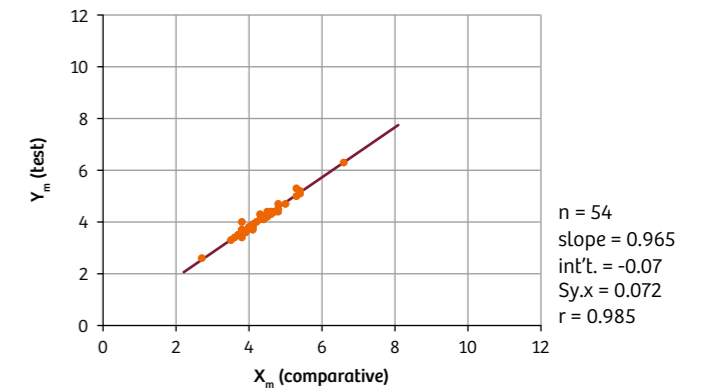
### K<sup>+</sup>

X: Nova Biomedical PHOX System  
Y: epoc System



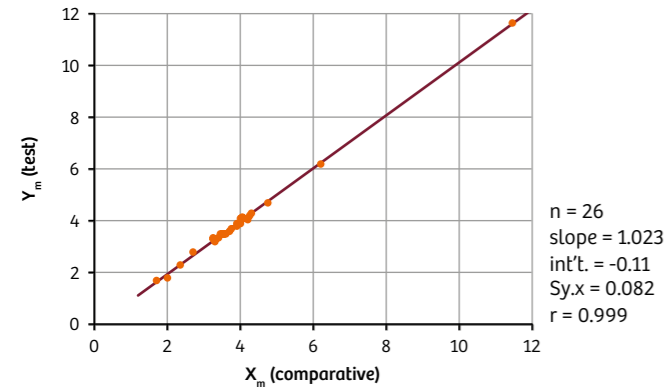
### K<sup>+</sup>

X: Ortho Clinical Laboratories VITROS System  
Y: epoc System



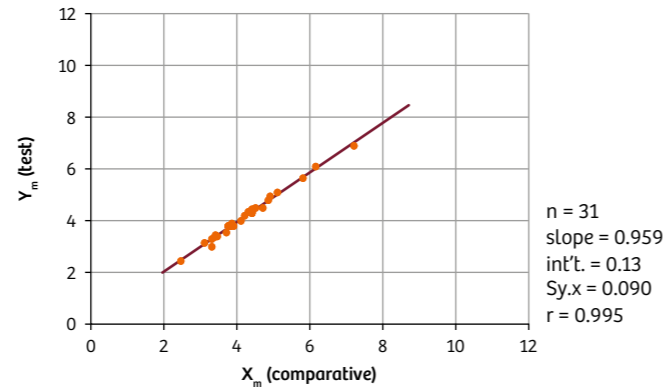
### K<sup>+</sup>

X: Radiometer ABL 700 System  
Y: epoc System



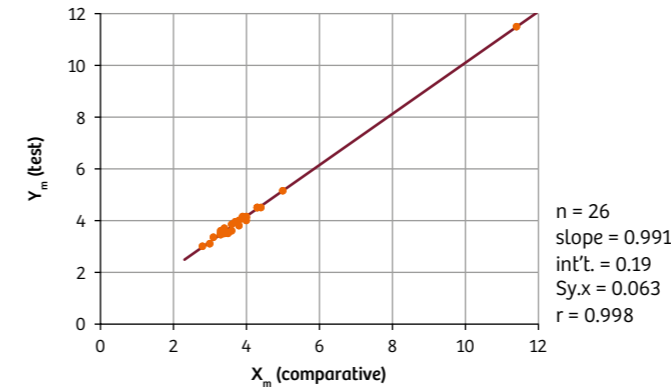
### K<sup>+</sup>

X: IL GEM PREMIER 3000 System  
Y: epoc System



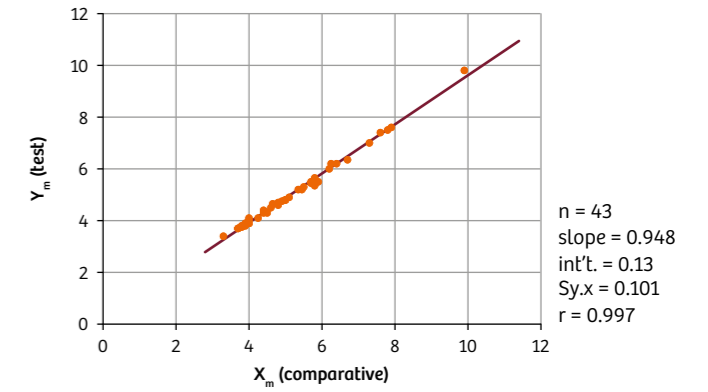
### K<sup>+</sup>

X: Beckman Coulter  
Y: epoc System



### K<sup>+</sup>

X: Siemens Dimension® Integrated Chemistry System  
