Principle

Intended Use

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with UniCel[®] DxC 800 System(s) and SYNCHRON[®] Systems AQUA CAL 1, 2 and 3, are intended for the quantitative determination of chloride concentration in human serum, plasma or urine.

Clinical Significance

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Methodology

The SYNCHRON[®] System(s) determines chloride ion concentration by indirect potentiometry utilizing a solid state chloride electrode in conjunction with a glass sodium reference electrode.

To measure chloride concentrations, a precise volume of sample (40 microliters) is mixed with a buffered solution. The ratio used is one part sample to 33 parts buffer. The high molar strength buffer is used to establish a constant activity of chloride ions, calibrating the electrode to concentration values.

Chemical Reaction Scheme

The solid state chloride electrode consists of a sparingly soluble silver chloride compound.(1) When sample buffer mixture contacts the electrode, changes in electrode potential occur as the chloride ions in the sample shift the following chemical equilibrium:

$AgCl_{(s)} = Ag^{+}_{(aq)} + Cl_{(aq)}$

A stable electrode potential, referenced to the sodium reference electrode, is reached when a new chemical equilibrium is established, which is in part determined by the solubility product (Ksp) of the silver chloride compound. The silver chloride based electrode responds to silver ion concentration change according to the Nernst equation:

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\begin{split} & \mathsf{E} = \mathsf{Constant} + (\mathsf{slope})(\mathsf{log}[\mathsf{Ag^+}]) \\ & \mathsf{Since} \\ & \mathsf{K_{sp}} = [\mathsf{Ag^+}][\mathsf{Cl^-}] \\ & \mathsf{Thus} \\ & \mathsf{E} = \mathsf{Constant} + (\mathsf{slope})(\mathsf{log}(\mathsf{K_{sp}}/[\mathsf{Cl^-}])) \end{split}
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The AgCl electrode indirectly responds to chloride ions, and the electrode potential is inversely proportional to the chloride ion concentration in the sample. For more accurate measurement, the reference reagent containing chloride ions is introduced to the flow cell after the sample cycle, and the same chemical equilibrium shift takes place. The differential potential (voltage) between sample and reference reagent cycles is used for chloride calculation.

Specimen

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes PST, SST and Red Top BD microtainers

Spot urines should be aliquoted into a 13 x 75 Clear Cap BD tube

24 hour urine collections are usually received in 3000 mL plastic urine collection jugs.

Chloride (Cl) – Serum, Plasma, Urine Beckman UniCel DxC Systems

Specimen Storage and Stability

Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.(2,3)

Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at 2°C to 8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.(3)

It is recommended that random urine assays be performed within 2 hours of collection. (4)



For timed specimens, the collection container is to be kept in the refrigerator or on ice during the collection period. No preservative is required. Upon receipt in the laboratory, the collection container must be stored refrigerated until testing is performed. **Testing must be performed within 4 days (96 hours) of start of collection**.(5,6,7)

Sample Volume

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the *Primary Tube Sample Template*.

Unacceptable Specimens

Urine samples aspirated by the IRIS IQ are not acceptable for urine chemistry testing.

Urine collected in a BD UA Preservative Tube is not acceptable for urine chemistry testing.

Refer to the *Procedural Notes* section of this chemistry information sheet for information on unacceptable specimens.

Reagents

Contents

Each kit contains the following items:

ISE Electrolyte Buffer Reagent **Kit Reorder # 467915** Two Electrolyte Buffer Reagent Bottles (2 x 2 L) ISE Electrolyte Reference Reagent **Kit Reorder # 467935** Two Electrolyte Reference Reagent Bottles (2 x 2 L)

Volumes per Test

Sample Volume	40 µL
Reagent Volume	
ISE Electrolyte Buffer	1.27 mL
ISE Electrolyte Reference	3.23 mL (not part of sample dilution)

Reactive Ingredients

Reagent Constituents	
ISE Electrolyte Buffer Beagent	

ISE Electrolyte Buffer Reagent Tris

230 mmol/L

Chloride (CI) – Serum, Plasma, Urine Beckman UniCel DxC Systems

ISE Electrolyte Reference Reagent	
Sodium	7 mmol/L
Potassium	0.2 mmol/L
Chloride	5 mmol/L
Carbon Dioxide	1.5 mmol/L
Calcium	0.1 mmol/L
Also non-reactive chemicals nec	cessary for optimal system performance.

CAUTION: Avoid skin contact with reagent. Use water to wash reagent from skin.

