

April 2019

**Na<sup>+</sup>, Ca<sup>2+</sup>, Cl<sup>-</sup>, K<sup>+</sup>, and pH**  
**Method Comparison Study of the OPTI CCA-TS and TS2, E-Lyte CCA Cassette**  
**with Roche 9180 Electrolyte Analyzer**

**Introduction:** The OPTI<sup>®</sup> E-Lyte CCA cassette is a new consumable developed by OPTI Medical Systems, Inc. featuring an electrolyte panel. The OPTI<sup>®</sup> E-Lyte CCA cassette provides the convenience of three sample types (whole blood, serum and plasma), automatic aspiration, room temperature storage, zero standby costs, and minimal maintenance, and is available on both the OPTI CCA-TS and OPTI CCA-TS2 Blood Gas and Electrolyte Analyzers.

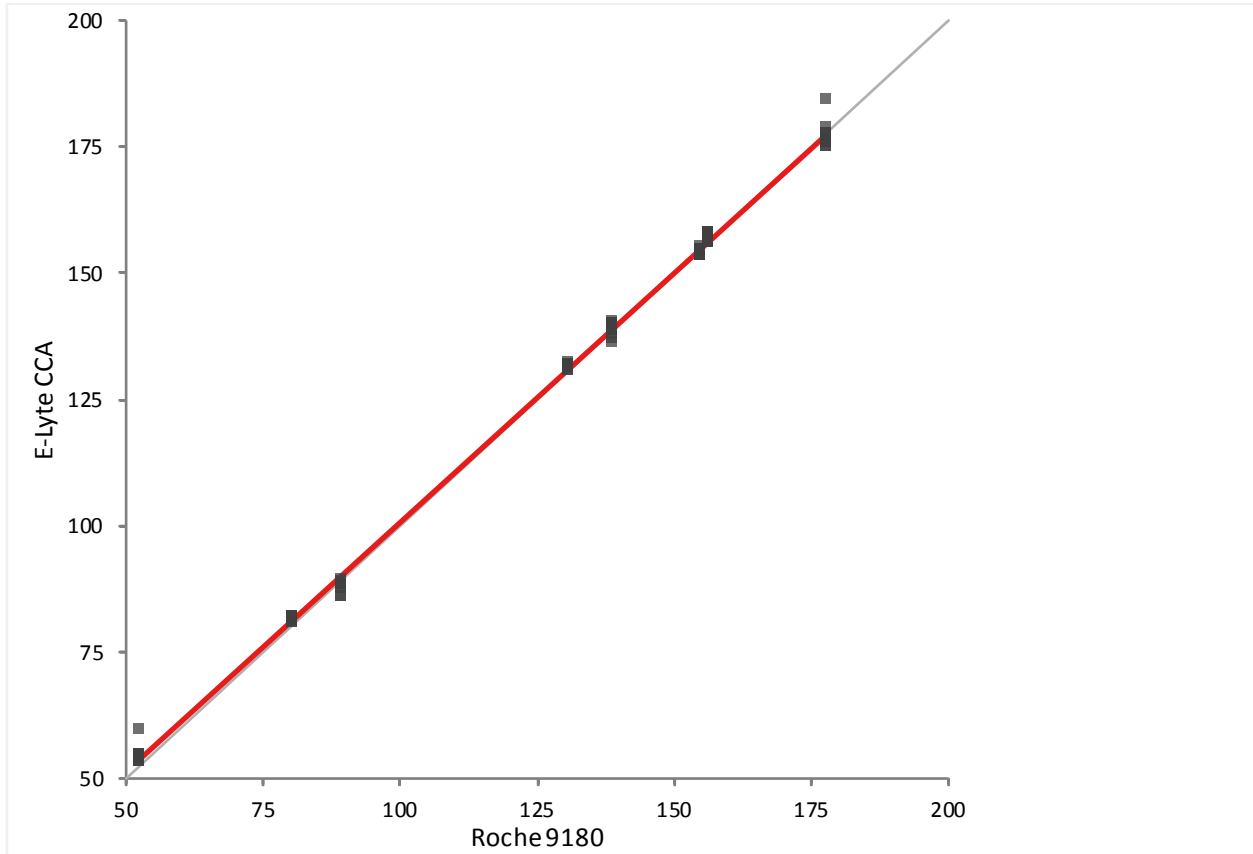
To verify the accuracy and validate the performance of the E-Lyte CCA cassette, testing was performed to compare Sodium, Calcium, Chloride, and Potassium results on the OPTI CCA-TS and OPTI-CCA TS2 Blood Gas and Electrolyte Analyzers with the Roche 9180 reference analyzer. In addition, results are included for pH for the CCA analyzers compared to the Radiometer ABL90 Flex. The results from OPTI Medical's performance testing are included in this document.

**Method:** One (1) lot of E-Lyte CCA cassettes was used in the study. The results of whole blood, plasma, and serum samples tested with E-Lyte CCA cassettes on two (2) TS and two (2) TS2 analyzers were combined respectively, and then compared to the results from reference analyzers (Roche 9180 and ABL90 FLEX) using the Analyse-it<sup>®</sup> software package. The linear regression for the correlation is plotted in this document. Samples were generated using tonometry and spiking procedures detailed in the Appendix at the end of this document.

**Objective:** To collect results for Na<sup>+</sup>, Ca<sup>2+</sup>, Cl<sup>-</sup>, and K<sup>+</sup>, and pH to validate the performance of the E-Lyte CCA cassette, tested with whole blood, plasma, and serum on the OPTI CCA-TS and OPTI-CCA TS2 analyzers, as well as on the following reference analyzers: Roche 9180 and Radiometer ABL90 Flex (pH only).

**Materials:**

- |   |   |
|---|---|
| • E-Lyte CCA Cassette BP7667  | Lot number: 903680                      |
| • OPTI CCA-TS and TS2 Analyzers   | TS SN: 2582, 3066<br>TS2 SN: 0152, 0143 |
| • Roche 9180 (Na <sup>+</sup> , Ca <sup>2+</sup> , Cl <sup>-</sup> , and K <sup>+</sup> ) | SN: U18-2013, U18-3189                  |
| • ABL90 Flex (pH only)  | SN: I393-090R0624N0007                  |
| • Analyse-it <sup>®</sup> software  |   |

**Whole Blood Results, Na<sup>+</sup> (data compared with Roche 9180, N=115):**

**Ordinary least-squares fit**

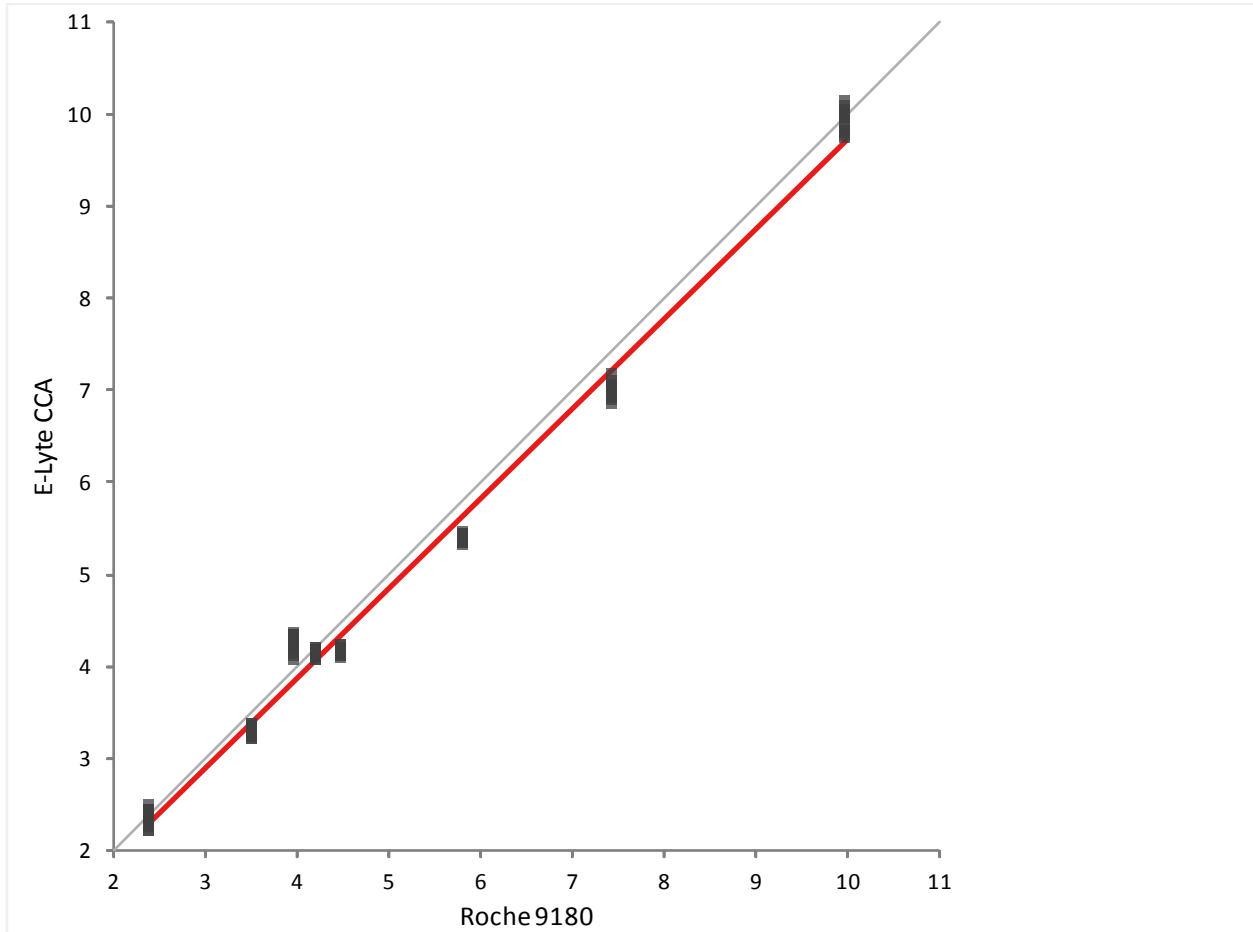
Equation    E-Lyte CCA = 2.0245 + 0.9866 Roche 9180

