Creatinine2

FOR USE WITH

ARCHITECT

Read Highlighted Changes: Revised December 2022.

REF 04S9520

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Creatinine2 (also referred to as Crea2)

INTENDED USE

The Creatinine2 assay is used for the quantitation of creatinine in human serum, plasma, or urine on the ARCHITECT c Systems.

The Creatinine2 assay is to be used as an aid in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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

The Creatinine2 assay is an automated clinical chemistry assay.

At an alkaline pH, creatinine in the sample reacts with picric acid to form a creatinine-picrate complex that absorbs at 500 nm. The rate of increase in absorbance 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 ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Creatinine2 Reagent Kit 04S95

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

REF	04S9520
Tests per cartridge set	450
Number of cartridge sets per kit	8
Tests per kit	3600
R1	53.9 mL
R2	21.4 mL

R2 Active ingredient: picric acid 5.500 g/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 and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[6-9]

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	
P234	Keep only in original container.
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
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.

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The following warnings and precautions apply to: R2	
	
DANGER	Contains picric acid.
H314	Causes severe skin burns and eye damage.
EUH001	Explosive when dry.
Prevention	
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
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.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.
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.	

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- When either the R1 or R2 reagent cartridge becomes empty, replace both cartridges.
- Upon receipt, place reagent cartridges in an upright position for 4 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 4 hours 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 ARCHITECT System 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	10 days	
Opened	15 to 30˚C	Until expiration date	Store in upright position.

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 15 to 30˚C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or 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 ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Creatinine2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

Installation of all the required SmartWash updates on the ARCHITECT c Systems Assay Disk Version 17.00 (or higher) and either the MULTIGENT Assay Disk Version 9.00 (or higher) or the Special Chemistry Assay Disk Version 7.00 (or higher) must be completed prior to performing the assay. See below for impacted assays:

				VERSION	
Assay Name	Short Name	REF	Assay Number	Conventional Units / Alternate Units	SI Units / Alternate Units
Ceruloplasmin	Cerul	6K91	2966	10	10 (c8000) 9 (c4000, c16000)
Immunoglobulin M	IgM	1E01	1059	13	12
Kappa Light Chains	Kappa	6K96	2959	10	10
Lambda Light Chains	Lambd	4P80	2958	8	8
Microalbumin	uAlb	2K98	2839	8	8
Prealbumin	PAlb	1E02	1062	13	13
Salicylate	Sali	3K01	2860	6	6
Protein, Urine/CSF	Upro	7D79	1044	12	10

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

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	88.4	µmol/L (serum)
	0.0884	mmol/L (urine)

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

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

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

Specimen Type	Collection Vessel
Serum	Serum tubes
	Serum separator tubes
Plasma	Dipotassium EDTA tubes
	Lithium heparin tubes
	Lithium heparin separator tubes
	Sodium heparin tubes
Urine (random specimens or timed specimens collected over intervals up to 24 hours)	Clean plastic or glass container with or without preservatives[10-12]

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- 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.
- 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.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low-speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25°C)	7 days[13]
	2 to 8°C	7 days[13]
	-20°C	3 months[14]
Urine	Room temperature (20 to 25°C)	3 days[11]
	2 to 8°C	3 days[11]
	-20°C	2 weeks[15]

Avoid multiple freeze/thaw cycles.[14, 15]

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[16] The storage information provided here is based on references or data maintained by the manufacturer.

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

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.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04S95 Creatinine2 Reagent Kit

Materials Required but not Provided

- Creatinine2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator
- Controls containing creatinine
- Saline (0.85% to 0.90% NaCl)

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. 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: 8.4 µL (serum/plasma), 8.0 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 ARCHITECT System Operations Manual, Section 5.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V1501 and/or commercially available control material package insert for preparation and usage.

- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Automated or manual sample dilutions have not been evaluated for the Creatinine2 assay.

