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

A. 510(k) Number:

k070104

B. Purpose for Submission:

New Device

C. Measurand:

Sodium, Potassium, Chloride

D. Type of Test:

Ion Selective Electrode

E. Applicant:

Diamond Diagnostics, Inc.

F. Proprietary and Established Names:

 proLYTE Electrolyte Analyzer

G. Regulatory Information:

1. Regulation section:

    21 CFR 862.1665 – Sodium Test System

    21 CFR 862.1600 – Potassium Test System

    21 CFR 862.1770 – Chloride Test System

2. Classification:

    Class II

3. Product code:

JGS - Electrode, Ion Specific, Sodium

CEM – Electrode, Ion Specific, Potassium

CGZ – Electrode, Ion Specific, Chloride

4. Panel:

75 - Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The proLYTE Electrolyte Analyzer is designed for clinical laboratory use by laboratory professionals to assess the levels of Sodium, Potassium, and Chloride found in whole blood, serum, plasma, and urine of patients. The analysis is performed in-vitro, and neither the analyzer nor any of its components come in contact with the patient.

This analyzer is used by laboratory trained technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte imbalance. These locations routinely conform to CLIA regulations, and conduct daily quality control programs.

For In Vitro Diagnostic Use

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

proLYTE Electrolyte Analyzer

I. Device Description:

The proLYTE is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium and chloride in serum, plasma, whole blood and prediluted urine samples**.**

J. Substantial Equivalence Information:

1. Predicate device name(s):

Medica EasyLYTE

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

k000926

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Measurement Method	Ion selective electrode	Ion selective electrode
Analytes measured	sodium, potassium, chloride	sodium, potassium, chloride
Sample matrix	Whole blood, plasma, serum, urine	Whole blood, plasma, serum, urine
Calibration	Automatic and on demand	Automatic and on demand

Differences		
Item	Device	Predicate
Measuring range whole blood, serum, plasma	Na: 45-210 mmol/L, K: 1.5-12 mmol/L Cl: 45-210 mmol/L	Na: 80-200 mmol/L, Cl: 1-10 mmol/L K: 80-200 mmol/L
Measuring range urine	Na: 30-1020 mmol/L, K: 20-505 mmol/L Cl: 25-506 mmol/L	Na: 80-200 mmol/L, Cl: 1-10 mmol/L K: 80-200 mmol/L
Blood analysis time	57 seconds	55 seconds
Urine analysis time	93 seconds	90 seconds
QC storage	Normal, abnormal 20 each	Normal, low, high, 20 each

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

None referenced

L. Test Principle:

The proLYTE measures sodium, potassium and chloride in whole blood, serum, plasma, and urine, using ion selective electrode technology. The flow-through sodium electrode contains a glass tube, specially formulated to be sensitive to sodium ions. The flow-through potassium and chloride electrodes incorporate a neutral carrier ionophore membrane. The potential of each electrode is measured relative to a fixed, stable voltage established by the silver/silver chloride reference electrode. An ion selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Within run precision was calculated with results from three whole blood, serum, plasma, and urine samples for each analyte. The samples concentrations were at the low and high end of the measuring range and within the measuring range. The protocol called for running 40 replicates of each sample without calibration between measurements. The replicates were run consecutively in one day. Some of the samples had fewer replicates due to instrument errors. The results are summarized below.

   Whole Blood

	Na+	K+	Cl-	Na+	K+	Cl-	Na+	K+	Cl-
Mean	114.6	2.27	51.3	139.5	3.91	91.1	162.6	6.15	120.7
%CV	0.9	1.7	2.0	0.8	1.5	0.9	0.6	1.4	0.9
n	39	39	39	39	39	39	39	39	39

   Serum

	Na+	K+	Cl-	Na+	K+	Cl-	Na+	Cl-
Mean	115.9	3.17	66.6	145.5	6.63	99.1	163.5	109.8
%CV	0.7	1.1	1.9	0.6	0.8	1.1	0.7	0.5
n	40	40	40	40	40	40	40	40