R<sup>2</sup>        0.999

Sy.x        2.82

**Comparability**

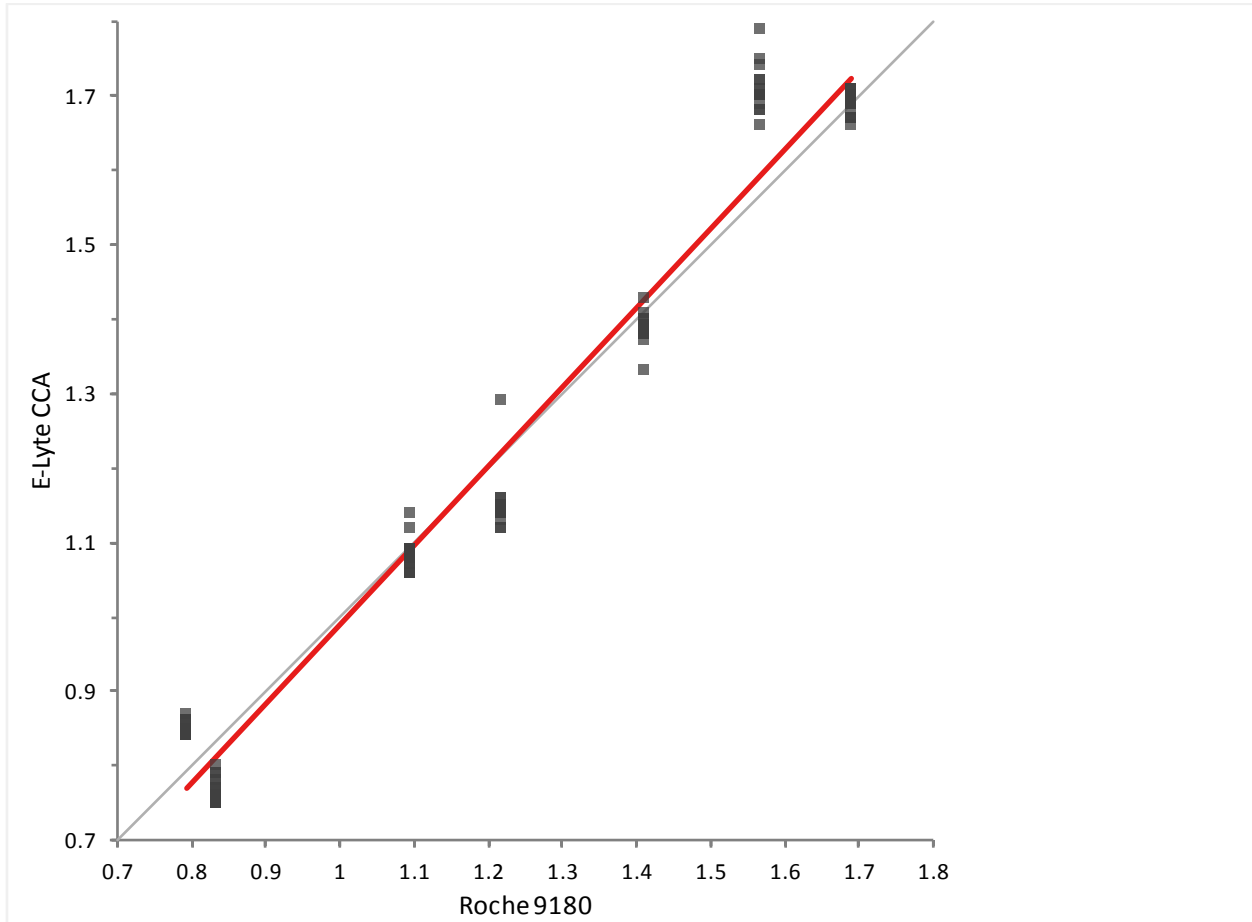
	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	120	0.41421	0.14669	to 0.68174	±4.0
High	160	-0.12255	-0.48372	to 0.23862	±4.0

**Whole Blood Results, K<sup>+</sup> (data compared with Roche 9180, N = 128):**

**Ordinary least-squares fit**

Equation    E-Lyte CCA = -0.0326 + 0.976 Roche 9180  
R<sup>2</sup>        0.995  
Sy.x        0.228275

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	2.80	-0.099678	-0.15776	to -0.04158	±0.50
High	6.20	-0.18110	-0.22452	to -0.13768	±0.50

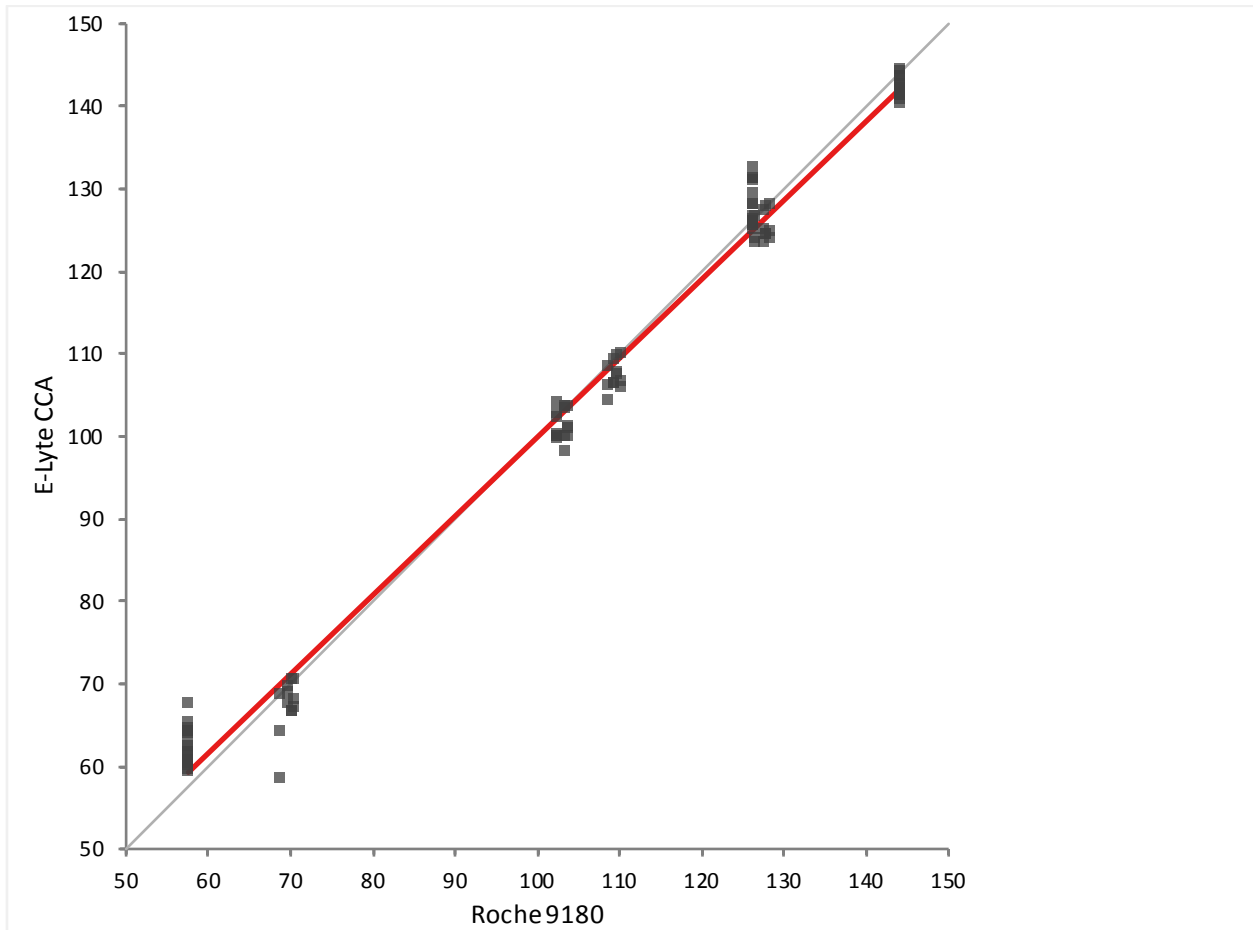
**Whole Blood Results, Ca<sup>2+</sup> (data compared with Roche 9180, N = 112):**

