

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

A. 510(k) Number:

k052927

B. Purpose for Submission:

Notification of intent to manufacture and market a new device.

C. Measurand:

Blood pH, Sodium, Potassium, Ionized Calcium, and Chloride

D. Type of Test:

Ion Selective Electrode (ISE)

E. Applicant:

Osmetech, Inc

F. Proprietary and Established Names:

OPTI LION Electrolyte Analyzer

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1120, Blood gases (PCO₂, PO₂) and blood pH test system
21 CFR 862.1665, Sodium test system
21 CFR 862.1600, Potassium test system
21 CFR 862.1145, Calcium test system
21 CFR 862.1170, Chloride test system
21 CFR 862.2160, Discrete photometric chemistry analyzer for clinical use

2. Classification:

Class II – analyte assays
Class I - analyzer

3. Product code:

CHL, electrode measurement, blood-gases (pco₂, po₂) and blood ph
JGS, electrode, ion specific, sodium
CEM, electrode, ion specific, potassium
JFP, electrode, ion specific, calcium
CGZ, electrode, ion-specific, chloride
JJE, analyzer, chemistry (photometric, discrete), for clinical use

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The Osmetech OPTI LION Electrolyte Analyzer is intended to be used for the measurement of sodium, potassium, chloride, ionized calcium and pH in samples of whole blood, serum and plasma as appropriate in either a traditional clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results. For Professional Use Only. For *In Vitro* Diagnostic Use.

Sodium

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adrenocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or

hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

Potassium

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K^+/H^+ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea and hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

Chloride

Chloride is an anion that exists predominantly in extracellular spaces. It maintains cellular integrity through its influence on osmotic pressure. It is also significant in monitoring acid-base balance and water balance. In metabolic acidosis, there is a reciprocal rise in chloride concentration when the bicarbonate concentration drops.

Decreased levels are found in severe vomiting, severe diarrhea, ulcerative colitis, pyloric obstruction, severe burns, heat exhaustion, diabetic acidosis, Addison's disease, fever and acute infections such as pneumonia.

Increased levels are found in dehydration, Cushing's syndrome, hyperventilation, eclampsia, anemia and cardiac decompensation.

Ionized Calcium

Calcium in blood is distributed as free calcium ions (50%) bound to protein, mostly albumin (40%) and 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI LION measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, *hypercalcemia*, is found in patients with increased intestinal absorption, increased mobilization from bone (osteolysis), decreased renal elimination, hyperparathyroidism and Addison's disease. Hypercalcemia may also be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.

Decreased calcium, *hypocalcemia*, is found in patients with decreased intestinal absorption, increased renal elimination, increased deposition of Calcium in the bones, increased binding to proteins when the pH increases or binding to citrate, and hypoparathyroidism.

Patients with renal disease caused by glomerular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method of accurately monitoring calcium status in renal disease.

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

Ionized calcium may be reported either as the actual ionized calcium, referred to actual pH of the patients, or as normalized ionized calcium, to a standard pH at pH 7.40. The binding of calcium by protein and small anions is influenced by pH and because of this relationship specimens should be analyzed at the pH of the patient's blood.

For more detailed information about the preanalytical variables affecting ionized calcium, please refer to the most current edition of CLSI document C31- Ionized Calcium Determinations: Pre-collection Variables, Specimen Choice, Collection, and Handling.

pH

The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

- primary bicarbonate deficit metabolic acidosis
- primary bicarbonate excess metabolic alkalosis
- primary hypoventilation respiratory acidosis
- primary hyperventilation respiratory alkalosis

An increase in blood, serum or plasma pH, *alkalemia*, may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO₂ due to hyperventilation.

A decrease of pH value, *acidemia*, in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H⁺-ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute, as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic, as the result of obstructive or restrictive respiratory diseases.

3. Special conditions for use statement(s):

For professional use only

4. Special instrument requirements:

The Osmetech Ion Selective Electrodes are intended for use on the Osmetech OPTI LION Electrolyte Analyzer only.

