Creatinine (CREAm) – Serum, Plasma, Urine, JP Drain Fluids — Technical Procedure 3122
Estimated Glomerular Filtration Rate (eGFR) CKD-EPI – Serum, Plasma
Beckman UniCel DxC Systems

Principle

Intended Use

CREm reagent, when used in conjunction with UniCel® DxC 800 System and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of creatinine concentration in human serum, plasma, urine or fluids.

Clinical Significance

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

The National Kidney Disease Education Program (NKDEP) suggests the use of an estimating or prediction equation to estimate glomerular filtration rate from serum creatinine for people with chronic kidney disease (CKD) and those at risk for CKD (diabetes, hypertension, cardiovascular disease, and family history of kidney disease). Primary reasons for these recommendations are:

- GFR and creatinine clearance are poorly inferred from serum creatinine alone. This is mainly because these are related inversely (non-linearly) to serum creatinine. The effects of age and gender, and to a lesser extent race, on creatinine production further inhibit effective interpretation.
- Creatinine is more often measured than urinary albumin. For patients with diabetic nephropathy, increased urinary albumin excretion often occurs before decreases in GFR. However, serum creatinine is measured frequently and may be the initial screening test for CKD.
- The normal serum creatinine reference interval does not necessarily reflect a normal GFR for an individual patient. Primary care providers and other specialists should routinely use an estimating equation to assess patients' kidney function.
- The CKD-EPI equation does not require weight or height variables. The equation yields a GFR result normalized to 1.73m^2 body surface area, which is an accepted average adult body surface area.

Methodology

The UniCel® DxC System(s) determine creatinine concentration by means of the Jaffe rate method.(1)

A precise volume of sample (16.5 microliters serum or 5.5 microliters urine) is injected in a reaction cup containing an alkaline picrate solution. The ratio used is one part sample to 35 parts reagent for serum and one part sample to 105 parts reagent for urine. Creatinine from the sample combines with the reagent to produce a red color complex. Absorbance readings are taken at 520 nanometers between 19 and 25 seconds after sample injection. The absorbance rate has been shown to be a direct measure of the concentration of creatinine in the sample.(2,3,4)

Chemical Reaction Scheme

Creatinine + Picric Acid ⟶ Creatinine-Picrate Complex (red)

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.

JP Drain Fluids should be received in a 13 x 75 Clear Cap BD tube

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.

Fluids other than JP Drain Fluids are unacceptable for testing at UCDHS.

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

Type of Specimen

Freshly drawn serum, plasma, fluids or properly collected urine (random/timed) are the preferred specimens. Whole blood is not recommended for use as a sample.

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.(6)

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.(6)

It is recommended that random urine assays be performed within 2 hours of collection. (7)

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.(6,7,8,9)

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*.

Reagents

Contents

Each kit contains the following items: **Kit Reorder # 472525**

Two Alkaline Buffer Bottles (1600 mL)
Two Picric Acid Solution Bottles (400 mL)
Instruction Insert

Volumes per Test

Sample Volume	Serum 16.5 µL
	Urine 5.5 µL
Total Reagent Volume	570 µL

Reactive Ingredients

Reagent Constituents

ALKALINE BUFFER:	
Sodium Hydroxide	0.188 mol/L
PICRIC ACID SOLUTION:	
Picric Acid	0.05 mol/L

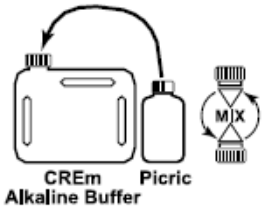
Also non-reactive chemicals necessary for optimal system performance.

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 and 2
At least two levels of control material
Saline

Reagent Preparation



1. Carefully pour 400 mL of Picric Acid Solution into the 1600 mL Alkaline Buffer bottle. Replace cap and mix at least 15 times by gentle inversion.
2. Record preparation date on the bottle.
3. If excessive foam is produced when mixing, allow foam to dissipate before loading.
4. Freshly prepared creatinine reagent may contain micro air bubbles that may result in calibration failure or calibration with low span. To prevent this phenomenon, allow the prepared reagent to sit with the cap loosened for a minimum of 30 minutes (or overnight) before loading onto the instrument.
5. Date and initial reagent container and document in reagent log before loading each new bottle.

