Principle

Intended Use

URIC reagent, when used in conjunction with UniCel® DxC System(s) and SYNCHRON® Systems Multi Calibrator, is intended for quantitative determination of uric acid in human serum, plasma or urine.

Clinical Significance

Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Methodology

URIC reagent is used to measure the uric acid concentration by a timed-endpoint method.(1) Uric acid is oxidized by uricase to produce allantoin and hydrogen peroxide. The hydrogen peroxide reacts with 4-aminoantipyrine (4-AAP) and 3,5-dichloro-2-hydroxybenzene sulfonate (DCHBS) in a reaction catalyzed by peroxidase to produce a colored product.

The SYNCHRON® System(s) automatically dilutes urine samples and proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 25 parts reagent for serum or plasma and one part diluted sample to 25 parts reagent for urine. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of uric acid in the sample and is used by the System to calculate and express the uric acid concentration.

Chemical Reaction Scheme

$$\text{Uric acid} + O_2 + H_2O \xrightarrow{\text{Uricase}} \text{Allantoin} + H_2O_2 + CO_2$$

$$H_2O_2 + \text{4-AAP} + \text{DCHBS} \xrightarrow{\text{Peroxidase}} \text{Quinonemine} + H_2O$$

4-AAP = 4-aminoantipyrine
DCHBS – 3,5-dichloro-2-hydroxybenzene sulfonate

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.(2,3) 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

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.(3,5)

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.(5)

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. Adjust pH of entire collection to 8-9.5 by adding a sufficient volume of sodium hydroxide solution (5% NaOH). **Testing must be performed within 4 days (96 hours) of start of collection**.(6,7)

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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: **Kit Reorder # 442785**

Two URIC Reagent Cartridges (2 X 300 tests)

Volumes per Test

Serum or Plasma

Sample Volume	12 µL
ORDAC Sample Volume	6 µL
Total Reagent Volume	300 µL
Cartridge Volumes	
A	270 µL
B	30 µL
C	-----

Urine

Sample Dilution Volumes	
Sample Volume	20 µL
Dilution Volume	180 uL
Diluted Sample Volume	12 µL
Total Reagent Volume	300 µL
Cartridge Volumes	
A	270 µL
B	30 µL
C	-----

Reactive Ingredients

Reagent Constituents

4-Aminoantipyrine	0.85 mmol/L
3,5-Dichloro-2-hydroxy-benzene sulfonate	3.4 mmol/L
Uricase	240 IU/L
Horseradish peroxidase	961 IU/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 Multi Calibrator

At least two levels of control material

Saline

DIL 1 for urine samples

Reagent Preparation

No preparation is required.

Date and initial cartridge and document in reagent log before loading each new cartridge.

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

URIC reagent, when stored unopened at 2°C to 8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent cartridge is stable for 30 days at 2°C to 8°C unless the expiration date is exceeded. **DO NOT FREEZE**.

DIL 1 stored unopened at room temperature is stable until the expiration date indicated on each cartridge. Once opened, DIL 1 is stable for 60 days on instrument or until the expiration date, if sooner.

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 Multi Calibrator **Kit Reorder # 442600**

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Multi Calibrator should be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Once opened, resealed calibrators are stable for 60 days at -15°C to -20°C unless the expiration date is exceeded or when calibration and quality control recoveries have shifted..

CAUTION!

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg.
Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.(5)

Calibration Information

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

Under typical operating conditions the URIC reagent cartridge must be calibrated every 14 days or with each new cartridge of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

This assay has within-lot calibration available. 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 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

The measurand (URIC) in this calibrator is traceable to each reference material for each analyte. The traceability process is based on prEN ISO 17511. The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned 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.

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.

Testing Procedure

1. If necessary, load 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:

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

Calculations are only performed on 24 hour collections (±15 minutes) and reported as mg/24hr.

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.(6)

Reference Intervals

Intervals	Sample Type	Conventional Units		S.I Units
Literature	Serum or Plasma (Male)	4.4 - 7.6 mg/dL		262 - 452 µmol/L
	Serum or Plasma (Female)	2.3 - 6.6 mg/dL		137 - 393 µmol/L
	Urine (timed)	250 - 750 mg/24 hrs		1.48 - 4.43 µmol/24 hrs
SYNCHRON	Serum or Plasma (Male)	4.8 - 8.7 mg/dL		286 - 518 µmol/L
	Serum or Plasma (Female)	2.6 - 8.0 mg/dL		155 - 476 µmol/L
UCDMC	Serum or Plasma	Male	3.9 - 8.0 mg/dL	232 - 476 µmol/L
	Serum or Plasma	Female	2.2 - 7.7 mg/dL	311 - 458 µmol/L
	Urine (24 hr)	250 - 750 mg/24 hrs		1.48 - 4.43 µmol/24 hrs

Refer to References (8,9,10) for guidelines on establishing laboratory-specific reference intervals.