I. Device Description:

The Osmetech OPTI LION Electrolyte Analyzer is a small, microprocessor-based instrument using optical fluorescence for the measurement of pH, sodium, potassium, ionized calcium and chloride. The device utilizes a disposable single use cassette containing five fluorescent optical sensors for the measurement of pH, sodium, potassium, ionized calcium. The disposable single use cassette contains five optical fluorescent sensors in a polycarbonate substrate, packaged with an insertable sample probe in a sealed foil pouch which bears a barcode label with calibration, lot identification, and expiration dating information.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Osmetech CCA
Roche OMNI
AVL 995
Roche COBAS Integra 800
AVL 9180

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

Osmetech CCA (k974784, k984299, k852473)
Roche OMNI (k945915, k990092)
AVL 995 (k895317)
Roche COBAS Integra 800 (k951595)
AVL 9180 (k972763)

3. Comparison with predicate:

This device is a modified version of the Osmetech CCA device. The device has been simplified to replace wet calibration with dry calibration in the cassette.

Feature	Osmetech OPTI LION	Roche 9180	Osmetech OPTI CCA-TS	Roche OMNI	Roche Cobas Integra 800	AVL 995
Measured Parameter:	pH Na+, K+, Cl-, Ca++,	Na+, K+, Cl-, Ca++, Li+	pH, PCO ₂ , PO ₂ , Na+, K+, Cl-, Ca++, ctHb, SO ₂ , Baro	pH, PCO ₂ , PO ₂ Na+, K+, Cl-, Ca++, Hct, Baro	72 Chemistry Assays including: Na+, K+, Cl-, Li+	pH, PCO ₂ , PO ₂
Sample Size:	125uL	95 uL	125uL	70 uL	97uL (direct) 20uL (indirect)	40 uL 25 uL (micro)
Sample Type:	Whole blood Serum Plasma	Whole blood Serum Plasma Urine Dialysate	Whole blood Serum Plasma	Whole blood Serum Plasma	Serum Plasma Urine CSF, Hemolysate	Whole Blood Serum Plasma
Analysis Time:	< 120 seconds	50 seconds	< 60	<60 seconds	60 seconds	120
Samples per Hour:	17/hr	60/hr without printed report, 45/hr with printed report	17/hr	40/hr	855 tests/hr	30
Sample Application:	Syringe, Sample Tube, Sample Cup Capillary	Syringe, Sample Tube, Sample Cup	Syringe, Capillary	Syringe, capillary	Sample Tube, Sample Cup	Syringe, Capillary
Sampling Technique:	aspiration	aspiration	aspiration	Injection - syringe Aspiration- capillary	aspiration	Aspiration
Dilution Ratio:	without dilution	without dilution	without dilution	Without dilution	With dilution / Without dilution	Without dilution

Feature	Osmetech OPTI LION	Roche 9180	Osmetech OPTI CCA-TS	Roche OMNI	Roche Cobas Integra 800	AVL 995
Measurement Range:						
Na+:	100 - 180 mmol/L	40-205 mmol/L	100 – 180 mmol/L	20 – 250 mmol/L	20 – 250 mmol/L	N/A
K+:	0.8 – 10 mmol/L	1.5 – 15 mmol/L	0.8 - 10 mmol/L	0.2 – 20 mmol/L	0.2 – 30 mmol/L	N/A
Cl-:	50 – 160 mmol/L	50 – 200 mmol/L	50 – 160 mmol/L	20 – 250 mmol/L	20 – 250 mmol/L	N/A
Ca++:	0.2 – 3.0 mmol/L	0.2 – 5.0 mmol/L	0.2 - 3.0 mmol/L	0.1 – 6.0 mmol/L	N/A	N/A
pH:	6.6 – 7.8 pH units	N/A	6.6 - 7.8 pH units	6.0 - 8.0 pH units	N/A	6.000-8.000
Resolution of Display:						
Na+:	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L	N/A
K+:	0.01 mmol/L	0.01 mmol/L	0.01 mmol/L	0.01 mmol/L	0.01 mmol/L	N/A
Cl-:	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L	N/A
Ca++:	0.01 mmol/L	0.001 mmol/L	0.01 mmol/L	0.001 mmol/L	N/A	N/A
pH:	0.001	N/A	0.001	0.001	N/A	0.001

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

The following documents were referenced in this submission as CLSI standards used by the company to prepare this submission: EP9-A2 *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition*, EP06-A2 *Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline*, EP05-A2 *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline-Second Edition*

L. Test Principle:

Ion Selective Electrode

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

To evaluate overall imprecision of the OPTI LION analyzer, and to estimate the cassette-to-cassette variability, precision studies were conducted following the CLSI guideline EP5-A. Typical within run, Between day and Total precision were determined from two runs per day over 20 days on two OPTI LION instruments in simulated low- and high-use tests using three levels of aqueous quality control material. The table below reflects the precision for one of the analyzers.

