Sodium (Na) - Serum, Plasma, Urine, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3145

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Michael Inn	October, 2000	Reformatted

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08/07/2013	No reference interval for spot/random urines	M. Inn	08/16/2013	G. Kost
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Sodium (Na) - Serum, Plasma, Urine, Dialysate Solutions
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For *In Vitro* Diagnostic Use Only

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 sodium concentration in human serum, plasma, urine or dialysate solutions.

Clinical Significance

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of hormone aldosterone), diabetes insipidus, adrenal hypertension, Addison‘s disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Methodology

The SYNCHRON® System(s) determines sodium ion concentration by indirect potentiometry utilizing two glass sodium electrodes (one acts as the reference electrode).

To measure sodium 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 coefficient for sodium ions, calibrating the electrode to concentration values.

Chemical Reaction Scheme

The sodium electrode is made of lithium-sodium-aluminum-silicate glass. It is essential that the outer layer of the glass electrode is adequately hydrated. When the sample buffer mixture contacts the electrode, sodium ions in the sample undergo an ion exchange process with the sodium ions in the hydrated layer of the electrode. Changes in electrode potential occur as the ion exchange process takes place. These changes in electrode potential are referenced to the reference electrode. The "referenced potential" follows the Nernst equation and allows the calculation of sodium concentration in the sample:

$$E = \text{Constant} + (\text{slope})\ (\log[Na^+])$$

For more accurate measurement, the reference reagent containing sodium ions is introduced into the flow cell after the sample cycle, and the same ion exchange process takes place. The differential potential (voltage) between sample and reference reagent cycles is used for the calculation.

Under ideal conditions, the electrode imparts a selectivity of 300:1 over potassium and is insensitive to hydrogen ions in solutions buffered from pH 6 to 10.

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.
Dialysate solutions should be aliquoted into a 13 x 75 Clear Cap BD tube

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(1) Freshly drawn serum, plasma, properly collected urine (random/timed) or dialysate solutions are the preferred specimens. Whole blood is not recommended for use as a sample.

Specimen Storage and Stability

1. 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)
2. 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.(2) Thawed samples should be mixed gently and re-centrifuged prior to analysis.
3. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period. No preservative is required.(3)
4. **Urine samples aspirated by the IRIS IQ are not acceptable for urine chemistry testing.**
5. **Urine collected in a BD UA Preservative Tube is not acceptable for urine chemistry testing.**

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.

Criteria for Unacceptable Specimens

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 Reagent

Tris	230 mmol/L

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 necessary 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, 2 and 3
At least two levels of control material

Reagent Preparation

1. No preparation is required.
2. 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

1. 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.
2. 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.
3. 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, 2 and 3 (**Kit Reorder #s 471288, 471291, 471294**)

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

1. If unopened, the calibrators should be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at +2°C to +8°C for 60 days unless the expiration date is exceeded.
2. Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibration Information

1. The system must have a valid calibration in memory before controls or patient samples can be run.
2. Under typical operating conditions the NA 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.
3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.
4. 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

Sodium (analyte) in this calibrator is traceable to NIST* SRM 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 HCl.

The following controls should be used in accordance with the package instructions for use inserts. Copies of these inserts can be found in the *Control IFUs* folder on the S drive (*S:\APS\ClinLab\PoliciesandProcedures\1000-8999CLINICALPATHOLOGY\3000-3999Chemistry\3000-3499AutomatedChemistry\Control IFUs*). 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.

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:

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

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.(4)

Reference Intervals

Intervals	Sample Type	Conventional Units		S.I Units
Literature	Serum or Plasma	136 - 145 mmol/L		136 - 145 mmol/L
	Urine (timed)	40 – 220 mmoL/24 hrs		40 – 220 mmoL/24 hrs
SYNCHRON	Serum or Plasma	136 – 144 mmol/L		136 – 144 mmol/L
UCDMC	Serum or Plasma	Premature	132 - 140 mmol/L	132 - 140 mmol/L
	Serum or Plasma	Mature < 1 yr	132 - 140 mmol/L	132 - 140 mmol/L
	Serum or Plasma	1 to 12 yr	132 - 140 mmol/L	132 - 140 mmol/L
	Serum or Plasma	> 12 yr	132 - 140 mmol/L	132 - 140 mmol/L
	Urine (random)*	N/A		N/A
	Urine (timed)	Infant	0.3 - 3.5 mmol/24 hrs	0.3 - 3.5 mmol/24 hrs
	Urine (timed)	Child	40 - 180 mmol/24 hrs	40 - 180 mmol/24 hrs
	Urine (timed)	Adult	40 - 220 mmol/24 hrs	40 - 220 mmol/24 hrs

Refer to References (5,6,7) for guidelines on establishing laboratory-specific reference intervals.