   Plasma

	Na+	K+	Cl-	Na+	K+	Cl-	Na+	K+	Cl-
Mean	114.2	2.77	46.4	139.6	3.87	80.4	161.8	6.53	113.4
%CV	0.9	1.9	2.0	0.7	0.8	0.9	0.6	1.0	0.9
n	34	34	34	34	34	34	34	34	34

   Urine

	Na+	K+	Cl-	Na+	K+	Cl-	Na+	K+	Cl-
Mean	60.9	31.12	78.6	173.3	104.15	156.4	279.8	168.83	231.9
%CV	0.9	1.5	2.0	0.6	0.7	1.9	0.8	1.0	0.8
n	34	34	34	35	35	35	35	35	35

   Total precision was calculated with results from three whole blood, serum, plasma, and urine samples for each analyte. The samples concentrations were at the low and high end of the measuring range and within the measuring range. The samples were measured twice each morning and twice each afternoon for ten consecutive days resulting in n=40 replicates. One whole blood sample and three urine samples had n=39 replicates due to instrument errors. The results are summarized below.

   Whole Blood

	Na+	K+	Cl-	Na+	K+	Cl-	Na+	K+	Cl-
Mean	115.7	2.43	47.1	140.2	4.32	90.2	164.0	6.46	119.6
%CV	1.3	4.1	2.5	0.8	2.3	1.1	0.7	2.1	0.9
n	40	40	39	40	40	40	40	40	40

Serum

	Na+	K+	Cl-	Na+	K+	Cl-	Na+	Cl-
Mean	113.5	2.65	48.7	117.2	4.00	91.6	144.6	132.1
%CV	1.8	2.5	2.5	0.9	1.5	1.2	0.4	0.6
n	40	40	40	40	40	40	40	40

Plasma

	K+	Cl-	Na+	K+	Cl-	Na+	K+	Cl-
Mean	1.8	53.5	140.5	3.85	81.1	162.5	6.61	114.8
%CV	1.5	1.5	0.9	1.2	1.4	1.0	2.4	1.1
n	40	40	40	40	40	40	40	40

Urine

	Na+	K+	Cl-	Na+	K+	Cl-	Na+	K+	Cl-
Mean	30.1	41.79	55.9	60.1	30.4	80.2	176.1	101.9	160.6
%CV	2.2	1.2	2.7	1.6	2.5	1.83	1.31	2.90	1.8
n	39	39	39	40	40	40	40	40	40

b. Linearity/assay reportable range:

Linearity was evaluated by preparing stock solutions with high concentrations of Na+, K+, and Cl- in whole blood, plasma, serum, and urine. These stocks were diluted to concentrations across the measuring ranges of each analyte and matrix. Linear regression was performed on the results using expected values based on the stock sample dilution. The reportable ranges claimed for whole blood, serum, and plasma are 45-210 mmol/L for sodium and chloride and 1.5-12 mmol/L for potassium. The reportable ranges claimed for urine are 30-1020 mmol/L for sodium, 20-505 mmol/L for potassium, and 25-506 mmol/L for chloride. The results are shown below.

Whole Blood

Parameter	Slope	Intercept	R^2	Conc. Tested	Measuring Range
Sodium	1.04	-10.99	0.999	13 – 244	45-210
Potassium	1.02	-0.29	0.998	1.4 – 37	1.5-12
Chloride	1.04	-4.32	0.998	17- 239	45-210

Plasma

Parameter	Slope	Intercept	R^2	Conc. Tested	Measuring Range
Sodium	1.03	-11.92	0.995	35-247	45-210
Potassium	1.00	0.04	0.999	1.4 – 15	1.5-12
Chloride	1.02	-6.72	0.999	30-230	45-210

Serum

Parameter	Slope	Intercept	R2	Conc. Tested	Measuring Range
Sodium	0.99	2.67	0.999	48 – 250	45-210
Potassium	0.98	0.44	0.998	1.5 – 14.5	1.5-12
Chloride	1.05	-12.10	1.000	26-216	45-210

