Alinity c ICT Sample Diluent (ICT Diluent)-17

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BIENNIAL REVIEW:

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SUPERSEDES: Procedure titled _____

INTENDED 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.

SUMMARY AND EXPLANATION OF THE TEST

Sodium is the major cation of extracellular fluid; it plays an essential role in the normal distribution of water and in the maintenance of osmotic pressure in extracellular fluid compartments. Decreased levels of sodium may be caused by an excessive use of diuretics, prolonged vomiting, a decrease in the intake of sodium in the diet, and metabolic acidosis. Increased levels of sodium may be found in Cushing's syndrome, severe dehydration, or in

high levels of salt intake without an adequate supply of water.[1,2]

Potassium is the major intracellular cation. The concentration of potassium in the erythrocytes is approximately 23 times the concentration in plasma. For this reason, only unhemolyzed samples must be used. Decreased levels of extracellular potassium are characterized by weakness in the muscles, irritability, paralysis, accelerated heartbeat, and eventually cardiac arrest, and may be caused by a poor intake of potassium in the diet, by a redistribution of extracellular potassium, and by an increased loss of body fluids rich in potassium. Abnormally elevated levels of extracellular potassium produce mental confusion, general weakness, numbness, flaccid paralysis in the extremities, a slowed heart rate, and eventually collapse of the peripheral vascular system and cardiac arrest. Causes of increased potassium levels may be linked to inappropriate intravenous therapy, dehydration, shock, diabetic ketoacidosis, and severe burns.[1,2]

Chloride is the major extracellular anion. The majority of ingested chloride is absorbed, and the excess is excreted along with other ions into the urine. Low levels of chloride are observed in the case of prolonged vomiting accompanied by the loss of hydrochloric acid (HCl), in metabolic alkalosis, in critical cases of Addison's disease, and in kidney disease resulting in loss of salt. Elevated levels of chloride are observed in metabolic acidosis associated with prolonged diarrhea and with loss of sodium bicarbonate ($NaHCO_3$), and in the case of renal tubular diseases in which there is a decreased excretion of hydrogen ion (H^+), which causes in turn a decrease in the reabsorption of bicarbonate ion (HCO_3^-).[1,2]

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)

For additional information on system and assay technology, **refer to the Alinity ci-series Operations Manual, Section 3.**

REAGENTS

Kit Contents

Alinity c ICT Sample Diluent 07P53

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

REF	**07P5320**
Tests per cartridge	935
Number of cartridges per kit	10
Tests per kit	9350*

REF	**07P5320**
R1	68.2 mL
R1 Active ingredient: buffer.	

*One test per sample can generate one to three results (Na^+, K^+, and Cl^-).

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[3], [4], [5], [6]

The following warnings and precautions apply to: ICT Sample Diluent*	
H402	Harmful to aquatic life.
Prevention	
P273	Avoid release to the environment.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EU 1272/2008 (CLP) has been implemented.

Safety Data Sheets are available at www.abbottdiagnostics.com or/and SDS folder.

For a detailed discussion of safety precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 8.**

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 7.**

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	15 to 30°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	15 to 30°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 15 to 30°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- a control value is out of the specified range

Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

Acetic acid odor from the diluent is normal.

For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity c Sodium, Potassium, and Chloride assay files must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, **refer to the Alinity ci-series Operations Manual.**

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes (with or without gel barrier)	For Potassium, hemolyzed specimens must not be used.
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin (full draw)	
Urine (random; 24-hour)	Without preservatives[1]	

Specimen Conditions

·For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.

·For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.

·NOTE: Multiple myeloma and lipid samples are known to give low results on diluted ISE systems due to the high level of proteins/lipids present in the sample.[7, 8]

·To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

·Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.

·Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross-contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

·they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Specimen Storage

Serum/Plasma[9, 10]

Temperature	Maximum Storage Time		
	Sodium	**Potassium**	**Chloride**
20 to 25°C	2 weeks	1 week	7 days
2 to 8°C	2 weeks	1 week	7 days
-20°C	1 year	1 year	> 1 year

Urine[9, 10, 11]

Temperature	Maximum Storage Time		
	Sodium	**Potassium**	**Chloride**
20 to 25°C	45 days	45 days	7 days
2 to 8°C	45 days	2 months	7 days
-20°C	1 year	1 year	7 days

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.[9]

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

PROCEDURE

Materials Provided

07P53 Alinity c ICT Sample Diluent

Materials Required but not Provided

·Alinity c Sodium, Potassium, and Chloride assay files

·09D2804 Alinity ICT Module

·08P7640 Alinity c-series ICT Reference Solution

·08P6901 Alinity c ICT Serum Calibrator Kit

·08P7001 Alinity c ICT Urine Calibrator Kit

·Commercially available controls containing sodium, potassium, and chloride

For information on materials required for operation of the instrument, **refer to the Alinity ci-series Operations Manual, Section 1.**

For information on materials required for maintenance procedures, **refer to the Alinity ci-series Operations Manual, Section 9.**

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

·If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.

·To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

·Minimum sample volume requirements:

·Sample volume for single test: 15 µL (serum/plasma/urine).

NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. **For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.**

·Refer to the Alinity c ICT Serum Calibrator Kit package insert, Alinity c ICT Urine Calibrator Kit package insert and commercially available control material package insert for preparation and usage.

·For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.

·For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Calibration

For instructions on performing a calibration**, refer to the Alinity ci-series Operations Manual, Section 5.**

Calibration is stable for approximately **1 day (24 hours),** but is required with each change in diluent lot. The laboratory may choose any calibration interval up to 24 hours. The use of a particular calibration time interval is dependent on individual laboratory policy or preference. Verify calibration with at least 2 levels of controls according to the laboratory quality control policy. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after

service procedures have been performed.

Quality Control Procedures

·At least two levels of controls (normal and abnormal) are to be run every day testing performed.

·If quality control results do not meet the acceptance criteria defined by laboratory quality control procedure, sample results may be suspect. Follow the laboratory quality control procedures to troubleshoot. Recalibration may be necessary. **For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.**

·Review quality control results and acceptance criteria following a change of ICT Sample Diluent, ICT Reference Solution, or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.*12*

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity c Sodium, Potassium, and Chloride assays utilize the Potentiometric data reduction method to generate a calibration and results.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Measuring Interval

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

Serum/Plasma

The measuring interval of the Alinity c Sodium assay is **100 to 200** mmol/L.

The measuring interval of the Alinity c Potassium assay is **1.0 to 10.0** mmol/L.

The measuring interval of the Alinity c Chloride assay is **50 to 150** mmol/L.

Urine

The measuring interval of the Alinity c Sodium assay is 20 to 400 mmol/L.

The measuring interval of the Alinity c Potassium assay is 1.0 to 300.0 mmol/L.

The measuring interval of the Alinity c Chloride assay is 20 to 300 mmol/L.

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

The Alinity c ICT (Na^+, K^+, Cl^-) assays are susceptible to certain endogenous and exogenous interferents. For a comprehensive list of potentially interfering substances, refer to SPECIFIC PERFORMANCE CHARACTERISTICS, Interference.

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 is susceptible to interference effects from 6N hydrochloric acid at 2.5 mL/dL.

EXPECTED VALUES

Manufacturer provided reference range will be adopted. Effort made to verify in house

The reference ranges provided in the table below are from Burtis et al., 2012.[13]

Reference Range

Serum/Plasma[13]

		Range (mmol/L)
Sodium	Premature, Cord	116 to 140

		Range (mmol/L)
	Premature, 48 hours	128 to 148
	Newborn, Cord	126 to 166
	Newborn	133 to 146
	Infant	139 to 146
	Child	138 to 145
	Adult	136 to 145
	> 90 years	132 to 146
Potassium	Premature, Cord	5.0 to 10.2
	Premature, 48 hours	3.0 to 6.0
	Newborn, Cord	5.6 to 12.0
	Newborn	3.7 to 5.9
	Infant	4.1 to 5.3
	Child	3.4 to 4.7
	Adult	3.5 to 5.1
	Plasma, Male	3.5 to 4.5
	Plasma, Female	3.4 to 4.4
Chloride	Cord	96 to 104
	Premature	95 to 110
	0 to 30 days	98 to 113
	Adult	98 to 107
	> 90 years	98 to 111