Pediatric and timed urine reference intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

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

There are no published reference intervals for dialysate solutions. These are custom solutions for each patient and results from analysis are used to verify accuracy of dialysate solution preparations.

Critical Values

Sodium results **≤ 120 mmol/L** and **≥ 160 mmol/L** are considered critical values and should be called immediately to the attending physician or charge nurse.

Procedural Notes

Anticoagulant Test Results

1. 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

[a] NSI = No Significant Interference (within ± 2.0 mmol/L or 2%).

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

Incompatible Anticoagulants

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (g/dL)[a]
Potassium Oxalate/ Sodium Fluoride	2.0 / 2.5 mg/mL	+3.5

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

Limitations

1. If urine samples are cloudy or turbid, it is recommended that they be centrifuged before transfer to a sample cup.
2. For each sodium measurement, the potassium concentration is used in the calculation of the sodium concentration. If the potassium chemistry is not calibrated, or the potassium value is out of range for the sample type, the sodium value will be suppressed for urine samples. Serum samples will use a nominal value for potassium.

   Urine sodium results with the error “DL” should be diluted 1 to 1 with MAS Urine Chemistry Control 1 and rerun. Calculate the patient’s sodium by subtracting the urine sodium control.

$$\frac{\text{Na}}{2} + \frac{\text{MAS UC1}}{2} = \text{urine sodium result from 1 to 1 dilution}$$

   If the diluted result is < 10 mmol/L, report urine sodium as < 10 mmol/L.

Interferences

1. The following substances were tested for interference with this methodology:

Interferences

Substance	Source	Level Tested	Observed Effect[a]
Bilirubin (unconjugated)	Bovine	30 mg/dL	NSI[b]
Hemoglobin	RBC Hemolysate	500 mg/dL	NSI
Lipemia	Intralipid[c]	500 mg/dL	NSI
Lithium	Lithium Acetoacetic Acid	20 mmol/L	+5 mmol/L
Benzalkonium chloride	NA[d]	0.5 mg/dL	-2 mmol/L
Methylbenzethonium Chloride	NA	0.2 mg/dL	-2 mmol/L

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

[b] NSI = No Significant Interference (within ±2 mmol/L or 2%).

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

[d] NA = Not applicable.

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

3. Refer to References (8,9,10) 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 ranges:

Analytical measurement Range (AMR)

Sample Type	Conventional Units	S.I. Units
Serum/Plasma/Fluids	100 - 200 mmol/L	100 - 200 mmol/L
Urine	10 - 300 mmol/L	10 - 300 mmol/L

Clinical Reportable Range:

Clinical Reportable Range (CRR)

Sample Type	Conventional Units	S.I. Units
Serum/Plasma/Fluids	100 - 200 mmol/L	100 - 200 mmol/L
Urine	10 - diluted result mmol/L	10 - diluted result mmol/L

Serum/plasma/fluid samples with concentrations below the AMR and CRR (< 100 mmol/L) should be reported as "**< 100 mmol/L**". Serum/plasma/fluid samples with concentrations greater than the AMR and CRR (> 200 mmol/L) should be reported as "**> 200 mmol/L**".

Urine samples with concentrations below the AMR and CRR (< 10 mmol/L) should be reported as "**< 10 mmol/**L" Results that are UL should be diluted times 2 with Urine Chemistry control 1 to verify result is <10mmol/L. Urine samples with concentrations greater than the AMR (> 300 mmol/L) should be diluted with deionized water and reanalyzed.

