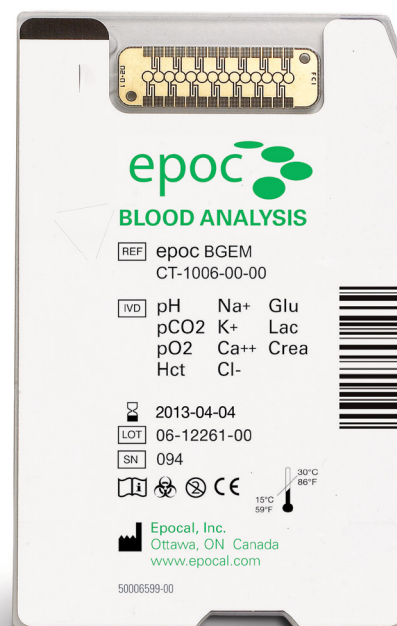




# Summary of Analytical Methods and Performance

## The epoc<sup>®</sup> Blood Analysis System

Data compilation provided by Alere





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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 or how closely multiple results analyzed on the same sample agree with each other.

***n*** is the number of data points included in the data set.

***x*** represents the comparison method in regression analysis.

***y*** represents the test method in regression analysis.

**Slope** describes the angle of the line that provides the best fit of the test and comparison results. A perfect slope would be 1.00. Deviations from 1.00 are an indication of proportional systematic error.<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>

**$S_{y,x}$**  describes the scatter of the data around the line of best fit. It provides an estimate of the random error between the methods and includes both the imprecision of the test and comparison methods, as well as possible matrix effect that vary from one sample to another.  $S_{y,x}$  will never be 0 because both methods have some imprecision.<sup>1</sup>

***r*** or **correlation coefficient** describes how well the results between the two methods change together. The lower the *r* values, the more scatter there is in the data. The main use of *r* is to help assess the reliability of the regression data – *r* should never be used as an indicator of method acceptability.<sup>1</sup>

1. James O. Westgard, Basic Method Evaluation, 3rd Edition (Madison, WI: Westgard QC, Inc., 2008) pp 77-78.

# 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.

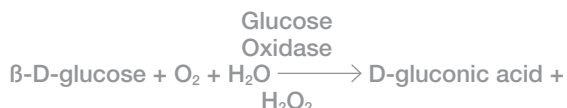
**Sodium** is measured by potentiometry using an ion selective membrane electrode. The concentration of sodium ions is obtained from the measured potential using the Nernst equation. The epoc® sodium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect)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

# Methodologies

**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,



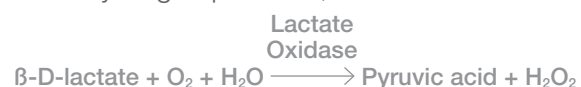
and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox mediated (ABTS (2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid) diammonium salt), horseradish peroxidase (HRP) catalyzed, reduction on a gold electrode.



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.



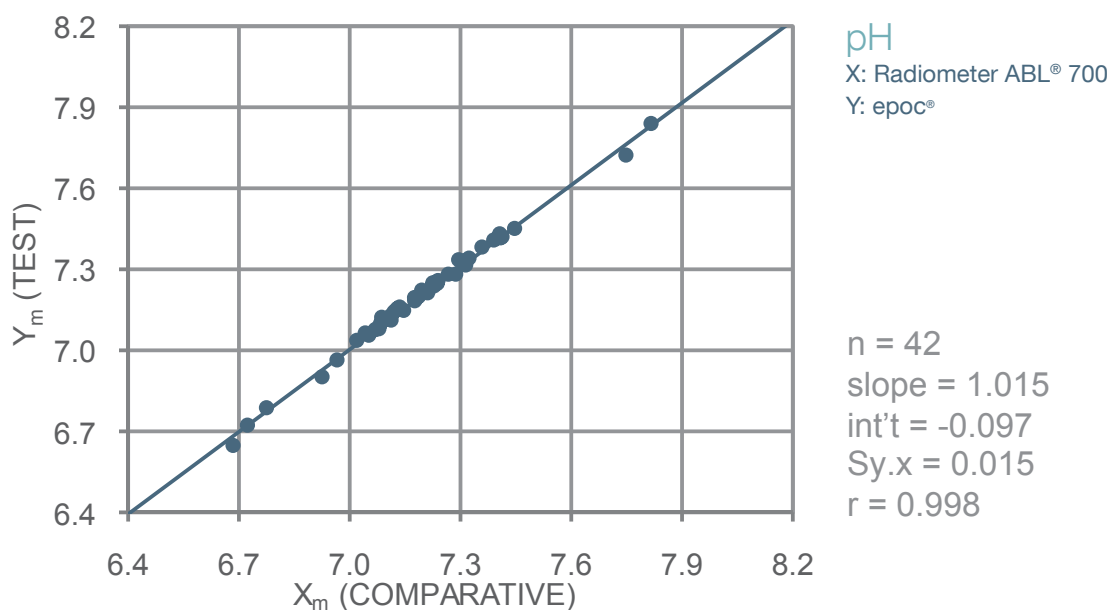
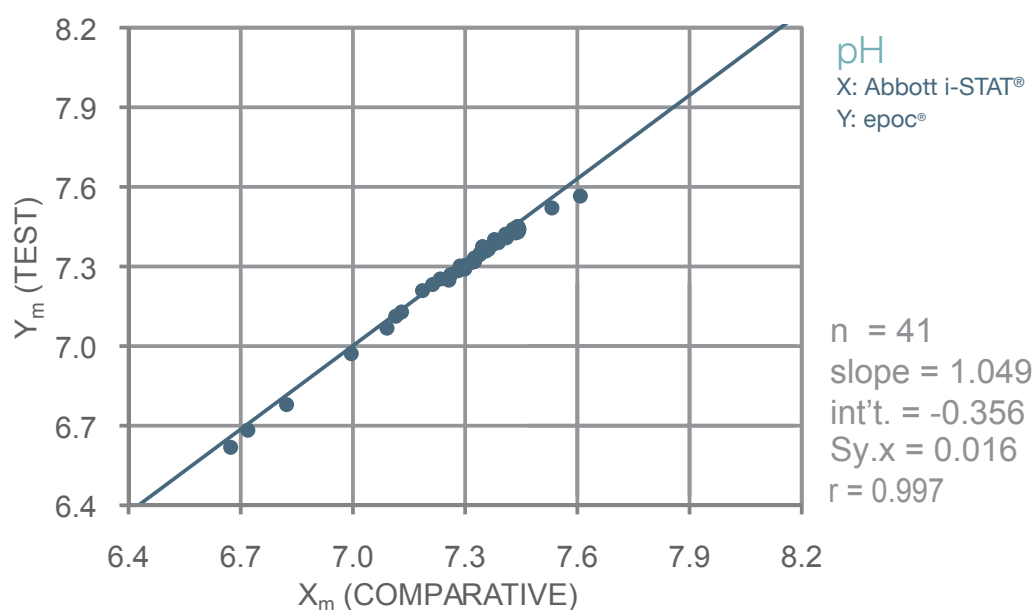
The reduction current is proportional to the concentration of lactate in the test fluid.

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

# pH Method Comparison

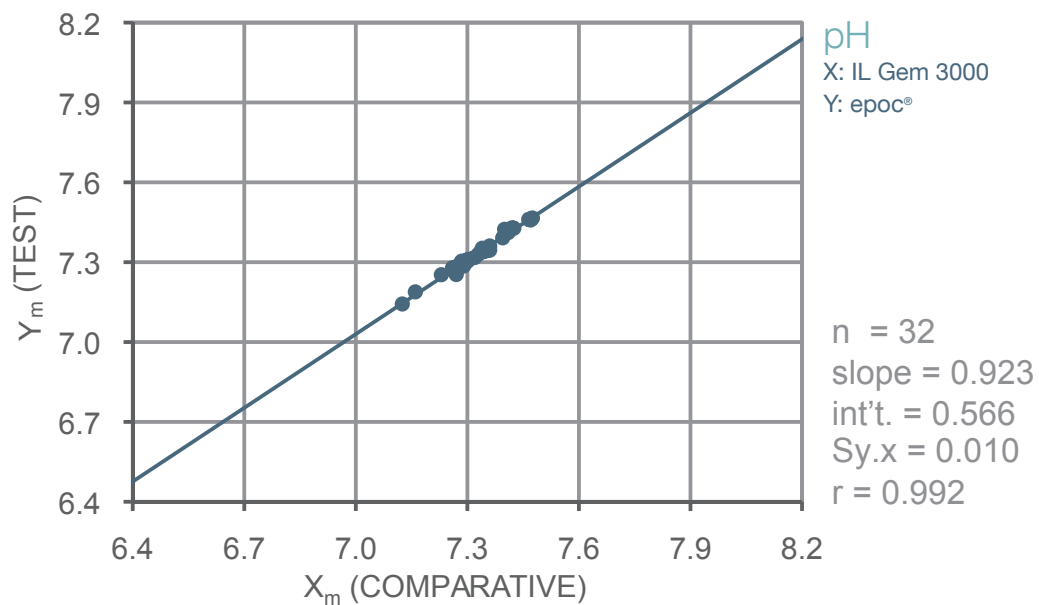
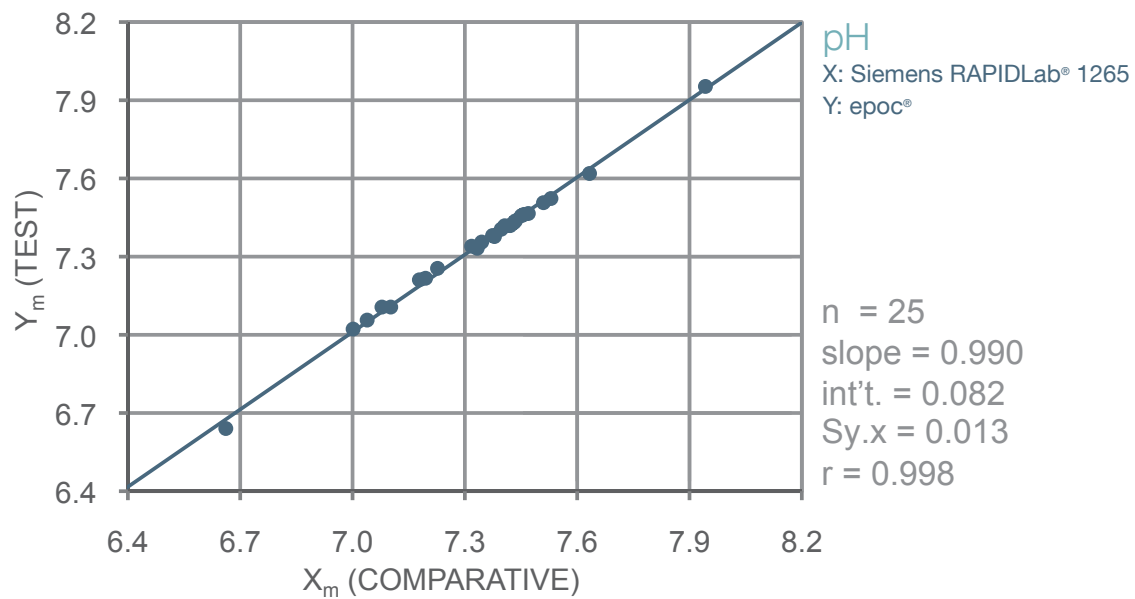
## pH

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

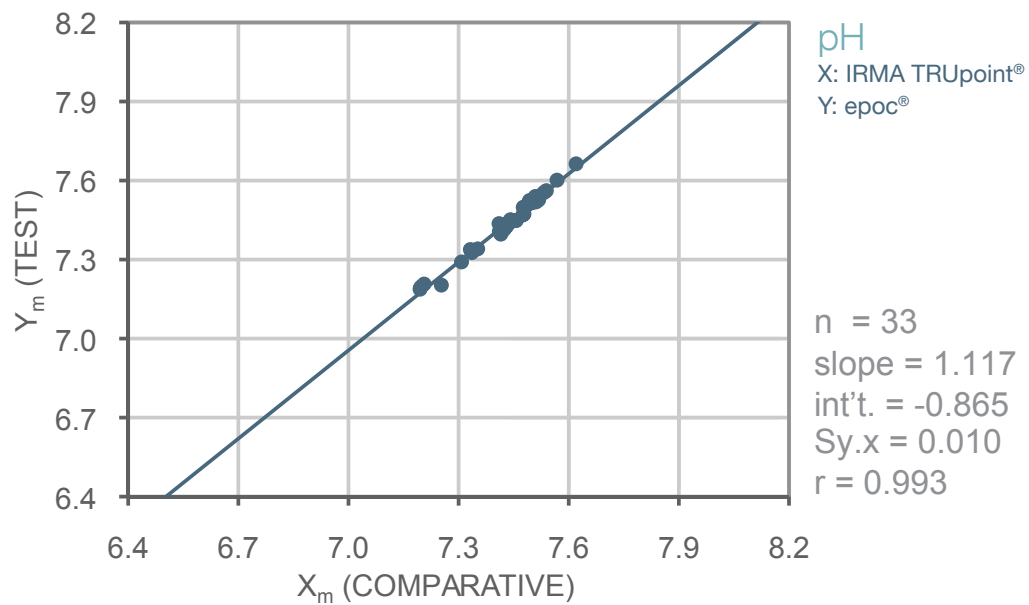
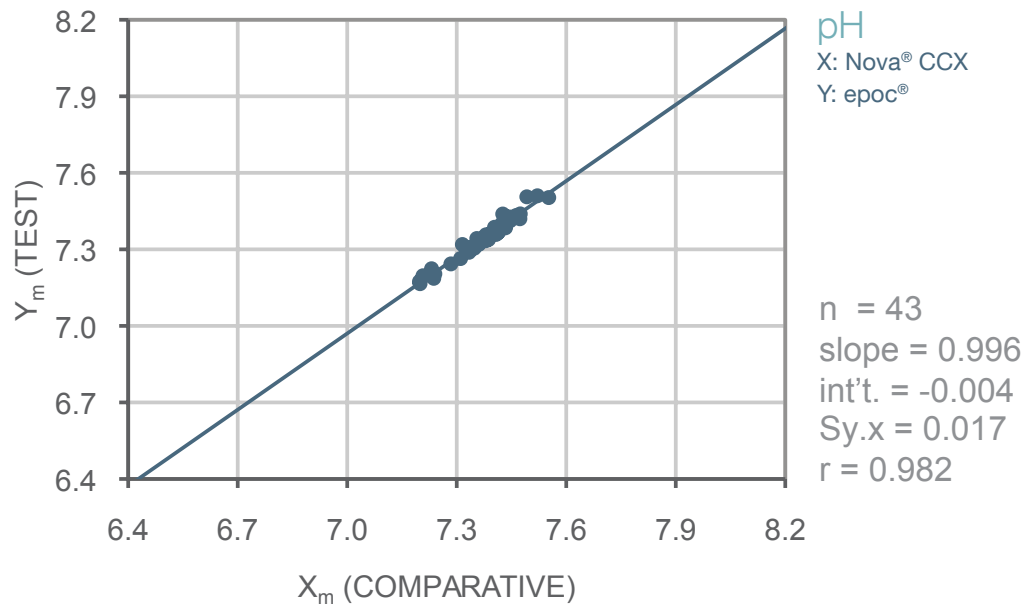




## pH Method Comparison...continued



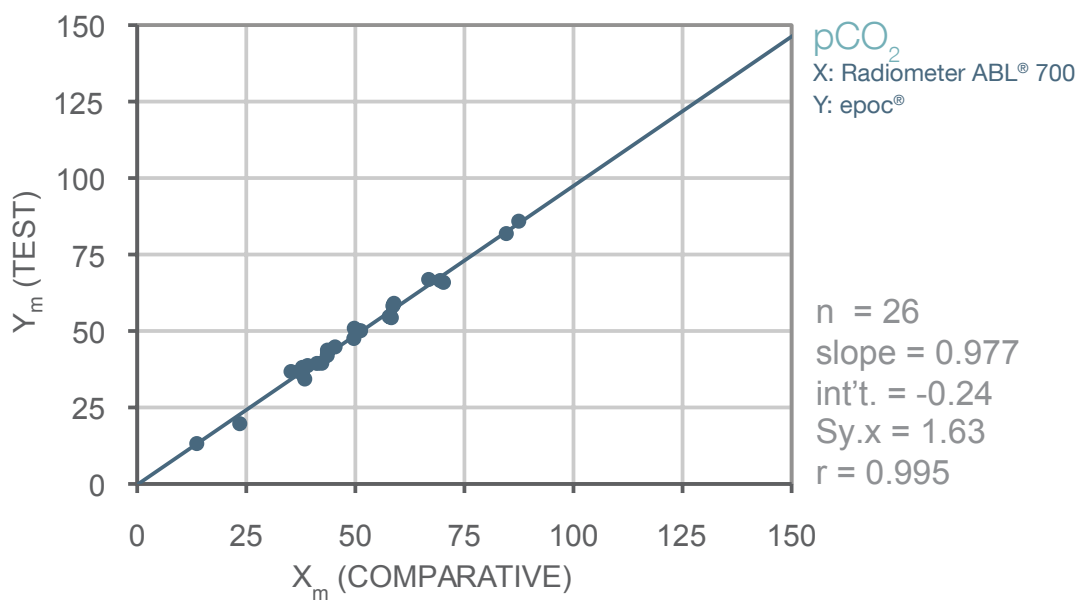
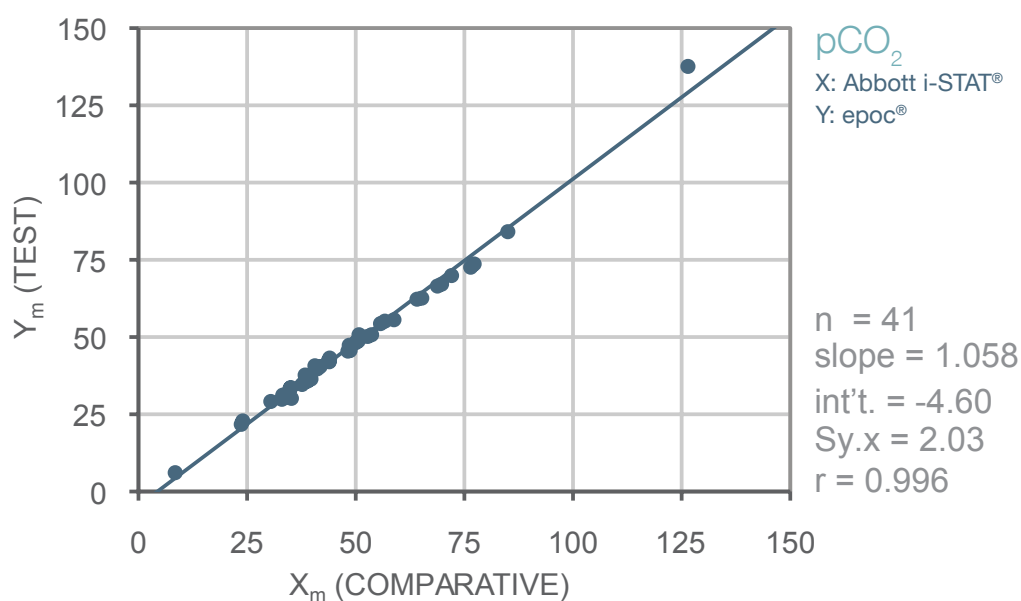
## pH Method Comparison...continued



