Alinity c Creatinine-11

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BIENNIAL REVIEW:

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SUPERSEDES: Procedure titled _____

INTENDED USE

The Alinity c Creatinine assay is used for the quantitative determination of creatinine in human serum, plasma, or urine on the Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Creatinine is eliminated from blood by glomerular filtration. Reduced renal function results in an increased serum creatinine concentration. Measurement of serum creatinine is used to diagnose and monitor acute and chronic renal disease, estimate glomerular filtration rate (GFR), or assess the status of renal dialysis patients. Urine creatinine analysis is used to

calculate creatinine clearance, confirm completeness of 24 hour collections, or serve as a reference quantity for other analytes, such as in calculation of the albumin/creatinine ratio.[1]

In 1886 Jaffe developed an assay for creatinine based upon the reaction between creatinine and sodium picrate.[2] In 1904 Folin[3] used this reaction for the quantitative determination of creatinine in urine. Kinetic procedures based on the observed reaction rates of various substances, including creatinine, with alkaline picrate have been proposed by Fabiny[4] and Soldin.[5] This improved Jaffe chemistry is a kinetic procedure which does not require deproteinization of the sample and is formulated to reduce the interference of serum proteins.

PRINCIPLES OF THE PROCEDURE

At an alkaline pH, creatinine in the sample reacts with picrate to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the concentration of creatinine in the sample.

Methodology: Kinetic Alkaline Picrate

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

REAGENTS

Kit Contents

Alinity c Creatinine Reagent Kit 07P99

REF	07P9920	07P9930
Tests per cartridge	300	1200
Number of cartridges per kit	10	10
Tests per kit	3000	12 000
R1	11.2 mL	33.7 mL
R2	11.6 mL	36.4 mL
R1 Active ingredients: Sodium hydroxide (0.8 mol/L).		
R2 Active ingredients: Picric acid (24 mmol/L).		

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.[6], [7], [8], [9]

The following warnings and precautions apply to: R1	
	
DANGER	Contains sodium hydroxide.
H314	Causes severe skin burns and eye damage.
H290	May be corrosive to metals.
Prevention	
P280	Wear protective gloves / protective clothing / eye protection.
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P234	Keep only in original container.
Response	
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water / shower.
P310	Immediately call a POISON CENTER or doctor / physician.
P390	Absorb spillage to prevent material damage.
Disposal	
P501	Dispose of contents / container in accordance with local

regulations.

The following warnings and precautions apply to: R2	
	Contains picric acid.
EUH001	Explosive when dry.

Picric acid is a flammable solid when wet as a paste (i.e., not less than 10% water), and explosive when dry. Prevent from forming crystals. Keep containers tightly sealed. Do not allow to dry out.

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	5 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.

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

INSTRUMENT PROCEDURE

The Alinity c Creatinine assay file 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.**

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mg/dL (Serum)	88.4	µmol/L
mg/dL (Urine)	0.0884	mmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

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

Other specimen types and anticoagulants have not been verified with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes (with or without gel barrier)	
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) EDTA Sodium heparin	
Urine (random specimens or timed specimens collected over intervals shorter than 24 hours)	Clean plastic or glass container without preservatives	
Urine (24 hour)	Clean plastic or glass container with preservatives	The preferred preservatives are boric acid and hydrochloric acid.*10* Reference ranges are provided for 24 hours excretion.

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.
- 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

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	20 to 25°C	7 days[11]
	2 to 8°C	7 days[11], [12]
	-20°C	3 months[11]
Urine	20 to 25°C	2 days[11]
	2 to 8°C	6 days[11], [12]
	-20°C	6 months[11]

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.[11]

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

07P99 Alinity c Creatinine Reagent Kit

Materials Required but not Provided

- Alinity c Creatinine assay file
- 08P6001 Alinity c Multiconstituent Calibrator Kit
- Commercially available controls containing creatinine
- Saline (0.85% to 0.90% NaCl) for specimen dilution

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: 5.3 µL (Serum), 8 µL (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 Multiconstituent Calibrator Kit package insert and commercially available control 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.**

Sample Dilution Procedures

Serum/Plasma

Samples with creatinine value exceeding 37.00 mg/dL (3270.8 µmol/L) are flagged with the code "> 37.00 mg/dL" (3270.8 µmol/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Urine