**Ordinary least-squares fit**

Equation E-Lyte CCA = -0.07526 + 1.065 Roche 9180  
 R<sup>2</sup> 0.980  
 Sy.x 0.069907

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	0.75	-0.02669	-0.05021	to -0.00318	±0.125
High	1.60	0.02834	0.00838	to 0.04831	±0.125

**Whole Blood Results, CI (data compared with Roche 9180, N = 99):**

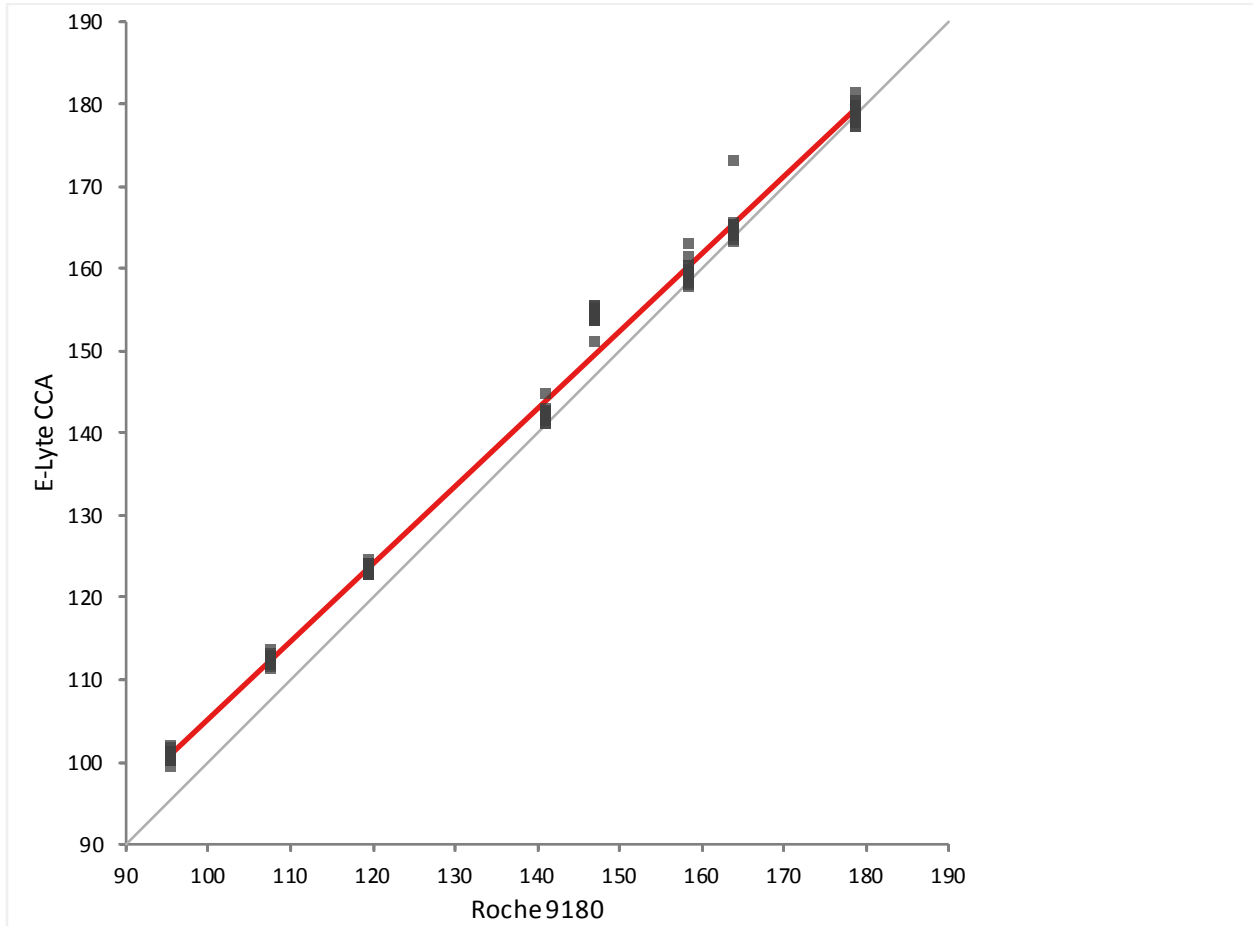


**Ordinary least-squares fit**

Equation    E-Lyte CCA = 4.168 + 0.9574 Roche 9180  
 R<sup>2</sup>        0.994  
 Sy.x        3.0623

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	80.0	0.7620	-0.0440	to 1.5681	±5.0
High	120.0	-0.9409	-1.6169	to -0.2649	±6.0

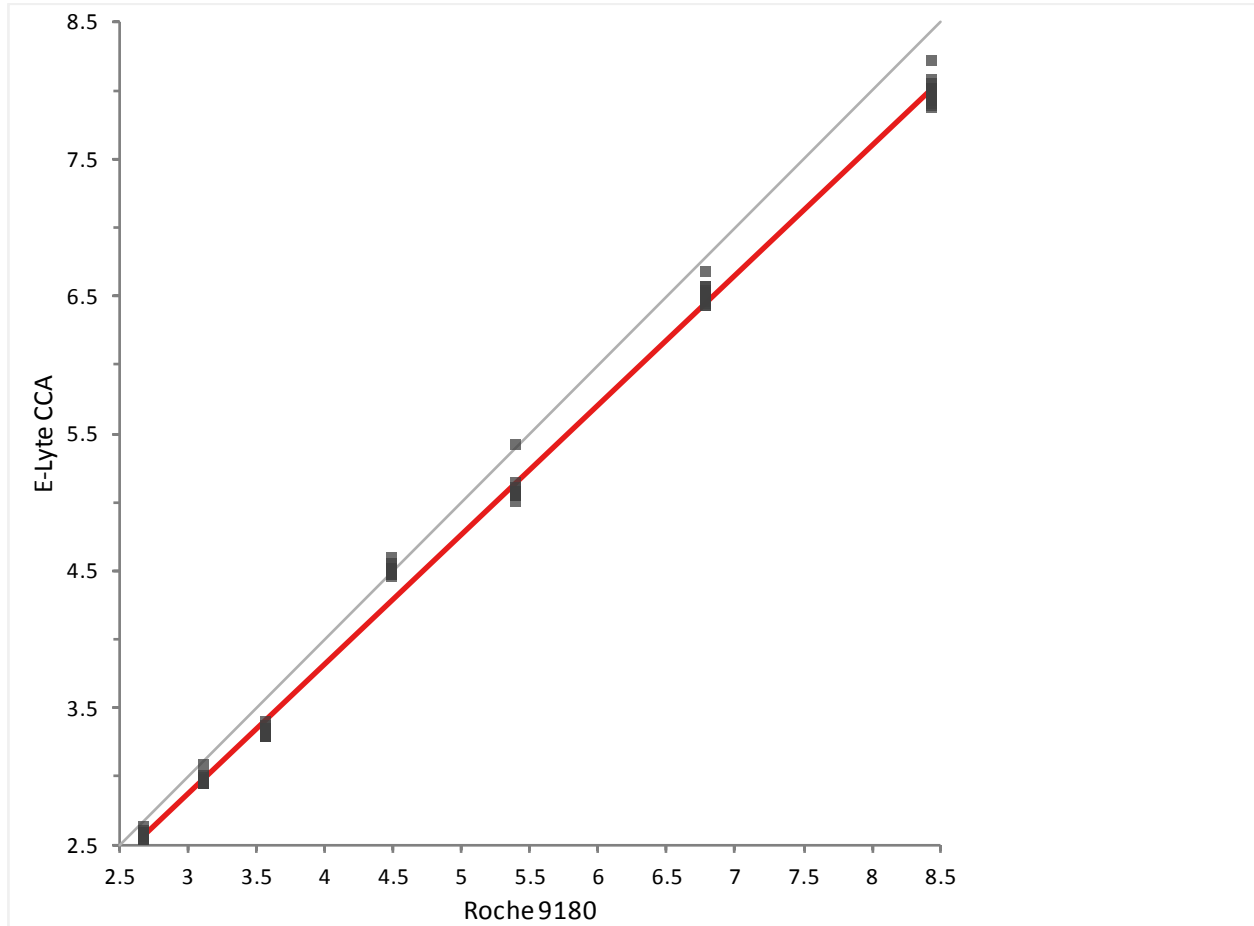
**Plasma Results, Na<sup>+</sup> (data compared with Roche 9180, N=128):**