Urine*13*

			Range (mmol/day)
Sodium	6 to 10 years	Male	41 to 115
		Female	20 to 69
	10 to 14 years	Male	63 to 177

			Range (mmol/day)
		Female	48 to 168
	Adult	Male	40 to 220
		Female	27 to 287
Potassium	6 to 10 years	Male	17 to 54
		Female	8 to 37
	10 to 14 years	Male	22 to 57
		Female	18 to 58
	Adult		25 to 125
Chloride	Infant		2 to 10
	Child < 6 years		15 to 40
	6 to 10 years	Male	36 to 110
		Female	18 to 74
	10 to 14 years	Male	64 to 176
		Female	36 to 173
	Adult		110 to 250
	> 60 years		95 to 195

For Sodium, Potassium, and Chloride, results expressed in mmol/L are equivalent to mEq/L; results expressed in mmol/day are equivalent to mEq/day.

24-Hour Urinary Excretion

Sodium, Potassium, and Chloride

To convert results from mmol/L to mmol/day (24-hour urinary excretion)

24-hour excretion = [(V × c) ÷ 1000] mmol/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mmol/L)

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

All studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

Serum

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 2 lots of the Alinity c ICT Sample Diluent, 2 lots of the Alinity c ICT Serum Calibrator Kit, 2 lots of commercially available controls and 2 instruments. Three controls and 2 human serum panels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.[14]

Sodium

				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	0.7

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %CV (Range[b])
						(1.2 - 1.6)	(0.6 - 0.9)

Potassium

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %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)

Chloride

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %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.

Urine

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 2 lots of the Alinity c ICT Sample Diluent, 2 lots of the Alinity c ICT Urine Calibrator Kit, 2 lots of commercially available controls and 2 instruments. Two controls and up to 3 human urine panels were assayed in a minimum of 2 replicates at 2 separate times per day for

a minimum of 20 days.[14]

Sodium

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %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)

Potassium

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %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	0.7

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %CV (Range[b])
						(0.11 - 0.12)	(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)

Chloride

Sample	Control Lot	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory (Total)[a] SD (Range[b])	Within-Laboratory (Total)[a] %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	1	240	193	0.7	0.4	1.2	0.6

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

Linearity

A study was performed based on guidance from CLSI EP06-A.*15*

Serum

The sodium assay is linear across the measuring interval of **100 to 200** mmol/L.

The potassium assay is linear across the measuring interval of **1.0 to 10.0** mmol/L.

The chloride assay is linear across the measuring interval of **50 to 150** mmol/L.

Urine

The sodium assay is linear across the measuring interval of 20 to 400 mmol/L.

The potassium assay is linear across the measuring interval of 1.0 to 300.0 mmol/L.

The chloride assay is linear across the measuring interval of 20 to 300 mmol/L.

Interference

Potentially Interfering Substances

A study was performed based on guidance from CLSI EP07-A2.*16*

Serum

Sodium

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

Potentially Interfering Substance	Interferent Level		Sodium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Unconjugated Bilirubin	30 mg/dL	513 µmol/L	115	100.4
			144	100.7
	60 mg/dL	1026 µmol/L	115	100.4
			145	100.0
Conjugated Bilirubin	20 mg/dL	237 µmol/L	112	100.9
			141	100.7
	30 mg/dL	356 µmol/L	113	100.9
			141	101.4
	60 mg/dL	712 µmol/L	112	100.6
			141	102.5†
Hemoglobin	500 mg/dL	5.0 g/L	128	101.6
			157	101.0
	1000 mg/dL	10.0 g/L	125	101.6
			151	102.6†
	2000 mg/dL	20.0 g/L	116	103.9†
			141	104.6†
Intralipid	1000 mg/dL	10.0 g/L	111	100.9
			140	100.0
	2000 mg/dL	20.0 g/L	106	100.9
			133	100.8
Ascorbic Acid	6 mg/dL	341 µmol/L	128	100.0
			154	99.4
Acetaminophen	20 mg/dL	1323 µmol/L	128	100.0
			152	100.0
Ibuprofen	50 mg/dL	2424 µmol/L	125	100.0

