DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 24, 2017

ABBOTT LABORATORIES
ZAMAN KHAN
ASSOCIATE DIRECTOR, REGULATORY AFFAIRS
DEPT. 09AA, BLDG. CP01-3
100 ABBOTT PARK ROAD
ABBOTT PARK IL 60064

Re: K170320
Trade/Device Name: Alinity c ICT Sample Diluent
Regulation Number: 21 CFR 862.1170
Regulation Name: Chloride test system
Regulatory Class: II
Product Code: CGZ, CEM, JGS
Dated: September 12, 2017
Received: September 13, 2017

Dear Zaman Khan:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k170320

Device Name
Alinity c ICT Sample Diluent

Indications for Use *(Describe)*
The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

Sodium measurements 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.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases 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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k170320
510(k) Summary (Summary of Safety and Effectiveness)

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

I. Applicant Name

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Date Summary Prepared: January 31, 2017

Date Summary Revised: October 19, 2017

II. Device Name

Alinity c ICT Sample Diluent

Device Classification: Class II
Classification Name: Electrode, ion-specific, chloride/potassium/sodium
Governing Regulation: 862.1170/862.1600/862.1665
Product Code: CGZ/CEM/JGS

III. Predicate Device

Reagent

ICT (Na^+, K^+, Cl^-) Sample Diluent (k980367), List No. (LN) 2P32 for use on Abbott ARCHITECT *c*8000 and Abbott AEROSET

IV. Description of Device

A. Alinity c ICT Sample Diluent

Kit Contents

Volumes (mL) listed in the table below indicate the volume per cartridge.

Component	**07P5320**
Tests per cartridge	935
Number of cartridges per kit	10
Test per kit	9350
Reagent 1 (R1)	68.2 mL

Reagent	**Active Ingredient**	**Concentration**
Reagent 1	Buffer	NA

B. Calibrators

1. The Alinity c ICT Serum Calibrator contains:

5 Bottles (2.9 mL each) of Alinity c ICT Serum Calibrators. Calibrators L and H contain Bovine Serum Albumin, Sodium chloride, Potassium chloride, and Sodium nitrate.

	Concentration		
Calibrator	**Sodium**	**Potassium**	**Chloride**
L	120 mmol/L	3.4 mmol/L	80 mmol/L
H	160 mmol/L	8.0 mmol/L	120 mmol/L

Calibrators L and H are manufactured gravimetrically using ACS grade sodium chloride, potassium chloride, and sodium nitrate. The concentrations of sodium and potassium are determined using flame photometry calibrated against NIST Standard Reference Material. The concentration of chloride is determined using titration with silver calibrated against NIST Standard Reference Material (NIST - National Institute of Standards and Technology).

2. Alinity c ICT Urine Calibrator

5 Bottles (2.9 mL each) of Alinity c ICT Urine Calibrators. Calibrators L and H contain sodium chloride, potassium chloride, and sodium nitrate.

	Concentration		
Calibrator	**Sodium**	**Potassium**	**Chloride**
Urine Cal L	50 mmol/L	9.0 mmol/L	50 mmol/L
Urine Cal H	180 mmol/L	90.0 mmol/L	180 mmol/L

Calibrators L and H are manufactured gravimetrically using ACS grade sodium chloride, potassium chloride, and sodium nitrate. The concentrations of sodium, potassium, and chloride are determined using reference method (flame photometry, titration using silver) calibrated against NIST SRM 918 and NIST SRM 919 (NIST - National Institute of Standards and Technology).

C. Principles of the Procedure

Ion-selective electrodes (ISE) for sodium, potassium, and chloride utilize membranes selective to each of these ions. An electrical potential (voltage) is developed across the membranes between the reference and measuring electrodes in accordance with the Nernst equation. The voltage is compared to previously determined calibrator voltages and converted into ion concentration.

Methodology: Ion-selective electrode diluted (Indirect)

V. Intended Use of the Device

The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

Sodium measurements 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.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases 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.

VI. Comparison of Technological Characteristics

The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c System.

