510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K222438

B Applicant

Siemens Healthcare Diagnostics Inc.

C Proprietary and Established Names

A-LYTE® Integrated Multisensor (IMT Na K Cl)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JGS	Class II	21 CFR 862.1665 - Sodium Test System	CH - Clinical Chemistry
CGZ	Class II	21 CFR 862.1170 - Chloride test system	CH - Clinical Chemistry
CEM	Class II	21 CFR 862.1600 - Potassium test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Addition of previously cleared assays to a new instrument

B Measurand:

Sodium (Na^+), Potassium (K^+) and Chloride (Cl^-)

C Type of Test:

Quantitative, ion specific electrodes

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The A-LYTE® Integrated Multisensor (IMT Na K Cl) is for in vitro diagnostic use in the quantitative determination of sodium, potassium, and chloride (Na, K, Cl) in human serum, plasma (lithium heparin) and urine using the Atellica CI ®analyzer.

Measurements of sodium obtained by this device are used 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.

Measurements of potassium obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:
Atellica® CI Analyzer

IV Device/System Characteristics:

A Device Description:

The A-LYTE® Integrated Multisensor (IMT Na, K, and Cl) is comprised of four electrodes (one ion selective electrode Na^+, K^+, Cl^- respectively) and one reference electrode.

Materials needed for the A-LYTE ® Integrated Multisensor (IMT, Na, K, and Cl) system but distributed separately include the A-LYTE IMT Standard A & Standard B + Salt-Bridge, A-LYTE IMT Diluent and A-LYTE IMT Diluent Check.

B Principle of Operation:
The A-LYTE® Integrated Multisensor (Na, K, Cl) uses indirect Integrated Multisensor Technology (IMT). There are four electrodes used to measure electrolytes. Three of these electrodes are ion selective for sodium, potassium and chloride. A reference electrode is also incorporated in the multisensory.

During the testing, a diluted sample is delivered to the sensor and Na^+, K^+, Cl^- ions establish equilibrium with the electrode surface. A potential is generated proportional to the logarithm of the analyte activity in the sample. The electrical potential generated on a sample is compared to the electrical potential generated on a standard solution, and the concentration of the desired ions is calculated by use of the Nernst equation.

The Atellica CI IMT system performs a two points automatic calibration in duplicate every 4 hours. In addition, the system will routinely perform a one point calibration check with each sample measurement. Auto-calibration occurs after power on, with the changing of standards A, B, or a sensor and when the system software is reset.

V Substantial Equivalence Information:

A Predicate Device Name(s):

TD-LYTE Integrated Multisensor (IMT, Na, K, Cl)

B Predicate 510(k) Number(s):

K151767

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222438	K151767
Device Trade Name	A-LYTE® Integrated Multisensor (IMT Na K Cl)	TD-LYTE Integrated Multisensor (IMT, Na, K, Cl) *
Intended Use/Indications For Use	For in vitro diagnostic use in the quantitative determination of sodium, potassium, and chloride (Na, K, Cl) in human serum, plasma (lithium heparin) and urine.	Same
Test Principle	Indirect potentiometric measurements with Integrated Multisensor Technology (IMT)	Same
Sample Type	Serum, plasma (lithium heparin) and urine	Same
Measuring Range	Serum/Plasma Na: 50-200 mmol/L K: 1-10 mmol/L	Same

	Cl: 50-200 mmol/L Urine Na: 10-300 mmol/L K: 2-300 mmol/L Cl: 20-330 mmol/L	
Special Instrument Requirement	Atellica CI ® Analyzer	Trinidad CH Analyzer*

*The TD-LYTE Integrated Multisensor (Na, K, Cl) was renamed A-LYTE® Integrated Multisensor (Na, K, Cl) and the Trinidad Clinical Chemistry (CC) system was renamed Atellica CH analyzer in K161954.

VI Standards/Guidance Documents Referenced:

CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures - Third Edition.

CLSI EP06, Evaluation of the Linearity of Quantitative Measurement Procedures - Second Edition.