Potentially Interfering Substance	Interferent Level		Sodium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
			150	100.0
Acetylcysteine	167 mg/dL	10.2 mmol/L	127	100.0
			153	100.0
Acetylsalicylic Acid	66 mg/dL	3.7 mmol/L	127	100.0
			153	100.0
Sodium Salicylate	35 mg/dL	2.2 mmol/L	127	102.4†
			151	101.3
	70 mg/dL	4.4 mmol/L	128	103.5†
			152	103.3†
Benzalkonium Chloride	1 mg/dL	0.01 g/L (0.001%)	116	100.9
			146	100.0
	5 mg/dL	0.05 g/L (0.005%)	116	102.6†
			145	102.1†
	10 mg/dL	0.1 g/L (0.01%)	115	106.1†
			143	106.3†

† > 2% interference.

Potassium

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

Potentially Interfering Substance	Interferent Level		Potassium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Unconjugated Bilirubin	30 mg/dL	513 µmol/L	3.0	100.0
			4.9	100.0

Potentially Interfering Substance	Interferent Level		Potassium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
	60 mg/dL	1026 µmol/L	2.9	103.4
			4.8	100.0
Conjugated Bilirubin	20 mg/dL	237 µmol/L	2.9	100.0
			4.8	100.0
	30 mg/dL	356 µmol/L	3.0	101.7
			4.9	98.0
	60 mg/dL	712 µmol/L	2.9	100.0
			4.8	100.0
Hemoglobin	100 mg/dL	1.00 g/L	3.3	109.1
			5.2	105.8
	125 mg/dL	1.25 g/L	3.3	112.1*
			5.2	107.7
	250 mg/dL	2.50 g/L	3.3	121.2*
			5.1	115.7*
Intralipid	1000 mg/dL	10.0 g/L	2.9	100.0
			4.7	102.1
	2000 mg/dL	20.0 g/L	2.8	100.0
			4.5	102.2
Ascorbic Acid	6 mg/dL	341 µmol/L	3.2	100.0
			5.1	100.0
Acetaminophen	20 mg/dL	1323 µmol/L	3.2	100.0
			5.1	100.0
Ibuprofen	50 mg/dL	2424 µmol/L	3.2	100.0
			5.1	100.0
Acetylcysteine	167 mg/dL	10.2 mmol/L	3.2	100.0

Potentially Interfering Substance	Interferent Level		Potassium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
			5.1	100.0
Acetylsalicylic Acid	66 mg/dL	3.7 mmol/L	3.2	100.0
			5.1	100.0
Sodium Salicylate	70 mg/dL	4.4 mmol/L	3.2	100.0
			5.1	100.0
Benzalkonium Chloride	1 mg/dL	0.01 g/L (0.001%)	3.0	103.3
			4.9	102.0
	5 mg/dL	0.05 g/L (0.005%)	3.0	110.0
			4.9	108.2
	10 mg/dL	0.1 g/L (0.01%)	2.9	127.6*
			4.8	118.8*

* > 10% interference.

Chloride

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

Potentially Interfering Substance	Interferent Level		Chloride	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Unconjugated Bilirubin	30 mg/dL	513 µmol/L	79	100.0
			114	100.0
	60 mg/dL	1026 µmol/L	79	100.0
			113	100.9
Conjugated Bilirubin	20 mg/dL	237 µmol/L	79	100.0
			113	100.0