NOTICE
Do not reuse old reagent or mix fresh reagent with old reagent.

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

Alkaline Buffer and Picric Acid Solution stored unopened and unmixed at room temperature are stable until the expiration dates indicated on each bottle. The combined Creatinine Reagent is stable on-instrument for 30 days from the date of preparation.

Do not freeze or refrigerate. If reagent is frozen in transit, thaw completely, warm to room temperature and mix thoroughly by gently inverting bottle a least 10 times.

NOTICE

At reduced temperature, a precipitate may form in the Alkaline Buffer or combined Creatinine Reagent. Do not filter the precipitate. DO NOT USE combined Creatinine Reagent until all precipitate is completely redissolved. It will redissolve upon warming to 21^{O}C to 25^{O}C without any loss of reactivity. A 25^{O}C water bath may be used to warm reagent. Mix after redissolving precipitate by inverting bottle 10 times.

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 LX AQUA CAL 1 and 2.(Kit Reorder #s 471288 and 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.

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 creatinine assay must be calibrated every 72 hours or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 800 Systems *Instructions for Use* (IFU) manual.

For calibration instructions, refer to the UniCel DxC 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 print out with error codes and the system will alert the operator of the failure. The explanation of these error codes can be found in the UniCel DxC 800 System *Instructions For Use* (IFU) manual.

Traceability

Creatinine (analyte) in this calibrator is traceable to IDMS*.

* *IDMS - Isotope Dilution Mass Spectroscopy.*

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

A minimum of two levels of control material will be analyzed each shift.

In addition, controls should be run under the following circumstances:

Upon loading new reagent.
Following specific maintenance or troubleshooting procedures as detailed in the UniCel DxC800 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.

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 Control 1	+2°C to +8°C**
MAS Urine Chemistry Control 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.
**Bottles of controls are stored at 2°C to 8°C. Once opened, controls are good for 30 days when stored at 2°C to 8°C.

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.

Timed Urine Specimens

Calculated from the following equations:

24 hr timed urine specimens:

$$\text{Urine Creatinine } \frac{\text{mg}}{\text{dL}} \text{ X } \frac{\text{dL}}{\text{100mL}} \text{ X Total volume collected (mL) = mg/24hr}$$

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

For creatinine clearance, the following equation is used:

$$\frac{\text{Urine Creatinine}}{\text{Serum Creatinine}} \text{ X } \frac{\text{Total volume collected (mL)}}{\text{Total time of collection (mins)}} \text{ = uncorrected X } \frac{\text{Std BSA}}{\text{BSA of pt}} \text{ = corrected creatinine clearance mL/min}$$

Standard Body Surface Area (BSA) = 1.73

BSA (A) calculation: log A = (0.425 log W (weight)) + (0.0725 log H (height)) - 2.144

Use total collection time in minutes. Do not round off total collection time**.**

Estimated Glomerular Filtration Rate (eGFR)

Calculated for certain patient populations using the IDMS-Traceable Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation:

$$GFR = 141 \times \min(S_{cr}/\kappa, 1)^{\alpha} \times \max(S_{cr}/\kappa, 1)^{-1.209} \times 0.993^{Age} \times 1.018 \text{ [if female]} \times 1.159 \text{ [if black]}$$

where:

Scr = serum creatinine in mg/dL,
κ is 0.7 for females and 0.9 for males,
α is -0.329 for females and -0.411 for males,
min indicates the minimum of S_{cr}/κ or 1, and
max indicates the maximum of S_{cr}/κ or 1.

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.

Creatinine Reference Intervals

The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.(10)

Reference Intervals

Intervals	Sample Type	Conventional Units
Literature	Serum or Plasma (Male)	0.9 - 1.3 mg/dL
	Serum or Plasma (female)	0.6 - 1.1 mg/dL
	Urine (Male)	800 - 2000 mg/24hrs
	Urine (Female)	600 - 1800 mg/24hrs
SYNCHRON	Serum or Plasma (Male)	0.64 - 1.27 mg/dL
	Serum or Plasma (female)	0.44 - 1.03 mg/dL
UCDMC	Serum or Plasma (Male)	0.64 - 1.27 mg/dL
	Serum or Plasma (female)	0.44 - 1.03 mg/dL
	Urine - 24 hr	1000 - 2000 mg/24hrs
	Urine - Creatinine Clearance	70 - 130 ml/min

Refer to References (11,12,13) for guidelines on establishing laboratory-specific reference intervals.