CLSI EP09c, Measurement Procedure Comparison and Bias Estimation Using Patient Samples- Third Edition.

CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory -Third Edition.

CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures– Second Edition.

CLSI EP07, Interference Testing in Clinical Chemistry –Third Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision

The precision study was performed in accordance with CLSI EP05-A3. Repeatability (within run) and within-laboratory precision for Na^+, K^+ and Cl^- were evaluated using quality control samples and native samples. Each sample was assayed in duplicate per run, two (2) runs per day for twenty (20) days using one (1) lot of reagent and one (1) instrument (N=80 for each sample). Repeatability and within-lab precision were calculated and summarized below. The within-lab precision includes the within-run (repeatability), between-run, and between-day variance components.

Sodium (Na)

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum 1	80	70.1	0.20	0.3	0.86	1.2
Serum QC 1	80	113	0.39	0.3	1.12	1.0
Serum QC 2	80	139	0.58	0.4	1.65	1.2
Serum QC 3	80	154	0.55	0.4	1.68	1.1
Urine 1	80	30.5	0.40	1.3	0.67	2.2
Urine QC 1	80	82.9	0.31	0.4	1.04	1.2
Urine 2	80	148	0.52	0.4	2.15	1.5
Urine 3	80	240	0.82	0.3	3.56	1.5

Potassium (K)

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum QC 1	80	2.44	0.01	0.5	0.03	1.1
Serum QC 2	80	4.04	0.01	0.4	0.04	1.1
Serum 1	80	6.03	0.02	0.4	0.07	1.2
Serum QC 3	80	7.16	0.02	0.3	0.08	1.1
Urine QC1	80	30.8	0.10	0.3	0.28	0.9
Urine QC2	80	75.4	0.15	0.2	0.79	1.0
Urine 1	80	248	1.01	0.4	3.21	1.3

Chloride (Cl)

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum QC 1	80	75.1	0.35	0.5	1.12	1.5
Serum QC 2	80	98.3	0.33	0.3	1.03	1.0
Serum QC 3	80	119	0.40	0.3	1.24	1.0
Serum 1	80	176	0.61	0.3	2.96	1.7
Urine 1	80	43.3	0.25	0.6	1.70	3.9
Urine QC 1	80	101	0.35	0.3	4.48	4.5
Urine QC 2	80	196	0.52	0.3	3.47	1.8
Urine 2	80	286	0.83	0.3	6.69	2.3

Reproducibility

A reproducibility study was performed in accordance with CLSI EP05-A3. Each sample was assayed five (5) times in one (1) run for five (5) days using three (3) instruments and three (3) sensor lots. Within-run (repeatability), between-day, between-sensor lot, between-instrument, and total reproducibility results were calculated. The results for the reproducibility studies are summarized below.

Sodium (Na)

			Repeatability		Between-Day		Between-Lot	
Sample	N	Mean mmol/L	SD mmol/L	CV%	SD mmol/L	CV%	SD mmol/L	CV%
Serum4	225	70.1	0.24	0.3	1.23	1.8	0.94	1.3
Serum QC 1	225	113	0.40	0.4	1.00	0.8	0.00	0.0
Serum3	225	139	0.40	0.3	0.80	0.6	0.20	0.1
Serum QC 2	225	154	0.50	0.3	1.10	0.7	0.70	0.5
Urine 1	225	30.4	0.38	1.3	0.75	2.5	0.52	1.7
Urine 3	225	81.1	0.26	0.3	1.35	1.7	0.04	0.1
Urine 4	225	150	0.50	0.3	2.40	1.6	1.50	1.0
Urine 6	225	267	1.00	0.4	8.40	3.2	3.70	1.4