Serum/Plasma

Samples with a creatinine value exceeding 37.34 mg/dL (3300.9 µmol/L) are flagged with the code ">37.34 mg/dL" (">3300.9 µmol/L").

Urine

The standard dilution factor for the Creatinine2 urine assay is 1:20. The system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Samples with a creatinine value exceeding 740.00 mg/dL (65.416 mmol/L) are flagged with the code ">740.00 mg/dL" (">65.416 mmol/L").

Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration is stable for approximately 10 days (240 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 requirements for your laboratory. 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

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least 2 levels of controls (low and high) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

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.[17]

RESULTS

Calculation

The Creatinine2 assay utilizes the Linear 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 ARCHITECT System Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[18]

Serum/Plasma

	mg/dL	µmol/L
Analytical Measuring Interval (AMI)[a]	0.09 - 37.34	8.0 - 3300.9
Reportable Interval[b]	0.04 - 37.34	3.5 - 3300.9

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in mg/dL (µmol/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with a creatinine value below LoQ are reported as "<0.09 mg/dL" ("<8.0 µmol/L").

Urine

	mg/dL	mmol/L
Analytical Measuring Interval (AMI)[a]	2.54 - 740.00	0.225 - 65.416
Reportable Interval[b]	1.24 - 740.00	0.110 - 65.416

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in mg/dL (mmol/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with a creatinine value below LoQ are reported as "<2.54 mg/dL" ("<0.225 mmol/L").

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- The Creatinine2 assay is susceptible to interference from cephalosporin class antibiotics[19] and eltrombopag [20] at therapeutically relevant interferent concentrations. The assay is also susceptible to interference from acetohexamide, glucose, hydroxocobalamin, and total protein.
- Specimens with conjugated bilirubin levels greater than 20 mg/dL or unconjugated bilirubin greater than 8 mg/dL may cause falsely depressed results with the Creatinine2 assay. To estimate sample icterus levels, refer to the Sample Interference Indices instructions for use to assess hemolysis (H), icterus (I) and lipemia (L) (HIL) indices.
- Substances that demonstrated interference with the Creatinine2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- SmartWashes for assays impacted by Creatinine2 must be configured to avoid interference due to reagent carryover. See the INSTRUMENT PROCEDURE section of this package insert for the required assay file updates.

EXPECTED VALUES

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

Reference Range (Serum Pediatric)[21]

Age	Range (mg/dL)	Range* (µmol/L)
0 - 14 days	0.42 - 1.05	37.1 - 92.8
15 days - < 1 year	0.31 - 0.53	27.4 - 46.9
1 - < 4 years	0.39 - 0.55	34.5 - 48.6
4 - < 7 years	0.44 - 0.65	38.9 - 57.5
7 - < 12 years	0.52 - 0.69	46.0 - 61.0
12 - < 15 years	0.57 - 0.80	50.4 - 70.7
15 - < 17 years Male	0.65 - 1.04	57.5 - 91.9
15 - < 17 years Female	0.59 - 0.86	52.2 - 76.0
17 - < 19 years Male	0.69 - 1.10	61.0 - 97.2
17 - < 19 years Female	0.60 - 0.88	53.0 - 77.8

Reference Range (Serum Adults)[22]

Age	Range (mg/dL)	Range* (µmol/L)
18 years - < 41 years Female	0.5 - 1.0	44.2 - 88.4
18 years - < 41 years Male	0.6 - 1.2	53.0 - 106.1
41 years - < 61 years Female	0.5 - 1.1	44.2 - 97.2
41 years - < 61 years Male	0.6 - 1.3	53.0 - 114.9
61 years and above Female	0.5 - 1.2	44.2 - 106.1
61 years and above Male	0.7 - 1.3	61.9 - 114.9

Reference Range (Urine, Random)[23]

Age	Range (mg/dL)	Range* (mmol/L)
Male < 40 years	24 - 392	2.122 - 34.653
Male ≥ 40 years	22 - 328	1.945 - 28.995
Female < 40 years	16 - 327	1.414 - 28.907
Female ≥ 40 years	15 - 278	1.326 - 24.575

