

Medica EasyRA Chemistry Analyzer ISE Performance

Topic: Electrolytes/Blood Gas/Metabolites

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The Medica EasyRA™ chemistry analyzer, a new random access benchtop clinical chemistry analyzer, contains an integral Medica ISE Module that measures sodium, potassium, chloride and lithium ions in serum using ion-selective electrode technology. The flow-through electrodes use selective membranes, specially formulated to be sensitive to the specific ions. The Medica EasyRA™ chemistry analyzer utilizes a Dallas chip to monitor the volumes and use-life of the ISE calibrants. The ISE module uses 70 µL of undiluted serum to perform all four ISE measurements in 33 seconds.

Performance characteristics for precision, linearity and accuracy (method comparison) are presented for sodium, potassium, chloride and lithium measurements using serum samples.

IMPRECISION: (NCCLS, EP5-A2)

Within-Run Precision was performed using two levels of human-based QC material in 5 replicates per day for 5 days.

Na	Medica QC Level a			Medica QC Level b		
	EasyRA 1	EasyRA 2	EasyRA 3	EasyRA 1	EasyRA 2	EasyRA 3
Grand Mean	143.64	145.47	145.70	161.10	162.46	162.76
SD	0.48	0.73	1.07	0.51	0.91	0.86
CV%	0.33	0.50	0.74	0.32	0.56	0.53
K						
Grand Mean	4.13	4.22	4.20	6.10	6.27	6.22
SD	0.03	0.04	0.05	0.03	0.09	0.05
CV%	0.83	0.89	1.18	0.50	1.45	0.72
Li						
Grand Mean	0.97	0.96	1.00	1.92	1.91	1.97
SD	0.00	0.00	0.01	0.01	0.01	0.01
CV%	0.48	0.52	0.68	0.53	0.54	0.51
Cl						
Grand Mean	99.74	99.08	101.86	117.16	117.54	119.23
SD	0.48	0.61	0.59	0.39	0.58	0.56
CV%	0.48	0.62	0.58	0.33	0.49	0.47

Total Precision was evaluated using two levels of human-based QC material in duplicate, twice a day over 20 days.

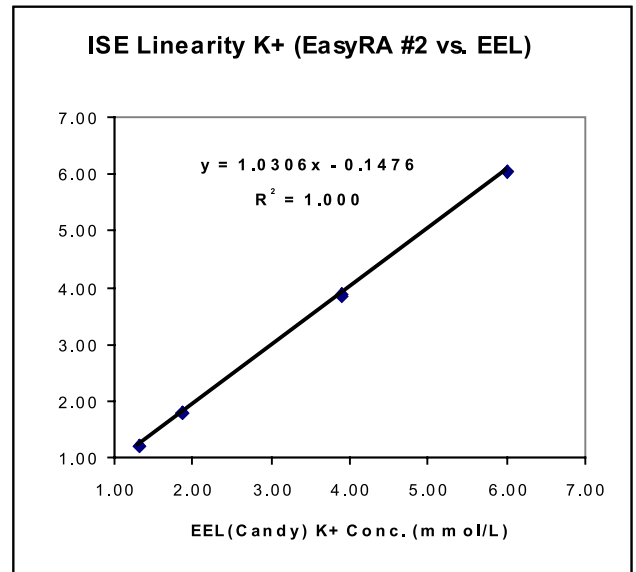
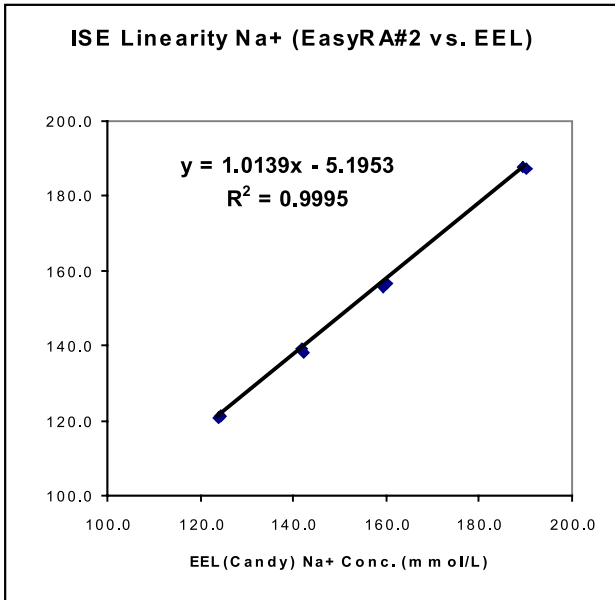
Na	Medica QC Level a		Medica QC Level b	
	Easy RA 1	EasyRA 2	EasyRA 1	EasyRA 2
Grand Mean	143.50	145.05	159.98	161.53
SD tot.	2.02	1.47	1.51	1.76
CV% tot.	1.41	1.02	0.95	1.09
K				
Grand Mean	4.15	4.20	6.10	6.18
SD tot.	0.06	0.10	0.06	0.09
CV% tot.	1.41	2.39	1.00	1.49
Li				
Grand Mean	0.94	0.95	1.86	1.90
SD tot.	0.02	0.01	0.06	0.02
CV% tot.	2.34	1.40	3.09	1.22
Cl				
Grand Mean	99.65	99.0	116.79	117.1
Sd tot.	0.75	1.00	0.97	1.02
CV% tot.	0.75	1.01	0.83	0.87