Potentially Interfering Substance	Interferent Level		Chloride	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
	30 mg/dL	356 µmol/L	79	100.0
			114	99.1
	60 mg/dL	712 µmol/L	79	99.4
			113	100.0
Hemoglobin	1000 mg/dL	10.0 g/L	90	106.7
			116	106.9
	2000 mg/dL	20.0 g/L	84	113.1*
			110	110.0
Intralipid	1000 mg/dL	10.0 g/L	78	101.3
			112	100.0
	2000 mg/dL	20.0 g/L	75	100.0
			107	100.9
Ascorbic Acid	6 mg/dL	341 µmol/L	85	100.0
			112	100.9
Acetaminophen	20 mg/dL	1323 µmol/L	84	100.6
			112	99.1
Ibuprofen	50 mg/dL	2424 µmol/L	78	100.0
			106	100.0
Acetylcysteine	16.7 mg/dL	1.0 mmol/L	86	100.0
			113	100.9
Acetylsalicylic Acid	66 mg/dL	3.7 mmol/L	84	101.2
			113	100.0
Sodium Salicylate	70 mg/dL	4.4 mmol/L	85	98.8
			113	100.0
Benzalkonium	1 mg/dL	0.01 g/L (0.001%)	81	100.0

Potentially Interfering Substance	Interferent Level		Chloride	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Chloride			112	100.0
	5 mg/dL	0.05 g/L (0.005%)	81	100.0
			112	100.0
	10 mg/dL	0.10 g/L (0.010%)	81	100.0
			111	100.3
Lithium Bromide	20 mg/dL	2.3 mmol/L	80	106.9
			111	106.8
	40 mg/dL	4.6 mmol/L	79	117.1*
			109	116.1*
Lithium Iodide	25.4 mg/dL	1.9 mmol/L	81	106.8
			111	107.2
	50.8 mg/dL	3.8 mmol/L	79	112.7*
			109	111.9*
Sodium Azide	163 mg/dL	25 mmol/L (0.163%)	80	105.0
			110	103.6
	325 mg/dL	50 mmol/L (0.325%)	79	107.6
			109	105.5

* > 10% interference.

Urine

Sodium

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

Potentially	Interferent Level	Sodium

Interfering Substance	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Protein	50 mg/dL	0.5 g/L	33	101.5
			204	100.2
Glucose	1000 mg/dL	55.5 mmol/L	33	100.0
			208	99.8
Ascorbate	200 mg/dL	11.4 mmol/L	33	100.0
			208	100.0
8.5N Acetic Acid	6.25 mL/dL	531 mmol/L	31	100.0
			195	100.5
Boric Acid	250 mg/dL	40.4 mmol/L	33	100.0
			208	99.8
6N Hydrochloric Acid	2.5 mL/dL	150 mmol/L	33	100.0
			205	100.7
6N Nitric Acid	5.0 mL/dL	300 mmol/L	31	100.0
			195	100.8
Sodium Oxalate	60 mg/dL	4.5 mmol/L	33	127.3*
			71	112.7*
			154	106.5
			206	103.6
Sodium Carbonate	1.25 g/dL	117.9 mmol/L	33	798.5*
			206	216.5*
Sodium Fluoride	400 mg/dL	95.3 mmol/L	33	381.8*
			205	146.2*
Acetaminophen	20 mg/dL	1323 µmol/L	39	100.0
			211	100.0
Ibuprofen	50 mg/dL	2424 µmol/L	38	100.0
			207	99.8

Potentially Interfering Substance	Interferent Level		Sodium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Acetylcysteine	167 mg/dL	10.2 mmol/L	39	100.0
			210	100.0
Conjugated Bilirubin	20 mg/dL	237 µmol/L	39	100.0
			216	100.5
	60 mg/dL	712 µmol/L	38	107.9
			213	102.8
Hemoglobin	1000 mg/dL	10.0 g/L	37	105.4
			207	101.2

* > 10% interference.

For pH range 3.52 to 8.58 and specific gravity range 1.004 to 1.027, sodium concentrations tested at 40 and 220 mmol/L demonstrated ≤ 10% interference.

