July 25, 2023

Siemens Healthcare Diagnostics Inc.
Anoop Joy
Regulatory Clinical Affairs Specialist
511 Benedict Avenue
Tarrytown, NY 10591

Re: K222438
Trade/Device Name: A-LYTE® Integrated Multisensor (IMT Na K Cl)
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ
Dated: January 31, 2023
Received: February 1, 2023

Dear Anoop Joy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222438

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

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K222438

1. APPLICANT

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue,
Tarrytown, NY 10591 USA

Contact: Anoop Joy
Regulatory Clinical Affairs Specialist
Phone: (516) 232-3307
E-mail: anoop.joy@siemens-healthineers.com

Date Prepared: July 20, 2023

2. Regulatory Information

Assay: A-LYTE Integrated Multisensor (IMT Na K Cl)

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

Classification Name: Electrode, Ion Specific, Sodium
Regulation: 21CFR862.1665
Classification: Class II
Product Code: JGS
Panel: Clinical Chemistry

Classification Name: Electrode, Ion Specific, Chloride
Regulation: 21CFR862.1170
Classification: Class II
Product Code: CGZ
Panel: Clinical Chemistry

Classification Name: Electrode, Ion Specific, Potassium
Regulation: 21CFR862.1600
Classification: Class II
Product Code: CEM
Panel: Clinical Chemistry

3. PREDICATE DEVICE INFORMATION

Predicate Device	510(k) #	Class	Code
TD-LYTE Integrated Multisensor (Na, K, Cl)[1]	K151767	Class II	JGS CEM CGZ

[1]Note: TD-LYTE Integrated Multisensor (Na, K, Cl) was renamed as A-LYTE Integrated Multisensor (Na, K, Cl) in K161954. The assay was commercialized as A-LYTE Integrated Multisensor (Na, K, Cl).

4. DEVICE DESCRIPTION

The A-LYTE Na, K, and Cl assays use 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 multisensor.

A diluted sample (1:10 with A-LYTE IMT Diluent (IMT Diluent)) is positioned in the sensor and Na+, K+ or 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.

5. INTENDED 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.

6. INDICATIONS FOR USE

Same as Intended use

7. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Below is a features comparison for the A-LYTE Integrated Multisensor (IMT Na K Cl) on the Atellica CI Analyzer and the predicate device Trinidad CH System.

Feature	**Predicate Device:** **TD-LYTE on Trinidad CH System[1]**	**New Device:** **IMT Na K Cl on Atellica CI Analyzer**
Intended Use:	The TD-LYTE Integrated Multisensor is intended for the in vitro diagnostic use in the quantitative determination of sodium, potassium and chloride (Na, K, Cl) in human serum, plasma and urine using the Trinidad CH System	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.
Indications for Use:	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.	Same
Device Technology:	Indirect potentiometric measurements with Integrated Multisensor Technology (IMT)	Same
Sample Type:	Serum/plasma/urine	Same
Instrument:	Trinidad CH System[1]	Atellica CI Analyzer
Analytical Measuring Interval:	**Serum/Plasma** Na: 50 – 200 mmol/L K: 1– 10 mmol/L Cl: 50 – 200 mmol/L **Urine**	Same

	Na: 10 – 300 mmol/L K: 2 – 300 mmol/L Cl: 20 – 330 mmol/L	
Reference Interval:	**Serum / Plasma** Na: 136–145 mmol/L K (serum): 3.5–5.1 mmol/L K (plasma): 3.4-4.5 mmol/L Cl: 98–107 mmol/L **Urine** Na: 40–220 mmol/L K: 25–125 mmol/L Cl: 110–250 mmol/L	Same

[1]Note: Trinidad CH System was renamed as Atellica CH System in K161954. The system was commercialized as Atellica CH System.