Urine samples are diluted 1:20 by the system using the Standard dilution option, then the system corrects the concentration by multiplying the result by the dilution factor. Urine samples with values exceeding 740.00 mg/dL (65.416 mmol/L) are flagged with the code "> 740.00 mg/dL" (> 65.416 mmol/L) and may be diluted with either the Automated Dilution

Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

Serum/Plasma

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Urine

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the measuring interval of 0.20 mg/dL (17.68 µmol/L) for the serum/plasma application, and 5.00 mg/dL (0.442 mmol/L) for the urine application, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

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

Calibration is stable for approximately **5 days (120 hours),** but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control procedure. 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 the laboratory quality control procedure, sample results may be suspect. Follow the established 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 reagent 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.[13]

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 Creatinine assay utilizes the Linear data reduction method to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

$$\text{Creatinine Clearance} = \frac{\text{(urine creatinine concentration) x (urine volume)}}{\text{(serum creatinine concentration) x (collection time)}} \times \frac{1.73}{\text{BSA*}}$$

* BSA = body surface area in square meters

NOTE: Urine and serum creatinine concentrations must be expressed in the same units, urine volume must be expressed in mL, and urine collection time must be expressed in minutes or seconds.

Estimated GFR (eGFR) can be calculated using the four-parameter equation from the Modification of Diet in Renal Disease (MDRD) study. In the United States, the National Kidney Disease Education Program (NKDEP) provides guidelines for calculating and reporting eGFR.[15] Guidelines may vary in other countries.

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 **mg/dL** (µmol/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity c Creatinine assay serum/plasma application is **0.20 to 37.00 mg/dL** (17.7 to 3270.8 µmol/L).

The measuring interval of the Alinity c Creatinine assay urine application is **5.00 to 740.00** mg/dL (0.442 to 65.416 mmol/L).

LIMITATIONS OF THE PROCEDURE

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

EXPECTED VALUES

24-Hour Urinary Excretion, adjusted per kg body weight

To convert results from mg/dL to mg/kg/day (24-hour urinary excretion):

24-hour excretion = [(V × c) ÷ (W x 100)] mg/kg/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mg/dL)

W = body weight (kg)

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

24-hour excretion = [(V × c) ÷ W] µmol/kg/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mmol/L)

W = body weight (kg)

24-Hour Urinary Excretion, not adjusted per kg body weight

To convert results from mg/dL to mg/day (24-hour urinary excretion):

24-hour excretion = [(V × c) ÷ 100)] mg/day

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mg/dL)

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)

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Range

The serum/plasma reference ranges are from an Abbott Laboratories study of normal healthy adults, age 18 or older (120 males and 120 females). The urine reference ranges are based on the data of Junge et al.*14*

Serum/Plasma

	Range (mg/dL)	**Range (µmol/L)**
Adult, Male	0.72 to 1.25	63.6 to 110.5
Adult, Female	0.57 to 1.11	50.4 to 98.1

Pediatrics refrence range will be adopted from Caliber study web site:

https://caliperdatabase.org/

Female Reference Intervals

Age	Lower Limit	Upper Limit	Sample Size	Lower Confidence Intervals	Higher Confidence Intervals
0 to < 15 Days	0.42	1.05	158	(0.32, 0.47)	(0.97, 1.06)
15 Days to < 1 Year	0.31	0.53	130	(0.31, 0.33)	(0.51, 0.55)
1 to < 4 Years	0.39	0.55	121	(0.38, 0.41)	(0.54, 0.55)
4 to < 7 Years	0.44	0.65	146	(0.43, 0.45)	(0.62, 0.67)
7 to < 12 Years	0.52	0.69	234	(0.52, 0.53)	(0.67, 0.71)
12 to < 15 Years	0.57	0.8	184	(0.55, 0.58)	(0.80, 0.86)
15 to < 17 Years	0.59	0.86	77	(0.58, 0.61)	(0.83, 0.87)
17 to < 19 Years	0.6	0.88	88	(0.59, 0.61)	(0.86, 0.90)