			Between-Instrument		Reproducibility	
Sample	N	Mean mmol/L	SD mmol/L	CV%	SD mmol/L	CV%
Serum4	225	70.1	0.25	0.4	1.59	2.3
Serum QC 1	225	113	0.00	0.0	1.00	0.9
Serum3	225	139	0.90	0.7	1.30	0.9
Serum QC 2	225	154	1.40	0.9	2.00	1.3
Urine 1	225	30.4	0.43	1.4	1.08	3.5
Urine 3	225	81.1	0.49	0.6	1.46	1.8
Urine 4	225	150	2.00	1.3	3.50	2.3
Urine 6	225	267	1.50	0.6	9.30	3.5

Potassium (K)

			Repeatability		Between-Day		Between-Lot	
Sample	**N**	**Mean mmol/L**	**SD mmol/L**	**CV %**	**SD mmol/L**	**CV %**	**SD mmol/L**	**CV%**
Serum QC 1	225	2.47	0.03	1.2	0.02	0.6	0.00	0.0
Serum QC 2	225	7.27	0.03	0.4	0.05	0.7	0.01	0.2
Serum3	225	4.30	0.01	0.2	0.02	0.6	0.01	0.1
Serum5	225	6.14	0.01	0.2	0.04	0.6	0.01	0.2
Urine 2	225	31.3	0.07	0.2	0.40	1.3	0.07	0.2
Urine 3	225	68.5	0.24	0.4	1.28	1.9	0.24	0.4
Urine 5	225	256	0.70	0.3	2.30	0.9	1.00	0.4

			Between-Instrument		Reproducibility	
Sample	**N**	**Mean mmol/L**	**SD mmol/L**	**CV%**	**SD mmol/L**	**CV%**
Serum QC 1	225	2.47	0.03	1.1	0.04	1.7
Serum QC 2	225	7.27	0.05	0.7	0.08	1.1
Serum3	225	4.30	0.03	0.7	0.04	1.0
Serum5	225	6.14	0.04	0.6	0.06	0.9
Urine 2	225	31.3	0.07	0.2	0.42	1.3
Urine 3	225	68.5	0.24	0.3	1.35	2.0
Urine 5	225	256	1.30	0.5	2.90	1.1

Chloride (Cl)

			Repeatability		Between-Day		Between-Lot	
Sample	**N**	**Mean mmol/L**	**SD mmol/L**	**CV%**	**SD mmol/L**	**CV%**	**SD mmol/L**	**CV%**
Serum QC 1	225	78.1	0.29	0.4	0.79	1.0	0.41	0.5
Serum QC 2	225	119	0.50	0.4	0.90	0.7	0.30	0.3
Serum3	225	108	0.30	0.3	0.80	0.7	0.20	0.2
Serum6	225	172	0.40	0.2	1.40	0.8	0.00	0.0
Urine 1	225	41.7	0.23	0.6	1.19	2.9	0.10	0.2
Urine 3	225	104	0.40	0.4	3.00	2.9	0.40	0.3
Urine 4	225	206	0.50	0.2	2.00	1.0	0.30	0.1
Urine 5	225	270	0.70	0.3	3.90	1.4	0.00	0.0

			Between-Instrument		Reproducibility	
Sample	**N**	**Mean mmol/L**	**SD mmol/L**	**CV%**	**SD mmol/L**	**CV%**
Serum QC 1	225	78.1	0.08	0.1	0.94	1.2
Serum QC 2	225	119	0.20	0.2	1.10	0.9
Serum3	225	108	0.30	0.3	0.90	0.8
Serum6	225	172	0.90	0.6	1.80	1.0
Urine 1	225	41.7	0.02	0.1	1.22	2.9

			Between-Instrument		Reproducibility	
Sample	**N**	**Mean mmol/L**	**SD mmol/L**	**CV%**	**SD mmol/L**	**CV%**
Urine 3	225	104	0.70	0.7	3.10	3.0
Urine 4	225	206	1.40	0.7	2.50	1.2
Urine 5	225	270	2.70	1.0	4.70	1.8