**Ordinary least-squares fit**

Equation E-Lyte CCA = 10.96 + 0.9428 Roche 9180  
 R<sup>2</sup> 0.997  
 Sy.x 2.16263

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	120	4.09401	3.63234	to 4.55569	±4.0
High	160	1.80587	1.32795	to 2.28378	±4.0

**Plasma Results, K<sup>+</sup> (data compared with Roche 9180, N = 112):**



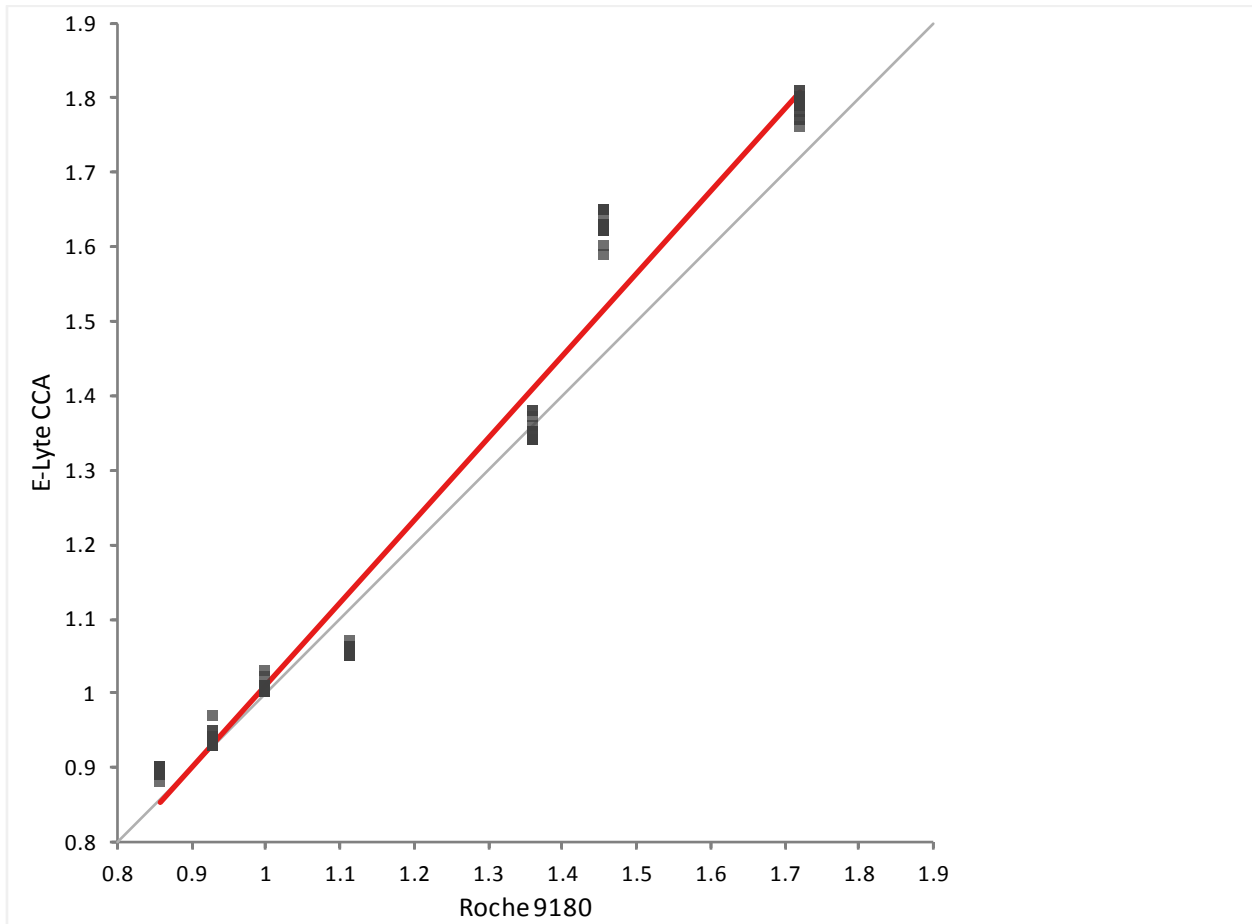
**Ordinary least-squares fit**

Equation E-Lyte CCA = -0.0427 + 0.9446 Roche 9180  
 R<sup>2</sup> 0.998  
 Sy.x 0.107935

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	2.80	-0.11244	-0.14248	to -0.08239	±0.50
High	6.20	-0.30081	-0.32495	to -0.27667	±0.50

**Plasma Results, Ca<sup>2+</sup> (data compared with Roche 9180, N = 112):**



**Ordinary least-squares fit**

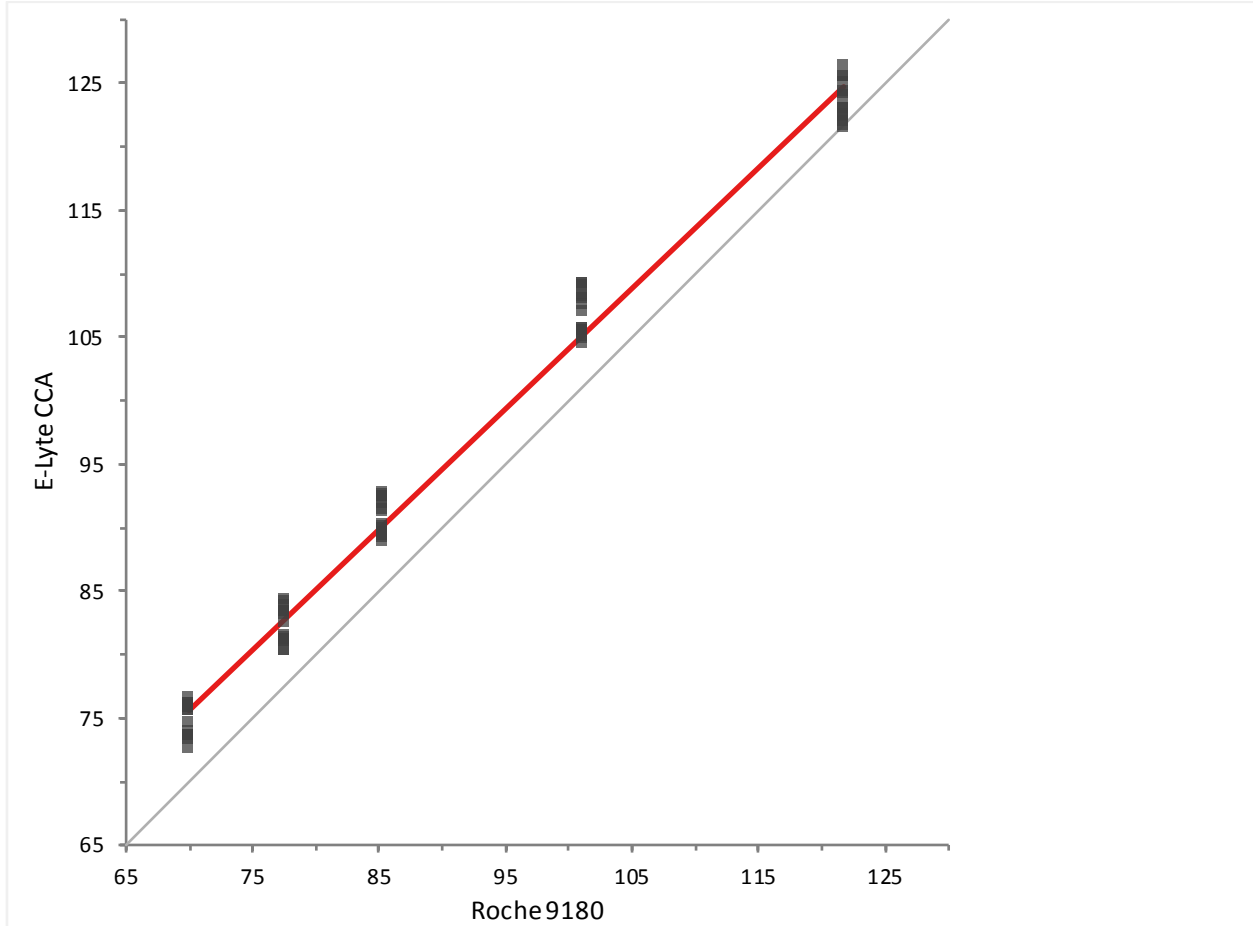
Equation E-Lyte CCA = -0.09636 + 1.107 Roche 9180  
 R<sup>2</sup> 0.983  
 Sy.x 0.061261