Materials Needed But Not Supplied With Reagent Kit

SYNCHRON[®] Systems AQUA CAL 1 and 2 At least two levels of control material

Reagent Preparation

No preparation is required. Date and initial reagent container(s) and document in reagent log before loading each new carboy.

Acceptable Reagent Performance

The acceptability of this reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria, as defined in the Clinical Chemistry Quality Control Procedure #3000.T.

Reagent Storage and Stability

ISE Electrolyte Reference reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days, unless the expiration date is exceeded.

ISE Electrolyte Buffer reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days, unless the expiration date is exceeded.

For any electrolyte reagents frozen in transit, warm to room temperature, and mix thoroughly. Mix by gently inverting the bottle at least 20 times to redissolve salts back into solution.

Equipment

This test is performed on the Beckman UniCel DxC 800 systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the UniCel DxC 800 systems Reference Manual for detailed instructions.

Calibration

Calibrator Required

SYNCHRON® Systems AQUA CAL 1, and 2 (Kit Reorder #s 471288, 471291)

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the calibrators should be stored at 2°C to 8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days unless the expiration date is exceeded.

Chloride (Cl) - Serum, Plasma, Urine Beckman UniCel DxC Systems

Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

The system must have a valid calibration in memory before controls or patient samples can be run.

Under typical operating conditions the CI assay must be calibrated every 24 hours or with each new bottle of reagent and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/ 800 System Instructions for Use (IFU) manual.

For detailed calibration instructions, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

Traceability

Chloride (analyte) in this calibrator is traceable to NIST* SRM 918a/919a.

*NIST=National Institute of Standards and Technology

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodologies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

At least two levels of control material should be analyzed each shift. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the UniCel DxC 800 System Instructions For Use manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow.

NOTICE	
Do not use controls containing diethylamine HCI.	

The following controls should be used in accordance with the package instructions for use inserts. Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Controls are compiled statistically in the LIS and reagent lot changes are documented on DxC Reagent Log sheets.

Quality Control Material

Control	Storage
MAS ChemTrak 1	+2°C to +8°C*
MAS ChemTrak 3	+2°C to +8°C*
MAS Urine Chemistry 1	+2°C to +8°C**
MAS Urine Chemistry 2	+2°C to +8°C**

*Controls are received frozen and stored at -15°C to -25°C. Bottles of controls in use are thawed and stored at 2°C to 8°C and are good for 14 days. **Urine controls are received and stored at 2°C to 8°C. Bottles of controls in use are stored at 2°C to 8°C and are good for 30 days.

Chloride (Cl) – Serum, Plasma, Urine Beckman UniCel DxC Systems

Testing Procedure

- 1. If necessary, load the reagent onto the system.
- 2. After reagent load is completed, calibration is required.
- 3. Program samples and controls for analysis.
- 4. After loading samples and controls onto the system, follow the protocols for system operation.

For detailed testing procedures, refer to the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

Calculations

UniCel DxC Systems perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

24 hr timed urine specimens are calculated from the following equation:

Urine Chloride $\frac{\text{mmol}}{\text{L}} \times \frac{\text{L}}{1000\text{mL}} \times \text{Total volume collected (mL)} = \text{mmol/24hr}$

Calculations are only performed on 24 hour collections (±15 minutes) and reported as mmol/24 hr. Do not round off total collection time.

Reporting Results

Equivalency between the SYNCHRON LX and UniCel DxC 800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

Reference Intervals

The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.(8)

F	Ret	e	er	nce	In	ter	va	S	

	Sample Type	Reference Intervals	
	Serum or Plasma	98 - 107 mmol/L	
Literature	Urine (timed)	110 – 250 mmoL/24 hrs	
SYNCHRON	Serum or Plasma	101 – 111 mmol/L	
	Serum or Plasma	95 - 110 mmol/L	
UCDMC	Urine (timed)	110 – 250 mmoL/24 hrs	

Refer to References (5, 8,9) for guidelines on establishing laboratory-specific reference intervals.

Reference interval for a spot or random urine sample has not been established.

Critical Values

None

Procedural Notes

Anticoagulant Test Results

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Compatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mmol/L)
Ammonium Heparin	14 Units/mL	NSI ^a
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	NSI

^a NSI = No Significant Interference (within ± 4.0 mmol/L or 4%).

The following anticoagulants were found to be incompatible with this method:

Incompatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mmol/L) ^a
EDTA	1.5 mg/mL	-5.3

^a Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

Limitations

If urine or fluid samples are cloudy or turbid or if samples are visibly contaminated with blood, it is recommended that they be centrifuged before analysis.