	Statistic	pH	Na	K	Cl	Ca
OPTI - Check Level 1						
	Within run SD	0.0197	1.1152	0.0773	1.8227	0.0915
	% CV	0.28%	0.97%	2.62%	2.22%	4.78%
	Between day SD	0.0111	0.5614	0.0159	0.6354	0.0332
	%CV	0.16%	0.49%	0.54%	0.77%	1.73%
	Total Precision SD	0.0209	1.2199	0.0917	2.1008	0.1051
	%CV	0.29%	1.06%	3.11%	2.56%	5.49%
	N	40	40	40	40	40
OPTI - Check Level 2						
	Within Run SD	0.0197	0.8883	0.0716	2.4216	0.0401
	% CV	0.27%	0.64%	1.62%	2.27%	2.91%
	Between day SD	0.0095	0.3323	0.0565	1.1978	0.0183
	%CV	0.13%	0.24%	1.28%	1.12%	1.33%
	Total Precision SD	0.0217	1.0167	0.1031	2.6586	0.516
	%CV	0.30%	0.73%	2.33%	2.49%	3.74%
	N	40	40	40	40	40
OPTI – Check Level 3						
	Within run SD	0.0197	0.9725	0.1120	3.0727	0.0176
	% CV	0.26%	0.60%	1.85%	2.34%	2.55%
	Between day SD	0.0090	0.3816	0.0558	1.1038	0.0105
	%CV	0.12%	0.23%	0.92%	0.84%	1.51%
	Total Precision SD	0.0219	1.1071	0.1460	3.5315	0.0184
	%CV	0.29%	0.68%	2.40%	2.68%	2.67%
	N	40	40	40	40	40

b. *Linearity/assay reportable range:*

Linearity studies were carried out based upon the CLSI guideline EP6-A. Linearity (aqueous)

The linearity of the OPTI LION analyzer for Na⁺, K⁺, and Ca²⁺ was tested using a dilution sequence of HEPES (4-(2-hydroxyethyl)piperazine-1-ethanesulfonic acid) buffers. Nine different concentrations were tested with three replicate measurements at each level being carried out on two LION instruments (SN 6104 and 6105) and the 9181 predicate.

The linearity of the OPTI LION analyzer for Cl⁻, was tested using a dilution sequence of phosphate based buffers containing NaCl. A different buffer was required for evaluating chloride linearity because the HEPES species interferes with the OPTI chloride fluorescent sensor. Nine different concentrations were tested with three replicate measurements at each level being carried out on two LION instruments and the 9181 predicate.

The linearity of the OPTI LION analyzer for pH was tested using a dilution sequence of HEPES based designed to cover the pH range 6.5 to 8.0. Nine different concentrations were tested with three replicate measurements at each level being carried out on two LION instruments and the 9181 predicate.

To analyze the data, linear, quadratic and cubic regressions were carried out for each data set.

	Linearity Range (6104)	Linearity Range (6105)
pH	6.8 – 8.0	6.8 – 8.0
Na ⁺	100mM – 194mM	100mM – 194mM
K ⁺	1.0mM – 9.6mM	1.0mM – 9.6mM
Cl ⁻	63mM – 147mM	63mM – 147mM
Ca ²⁺	0.3mM – 2.0mM	0.3mM – 2.0mM

Linear regression for the OPTI LION pH SN 6104 $y = 1.0034x - 0.0462$ Linear
 regression for the OPTI LION pH SN 6105 $y = 1.0247x - 0.2111$ n=24

Linear regression for the OPTI LION Na⁺ SN 6104 $y = 0.9637x + 5.5136$ Linear
 regression for the OPTI LION Na⁺ SN 6105 $y = 0.9377x + 8.3980$ n=26

Linear regression for the OPTI LION K⁺ SN 6104 $y = 0.9632x + 0.1746$ Linear
 regression for the OPTI LION K⁺ SN 6105 $y = 0.9492x + 0.187$ n=26

Linear regression for the OPTI LION Cl⁻ SN 6104 $y = 1.0066x - 2.0589$ Linear
 regression for the OPTI LION Cl⁻ SN 6105 $y = 1.0499x - 4.4624$ n=27

Linear regression for the OPTI LION Ca²⁺ SN 6104 $y = 0.9791x + 0.0078$ Linear
 regression for the OPTI LION Ca²⁺ SN 6105 $y = 0.9952x + 0.0017$ n=26

Linearity (plasma)

To evaluate linearity from of the OPTI LION Analyzer when running plasma samples, plasma was pooled from a single donor and either spiked, diluted or tonometered to generate 7 different levels of each analyte. The linearity study was carried out following the CLSI guideline EP6-A.