A comparison of the candidate assay (Alinity c ICT Sample Diluent, List No. 07P53) and the predicate assay (ICT (Na^+, K^+, Cl^-) Sample Diluent, List No. 2P32 on the ARCHITECT System) is presented in Table 1 and Table 2 starting on page 5.

Table 1: Assay Similarities

Characteristics	Candidate Assay Alinity c ICT Sample Diluent (LN 07P53)	Predicate Assay (k980367) ICT (Na^+, K^+, Cl^-) Sample Diluent Assay on the AEROSET/ARCHITECT *c*8000 System (LN 2P32)
Technical Characteristics		
Reagent Formulation	Active Ingredient: Buffer	Same bulk as Alinity c.
Analyte Measured	Sodium, potassium, and chloride.	Same
Intended Use/Indications for Use	The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine.	Same
Assay Principle	Ion-selective electrode diluted (Indirect).	Same
Detection of Analyte	Potentiometric.	Same
Specimen Type	Human serum, plasma or urine.	Same
Performance Characteristics		
Assay Range	**Serum/Plasma** Sodium: 100 to 200 mmol/L. Potassium 1.0 to 10.0 mmol/L. Chloride: 50 to 150 mmol/L. **Urine** Sodium: 20 to 400 mmol/L. Potassium: 1.0 to 300.0 mmol/L. Chloride: 20 to 300 mmol/L.	Same
Measuring Interval	**Serum/Plasma** The measuring interval for the sodium assay is 100 to 200 mmol/L. The measuring interval for the potassium assay is 1.0 to 10.0 mmol/L. The measuring interval for the chloride assay is 50 to 150 mmol/L. **Urine** The measuring interval for the sodium assay is 20 to 400 mmol/L. The measuring interval for the potassium assay is 1.0 to 300.0 mmol/L. The measuring interval for the chloride assay is 20 to 300 mmol/L.	Same

Characteristics	Candidate Assay Alinity c ICT Sample Diluent (LN 07P53)	Predicate Assay (k980367) ICT (Na^+, K^+, Cl^-) Sample Diluent Assay on the AEROSET/ARCHITECT *c*8000 System (LN 2P32)
Tube Type Equivalency	**Serum** Serum tubes (with or without gel barrier). **Plasma** Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin (full draw)	Same
Use of Calibrators	Yes	Same
Use of Controls	Yes, commercially available controls	Same

Table 2: Assay Differences

Assay Characteristics	Candidate Assay Alinity c ICT Sample Diluent (LN 07P53)	Predicate Assay (k980367) ICT (Na^+, K^+, Cl^-) Sample Diluent Assay on the AEROSET/ARCHITECT *c*8000 System (LN 2P32)
Technical Characteristics		
Reagent Container	Polypropylene Black colorant	High Density Polyethylene Natural color (Contains no colorant)
Closure Material (contact only)	High Density Polyethylene Black color	F217 cap liner Polyethylene Foam between Low-Density Polyethylene liners Green color.

VII. Summary of Nonclinical Performance

Within-Laboratory Precision (20-Day)

Alinity c ICT Sample Diluent Sodium assay – Serum Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

				Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**Control Lot**	**n**	**Mean (mmol/L)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	1	249	125	0.5	0.4	0.9 (0.8 – 1.0)	0.7 (0.6 – 0.8)
	2	249	125	0.5	0.4	0.9 (0.8 - 0.9)	0.7 (0.6 – 0.8)
Control Level 2	1	252	144	0.5	0.4	0.9 (0.8 – 1.0)	0.6 (0.6 – 0.7)
	2	249	144	0.5	0.4	0.9 (0.8 – 1.0)	0.6 (0.5 – 0.7)
Control Level 3	1	249	161	0.5	0.3	1.0 (0.9 – 1.1)	0.6 (0.6 – 0.7)
	2	249	161	0.6	0.4	1.1 (0.9 – 1.2)	0.7 (0.6 – 0.7)
Panel A	N/A	496	112	0.4	0.4	0.8 (0.6 – 0.9)	0.7 (0.6 – 0.8)
Panel B	N/A	498	190	0.8	0.4	1.4 (1.2 – 1.6)	0.7 (0.6 – 0.9)

[a] Includes within-run, between-run, and between-day variability.
[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

The precision of the Alinity c ICT Sample Diluent Sodium assay was considered acceptable if the within-laboratory (total) imprecision (within-run, between-run, and between-day) was ≤ 1.5 % CV for serum samples targeted between 131.0 to 153.0 mmol/L.