Normal Ranges of Creatinine Clearance[24]

Age/Gender	Range (mL/min/1.73 m^2)	Range (mL/s/1.73 m^2)
Adult (male)	85 - 125	1.42 - 2.08
Adult (female)	75 - 115	1.25 - 1.92

* Alternate result units were calculated by Abbott and are not included in the citation provided.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

Precision

Within-Laboratory Precision

Serum/Plasma

A study was performed based on guidance from CLSI EP05-A3.[25] Testing was conducted using 3 lots of the Creatinine2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 human serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	1.42	0.015	1.0	0.050 (0.016 - 0.050)	3.5 (1.1 - 3.5)
Control Level 2	80	5.91	0.035	0.6	0.147 (0.047 - 0.147)	2.5 (0.8 - 2.5)
Panel A	80	0.25	0.008	3.1	0.011 (0.010 - 0.011)	4.5 (3.9 - 4.5)
Panel B	80	26.00	0.121	0.5	0.588 (0.185 - 0.588)	2.3 (0.7 - 2.3)
Panel C	80	36.36	0.130	0.4	0.777 (0.260 - 0.777)	2.1 (0.7 - 2.1)

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (µmol/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	125.3	1.30	1.0	4.42 (1.36 - 4.42)	3.5 (1.1 - 3.5)
Control Level 2	80	522.4	3.03	0.6	13.02 (4.14 - 13.02)	2.5 (0.8 - 2.5)
Panel A	80	22.2	0.65	2.9	0.99 (0.82 - 0.99)	4.5 (3.7 - 4.5)
Panel B	80	2298.3	10.70	0.5	51.94 (16.33 - 51.94)	2.3 (0.7 - 2.3)
Panel C	80	3214.3	11.49	0.4	68.67 (22.97 - 68.67)	2.1 (0.7 - 2.1)

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Urine

A study was performed based on guidance from CLSI EP05-A3.[25] Testing was conducted using 3 lots of the Creatinine2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 human urine panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	57.77	0.491	0.9	1.194 (0.781 - 1.194)	2.1 (1.4 - 2.1)
Control Level 2	80	132.61	1.165	0.9	3.158 (1.860 - 3.158)	2.4 (1.4 - 2.4)
Panel A	80	5.37	0.233	4.3	0.294 (0.221 - 0.294)	5.5 (4.2 - 5.5)
Panel B	80	278.12	1.958	0.7	5.003 (2.671 - 5.003)	1.8 (1.0 - 1.8)
Panel C	80	701.12	3.303	0.5	12.844 (7.631 - 12.844)	1.8 (1.1 - 1.8)

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Sample	n	Mean (mmol/L)	Within-Run (Repeatability) SD	Within-Run (Repeatability) %CV	Within-Laboratory[a] SD (Range[b])	Within-Laboratory[a] %CV (Range[b])
Control Level 1	80	5.106	0.0434	0.8	0.1055 (0.0690 - 0.1055)	2.1 (1.4 - 2.1)
Control Level 2	80	11.723	0.1030	0.9	0.2791 (0.1644 - 0.2791)	2.4 (1.4 - 2.4)
Panel A	80	0.475	0.0207	4.4	0.0261 (0.0195 - 0.0261)	5.5 (4.2 - 5.5)
Panel B	80	24.586	0.1730	0.7	0.4423 (0.2361 - 0.4423)	1.8 (1.0 - 1.8)
Panel C	80	61.979	0.2920	0.5	1.1354 (0.6746 - 1.1354)	1.8 (1.1 - 1.8)

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Reproducibility

Serum/Plasma

A study was performed based on guidance from CLSI EP05-A3.[25] Testing was conducted using 1 lot of Creatinine2 reagent, 1 lot of Consolidated Chemistry Calibrator, 1 lot of each commercially available control, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Five levels of controls were tested in a minimum of 3 replicates (from separate sample cups), 2 times per day (separated by a minimum of two hours), on at least 5 different days.