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

Critical Values

For children ≤ 10 years old, a uric acid result **≥ 10.0 mg/dL** is considered a critical value and should be called immediately to the attending physician or charge nurse.

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[a]

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Ammonium Heparin	14 Units/mL	NSI[b]
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

[b] NSI = No Significant Interference (within ±0.3 mg/dL or 4%).

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

Incompatible Anticoagulants[a]

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (mg/dL)[b]
Potassium Oxalate/ Sodium Fluoride	2.0 / 2.5 mg/mL	-0.7

[a] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

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

Limitations

None identified

Interferences

The following substances were tested for interference with this methodology:

Interferences

Substance	Source	Level Tested	Observed Effect[a]
Bilirubin (unconjugated)	Bovine	10 mg/dL	≤ ± 0.7 mg/dL or 10%
Bilirubin (Total)	Porcine	2.6 mg/dL DBIL	- 0.4 @ 2.6 mg/dL URIC
		5.2 mg/dL TBIL	- 1.0 @ 8.7 mg/dL URIC
Hemoglobin	BC Hemolysate	300 mg/dL	≤ ± 0.7 mg/dL or 10%
Lipemia	Human	Serum index 5	≤ ± 0.7 mg/dL or 10%
Albumin[b]	Human Cohn Fraction V[c]	8 g/dL	-0.5 mg/dL
Ascorbate (Serum)	SIGMA[d]	1.5 mg/dL	-0.3 mg/dL
Ascorbate (Urine)	SIGMA	20 mg/dL	+3.0 mg/dL

[a] Plus (+) or minus (-) signs in this column signify positive or negative interference.
[b] Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.
[c] Pentex Diagnostic Division, Miles, Inc., Kankakee, IL.
[d] SIGMA-Aldrich Co., St. Louis, MO.

Interferences should also be suspected from the following substances: Theophylline metabolites (1,3-dimethyluric acid and 1-methyluric acid), catecholamines, methylene blue, sulfasalazine, EDTA, sodium fluoride, and other reducing agents.

Refer to References (11,12,13) 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 or Plasma	0.5 - 12.0 mg/dL	30 – 714 µmol/L
Serum or Plasma (ORDAC)	9.0 – 21.0 mg/dL	536 – 1250 µmol/L
Urine	5 – 120 mg/dL	300 – 7140 µmol/L

Clinical Reportable Range:

Clinical Reportable Range (CRR)

Sample Type	Conventional Units	S.I. Units
Serum or Plasma	0.5 - diluted result mg/dL	30 – diluted result µmol/L
Urine	5 – diluted result mg/dL	300 – diluted result µmol/L

Serum or plasma samples with concentrations below the AMR and CRR (0.5 mg/dL) are reported as "**< 0.5 mg/dL**".

Urine samples with concentrations below the AMR and CRR (5 mg/dL) will are as "**< 5 mg/dL**".

Samples with concentrations greater than the AMR should be diluted with saline 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 the URIC determination is 0.5 mg/dL (30 µmol/L) for serum or plasma and 5.0 mg/dL (300 µmol/L) for urine.

Equivalency

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

As determined by Beckman.

Serum or Plasma (urea nitrogen in the range of 0.3 to 10.8 mg/dL):

Y (SYNCHRON LX Systems)	= 0.977X - 0.02
N	= 79
MEAN (SYNCHRON LX Systems)	= 5.44
MEAN (SYNCHRON CX7 DELTA)	= 5.59
CORRELATION COEFFICIENT (r)	= 0.999

Urine (in the range of 5.6 to 64.3 mg/dL):

Y (SYNCHRON LX Systems)	= 0.996X + 0.12
N	= 78
MEAN (SYNCHRON LX Systems)	= 29.0
MEAN (SYNCHRON CX7 DELTA)	= 29.0
CORRELATION COEFFICIENT (r)	= 0.999

Refer to References (14) for guidelines on performing equivalency testing.

As determined at UCDMC.