The linearity of the OPTI LION analyzer for Na⁺, K⁺, and Ca²⁺ was tested using pooled plasma which was either spiked with a salt mixture or diluted with deionized water. Seven different concentrations were tested with three different replicate measurements at each level being carried out on two LION analyzers (SN 6104 and SN 6105) and the predicate.

	Linearity Range (6104)	Linearity Range (6105)
pH	6.8 – 7.8	6.8 – 7.8
Na ⁺	69 mM – 175 mM	69 mM – 175 mM
K ⁺	1.7 mM – 7.3 mM	1.7 mM – 7.3 mM
Cl ⁻	74 mM – 174 mM	74 mM – 174 mM
Ca ²⁺	0.75 mM – 2.0 mM	0.75 mM – 2.0 mM

Linear regression for the OPTI LION pH SN 6104 $y = 0.9969x + 0.0419$ Linear
 regression for the OPTI LION pH SN 6105 $y = 1.015x - 0.0962$ n=21

Linear regression for the OPTI LION Na⁺ SN 6104 $y = 1.0185x - 1.4146$ Linear
 regression for the OPTI LION Na⁺ SN 6105 $y = 0.9698x + 2.6994$ n=18

Linear regression for the OPTI LION K⁺ SN 6104 $y = 1.0028x + 0.0496$ Linear
 regression for the OPTI LION K⁺ SN 6105 $y = 0.9504x + 0.0965$ n=21

Linear regression for the OPTI LION Cl⁻ SN 6104 $y = 0.9382x - 5.4288$ Linear
 regression for the OPTI LION Cl⁻ SN 6105 $y = 1.0537x - 3.4643$ n=18

Linear regression for the OPTI LION Ca²⁺ SN 6104 $y = 1.1163x + 0.0993$ Linear
 regression for the OPTI LION Ca²⁺ SN 6105 $y = 1.0828x + 0.0791$ n=21

Linearity (whole blood)

To evaluate linearity from of the OPTI LION Analyzer when using whole blood samples, tubes of heparinized blood was collected and pooled from a single donor and either spiked, diluted or tonometered to generate 7 different levels of each analyte. The linearity study was carried out following the CLSI guideline EP6-A.

The linearity of the OPTI LION analyzer for Na⁺, K⁺, and Ca²⁺ was tested using blood samples which were either spiked with a salt mixture for elevated samples or diluted with plasma mixed with a buffer and then added to the original samples packed red cells. Seven different concentrations were tested with three different replicate measurements at each level being carried out on two LION analyzers (SN 6104 and SN 6105) and the predicate.

	Linearity Range (6104)	Linearity Range (6105)
pH	6.9 – 7.7	6.9 – 7.7
Na ⁺	69 mM – 181 mM	69 mM – 181 mM
K ⁺	2.8 mM – 8.2 mM	2.8 mM – 8.2 mM
Cl ⁻	60 mM – 181 mM	60 mM – 181 mM
Ca ²⁺	0.8 mM – 1.5 mM	0.8 mM – 1.5 mM

Linear regression for the OPTI LION pH SN 6104 $y = 0.9595x + 0.2953$ Linear regression for the OPTI LION pH SN 6105 $y = 0.9674x + 0.2297$ n=21

Linear regression for the OPTI LION Na⁺ SN 6104 $y = 1.1134x - 14.723$ Linear regression for the OPTI LION Na⁺ SN 6105 $y = 1.094x - 14.748$ n=21

Linear regression for the OPTI LION K⁺ SN 6104 $y = 1.0273x + 0.2004$ Linear regression for the OPTI LION K⁺ SN 6105 $y = 1.0077x + 0.2072$ n=24

Linear regression for the OPTI LION Cl⁻ SN 6104 $y = 1.117x - 17.57$ Linear regression for the OPTI LION Cl⁻ SN 6105 $y = 1.1639x - 20.936$ n=21

Linear regression for the OPTI LION Ca²⁺ SN 6104 $y = 1.0336x + 0.0441$ Linear regression for the OPTI LION Ca²⁺ SN 6105 $y = 1.0093x + 0.0235$ n=24

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

The response of the OPTI LION analyzer was evaluated against NIST human serum reference materials 956b and 909b and was found to recover the values of the NIST standards for Na and Ca and is indirectly traceable to the reference materials for K and Cl.