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	0.75	-0.01596	-0.03716	0.00524	±0.125
High	1.60	0.07515	0.05590	0.09440	±0.125



**Plasma Results, CI (data compared with Roche 9180, N = 80):**

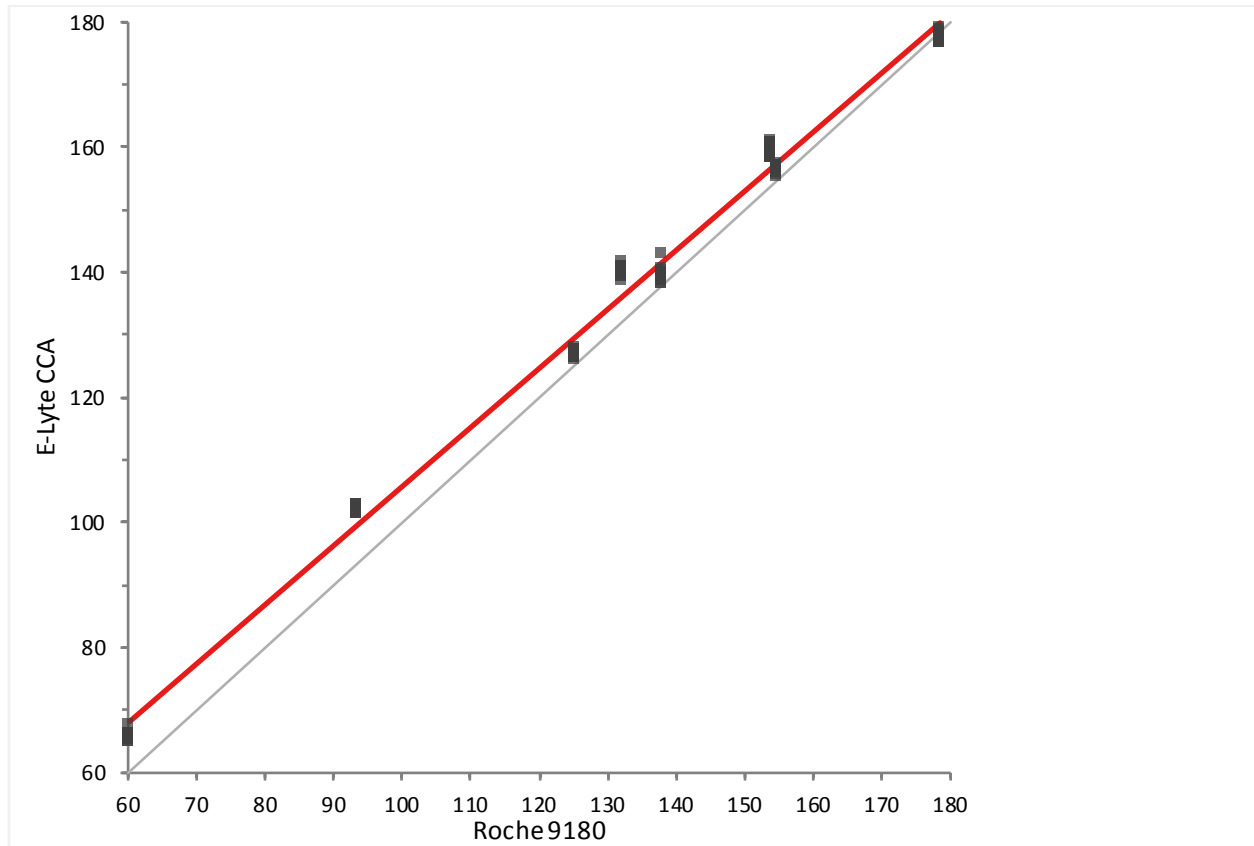


**Ordinary least-squares fit**

Equation E-Lyte CCA = 9.107 + 0.9501 Roche 9180  
 R<sup>2</sup> 0.995  
 Sy.x 1.8009

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	80.0	5.1127	4.6446	to 5.5809	±5.0
High	120.0	3.1155	2.3705	to 3.8605	±6.0

**Serum Results, Na<sup>+</sup> (data compared with Roche 9180, N=128):**

**Ordinary least-squares fit**

Equation E-Lyte CCA = 11.32 + 0.9448 Roche 9180

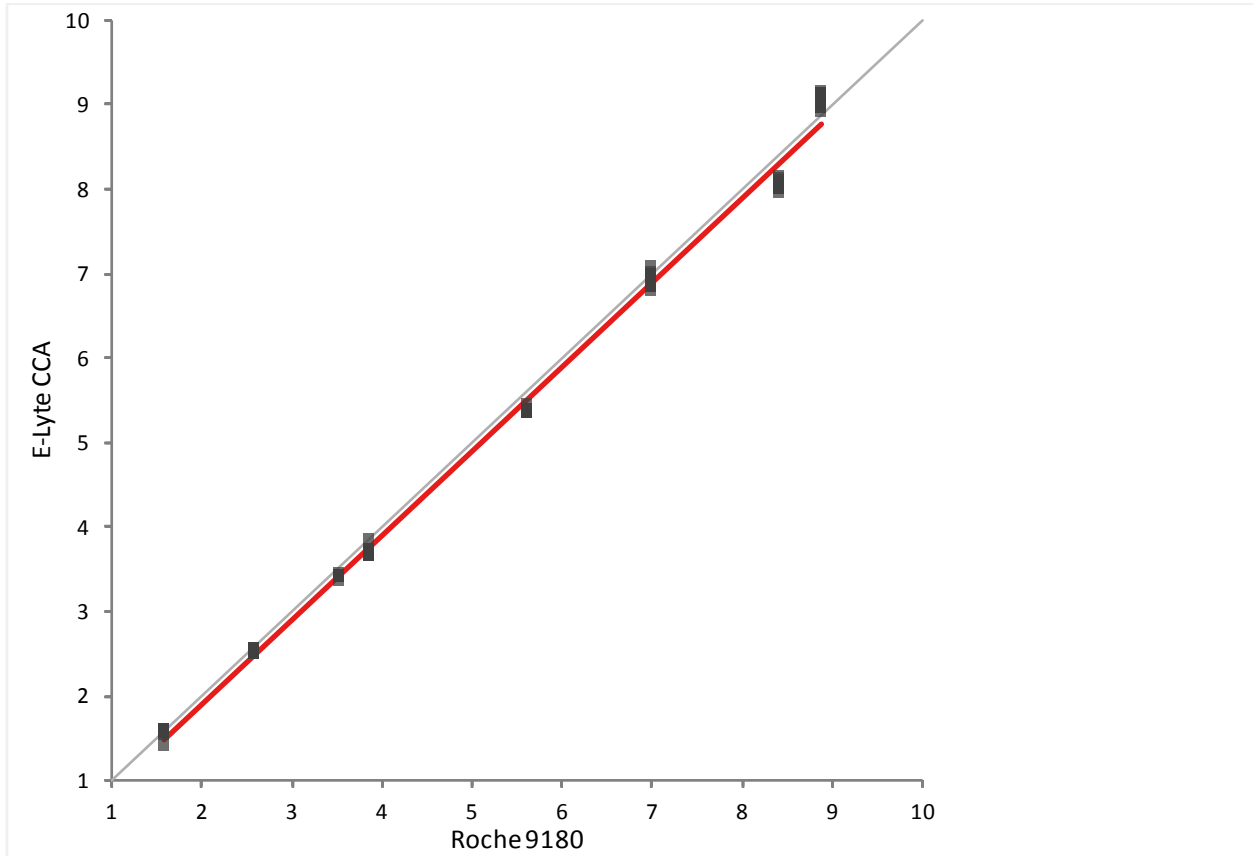
R<sup>2</sup> 0.997

Sy.x 2.7247

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	120	4.68883	4.19533	to 5.18233	±4.0
High	160	2.47982	1.84712	to 3.11252	±4.0