Y: epoc System





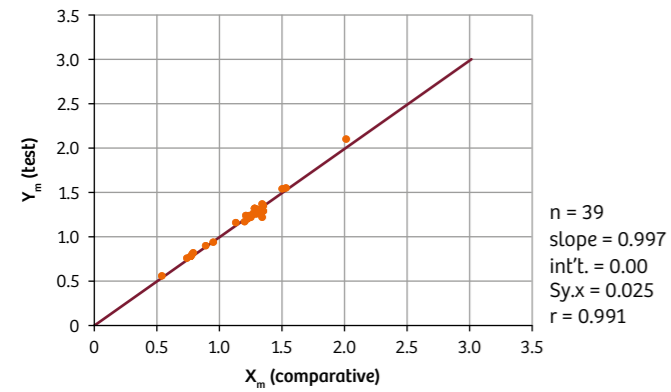
# Ionized Calcium Method Comparison

## Ionized Calcium mmol/L

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

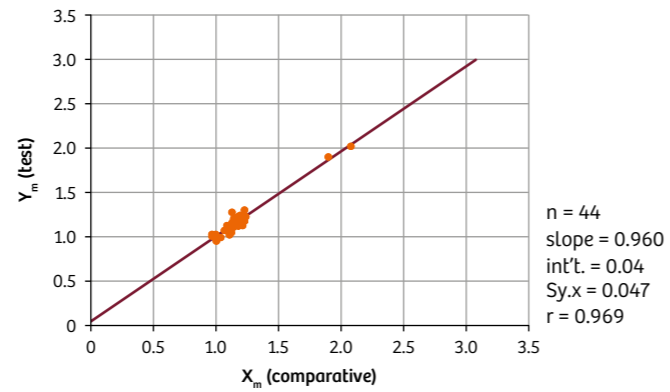
### Ca<sup>++</sup>

X: Abbott I-STAT System  
Y: epoc System



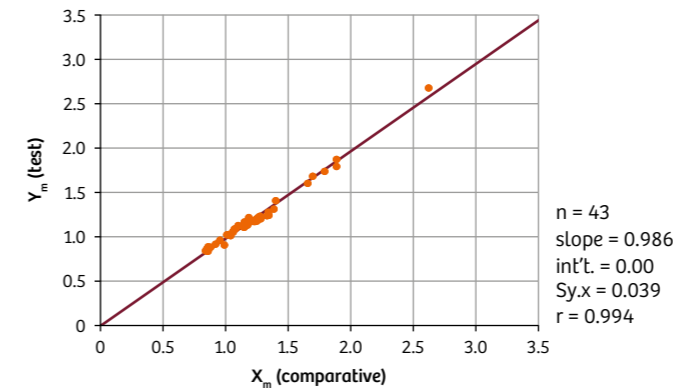
### Ca<sup>++</sup>

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



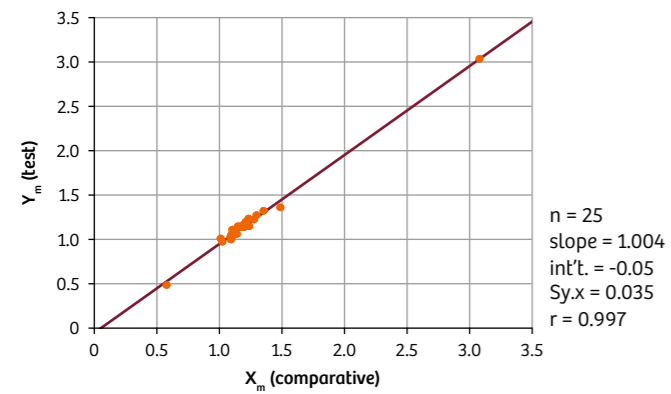
### Ca<sup>++</sup>

X: Nova Biomedical PHOX System  
Y: epoc System



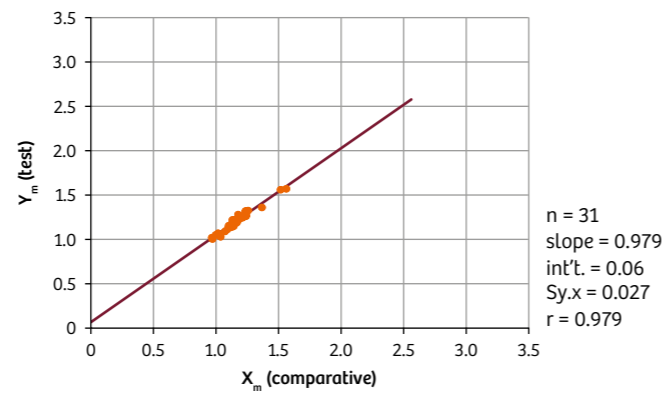
### Ca<sup>++</sup>

X: Radiometer ABL 700 System  
Y: epoc System



