

K963542

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510(K) NOTIFICATION

Sigma Diagnostics
545 South Ewing Avenue
St. Louis, MO 63103

CX[®]3 Electrolyte Reference Reagent
Procedure Number E3891
August 31, 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

Increased sodium levels are seen in congestive heart failure, nephrosis, hyperlipidemia and hyperglycemia. Decreased levels can be observed with excessive sweating and vomiting, with different types of diabetes, and with use of diuretic drugs.

Increased potassium levels can be due to renal failure and decrease mineralocorticoid activity, such as in Addison's disease. Decreased potassium levels can be caused by renal and adrenal conditions with metabolic alkalosis or acidosis.

Increased chloride levels may be due to hyperparathyroidism. Low levels may be due to Addison's disease, intestinal obstruction, rickettsial disease and Waterhouse-Friderichsen Syndrome.

The CO₂ content is decreased in metabolic acidosis and respiratory alkalosis, whereas the level is increased in metabolic alkalosis and respiratory acidosis.

The Sigma Diagnostics methods use ion selective electrodes for determining sodium, potassium, and chloride and rate of pH change for determining carbon dioxide on the SYNCHRON CX[®]3 System.

The safety and effectiveness of Sigma Diagnostics Electrolyte Reference Reagent, Procedure Number E3891, are demonstrated by its substantial equivalency to Beckman Electrolyte Reference Reagent Kit, Part No. 443315. Both electrolyte reference reagents are used to measure sodium, chloride, potassium, and carbon dioxide concentrations in serum or plasma, sodium, potassium, and chloride concentrations in urine, and chloride concentrations in CSF on the SYNCHRON CX[®]3 System, and the reaction principles for both reagents are identical. In comparison studies, the following data was obtained:

<u>Serum Analyte</u>	<u>Correlation Coefficient</u>	<u>Regression equation</u>
Sodium	0.963	$y = 0.90x + 13.48$
Potassium	0.999	$y = 0.98x + 0.08$
Chloride	0.973	$y = 0.91x + 10.52$
Total CO ₂	0.992	$y = 0.95x + 1.54$

<u>Urine Analyte</u>	<u>Correlation Coefficient</u>	<u>Regression equation</u>
Sodium	0.997	$y = 0.95x - 0.10$
Potassium	0.998	$y = 0.97x + 0.49$
Chloride	0.997	$y = 0.97x + 2.06$

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SUMMARY OF SAFETY AND EFFECTIVENESS(cont.)

<u>CSF Analyte</u>	<u>Correlation Coefficient</u>	<u>Regression equation</u>
Chloride	0.891	$y = 0.98x + 4.00$

With-in run precision and total precision for sodium demonstrated %CV's of less than 1.1 % on serum samples and less than 1.2 % on urine samples. With-in run precision and total precision for potassium demonstrated %CV's of less than 1.0 % on serum samples and less than 1.6 % on urine samples. With-in run precision and total precision for chloride demonstrated %CV's of less than 1.3 % on serum samples, less than 1.9 % on urine samples, and less than 1.8 % on CSF samples. The Sigma Diagnostics Electrolyte Reference Reagent has been determined to be linear to the following limits on the SYNCHRON CX*3 System:

<u>Analyte</u>	<u>Serum (mmol/L)</u>	<u>Urine (mmol/L)</u>	<u>CSF (mmol/L)</u>
Sodium	100.0 - 200.0	10 - 200	NA
Potassium	1.00 - 15.00	2 - 200	NA
Chloride	50.0 - 200.0	15 - 300	50 - 200
Total CO ₂	5.0 - 40.0	NA	NA