510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k170320

B. Purpose for Submission:

New device

C. Measurand:

Sodium, Potassium, Chloride

D. Type of Test:

Quantitative ion selective electrodes

E. Applicant:

Abbott Laboratories

F. Proprietary and Established Names:

Alinity c ICT Sample Diluent

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JGS	II	862.1665, Sodium Test System	75-Chemistry
CEM	II	862.1600, Potassium Test System	75-Chemistry
CGZ	II	862.1170, Chloride Test System	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) 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 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.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   Alinity c System (cleared in k170316)

I. Device Description:

The Alinity c ICT Sample Diluent is for use with the Alinity c ICT module on the Alinity c System. The Alinity c ICT Sample Diluent consists of 68.2 mL reagent 1 and buffer for 9350 tests (935 tests per cartridge, x10 cartridges per kit). One test per sample can generate one to three results (Na+, K+, and Cl-).

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Abbott AEROSET System

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

   k980367

3. Comparison with predicate:

Similarities		
Item	Candidate Device Alinity c ICT Sample Diluent on the Alinity c System k170320	Predicate Device AEROSET System k980367
Intended Use	For the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine.	Same
Analyte Measured	Sodium, Potassium, and Chloride	Same
Assay Principle	Solid-state ion-selective electrode diluted (Indirect) with an Integrated Chip Technology module	Same
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
Detection of Analyte	Potentiometric	Same
Specimen Type	Human serum, plasma, or urine	Same

Differences		
Item	Candidate Device Alinity c ICT Sample Diluent on the Alinity c System k170320	Predicate AEROSET System k980367
Closure material for reagent container	High Density Polyethylene Black color	F217 cap liner Polyethylene foam between Low-Density Polyethylene liners Green color
Reagent Container	Polypropylene Black colorant	High Density Polyethylene Natural color (Does not contain colorant)

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

CLSI C24-A3: Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approve Guideline, 3rd Edition

CLSI EP05-A2: Evaluation of Precision of Quantitative Measurement Methods, 2nd Edition

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach, 2nd Edition

CLSI EP07-A2: Interference Testing in Clinical Chemistry, 2nd Edition

CLSI EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition

CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents, Approved Guideline

L. Test Principle:

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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision testing was performed in accordance with CLSI EP05-A2 guideline. Precision for Na+, K+, and Cl- were evaluated by testing two lots of controls, serum pools, and urine pools in three replicates per run, two runs per day for 20 days. Serum and urine pools were tested using two reagent lots. The studies were performed on two instruments.
Precision studies for serum sodium, potassium, and chloride are shown in the table below for one representative lot.

			Within-run		Total*	
Test	Samples	Mean (mmol/L)	SD	%CV	SD	%CV
Serum Na+	Control Level 1	125	0.5	0.4	0.9	0.7
	Control Level 2	144	0.5	0.4	0.9	0.6
	Control Level 3	161	0.5	0.3	1.0	0.6
	Panel A	112	0.4	0.4	0.8	0.7
	Panel B	190	0.8	0.4	1.4	0.7
Serum K+	Control Level 1	2.8	0.03	0.9	0.04	1.4
	Control Level 2	4.0	0.02	0.6	0.03	0.8
	Control Level 3	6.8	0.03	0.4	0.05	0.7
	Panel A	1.6	0.02	1.1	0.03	1.7
	Panel B	9.4	0.04	0.4	0.06	0.7

			Within-run		Total*	
Test	Samples	Mean (mmol/L)	SD	%CV	SD	%CV
Serum Cl-	Control Level 1	85	0.5	0.6	0.7	0.8
	Control Level 2	95	0.4	0.4	0.6	0.7
	Control Level 3	110	0.5	0.5	0.8	0.7
	Panel A	55	0.3	0.6	0.6	1.0
	Panel B	132	0.6	0.4	1.0	0.8

*includes within run, between run, between day, between lots and between instrument

Precision studies for urine sodium, potassium, and chloride are shown in the table below for one representative lot.

			Within-run		Total	
Test	Samples	Mean (mmol/L)	SD	%CV	SD	%CV
Urine Na+	Control Level 1	92	0.6	0.7	1.0	1.1
	Control Level 2	161	0.7	0.4	1.0	0.6
	Panel A	21	0.5	2.3	0.6	2.9
	Panel B	383	1.5	0.4	3.9	1.0
Urine K+	Control Level 1	16.6	0.06	0.3	0.13	0.8
	Control Level 2	58.1	0.17	0.3	0.34	0.6
	Panel A	1.7	0.02	1.4	0.04	2.4
	Panel B	127.7	0.35	0.3	0.68	0.5
	Panel C	284.5	0.82	0.3	1.91	0.7
Urine Cl-	Control Level 1	103	0.5	0.4	0.9	0.9
	Control Level 2	193	0.7	0.4	1.2	0.6
	Panel A	24	0.3	1.1	0.4	1.6
	Panel B	273	0.9	0.3	2.2	0.8

b. Linearity/assay reportable range:

The linearity studies were performed according to the CLSI EP06-A guideline. A minimum of eleven equally spaced serum or urine samples covering the measurement range were prepared by mixing high and low sample concentrations. Four replicates were measured for each sample.