8. PERFORMANCE CHARACTERISTICS DATA

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2. The Na assay is designed to have a limit of quantitation (LoQ) ≤ 50 mmol/L (50 mEq/L) with ≤ 20% total error for serum and plasma, and ≤ 10 mmol/L (10 mEq/L) with ≤ 30% total error for urine. The K assay is designed to have a LoQ ≤ 1 mmol/L (1 mEq/L) with ≤ 20% total error for serum and plasma, and ≤ 2 mmol/L (2 mEq/L) with ≤ 30% total error for urine. The Cl assay is designed to have a LoQ ≤ 50 mmol/L (50 mEq/L) with ≤ 20% total error for serum and plasma, and ≤ 20 mmol/L (20 mEq/L) with ≤ 30% total error for urine.

Sample Type	Assay	Limit of Quantitation (LoQ) mmol/L (mEq/L)	Determinations	Total Analytical Error Limit (%)[a]
Serum and plasma	Na	43.4 (43.4)	180	≤ 20
Urine	Na	6.12 (6.12)	180	≤ 30
Serum and plasma	K	0.606 (0.606)	180	≤ 20
Urine	K	1.22 (1.22)	180	≤ 30
Serum and plasma	Cl	40.4 (40.4)	180	≤ 20
Urine	Cl	8.70 (8.70)	180	≤ 30

[a] Calculated using the Westgard model.

Linearity

Linearity studies were performed following CLSI EP06-ED2. Dilution series composed of at least nine levels created by mixing the high and low pools of serum and urine. Measurements were made with N=5 replicates per level. The results of the linear regression analysis are summarized in the table below.

Specimen Type	Regression	Claimed Linear Range
Serum (Na)	y=0.9858x - 0.53	50–200 mmol/L (mEq/L)
Serum (K)	y=0.98229x - 0.0085	1–10 mmol/L (mEq/L)
Serum (Cl)	y=1.00040x + 0.037	50–200 mmol/L (mEq/L)
Urine (Na)	y=0.9505x - 5.556	10–300 mmol/L (mEq/L)
Urine (K)	y=0.9668x - 0.020	2–300 mmol/L (mEq/L)
Urine (Cl)	y=1.00429x - 2.135	20–330 mmol/L (mEq/L)

The results demonstrated linearity of the claimed measuring range.

Precision

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

Sodium (Na)

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

Potassium (K)

Sample Type	N	Mean mmol/L (mEq/L)	Repeatability SD[a] mmol/L (mEq/L)	Repeatability CV[b] (%)	Within-Laboratory Precision SD mmol/L (mEq/L)	Within-Laboratory Precision CV (%)
Serum QC 1	80	2.44 (2.44)	0.01 (0.01)	0.5	0.03 (0.03)	1.1
Serum QC 2	80	4.04 (4.04)	0.01 (0.01)	0.4	0.04 (0.04)	1.1
Serum 1	80	6.03 (6.03)	0.02 (0.02)	0.4	0.07 (0.07)	1.2
Serum QC 3	80	7.16 (7.16)	0.02 (0.02)	0.3	0.08 (0.08)	1.1
Urine QC 1	80	30.8 (30.8)	0.10 (0.10)	0.3	0.28 (0.28)	0.9
Urine QC 2	80	75.4 (75.4)	0.15 (0.15)	0.2	0.79 (0.79)	1.0
Urine 1	80	248 (248)	1.01 (1.01)	0.4	3.21 (3.21)	1.3

Chloride (Cl)

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

[a] Standard deviation.
[b] Coefficient of variation.