Sample	n	Mean (mg/dL)	Repeatability SD	Repeatability %CV	Within-Laboratory[a] SD	Within-Laboratory[a] %CV	Reproducibility[b] SD	Reproducibility[b] %CV
Control Level 1	90	1.24	0.016	1.3	0.016	1.3	0.029	2.3
Control Level 2	90	5.60	0.035	0.6	0.040	0.7	0.061	1.1
Control Level A	90	0.69	0.012	1.7	0.012	1.7	0.016	2.4
Control Level B	90	1.89	0.021	1.1	0.023	1.2	0.030	1.6
Control Level C	90	5.66	0.035	0.6	0.042	0.7	0.056	1.0

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Sample	n	Mean (µmol/L)	Repeatability SD	Repeatability %CV	Within-Laboratory[a] SD	Within-Laboratory[a] %CV	Reproducibility[b] SD	Reproducibility[b] %CV
Control Level 1	90	110.0	1.45	1.3	1.45	1.3	2.59	2.4
Control Level 2	90	495.2	3.03	0.6	3.48	0.7	5.38	1.1
Control Level A	90	60.8	0.99	1.6	1.02	1.7	1.44	2.4
Control Level B	90	167.5	1.82	1.1	1.95	1.2	2.58	1.5
Control Level C	90	500.7	3.13	0.6	3.69	0.7	4.91	1.0

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Urine

A study was performed based on guidance from CLSI EP05-A3.[25] Testing was conducted using 1 lot of Creatinine2 reagent, 1 lot of Consolidated Chemistry Calibrator, 1 lot of each commercially available control, and 3 instruments. Each instrument was operated by a different technician, and each technician prepared an individual sample set. Four levels of controls were tested in a minimum of 3 replicates (from separate sample cups), 2 times per day (separated by a minimum of two hours), on at least 5 different days.

Sample	n	Mean (mg/dL)	Repeatability SD	Repeatability %CV	Within-Laboratory[a] SD	Within-Laboratory[a] %CV	Reproducibility[b] SD	Reproducibility[b] %CV
Control Level 1	90	59.69	0.657	1.1	0.671	1.1	0.912	1.5
Control Level 2	90	130.63	2.812	2.2	2.916	2.2	3.103	2.4
Control Level A	90	70.64	0.837	1.2	0.947	1.3	1.402	2.0
Control Level B	90	134.81	1.296	1.0	1.392	1.0	1.886	1.4

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Sample	n	Mean (mmol/L)	Repeatability SD	Repeatability %CV	Within-Laboratory[a] SD	Within-Laboratory[a] %CV	Reproducibility[b] SD	Reproducibility[b] %CV
Control Level 1	90	5.277	0.0581	1.1	0.0593	1.1	0.0806	1.5
Control Level 2	90	11.548	0.2485	2.2	0.2577	2.2	0.2742	2.4
Control Level A	90	6.245	0.0740	1.2	0.0838	1.3	0.1240	2.0
Control Level B	90	11.917	0.1146	1.0	0.1230	1.0	0.1667	1.4

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

[b] Includes repeatability (within-run), between-run, between-day, and between-instrument variability.

Accuracy

Serum

A study was performed to estimate the bias of the Creatinine2 assay relative to standard reference material NIST SRM 967. Testing was conducted using 3 lots of the Creatinine2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias ranged from -4.1% to 0.4% across all instruments, calibrator and reagent lots.