The OPTI LION cassette is designed for storage at 15 – 35°C for 6 months. To assure OPTI LION stability, a validation of the OPTI LION disposable was tested in final configuration. Specifically, OPTI LION cassettes are stored over the labeled temperature range for the duration of the shelf life period. Periodically, measurements were performed to demonstrate that the system is capable of maintaining accuracy throughout the shelf life period. Stability testing was performed on a representative prototype system. The data supports six months shelf life stability.

d. Detection limit:

The detection limit for the OPTI LION was determined based on the linearity ranges established with gravimetrically prepared aqueous standard solutions:

	Linearity Range
pH	6.8 – 8.0
Na ⁺	100mM – 194mM
K ⁺	1.0mM – 9.6mM
Cl ⁻	63mM – 147mM
Ca ²⁺	0.3mM – 2.0mM

e. Analytical specificity:

Interference studies were conducted following the experimental protocol recommended in CLSI EP7-A. Plasma was spiked with known interferents and compared against control samples. The following effects are caused by the interferents at the levels listed below.

Interferent (level)	Effect – averaged between two instruments
Fluorescein (25 mg/dL)	Causes instability in the sensor: unable to get readings
Nickel Sulphate (0.1 mmol/L)	Causes instability in Na, increased K reading by 1.078 mmol/L, increased Cl by 27.88 mmol/L, increased Ca reading by 0.251 mmol/L
Methylene Blue (25 mg/dL)	Causes instability in the sensors: unable to get readings
Indocyanine Green (0.5 mg/dL)	Increases Na by 10.4 mmol/L, increases Cl by 11.28 mmol/L
Ammonium Chloride (5)	Increases K by 2.53 mmol/L

mmol/L)	
<i>Interferent (level)</i>	<i>Effect – averaged between two instruments</i>
Oxalic Acid (800 mg/dL)	Causes instability in the sensors: unable to get readings
Phenylacetic Acid (10 mmol/L)	Decreases pH by 0.1202, increases by 8.26 mmol/L in Na, Cl increases measurement by 9.94 mmol/L
Sodium Thiocyanate (3 mmol/L)	Increases Na by 13.82 mmol/L, Cl increased by 11.48 mmol/L
Sodium EDTA (800 mg/dL)	pH decreases by 0.441, Na decreases by 22.53 mmol/L, decreases K by 0.566 mmol/L, decreases Cl measurement by 5.22 mmol/L
Sodium Citrate (30 mg/dL)	Decreases Ca by 0.207 mmol/L
Sodium Citrate (100 mg/dL)	Instability in Na sensor: unable to read, decreases Cl measurement by 8.16 mmol/L
Sodium Salicylate (10 mmol/L)	Instability in Na sensor: unable to read, increases K measurement by 1.823 mmol/L, increases by 29.13 mmol/L in Cl, 0.512 mmol/L increase in Ca
Sodium Bisulphate (11.5 mmol/L)	Decreases pH by 0.1658, decreases Na by 6.31 mmol/L

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison studies were performed at 3 clinical sites. The method comparisons were carried out following the protocol recommended in the CLSI guideline EP9-A2. Duplicate measurements of 52 samples were carried out on both the OPTI LION analyzer and the predicate device. Linear regression statistics were as follows: Sodium $y = 1.0067x + 1.0738$, pH $y = 0.9431x + 0.4137$, Calcium $y = 0.9496x + 0.0632$, Chloride $y = 0.9492x + 6.6845$, Potassium $y = 0.9955x - 0.0066$.

b. *Matrix comparison:*

Linear regression studies were performed to compare plasma, serum, and aqueous samples with the OPTI LION and the predicate device. The linear regression for each matrix are presented below.