Potassium

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

Potentially Interfering Substance	Interferent Level		Potassium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Protein	50 mg/dL	0.5 g/L	23.7	100.4
			117.9	100.2
Glucose	1000 mg/dL	55.5 mmol/L	23.8	100.0
			118.5	100.0
Ascorbate	200 mg/dL	11.4 mmol/L	23.8	100.0
			118.7	100.0
8.5N Acetic Acid	6.25 mL/dL	531 mmol/L	22.5	100.9
			112.2	100.1

Potentially Interfering Substance	Interferent Level		Potassium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Boric Acid	250 mg/dL	40.4 mmol/L	23.8	100.0
			118.4	100.0
6N Hydrochloric Acid	2.5 mL/dL	150 mmol/L	23.7	100.8
			118.3	100.6
6N Nitric Acid	5.0 mL/dL	300 mmol/L	22.5	100.9
			112.6	100.2
Sodium Oxalate	60 mg/dL	4.5 mmol/L	23.7	100.0
			118.9	100.0
Sodium Carbonate	1.25 g/dL	117.9 mmol/L	23.8	100.0
			119.2	99.5
Sodium Fluoride	400 mg/dL	95.3 mmol/L	23.9	99.6
			118.8	99.9
Acetaminophen	20 mg/dL	1323 µmol/L	24.4	100.0
			132.0	96.1
Ibuprofen	50 mg/dL	2424 µmol/L	24.3	100.0
			126.7	100.0
Acetylcysteine	167 mg/dL	10.2 mmol/L	24.3	100.0
			126.6	100.1
Conjugated Bilirubin	20 mg/dL	237 µmol/L	25.7	100.0
			123.2	99.9
	60 mg/dL	712 µmol/L	25.4	100.0
			120.3	99.5
Hemoglobin	125 mg/dL	1.3 g/L	26.3	101.5
			126.4	100.0
	500 mg/dL	5.0 g/L	25.5	105.1

Potentially Interfering Substance	Interferent Level		Potassium	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
			122.2	101.1
	1000 mg/dL	10.0 g/L	24.5	112.2*
			117.9	103.0

* > 10% interference.

For pH range 3.58 to 8.03 and specific gravity range 1.010 to 1.025, potassium concentrations tested at 25.0 and 125.0 mmol/L demonstrated ≤ 10% interference.

Chloride

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

Potentially Interfering Substance	Interferent Level		Chloride	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
Protein	50 mg/dL	0.5 g/L	102	101.0
			234	100.2
Glucose	1000 mg/dL	55.5 mmol/L	103	100.0
			237	99.8
Ascorbate	200 mg/dL	11.4 mmol/L	103	101.0
			236	100.0
8.5N Acetic Acid	6.25 mL/dL	531 mmol/L	98	99.0
			222	100.0
Boric Acid	250 mg/dL	40.4 mmol/L	103	100.0
			235	100.0
6N Hydrochloric Acid	2.5 mL/dL	150 mmol/L	103	250.5*
			236	165.3*
6N Nitric Acid	5.0 mL/dL	300 mmol/L	98	96.9

Potentially Interfering Substance	Interferent Level		Chloride	
	Default Units	Alternate Units	Target Level (mmol/L)	Recovery (% of Target)
			223	98.2
Sodium Oxalate	60 mg/dL	4.5 mmol/L	103	101.0
			236	100.0
Sodium Carbonate	1.25 g/dL	117.9 mmol/L	104	101.9
			238	101.3
Sodium Fluoride	400 mg/dL	95.3 mmol/L	103	96.1
			236	100.4
Acetaminophen	20 mg/dL	1323 µmol/L	114	100.0
			258	100.0
Ibuprofen	50 mg/dL	2424 µmol/L	107	100.9
			252	100.0
Acetylcysteine	16.7 mg/dL	1.0 mmol/L	115	100.9
			261	100.8
Conjugated Bilirubin	20 mg/dL	237 µmol/L	107	100.0
			245	100.0
	60 mg/dL	712 µmol/L	105	100.0
			241	100.4
Hemoglobin	1000 mg/dL	10.0 g/L	103	106.8
			236	103.6

* > 10% interference.

For pH range 3.52 to 7.97 and specific gravity range 1.006 to 1.033, chloride concentrations tested at 110 and 250 mmol/L demonstrated ≤ 10% interference.

Interferences from medication or endogenous substances may affect results.[17]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[18]

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

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