Urine

Parameter	Slope	Intercept	R2	Conc. Tested	Measuring Range
Sodium	1.00	-3.1	0.999	25 – 1055	30-1020
Potassium	1.00	5.5	0.999	18 – 530	20-505
Chloride	1.02	-8.4	0.999	30- 920	25-506

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

Calibrators were previously cleared under k031159.

d. *Detection limit:*

Reportable ranges were determined based on the linearity studies (see above).

e. *Analytical specificity:*

Plasma samples were prepared with high and low concentrations of sodium (129 and 151 mmol/L), potassium (3 and 5.7 mmol/L), and chloride (84 and 115 mmol/L). Interferents were added to these samples and tested. The results were compared to sodium, potassium, and chloride samples without interferent. No interference was defined by the sponsor as a difference of <2 mmol/L for sodium, <0.25 mmol/L for potassium, and <2.8 mmol/L for chloride. The following compounds did not interfere with the results: Salicylic acid at 5 mM, Bilirubin at 500 uM, Triglycerides at 30 mM, Lithium at 3.2 mM, and 40% hematocrit. Albumin, Bromide, and Thiocyanate did cause interference at the concentrations shown below.

Interferent	Concentration
Bromide	3 mmol/L
Thiocyanate	2 mmol/L
Albumin	20 g/L

f. *Assay cut-off:*

No Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparisons to predicate devices were performed with whole blood, plasma, serum and urine patient samples. A small number of samples were spiked or diluted to fully span the claimed measuring ranges. The results are summarized below.

	Whole Blood				
	slope	intercept	R^2	n	conc. tested
Sodium	1.04	-3.67	.985	55	46.7-204.8
Potassium	0.91	0.44	.981	58	1.59-10.14
Chloride	1.01	-1.11	.987	57	47.8-201.4
	Plasma				
	slope	intercept	R^2	n	conc. tested
Sodium	1.06	-8.33	.991	46	46.8-205.5
Potassium	0.97	0.15	.007	44	1.58-10.99
Chloride	1.02	-3.45	.987	47	49.3-193.4
	Serum				
	slope	intercept	R^2	N	conc. tested
Sodium	1.07	-8.41	.992	69	48.7-205.4
Potassium	0.90	0.44	.995	65	1.70-10.26
Chloride	1.08	-8.82	.988	64	48.9-199.1
	Urine				
	slope	intercept	R^2	n	conc. tested
Sodium	1.07	-9.15	0.999	43	34.5-1012
Potassium	1.04	-3.91	0.996	42	21.9-503.1
Chloride	1.00	-8.43	0.996	42	27.9-505.3

b. *Matrix comparison:*

Assay performance in all claimed matrices is addressed in the method comparison studies described above.

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 value given in the tables below are intended to be used only as a guide. Each laboratory or testing site should establish its own range of normal values, taking into account factors such as age, sex, diet, and other determinants of electrolyte levels.

Whole Blood, Serum, Plasma (mmol/L or mEq/L)

Sodium (Na+) 135 to 148

Potassium (K+) 3.5 to 5.3

 Chloride (Cl-) 98 to 107

Urine (mmoL/L or mEq/L) spot

Sodium (Na+) 40 to 220

Potassium (K+) 25 to 120

Chloride (Cl-) 110 to 250

1 Tietz, N.W. (ed.) Fundamentals of Clinical Chemistry, 2nd ed. (1976), p. 875-77

 2 Geige Scientific Tables, Vol. 3, 8th edition

N. Instrument Name:

Diamond Diagnostics proLYTE Electrolyte Analyzer

O. System Descriptions:

1. Modes of Operation:

Fully automated with 'Yes' or 'No' commands for menu navigation.

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:

Manual

4. Specimen Sampling and Handling:

   Samples are manually placed on the instrument one at a time, tested, and removed.

5. Calibration:

   One point automated on board calibration performed every four hours or upon request. The slope is calculated during calibration and stored for sample measurement.

6. Quality Control:

   Controls are run manually and recommended daily. Results can be stored in instrument memory for future use.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable

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.