Male Reference Intervals

Age	Lower Limit	Upper Limit	Sample Size	Lower Confidence Intervals	Higher Confidence Intervals
0 to < 15 Days	0.42	1.05	158	(0.32, 0.47)	(0.97, 1.06)
15 Days to < 1 Year	0.31	0.53	130	(0.31, 0.33)	(0.51, 0.55)
1 to < 4 Years	0.39	0.55	121	(0.38, 0.41)	(0.54, 0.55)
4 to < 7 Years	0.44	0.65	146	(0.43, 0.45)	(0.62, 0.67)
7 to < 12 Years	0.52	0.69	234	(0.52, 0.53)	(0.67, 0.71)
12 to < 15 Years	0.57	0.8	184	(0.55, 0.58)	(0.80, 0.86)
15 to < 17 Years	0.65	1.04	68	(0.63, 0.68)	(1.00, 1.08)
17 to < 19 Years	0.69	1.1	86	(0.66, 0.72)	(1.08, 1.13)

Urine*14*

	Adult Male	**Adult Female**
Concentration Range*	63 to 166 mg/dL (5.6 to 14.7 mmol/L)	47 to 110 mg/dL (4.2 to 9.7 mmol/L)
24 Hour Excretion*14*	12.1 to 28.9 mg/kg/day (107 to 256 µmol/kg/day)	10.7 to 26.0 mg/kg/day (95 to 230 µmol/kg/day)
	950 to 2490 mg/day (8.4 to 22.0 mmol/day)	710 to 1650 mg/day (6.3 to 14.6 mmol/day)
Creatinine Clearance*14*	Adult Male: 66 to 163 mL/min/1.73 m^2 BSA (1.10 to 2.72 mL/sec/1.73 m^2 BSA)	
	Adult Female: 66 to 165 mL/min/1.73 m^2 BSA (1.10 to 2.75 mL/sec/1.73 m^2 BSA)	

* Concentration is based on a daily urine output of 1.5 L.

National Kidney Disease Education Program (NKDEP) guidelines recommend that, for patients 18 and older, estimated GFR (eGFR) values greater than or equal to 60 mL/min/1.73 m^2 are reported as eGFR ≥ 60 mL/min/1.73 m^2.15

SPECIFIC PERFORMANCE CHARACTERISTICS

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

The Alinity c analyzer and the ARCHITECT c System and AEROSET System utilized the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 1 lot of the Alinity c Creatinine Reagent Kit, 1 lot of the Alinity c Multiconstituent Calibrator Kit, and 1 lot of commercially available controls and 1 instrument. Three serum controls and 2 urine controls were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.*16*

Serum/Plasma

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	0.72	0.011	1.5	0.014	1.9
Control Level 2	120	2.00	0.025	1.2	0.038	1.9
Control Level 3	120	6.34	0.035	0.6	0.102	1.6

[a] Includes within-run, between-run, and between-day variability.

Sample	n	Mean (µmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	63.6	0.95	1.5	1.22	1.9
Control Level 2	120	177.0	2.17	1.2	3.34	1.9
Control Level 3	120	560.3	3.09	0.6	9.00	1.6

[a] Includes within-run, between-run, and between-day variability.

Urine

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	67.71	1.173	1.7	1.371	2.0
Control Level 2	120	122.93	1.896	1.5	2.418	2.0

[a] Includes within-run, between-run, and between-day variability.

Sample	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	5.986	0.1038	1.7	0.1212	2.0
Control Level 2	120	10.867	0.1677	1.5	0.2138	2.0

[a] Includes within-run, between-run, and between-day variability.

Accuracy

This study was performed on the ARCHITECT c System.

Representative data from studies using **IDMS** traceable **NIST SRM 967** are summarized below.

	SRM 967 Level 1 (Target 0.753 mg/dL)	SRM 967 Level 2 (Target 3.916 mg/dL)
N	11	11
Concentration (mg/dL)	0.747	3.810
Bias (mg/dL)	-0.006	-0.106
%Bias	-0.84	-2.70
Total Error (%)*	10.74	9.06

* Total Error = %Bias + 2 x %CV

Total error was calculated using the absolute %Bias from the target SRM 967 values and total imprecision (%CV) determined at creatinine concentrations within 1 mg/dL of the SRM 967 target values.

Total Error Level 1 = 0.84% + 2 x 4.95% = 10.74%.

