

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

A. 510(k) Number:

k082462

B. Purpose for Submission:

New Device

C. Measurand:

Sodium, Potassium, Chloride, Calcium, Lithium

D. Type of Test:

Ion Selective Electrode

E. Applicant:

Diamond Diagnostics, Inc.

F. Proprietary and Established Names:

Diamond Diagnostics GemLyte Electrolyte Analyzer

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1665 – Sodium Test System

21 CFR 862.1600 – Potassium Test System

21 CFR 862.1170 – Chloride Test System

21 CFR 862.1145 – Calcium Test System

21 CFR 862.3560 – Lithium Test System

2. Classification:

Class II

3. Product code:

JGS - Electrode, Ion Specific, Sodium

CEM – Electrode, Ion Specific, Potassium

CGZ – Electrode, Ion Specific, Chloride

JFP – Electrode, Ion Specific, Calcium

JIH – Flame Photometry, Lithium

4. Panel:

75 – Chemistry (Sodium, Potassium, Chloride, Calcium)

91 – Toxicology (Lithium)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

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

The GemLyte Potassium Assay is intended to measure potassium in whole blood, plasma, serum, and urine on the GemLyte Electrolyte Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

The GemLyte Sodium Assay is intended to measure sodium in whole blood, plasma, serum, and urine on the GemLyte Electrolyte Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The GemLyte Chloride Assay is intended to measure the level of chloride in whole blood, plasma, serum, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The GemLyte Calcium Assay is intended to measure the ionized calcium level in whole blood, plasma and serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

The GemLyte Lithium Assay is intended to measure lithium (from the drug lithium carbonate) in whole blood, plasma and serum. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Diamond Diagnostics GemLyte Electrolyte Analyzer

I. Device Description:

The GemLyte is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium in serum, plasma, whole blood and prediluted urine samples. GemLyte analyzer is fully automated with simple 'Yes' or 'No' commands for menu navigation. The analyzer self-calibrates using Diamond Diagnostics Fluid Pack (k013850) every 4 hours through out the day or on request. Diamond Diagnostics controls (k033063) are the recommended quality control material to be used daily.

J. Substantial Equivalence Information:

1. Predicate device name(s):

AVL 9180 Electrolyte Analyzer

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

k961458

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Measurement Method	Ion selective electrodes	Same
Analytes measured	sodium, potassium, chloride, calcium, lithium	Same
Sample matrix	Whole blood, plasma, serum, urine	Same + dialysate
Analysis time	57 seconds	Same
Calibration	Automatic and on demand	Same
Reagent Pack	Standard A 350 ml Standard B 85 ml Standard C 85 ml Reference Solution 85 ml Waste bag	Same

Differences		
Item	Device	Predicate
Measuring range whole blood, serum, plasma	Na ⁺ : 40-200 mmol/L K ⁺ : 1.7-15 mmol/L Cl ⁻ : 50-200 mmol/L Ca ⁺⁺ : 0.3-5.0 mmol/L Li ⁺ : 0.2-5.5 mmol/L	Na ⁺ : 40-205 mmol/L K ⁺ : 1.5-15 mmol/L Cl ⁻ : 50-200 mmol/L Ca ⁺⁺ : 0.2-5.0 mmol/L Li ⁺ : 0.1-6.0 mmol/L
Measuring range urine	Na ⁺ : 3-300 mmol/L K ⁺ : 5-120 mmol/L Cl ⁻ : 15-300 mmol/L	Na ⁺ : 1-300 mmol/L K ⁺ : 4.5-120 mmol/L Cl ⁻ : 1-300 mmol/L

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

None referenced

L. Test Principle:

The GemLyte measures sodium, potassium and chloride in whole blood, serum, plasma, and urine and ionized calcium and lithium in whole blood, serum, and plasma, 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, chloride, ionized calcium, and lithium 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 sample concentrations were across the measuring range. The protocol called for running 30 replicates of each sample without calibration between measurements. The replicates were run consecutively in one day. The results are summarized below.