Urine

A study was performed to estimate the bias of the Creatinine2 assay relative to standard reference material NIST SRM 914. Testing was conducted using 3 concentrations of standard across 3 lots of the Creatinine2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias ranged from -4.8% to 3.3% across all concentrations of standard, instruments, calibrator and reagent lots.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[26] Testing was conducted using 3 lots of the Creatinine2 reagent kit on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

Serum/Plasma

	mg/dL	µmol/L
LoB[a]	0.02	1.8
LoD[b]	0.04	3.5
LoQ[c]	0.09	8.0

Urine

	mg/dL	mmol/L
LoB[a]	0.93	0.082
LoD[b]	1.24	0.110
LoQ[c]	2.54	0.225

[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 and was determined from n ≥ 60 replicates of low-analyte level samples.

Linearity

A study was performed based on guidance from CLSI EP06-A.[27]
This assay is linear across the analytical measuring interval of 0.09 to 37.34 mg/dL (8.0 to 3300.9 µmol/L) for serum, and 2.54 to 740.00 mg/dL (0.225 to 65.416 mmol/L) for urine.

Analytical Specificity

Interference

Serum/Plasma

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[28]
Each substance was tested at 2 levels of the analyte (approximately 0.6 mg/dL and 2.0 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)

Potentially Interfering Substance	Interferent Level		Analyte Level	
	Default Units	Alternate Units	Default Units	Alternate Units
Acetoacetate	20 mg/dL	1.96 mmol/L	0.6 mg/dL	53.0 µmol/L
			2.0 mg/dL	176.8 µmol/L
Bilirubin - conjugated	20 mg/dL	237.20 µmol/L	0.6 mg/dL	53.0 µmol/L
	40 mg/dL	474.40 µmol/L	2.0 mg/dL	176.8 µmol/L
Bilirubin - unconjugated	8 mg/dL	136.80 µmol/L	0.6 mg/dL	53.0 µmol/L
	40 mg/dL	684.00 µmol/L	2.0 mg/dL	176.8 µmol/L
Glucose	250 mg/dL	13.88 mmol/L	0.6 mg/dL	53.0 µmol/L
	750 mg/dL	41.63 mmol/L	2.0 mg/dL	176.8 µmol/L
Hemoglobin	1000 mg/dL	10.00 g/L	0.6 mg/dL	53.0 µmol/L
			2.0 mg/dL	176.8 µmol/L
Total protein	5.4 - 8.4 g/dL*	54.0 - 84.0 g/L	0.6 mg/dL	53.0 µmol/L
	11.0 g/dL**	110.0 g/L	2.0 mg/dL	176.8 µmol/L
Triglycerides	750 mg/dL	8.47 mmol/L	0.6 mg/dL	53.0 µmol/L
	1500 mg/dL	16.94 mmol/L	2.0 mg/dL	176.8 µmol/L

* Interference relative to a reference protein sample at 7.0 g/dL.
** Interference relative to a reference protein sample at 5.7 g/dL.

Interference beyond ± 10% [based on 95% Confidence Interval (CI)] was observed at the concentrations shown below for the following substances.

Interference Beyond ± 10% (Based on 95% CI)

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Bilirubin - conjugated	40 mg/dL	474.40 µmol/L	0.6 mg/dL	53.0 µmol/L	-14% (-16%, -13%)
Bilirubin - unconjugated	10 mg/dL	171.00 µmol/L	0.6 mg/dL	53.0 µmol/L	-11% (-12%, -9%)
Glucose	1000 mg/dL	55.50 mmol/L	0.6 mg/dL	53.0 µmol/L	42% (41%, 44%)
Glucose	1000 mg/dL	55.50 mmol/L	2.0 mg/dL	176.8 µmol/L	13% (13%, 14%)
Total protein	5.0 g/dL*	50.00 g/L	0.6 mg/dL	53.0 µmol/L	-14% (-15%, -14%)
Total protein	9.1 g/dL*	91.00 g/L	0.6 mg/dL	53.0 µmol/L	12% (11%, 12%)
Total protein	15.3 g/dL**	153.00 g/L	2.0 mg/dL	176.8 µmol/L	20% (19%, 21%)
Triglycerides	1000 mg/dL	11.29 mmol/L	0.6 mg/dL	53.0 µmol/L	11% (9%, 12%)

* Interference relative to a reference protein sample at 7.0 g/dL.
** Interference relative to a reference protein sample at 5.7 g/dL.