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.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for NA determination is 100 mmol/L for serum or plasma, and 10 mmol/L for urine. Urine results less than 10 mmol/L are reported as < 10 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 100.1 to 190.8 mmol/L):

Y (SYNCHRON LX Systems)	= 0.979X + 2.20
N	= 236
MEAN (SYNCHRON LX Systems)	= 141.1
MEAN (SYNCHRON CX Systems)	= 141.9
CORRELATION COEFFICIENT (r)	= 0.992

Urine (in the range of 17.9 to 265.2 mmol/L):

Y (SYNCHRON LX Systems)	= 1.005X + 0.48
N	= 100
MEAN (SYNCHRON LX Systems)	= 113.9
MEAN (SYNCHRON CX Systems)	= 112.8
CORRELATION COEFFICIENT (r)	= 0.999

Serum or Plasma (in the range of 104 to 200 mmol/L):

Y (UniCel DxC Systems)	= 1.012X - 0.07
N	= 149
MEAN (UniCel DxC Systems)	= 141.7
MEAN (SYNCHRON LX Systems)	= 140.7
CORRELATION COEFFICIENT (r)	= 0.997

Urine (in the range of 18 to 294 mmol/L):

Y (UniCel DxC Systems)	= 1.017X - 1.57
N	= 110
MEAN (UniCel DxC Systems)	= 125.3
MEAN (SYNCHRON LX Systems)	= 124.8
CORRELATION COEFFICIENT (r)	= 0.999

Refer to References (11) 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 104 to 163 mmol/L):

Y (UniCel DxC800-4118)	= 1.041X - 6.7
N	= 31
MEAN (UniCel DxC800-4118)	= 136.1
MEAN (UniCel DxC800-1805)	= 137.2
CORRELATION COEFFICIENT (r)	= 0.9973

Urine (in the range of 11 to 240 mmol/L):

Y (UniCel DxC800-4118)	= 0.991X + 1.9
N	= 23
MEAN (UniCel DxC800-4118)	= 88.9
MEAN (SYNCHRON LX20PRO-2194)	= 87.8
CORRELATION COEFFICIENT (r)	= 0.9999

Serum or Plasma (in the range of 104 to 163 mmol/L):

Y (UniCel DxC800-4427)	= 1.080X - 13.1
N	= 31
MEAN (UniCel DxC800-4427)	= 135.0
MEAN (UniCel DxC800-1805)	= 137.2
CORRELATION COEFFICIENT (r)	= 0.9973

Urine (in the range of 11 to 240 mmol/L):

Y (UniCel DxC800-4427)	= 1.019X + 1.2
N	= 23
MEAN (UniCel DxC800-4427)	= 90.6
MEAN (USYNCHRON LX20PRO-2194)	= 87.8
CORRELATION COEFFICIENT (r)	= 0.9970

Serum or Plasma (in the range of 104 to 163 mmol/L):

Y (UniCel DxC800-4449)	= 1.051X - 6.1
N	= 31
MEAN (UniCel DxC800-4449)	= 138.0
MEAN (UniCel DxC800-1805)	= 137.2
CORRELATION COEFFICIENT (r)	= 0.9963

Urine (in the range of 11 to 240 mmol/L):

Y (UniCel DxC800-4449)	= 1.021X + 0.2
N	= 23
MEAN (UniCel DxC800-4449)	= 89.8
MEAN (SYNCHRON LX20PRO-2194)	= 87.8
CORRELATION COEFFICIENT (r)	= 0.9996

Serum or Plasma (in the range of 100 to 163 mmol/L):

Y (UniCel DxC800-4427)	= 1.037X - 6.1
N	= 31
MEAN (UniCel DxC800-4427)	= 135.0
MEAN (UniCel DxC800-4118)	= 136.1
CORRELATION COEFFICIENT (r)	= 0.9961

Urine (in the range of 12 to 239 mmol/L):

Y (UniCel DxC800-4427)	= 1.028X - 0.7
N	= 23
MEAN (UniCel DxC800-4427)	= 90.6
MEAN (UniCel DxC800-4118)	= 88.9
CORRELATION COEFFICIENT (r)	= 0.9979

Serum or Plasma (in the range of 100 to 163 mmol/L):

Y (UniCel DxC800-4449)	= 1.009X + 0.7
N	= 31
MEAN (UniCel DxC800-4449)	= 138.0
MEAN (UniCel DxC800-4118)	= 136.1
CORRELATION COEFFICIENT (r)	= 0.9975

