

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k070531

**B. Purpose for Submission:**

New device- ISE module for the DataPro Clinical Chemistry Analyzer (k042767)

**C. Measurand:**

Chloride, Potassium, and Sodium

**D. Type of Test:**

Ion Specific Electrode

**E. Applicant:**

Thermo Fisher Scientific

**F. Proprietary and Established Names:**

ISE Na, ISE K, and ISE Cl

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1170 Chloride Test

21 CFR 862.1600 Potassium Test

21 CFR 862.1665 Sodium Test

2. Classification:

Class II

3. Product code:

CGZ- Electrode, Ion- Specific Chloride

CEM- Electrode Ion- Specific, Potassium

JGS- Electrode Ion-Specific, Sodium

4. Panel:

75 (Chemistry)

**H. Intended Use:**

1. Intended use(s):

See indications for use statement below.

2. Indication(s) for use:

The ISE module of the DataPro™ Plus Clinical Chemistry Analyzer is intended for the quantitative determination of **sodium, potassium and chloride in serum**, using ion-selective (ISE) electrodes.

**Sodium:** Disorders of the sodium ion ( $\text{Na}^+$ ) can be caused by excessive loss, gain or retention of  $\text{Na}^+$  or excessive retention of water. Low  $\text{Na}^+$  can be associated with renal failure, congestive heart failure and cirrhosis. An increase in  $\text{Na}^+$  is seen in neurological disorders such as tremors, ataxia, confusion and coma.

**Potassium:** Disturbances of potassium ( $\text{K}^+$ ) homeostasis has serious consequences and can lead to tachycardia when low. When high, respiratory weakness peripheral vascular collapse and cardiac arrest is evident. It is also seen in conditions associated with Addison's disease. Levels higher than 10mmol/L are fatal in most cases.

**Chloride:** When the chloride ion ( $\text{Cl}^-$ ) is unbalanced in the serum, it is usually a sign of an underlying disturbance in fluid and acid-base homeostasis. A low  $\text{Cl}^-$  concentration is observed in individuals with salt-losing nephritis whereas an increase in  $\text{Cl}^-$  can indicate acute renal failure and metabolic acidosis.

**The ISE module, and all of the reagents included in this test system are for in vitro diagnostic use only.**

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

DataPro Plus Clinical Chemistry Analyzer

**I. Device Description:**

The ISE Cl, Na and K reagents include a buffer, mid standard, reference solution, low and high serum standard, internal reference solution and sodium/potassium selectivity check solution.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Olympus AU400 ISE Module

2. Predicate K number(s):

k981743

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Analytes	Na, K, and Cl	Na, K, and Cl
Sample	Serum	Serum

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
System	Vertical Channel	Vertical block, Flow Cell
Sample Volume	100 µl	20 µl
Measuring Range	Sodium: 113-190 mmol/L Potassium 1.3-8.6 mmol/L Chloride: 50 -148 mmol/L	Sodium: 50-200 mmol/L Potassium: 1-10 mmol/L Chloride: 50- 200 mmol/L

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

EP5- Evaluation of precision performance of clinical chemistry devices.

**L. Test Principle:**

The ISE module operates with direct measurement of electrolytes through membrane ion selective electrodes. Electrodes operate upon selective electrolyte detection properties of

membrane electrolyte filled sensors. A potential is developed and then referred to the reference electrode at the ion selective membrane. This is done by means of the ion selective membrane which develops a potential with respect to reference electrode.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was assessed per CLSI EP5. Six samples were run in duplicate twice a day for twenty days. The within run, between run, between day and total precision results for all three analytes are presented in the table below.