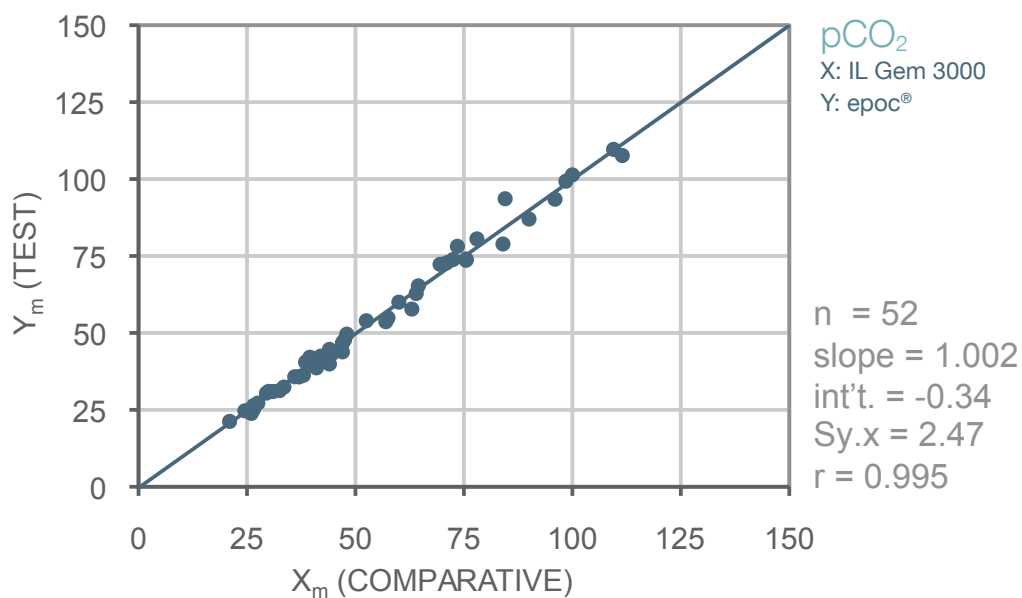
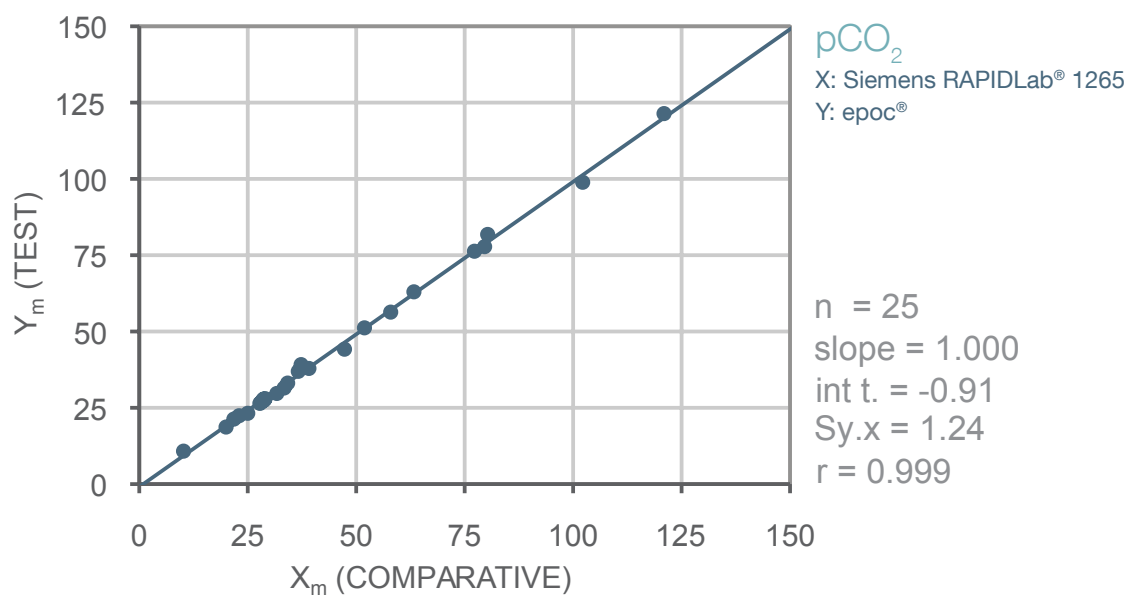
# pCO<sub>2</sub> Method Comparison

## pCO<sub>2</sub>

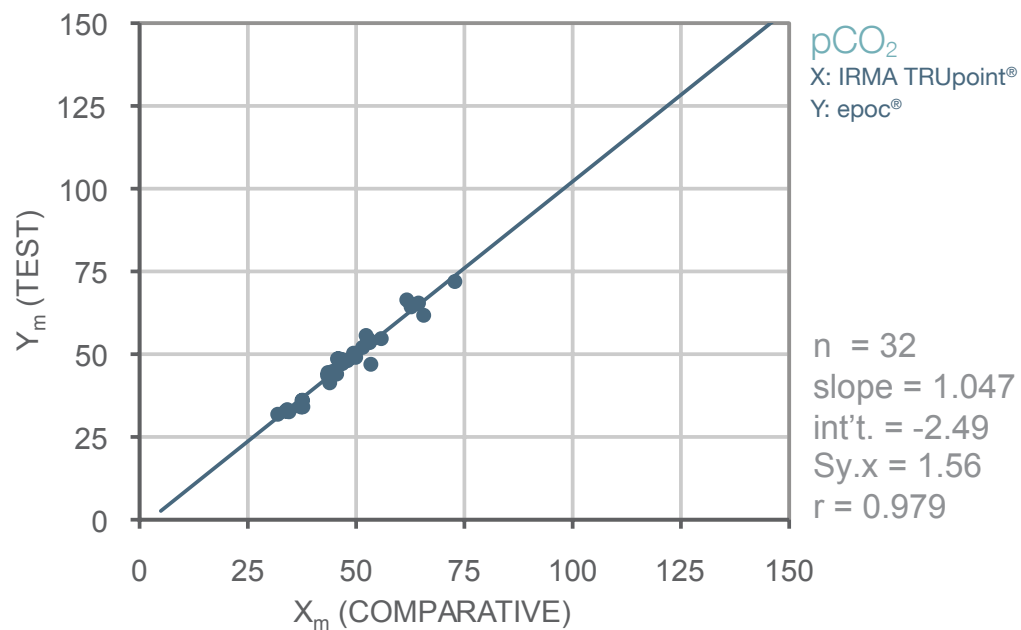
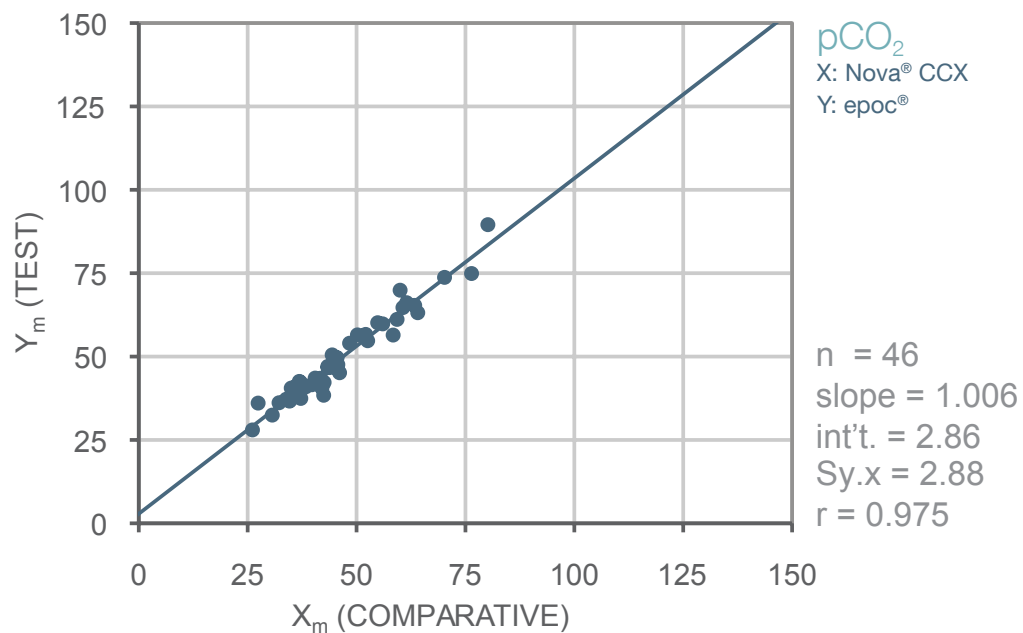
Precision	n	Mean	SD	%CV
Level 1	24	67.2	2.30	3.41%
Level 3	25	20.8	0.68	3.25%



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



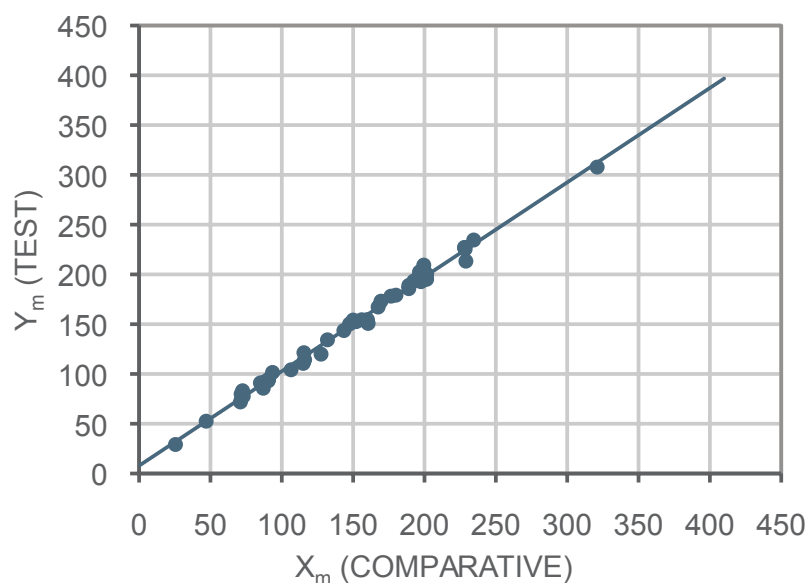
## pCO<sub>2</sub> Method Comparison...continued



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

pCO<sub>2</sub>

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



pO<sub>2</sub>

X: Abbott i-STAT®

Y: epoc®

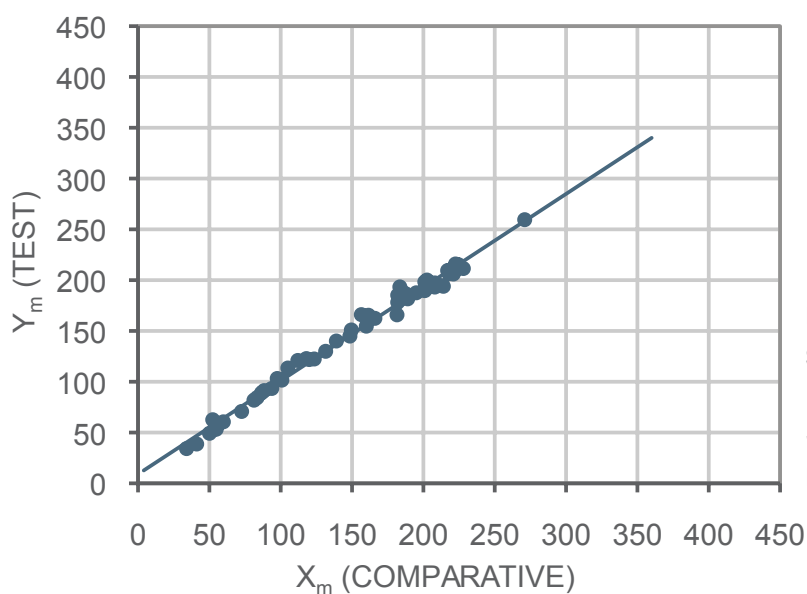
n = 42

slope = 0.949

int't. = 7.86

Sy.x = 4.78

r = 0.997



pO<sub>2</sub>

X: Radiometer ABL® 715

Y: epoc®

n = 51

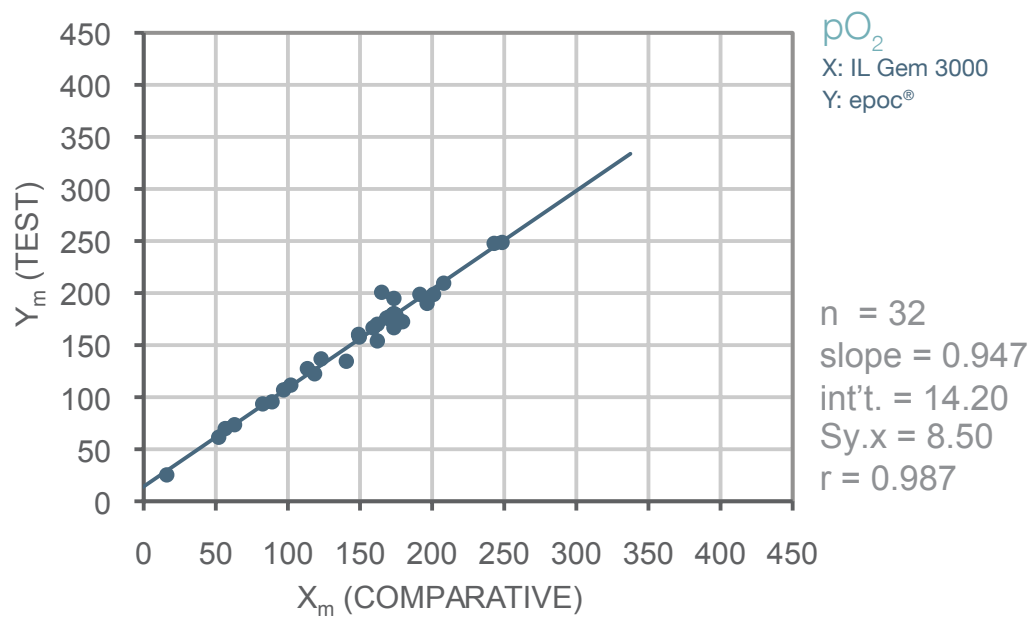
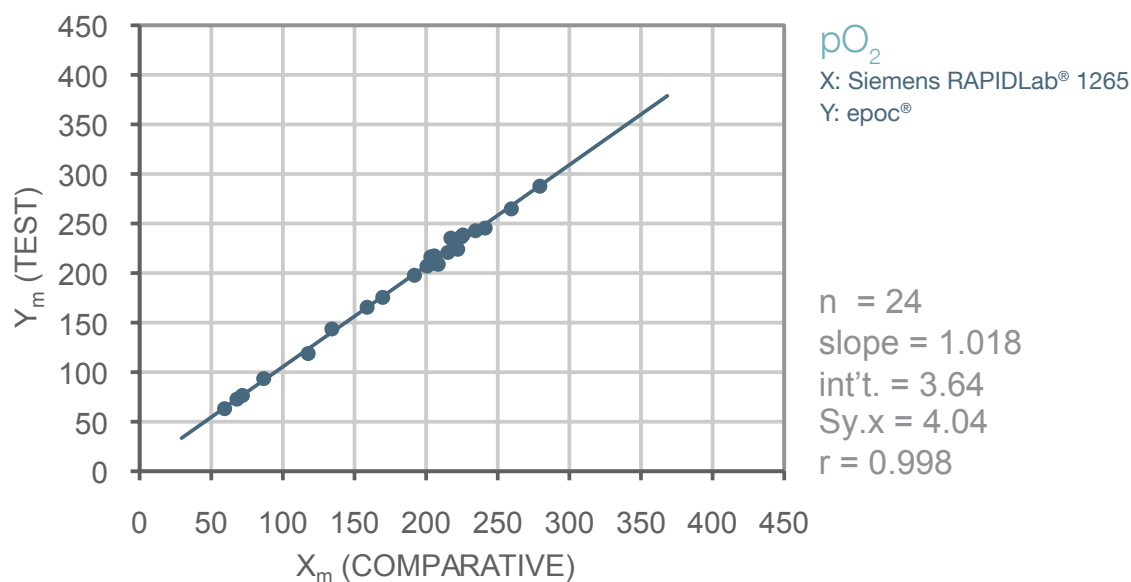
slope = 0.919