Linearity: (NCCLS, EP6-A)

The responses of the ISE sensors are linear over the following ranges as determined using NIST Secondary Standards:

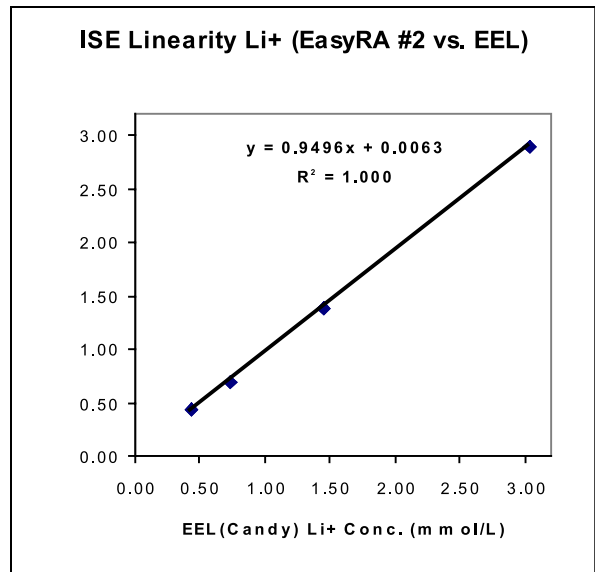
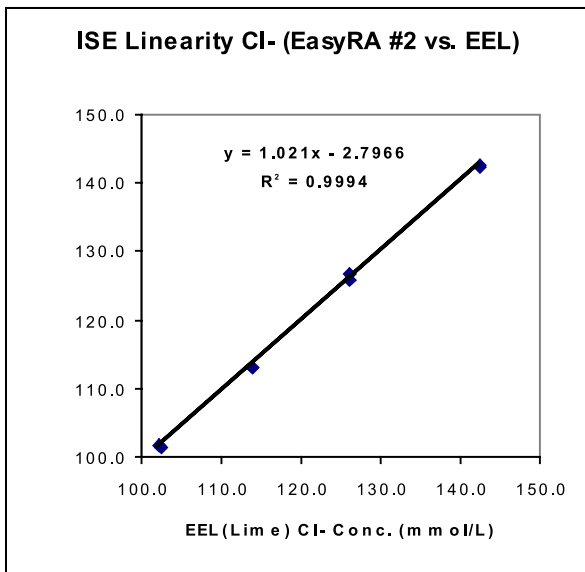
Sodium: linear 100 to 200 mmol/L

