

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k051646

B. Purpose for Submission:

This is a new submission for the clearance of ISE reagents.

C. Measurand:

Chloride, Potassium, and Sodium

D. Type of Test:

Ion Specific Electrode

E. Applicant:

Pointe Scientific, Inc.

F. Proprietary and Established Names:

ISE Diluent

1N KCl

Internal Reference and ISE Standards Low and High

G. Regulatory Information:

1. Regulation section:

21CFR Sec.- 862.1170-Chloride test system.

21 CFR Sec.-862.1600-Potassium test system.

21 CFR Sec.-862.1665-Sodium test system.

2. Classification:

Class II

3. Product code:

CGZ - Electrode, Ion-Specific, Chloride

CEM - Electrode, Ion-Specific, Potassium

JGS - Electrode, Ion-Specific, Sodium

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

Claims use in serum, plasma and urine.

2. Indication(s) for use:

This product is to be used for the quantitative determination of Electrolytes (Sodium, Potassium and Chloride) in human serum. The determination of Electrolytes is most commonly performed for the diagnosis and treatment of diseases causing an electrolyte imbalance. Sodium determinations are often used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addisons disease and a number of other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte imbalance in the diagnosis and treatment of diseases characterized by low and high potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

3. Special conditions for use statement(s):

None

4. Special instrument requirements:

Roche Hitachi 917 analyzer

I. Device Description:

The ISE Diluent, ISE Internal Reference and 1N KCL are aqueous solutions containing an anti-microbial agent at known ionic concentration.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Hitachi 917 analyzer with ISE

2. Predicate 510(k) number(s):

k953239

3. Comparison with predicate:

<u>Contents</u>	<u>Roche (before reconstitution)</u>	<u>Pointe Scientific</u>
<i>ISE Diluent:</i>		
Boric Acid	650 mmol/L	Borate Buffer
Nonreactive Ingredient	preservative	anti-microbial 0.05%
<i>1N KCL:</i>		
Potassium Chloride	1 mol/L	1
mol/L		
Nonreactive Ingredient	Preservative	anti-microbial 0.01%
<i>Internal Reference:</i>		
Boric Acid	650 mmol/L	Borate Buffer
Sodium Chloride	32.3 mmol/L	3.2 mmol/L
Sodium Bicarbonate	12.9 mmol/L	1.3 mmol/L
Potassium Phosphate	1.6 mmol/L	0.15mmol/L
Nonreactive Ingredient	preservative	anti-microbial 0.05%
	<u>Thermo ALKO</u>	<u>Pointe Scientific</u>
<i>ISE Standard LOW</i>		
Sodium	120 mmol/L	120 mmol/L
Potassium	3.0 mmol/L	3.0 mmol/L
Chloride	80.0 mmol/L	80.0 mmol/L
<i>ISE Standard HIGH</i>		
Sodium	160 mmol/L	160 mmol/L
Potassium	7.0 mmol/L	7.0 mmol/L
Chloride	120.0 mmol/L	120.0 mmol/L

K. Standard/Guidance Document Referenced (if applicable):

CLSI Document EP5-T2

CLSI Document EP7-P

L. Test Principle:

The measurement of these constituents (Cl, K, Na) are based on Potentiometry, which is the measurement of the change in the “electromotive force” between the measuring electrode and a reference electrode. The internal reference standard maintains a constant ionic concentration between the two electrodes. The introduction of a sample will change this concentration affecting the “electromotive force,” this difference is then used to calculate the unknown, based on known standards that are used during the calibration of the ISE analytes.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Within Day Precision

Day to Day Precision

Sample I (n=20), units = mmol/L

	<u>Mean</u>	<u>S.D.</u>	<u>C.V.%</u>
Sodium	147	1.07	0.728
Potassium	4.7	0.031	0.660
Chloride	110	0.98	0.891

Sample I (n=20) , units = mmol/L

	<u>Mean</u>	<u>S.D.</u>	<u>C.V.%</u>
Sodium	142	1.700	1.197
Potassium	4.4	0.076	1.727
Chloride	106	1.442	1.360

Sample II (n=20) , units = mmol/L

	<u>Mean</u>	<u>S.D.</u>	<u>C.V.%</u>
Sodium	159	0.47	0.296
Potassium	7.7	0.020	0.260
Chloride	120	0.37	0.308

Sample II (n=20) , units = mmol/L

	<u>Mean</u>	<u>S.D.</u>	<u>C.V.%</u>
Sodium	158	2.700	1.709
Potassium	7.5	0.151	2.013
Chloride	119	1.842	1.548

b. *Linearity/assay reportable range:*

The assay range for this reagent product was determined by running commercially available Linearity standards. The Pointe Scientific ISE solutions demonstrate that they meet their linearity claims. The assay ranges are listed below.

Sodium: 80 – 180 mmol/L

Potassium: 1.5 – 10.0 mmol/L

Chloride: 45 – 140 mmol/L

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Subject of k963734 calibrators were cleared under k963734. Controls are not the subject of this review.

d. *Detection limit:*

Not Applicable

e. *Analytical specificity:*

Interference by bilirubin, triglyceride and hemoglobin was investigated by the following modification of the recommended preparation and testing protocols in CLSI document EP7-P. Bilirubin to 30 mg/dl, Triglyceride to 1000mg/dl

and Hemoglobin to 400 mg/dl were each demonstrated not to interfere in the ISE assays. (Less than 10.0%)

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

A comparison study was performed at Pointe Scientific investigating the relationship between values determined using the Roche Diagnostics ISE solutions, and values determined using the Pointe Scientific, Inc. ISE solutions. Pointe ISE solutions were calibrated with Thermo ALKO Standards manufactured for Pointe. This study was performed on actual patient specimens supplied by a local medical institution (Detroit Medical Ctr.). The study was performed on a Roche Diagnostics Hitachi 917 chemistry analyzer and gave the following correlation data.

Analyte Name	Correlation Coefficient	Regression Equation
Sodium	0.995	$y = 0.952x + 7.29$
Chloride	0.993	$y = 0.928x + 7.79$
Potassium	0.998	$y = 0.996x + 0.039$

This study was performed using 110 samples ranging from 104 to 177 for Sodium, 2.0-9.7 for Potassium and 97-145 for Chloride. These results indicate acceptable agreement between these methods on routine patient specimens encountered by the laboratory.

b. Matrix comparison:

The claim is for serum only.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The sponsor has provided reference ranges based on recommendations in the published literature.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.