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[28]
Each substance was tested at 2 levels of the analyte (approximately 0.6 mg/dL and 2.0 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)

Potentially Interfering Substance	Interferent Level	
	Default Units	Alternate Units
Acetaminophen	160 mg/L	1059.20 µmol/L
Acetohexamide	0.5 mg/dL	15.41 µmol/L
Acetylcysteine	150 mg/L	919.50 µmol/L
Acetylsalicylic acid	30 mg/L	166.50 µmol/L
Ampicillin-Na	80 mg/L	215.41 µmol/L
Ascorbic acid	60 mg/L	340.80 µmol/L
Azlocillin	7 g/L	15.22 mmol/L
Biotin	4250 ng/mL	17.38 µmol/L
Ca-dobesilate	60 mg/L	143.40 µmol/L
Cefotaxime	53 mg/dL	1166.00 µmol/L
Cefoxitin	47 mg/L	109.98 µmol/L
Cephalothin	11 mg/dL	277.20 µmol/L
Cyclosporine	2 mg/L	1.66 µmol/L
Doxycycline	20 mg/L	45.00 µmol/L
Eltrombopag	10 mg/L	22.60 µmol/L
Hydroxocobalamin (Cyanokit)	187 mg/L	138.89 µmol/L
Ibuprofen	220 mg/L	1067.00 µmol/L
Levodopa	8 mg/L	40.56 µmol/L
Methyldopa	100 mg/L	473.00 µmol/L
Metronidazole	130 mg/L	759.20 µmol/L
Nitrofurantoin	0.3 mg/dL	12.60 µmol/L
Nitroglycerin	0.015 mg/L	66.05 nmol/L
Norfenefrine	4 mg/L	26.14 µmol/L
Phenylbutazone	330 mg/L	1069.20 µmol/L
Rifampicin	50 mg/L	61.00 µmol/L
Sodium heparin	4 U/mL	N/A
Sulbactam	240 mg/L	1028.98 µmol/L
Sulfamethoxazole	40 mg/dL	1579.16 µmol/L
Sulfapyridine	30 mg/dL	1203.00 µmol/L
Sulfasalazine	500 mg/L	1255.00 µmol/L
Theophylline (1.3-dimethylxanthine)	60 mg/L	333.00 µmol/L
Trimethoprim	5 mg/dL	172.00 µmol/L

N/A = Not Applicable

Interference beyond ± 10% [based on 95% Confidence Interval (CI)] was observed at the concentrations shown below for the following substances.

Interference Beyond ± 10% (Based on 95% CI)

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Acetohexamide	1.5 mg/dL	46.24 µmol/L	0.6 mg/dL	53.0 µmol/L	18% (16%, 20%)
Acetohexamide	2 mg/dL	61.65 µmol/L	2.0 mg/dL	176.8 µmol/L	10% (10%, 11%)
Cefoxitin	71 mg/L	166.14 µmol/L	0.6 mg/dL	53.0 µmol/L	14% (12%, 16%)
Cefoxitin	119 mg/L	278.46 µmol/L	2.0 mg/dL	176.8 µmol/L	13% (12%, 14%)
Cephalothin	180 mg/dL	4536.00 µmol/L	0.6 mg/dL	53.0 µmol/L	193% (190%, 196%)
Cephalothin	180 mg/dL	4536.00 µmol/L	2.0 mg/dL	176.8 µmol/L	56% (55%, 57%)
Eltrombopag	300 mg/L	678.00 µmol/L	0.6 mg/dL	53.0 µmol/L	53% (51%, 55%)
Eltrombopag	25 mg/L	56.50 µmol/L	2.0 mg/dL	176.8 µmol/L	-12% (-12%, -11%)
Hydroxocobalamin (Cyanokit)	375 mg/L	278.52 µmol/L	0.6 mg/dL	53.0 µmol/L	16% (14%, 18%)
Hydroxocobalamin (Cyanokit)	2259 mg/L	1677.81 µmol/L	2.0 mg/dL	176.8 µmol/L	19% (19%, 20%)
Methyldopa	200 mg/L	946.00 µmol/L	0.6 mg/dL	53.0 µmol/L	-17% (-18%, -15%)