Assay	Mean	Within Run		Between Run		Between Day		Total	
		SD	CV%	SD	CV%	SD	CV%	SD	CV%
Sodium (mmol/L)	128.3	1.3	1.0	0.7	0.6	0.2	0.2	1.5	1.2
	141.7	0.9	0.6	1.4	1.0	1.8	1.2	2.4	1.7
Potassium (mmol/L)	3.77	0.04	1.1	0.04	0.9	0.06	1.7	0.08	2.2
	5.78	0.09	1.5	0.04	0.7	0.02	0.3	0.10	1.7
Chloride (mmol/L)	96.2	0.9	1.0	0.8	0.8	0.5	0.5	1.3	1.4
	108.9	0.9	0.8	1.6	1.5	0.4	0.4	1.9	1.7

b. *Linearity/assay reportable range:*

The sponsor conducted linearity studies using prepared linearity materials. The data obtained supported the claimed range for the three analytes as follows: 113.0-190 mmol/L for sodium, 1.40-8.6 mmol/L for potassium and 50 -148 mmol/L for chloride. The results are presented in the table below.

Analyte	N	Slope	Intercept	Error mmol/L	Allowable Error (mmol/L)	Range
Sodium	5	0.96	6.3	0.87	3.4	113.0-190.0
Potassium	5	0.96	0.17	0.21	0.425	1.40-8.59
Chloride	5	1.00	1.0	2.3%	4.3%	50.0-148.0

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

Sodium, potassium and chloride contained within the reagents are traceable to a NIST standard (SRM 918a, SRM 919a).

d. *Detection limit:*

See linearity/assay reportable range above.

e. *Analytical specificity:*

Interference by bilirubin, lipemia and hemoglobin was assessed. There was no interference found with concentrations up to 2000 mg/dL for lipemia, 60 mg/dL for conjugated and unconjugated bilirubin, and 1000 mg/dL for hemoglobin.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

A comparison study was performed with the AU400 ISE (x) against the DataPro ISE (y). The results for all three analytes are shown in the table below.

Analyte	N	Slope	Intercept	Correlation Coefficient	Sample Range (mmol/L)
Sodium	59	0.986	0.8	0.970	116 – 179
Potassium	60	1.036	-0.06	0.996	1.4 – 8.4
Chloride	68	0.964	6.6	0.990	55 – 147

b. *Matrix comparison:*

Not applicable as this device is intended for use with 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 referenced the ranges published in Tietz, N.W., Textbook of Clinical Chemistry, W.B. Saunders Co., Philadelphia, 1986, p. 1172-1191 in their package insert.

Sodium: 136-146 mmol/L

Potassium: 3.5- 5.0 mmol/L

Chloride: 98 – 106 mmol/L

**N. Instrument Name:**

DataPro Plus Clinical Chemistry Analyzer

**O. System Descriptions:**

1. Modes of Operation:

The DataPro Plus Clinical Chemistry Analyzer is intended to be used a traditional clinical laboratory setting. The analyzer performs various modes: end point with sample blank, fast and two-point kinetics (0 and 1<sup>st</sup> order), turbidimetric and potentiometric ISE. The device is used for single sample testing.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes   X   or No \_\_\_\_\_

3. Specimen Identification:

A bar code option is available.

4. Specimen Sampling and Handling:

Pressurized standards are delivered to the electrodes. The DataPro ISE module for sodium, potassium and chlorine utilizes a permeable membrane that is specific for each ion of interest in the sample solution. An electrical potential is developed according to the Nernst equation for a specific ion. When compared to a reference solution this electrical potential is translated into voltage and then into the ion concentration of the sample solution.

5. Calibration:

Uses factor, standard or calibration curves with two (up to ten) standards with automatic curve adjust. A one or two point calibration is performed at the end of every sample. ISE calibrations do not require operator action as they are automatically performed.

6. Quality Control:

In the labeling the sponsor recommends that normal and abnormal control serum of known concentrations of sodium, potassium and chloride should be analyzed routinely with each group of unknown samples.

- Levy Jennings plots, Westgard rules.
- Data import and export to other programs and/or remote terminals..
- Automatic backup protection.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

**Q. Proposed Labeling:**

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

**R. Conclusion:**

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