int't. = 9.01

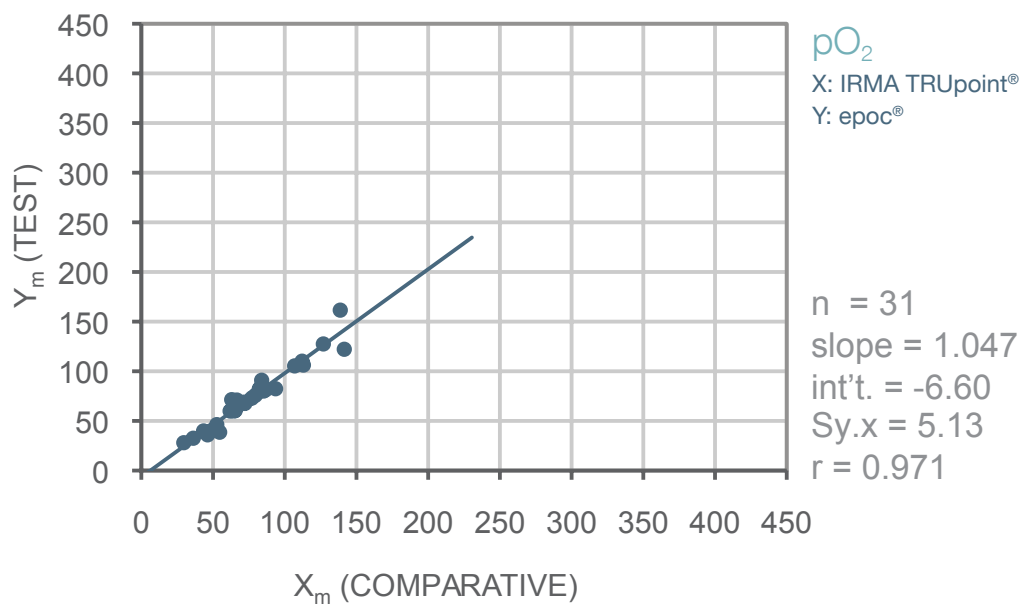
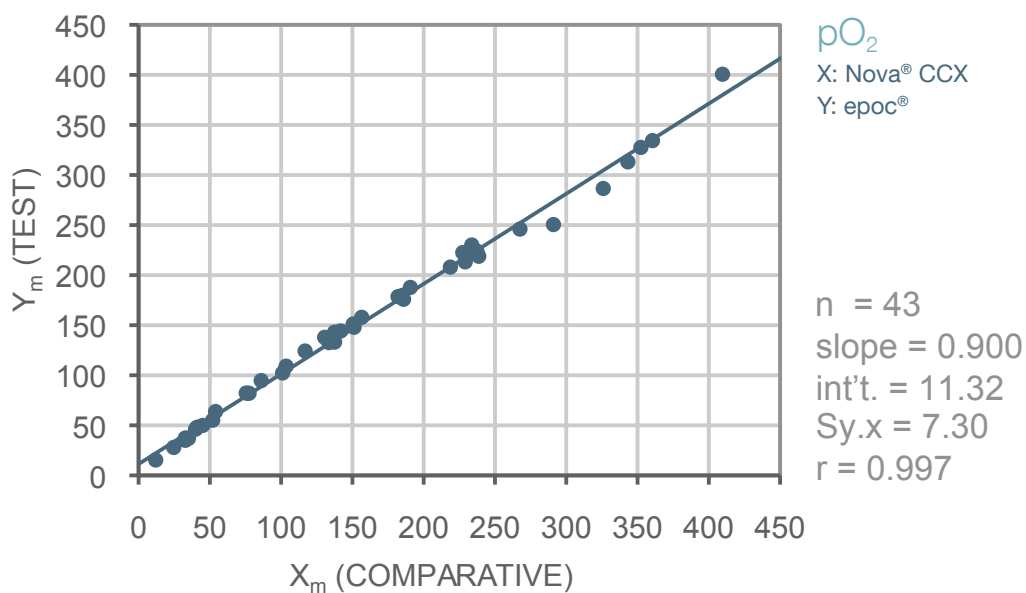
Sy.x = 5.80

r = 0.995

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



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

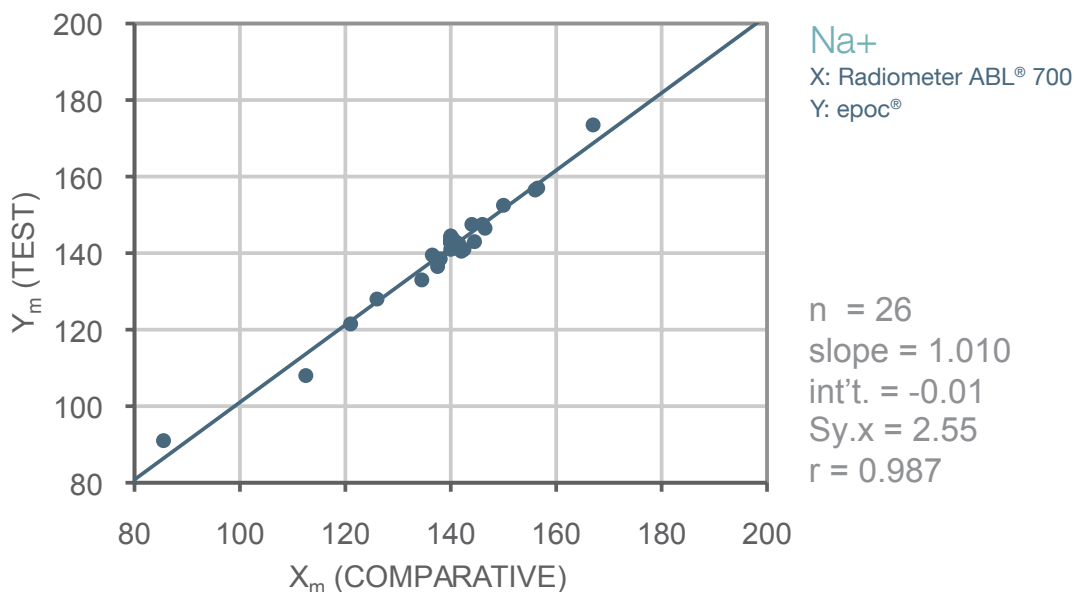
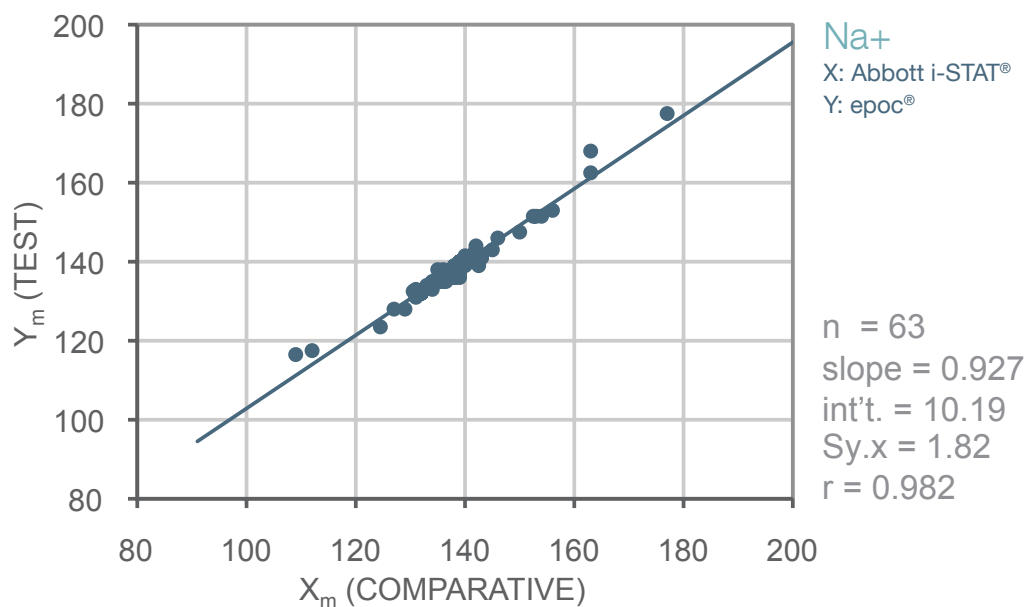




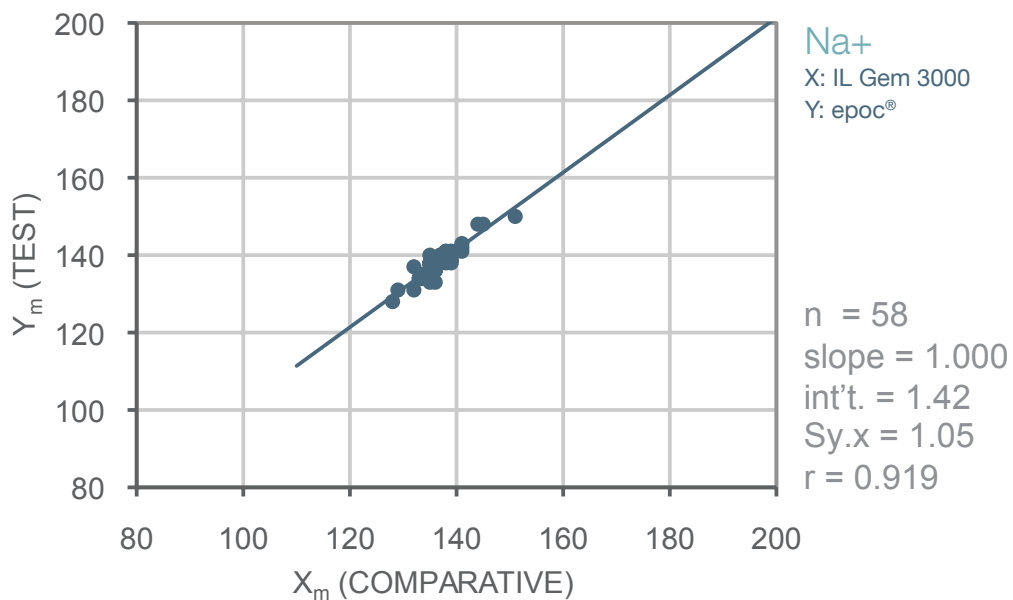
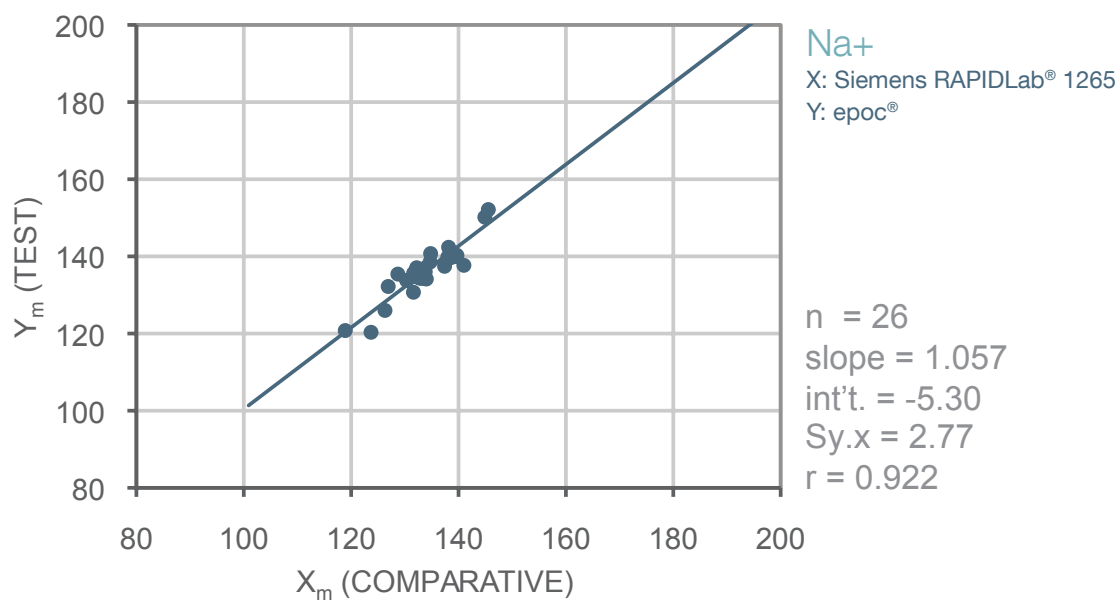
# Sodium Method Comparison

## Sodium mmol/L

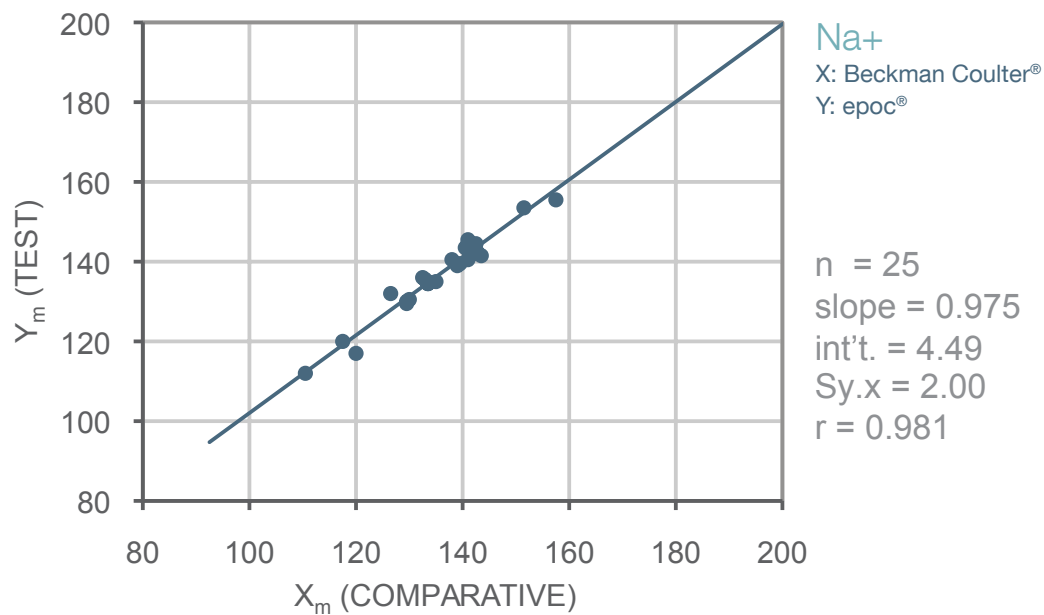
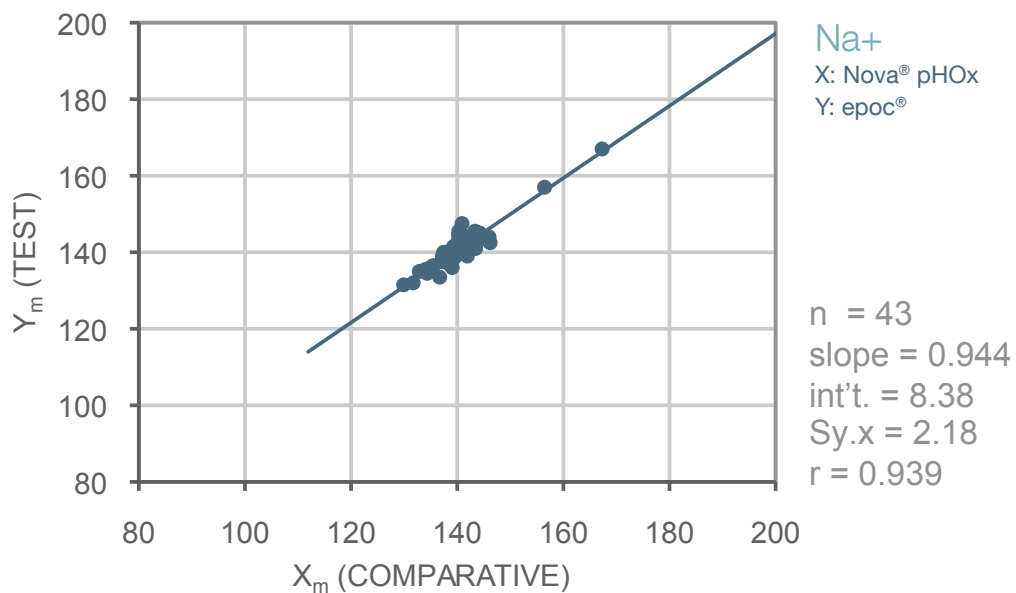
Precision	n	Mean	SD	%CV
Level 1	27	113	0.82	0.73%
Level 3	27	166	1.07	0.64%



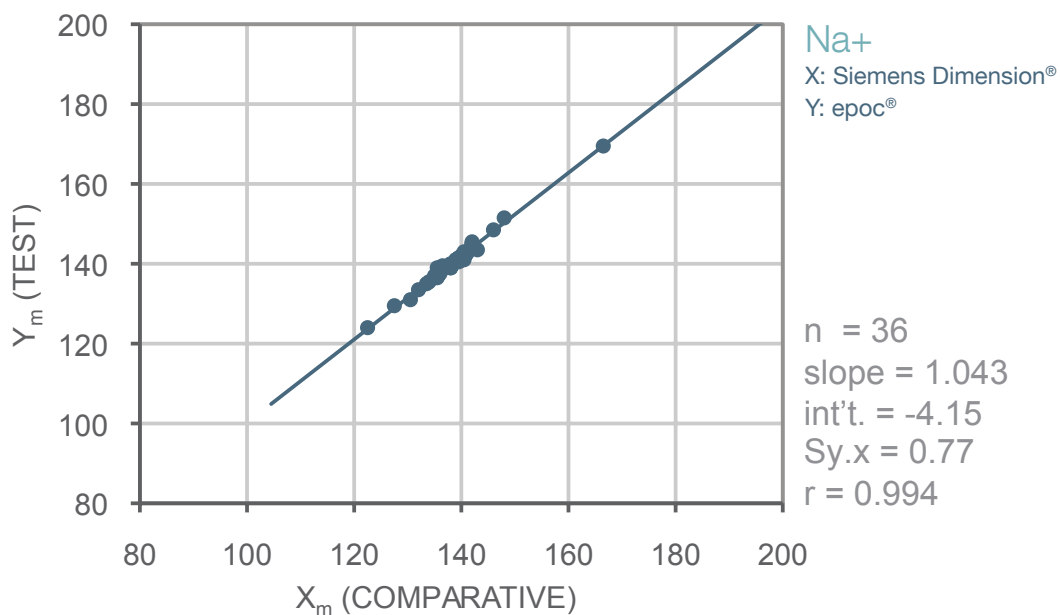
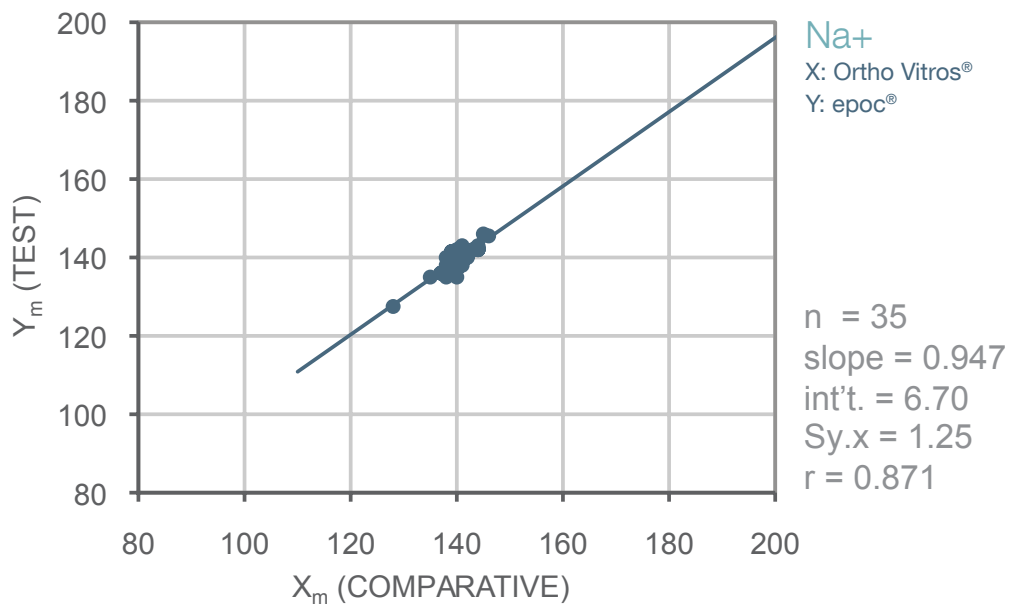
## Sodium Method Comparison...continued