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

A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.

The following comment will be appended to each fluid creatinine result:

This test was developed and its performance characteristics determined by UCDMC, Chemistry and Urinalysis Section, Clinical Laboratory. This test is not FDA approved; the test is performed in a CLIA certified laboratory qualified to perform high complexity clinical testing, and FDA approval is not required. The assay should not be regarded as investigational or for research use only.

eGFR Reference Interval:

> 60 mL/min./1.73 square meters

eGFR will be calculated only for patients ≥ 18 years of age. Patients < 18 years of age will have the comment "Test not performed" resulted.

For values **less than or equal to 60 mL/min/1.73 m^2**, the report will give the numerical estimate rounded to a whole number (e.g., "32 mL/min/1.73 m^2").

The following comment will be appended to each result:

The Chronic Kidney Disease Epidemiology Collaborative (CKD-EPI) equation provides more accurate estimation of glomerular filtration rate (eGFR) including for values > 60 mL/min/1.73 m^2 when compared to the previous Modification of Diet in Renal Disease (MDRD) equation. The eGFR (regardless of calculation method) is not reliable in certain groups, including severely ill patients, pregnant women, transplant recipients, medically unstable patients including those with acute kidney injury, or in persons with extremes of body size, muscle mass, or nutritional status. Application of the CKD-EPI eGFR calculation may lead to errors in GFR estimation in these clinical settings.

The equation has been most extensively evaluated in people with chronic kidney disease and reduced GFR and is less accurate for persons with normal or mildly impaired kidney function.

Quantification of eGFR values of 60 mL/min/1.73 m^2 and below have more clinical implications for classification of kidney function than values above this level.

Note: The estimated GFR result assumes a steady-state and is most accurate for GFRs ≤ 60mL/min./1.73m^2. The eGFR is not reliable in certain groups, including severely ill patients. Also, patients > 59 years of age can have a mildly reduced GFR due to aging. The CKD-EPI equations used to estimate GFR have been validated only in Caucasians and African-Americans 18 years of age or older. The equations have not been validated in other population groups, including pregnant women, transplant recipients, medically unstable patients including those with acute renal failure, or in persons with extremes of body size, muscle mass, or nutritional status. Application of the MDRD calculation in these cases may lead to errors in GFR estimation.

For more information, refer to the NKDEP website: http://www.nkdep.nih.gov

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 (mg/dL)[a]
Ammonium Heparin	14 Units/mL	NSI
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 ± 0.2 mg/dL or 6%).

Limitations

If urine samples are cloudy or turbid, it is recommended that they be centrifuged before transfer to a sample cup.

Interferences

The following substances were tested for interference with this methodology:

Interferences

Substance	Source	Level Tested	Observed Effect[a]
Acetoacetic Acid	Acetoacetic Lithium Salt	5 mg/dL	+ 0.04 mg/dL[b]
		50 mg/dL	+ 0.4 mg/dL[b]
		125 mg/dL	+ 0.9 mg/dL
		500 mg/dL	+ 3.5 mg/dL
Bilirubin (unconjugated)	Bovine	20 mg/dL	- 0.2 mg/dL
Cefaclor	NA[c]	100 ug/dL	+ 0.2 mg/dL
Cefoxitin	Cefoxitin sodium salt	50 µg/dL	+ 0.2 mg/dL
Cephalothin	NA	NA	+0.2 mg/dL
α-D-Glucose	NA	NA	+ 0.2 mg/dL
Fluorescein	Fluorescein Disodium Salt	220 mg/dL	Results suppressed
Glutathione	NA	1.5 mmol/L	+ 0.2 mg/dL
Hemoglobin	RBC hemolysate	500 mg/dL	NSI[d]
L-Dopa	NA	160 mg/dL	- 0.2 mg/dL
Lipemia	Intralipid[e]	500 mg/dL	NSI
	Human	Serum Index 8	NSI
Methyl dopa	NA	10 mg/dL	- 0.2 mg/dL
Pyruvic acid	NA	5 mg/dL	+ 0.2 mg/dL
Sulfasalazine	NA	60 mg/dL	NSI
Sulfobromophthalein	Sulfobromophthalein sodium salt	2.0 mg/dL	NSI

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

[b] The observed effect at 5 and 50 mg/dL levels of acetoacetic acid are calculated based on the extrapolation of the interference data collected with 0, 125, 250, 375, and 500 mg/dL of acetoacetic acid.