### Ca<sup>++</sup>

X: IL GEM PREMIER 3000 System  
Y: epoc System



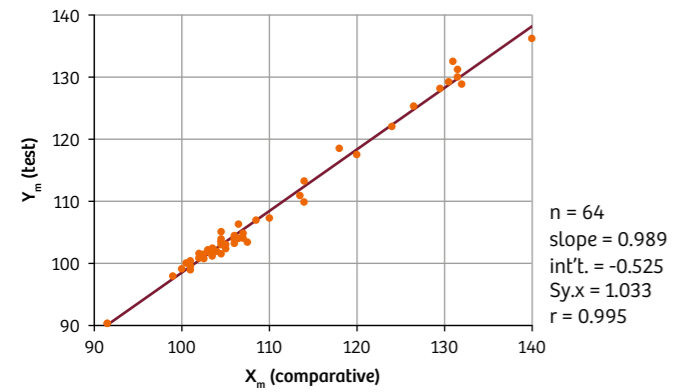
# Chloride Method Comparison

## Chloride mmol/L

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

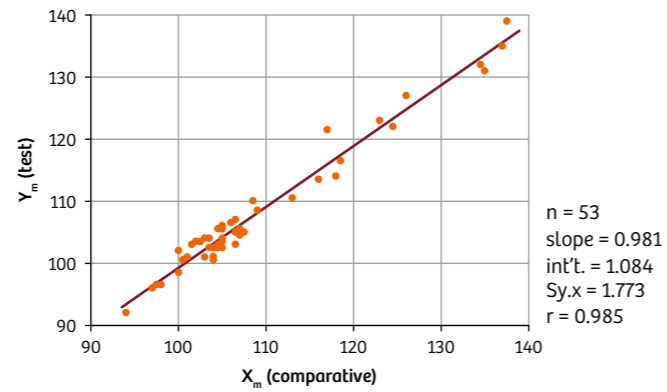
### Chloride

X: Abbott I-STAT System  
Y: epoc System



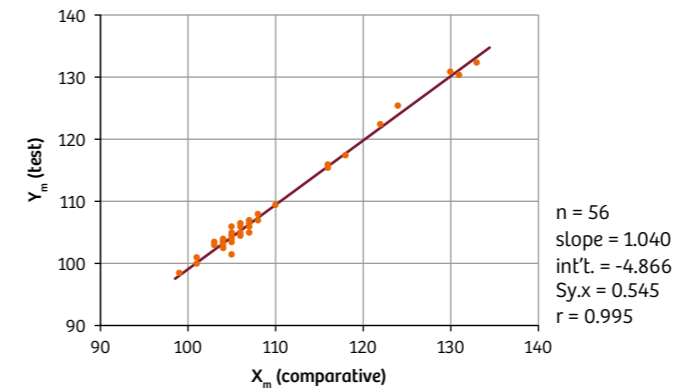
### Chloride

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



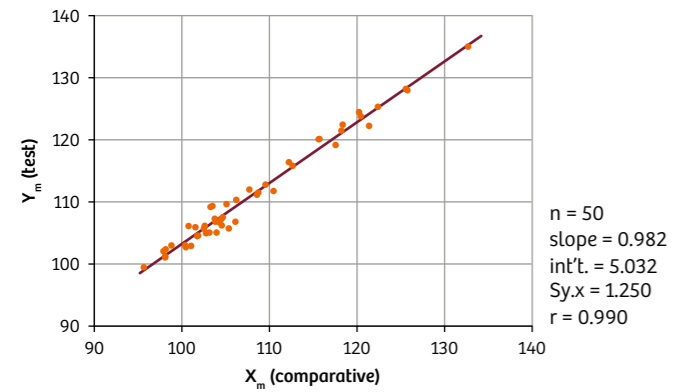
### Chloride

X: Radiometer ABL 800 System  
Y: epoc System



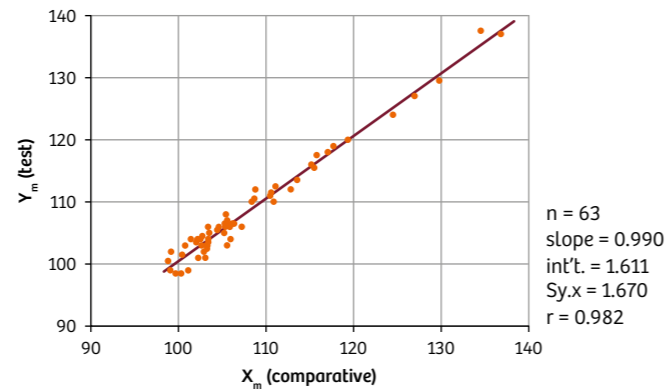
### Chloride

X: ROCHE COBAS 6000 System  
Y: epoc System