Serum or Plasma (in the range of 1.2 to 11.5 mg/dL):

Y (UniCel DxC800-4118)	= 0.974X + 0.00
N	= 24
MEAN (UniCel DxC800-4118)	= 4.87
MEAN (UniCel DxC800-1805)	= 5.00
CORRELATION COEFFICIENT (r)	= 0.9996

Serum or Plasma (in the range of 1.2 to 11.5 mg/dL):

Y (UniCel DxC800-4427)	= 0.973X - 0.05
N	= 24
MEAN (UniCel DxC800-4427)	= 4.82
MEAN (UniCel DxC800-1805)	= 5.00
CORRELATION COEFFICIENT (r)	= 0.9993

Serum or Plasma (in the range of 1.2 to 11.5 mg/dL):

Y (UniCel DxC800-4449)	= 0.973X - 0.05
N	= 24
MEAN (UniCel DxC800-4449)	= 4.81
MEAN (UniCel DxC800-1805)	= 5.00
CORRELATION COEFFICIENT (r)	= 0.9993

Serum or Plasma (in the range of 1.2 to 11.1 mg/dL):

Y (UniCel DxC800-4427)	= 0.999X - 0.05
N	= 24
MEAN (UniCel DxC800-4427)	= 4.82
MEAN (UniCel DxC800-4118)	= 4.87
CORRELATION COEFFICIENT (r)	= 0.9995

Serum or Plasma (in the range of 1.2 to 11.1 mg/dL):

Y (UniCel DxC800-4449)	= 0.999X - 0.05
N	= 24
MEAN (UniCel DxC800-4449)	= 4.81
MEAN (UniCel DxC800-4118)	= 4.87
CORRELATION COEFFICIENT (r)	= 0.9997

Serum or Plasma (in the range of 1.2 to 11.0 mg/dL):

Y (UniCel DxC800-4427)	= 1.000X + 0.00
N	= 24
MEAN (UniCel DxC800-4449)	= 4.81
MEAN (UniCel DxC800-4427)	= 4.82
CORRELATION COEFFICIENT (r)	= 0.9998

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]		%CV
		mg/dL	µmol/L	mg/dL	µmol/L	
Within-run	Serum/Plasma	0.15	9.0	7.5	450.0	2.0
	Serum/Plasma (ORDAC)	NA[b]	NA	NA	NA	10.0
	Urine	1.0	60.0	33.0	1980.0	3.0
Total	Serum/Plasma	0.22	13.5	7.5	450.0	3.0
	Serum/Plasma (ORDAC)	NA	NA	NA	NA	15.0
	Urine	2.0	120.0	33.0	1980.0	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.

[b] NA = Not applicable

Precision established at UCDMC

Type of Precision	Sample Type	n	Mean (mg/dL)	1 SD	%CV
DxC800-4118 Within-run	SYNCHRON 1	20	2.66	0.05	1.9
	SYNCHRON 3	20	11.09	0.08	0.7
DxC800-4427 Within-run	SYNCHRON 1	20	2.60	0.00	0.0
	SYNCHRON 3	20	11.26	0.05	0.4
DxC800-4449 Within-run	SYNCHRON 1	20	2.61	0.03	1.2
	SYNCHRON 3	20	10.92	0.09	0.8

Type of Imprecision	Sample Type	n	Mean (mg/dL)	SD	%CV
DxC800-4118 Day to Day	MAS ChemTrak 1	349	2.9	0.06	2.1
	MAS ChemTrak 3	347	9.0	0.16	1.8
DxC800-4427 Day to Day	MAS ChemTrak 1	351	2.9	0.05	1.7
	MAS ChemTrak 3	349	9.0	0.18	2.0
DxC800-4449 Day to Day	AS ChemTrak 1	348	2.9	0.05	1.7
	MAS ChemTrak 3	356	8.9	0.16	1.8

Comparative performance

Data for a SYNCHRON LX System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.(14)

Table 9 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	2.42	0.03	1.1
	Serum Control 2	1	80	10.48	0.05	0.5
	Urine Control 1	1	80	41.57	0.65	1.6
	Urine Control 2	1	80	14.12	0.20	1.4
Total	Serum Control 1	1	80	2.42	0.05	1.9
	Serum Control 2	1	80	10.48	0.08	0.8
	Urine Control 1	1	80	41.57	1.42	3.4
	Urine Control 2	1	80	14.12	0.25	1.8

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

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			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
5/24/2011	update	M.Inn	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, controls, and pH adjustment	kdagang	04/15/2015	J. Gregg