Assay Comparison

The performance of the Atellica CH IMT Na K Cl assay on the Atellica CI Analyzer (y) was compared with the performance of the comparative assay on the indicated system (x) and is designed to have a correlation coefficient of ≥ 0.980. The A-LYTE Na assay is designed to have a slope of 1.00 ± 0.05 for serum and urine specimens. The A-LYTE K assay is designed to have a slope of 1.00 ± 0.07 for serum specimens, and a slope of 1.00 ± 0.05 for urine specimens. The A-LYTE Cl assay is designed to have a slope of 1.00 ± 0.05 for serum and urine specimens. Assay comparison was determined using the Weighted Deming regression model in accordance with CLSI Document EP09c. The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Atellica CH Na on Atellica CH Analyzer	y = 1.00x - 2.69 mmol/L (y = 1.00x - 2.69 mEq/L)	53.2–192 mmol/L (53.2–192 mEq/L)	123	0.998
Urine	Atellica CH Na on Atellica CH Analyzer	y = 1.02x - 4.47 mmol/L (y = 1.02x - 4.47 mEq/L)	20.1–237 mmol/L (20.1–237 mEq/L)	117	0.999
Serum	Atellica CH K on Atellica CH Analyzer	y = 0.97x + 0.0353 mmol/L (y = 0.97x + 0.0353 mEq/L)	1.40–9.85 mmol/L (1.40–9.85 mEq/L)	119	1.000
Urine	Atellica CH K on Atellica CH Analyzer	y = 1.02x -0.209 mmol/L (y = 1.02x -0.209 mEq/L)	6.22–246 mmol/L (6.22–246 mEq/L)	117	0.999
Serum	Atellica CH Cl on Atellica CH Analyzer	y = 0.99x + 0.161 mmol/L (y = 0.99x + 0.161 mEq/L)	52.7–196 mmol/L (52.7–196 mEq/L)	123	0.999
Urine	Atellica CH Cl on Atellica CH Analyzer	y = 0.99x - 0.582 mmol/L (y = 0.99x - 0.582 mEq/L)	24.3–314 mmol/L (24.3–314 mEq/L)	127	0.991

[a] Number of samples tested.
[b] Correlation coefficient.

Reproducibility

Reproducibility was determined in accordance with CLSI Document EP05-A3.13 Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 sensor lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

Sodium (Na)

			Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
Sample	N[a]	Mean mmol/L (mEq/L)	SD[b] mmol/L (mEq/L)	CV[c] (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)
Serum QC	225	113 (113)	0.40 (0.40)	0.4	1.00 (1.00)	0.8	0.00 (0.00)	0.0	0.00 (0.00)	0.0	1.00 (1.00)	0.9
Serum QC	225	154 (154)	0.50 (0.50)	0.3	1.10 (1.10)	0.7	0.70 (0.70)	0.5	1.40 (1.40)	0.9	2.00 (2.00)	1.3
Normal Human Serum	225	139 (139)	0.40 (0.40)	0.3	0.80 (0.80)	0.6	0.20 (0.20)	0.1	0.90 (0.90)	0.7	1.30 (1.30)	0.9
Normal Human Serum	225	70.1 (70.1)	0.24 (0.24)	0.3	1.23 (1.23)	1.8	0.94 (0.94)	1.3	0.25 (0.25)	0.4	1.59 (1.59)	2.3
Normal Human Urine	225	30.4 (30.4)	0.38 (0.38)	1.3	0.75 (0.75)	2.5	0.52 (0.52)	1.7	0.43 (0.43)	1.4	1.08 (1.08)	3.5
Normal Human Urine	225	81.1 (81.1)	0.26 (0.26)	0.3	1.35 (1.35)	1.7	0.04 (0.04)	0.1	0.49 (0.49)	0.6	1.46 (1.46)	1.8
Normal Human Urine	225	150 (150)	0.50 (0.50)	0.3	2.40 (2.40)	1.6	1.50 (1.50)	1.0	2.00 (2.00)	1.3	3.50 (3.50)	2.3
Normal Human Urine	225	267 (267)	1.00 (1.00)	0.4	8.40 (8.40)	3.2	3.70 (3.70)	1.4	1.50 (1.50)	0.6	9.30 (9.30)	3.5

Potassium (K)

			Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
Sample	N[a]	Mean mmol/L (mEq/L)	SD[b] mmol/L (mEq/L)	CV[c] (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)
Serum QC	225	2.47 (2.47)	0.03 (0.03)	1.2	0.02 (0.02)	0.6	0.00 (0.00)	0.0	0.03 (0.03)	1.1	0.04 (0.04)	1.7
Serum QC	225	7.27 (7.27)	0.03 (0.03)	0.4	0.05 (0.05)	0.7	0.01 (0.01)	0.2	0.05 (0.05)	0.7	0.08 (0.08)	1.1

Normal Human Serum	225	4.30 (4.30)	0.01 (0.01)	0.2	0.02 (0.02)	0.6	0.01 (0.01)	0.1	0.03 (0.03)	0.7	0.04 (0.04)	1.0
Normal Human Serum	225	6.14 (6.14)	0.01 (0.01)	0.2	0.04 (0.04)	0.6	0.01 (0.01)	0.2	0.04 (0.04)	0.6	0.06 (0.06)	0.9
Normal Human Urine	225	31.3 (31.3)	0.07 (0.07)	0.2	0.40 (0.40)	1.3	0.07 (0.07)	0.2	0.07 (0.07)	0.2	0.42 (0.42)	1.3
Normal Human Urine	225	68.5 (68.5)	0.24 (0.24)	0.4	1.28 (1.28)	1.9	0.24 (0.24)	0.4	0.24 (0.24)	0.3	1.35 (1.35)	2.0
Normal Human Urine	225	256 (256)	0.70 (0.70)	0.3	2.30 (2.30)	0.9	1.00 (1.00)	0.4	1.30 (1.30)	0.5	2.90 (2.90)	1.1

Chloride (Cl)

			Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
Sample	N[a]	Mean mmol/L (mEq/L)	SD[b] mmol/L (mEq/L)	CV[c] (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)	SD mmol/L (mEq/L)	CV (%)
Serum QC	225	78.1 (78.1)	0.29 (0.29)	0.4	0.79 (0.79)	1.0	0.41 (0.41)	0.5	0.08 (0.08)	0.1	0.94 (0.94)	1.2
Serum QC	225	119 (119)	0.50 (0.50)	0.4	0.90 (0.90)	0.7	0.30 (0.30)	0.3	0.20 (0.20)	0.2	1.10 (1.10)	0.9
Normal Human Serum	225	108 (108)	0.30 (0.30)	0.3	0.80 (0.80)	0.7	0.20 (0.20)	0.2	0.30 (0.30)	0.3	0.90 (0.90)	0.8
Normal Human Serum	225	172 (172)	0.40 (0.40)	0.2	1.40 (1.40)	0.8	0.00 (0.00)	0.0	0.90 (0.90)	0.6	1.80 (1.80)	1.0
Normal Human Urine	225	41.7 (41.7)	0.23 (0.23)	0.6	1.19 (1.19)	2.9	0.10 (0.10)	0.2	0.02 (0.02)	0.1	1.22 (1.22)	2.9
Normal Human Urine	225	104 (104)	0.40 (0.40)	0.4	3.00 (3.00)	2.9	0.40 (0.40)	0.3	0.70 (0.70)	0.7	3.10 (3.10)	3.0
Normal Human Urine	225	206 (206)	0.50 (0.50)	0.2	2.00 (2.00)	1.0	0.30 (0.30)	0.1	1.40 (1.40)	0.7	2.50 (2.50)	1.2
Normal Human Urine	225	270 (270)	0.70 (0.70)	0.3	3.90 (3.90)	1.4	0.00 (0.00)	0.0	2.70 (2.70)	1.0	4.70 (4.70)	1.8

a Number of results.
b Standard deviation.
c Coefficient of variation.