### Chloride

X: Beckman Coulter DXC System  
Y: epoc System



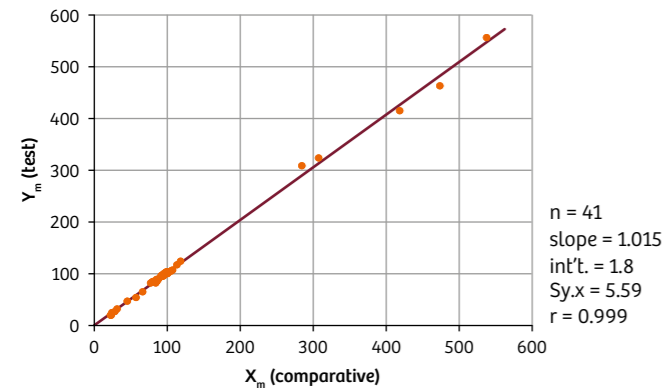
# Glucose Method Comparison

## 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%

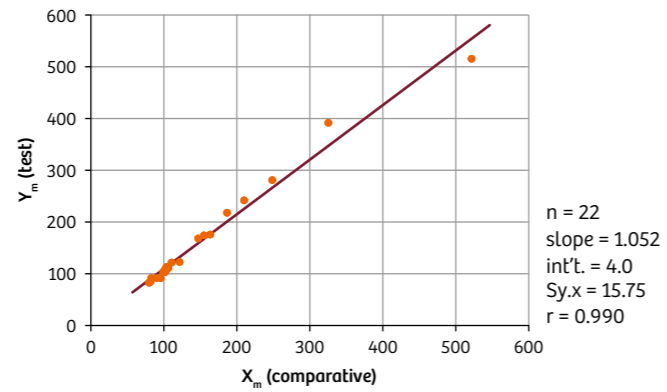
### Glucose

X: Abbott I-STAT System  
Y: epoc System



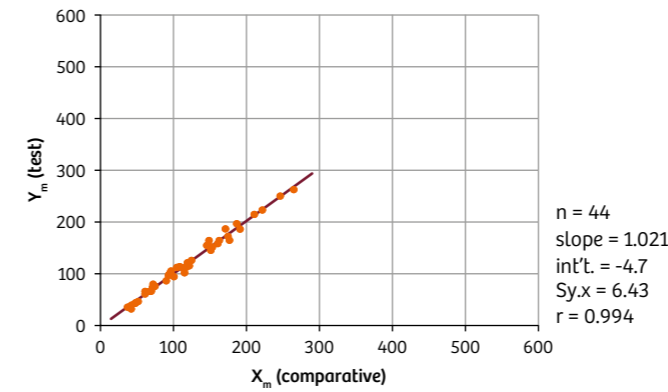
### Glucose

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



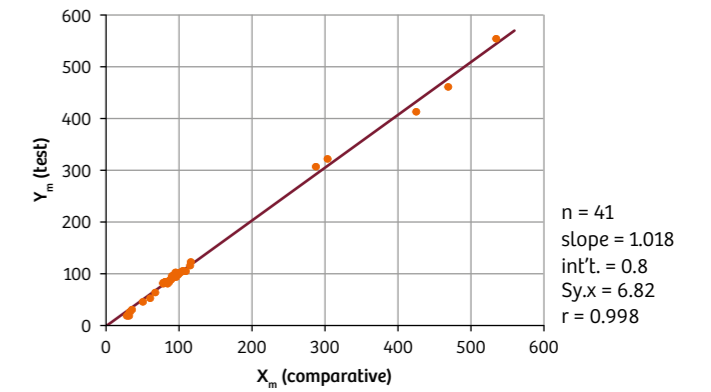
### Glucose

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



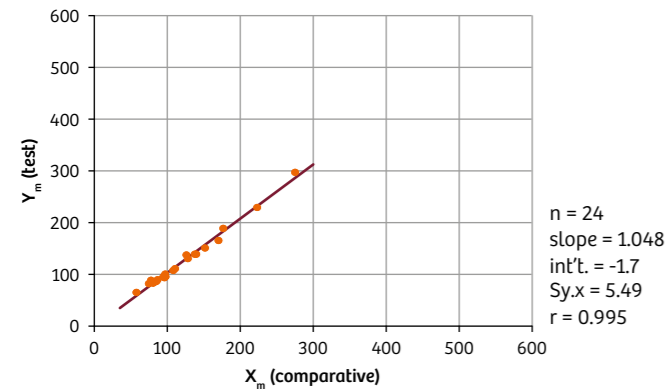
### Glucose

X: Ortho Clinical Laboratories VITROS System  
Y: epoc System