[c] NA = Not applicable.

[d] NSI = No Significant Interference (within ±0.2 mg/dL or 6%).

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

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

Refer to References (15,16,17) for other interferences caused by drugs, disease and preanalytical variables.

Performance Characteristics

Analytical Measurement Range (AMR)

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

Analytical Measurement Range

Sample Type	Conventional Units
Serum/Plasma/Fluids	0.10 - 25.00 mg/dL
Urine	10 - 400 mg/dL

Clinical Reportable Range (CRR) (as determined on site):

Clinical Reportable Range

Sample Type	Conventional Units
Serum/Plasma/Fluids	0.10 - diluted result mg/dL
Urine	10 - diluted result mg/dL

Serum/plasma/fluid samples with concentrations below the AMR and CRR (< 0.10 mg/dL) are reported as "**< 0.10 mg/dL**".

Serum/plasma/fluid samples with concentrations greater than the AMR (> 25.0 mg/dL) are diluted with saline and reanalyzed.

Urine samples with concentrations below the AMR and CRR (< 10.0 mg/dL) are reported as "**< 10.0 mg/dL**".

Urine samples with concentrations greater than the AMR (> 400.0 mg/dL) are diluted with saline and reanalyzed.

Dilutions are 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 this analyte determination is 0.10 mg/dL for serum or plasma and 10 mg/dL for urine.

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 1.0 to 24.3 mg/dL):

Y (UniCel DxC Systems)	= 1.037X – 0.01
N	= 137
MEAN (UniCel DxC Systems)	= 2.8
MEAN (SYNCHRON LX Systems)	= 2.7
CORRELATION COEFFICIENT (r)	= 0.999

Urine (in the range of 17.9 to 412.7 mg/dL):

Y (UniCel DxC Systems)	= 1.000X + 0.97
N	= 110
MEAN (UniCel DxC Systems)	= 136.1
MEAN (SYNCHRON LX Systems)	= 135.2
CORRELATION COEFFICIENT (r)	= 1.000

Serum (in the range of 4.42 to 22.45 mg/dL):

Y (UniCel DxC Systems)	= 1.001X – 0.03
N	= 39
MEAN (UniCel DxC Systems)	= 4.42
MEAN (IDMS* reference procedure (16))	= 4.40
CORRELATION COEFFICIENT (r)	= 0.9996

*IDMS = Isotope Dilution Mass Spectroscopy

Refer to References (19) 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 0.30 to 24.38 mg/dL):

Y (UniCel DxC800-4118)	= 0.962X + 0.031
N	= 58
MEAN (UniCel DxC800-4118)	= 2.475
MEAN (UniCel DxC800-1805)	= 2.541
CORRELATION COEFFICIENT (r)	= 0.9994

Urine (in the range of 27.30 to 372.40 mg/dL):

Y (UniCel DxC800-4118)	= 0.991X + 1.054
N	= 24
MEAN (UniCel DxC800-4118)	= 126.462
MEAN (SYNCHRON LX20PRO-2194)	= 126.579
CORRELATION COEFFICIENT (r)	= 0.9997

Serum or Plasma (in the range of 0.30 to 24.38 mg/dL):

Y (UniCel DxC800-4427)	= 0.966X - 0.004
N	= 58
MEAN (UniCel DxC800-4427)	= 2.450
MEAN (UniCel DxC800-1805)	= 2.541
CORRELATION COEFFICIENT (r)	= 0.9994

Urine (in the range of 27.30 to 372.40 mg/dL):

Y (UniCel DxC800-4427)	= 0.987X + 1.148
N	= 24
MEAN (UniCel DxC800-4427)	= 126.078
MEAN (SYNCHRON LX20PRO-2194)	= 126.579
CORRELATION COEFFICIENT (r)	= 0.9999