Interferences

The following substances were tested for interference with this methodology:

Interferences

Substance	Source Level Tested		Interferences ^a	
Bilirubin (unconjugated)	Bovine	30 mg/dL	NSI ^b	
Hemoglobin	RBC Hemolysate 500 mg/dL N		NSI	
Lipemia	Intralipid ^c	Intralipid ^c 500 mg/dL NSI		
Acetylsalicylic Acid	NA ^d	60 mgl/dL	NSI	
Ammonium Nitrate	NA	40 mmol/L	NSI	
Cefotaxime	Cefotaxime sodium salt	500 µg/mL	NSI	
Cefoxitin	Cefoxitin sodium salt	200 µg/mL	NSI	
Sulfobromophthalein	Sulfobromophthalein sodium salt 2.0 mg/dL NSI		NSI	
N-Acetyl Cysteine	NA	2 mmol/L	+3 mmol/L	
Bromide	Lithium Bromide	1 mmol/L	+8 mmol/L	
lodide	Sodium Iodide	4 mmol/L	+2 mmol/L	
L-Dopa	NA	40 µg/mL	-3 mmol/L	

^a Plus (+) or minus (-) signs in this column signify positive or negative interference.

Chloride (CI) – Serum, Plasma, Urine Beckman UniCel DxC Systems

^b NSI = No Significant Interference (within ±4.0 mmol/L or 4%).

^c Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

^d NA = Not applicable.

Grossly lipemic samples should be ultracentrifuged and the analysis performed on the infranate.

Refer to References (10,11,12) for other interferences caused by drugs, disease and preanalytical variables.

Performance Characteristics

Analytical Measurement Range

The SYNCHRON[®] System(s) method for the determination of this analyte provides the following analytical range:

Analytical measurement Range (AMR)

Sample Type	Conventional Units
Serum/Plasma	50 - 200 mmol/L
Urine	15 - 300 mmol/L

Clinical Reportable Range

Clinical Reportable Range (CRR)

Sample Type	Conventional Units
Serum/Plasma	50 - 200 mmol/L
Urine	15 - 300 mmol/L

Serum/plasma samples with concentrations below the AMR and CRR (< 50 mmo/L) are reported as "< 50 mmol/L". Serum/plasma/fluid samples with concentrations greater than the AMR and CRR (> 200 mmol/L) are reported as "> 200 mmol/L".

Urine samples with concentrations below the AMR and CRR (< 15 mmol/L) are reported as "< 15 mmolL". Urine samples with concentrations greater than the AMR and CRR (> 300 mmol/L) are reported as "> 300 mmol/L".

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for CI determination is 50 mmol/L for serum, plasma or fluids and 15 mmol/L for urine. Urine results less than 15 mmol/L are reported as < 15 mmol/L.

Equivalency

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

As determined by Beckman

Serum or Plasma (in the range of 83.36 to 179.93 mmol/L):

· •	,
Y (SYNCHRON LX Systems)	= 1.018X - 1.92
Ν	= 99
MEAN (SYNCHRON LX Systems)	= 114.3
MEAN (SYNCHRON CX Systems)	= 114.2
CORRELATION COEFFICIENT (r)	= 0.992

Chloride (Cl) – Serum, Plasma, Urine Beckman UniCel DxC Systems

Technical Procedure 3119

Urine (in the range of 15.6 to 290.4 mmol/L): Y (SYNCHRON LX Systems) N MEAN (SYNCHRON LX Systems) MEAN (SYNCHRON CX Systems) CORRELATION COEFFICIENT (r)	= 0.986X + 0.15 = 125 = 129.3 = 130.9 = 0.997
Serum or Plasma (in the range of 53 to 200 mmol/L): Y (UniCel DxC Systems) N MEAN (UniCel DxC Systems) MEAN (SYNCHRON LX Systems) CORRELATION COEFFICIENT (r)	= 1.005X - 0.86 = 194 = 108.0 = 108.3 = 0.997
Urine (in the range of 14.9 to 300 mmol/L): Y (UniCel DxC Systems) N MEAN (UniCel DxC Systems) MEAN (SYNCHRON LX Systems) CORRELATION COEFFICIENT (r)	= 0.982X + 0.52 = 72 = 141.8 = 143.8 = 1.000

Refer to References (13) for guidelines on performing equivalency testing.

Equivalency assessed by Deming regression analysis of patient samples to accepted clinical methods.