2. Linearity:

The linearity studies were performed following the recommendations in the CLSI guideline EP06 2nd Edition. For each analyte, nine (9) equally spaced samples were prepared by mixing high and low concentration samples to cover the claimed measurement range. Five (5) replicates were measured for each sample using one (1) instrument and one (1) reagent lot. The mean of these replicates was compared to the expected values and the results of weighted linear (for Na, K serum and urine) or ordinary (for Cl serum and urine) linear regressions are summarized in the table below:

Analyte in Serum	**Claimed Measuring Range (mmol/L)**	**Sample Range Tested (mmol/L)**	**Slope**	**Intercept**	**R^2**
Sodium (Na)	50 to 200	46.0 to 217	0.986	-0.53	0.999
Potassium (K)	1 to 10	0.827 to 11.2	0.982	-0.0085	0.999
Chloride (Cl)	50 to 200	44.6 to 215	1.000	0.037	0.999

Analyte in Urine	**Claimed Measuring Range (mmol/L)**	**Sample Range Tested (mmol/L)**	**Slope**	**Intercept**	**R^2**
Sodium (Na)	10 to 300	8.41 to 313	0.951	-5.556	0.991
Potassium (K)	2 to 300	1.82 to 332	0.967	-0.020	0.999
Chloride (Cl)	20 to 330	19 to 355	1.004	-2.135	0.999

3. Analytical Specificity/Interference:

Interference studies were performed following the recommendations in the CLSI guideline EP07 3rd edition to determine the effects from potential endogenous and exogenous substances on the sensor performance using urine and serum samples. In this study, samples with high and low analyte levels were divided into two groups: i.e., test sample (with added interferent) and control sample (with no added interferent). Each test sample and control sample was assayed in five (5) replicates with one (1) reagent lot on one (1) instrument.

The sponsor defines that interference is considered non-significant if the bias between the test and control sample are within ± 10% for all tested interferences. The highest concentration tested that showed non-significant interference are summarized below:

Sodium (serum)

Substances	Maximum concentration tested that demonstrated no significant interference
Hemoglobin	1000 mg/dL
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Lipemia (Intralipid)	3000 mg/dL
Lipemia (Trig Fraction)	1125 mg/dL
Potassium	10 mM
Magnesium	20 mg/dL
Calcium	20 mg/dL
Lithium	3.5 mg/dL
Borate	2.5 mg/dL
Acetate	20 mg/dL
Benzoate	10 mg/dL
Citrate	1 g/dL
Ammonium	0.5 mmol/L
Thiopental	14 mg/dL

Sodium (urine)

Substances	Maximum concentration tested that demonstrated no significant interference
Hemoglobin	500 mg/dL
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Lipemia (Intralipid)	2000 mg/dL
Lipemia (Trig)	250 mg/dL
Acetaminophen	200 mg/dL
N-Acetyl cysteine	2 mg/dL
Ascorbic Acid	60 mg/dL
Sodium Cefoxitin	660 mg/dL
Gentamycin Sulfate	10 mg/dL
Ibuprofen	500 mg/dL
Levodopa	15 mg/dL
Ofloxacin	90 mg/dL
Phenazopyridine	30 mg/dL
Tetracycline	15 mg/dL
pH	4 and 8

Potassium (serum)

Substances	Maximum concentration tested that demonstrated no significant interference
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Lipemia (Intralipid)	3000 mg/dL
Lipemia (Trig Fraction)	2000 mg/dL

Substances	Maximum concentration tested that demonstrated no significant interference
Magnesium	20 mg/dL
Calcium	20 mg/dL
Lithium	3.5 mg/dL
Borate	2.5 mg/dL
Acetate	20 mg/dL
Benzoate	10 mg/dL
Citrate	1 g/dL
Ammonium	0.5 mmol/L
Iron	0.25 g/dL

Potassium (urine)