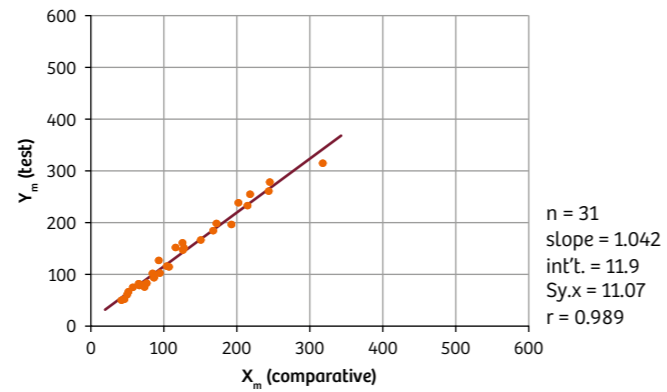
### Glucose

X: Radiometer ABL 700 System  
Y: epoc System



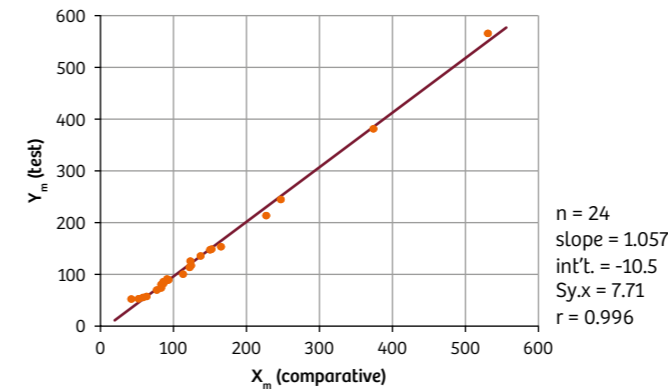
### Glucose

X: IL GEM PREMIER 3000 System  
Y: epoc System



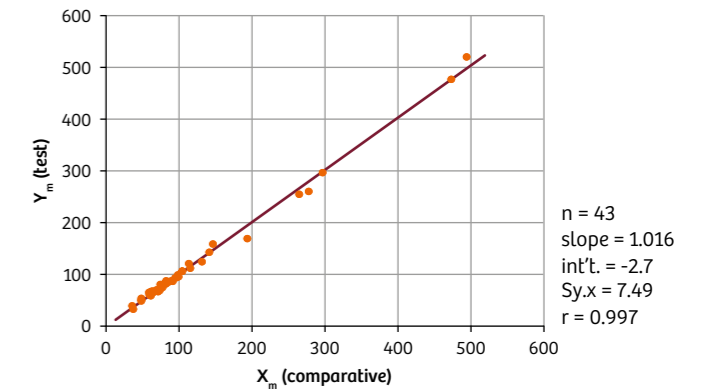
### Glucose

X: Beckman Coulter DXC System  
Y: epoc System



### Glucose

X: Siemens Dimension® Integrated Chemistry System  
Y: epoc System



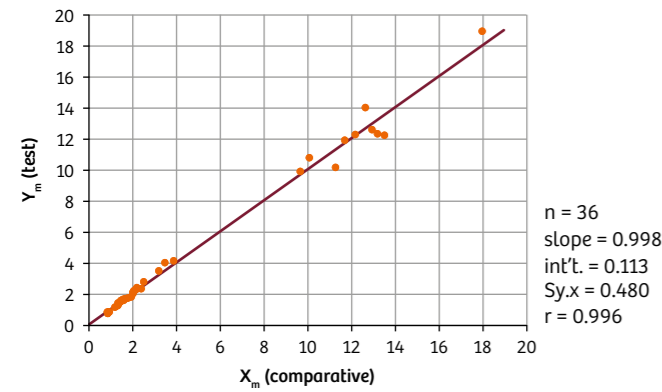
# Lactate Method Comparison

## 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%

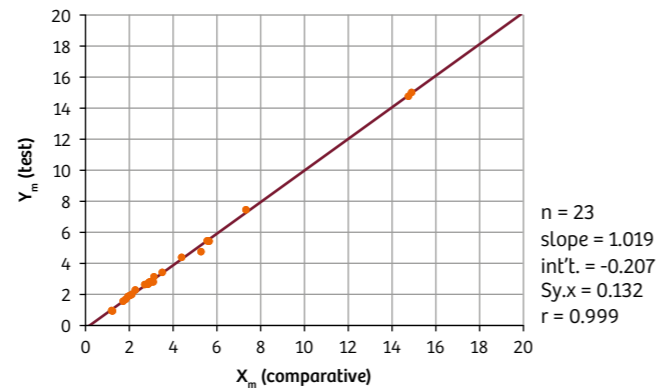
### Lactate

X: Abbott I-STAT System  
Y: epoc System