**Serum Results, K<sup>+</sup> (data compared with Roche 9180, N = 128):**



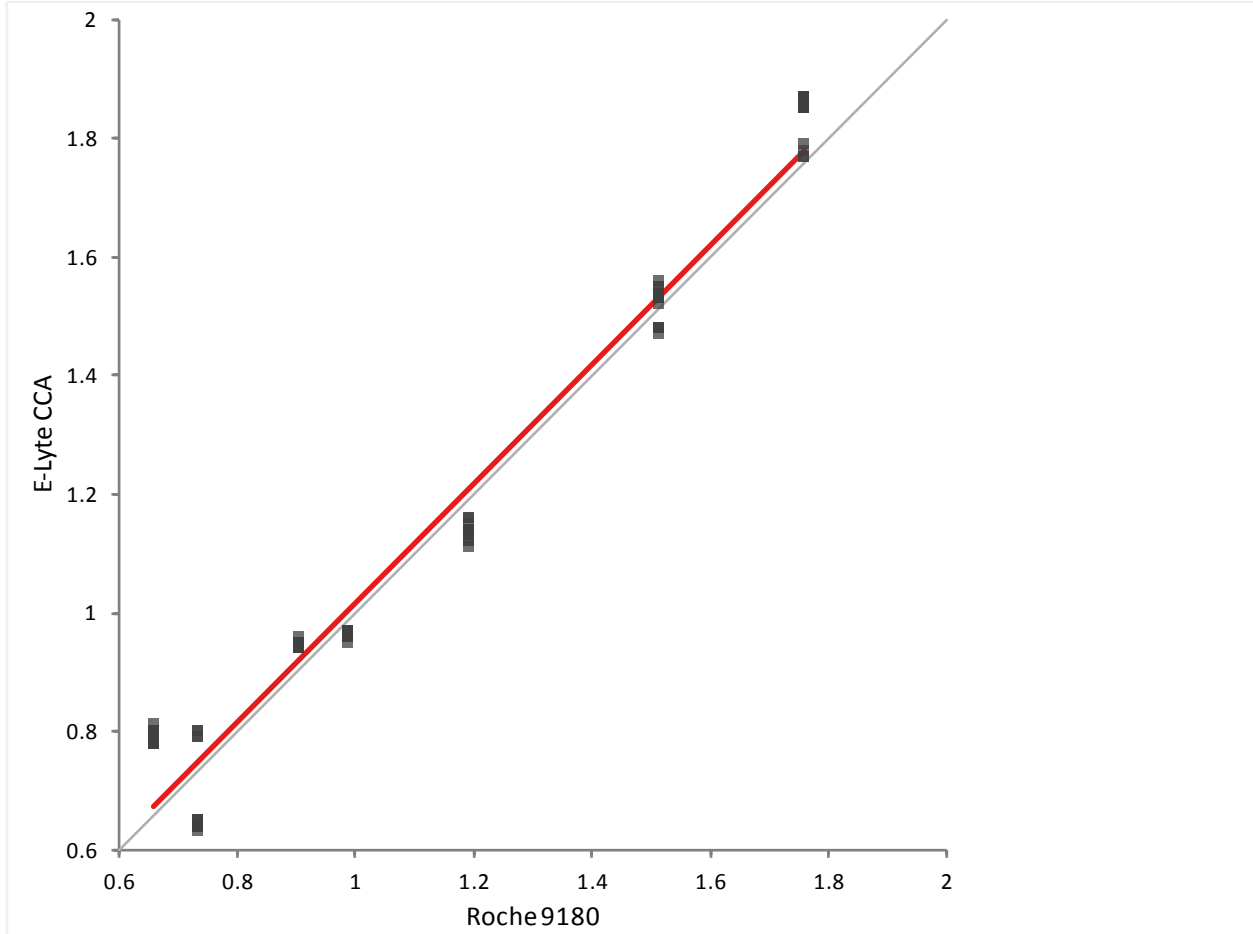
**Ordinary least-squares fit**

Equation    E-Lyte CCA = -0.09974 + 0.9993 Roche 9180  
R<sup>2</sup>        0.998  
Sy.x        0.160109

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	120	-0.10162	-0.14001	to -0.06323	±0.50
High	160	-0.10390	-0.13407	to -0.07372	±0.50

**Serum Results, Ca<sup>2+</sup> (data compared with Roche 9180, N = 112):**



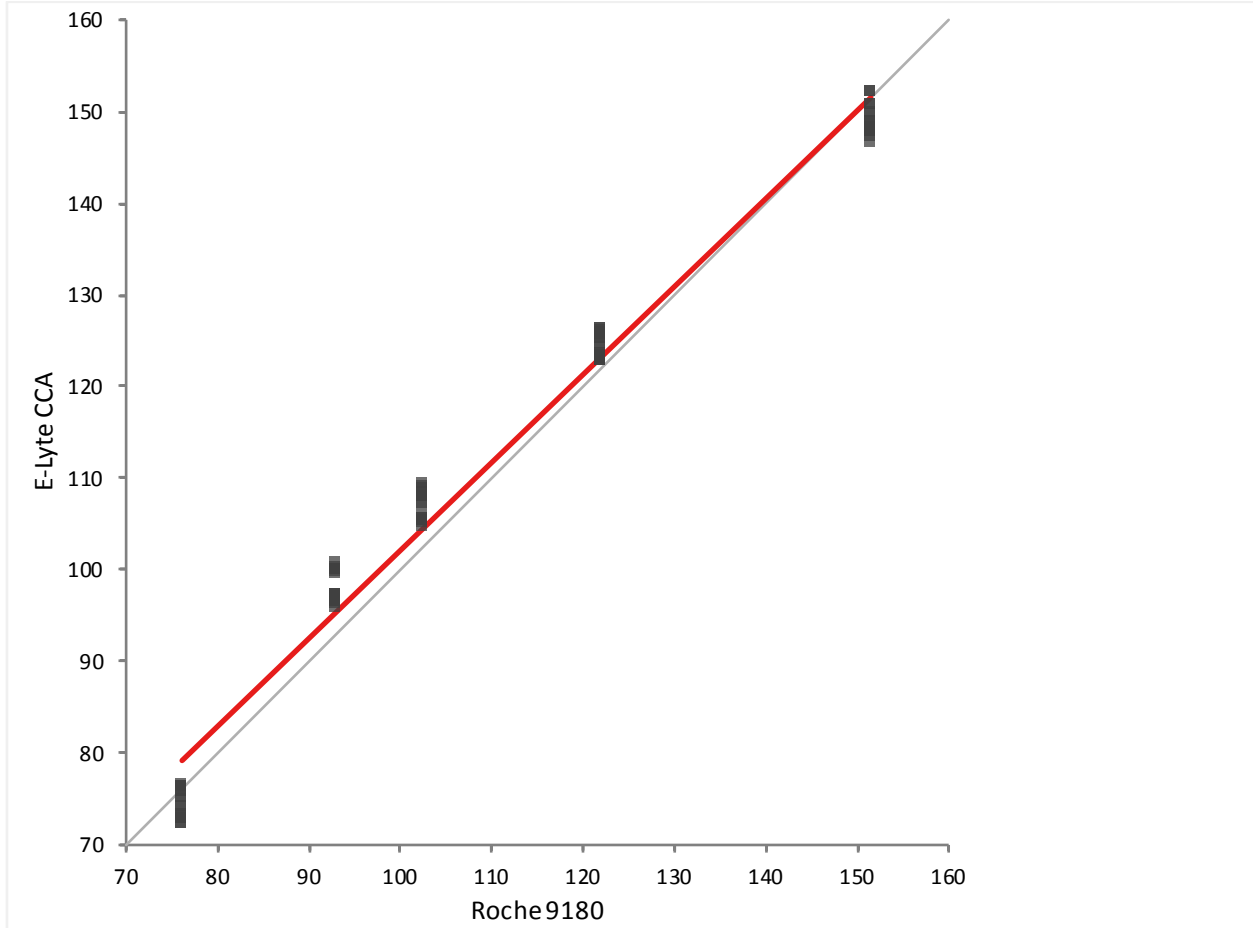
**Ordinary least-squares fit**

Equation E-Lyte CCA = 0.0124 + 1.005 Roche 9180  
 R<sup>2</sup> 0.982  
 Sy.x 0.073922