Aqueous:

Linear regression for the OPTI LION pH SN 6104 $y = 1.0034x - 0.0462$ Linear regression for the OPTI LION pH SN 6105 $y = 1.0247x - 0.2111$ n=24

Linear regression for the OPTI LION Na⁺ SN 6104 $y = 0.9637x + 5.5136$ Linear
regression for the OPTI LION Na⁺ SN 6105 $y = 0.9377x + 8.3980$ n = 26

Linear regression for the OPTI LION K⁺ SN 6104 $y = 0.9632x + 0.1746$ Linear
regression for the OPTI LION K⁺ SN 6105 $y = 0.9492x + 0.187$ n=26

Linear regression for the OPTI LION Cl⁻ SN 6104 $y = 1.0066x - 2.0589$ Linear
regression for the OPTI LION Cl⁻ SN 6105 $y = 1.0499x - 4.4624$ n=27

Linear regression for the OPTI LION Ca²⁺ SN 6104 $y = 0.9791x + 0.0078$ Linear
regression for the OPTI LION Ca²⁺ SN 6105 $y = 0.9952x + 0.0017$ n=26

Plasma:

Linear regression for the OPTI LION pH SN 6104 $y = 0.9969x + 0.0419$ Linear
regression for the OPTI LION pH SN 6105 $y = 1.015x - 0.0962$ n=21

Linear regression for the OPTI LION Na⁺ SN 6104 $y = 1.0185x - 1.4146$ Linear
regression for the OPTI LION Na⁺ SN 6105 $y = 0.9698x + 2.6994$ n=18

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Linear regression for the OPTI LION Cl⁻ SN 6104 $y = 0.9382x - 5.4288$ Linear
regression for the OPTI LION Cl⁻ SN 6105 $y = 1.0537x - 3.4643$ n=18

Linear regression for the OPTI LION Ca²⁺ SN 6104 $y = 1.1163x + 0.0993$ Linear
regression for the OPTI LION Ca²⁺ SN 6105 $y = 1.0828x + 0.0791$ n=21

Serum:

Linear regression for the OPTI LION pH SN 6104 $y = 0.9595x + 0.2953$ Linear
regression for the OPTI LION pH SN 6105 $y = 0.9674x + 0.2297$ n=21

Linear regression for the OPTI LION Na⁺ SN 6104 $y = 1.1134x - 14.723$ Linear
regression for the OPTI LION Na⁺ SN 6105 $y = 1.094x - 14.748$ n=21

Linear regression for the OPTI LION K⁺ SN 6104 $y = 1.0273x + 0.2004$ Linear
regression for the OPTI LION K⁺ SN 6105 $y = 1.0077x + 0.2072$ n=24

Linear regression for the OPTI LION Cl⁻ SN 6104 $y = 1.117x - 17.57$ Linear
regression for the OPTI LION Cl⁻ SN 6105 $y = 1.1639x - 20.936$ n=21

Linear regression for the OPTI LION Ca²⁺ SN 6104 $y = 1.0336x + 0.0441$ Linear
regression for the OPTI LION Ca²⁺ SN 6105 $y = 1.0093x + 0.0235$ n=24

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:

Expected values for Sodium, Potassium, Chloride, Calcium and pH are well established in published literature. However region specific reference values should be established by each laboratory.

N. Instrument Name:

Osmetech OPTI LION Analyzer

O. System Descriptions:

1. Modes of Operation:

The Osmetech OPTI LION Electrolyte Analyzer is intended to be used in either a traditional clinical laboratory setting or point of care locations by minimally qualified personnel. 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:

Specimen identification is manually typed into the device prior to patient sampling via an

LED touch screen.

4. Specimen Sampling and Handling:

Samples are aspirated into the ISE cassette via a “fillport” and sample probe from Vacutainer tubes, syringes and/or sample cups.

5. Calibration:

The OPTI LION system uses proprietary fluorescent intensity at discrete standard levels for calibration with each lot of analyte cassettes. Each lot of OPTI LION cassettes is calibrated during the manufacturing process. Each cassette has a barcode label containing the calibration information as well as the expiration date and lot number. Prior to running a sample, the cassette barcode is read into the analyzer and the calibration information is loaded. The cassette is installed and a calibration is performed.

6. Quality Control:

The OPTI LION system uses Osmetech electrolyte controls (OPTI-CHECK LYTES sold separately) or an equivalent material. Controls are run on initial use of each lot of cassette and at 2 month intervals.

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.