Specimen Equivalency

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09c. The following results were obtained:

Assay	Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Na	Lithium heparin plasma	Serum	y = 1.02x - 1.87 mmol/L (y = 1.02x - 1.87 mEq/L)	53.4–190 mmol/L (53.4–190 mEq/L)	138	0.994
K[c]	Lithium heparin plasma	Serum	y = 0.99x - 0.207 mmol/L (y = 0.99x - 0.207 mEq/L)	1.41–9.33 mmol/L (1.41–9.33 mEq/L)	56	0.983
Cl	Lithium heparin plasma	Serum	y = 1.00x - 0.201 mmol/L (y = 1.00x - 0.201 mEq/L)	53.7–197 mmol/L (53.7–197 mEq/L)	136	0.998

[a] Number of samples tested.
[b] Correlation coefficient.
[c] 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.

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

The A-LYTE IMT Na K Cl multisensor was evaluated for interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07 using the A-LYTE IMT Na K Cl multisensor. Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Serum/Plasma Interference - Sodium (Na)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	1000 mg/dL (10 g/L)	136 (136)	-6
	1000 mg/dL (10 g/L)	159 (159)	-6
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	128 (128)	1
	60 mg/dL (1026 µmol/L)	146 (146)	1
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	132 (132)	0
	60 mg/dL (1026 µmol/L)	151 (151)	0
Lipemia (Intralipid®)	3000 mg/dL (30 g/L)	122 (122)	1
	3000 mg/dL (30 g/L)	140 (140)	1
Lipemia (Trig Fraction)	1125 mg/dL (11.3 g/L)	124 (124)	4
	1125 mg/dL (11.3 g/L)	145 (145)	4

Serum/Plasma Interference - Potassium (K)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	2.92 (2.92)	0
	60 mg/dL (1026 µmol/L)	4.98 (4.98)	0
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	2.87 (2.87)	0
	60 mg/dL (1026 µmol/L)	4.84 (4.84)	0
Lipemia (Intralipid)	3000 mg/dL (30 g/L)	2.74 (2.74)	6
	3000 mg/dL (30 g/L)	4.53 (4.53)	1
Lipemia (Trig Fraction)	2000 mg/dL (20.0 g/L)	3.04 (3.04)	2
	2000 mg/dL (20.0 g/L)	5.45 (5.45)	-1

Serum/Plasma Interference - Chloride (Cl)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	1000 mg/dL (10 g/L)	93.6 (93.6)	-9
	1000 mg/dL (10 g/L)	119 (119)	-7
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	89.1 (89.1)	0
	60 mg/dL (1026 µmol/L)	112 (112)	0
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	90.5 (90.5)	0
	60 mg/dL (1026 µmol/L)	113 (113)	-1
Lipemia (Intralipid)	3000 mg/dL (30 g/L)	91.9 (91.9)	2
	3000 mg/dL (30 g/L)	118 (118)	1
Lipemia (Trig Fraction)	1125 mg/dL (11.3 g/L)	85.6 (85.6)	6
	1125 mg/dL (11.3 g/L)	103 (103)	5

Urine Interference - Sodium (Na)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	500 mg/dL (5 g/L)	58.2 (58.2)	-9
	500 mg/dL (5 g/L)	214 (214)	-2
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	47.0 (47.0)	2
	60 mg/dL (1026 µmol/L)	197 (197)	2
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	51.8 (51.8)	-1
	60 mg/dL (1026 µmol/L)	205 (205)	1

Lipemia (Intralipid)	2000 mg/dL (20 g/L)	43.8 (43.8)	2
	2000 mg/dL (20 g/L)	189 (189)	1
Lipemia (Trig Fraction)	250 mg/dL (2.5 g/L)	47.7 (47.7)	6
	250 mg/dL (2.5 g/L)	205 (205)	2

Urine Interference - Potassium (K)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	750 mg/dL (7.5 g/L)	24.1 (24.1)	9
	750 mg/dL (7.5 g/L)	184 (184)	2
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	21.2 (21.2)	0
	60 mg/dL (1026 µmol/L)	191 (191)	1
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	21.1 (21.1)	-1
	60 mg/dL (1026 µmol/L)	191 (191)	-1
Lipemia (Intralipid)	2000 mg/dL (20 g/L)	20.3 (20.3)	1
	2000 mg/dL (20 g/L)	184 (184)	1
Lipemia (Trig Fraction)	2000 mg/dL (20 g/L)	21.8 (21.8)	3
	2000 mg/dL (20 g/L)	177 (177)	2