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	0.75	0.015853	-0.003235	to 0.034941	±0.125
High	1.60	0.019765	-0.003001	to 0.042531	±0.125

**Serum Results, CI (data compared with Roche 9180, N = 96):**

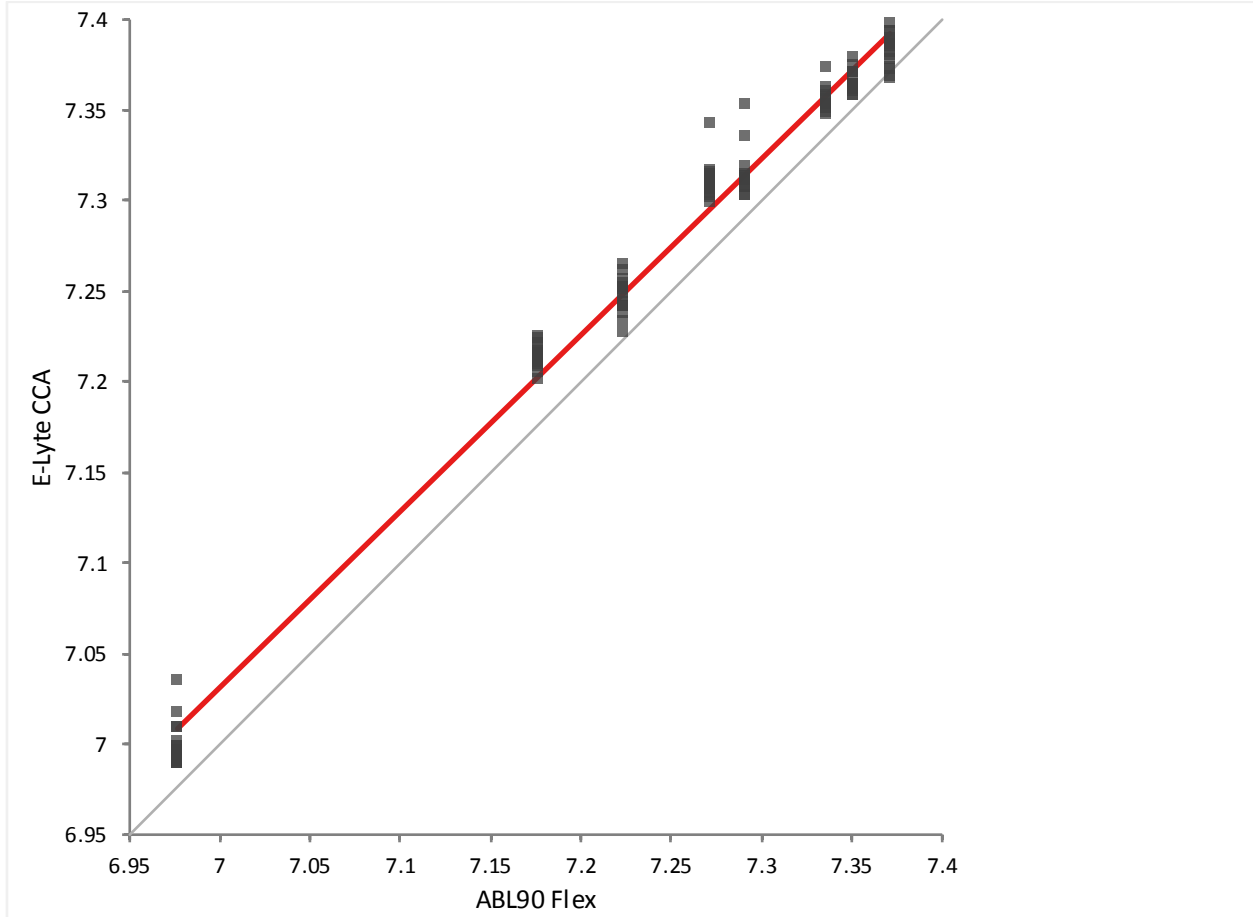


**Ordinary least-squares fit**

Equation    E-Lyte CCA = 6.159 + 0.9596 Roche 9180  
 R<sup>2</sup>        0.991  
 Sy.x        3.4371

**Comparability**

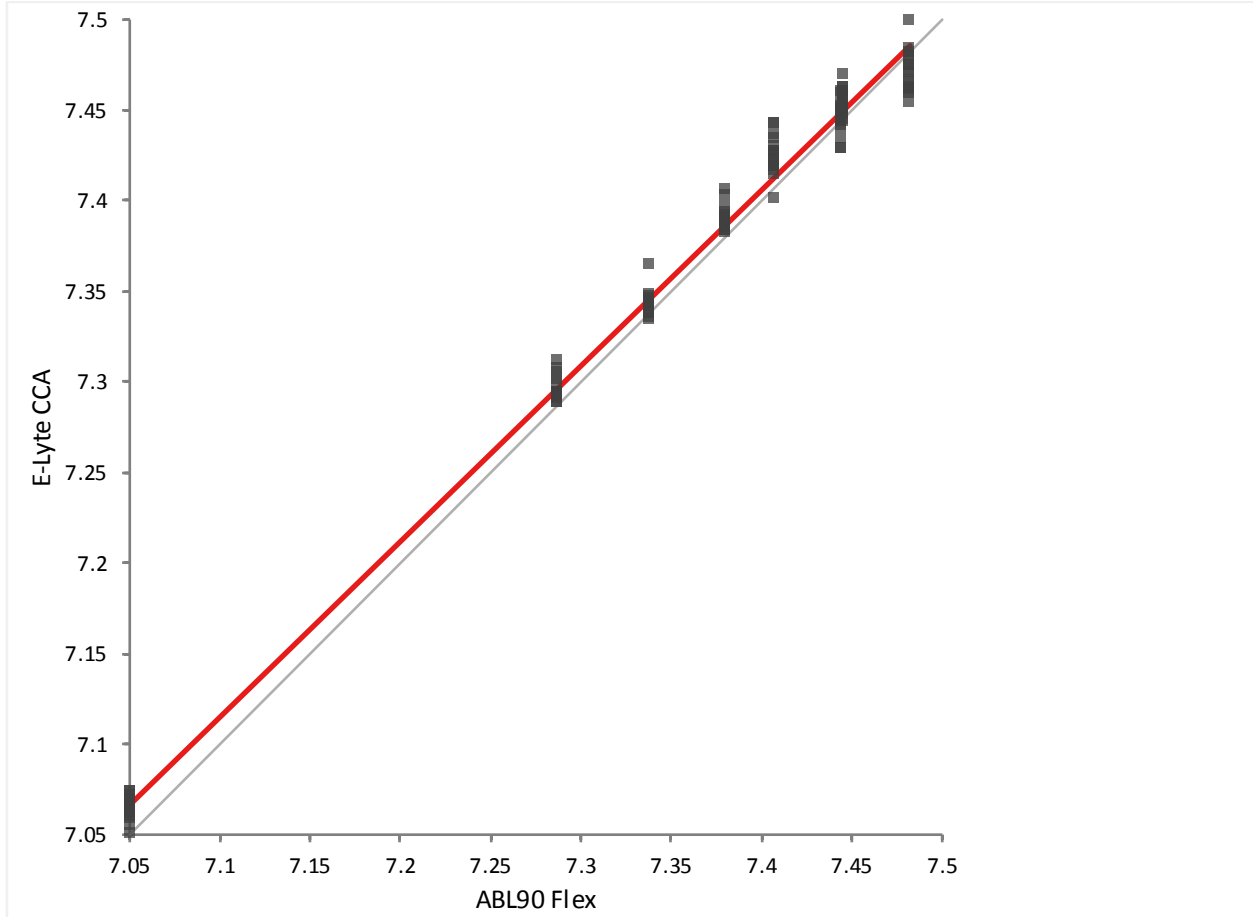
	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	80.0	2.9272	1.7791	to 4.0753	±5.0
High	120.0	1.3110	0.4796	to 2.1424	±6.0

**Whole Blood Results, pH (data compared with ABL90 Flex, N = 128):**

**Ordinary least-squares fit**

Equation    E-Lyte CCA = 0.2216 + 0.9728 ABL90 Flex  
 R<sup>2</sup>        0.994  
 Sy.x        0.012561