Urine (in the range of 12 to 239 mmol/L):

Y (UniCel DxC800-4449)	= 1.031X - 1.8
N	= 23
MEAN (UniCel DxC800-4449)	= 89.8
MEAN (UniCel DxC800-4118)	= 88.9
CORRELATION COEFFICIENT (r)	= 0.9998

Serum or Plasma (in the range of 99 to 165 mmol/L):

Y (UniCel DxC800-4449)	= 0.973X + 6.7
N	= 32
MEAN (UniCel DxC800-4449)	= 138.0
MEAN (UniCel DxC800-4427)	= 135.0
CORRELATION COEFFICIENT (r)	= 0.9954

Urine (in the range of 12 to 242 mmol/L):

YY (UniCel DxC800-4449)	= 1.003X - 1.0
N	= 23
MEAN (UniCel DxC800-4449)	= 89.8
MEAN (UniCel DxC800-4427)	= 90.6
CORRELATION COEFFICIENT (r)	= 0.9987

Precision

A properly operating SYNCHRON LX System 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]	%CV
		mmol/L	mmol/L	
Within-run	Serum/Plasma	1.0	100.0	1.0
	Urine	2.0	50.0	4.0
Total	Serum/Plasma	1.5	100.0	1.5
	Urine	3.0	50.0	6.0

[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.

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Precision established at UCDMC

Type of Precision	Sample Type	n	Mean (mmol/L)	1 SD	%CV
DxC800-4118 Within-run	SYNCHRON 1	20	112.5	0.6	0.5
	SYNCHRON 3	20	159.1	0.8	0.5
	MAS Urine Chemistry 1	20	82.7	0.6	0.7
	MAS Urine Chemistry 2	20	168.1	0.7	0.4
DxC800-4427 Within-run	SYNCHRON 1	20	112.4	0.8	0.7
	SYNCHRON 3	20	164.2	0.9	0.5
	MAS Urine Chemistry 1	20	81.7	0.6	0.7
	MAS Urine Chemistry 2	20	168.2	0.8	0.5
DxC800-4449 Within-run	SYNCHRON 1	20	111.9	0.6	0.5
	SYNCHRON 3	20	158.7	0.9	0.6
	MAS Urine Chemistry 1	20	81.5	0.7	0.8
	MAS Urine Chemistry 2	20	168.6	0.9	0.5

Type of Imprecision	Sample Type	n	Mean (mmol/L)	SD	%CV
DxC800-4118 Day to Day	MAS ChemTrak 1	1327	144	1.0	0.7
	MAS ChemTrak 3	1323	120	0.8	0.7
	MAS Urine Chemistry 1	265	82	1.2	1.5
	MAS Urine Chemistry 2	265	166	2.1	1.3
DxC800-4427 Day to Day	MAS ChemTrak 1	1327	144	1.0	0.7
	MAS ChemTrak 3	1323	120	0.8	0.7
	MAS Urine Chemistry 1	357	82	1.2	1.5
	MAS Urine Chemistry 2	357	166	2.4	1.4
DxC800-4449 Day to Day	MAS ChemTrak 1	1327	144	1.0	0.7
	MAS ChemTrak 3	1323	120	0.8	0.7
	MAS Urine Chemistry 1	350	82	1.3	1.6
	MAS Urine Chemistry 2	343	167	2.2	1.3

Comparative Performance

As determined by Beckman

Data for the SYNCHRON LX System evaluated using the NCCLS Approved Guideline EP5-A appears in the table below.(12)

NCCLS EP5-A Precision Estimate Method

Type of Imprecision	Sample Type	No. Systems	No. Data Points[a]	Test Mean Value (mmol/L)	EP5-T2 Calculated Point Estimates	
					SD	%CV
Within-run	Serum Control 1	1	80	109.9	0.72	0.7
	Serum Control 2	1	80	156.2	0.80	0.5
	Urine Control 1	1	80	84.5	0.55	0.7
	Urine Control 2	1	80	165.9	1.27	0.8
Total	Serum Control 1	1	80	109.9	0.98	0.9
	Serum Control 2	1	80	156.2	1.17	0.8
	Urine Control 1	1	80	84.5	0.91	1.1
	Urine Control 2	1	80	165.9	161	1.0

[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® 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.

References

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