The Alinity c ICT Sample Diluent Sodium assay demonstrated acceptable precision.

Alinity c ICT Sample Diluent Potassium assay – Serum Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

				Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**Control Lot**	**n**	**Mean (mmol/L)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	1	246	2.8	0.03	0.9	0.04 (0.04-0.04)	1.4 (1.3-1.5)
	2	246	2.8	0.01	0.3	0.01 (0.00-0.02)	0.4 (0.0-0.6)
Control Level 2	1	246	4.0	0.02	0.6	0.03 (0.03-0.03)	0.8 (0.8-0.9)
	2	246	4.0	0.01	0.3	0.02 (0.02-0.02)	0.5 (0.5-0.5)
Control Level 3	1	246	6.8	0.03	0.4	0.05 (0.04-0.05)	0.7 (0.6-0.7)
	2	246	6.8	0.03	0.5	0.05 (0.04-0.05)	0.7 (0.6-0.7)
Panel A	N/A	491	1.6	0.02	1.1	0.03 (0.00-0.04)	1.7 (0.0-2.7)
Panel B	N/A	492	9.4	0.04	0.4	0.06 (0.05-0.07)	0.7 (0.5-0.8)

[a] Includes within-run, between-run, and between-day variability.
[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

The precision Alinity c ICT Sample Diluent Potassium assay was considered acceptable if the within-laboratory (total) imprecision (within-run, between-run, and between-day) was ≤ 2.7 % CV for serum samples targeted between 4.0 to 6.0 mmol/L.

The Alinity c ICT Sample Diluent Potassium assay demonstrated acceptable precision.

Alinity c ICT Sample Diluent Chloride assay – Serum Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
				SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	1	243	85	0.5	0.6	0.7 (0.6-0.8)	0.8 (0.7-0.9)
	2	243	84	0.4	0.5	0.6 (0.5-0.7)	0.7 (0.5-0.9)
Control Level 2	1	243	95	0.4	0.4	0.6 (0.6-0.7)	0.7 (0.6-0.8)
	2	243	94	0.4	0.5	0.6 (0.5-0.7)	0.6 (0.5-0.7)
Control Level 3	1	243	110	0.5	0.5	0.8 (0.6-0.9)	0.7 (0.5-0.9)
	2	243	109	0.5	0.5	0.7 (0.5-0.9)	0.7 (0.5-0.8)
Panel A	N/A	486	55	0.3	0.6	0.6 (0.4-0.6)	1.0 (0.8-1.2)
Panel B	N/A	485	132	0.6	0.4	1.0 (0.7-1.3)	0.8 (0.5-0.9)

[a] Includes within-run, between-run, and between-day variability.
[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

The precision Alinity c ICT Sample Diluent Chloride assay was considered acceptable if the within-laboratory (total) imprecision (within-run, between-run, and between-day) was ≤ 2.0 % CV for serum samples targeted between 89.0 to 99.0 mmol/L.

The Alinity c ICT Sample Diluent Chloride assay demonstrated acceptable precision.

Alinity c ICT Sample Diluent Sodium assay – Urine Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
				SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	1	240	92	0.6	0.7	1.0 (0.9-1.1)	1.1 (1.0-1.2)
	2	240	92	0.5	0.5	0.7 (0.7-0.8)	0.8 (0.7-0.9)
Control Level 2	1	240	161	0.7	0.4	1.0 (0.9-1.1)	0.6 (0.6-0.7)
	2	240	161	0.6	0.4	1.5 (1.0-1.8)	0.9 (0.7-1.1)
Panel A	N/A	480	21	0.5	2.3	0.6 (0.5-0.8)	2.9 (2.3-3.7)
Panel B	N/A	480	383	1.5	0.4	3.9 (2.5-4.7)	1.0 (0.7-1.2)

[a] Includes within-run, between-run, and between-day variability.
[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

The precision Alinity c ICT Sample Diluent Sodium assay was considered acceptable if the within-laboratory (total) imprecision (within-run, between-run, and between-day) was ≤ 3.0 % CV for urine samples targeted between 79.0 to 181.0 mmol/L.