Analyte	Sample concentrations tested
Na+, serum (mmol/L)	259, 240, 222, 209, 198, 181, 166, 153, 139, 113, 104, 74, 27
K+, serum (mmol/L)	14.3, 12.7, 11.3, 9.6, 8.1, 6.6, 5.0, 3.5, 2.2, 1.1, 0.8, 0.5
Cl-, serum (mmol/L)	172, 164, 151, 137, 126, 113, 100, 87, 75, 62, 51, 40, 22
Na+, urine (mmol/L)	474, 439, 381, 320, 259, 201, 138, 78, 36, 27, 22, 12, 5, 1
K+, urine (mmol/L)	366.0, 334.5, 284.3, 236.0, 186.1, 135.8, 86.2, 29.3, 1.7, 0.6, 0.1
Cl-, urine (mmol/L)	346, 316, 270, 225, 173, 125, 76, 31, 13, 8, 5

The linear regression results are summarized in the table below.

Analyte	Slope	Intercept	r	Range tested (mmol/L)	Claimed measuring range (mmol/L)
Na+, serum	1.0068	-0.09	1.00	27 - 259	100 - 200
K+, serum	1.0033	-0.01	1.00	0.5 - 14.3	1.0 - 10.0
Cl-, serum	1.0123	-0.19	1.00	22 - 172	50 - 150
Na+, urine	0.9794	-0.15	1.00	1 - 474	20 - 400
K+, urine	0.9934	-0.04	1.00	0.1 - 366	1.0 - 300.0
Cl-, urine	0.9701	-0.20	0.9994	5 - 346	20 - 300

The linearity studies support the claimed measuring ranges for each sample type, as shown in the table above.

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

Traceability.
The Alinity c ICT Sample Diluent and calibrators have the same bulk material as the diluent and calibrators cleared for use with the predicate device, ARCHITECT ICT (Na+, K+, Cl-) Sample Diluent. The reagent container for Alinity c ICT Sample Diluent has changed, and performance has been established on the Alinity c System as the candidate test system in this submission. Assay traceability is the same as established under clearance in k980367.

Stability.
The protocols for stability and acceptance criteria were reviewed and found to be adequate. The Alinity c ICT Sample Diluent is stable for 14 months when stored at 15 to 30 °C, and onboard the instrument for 30 days. Real time reagent stability studies are on-going and scheduled to continue for a maximum of 25 months.

d. *Detection limit:*

The upper and lower limits of the measuring ranges for sodium, potassium, and chloride are supported by linearity studies. Refer to M.1.b. linearity section above.

e. *Analytical specificity:*

Interference studies were performed according to CLSI document EP07-A2 to determine the effects of potential interferences on the sodium, potassium, and chloride in serum and urine. Various concentrations of interferents were spiked into low and high levels of each analyte in serum or urine. Each sample was tested with a minimum of 12 replicates. The sponsor states that interference was considered non-significant if the difference in measured concentration between the test and control samples is within ±2% for serum sodium, ±10% for urine sodium, ±10% for serum and urine potassium, and ±10% for serum and urine chloride.

The highest concentration of each interferent that did not show interference for the serum sodium, potassium, and chloride assays is shown in the table below.

Analyte	Interferent	Highest concentration tested that did not show significant interference
Serum Na+	Unconjugated Bilirubin	≤ 60 mg/dL
	Conjugated Bilirubin	≤ 30 mg/dL
	Hemoglobin	≤ 500 mg/dL
	Triglycerides (Intralipid)	≤ 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
Serum K+	Unconjugated Bilirubin	≤ 60 mg/dL
	Conjugated Bilirubin	≤ 60 mg/dL
	Hemoglobin	≤ 100 mg/dL
	Triglycerides (Intralipid)	≤ 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
Serum Cl-	Unconjugated Bilirubin	≤ 60 mg/dL
	Conjugated Bilirubin	≤ 20 mg/dL
	Hemoglobin	≤ 1000 mg/dL
	Triglycerides (Intralipid)	≤ 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

The highest concentration of each interferent that did not show interference for the urine sodium, potassium, and chloride assays is shown in the table below.

Analyte	Interferent	Highest concentration tested that did not show significant interference
Urine Na+	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	3.52 to 8.58
	Specific Gravity	1.004 to 1.027
Urine K+	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	3.58 to 8.03
	Specific Gravity	1.010 to 1.025

Analyte	Interferent	Highest concentration tested that did not show significant interference
Urine Cl-	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	3.52 to 7.97
	Specific Gravity	1.006 to 1.033

The sponsor added the following limitations to their labeling:

- The Alinity c Sodium assay serum application is susceptible to interference effects from conjugated bilirubin at 60 mg/dL, hemoglobin at 1000 mg/dL, sodium salicylate at 35 mg/dL, and benzalkonium chloride at 5 mg/dL.
- The Alinity c Sodium assay urine application demonstrated greater than 10% interference with sodium carbonate at 1.25 g/dL, sodium fluoride at 400 mg/dL, and sodium oxalate at 60 mg/dL at low sodium concentrations, 71 mmol/L.
- The Alinity c Potassium assay serum application is susceptible to interference effects from hemoglobin (hemolysis) at 125 mg/dL, and benzalkonium chloride at 10 mg/dL.
- The Alinity c Potassium assay urine application is susceptible to interference effects from hemoglobin (hemolysis) at 1000 mg/dL.
- The Alinity c Chloride assay serum application is susceptible to interference effects from hemoglobin (hemolysis) at 2000 mg/dL, lithium bromide at 40 mg/dL, and lithium iodide at 50.8 mg/dL.
- The Alinity c Chloride assay urine application demonstrated greater than 10% interference from 6N hydrochloric acid at 2.5 mL/dL.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed using a minimum of 100 human serum specimens with analyte concentrations within the analytical ranges of sodium, potassium, and chloride. A minimum of 100 urine samples for sodium, potassium, and chloride were used for the urine application. Samples were measured using the candidate device, Alinity c ICT Sample Diluent on the Alinity c System, and compared to the ICT Sample Diluent on the ARCHITECT c8000 instrument. Less than 10% of the samples were altered by spiking and diluting human serum samples and urine. The regression analysis using Passing-Bablok regression for the first replicate on the predicate device versus mean values of the predicate is summarized in the table below.

Analyte	N	Slope	Intercept	r	Test Range (mmol/L)	Claimed Measuring Range (mmol/L)
Na+, serum	141	1.00	-0.50	1.000	101 - 197	100 - 200
K+, serum	122	1.00	0.00	1.000	1.3 - 9.4	1.0 - 10.0
Cl-, serum	120	1.00	0.00	1.000	52 - 148	50 - 150
Na+, urine	101	0.99	0.88	1.000	22 - 386	20 - 400
K+, urine	107	1.05	-1.23	1.000	4.3 - 266.1	1.0 - 300.0
Cl-, urine	112	1.00	-0.30	1.000	25 - 299	20 - 300

b. Matrix comparison:

A matrix comparison study was performed to demonstrate the equivalence between serum and plasma samples when measuring sodium, potassium, and chloride on the Alinity c Analyzer. Blood was collected from a minimum of 40 donors in the control tube type (serum) and in the following evaluation tube types: serum separator, lithium heparin, sodium heparin, and lithium heparin plasma separator. Singlicate measurements of the evaluation tube were compared to the mean of the reference tube. The following regression equations were obtained from the matrix comparison study for sodium, potassium, and chloride analytes:

Analyte	Matrix	N	Test range (mmol/L)	Slope	Intercept	r
Na+	Serum vs LiHep	50	110 - 184	1.00	-0.50	1.00
K+	Serum vs LiHep	47	1.0 - 9.0	0.99	-0.02	0.99
Cl-	Serum vs LiHep	48	58 - 147	1.01	-0.39	1.00
Na+	Serum vs NaHep	50	110 - 184	1.00	0.50	1.00

Analyte	Matrix	N	Test range (mmol/L)	Slope	Intercept	r
K+	Serum vs NaHep	47	1.0 - 9.0	0.97	-0.09	0.99
Cl-	Serum vs NaHep	48	58 - 147	1.02	-1.98	1.00
Na+	Serum vs LiHep with SS	50	110 - 184	1.00	-0.50	1.00
K+	Serum vs LiHep with SS	47	1.0 - 9.0	0.96	-0.02	0.99
Cl-	Serum vs LiHep with SS	48	58 - 147	1.02	-1.54	1.00
Na+	Serum vs SS	50	110 - 184	1.00	-1.54	1.01
K+	Serum vs SS	47	1.0 - 9.0	1.00	0.10	1.00
Cl-	Serum vs SS	48	58 - 147	1.00	0.25	1.00

*LiHep = Lithium heparin; NaHep = Sodium heparin; SS = Serum separator

The results of the matrix comparison study support that serum, lithium heparin, and sodium heparin plasma specimens are suitable for use with the Alinity c ICT Sample Diluent.

3. Clinical studies:

   a. *Clinical Sensitivity:*

      Not applicable.

   b. *Clinical specificity:*

      Not applicable.

   c. *Other clinical supportive data (when a. and b. are not applicable):*

      Not applicable.

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

The expected values for adults are values are provided in the product insert based on the literature.[1]

Serum/Plasma (mmol/L)	
Sodium	136 - 145
Potassium	
Adult, Serum	3.5 - 5.1
Plasma, Male	3.5 - 4.5
Plasma, Female	3.4 - 4.4
Chloride	98 - 107
Urine (mmol/day)	
Sodium	
Male	20 - 220
Female	27 - 287
Potassium	25 - 125
Chloride	110 - 250

1. Burtis CA, Ashwood ER, Bruns DE, editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*, 5th ed. St. Louis, MO: Elsevier Saunders; 2012: 2139, 2164, 2168.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

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