## Sodium Method Comparison...continued



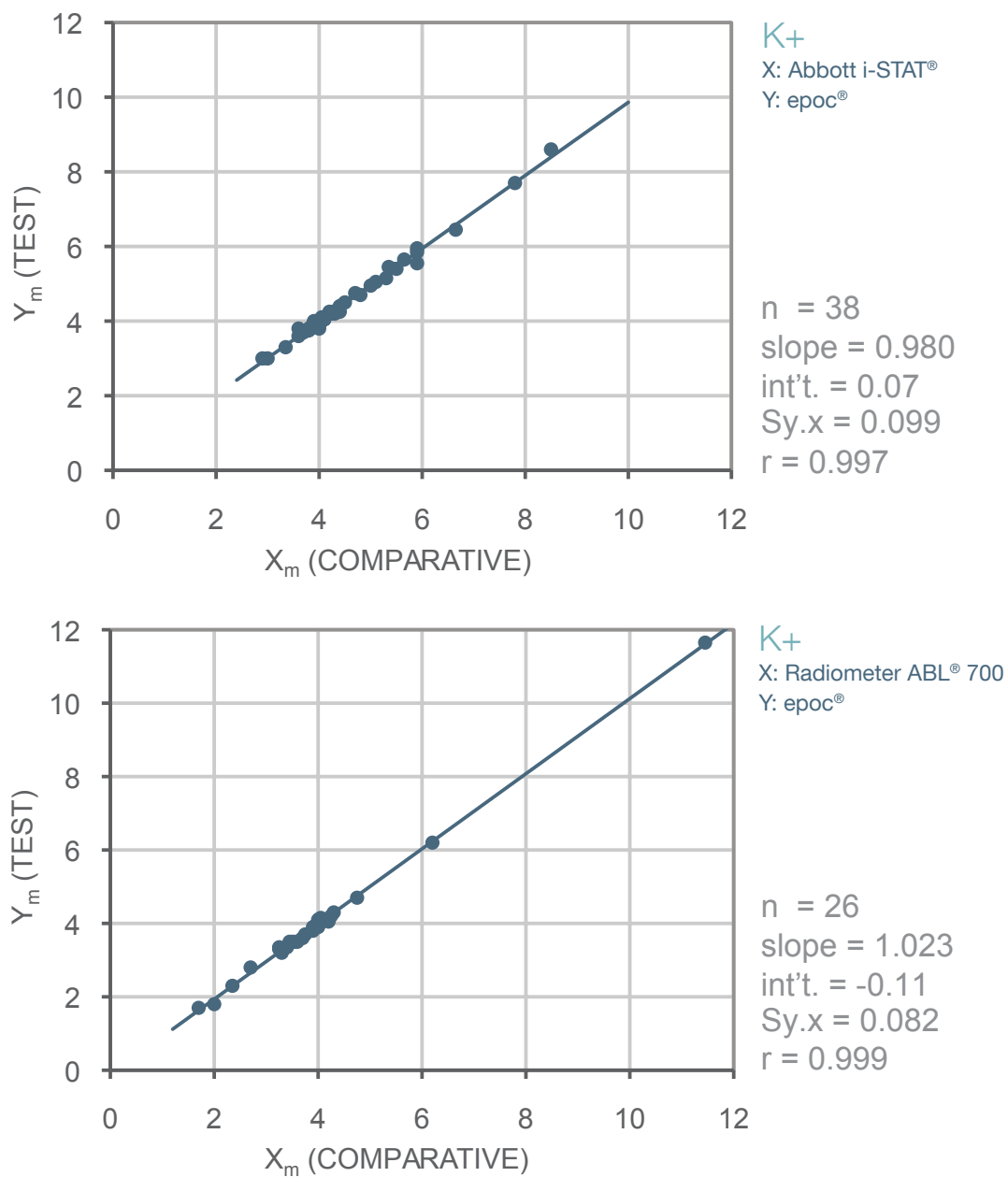
## Sodium Method Comparison...continued



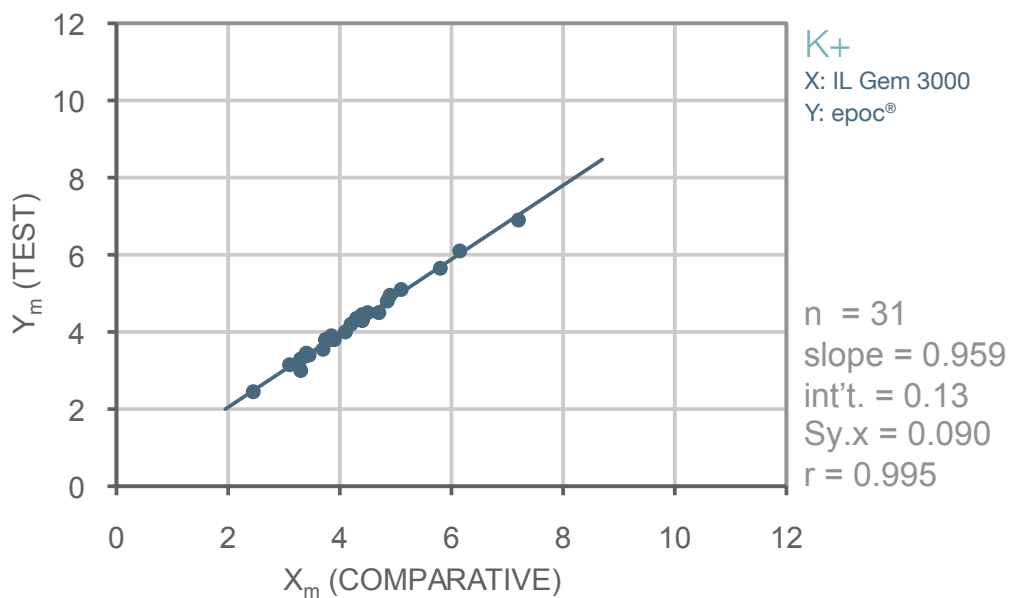
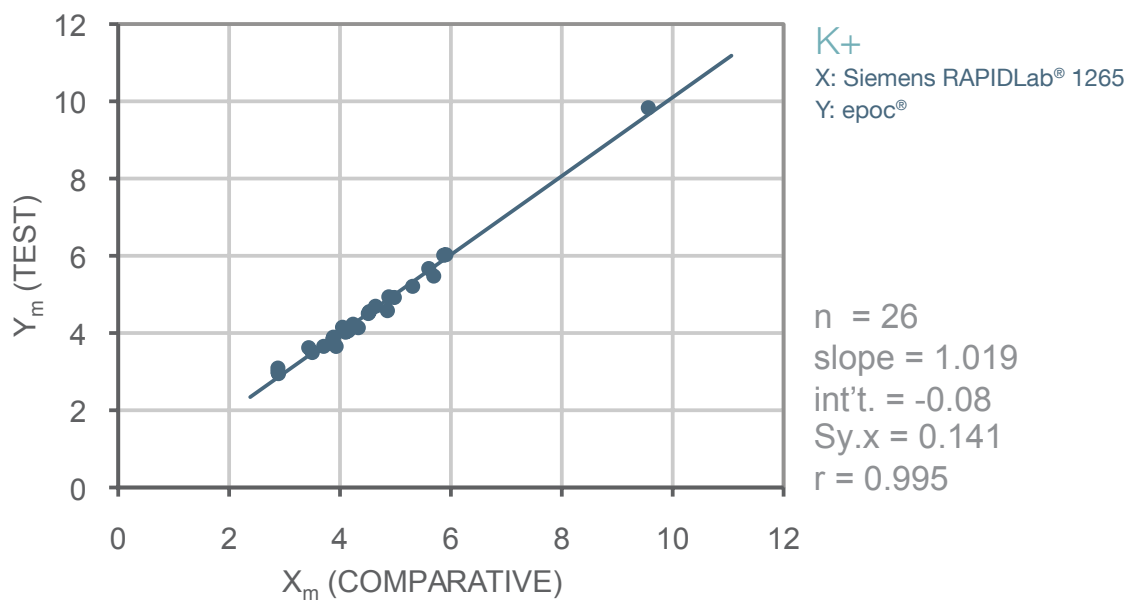
# Potassium Method Comparison

## Potassium mmol/L

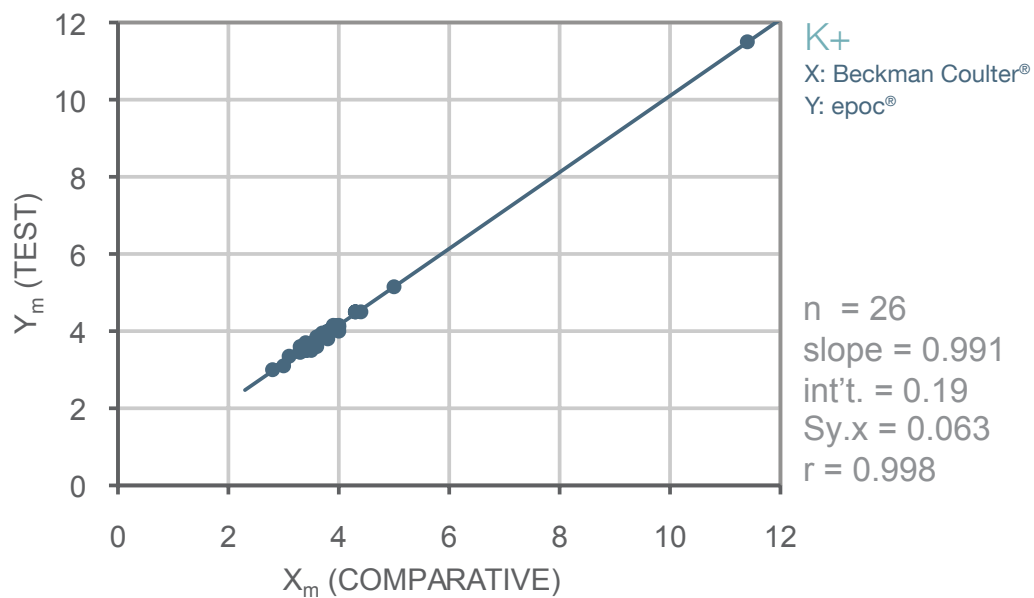
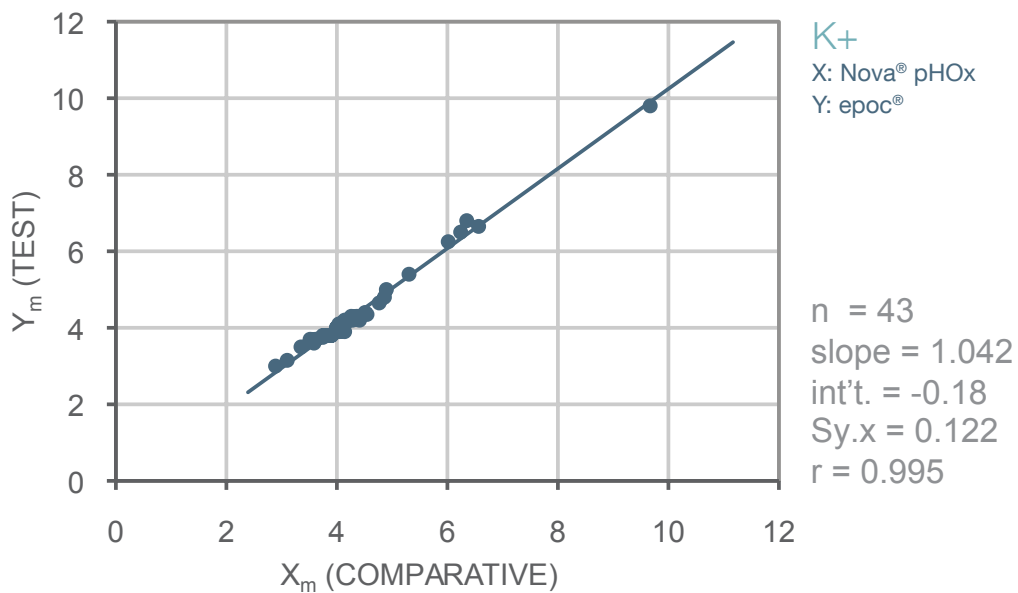
Precision	n	Mean	SD	%CV
Level 1	27	2.1	0.043	2.04%
Level 3	27	6.3	0.075	1.20%



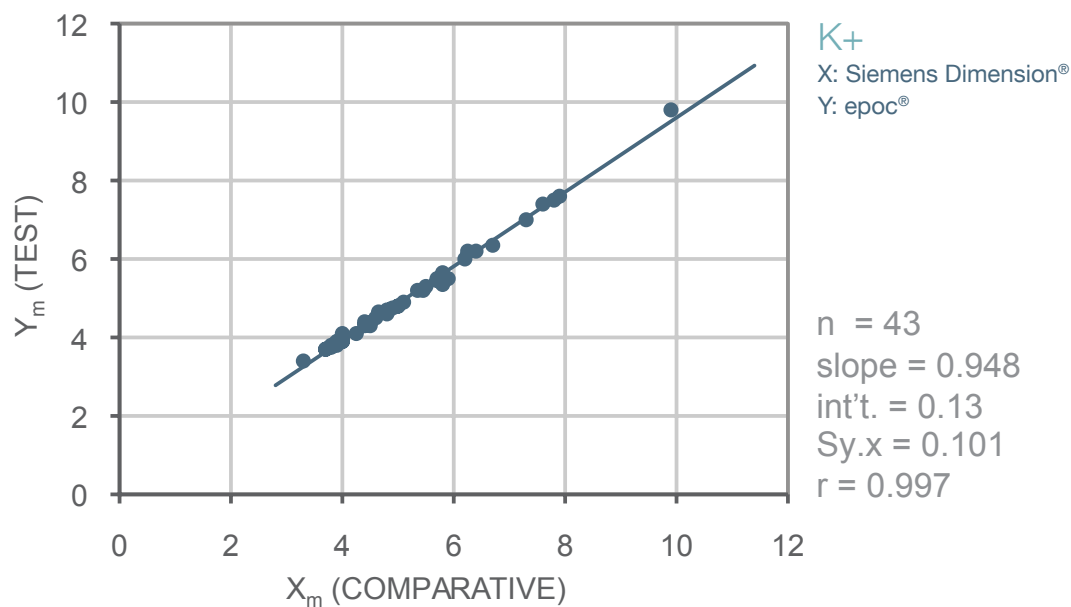
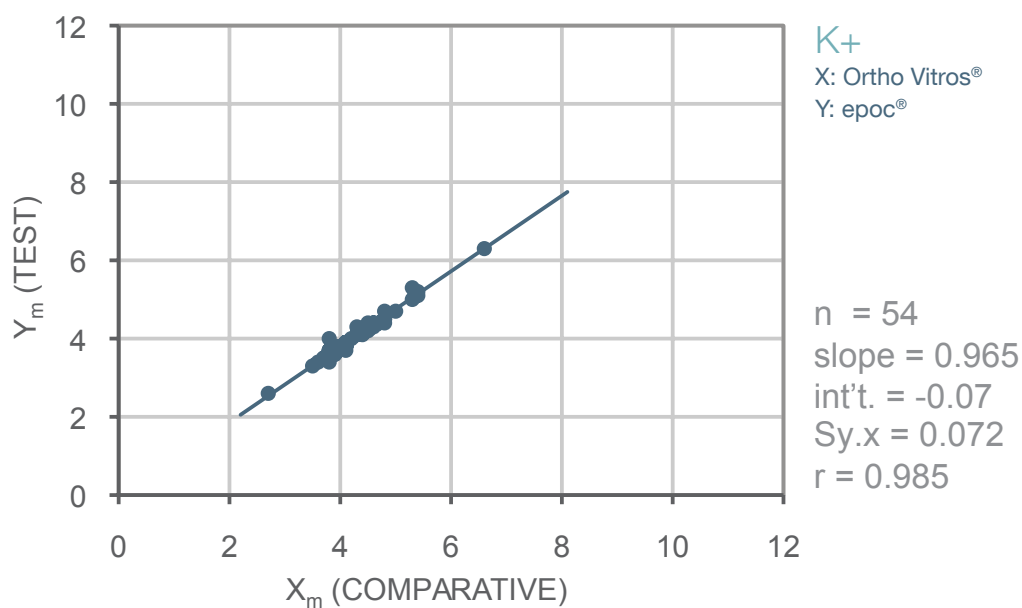
## Potassium Method Comparison *continued*