The Alinity c ICT Sample Diluent Sodium assay demonstrated acceptable precision.

Alinity c ICT Sample Diluent Potassium assay – Urine Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
				SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	1	240	16.6	0.06	0.3	0.13 (0.13-0.14)	0.8 (0.8-0.9)
	2	240	16.6	0.05	0.3	0.12 (0.11-0.12)	0.7 (0.7-0.7)
Control Level 2	1	240	58.1	0.17	0.3	0.34 (0.29-0.39)	0.6 (0.5-0.7)
	2	240	58.2	0.17	0.3	0.49 (0.29-0.62)	0.8 (0.5-1.1)
Panel A	N/A	480	1.7	0.02	1.4	0.04 (0.04-0.04)	2.4 (2.3-2.6)
Panel B	N/A	480	127.7	0.35	0.3	0.68 (0.50-0.83)	0.5 (0.4-0.6)
Panel C	N/A	479	284.5	0.82	0.3	1.91 (1.65-2.12)	0.7 (0.6-0.7)

[a] Includes within-run, between-run, and between-day variability.
[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

The precision Alinity c ICT Sample Diluent Potassium assay was considered acceptable if the within-laboratory (total) imprecision (within-run, between-run, and between-day) was ≤ 3 % CV for urine samples targeted between 31.0 to 84.0 mmol/L.

The Alinity c ICT Sample Diluent Potassium assay demonstrated acceptable precision.

Alinity c ICT Sample Diluent Chloride assay – Urine Samples

Precision was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP05-A2.

A summary of results is presented below:

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
				SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	1	240	103	0.5	0.4	0.9 (0.8-1.0)	0.9 (0.8-0.9)
	2	240	103	0.5	0.5	0.8 (0.8-0.8)	0.8 (0.8-0.8)
Control Level 2	1	240	193	0.7	0.4	1.2 (1.1-1.3)	0.6 (0.6-0.7)
	2	240	193	0.7	0.4	1.9 (1.3-2.4)	1.0 (0.7-1.2)
Panel A	N/A	479	24	0.3	1.1	0.4 (0.1-0.5)	1.6 (0.4-2.2)
Panel B	N/A	480	273	0.9	0.3	2.2 (1.9-2.3)	0.8 (0.7-0.8)

[a] Includes within-run, between-run, and between-day variability.
[b] Maximum and minimum SD or %CV for each reagent lot and instrument combination.

The precision Alinity c ICT Sample Diluent Chloride assay was considered acceptable if the within-laboratory (total) imprecision (within-run, between-run, and between-day) was ≤ 1.8 % CV for urine samples targeted between 79.0 to 218.0 mmol/L.

The Alinity c ICT Sample Diluent Chloride assay demonstrated acceptable precision

Linearity

Alinity c ICT Sample Diluent Sodium, Potassium, Chloride assays – Serum Samples

Linearity was evaluated based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP06-A.

The mean observed linear range concentrations ranged from 27 to 259 mmol/L for the sodium sample set.

The mean observed linear range concentrations ranged from 0.5 to 14.3 mmol/L for the potassium sample set.

The mean observed linear range concentrations ranged from 22 to 172 mmol/L for the chloride sample set.

Alinity c ICT Sample Diluent Sodium, Potassium, Chloride assays – Urine Samples

Linearity was evaluated based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP06-A.

The mean observed linear range concentrations ranged from 1 to 474 mmol/L for the sodium sample set.

The mean observed linear range concentrations ranged from 0.1 to 366.0 mmol/L for the potassium sample set.

The mean observed linear range concentrations ranged from 5 to 346 mmol/L for the chloride sample set.

Measuring Interval

Serum

- The measuring interval of the Alinity c ICT Sodium assay is 100 to 200 mmol/L.
- The measuring interval of the Alinity c ICT Potassium assay is 1.0 to 10.0 mmol/L.
- The measuring interval of the Alinity c ICT Chloride assay is 50 to 150 mmol/L.