Total Error Level 2 = 2.70% + 2 x 3.18% = 9.06%.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2. Testing was conducted using 3 lots of the Alinity c Creatinine Reagent Kit on each of 2 instruments over a minimum of 3 days. The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below. These representative data support the lower limit of the measuring interval.[17]

Serum/Plasma

	mg/dL	µmol/L
LoB[a]	0.03	2.7
LoD[b]	0.06	5.3
LoQ[c]	**0.10**	8.8

[a]The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b]The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c]The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

Urine

	mg/dL	mmol/L
LoB[a]	1.38	0.122
LoD[b]	2.07	0.183
LoQ[c, d]	**5.00**	0.442

[a]The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b]The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c]The LoQ is defined as the lowest concentration at which a maximum allowable precision of **20 %CV was met**.

[d]This value represents the observed LoQ on the ARCHITECT System. The LoQ observed on the Alinity c analyzer supports this LoQ.

Linearity

A study was performed based on guidance from CLSI EP06-A.[18]

Serum/Plasma

This assay is linear across the measuring interval of **0.20 to 37.00 mg/dL** (17.7 to 3270.8 µmol/L).

Urine

This assay is linear across the measuring interval of **5.00 to 740.00 mg/dL** (0.442 to 65.416 mmol/L).

Interference

This study was performed on the AEROSET System.

Potentially Interfering Endogenous Substances and Potentially Interfering Drugs

Interference studies were conducted using an acceptance criteria of ≤ 10% of the target value. Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Medical Decision Level 1

Potentially Interfering Substance	**Interferent Level**		**Target Level (mg/dL)**	**Recovery (% of Target)**
	Default Units	**Alternate Units**		
Bilirubin	30 mg/dL	513 µmol/L	1.55	98
	60 mg/dL	1026 µmol/L	1.55	**72**
Hemoglobin	1000 mg/dL	10 g/L	1.40	105
	2000 mg/dL	20 g/L	1.40	109
Intralipid	750 mg/dL	7.5 g/L	1.43	99
	1000 mg/dL	10.0 g/L	1.43	98
Ascorbate	1.5 mg/dL	85 µmol/L	1.52	99
	3.0 mg/dL	170 µmol/L	1.52	99
Glucose	300 mg/dL	16.5 mmol/L	1.52	107
	600 mg/dL	33 mmol/L	1.52	116
Protein	10.6 g/dL	106 g/L	1.54	108
	14.3 g/dL	143 g/L	1.54	115

Medical Decision Level 2

Potentially Interfering Substance	**Interferent Level**		**Target Level (mg/dL)**	**Recovery (% of Target)**
	Default Units	**Alternate Units**		
Bilirubin	30 mg/dL	513 µmol/L	5.33	95
	60 mg/dL	1026 µmol/L	5.33	**75**

Potentially Interfering Substance	Interferent Level		Target Level (mg/dL)	Recovery (% of Target)
	Default Units	Alternate Units		
Hemoglobin	1000 mg/dL	10 g/L	4.70	102
	2000 mg/dL	20 g/L	4.70	103
Intralipid	750 mg/dL	7.5 g/L	4.62	99
	1000 mg/dL	10.0 g/L	4.62	99
Ascorbate	1.5 mg/dL	85 µmol/L	5.23	100
	3.0 mg/dL	170 µmol/L	5.23	100
Glucose	300 mg/dL	16.5 mmol/L	5.00	101
	600 mg/dL	33 mmol/L	5.00	103
Protein	10.8 g/dL	108 g/L	5.57	99
	14.7 g/dL	147 g/L	5.57	99

For the urine application, acetic acid (8.5 N) up to 6.25 mL/dL, ascorbate up to 200 mg/dL, boric acid up to 250 mg/dL, glucose up to 1000 mg/dL, hydrochloric acid (6 N) up to 2.5 mL/dL, nitric acid (6 N) up to 5.0 mL/dL, protein up to 50 mg/dL, sodium carbonate up to 1.25 g/dL, sodium fluoride up to 400 mg/dL, and sodium oxalate up to 60 mg/dL demonstrated less than 10% interference.

Interferences from medication or endogenous substances may affect results.[19]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[20]

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Creatinine vs ARCHITECT Creatinine	Serum	mg/dL	138	1.00	0.03	0.97	0.65 - 35.07
		µmol/L	138	1.00	2.29	0.97	57.1 - 3100.2
	Urine	mg/dL	68	1.00	1.00	1.01	11.01 - 640.40
		mmol/L	68	1.00	0.09	1.01	0.973 - 56.612

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