## Potassium Method Comparison *continued*



## Potassium Method Comparison...continued

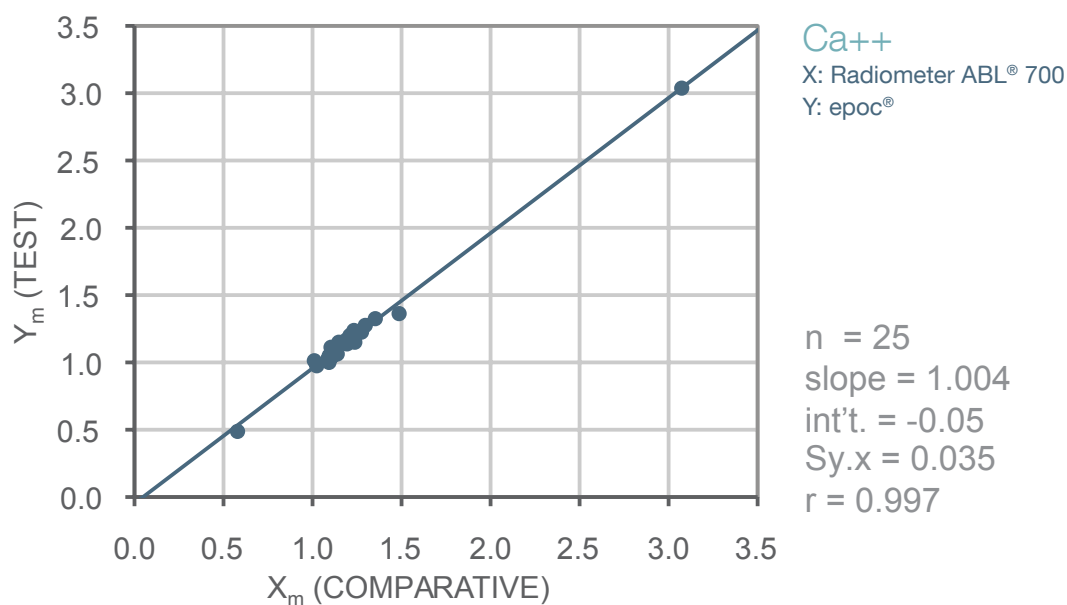
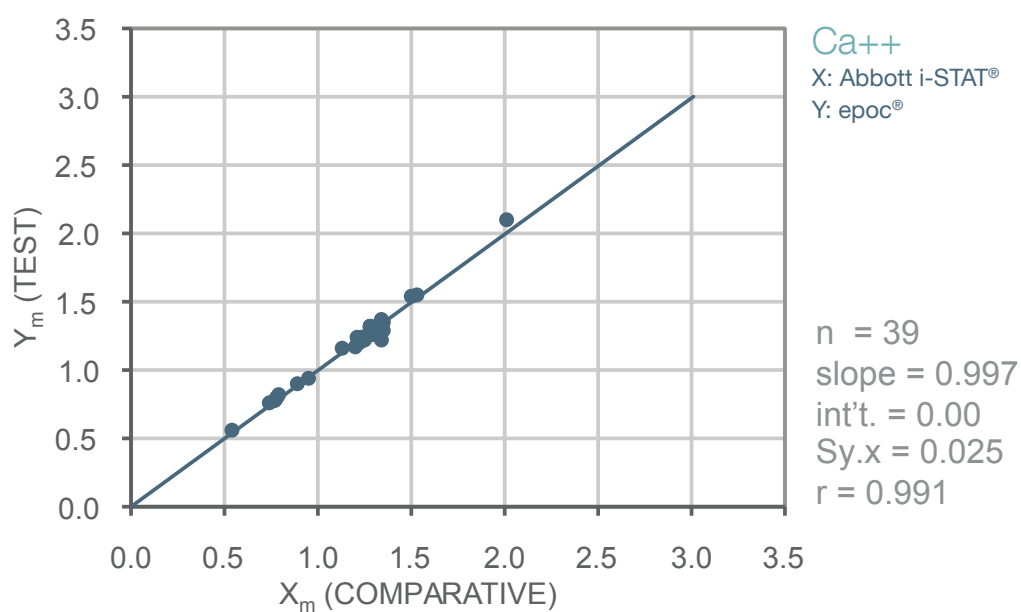




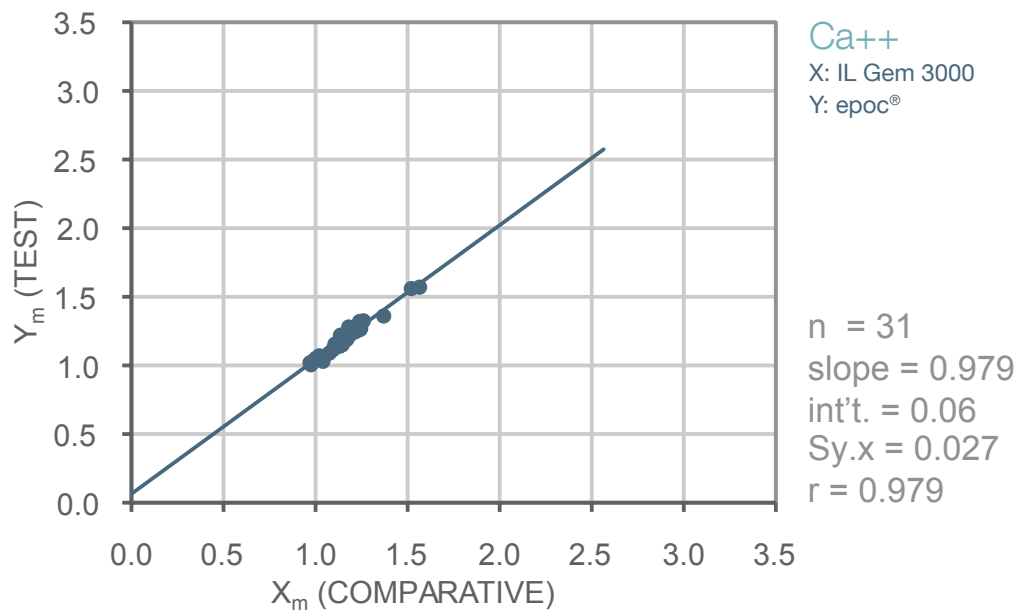
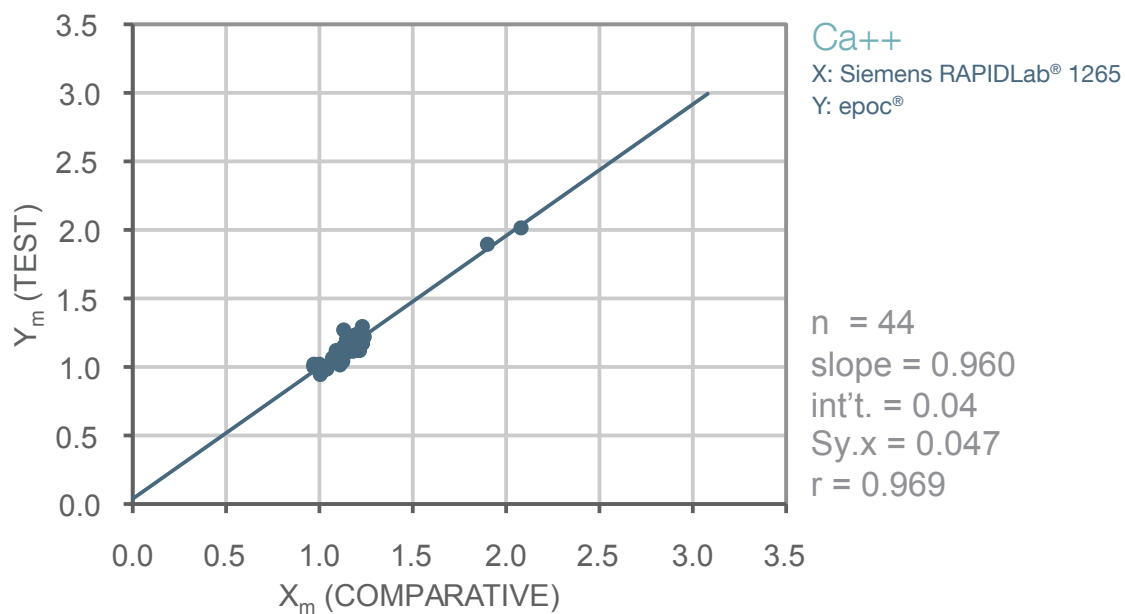
# Ionized Calcium Method Comparison

## Ionized Calcium mmol/L

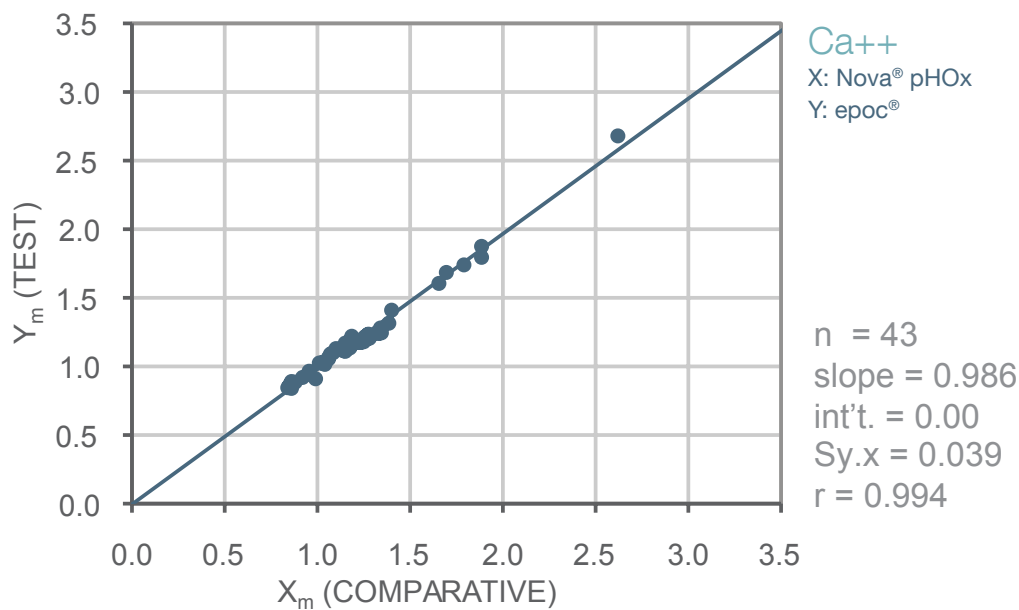
Precision	n	Mean	SD	%CV
Level 1	26	1.53	0.019	1.25%
Level 3	27	0.67	0.009	1.40%



## Ionized Calcium Method Comparison ...continued



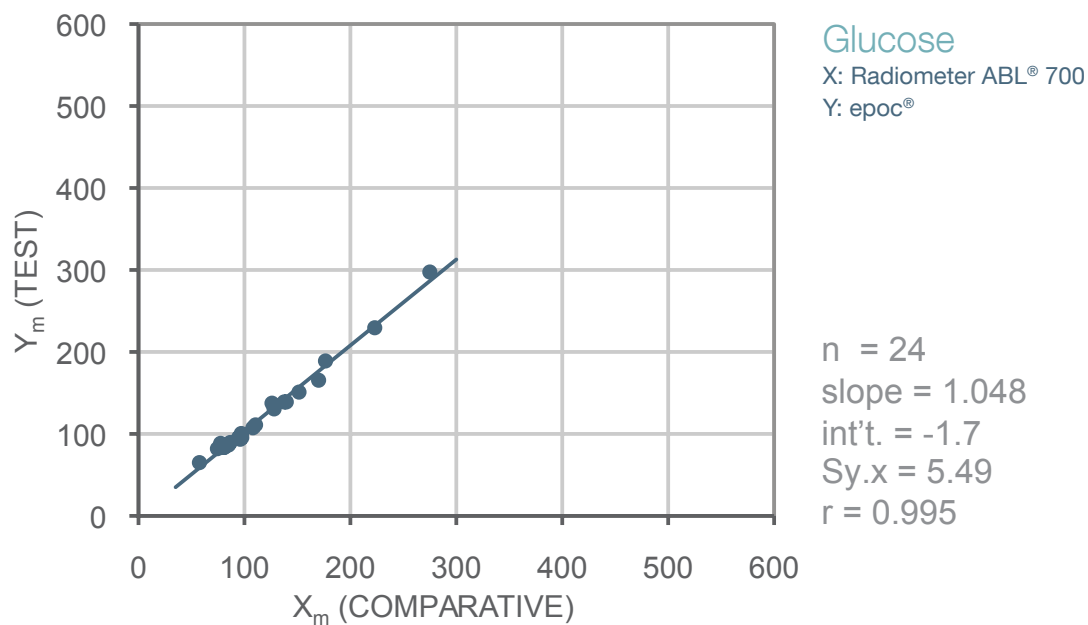
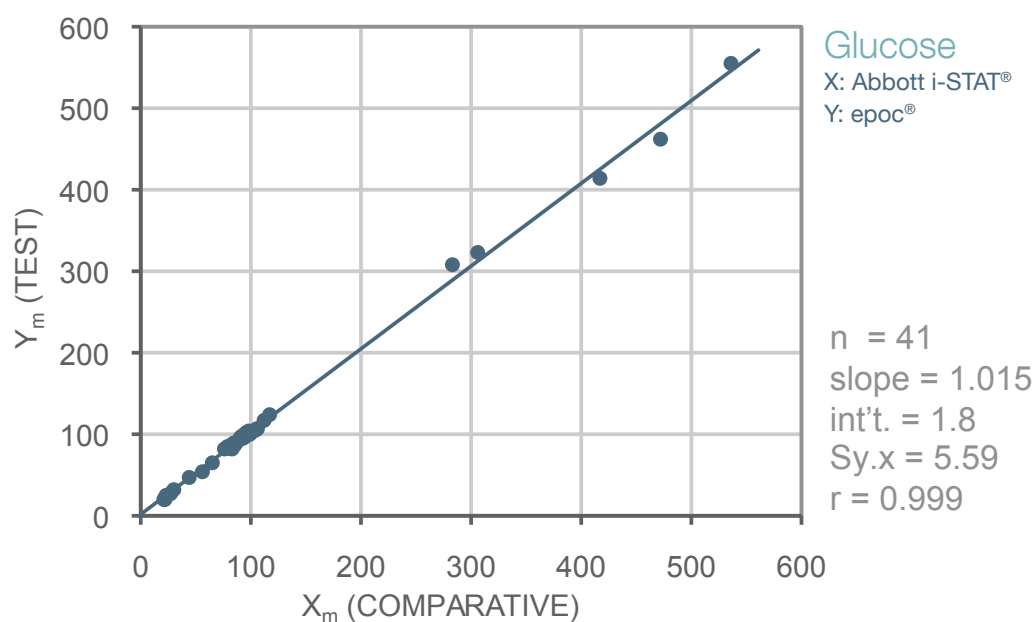
# Ionized Calcium Method Comparison ...continued



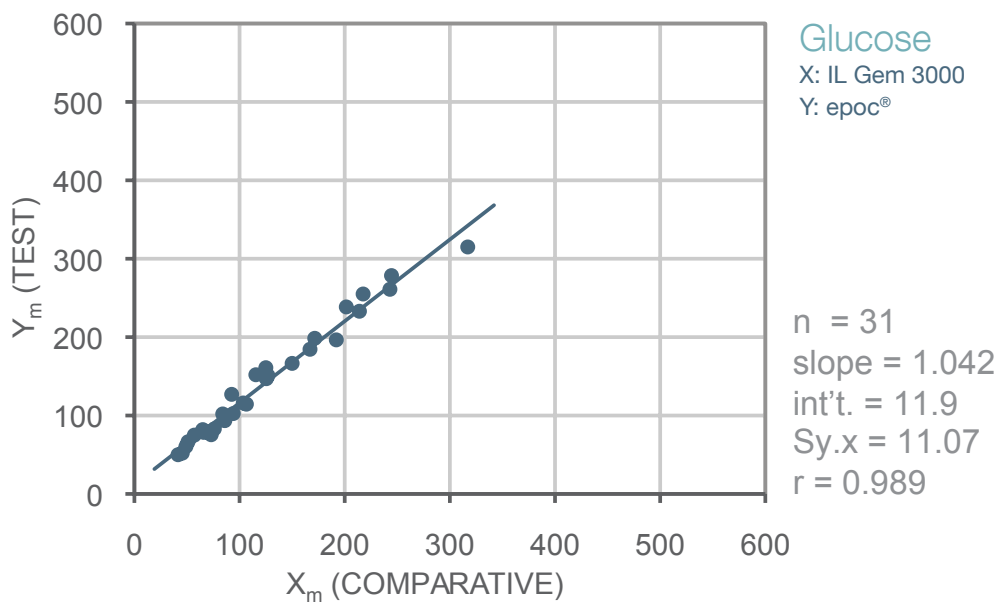
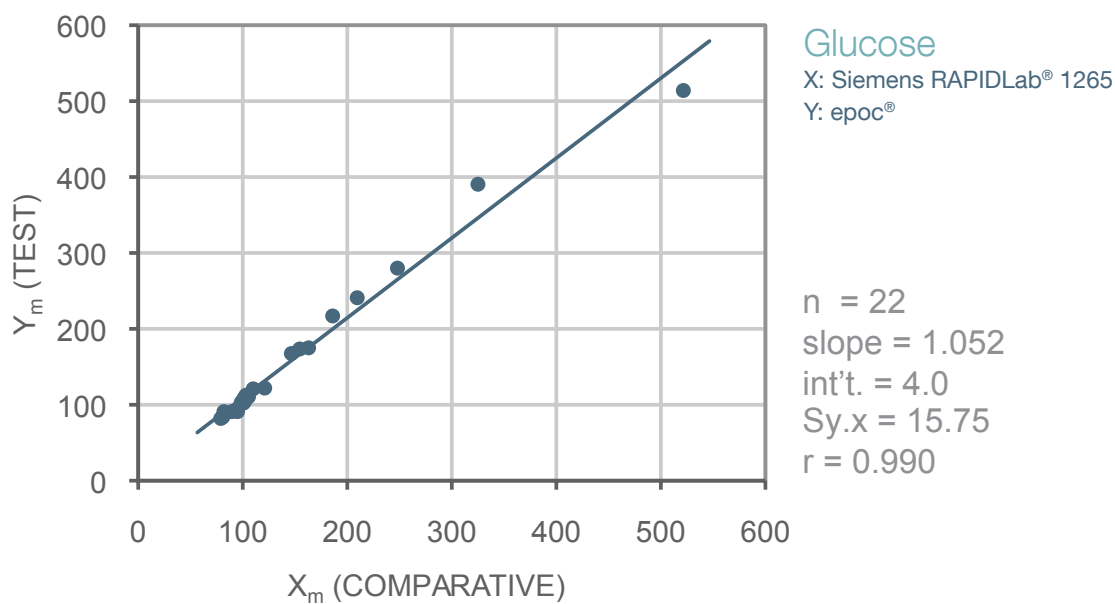
# Glucose Method Comparison