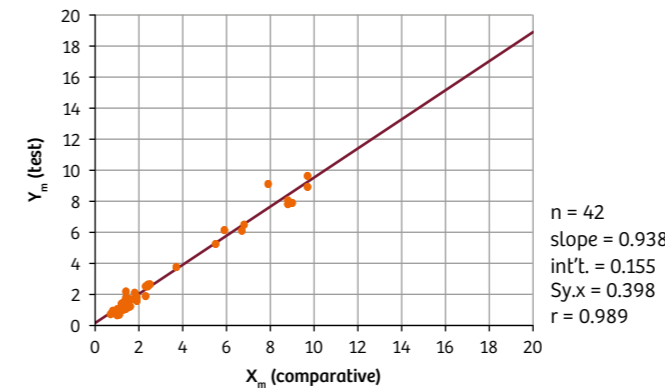
### Lactate

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



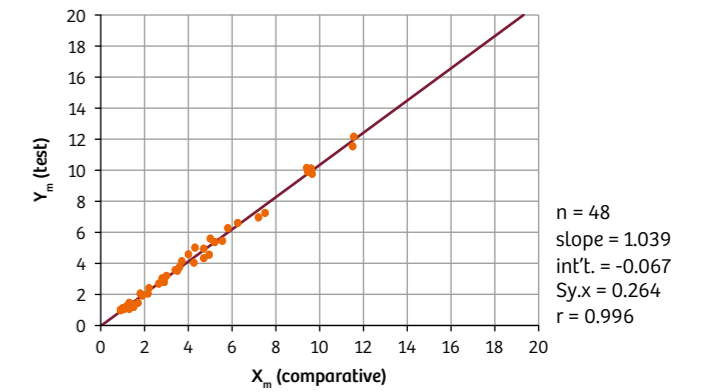
### Lactate

X: Ortho Clinical Laboratories VITROS System  
Y: epoc System



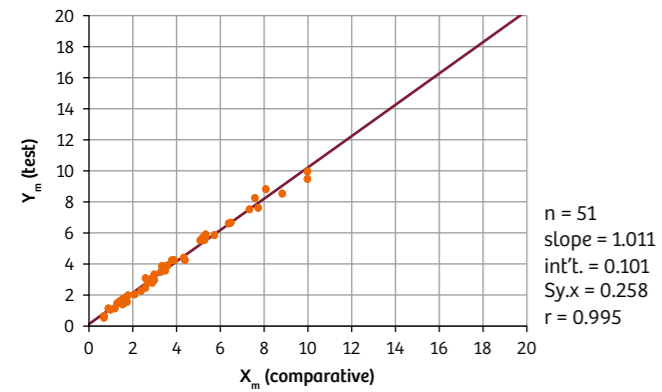
### Lactate

X: Roche MODULAR System  
Y: epoc System



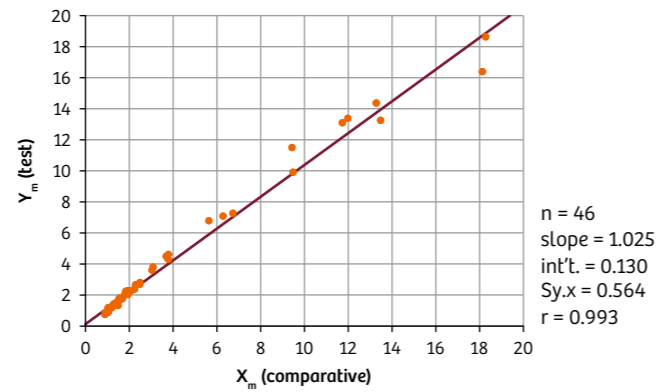
### Lactate

X: Radiometer ABL 700 System  
Y: epoc System



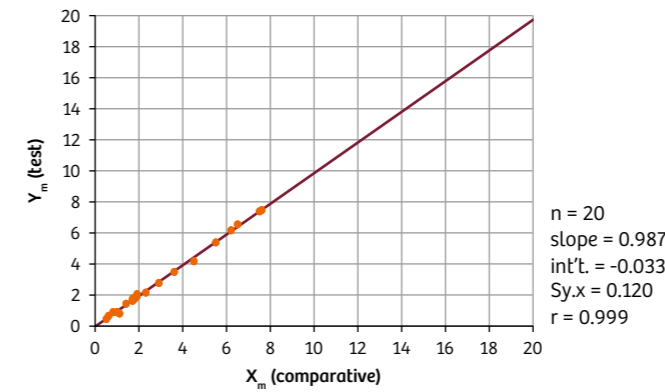
### Lactate

X: IL GEM PREMIER 4000 System  
Y: epoc System



### Lactate

X: Siemens Dimension® Integrated Chemistry System  
Y: epoc System