Urine

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[28] / CLSI EP37, 1st ed. [29] Each substance was tested at 2 levels of the analyte (approximately 15 mg/dL and 400 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)

	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Acetoacetate	480 mg/dL	47.04 mmol/L
Ascorbate	220 mg/dL	12 496.00 µmol/L
Glucose	1000 mg/dL	55.50 mmol/L
Protein	50 mg/dL	0.50 g/L
Urobilinogen	40 mg/dL	0.40 g/L

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[28] / CLSI EP37, 1st ed.[29] Each substance was tested at 2 levels of the analyte (approximately 15 mg/dL and 400 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)

	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Acetaminophen	16 mg/dL	1059.20 µmol/L
Acetic acid (8.5N)	6.25 mL/dL	531.25 mmol/L
Acetylcysteine	15 mg/dL	919.50 µmol/L
Biotin	4250 ng/mL	17.38 µmol/L
Boric acid	250 mg/dL	40.43 mmol/L
Cefoxitin	100 mg/dL	2340.00 µmol/L
Cephalothin	180 mg/dL	4536.00 µmol/L
Homogentisic acid	3.5 g/L	20.81 mmol/L
Hydrochloric acid (6N)	2.5 mL/dL	150.74 mmol/L
Hydroxocobalamin (Cyanokit)	180 mg/L	133.69 µmol/L
Ibuprofen	22 mg/dL	1067.00 µmol/L
Levodopa	700 mg/L	3549.00 µmol/L
Methyldopa	20 mg/L	94.60 µmol/L
Nitric acid (6N)	5.0 mL/dL	299.90 mmol/L
Nitrofurantoin	150 mg/L	630.00 µmol/L
Nitrofurazone	3 mg/L	15.14 µmol/L
Sodium carbonate	1.25 g/dL	117.94 mmol/L
Sodium fluoride	400 mg/dL	95.26 mmol/L
Sodium oxalate	60 mg/dL	4477.61 µmol/L

Interference beyond ± 10% [based on 95% Confidence Interval (CI)] was observed at the concentrations shown below for the following substances.

Interference Beyond ± 10% (Based on 95% CI)

Potentially	Interferent Level		Analyte Level		%
Interfering Substance	**Default Units**	**Alternate Units**	**Default Units**	**Alternate Units**	**Interference (95% CI)**
Cefoxitin	400 mg/dL	9360.00 µmol/L	15 mg/dL	1.33 mmol/L	26% (24%, 27%)
Levodopa	1000 mg/L	5070.00 µmol/L	15 mg/dL	1.33 mmol/L	15% (13%, 16%)

Interferences from medication or endogenous substances may affect results.[30]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[31] using the Passing-Bablok regression method.

Creatinine2 vs Creatinine on the ARCHITECT c System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	128	mg/dL	1.00	-0.01	0.96	0.47 - 35.72
		(µmol/L)		(-0.25)		(41.2 - 3157.5)
Urine	129	mg/dL	1.00	-1.23	1.01	6.65 - 727.61
		(mmol/L)		(-0.11)		(0.587 - 64.321)

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Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
CONTAINS: PICRIC ACID	Contains Picric Acid: Prevent from forming crystals. Do not allow to dry out.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCT OF IRELAND	Product of Ireland
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

The ARCHITECT c System family of instruments consists of c4000, c8000, and c16000 instruments.


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For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, report it to the manufacturer and to your national authority.

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