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	7.20	0.025935	0.0236	to 0.0283	±0.04
High	7.60	0.015064	0.0082	to 0.0219	±0.04

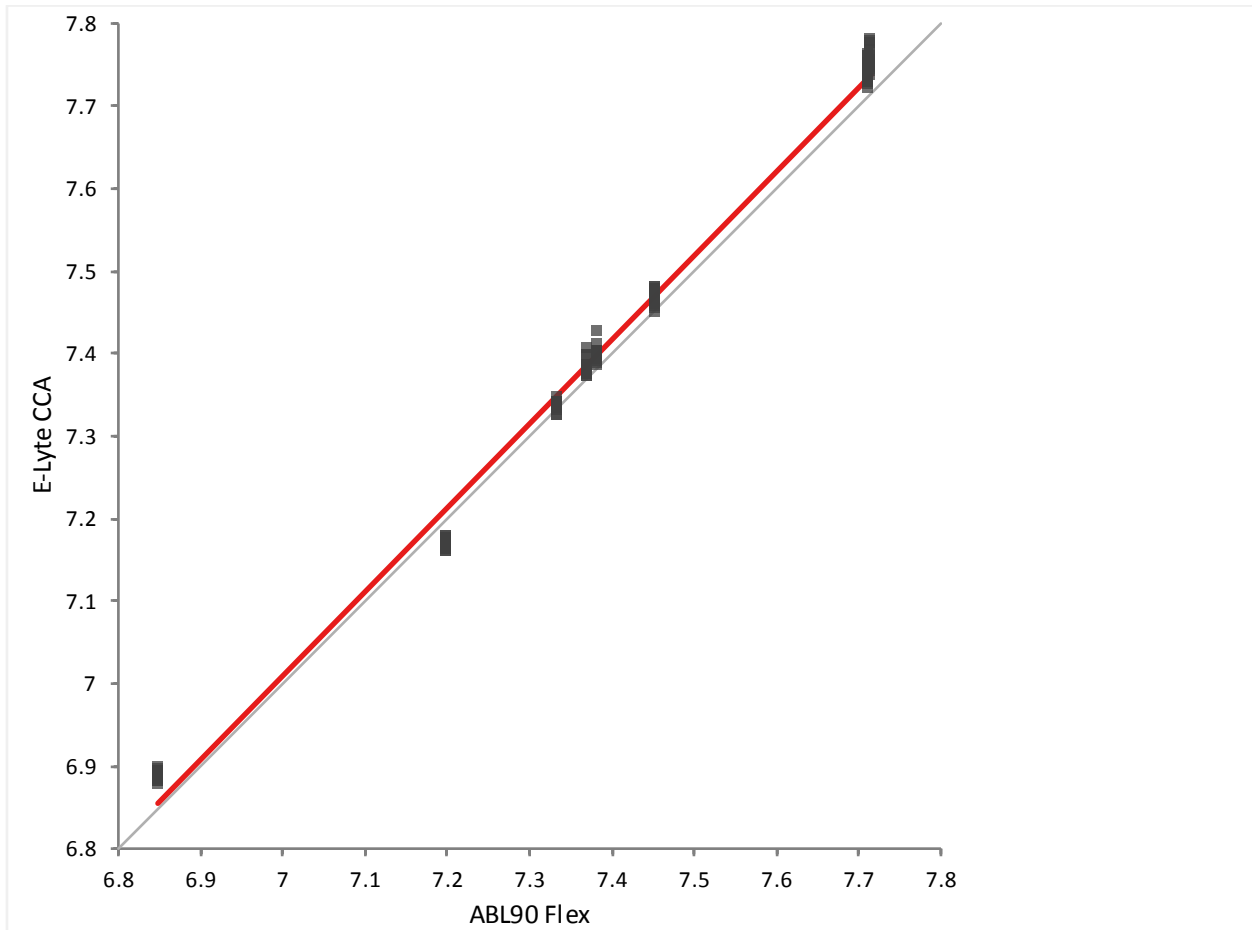
**Plasma Results, pH (1 lot of E-Lyte CCA, data compared with ABL90 Flex, N = 128)**

**Ordinary least-squares fit**

Equation    E-Lyte CCA = 0.2292 + 0.9698 ABL90 Flex  
 R<sup>2</sup>        0.996  
 Sy.x        0.010860

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	7.20	0.011917	0.008955	to 0.014880	±0.04
High	7.60	-0.000153	-0.004238	to 0.003931	±0.04

**Serum Results, pH (1 lot of E-Lyte CCA, data compared with ABL90 Flex, N = 128)**



**Ordinary least-squares fit**

Equation    E-Lyte CCA = -0.1162 + 1.018 ABL90 Flex  
 R<sup>2</sup>        0.996  
 Sy.x        0.022915

**Comparability**

	X*	Mean difference (Y* - X*)	95% CI		Allowable difference
Low	7.20	0.013194	0.008355	to 0.018032	±0.04
High	7.60	0.020379	0.015107	to 0.025652	±0.04



**Conclusion:**

- The E-Lyte CCA cassette has been demonstrated to give accurate results across the critical range for  $\text{Na}^+$ ,  $\text{Ca}^{2+}$ ,  $\text{Cl}^-$ ,  $\text{K}^+$  in whole blood, plasma and serum samples when compared to the Roche 9180.
- The slopes of the linear regressions performed on the data fell within a range of 0.9 to 1.1 with the exception of Ca (1.107 in plasma compared to Roche 9180).
- The  $R^2$  values for all of the regressions were greater than or equal to 0.98.
- The E-Lyte CCA cassette has been demonstrated to give accurate results across the critical range for pH in whole blood, plasma and serum samples when compared to the Radiometer ABL90 Flex.

## **APPENDIX**

### **WHOLE BLOOD ELECTROLYTE STUDY**

- a) Obtain N=10 tubes of whole blood sample.
- b) Spike or dilute the whole blood with spike solution or diluent to make 7 levels of electrolytes and cover the Na range 100 to 180mM, K range 0.8 to 10mM, Cl range 50 to 160mM and Ca range 0.2 to 3mM.
- c) All whole blood samples will be tonometered with 6% CO<sub>2</sub> / 12% O<sub>2</sub> gas for at least 25 minutes.
- d) N=4 repeats of each sample level will be run in parallel on the instruments mentioned below:
  - N=2 OPTI CCA TS instruments
  - N=2 OPTI CCA TS2 instruments
  - N=2 Roche 9180 analyzers
  - N=1 ABL90 FLEX analyzer
- e) N=1 lot of E-Lyte CCA cassettes will be tested.
- f) Use capillary for sample aspiration.

### **PLASMA ELECTROLYTE STUDY**

- a) Obtain N=20 tubes of whole blood sample in plasma tube. Centrifuge the blood to obtain plasma sample.
- b) Spike or dilute the plasma with spike solution or diluent to make 7 levels of electrolytes and cover the Na range 100 to 180mM, K range 0.8 to 10mM, Cl range 50 to 160mM and Ca range 0.2 to 3mM.
- c) All the plasma samples will be tonometered with 6% CO<sub>2</sub> / 12% O<sub>2</sub> gas for at least 25 minutes.
- d) N=4 repeats of each sample level will be run in parallel on the instruments mentioned below:
  - N=2 OPTI CCA TS instruments
  - N=2 OPTI CCA TS2 instruments
  - N=2 Roche 9180 analyzers
  - N=1 ABL90 FLEX analyzer
- e) N=1 lot of E-Lyte CCA cassettes will be tested.
- f) Use sample aspiration tube for sample aspiration.

### **SERUM ELECTROLYTE STUDY**

- a) Obtain N=20 tubes of whole blood sample in serum tube. Centrifuge the blood to obtain serum sample.
- b) Spike or dilute the serum with spike solution or diluent to make 7 levels of electrolytes and cover the Na range 100 to 180mM, K range 0.8 to 10mM, Cl range 50 to 160mM and Ca range 0.2 to 3mM.
- c) All the serum samples will be tonometered with 6% CO<sub>2</sub> / 12% O<sub>2</sub> gas for at least 25 minutes.
- d) N=4 repeats of each sample level will be run in parallel on the instruments mentioned below:
  - N=2 OPTI CCA TS instruments
  - N=2 OPTI CCA TS2 instruments
  - N=2 Roche 9180 analyzers
  - N=1 ABL90 FLEX analyzer
- e) N=1 lot of E-Lyte CCA cassettes will be tested.
- f) Use sipper for sample aspiration.