Urine

- The measuring interval of the Alinity c ICT Sodium assay is 20 to 400 mmol/L.
- The measuring interval of the Alinity c ICT Potassium assay is 1.0 to 300.0 mmol/L.
- The measuring interval of the Alinity c ICT Chloride assay is 20 to 300 mmol/L.

The measuring interval is defined as the range of values in mmol/L which meets the limits of acceptable performance for linearity, imprecision, and bias. The inputs to the measuring interval include imprecision and linearity.

Interference

Alinity c ICT Sample Diluent Sodium assay Serum Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For sodium serum a bias of > 2% was considered significant interference.

The Alinity c ICT Sample Diluent Sodium assay using the serum application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Unconjugated Bilirubin	≤ 60 mg/dL
Conjugated Bilirubin	≤ 30 mg/dL
Hemoglobin	≤ 500 mg/dL
Triglycerides	≤ 2000 mg/dL
Ascorbic Acid	≤ 6 mg/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 167 mg/dL
Acetylsalicylic Acid	≤ 66 mg/dL
Benzalkonium Chloride	≤ 1 mg/dL

Alinity c ICT Sample Diluent Potassium assay – Serum Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For potassium serum a bias of > 10% was considered significant interference.

The Alinity c ICT Sample Diluent Potassium assay using the serum application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Unconjugated Bilirubin	≤ 60 mg/dL
Conjugated Bilirubin	≤ 60 mg/dL
Hemoglobin	≤ 100 mg/dL
Triglycerides	≤ 2000 mg/dL
Ascorbic Acid	≤ 6 mg/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 167 mg/dL
Acetylsalicylic Acid	≤ 66 mg/dL
Sodium Salicylate	≤ 70 mg/dL
Benzalkonium Chloride	≤ 5 mg/dL

Alinity c ICT Sample Diluent Chloride assay – Serum Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For chloride serum a bias of > 10% was considered significant interference.

The Alinity c ICT Sample Diluent Chloride assay using the serum application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Unconjugated Bilirubin	≤ 60 mg/dL
Conjugated Bilirubin	≤ 20 mg/dL
Hemoglobin	≤ 1000 mg/dL
Triglycerides	≤ 2000 mg/dL
Ascorbic Acid	≤ 6 mg/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 16.7 mg/dL
Acetylsalicylic Acid	≤ 66 mg/dL
Sodium Salicylate	≤ 70 mg/dL
Benzalkonium Chloride	≤ 10 mg/dL
Lithium Bromide	≤ 20 mg/dL
Lithium Iodide	≤ 25.4 mg/dL
Sodium Azide	≤ 325 mg/dL

Alinity c ICT Sample Diluent Sodium assay – Urine Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For sodium urine a bias of > 10% was considered significant interference.

The Alinity c ICT Sample Diluent Sodium assay using the urine application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Protein	≤ 50 mg/dL
Glucose	≤ 1000 mg/dL
Ascorbate	≤ 200 mg/dL
8.5 N Acetic Acid	≤ 6.25 mL/dL
Boric Acid	≤ 250 mg/dL
6 N Hydrochloric Acid	≤ 2.5 mL/dL
6 N Nitric Acid	≤ 5.0 mL/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 167 mg/dL
Conjugated Bilirubin	≤ 60 mg/dL
Hemoglobin	≤ 1000 mg/dL
pH (range)	3.52 to 8.58
Specific Gravity (range)	1.004 to 1.027

Alinity c ICT Sample Diluent Potassium assay – Urine Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For potassium urine a bias of > 10% was considered significant interference.

The Alinity c ICT Sample Diluent Potassium assay using the urine application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Protein	≤ 50 mg/dL
Glucose	≤ 1000 mg/dL
Ascorbate	≤ 200 mg/dL
8.5 N Acetic Acid	≤ 6.25 mL/dL
Boric Acid	≤ 250 mg/dL
6 N Hydrochloric Acid	≤ 2.5 mL/dL
6 N Nitric Acid	≤ 5.0 mL/dL
Sodium Oxalate	≤ 60 mg/dL
Sodium Carbonate	≤ 1.25 g/dL
Sodium Fluoride	≤ 400 mg/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 167 mg/dL
Conjugated Bilirubin	≤ 60 mg/dL
Hemoglobin	≤ 500 mg/dL
pH (range)	3.58 to 8.03
Specific Gravity (range)	1.010 to 1.025

Alinity c ICT Sample Diluent Chloride assay – Urine Samples

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

For potassium urine a bias of > 10% was considered significant interference.