## Glucose mg/dL

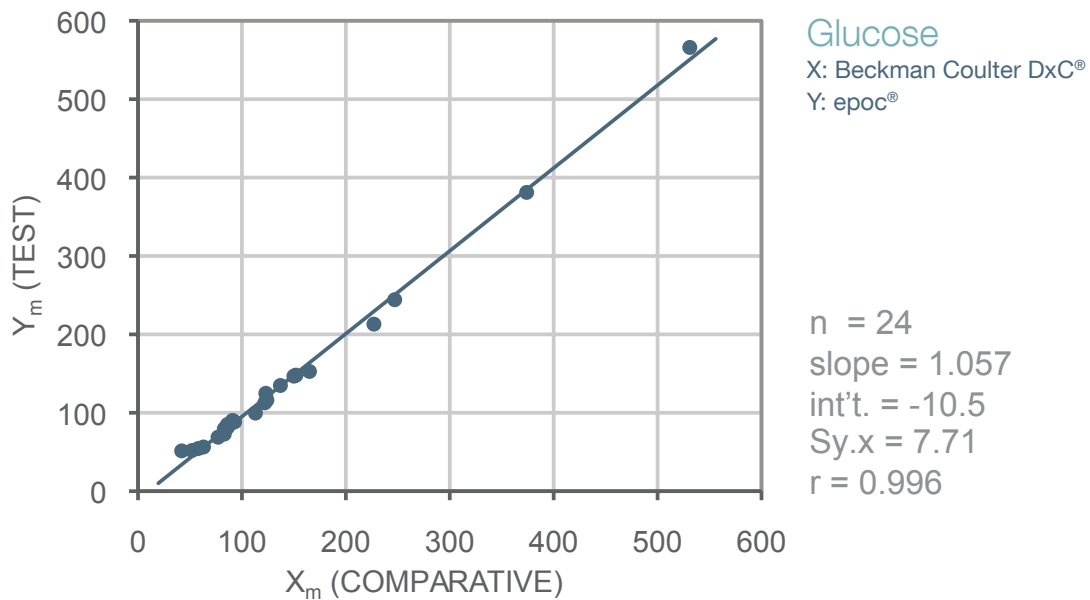
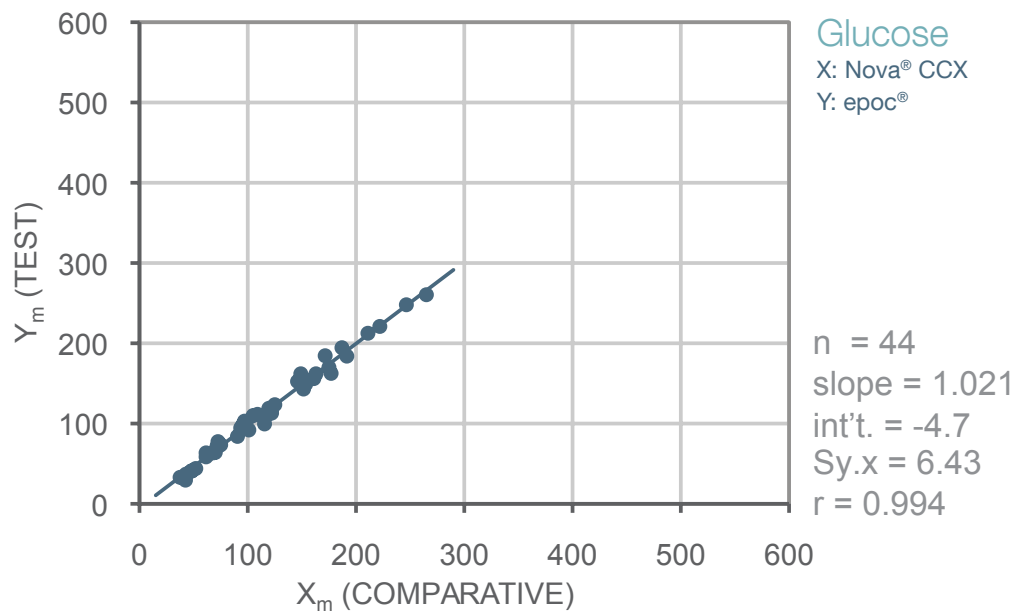
Precision	n	Mean	SD	%CV
Level 1	27	41.9	1.24	2.96%
Level 3	27	278	6.84	2.46%



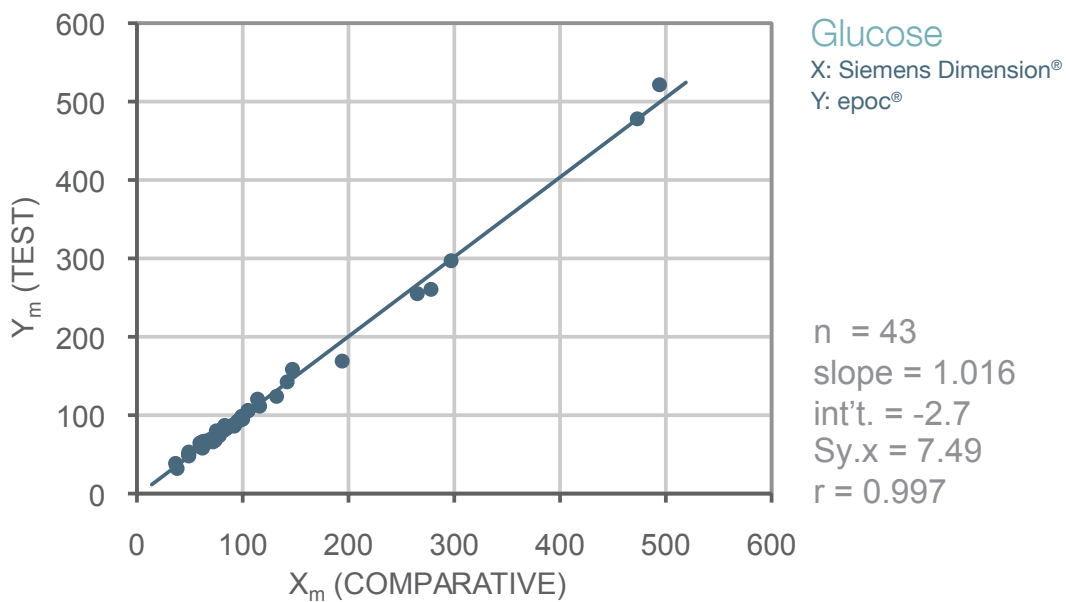
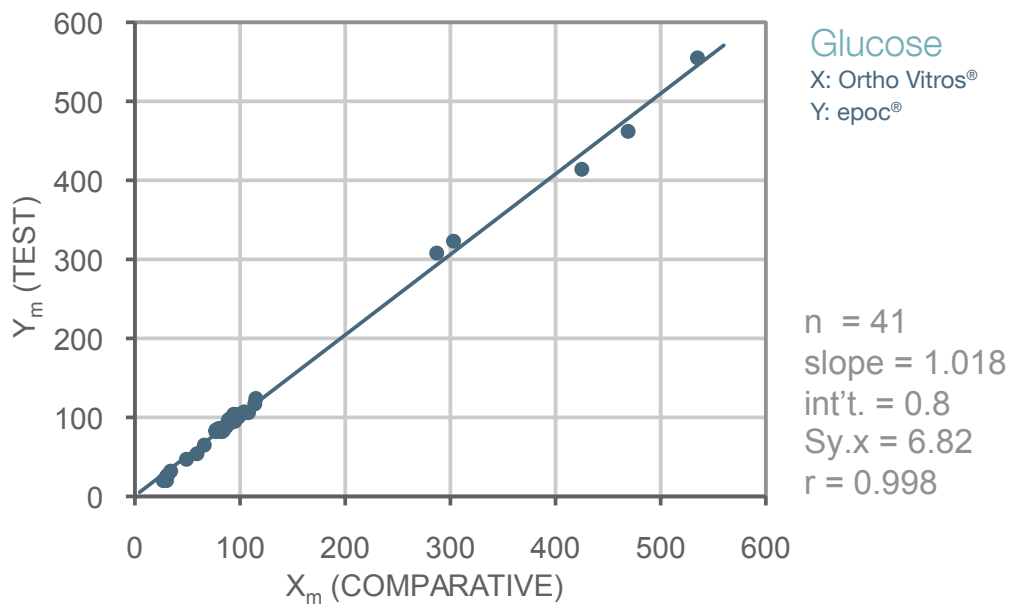
## Glucose Method Comparison...continued



## Glucose Method Comparison...continued



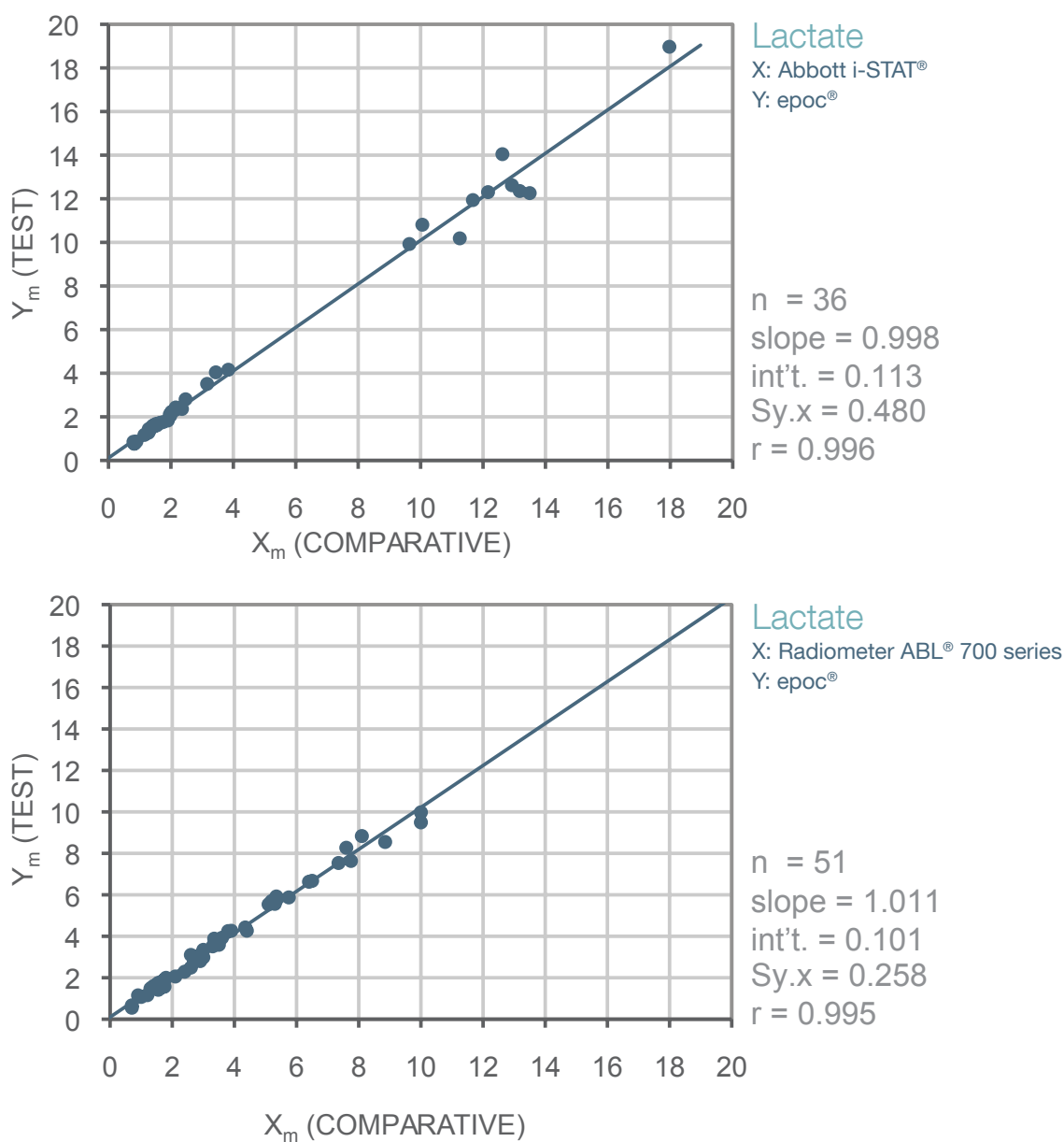
## Glucose Method Comparison...continued



# Lactate Method Comparison

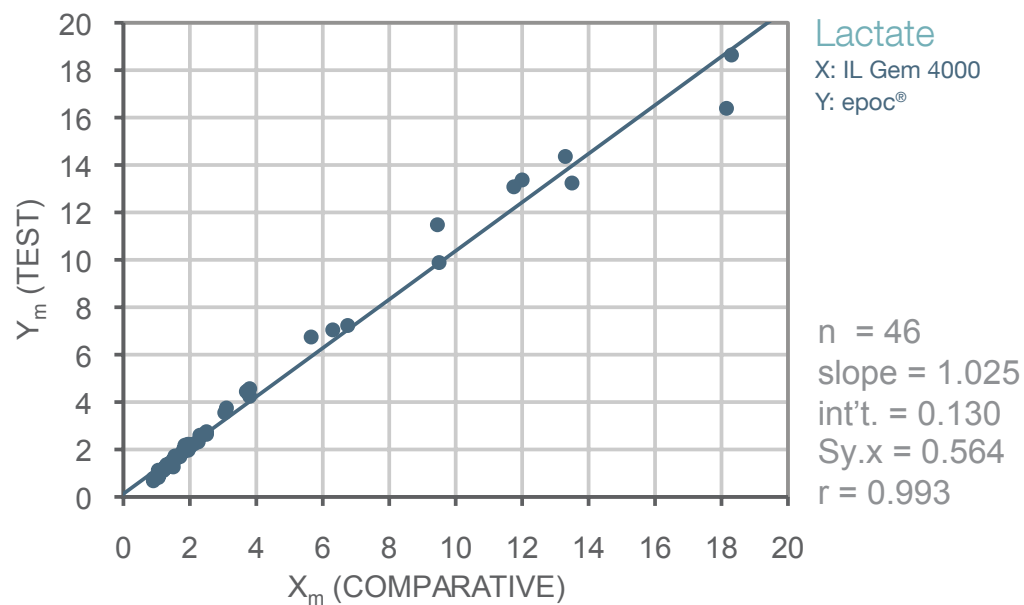
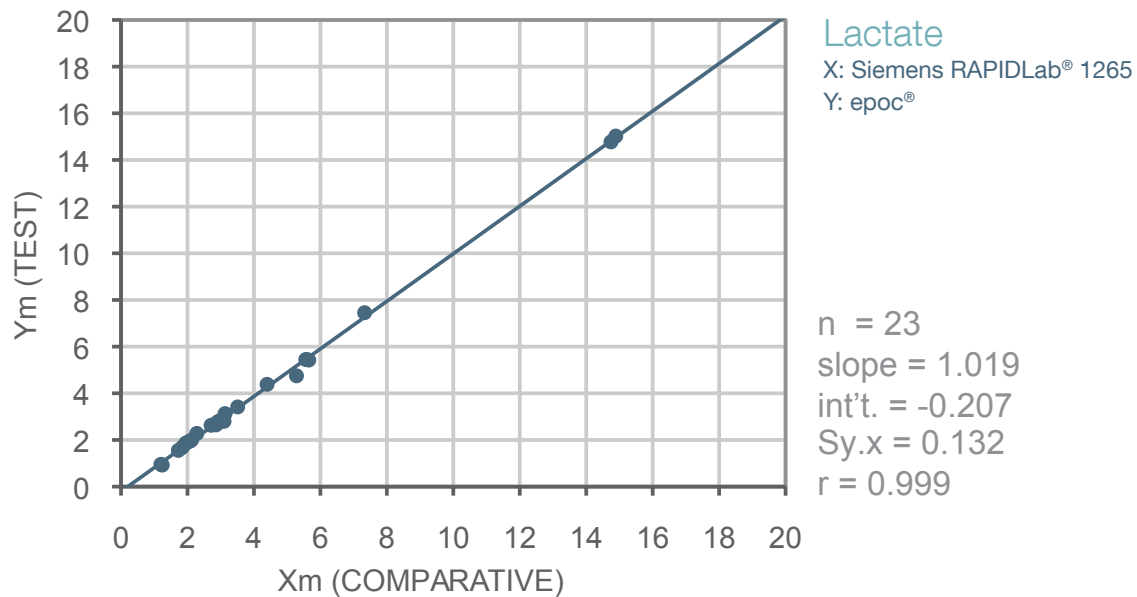
## Lactate mmol/L