Potassium: linear 1.0 to 10.0 mmol/L



Chloride: linear 50 to 150 mmol/L

Lithium: linear 0.2 to 3.5 mmol/L



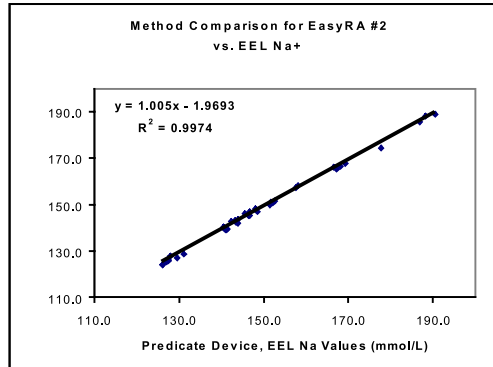
ACCURACY/ METHOD COMPARISON (NCCLS, EP9-A2):

Method comparison data for the Na⁺, K⁺, Li⁺ components of the ISE module in the EasyRA Chemistry analyzer were collected vs. corresponding data obtained from the Medica EasyElectrolytes Analyzer. Data for the Cl⁻ electrode were compared to the data obtained on the Medica Na/K/Cl EasyElectrolytes Analyzer.

In all cases, the data shown represent single results obtained on the Medica EasyRA Chemistry Analyzer vs. the average of 2 replicate values obtained on the appropriate Medica EasyElectrolytes Na/K/Li or Na/K/Cl Analyzer.

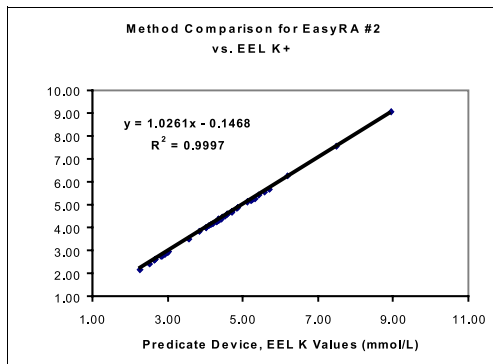
Sodium: 40 serum samples were evaluated that ranged from 126.1 to 190.5 mmol/L.

Slope: 1.01
Intercept: - 1.97
Correlation Coefficient: 0.9974



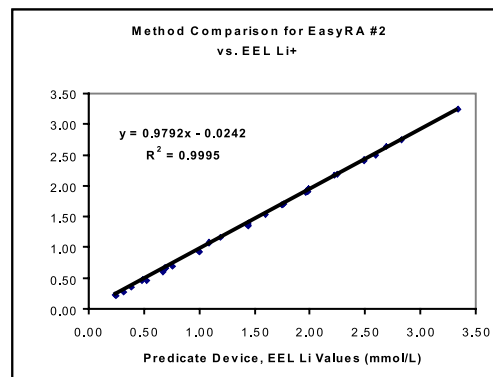
Potassium: 42 serum samples were evaluated that ranged from 2.27 to 8.93 mmol/L.

Slope: 1.03
Intercept: 0.15
Correlation Coefficient: 0.9997



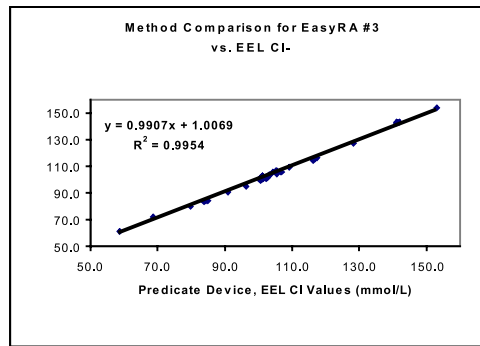
Lithium: 40 serum samples were evaluated that ranged from 0.24 to 3.34 mmol/L.

Slope: 0.98
Intercept: 0.02
Correlation Coefficient: 0.9995



Chloride: 40 serum samples were evaluated that ranged from 59 to 142 mmol/L.

Slope: 0.99
Intercept: 1.01
Correlation Coefficient: 0.9954



Conclusion:

The EasyRA Chemistry Analyzer is an accurate and precise instrument for the analysis of sodium, potassium, lithium and chloride electrolytes.

NOTE: The EasyRA analyzer is under FDA review and a 510K clearance is pending.