The Alinity c ICT Sample Diluent Chloride assay using the urine application is not susceptible to interference effects from the following interferents at the interferent levels listed in the table below:

Interferent	**Interferent Level**
Protein	≤ 50 mg/dL
Glucose	≤ 1000 mg/dL
Ascorbate	≤ 200 mg/dL
8.5 N Acetic Acid	≤ 6.25 mL/dL
Boric Acid	≤ 250 mg/dL
6 N Nitric Acid	≤ 5.0 mL/dL
Sodium Carbonate	≤ 1.25 g/dL
Sodium Fluoride	≤ 400 mg/dL
Sodium Oxalate	≤ 60 mg/dL
Acetaminophen	≤ 20 mg/dL
Ibuprofen	≤ 50 mg/dL
Acetylcysteine	≤ 16.7 mg/dL
Conjugated Bilirubin	≤ 60 mg/dL
Hemoglobin	≤ 1000 mg/dL
pH (range)	3.52 to 7.97
Specific Gravity (range)	1.006 to 1.033

Method Comparison

Alinity c ICT Sample Diluent Sodium, Potassium and Chloride assay – Serum and Urine Samples

The method comparison study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP09-A3.

Human serum and urine specimens that spanned the measuring interval of the assay were evaluated for serum and urine testing respectively.

The results analyzed using Passing-Bablok regression method are summarized in the tables below:

Sodium

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Sodium vs ARCHITECT Sodium	Serum	mmol/L	141	1.00	-0.50	1.00	101-197
	Urine	mmol/L	101	1.00	0.88	0.99	22-386

Potassium

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Potassium vs ARCHITECT Potassium	Serum	mmol/L	122	1.00	0.00	1.00	1.3-9.4
	Urine	mmol/L	107	1.00	-1.23	1.05	4.3-266.1

Chloride

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Chloride vs ARCHITECT Chloride	Serum	mmol/L	120	1.00	0.00	1.00	52-148
	Urine	mmol/L	112	1.00	-0.30	1.00	25-299

The method comparison study results for the investigational method, Alinity c ICT Sample Diluent Sodium, Potassium, and Chloride, versus the comparator method, ARCHITECT ICT Sample Diluent Sodium, Potassium, and Chloride, are acceptable.

Tube Type Equivalency

Alinity c ICT Sample Diluent Sodium, Potassium, and Chloride assay

Tube type equivalency was performed based on guidance from the Clinical Laboratory Standards Institute (CLSI) document EP07-A2 to evaluate whether specific blood collection tube types are suitable for use with the Alinity c ICT Sample Diluent for the Sodium, Potassium, and Chloride assays.

Samples were collected from a minimum of 40 donors and evaluated across tube types.

The following blood collection tube types are acceptable for use with the Alinity c ICT Sample Diluent Sodium, Potassium, and Chloride assays:

- Serum
- Serum separator
- Lithium heparin
- Sodium heparin
- Lithium heparin plasma separator

VIII. Summary of Clinical Performance

This section does not apply.

IX. Conclusion Drawn from Nonclinical Laboratory Studies

The similarities and differences between the candidate assay (Alinity c ICT Sample Diluent, List No. 07P53) and the predicate assay (ICT (Na^+, K^+, Cl^-) Sample Diluent, List No. 2P32) are presented in the table on page 5. The minor differences between the candidate ICT sodium, potassium and chloride assays and the predicate ICT sodium, potassium and chloride assays raise no new issues of safety and effectiveness. The performance results presented in this 510(k) demonstrate that the Alinity c ICT Sample Diluent is safe and effective for the stated intended use.

The results presented in this 510(k) premarket notification demonstrate that the Alinity c ICT Sample Diluent is substantially equivalent to the respective predicate device (ICT (Na^+, K^+, Cl^-) Sample Diluent (k980367)).