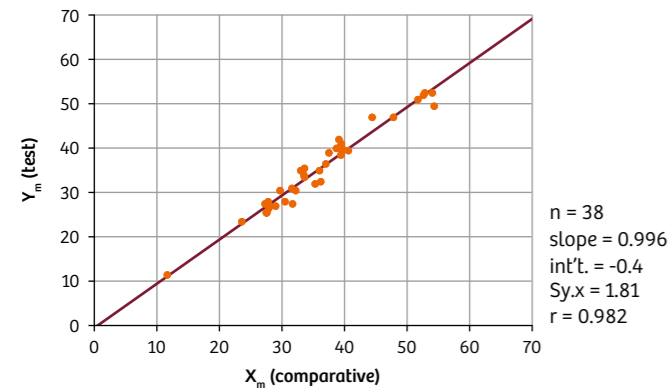
# Hematocrit Method Comparison

## Hematocrit %PCV

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

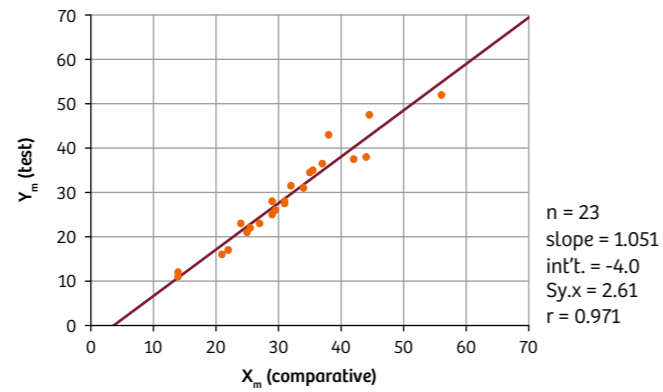
### Hct

X: Radiometer ABL 825 System  
Y: epoc System



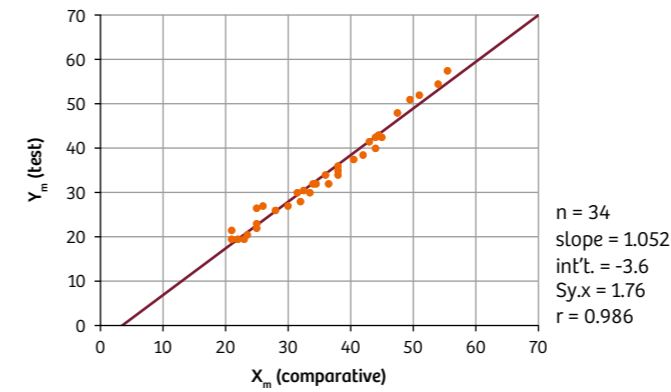
### Hct

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



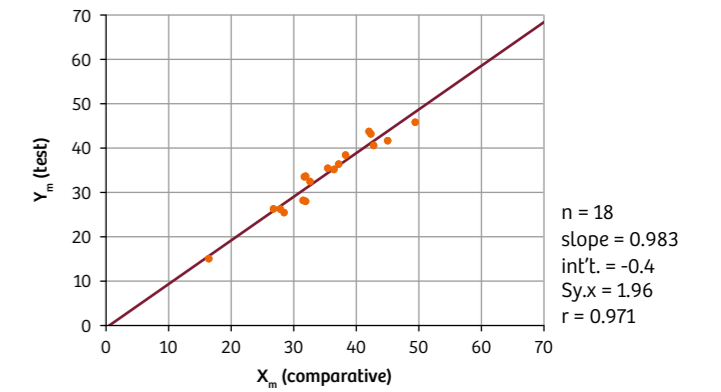
### Hct

X: Nova Biomedical PHOX System  
Y: epoc System



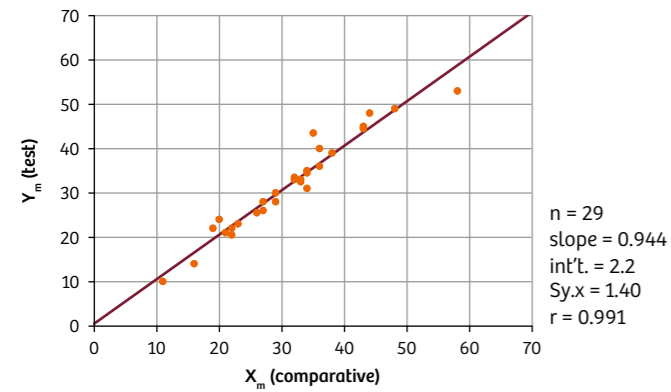
### Hct

X: Sysmex XE System  
Y: epoc System



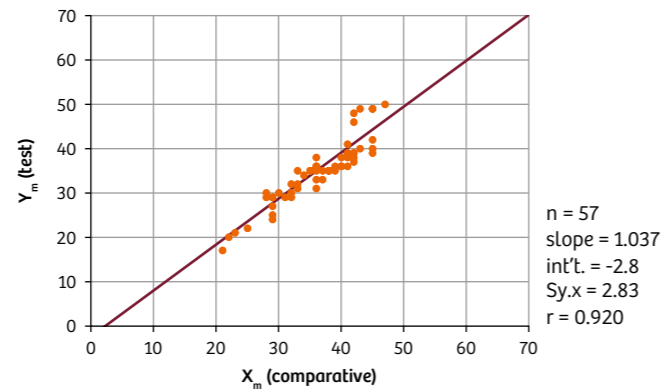
### Hct

X: Abbott I-STAT System  
Y: epoc System