Urine Interference - Chloride (Cl)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mmol/L (mEq/L)	Percent Bias
Hemoglobin	500 mg/dL (5 g/L)	56.9 (56.9)	-7
	500 mg/dL (5 g/L)	210 (210)	-2
Bilirubin, conjugated	60 mg/dL (1026 µmol/L)	52.7 (52.7)	-1
	60 mg/dL (1026 µmol/L)	212 (212)	-1
Bilirubin, unconjugated	60 mg/dL (1026 µmol/L)	54.9 (54.9)	0
	60 mg/dL (1026 µmol/L)	210 (210)	-1
Lipemia (Intralipid)	2000 mg/dL (20 g/L)	54.7 (54.7)	1
	2000 mg/dL (20 g/L)	200 (200)	1
Lipemia (Trig Fraction)	500 mg/dL (5.0 g/L)	53.9 (53.9)	8
	500 mg/dL (5.0 g/L)	202 (202)	2

Non-Interfering Substances

The following substances do not interfere with the A-LYTE IMT Na K Cl multisensor at the concentrations indicated in the table below. Bias due to these substances is ≤ 10%. The Na and Cl assay interferences were tested with urine pools at approximately 50 mmol/L and 200 mmol/L of Na and Cl. The K assay interference was tested with urine pools at approximately 25 mmol/L and 200 mmol/L of K. The Na assay interferences were tested with serum pools at approximately 130 mmol/L and 150 mmol/L of Na. The K assay interference was tested with serum pools at approximately 3 mmol/L and 5 mmol/L of K. The Cl assay interference was tested with serum pools at approximately 90 mmol/L and 110 mmol/L of Cl.

Substance	Specimen Type	Substance Test Concentration Common Units (SI Units)
Acetaminophen	Urine	200 mg/dL (13,231 µmol/L)
N-Acetyl cysteine	Urine	2 mg/dL (123 µmol/L)
Ascorbic acid	Urine	60 mg/dL (3409 µmol/L)
Bromide (Cl)	Serum	35 mg/dL (4375 µmol/L)
Citrate (Na, K)	Serum	1 g/dL (52,051 µmol/L)
Citrate (Cl)	Serum	0.5 g/dL (26,025 µmol/L)
Fluoride (Cl)	Serum	0.25 g/dL (132 µmol/L)
Gentamycin sulfate	Urine	10 mg/dL (194 µmol/L)
Ibuprofen (Na, K)	Urine	500 mg/dL (24,272 µmol/L)
Ibuprofen (Cl)	Urine	400 mg/dL (19,418 µmol/L)
Iodine (Cl)	Serum	25 mg/dL (1975 µmol/L)
Iron (K)	Serum	0.25 g/dL (44,767 µmol/L)
Levodopa	Urine	15 mg/dL (761 µmol/L)
Ofloxacin (Na, K)	Urine	90 mg/dL (2491 µmol/L)
Ofloxacin (Cl)	Urine	80 mg/dL (2214 µmol/L)
Phenazopyridine	Urine	30 mg/dL (1407 µmol/L)
Salicylate (Cl)[a]	Serum	50 mg/dL (3623 µmol/L)
Sodium cefoxitin	Urine	660 mg/dL (14,686 µmol/L)
Tetracycline	Urine	15 mg/dL (338 µmol/L)
Low pH	Urine	pH 4
High pH	Urine	pH 8

[a] Bias due to salicylate is ≤ 15%.

9. CONCLUSION

The candidate devices are substantially equivalent to the Predicate devices and yields substantially equivalent Performance Characteristics.