As determined at UCDMC

Serum or Plasma (in the range of 54 to 150 mmol/L): Y (UniCel DxC800-4118) N MEAN (UniCel DxC800-4118) MEAN (UniCel DxC800-1805) CORRELATION COEFFICIENT (r)	= 0.919X + 5.6 = 56 = 100.8 = 103.6 = 0.9971
Urine (in the range of 20 to 236 mmol/L): Y (SYNCHRON LX20PRO-4118) N MEAN (UniCel DxC800-4118) MEAN (SYNCHRON LX20PRO-2194) CORRELATION COEFFICIENT (r)	= 0.998X - 1.2 = 23 = 102.3 = 103.7 = 0.9995
Serum or Plasma (in the range of 54 to 150 mmol/L): Y (UniCel DxC800-4427) N MEAN (UniCel DxC800-4427) MEAN (UniCel DxC800-1805) CORRELATION COEFFICIENT (r)	= 0.947X + 1.9 = 56 = 100.0 = 103.6 = 0.9948
Urine (in the range of 20 to 236 mmol/L): Y (SYNCHRON LX20PRO-4427) N MEAN (UniCel DxC800-4427) MEAN (USYNCHRON LX20PRO-2194) CORRELATION COEFFICIENT (r)	= 1.000X - 1.9 = 23 = 101.8 = 103.7 = 0.9957

Chloride (Cl) – Serum, Plasma, Urine Beckman UniCel DxC Systems **Technical Procedure 3119**

beekingin onioer byo oystems	
Serum or Plasma (in the range of 54 to 150 mmol/L): Y (UniCel DxC800-4449)	= 0.922X + 5.7
N	= 56
MEAN (UniCel DxC800-4449)	= 101.2
MEAN (UniCel DxC800-1449) MEAN (UniCel DxC800-1805)	= 101.2 = 103.6
CORRELATION COEFFICIENT (r)	= 0.9967
Urine (in the range of 20 to 236 mmol/L):	
Y (SYNCHRON LX20PRO-4449)	= 1.040X - 3.3
Ň	= 23
MEAN (UniCel DxC800-4449)	= 104.6
MEAN (SYNCHRON LX20PRO-2194)	= 103.7
CORRELATION COEFFICIENT (r)	= 0.9994
Serum or Plasma (in the range of 56 to 186 mmol/L):	
Y (UniCel DxC800-4427)	= 1.027X - 3.5
Ν	= 57
MEAN (UniCel DxC800-4427)	= 101.5
MEAN (UniCel DxC800-4118)	= 102.3
CORRELATION COEFFICIENT (r)	= 0.9981
Urine (in the range of 18 to 232 mmol/L):	
Y (UniCel DxC800-4427)	= 1.002X - 0.7
N	= 1.002 × - 0.7
MEAN (UniCel DxC800-4427)	= 101.8
MEAN (UniCel DxC800-4118)	= 102.3
CORRELATION COEFFICIENT (r)	= 0.9974
Serum or Plasma (in the range of 56 to 186 mmol/L):	
Y (UniCel DxC800-4449)	= 0.995X + 0.9
N	= 57
MEAN (UniCel DxC800-4449)	= 102.7
MEAN (UniCel DxC800-4118)	= 102.3
CORRELATION COEFFICIENT (r)	= 0.9979
Urine (in the range of 18 to 232 mmol/L):	
Y (UniCel DxC800-4449)	= 1.041X - 2.0
N	= 23
MEAN (UniCel DxC800-4449)	= 104.6
MEAN (UniCel DxC800-4118)	= 102.3
CORRELATION COEFFICIENT (r)	= 0.9996
Serum or Plasma (in the range of 55 to 187 mmol/L):	
Y (UniCel DxC800-4449)	= 0.962X + 5.0
N	= 59
MEAN (UniCel DxC800-4449)	= 104.7
MEAN (UniCel DxC800-4427)	= 103.6
CORRELATION COEFFICIENT (r)	= 0.9967
	- 0.0007
Urine (in the range of 18 to 234 mmol/L):	
Y (UniCel DxC800-4449)	= 1.040X - 1.2
Ν	= 23
MEAN (UniCel DxC800-4449)	= 104.6
MEAN (UniCel DxC800-4427)	= 101.8
CORRELATION COEFFICIENT (r)	= 0.9980

Precision

A properly operating UniCel DxC System(s) should exhibit imprecision values less than or equal to the maximum performance limits in the table below. Maximum performance limits were derived by an examination of the imprecision of various methods, proficiency test summaries, and literature sources.