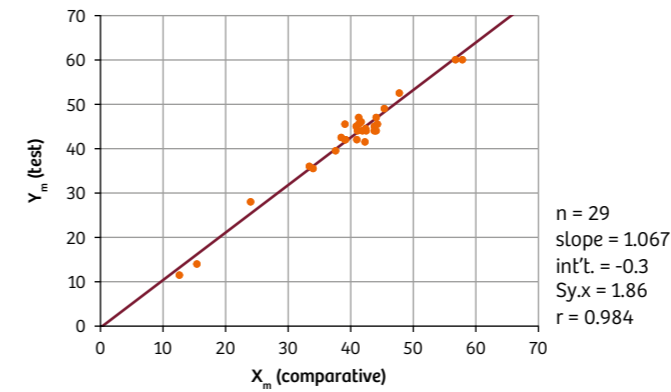
### Hct

X: IL GEM PREMIER 3000 System  
Y: epoc System



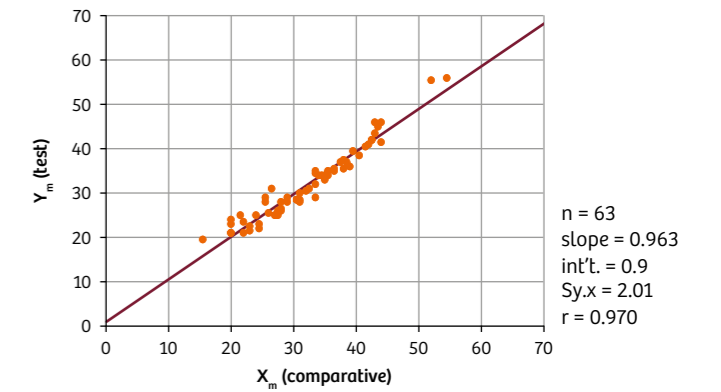
### Hct

X: Beckman Coulter LH System  
Y: epoc System



### Hct

X: Microcentrifugation (spun)  
Y: epoc System



# Creatinine Method Comparison

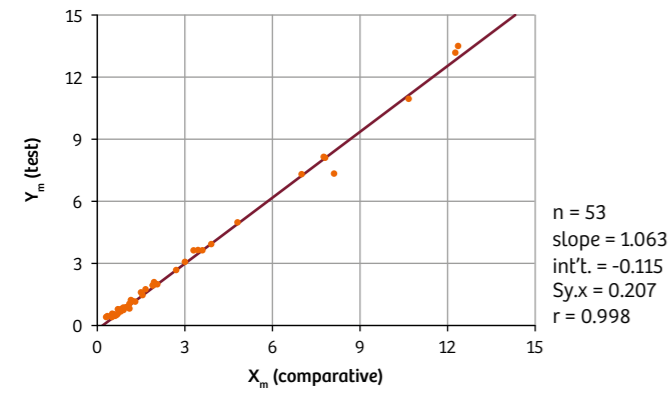
# Notes

## 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%

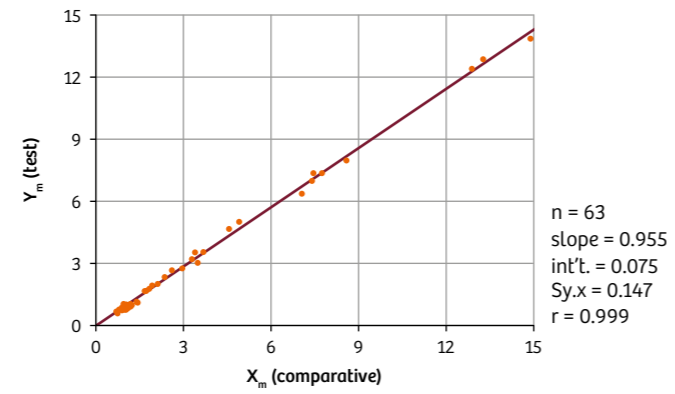
### Creatinine

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



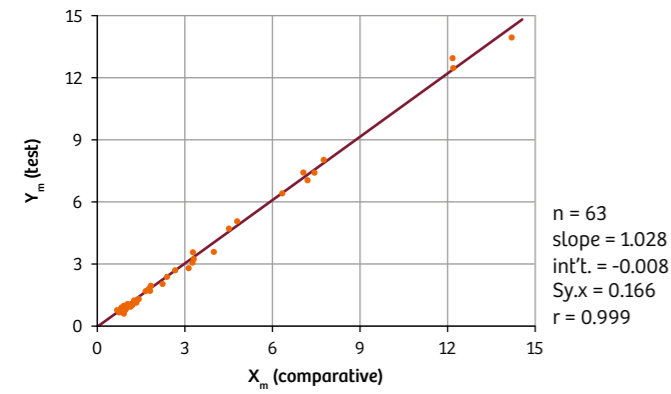
### Creatinine

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