Serum or Plasma (in the range of 0.30 to 24.38 mg/dL):

Y (UniCel DxC800-4449)	= 0.969X + 0.041
N	= 57
MEAN (UniCel DxC800-4449)	= 2.536
MEAN (UniCel DxC800-1805)	= 2.575
CORRELATION COEFFICIENT (r)	= 0.9997

Urine (in the range of 27.30 to 372.40 mg/dL):

Y (UniCel DxC800-4449)	= 1.007X + 0.499
N	= 24
MEAN (UniCel DxC800-4449)	= 128.013
MEAN (SYNCHRON LX20PRO-2194)	= 126.579
CORRELATION COEFFICIENT (r)	= 0.9999

Serum or Plasma (in the range of 0.24 to 23.30 mg/dL):

Y (UniCel DxC800-4427)	= 1.003X - 0.032
N	= 63
MEAN (UniCel DxC800-4427)	= 2.310
MEAN (UniCel DxC800-4118)	= 2.334
CORRELATION COEFFICIENT (r)	= 0.9999

Urine (in the range of 26.92 to 370.87 mg/dL):

Y (UniCel DxC800-4427)	= 0.996X + 0.098
N	= 24
MEAN (UniCel DxC800-4427)	= 126.078
MEAN (UniCel DxC800-4118)	= 126.462
CORRELATION COEFFICIENT (r)	= 0.9999

Serum or Plasma (in the range of 0.24 to 23.30 mg/dL):

Y (UniCel DxC800-4449)	= 1.007X + 0.012
N	= 62
MEAN (UniCel DxC800-4449)	= 2.391
MEAN (UniCel DxC800-4118)	= 2.362
CORRELATION COEFFICIENT (r)	= 0.9997

Serum or Plasma (in the range of 0.15 to 23.34 mg/dL):

Y (UniCel DxC800-4449)	= 1.004X + 0.044
N	= 62
MEAN (UniCel DxC800-4449)	= 2.391
MEAN (UniCel DxC800-4427)	= 2.338
CORRELATION COEFFICIENT (r)	= 0.9997

Urine (in the range of 26.92 to 370.87 mg/dL):

Y (UniCel DxC800-4449)	= 1.017X - 0.573
N	= 24
MEAN (UniCel DxC800-4449)	= 128.013
MEAN (UniCel DxC800-4118)	= 126.462
CORRELATION COEFFICIENT (r)	= 0.9997

Urine (in the range of 26.66 to 367.17 mg/dL):

Y (UniCel DxC800-4449)	= 1.021X - 0.672
N	= 24
MEAN (UniCel DxC800-4449)	= 128.013
MEAN (UniCel DxC800-4427)	= 126.078
CORRELATION COEFFICIENT (r)	= 0.9997

The UCDHS Clinical Laboratory conducted a validation study comparing a minimum of 20 paired comparisons of JP wound drain fluids (i.e., Jackson-Pratt [JP] Drains) Specimens were tested on each chemistry analyzer with paired specimens sent to ARUP Reference Laboratory (Salt Lake City, UT) for comparison using a validated assay on an Abbott Architect ci8200. Mean bias was calculated and accuracy was determined using one-way analysis of variance (ANOVA). For statistically significant ANOVA values, post-hoc analysis was performed using the Tukey's HSD test. Least squares linear regression was also performed to determine assay correlation against ARUP. Since assay interferences (as defined by the manufacturer) remain the same, interference studies were not performed for these known analytes.

JP Drain Fluid (in the range of 0.47 – 10.47 mg/dL):

Y (UniCel DxC800-4449)	= 0.9493X – 0.041
N	= 28
MEAN (UniCel DxC800-4449)	= 1.75
MEAN (ARUP Abbott Architect ci8200)	= 1.62
CORRELATION COEFFICIENT (r^2)	= 0.9998

JP Drain Fluid (in the range of 0.51 – 10.37 mg/dL):

Y (UniCel DxC800-4427)	= 0.9596X – 0.045
N	= 28
MEAN (UniCel DxC800-4427)	= 1.73
MEAN (ARUP Abbott Architect ci8200)	= 1.62
CORRELATION COEFFICIENT (r^2)	= 0.9990