Substances	Maximum concentration tested that demonstrated no significant interference
Hemoglobin	750 mg/dL
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Lipemia (Intralipid)	2000 mg/dL
Lipemia (Trig)	2000 mg/dL
Acetaminophen	200 mg/dL
N-Acetyl cysteine	2 mg/dL
Ascorbic Acid	60 mg/dL
Sodium Cefoxitin	660 mg/dL
Gentamycin Sulfate	10 mg/dL
Ibuprofen	500 mg/dL
Levodopa	15 mg/dL
Ofloxacin	90 mg/dL
Phenazopyridine	30 mg/dL
Tetracycline	15 mg/dL
pH	4 and 8

Chloride (serum)

Substances	Maximum concentration tested that demonstrated no significant interference
Hemoglobin	1000 mg/dL
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Lipemia (Intralipid)	3000 mg/dL
Lipemia (Trig Fraction)	1125 mg/dL
Borate	2.5 mg/dL
Acetate	20 mg/dL
Benzoate	150 mg/dL
Citrate	0.5 g/dL
Sulfate	2 mmol/L
Salicylate	50 mg/dL

Substances	Maximum concentration tested that demonstrated no significant interference
Oxalate	0.5 mmol/L
Fluoride	0.25g/dL
Iodine	25 mg/dL
Bromide	35 mg/dL

Chloride (urine)

Substances	Maximum Concentration tested that demonstrated no significant interference
Hemoglobin	500 mg/dL
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Lipemia (Intralipid)	2000 mg/dL
Lipemia (Trig)	500 mg/dL
Acetaminophen	200 mg/dL
N-Acetyl cysteine	2 mg/dL
Ascorbic Acid	60 mg/dL
Sodium Cefoxitin	660 mg/dL
Gentamycin Sulfate	10 mg/dL
Ibuprofen	400 mg/dL
Levodopa	15 mg/dL
Ofloxacin	80 mg/dL
Phenazopyridine	30 mg/dL
Tetracycline	15 mg/dL
pH	4 and 8

The sponsor added the following limitations in the package insert:

- Avoid hemolyzed samples for potassium. Hemolyzed samples may give incorrect elevated potassium. Intracellular potassium concentration is 30-50-fold greater than that of extracellular serum or plasma.
- Samples exposed to benzalkonium salts present in certain blood catheter devices will cause falsely elevated sodium and potassium measurements.*

*Koch TR, Cook JD. Benzalkonium interference with test methods for potassium and sodium. Clin. Chem. 1990; 36:807-8.

4. Assay Reportable Range:

Based on the limit of quantification (LoQ), precision, linearity, and dilution recovery the ranges over which results can be reported are provided below:

Analyte	Analytical Measuring Interval (AMI) (mmol/L)	Extended Measuring Interval (EMI) (mmol/L)
Na^+ (serum)	50 – 200	NA
K^+(serum)	1 – 10	NA
Cl^- (serum)	50 – 200	NA

Analyte	Analytical Measuring Interval (AMI) (mmol/L)	Extended Measuring Interval (EMI) (mmol/L)
Na^+(urine)	10 – 300	300 – 600
K^+(urine)	2 – 300	300 – 600
Cl^-(urine)	20 – 330	330 – 660

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability

The A-LYTE Na assay is traceable to a flame emission spectrophotometry reference method, which uses reference materials from the National Institute of Standards and Technology (NIST), via patient sample correlation and is verified using NIST Reference Serum.

The A-LYTE K assay is traceable to a flame emission spectrophotometry reference method, which uses reference materials from the National Institute of Standards and Technology (NIST), via patient sample correlation and is verified using NIST Reference Serum.

The A-LYTE Cl assay is traceable to a colorimetric reference method, which uses reference materials from the National Institute of Standards and Technology (NIST), via patient sample correlation and is verified using NIST Reference Serum.

Stability

The A-LYTE® Integrated Multisensor (Na, K, Cl) is stable for 14 days on board or for testing up to 5000 samples per sensor, whichever comes first.

6. Detection Limit:

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ) were evaluated in accordance with CLSI EP17-A2.