Whole Blood (mmol/L)

Sample 1	Na+	K+	Cl-	Ca2+	Li+
Mean	103.1	3.8	66.8	0.70	0.36
%CV	0.29	0.86	0.49	1.5	4.73
n	30	30	30	30	30

Sample 2	Na+	K+	Cl-	Ca2+	Li+
Mean	137.2	5.1	104.0	1.14	0.68
%CV	0.51	1.18	0.57	1.6	3.64
N	30	30	30	30	30

Sample 3	Na+	K+	Cl-	Ca2+	Li+
Mean	156.8	7.8	118.8	1.33	1.32
%CV	0.14	1.31	0.46	1.6	2.36
n	30	30	30	30	30

Plasma (mmol/L)

Sample 1	Na+	K+	Cl-	Ca2+	Li+
Mean	111.2	2.3	70.7	0.82	0.46
%CV	0.36	1.13	0.44	1.03	2.95
n	30	30	30	30	30

Sample 2	Na+	K+	Cl-	Ca2+	Li+
Mean	140.2	4.0	97.3	1.18	0.95
%CV	0.16	0.81	0.16	0.81	1.87
n	30	30	30	30	30

Plasma (mmol/L)

Sample 3	Na+	K+	Cl-	Ca2+	Li+
Mean	165.0	6.6	113.9	1.65	1.60
%CV	0.27	0.57	0.34	1.26	1.74
n	30	30	30	30	30

Serum (mmol/L)

Sample 1	Na+	K+	Cl-	Ca2+	Li+
Mean	111.3	2.78	52.2	0.66	0.38
%CV	0.54	1.39	0.94	1.65	0.88
n	30	30	30	30	30

Sample 2	Na+	K+	Cl-	Ca2+	Li+
Mean	140.7	6.07	99.9	0.92	1.19
%CV	0.14	0.78	0.21	1.04	2.57
n	30	30	30	30	30

Sample 3	Na+	K+	Cl-	Ca2+	Li+
Mean	158.9	9.01	111.9	1.53	1.99
%CV	0.28	0.87	0.29	1.09	1.92
n	30	30	30	30	30

Urine (mmol/L)

Sample 1	Na+	K+	Cl-
Mean	37.6	23.9	111.9
%CV	4.12	0.90	0.49
n	30	30	30
Sample 2			
Mean	137.1	56.2	181.3
%CV	1.19	2.74	1.10
n	30	30	30
Sample 3			
Mean	212.6	85.5	291.1
%CV	0.66	3.33	0.91
n	30	30	30

Total precision was calculated with results from three whole blood, serum, plasma, and urine samples for each analyte. The samples concentrations were across the measuring range. The samples were measured twice a day in duplicate for ten consecutive days resulting in n=40 replicates. A second study for sodium and chloride was conducted in a similar manner to determine precision at higher levels and resulted in 20 and 14 replicates respectively. One whole blood sample and three urine samples had n=39 replicates due to instrument errors. The results are summarized below.

Whole Blood (mmol/L)

Sample 1	Na+	K+	Cl-	Ca2+	Li+
Mean	112.09	5.00	77.50	0.83	0.27
%CV	0.8	16.3	1.5	2.8	17.2
n	40	40	40	40	40

Sample 2	Na+	K+	Cl-	Ca2+	Li+
Mean	131.4	13.8	102.4	1.10	0.64
%CV	1.1	4.2	1.5	3.6	7.0
N	40	40	40	40	40

Sample 3	Na+	K+	Cl-	Ca2+	Li+
Mean	152.4	14.5	123.52	1.3209	1.7911
%CV	0.8	1.7	2.7	4.3	4.0
n	40	40	40	40	40

Plasma (mmol/L)

Sample 1	Na+	K+	Cl-	Ca2+	Li+
Mean	111.0	2.37	64.9	0.79	0.45
%CV	1.33	2.83	2.19	2.04	4.53
n	40	40	40	40	40