JP Drain Fluid (in the range of 0.47 – 10.24 mg/dL):

Y (UniCel DxC800-4118)	= 0.9703X – 0.0618
N	= 28
MEAN (UniCel DxC800-4118)	= 1.73
MEAN (ARUP Abbott Architect ci8200)	= 1.62
CORRELATION COEFFICIENT (r^2)	= 0.9990

ANOVA P-value 0.089

Precision

A properly operating SYNCHRON® or 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]	%CV
		mg/dL	mg/dL	
Within-run	Serum/Plasma	0.1	3.3	3.0
Total	Serum/Plasma	0.2	3.3	4.5
Within-run	Urine	2.0	66.7	3.0
Total	Urine	3.0	66.7	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.

Precision established at UCDMC

Type of Precision	Sample Type	n	Mean (mg/dL)	1 SD	%CV
DxC800-4118 Within-run	SYNCHRON 1	20	0.994	0.029	3.0
	SYNCHRON 3	20	7.731	0.035	0.5
	MAS Urine Chemistry 1	20	71.137	0.599	0.8
	MAS Urine Chemistry 2	20	170.903	1.227	0.7
DxC800-4427 Within-run	SYNCHRON 1	20	0.968	0.028	2.9
	SYNCHRON 3	20	7.623	0.055	0.7
	MAS Urine Chemistry 1	20	70.575	0.420	0.6
	MAS Urine Chemistry 2	20	169.738	0.865	0.5
DxC800-4449 Within-run	SYNCHRON 1	20	1.034	0.023	2.2
	SYNCHRON 3	20	7.713	0.058	0.7
	MAS Urine Chemistry 1	20	70.385	0.471	0.7
	MAS Urine Chemistry 2	20	169.577	1.035	0.6

Type of Imprecision	Sample Type	n	Mean (mg/dL)	SD	%CV
DxC800-4118 Day to Day	MAS ChemTrak 1	1323	0.75	0.024	3.2
	MAS ChemTrak 3	1327	6.55	0.093	1.4
	MAS Urine Chemistry 1	274	70.85	1.358	1.9
	MAS Urine Chemistry 2	269	167.43	3.203	1.9
DxC800-4427 Day to Day	MAS ChemTrak 1	1321	0.75	0.019	2.5
	MAS ChemTrak 3	1321	6.55	0.073	1.1
	MAS Urine Chemistry 1	372	70.68	1.212	17
	MAS Urine Chemistry 2	377	166.63	2.931	1.8
DxC800-4449 Day to Day	MAS ChemTrak 1	1336	0.75	0.048	6.4
	MAS ChemTrak 3	1333	6.57	0.091	1.4
	MAS Urine Chemistry 1	359	69.90	1.242	1.8
	MAS Urine Chemistry 2	382	165.67	3.037	1.8

Comparative Performance

The data for a SYNCHRON LX® System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.(20) Each laboratory should characterize their own instrument performance for comparison purposes.

As determined by Beckman

NCCLS EP5-T2 Precision Estimate Method

Type of Imprecision	Sample Type		No. Systems	No. Data Points[a]	Test Mean Value (mg/dL)	EP5-T2 Calculated Point Estimates	
						SD	%CV
Within-run	Serum	Control 1	1	80	0.57	0.03	4.8
	Serum	Control 2	1	80	7.86	0.08	1.0
	Urine	Control 1	1	80	90.90	0.71	0.8
	Urine	Control 2	1	80	244.73	1.72	0.7
Total	Serum	Control 1	1	80	0.57	0.05	8.2
	Serum	Control 2	1	80	7.86	0.25	3.1
	Urine	Control 1	1	80	90.90	2.28	2.5
	Urine	Control 2	1	80	244.73	6.94	2.8

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.

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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
July, 2008	IDMS traceablilty & eGFR	M. Inn		
			09/15/2009	G. Kost
			10/12/2010	G. Kost
12/2010	update	M.Inn		
06/28/2011	Added Fluids as a sample type	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
09/01/2016	Specified required QC interval, general update, added validation for JP drain specimens	kdagang	09/01/2016	J. Gregg
10/17/2016	changed eGFR from MDRD to CKD-EPI	kdagang	10/31/2016	L. Howell