LoB was determined non-parametrically by running four (4) blank samples in five (5) replicates per sample for three (3) days on three (3) instruments. The LoD was determined parametrically by running four (4) low samples of each sample type in five (5) replicates per sample for three (3) days on three (3) instruments. LoQ was determined by testing four (4) low samples of each sample type in five (5) replicates per sample for three (3) days on three (3) instruments. The results are summarized in the table below:

Sodium	**LoB (mmol/L)**	**LoD (mmol/L)**	**LoQ (mmol/L)**	**Observed Total Error at LoQ**
Serum	9.69	11.1	43.4	6%
Urine	2.74	3.18	6.12	15%

Potassium	**LoB (mmol/L)**	**LoD (mmol/L)**	**LoQ (mmol/L)**	**Observed Total Error at LoQ**
Serum	0.0848	0.0969	0.606	10%
Urine	0.0403	0.0545	1.22	4%

Chloride	LoB (mmol/L)	LoD (mmol/L)	LoQ (mmol/L)	Observed Total Error at LoQ
Serum	3.23	3.54	40.4	3%
Urine	6.5	6.94	8.7	15%

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies were performed following the CLSI guideline EP09c 3rd edition. Patient samples for each sample type, i.e., serum and urine, were each tested on the predicate test system (x) and on the candidate test system. Two replicates were processed for each sample on both systems. The first replicate results were used in statistical analyses. Weighted-Deming regression analyses for the three measurands are summarized below:

Analyte	Specimen Type	N	Slope	Intercept	Correlation Coefficient (r)	Concentration Range Tested (mmol/L)	Claimed Measuring range (mmol/L)
Na	Serum	123	1.00	-2.69	0.998	53.2-192	50-200
Na	Urine	117	1.02	-4.47	0.999	20.1-237	10-300
K	Serum	119	0.97	0.0353	1.000	1.40-9.85	1-10
K	Urine	117	1.02	-0.209	0.999	6.22-246	2-300
Cl	Serum	123	0.99	0.161	0.999	52.7-196	50-200
Cl	Urine	127	0.99	-0.582	0.991	24.3-314	20-330

2. Matrix Comparison:

Serum and lithium heparin plasma equivalency was demonstrated for the sodium, potassium, and chloride assays on the Atellica® CI analyzer by testing matched samples. Two replicates of each sample were tested and only the first replicate was used for the analyses. The table below summarizes Deming linear regression result statistics when comparing lithium heparin plasma sample results (Y) to serum sample results (X):

Analyte	Specimen Type (Y)	Reference Specimen (x)	N	Slope	Intercept	Correlation Coefficient (r)	Tested Concentration Range (mmol/L)
Na	Lithium Heparin Plasma	Serum	138	1.02	-1.87	0.994	53.4-190
K*			56	0.99	-0.207	0.914	1.41-9.33
Cl			136	1.00	-0.201	0.998	53.7-197

* The sponsor included the following statement in the labeling:

It is documented in the literature that potassium concentrations in plasma specimens can be lower than in serum specimens as a consequence of platelet rupture during coagulation. The extent of the potential difference is dependent on the platelet count in the specimen. The lower potassium reference intervals for plasma specimens compared to serum specimens reflect this known occurrence.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The sponsor provided information to support the following reference intervals that are cited from literature[1,2].

Specimen Type	Analyte	Reference Interval
Serum	Na	136-145 mmol/L
	K	3.5-5.1 mmol/L
	Cl	98-107 mmol/L
Plasma	Na	136-145 mmol/L
	K	3.4-4.5 mmol/L
	Cl	98-107 mmol/L
Urine	Na	40-220 mmol/24 hr
	K	25-125 mmol/24 hr
	Cl	110-250 mmol/24 hr

References:
1. Fischbach, F., Dunning, M. (2015) A manual of laboratory and diagnostic tests (9th ed), Philadelphia, PA: Wolters Kluwer Health/Lippincott Williams & Wilkins. (P245 Na Urine 40- 220 mmol/24 hrs and P246 K Urine 25-125 mmol/24 hrs)
2. Bruns et al. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 5th ed. Philadelphia, PA (P813 Cl Urine- 110-250 mmol/24 hrs)

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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