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

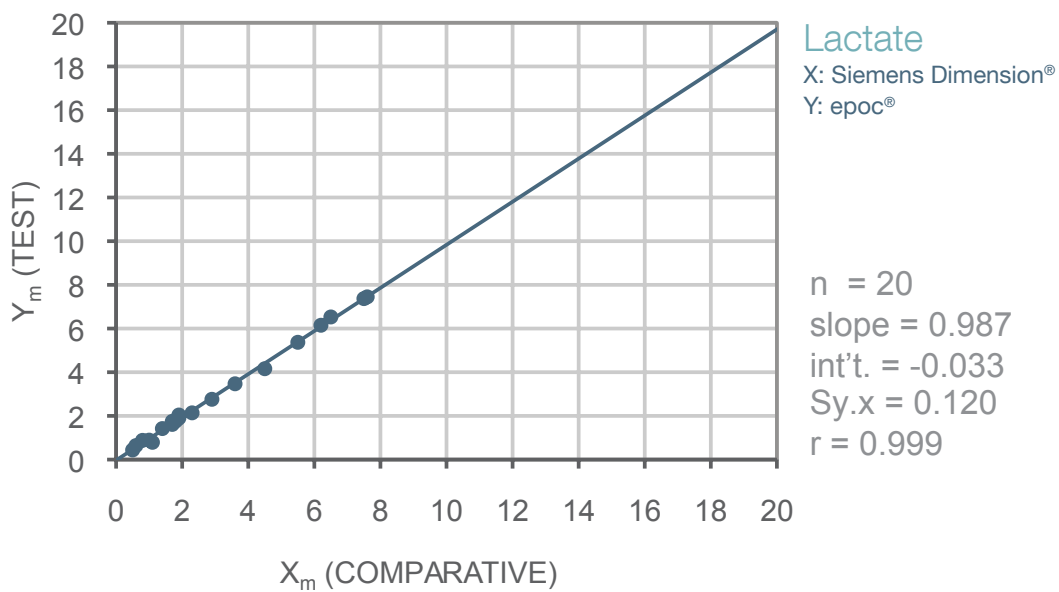
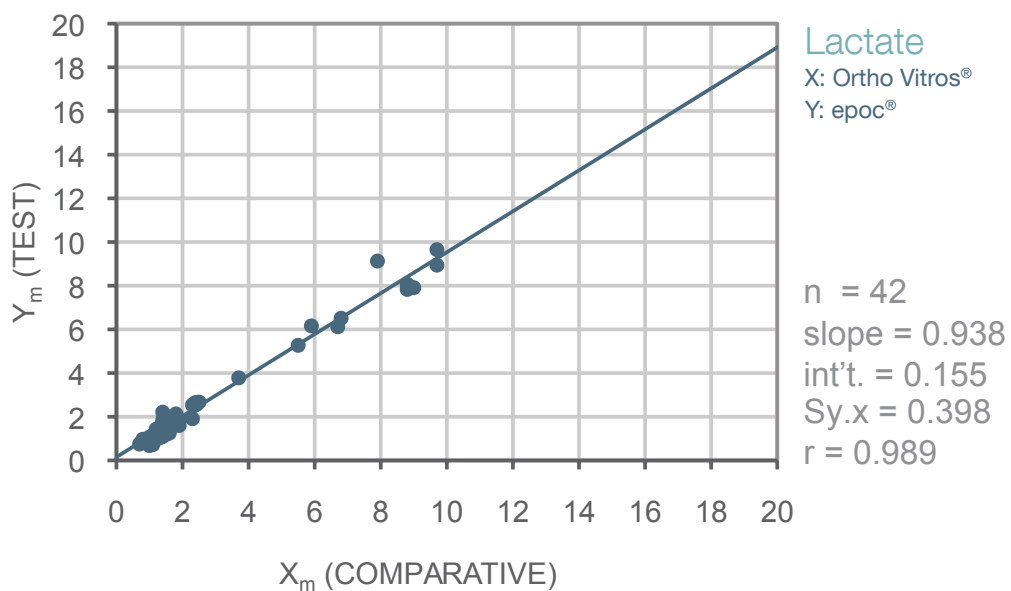




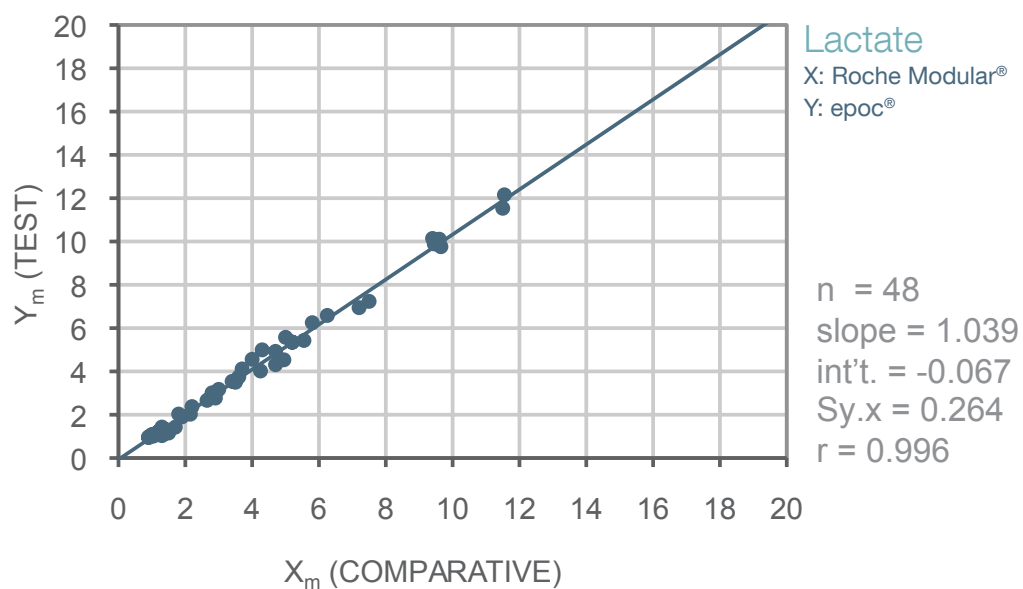
## Lactate Method Comparison...continued



## Lactate Method Comparison...continued



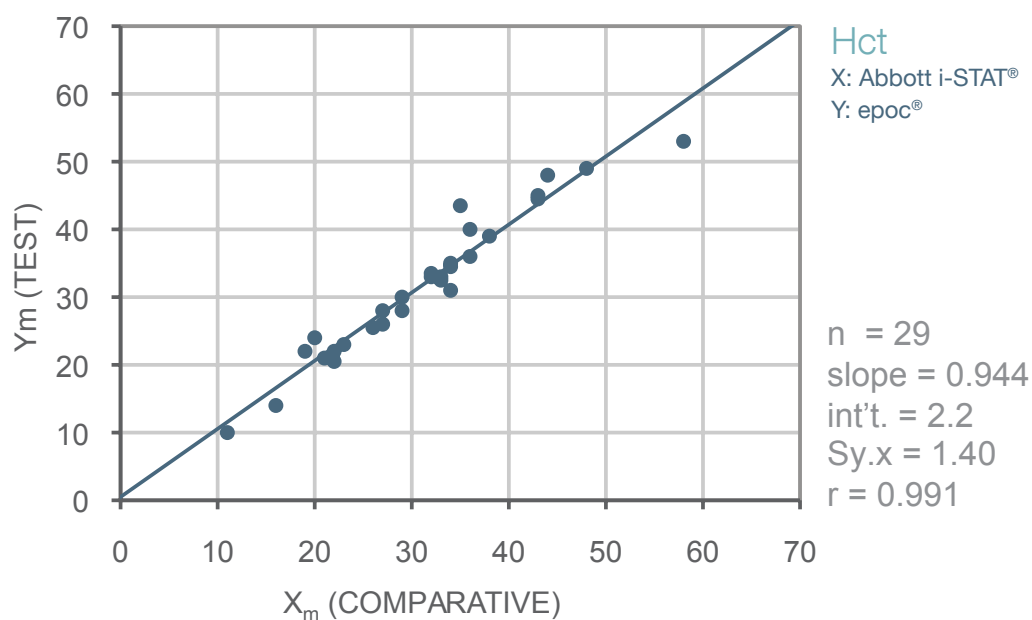
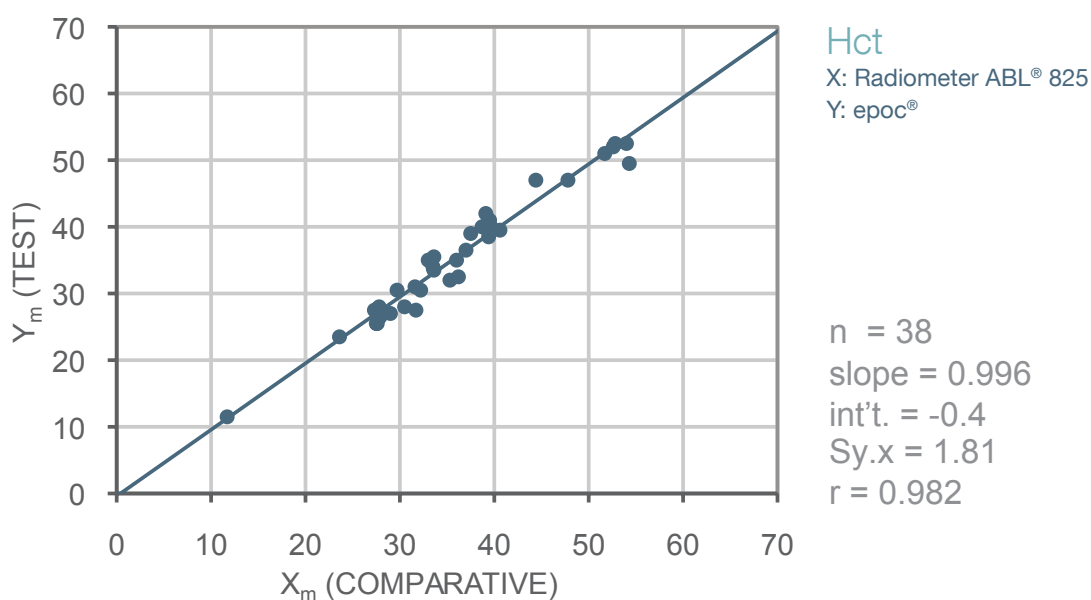
## Lactate Method Comparison...continued

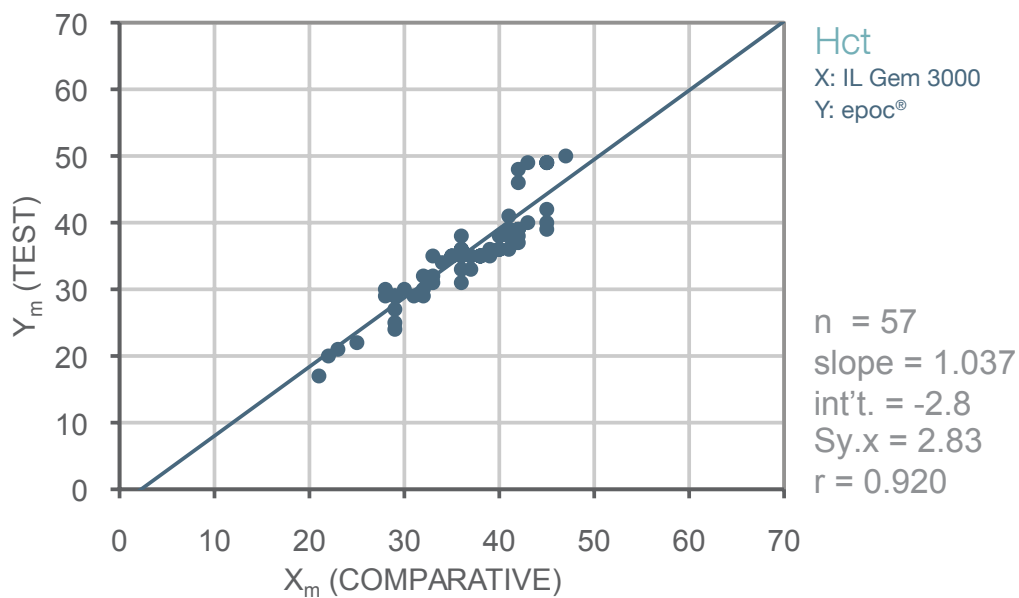
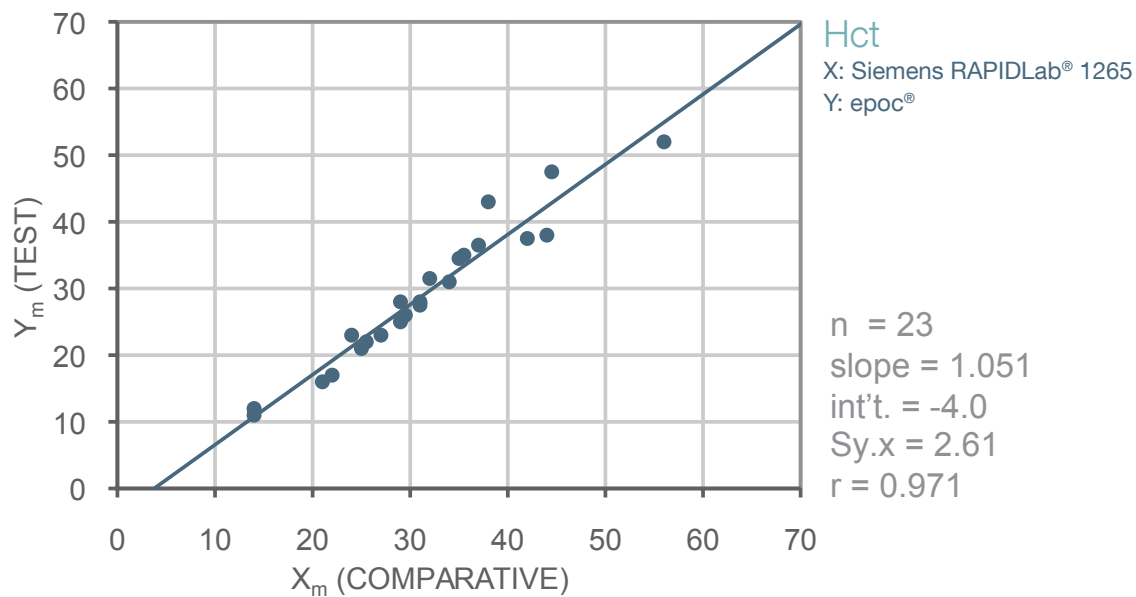


# Hematocrit Method Comparison

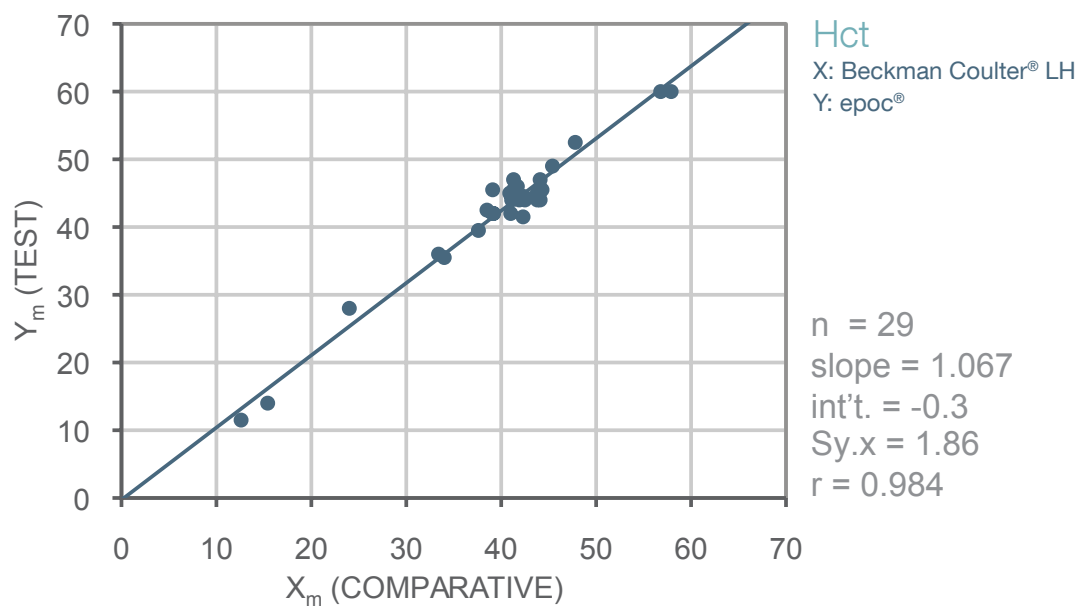
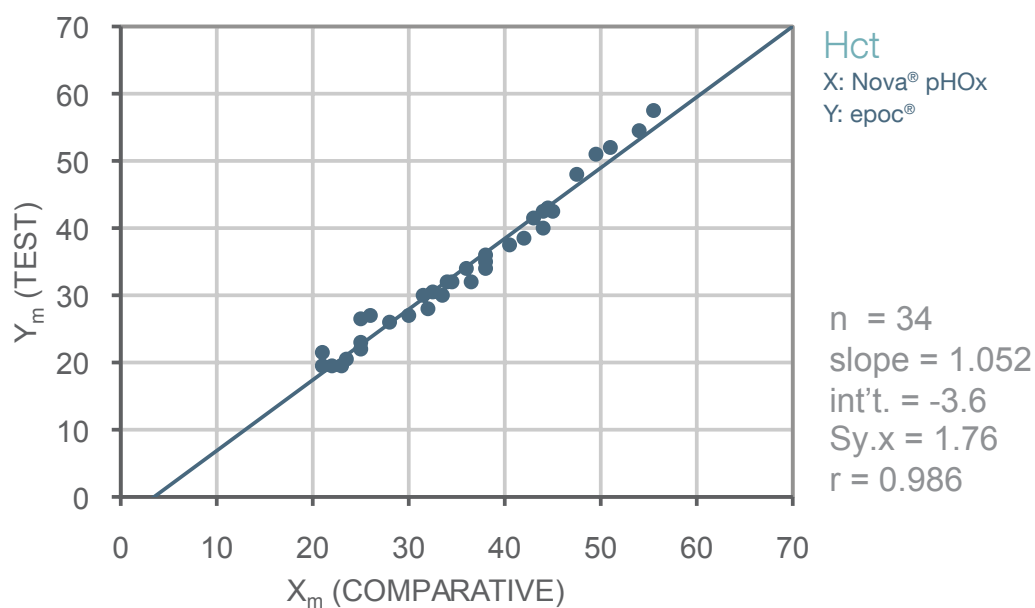
## Hematocrit %PCV