Sample 2	Na+	K+	Cl-	Ca2+	Li+
Mean	139.9	4.0	93.8	1.11	1.00
%CV	0.57	1.40	0.54	3.98	5.11
n	40	40	40	40	40

Sample 3	Na+	K+	Cl-	Ca2+	Li+
Mean	164.5	6.6	110.5	1.37	1.51
%CV	0.93	1.32	0.67	4.13	3.52
n	40	40	40	40	40

Serum (mmol/L)

Sample 1	Na+	K+	Cl-	Ca2+	Li+
Mean	110.0	2.80	68.2	0.70	0.40
%CV	1.0	3.0	1.7	4.1	4.9
n	40	40	40	40	40

Serum (mmol/L)

Sample 2	Na+	K+	Cl-	Ca2+	Li+
Mean	140.4	6.03	99.8	1.29	1.62
%CV	1.5	1.3	1.4	4.7	5.0
n	40	40	40	40	40

Sample 3	Na+	K+	Cl-	Ca2+	Li+
Mean	161.2	6.88	118.6	1.406	2.157
%CV	1.1	2.0	1.1	3.8	4.3
n	40	40	40	40	40

Urine (mmol/L)

Sample 1	Na+	K+	Cl-
Mean	51.6	17.9	60.9
%CV	3.8	3.9	2.6
n	40	40	40
Sample 2			
Mean	99.1	24.7	115.3
%CV	1.4	4.1	0.6
n	40	40	40
Sample 3			
Mean	212.6	85.5	291.1
%CV	0.66	3.33	0.91
n	30	30	30

Urine (mmol/L)

	Na+	Cl-
Mean	213.9	288.7
%CV	1.2	1.7
n	20	14

b. *Linearity/assay reportable range:*

Linearity was evaluated by preparing stock solutions with high concentrations of Na⁺, K⁺, Cl⁻, Ca²⁺, and Li⁺ in whole blood, plasma, serum, and Na⁺, K⁺, and Cl⁻ in urine. Linear regression was performed on the results using expected values based on the stock sample dilution. The results are shown below.

Whole Blood

Parameter	Slope	Intercept	R ²	Conc. Tested	Measuring Range
Sodium	0.997	2.685	0.992	40-205	40-200
Potassium	0.970	0.26	0.995	2.0-14.89	1.7-15
Chloride	1.021	-1.709	0.995	58-196	50-200

Parameter	Slope	Intercept	R2	Conc. Tested	Measuring Range
Calcium	0.979	0.095	0.999	0.102-4.03	0.3-5
Lithium	0.999	-0.048	0.999	0.099-5.683	0.2-5.5

Plasma

Parameter	Slope	Intercept	R2	Conc. Tested	Measuring Range
Sodium	0.984	-1.576	0.996	47-196.2	40-200
Potassium	1.013	-0.499	0.995	1.91-13.64	1.7-15
Chloride	0.993	-1.795	0.995	56.2-196	50-200
Calcium	1.017	0.039	0.998	0.116-4.573	0.3-5
Lithium	1.001	-0.010	0.995	0.11-5.5	0.2-5.5

Serum

Parameter	Slope	Intercept	R2	Conc. Tested	Measuring Range
Sodium	0.999	-1.1465	0.999	41-197	40-200
Potassium	1.032	-0.8941	0.990	1.7-14.4	1.7-15
Chloride	1.018	-5.580	0.993	50-192	50-200
Calcium	0.963	0.191	0.998	0.39-4.7	0.3-5
Lithium	1.024	-0.124	0.9988	0.2 – 5.2	0.2-5.5

Urine

Parameter	Slope	Intercept	R2	Conc. Tested	Measuring Range
Sodium	0.999	2.1056	0.999	3-296	3-300
Potassium	0.983	0.6103	0.991	4.6-118	5-120
Chloride	0.980	6.272	0.999	1-297	15-300

The data provided in the linearity studies and method comparison study supports the sponsor's claims of the following reportable ranges:

Measuring range whole blood, serum, plasma	Na ⁺ : 40-200 mmol/L K ⁺ : 1.7-15 mmol/L Cl ⁻ : 50-200 mmol/L Ca ⁺⁺ : 0.3-5.0 mmol/L Li ⁺ : 0.2-5.5 mmol/L
Measuring range urine	Na ⁺ : 3-300 mmol/L K ⁺ : 5-120 mmol/L Cl ⁻ : 15-300 mmol/L

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

Calibrators were previously cleared under k013850 and controls under k033063.

d. *Detection limit:*

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

e. Analytical specificity:

Plasma samples were prepared with high and low concentrations of sodium (130 and 150 mmol/L), potassium (3 and 5 mmol/L), chloride (85 and 115 mmol/L), ionized calcium (1 and 2 mmol/L), and lithium (0.2 and 1.5 mmol/L). Interferants were added to these samples and tested: salicylic acid (4.4 mM), bicarbonate (40 mM), albumin (60 g/L), triglycerides (30 mM), lithium (3.2 mM), bromide (32 mM), thiocyanate (7 mM), sodium (30 mM), magnesium (15 mM), and calcium (2 mM). 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, <2.8 mmol/L for chloride, < 0.17 mmol/L for ionized calcium, and <0.3 mmol/L for lithium. Albumin at 60 g/L, bromide at 32 mM, and thiocyanate at 7 mM showed interference with the chloride test. None of the substances caused interference in the sodium, potassium, ionized calcium and lithium assays.

The sponsor lists in the labeling that hemolyzed or icteric samples should not be used as these potential interferants have not been evaluated.

f. Assay cut-off:

No Applicable

2. Comparison studies:

a. Method comparison with predicate device:

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

	Whole Blood (mmol/L)				
	slope	intercept	R²	n	conc. tested
Sodium	0.988	1.04	0.9962	128	42.3-188.1
Potassium	0.972	0.223	0.9957	112	1.7-14.46
Chloride	1.011	-0.49	0.9882	123	54.0-191.4
Calcium	0.994	0.019	0.9885	124	0.304-4.514
Lithium	0.983	-0.049	0.9919	123	0.255-5.410
	Plasma (mmol/L)				
	slope	intercept	R²	n	conc. tested
Sodium	0.987	0.87	0.9977	105	43.5-194.4

	slope	intercept	R²	n	conc. tested
Potassium	1.006	-0.014	0.9973	107	1.7-13.97
Chloride	1.022	-3.23	0.9879	115	55.2-193.2
Calcium	0.971	0.042	0.9915	123	0.363-4.386
Lithum	0.993	0.002	0.9878	115	0.298-5.071
Serum (mmol/L)					
	slope	intercept	R²	N	conc. Tested
Sodium	0.990	0.03	0.9964	122	44.6-196.9
Potassium	0.981	0.085	0.9979	127	1.7-14.64
Chloride	1.021	-2.57	0.9687	125	50.7-185.7
Calcium	0.970	0.036	0.9842	120	0.655-4.309
Lithum	1.004	0.092	0.9876	131	0.213-5.149
Urine (mmol/L)					
	slope	intercept	R²	n	conc. tested
Sodium	0.983	-2.57	0.9843	118	8-296
Potassium	0.965	0.34	0.9934	108	5.3-118.2
Chloride	0.976	-1.86	0.9807	118	15-272

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 values 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)

Na⁺ 136 - 145 mmol/L

K⁺ 3.5 - 5.1 mmol/L

Cl⁻ 97 - 111 mmol/L

iCa⁺⁺ 1.0 - 1.30 mmol/L

Li⁺ 0.6 - 1.2 mmol/L

Urine (mmol/L)

Na⁺ 40 - 220 mmol/L

K⁺ 25 - 120 mmol/L

Cl⁻ 110 - 250 mmol/L

From Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd ed. (Philadelphia: W.B. Saunders, Co., 1994)

N. Instrument Name:

Diamond Diagnostics GemLyte 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 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.