As determined by Beckman

Maximum Performance Limits

Type of Precision Sample Type		1 SD	Changeover Value ^a mmol/L	%CV
Within run	Serum/Plasma	2.0	100	2.0
Within-run	Urine	3.0	100	3.0
Tatal	Serum/Plasma	3.0	100	3.0
Total	Urine	4.5	100	4.5

^a When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Type of Precision	Sample Type	n	Mean (mmol/L)	1 SD	%CV
	SYNCHRON 1	20	80.8	0.4	0.5
DxC800-4118	SYNCHRON 3	20	115.8	1.0	0.9
Within-run	MAS Urine Chemistry 1	20	48.8	0.5	1.1
	MAS Urine Chemistry 2	20	150.1	0.9	0.6
	SYNCHRON 1	20	78.7	0.7	0.9
DxC800-4427	SYNCHRON 3	20	116.3	0.4	0.4
Within-run	MAS Urine Chemistry 1	20	49.0	0.5	0.9
	MAS Urine Chemistry 2	20	149.3	0.8	0.5
	SYNCHRON 1	20	77.8	0.7	0.9
DxC800-4449	SYNCHRON 3	20	112.8	1.1	0.9
Within-run	MAS Urine Chemistry 1	20	48.5	0.5	1.1
	MAS Urine Chemistry 2	20	150.7	0.7	0.4

Precision established at UCDMC

Chloride (CI) – Serum, Plasma, Urine Beckman UniCel DxC Systems

Technical Procedure 3119

Type of Imprecision	Sample Type	n	Mean (mmol/L)	SD	%CV
	MAS ChemTrak 1	1333	101	1.2	1.2
DxC800-4118	MAS ChemTrak 3	1325	88	1.1	1.3
Day to Day	MAS Urine Chemistry 1	267	49	1.1	2.2
	MAS Urine Chemistry 2	272	146	2.3	1.6
	MAS ChemTrak 1	1323	101	1.1	1.1
DxC800-4427	MAS ChemTrak 3	1320	88	0.9	1.0
Day to Day	MAS Urine Chemistry 1	358	49	1.2	2.4
	MAS Urine Chemistry 2	360	147	2.4	1.6
	MAS ChemTrak 1	1337	101	1.2	1.2
DxC800-4449 Day to Day	MAS ChemTrak 3	1332	88	1.0	1.1
	MAS Urine Chemistry 1	351	49	1.1	2.2
	MAS Urine Chemistry 2	342	146	2.2	1.5

Comparative Performance

The data for a SYNCHRON LX System evaluated using the NCCLS Approved Guideline EP5-A appears in the table below.(14)

As determined by Beckman

NCCLS EP5-A Precision Estimate Method

Type of Imprecision	Sample Type	No.	No. Data Points ^a	Test Mean Value	EP5-A Calculated Point Estimates	
Imprecision	oumpie Type	Systems	Points	(mmol/L)	SD	%CV
	Serum Control 1	1	80	79.88	0.37	0.5
Within-run	Serum Control 2	1	80	118.44	0.60	0.5
vvitnin-run	Urine Control 1	1	80	82.27	0.50	0.6
	Urine Control 2	1	80	203.76	1.45	0.7
	Serum Control 1	1	80	79.88	0.78	1.0
Total	Serum Control 2	1	80	118.44	1.03	0.9
Total	Urine Control 1	1	80	82.27	0.70	0.9
	Urine Control 2	1	80	203.76	2.62	1.3

^a The point estimate is based on the data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on a SYNCHRON $LX^{(R)}$ System and are not intended to represent the performance specifications for this reagent.

Additional Information

For more detailed information on UniCel DxC Systems, refer to the *Instructions for Use* and *Reference* manual.

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https://www.beckmancoulter.com/wsrportal/techdocs?docname=/cis/A18480/AH/EN_CL.pdf

Prepared By	Date Adopted	Supersedes Procedure #
Michael Inn	October, 2000	Reformatted

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
			11/27/2000	G. Kost
			12/28/2001	G.Kost
			10/16/2002	G. Kost
			10/10/2003	S. Devaraj
			10/25/2004	S. Devaraj
			11/28/2005	G. Kost
			09/26/2006	G. Kost
			11/05/2007	G. Kost
			06/16/2008	G. Kost
			09/15/2009	G. Kost
			10/12/2010	G. Kost
12/2010	update	M. Inn		
06/28/2011	Removed sample types CSF & fluids	M.Inn	07/06/2011	G. Kost
			11/16/2011	G. Kost
08/07/2013	No reference interval for spot/random urines	M. Inn	08/16/2013	G. Kost
			09/17/2013	G. Kost
04/03/2015	Updated 24-hour collection stability	kdagang	04/15/2015	J. Gregg