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

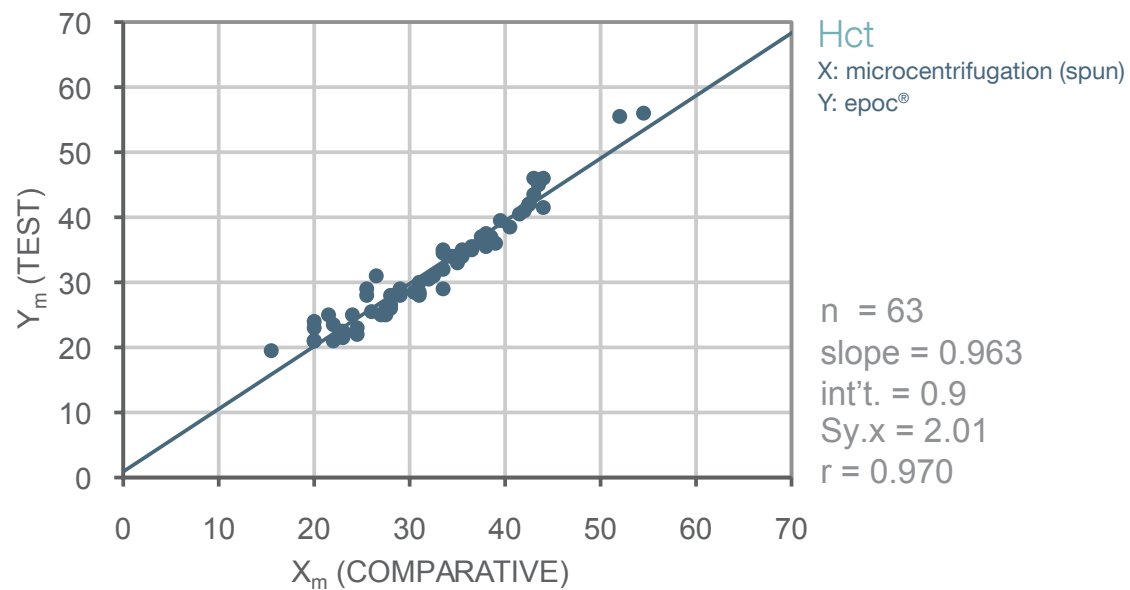
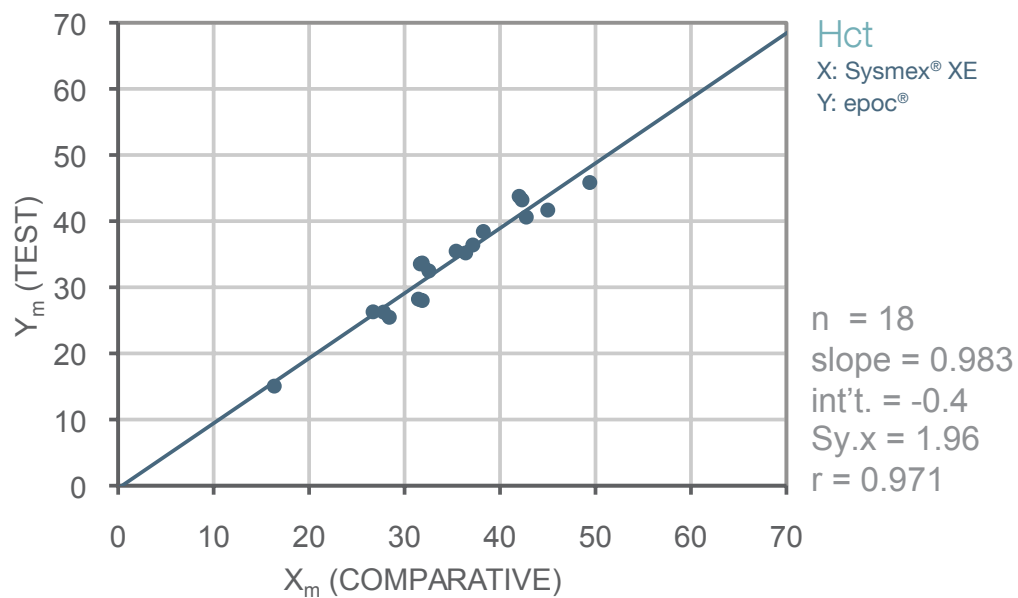




## Hematocrit Method Comparison...continued



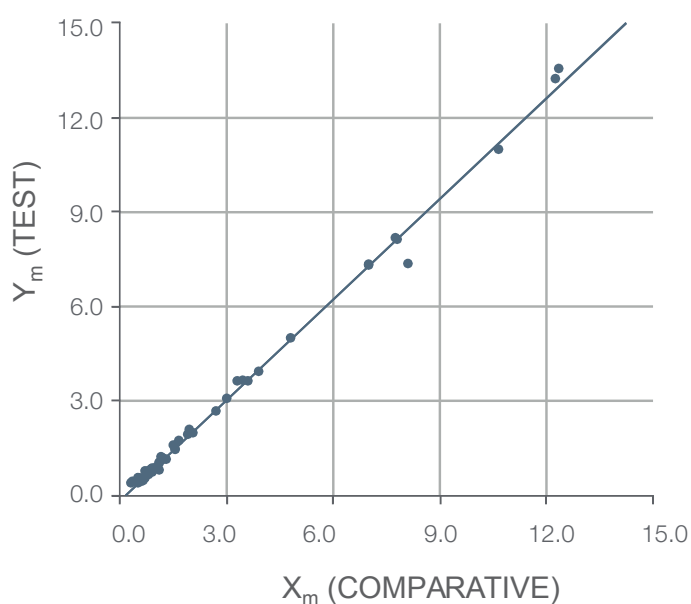
## Hematocrit Method Comparison...continued



# 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%



Crea

X: Siemens Advia®

Y: epoc®

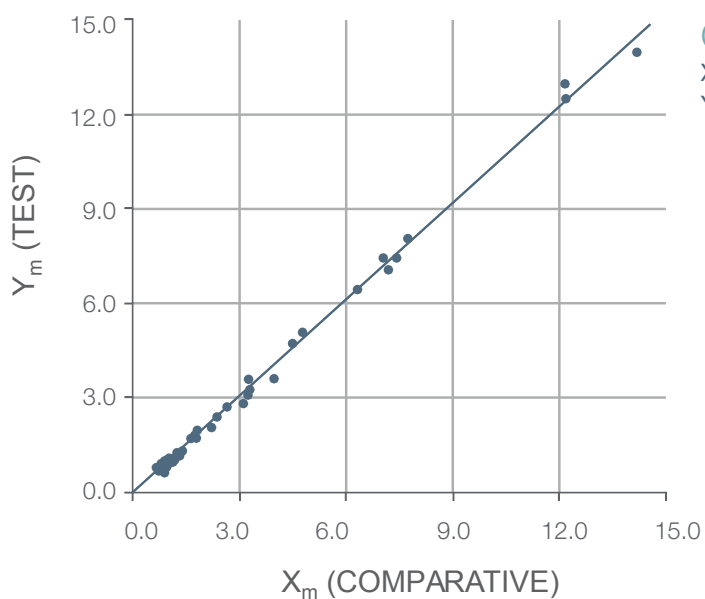
n = 53

slope = 1.063

int't. = -0.115

Sy.x = 0.207

r = 0.998



Crea

X: Beckman Coulter AU® 680

Y: epoc®

n = 63

slope = 1.028

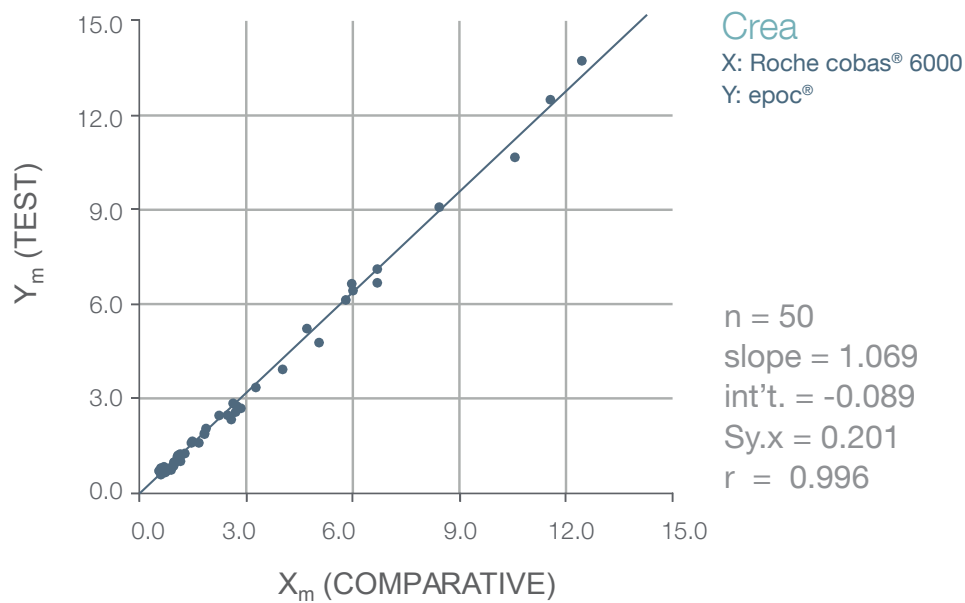
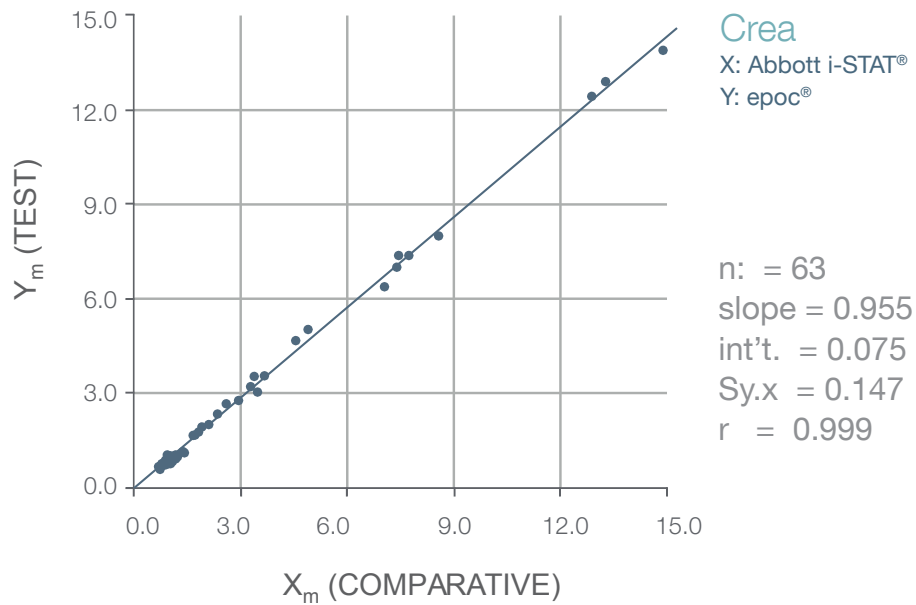
int't. = -0.008

Sy.x = 0.166

r = 0.999



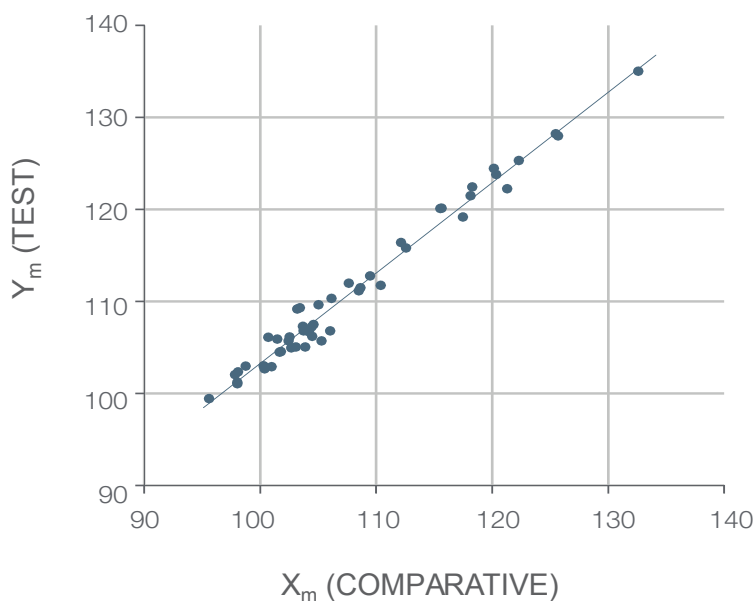
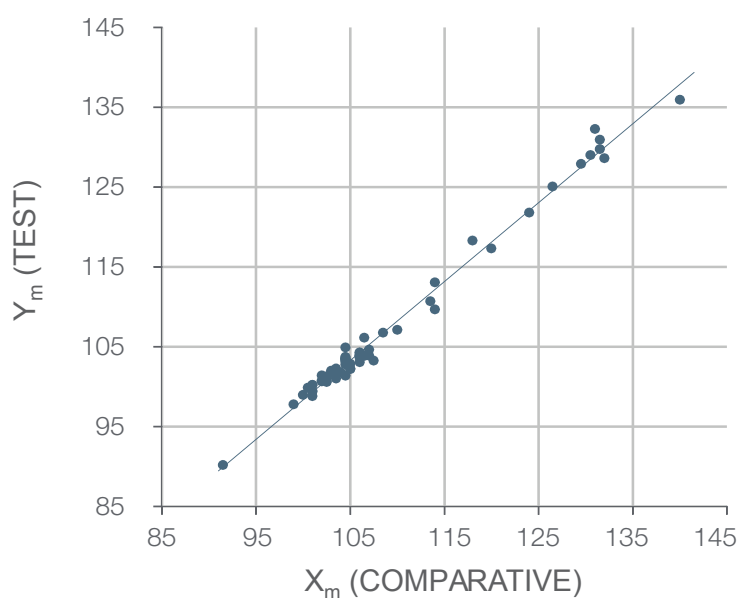
## Creatinine Method Comparison...continued



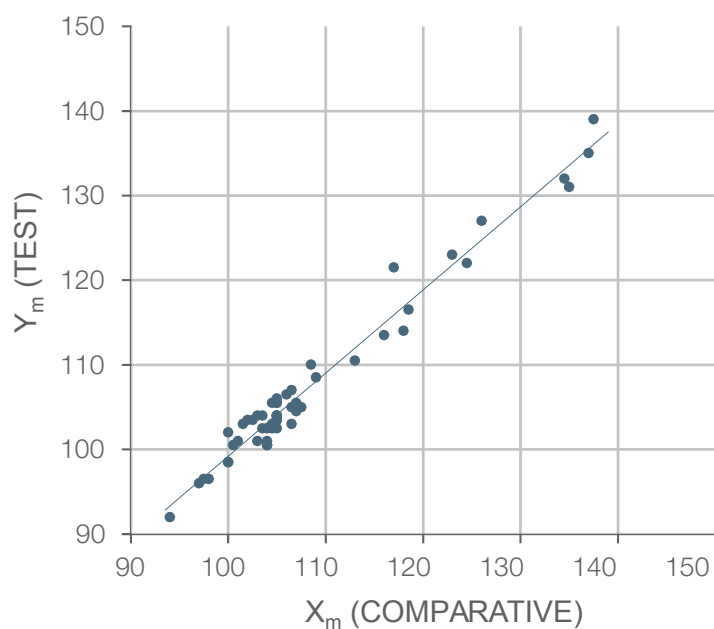
# Chloride Method Comparison

## Chloride mmol/L

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

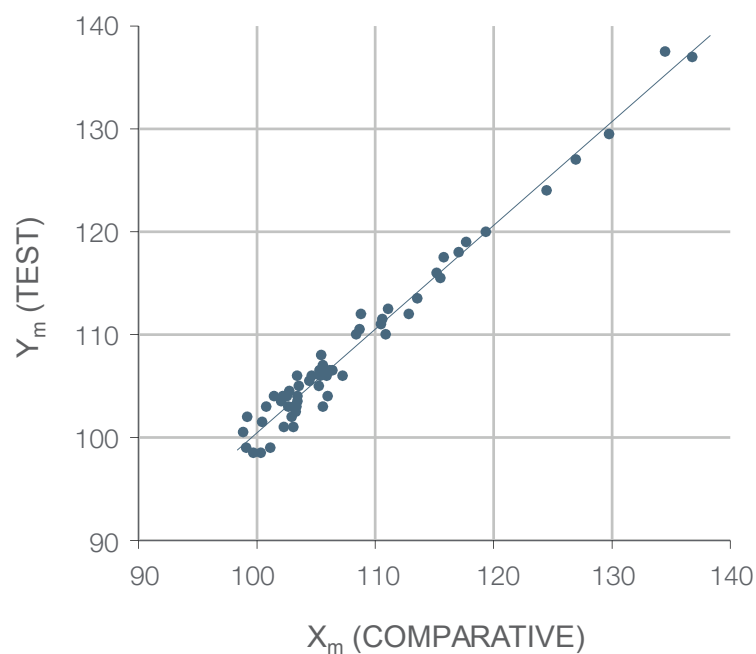


## Chloride Method Comparison ...continued



$Cl^-$   
 X: Siemens Advia®  
 Y: epoc®

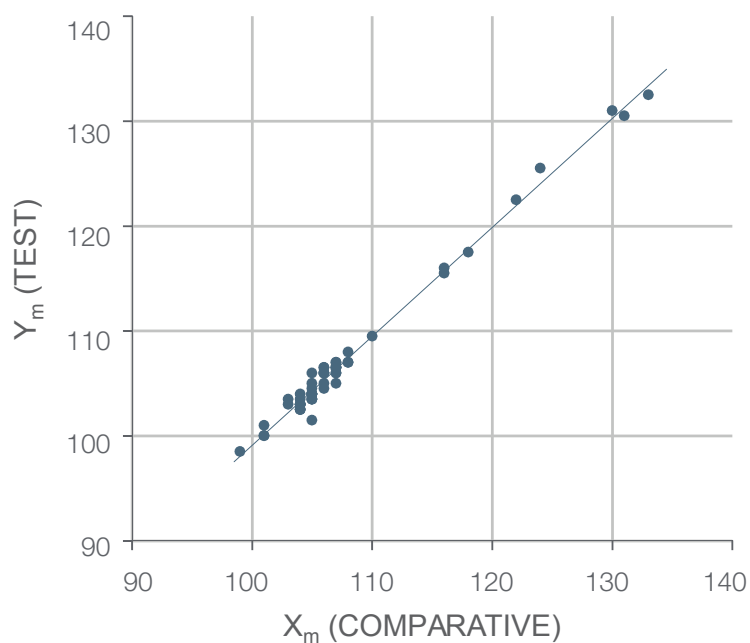
n = 53  
 slope = 0.981  
 int't. = 1.084  
 Sy.x = 1.773  
 r = 0.985



$Cl^-$   
 X: Beckman Coulter DxC®  
 Y: epoc®

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

## Chloride Method Comparison...continued



Cl-

X: Radiometer AB<sup>L</sup> 800

Y: epoc<sup>®</sup>

n = 56

slope = 1.040

int't. = -4.866

Sy.x = 0.545

r = 0.995

# Notes

# Notes





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