Wake Forest Baptist Medical Center	**Uric Acid CC-CH20**	**Dept:**	Clinical Core Lab/Cancer Center- Chemistry Section
		Effective Date:	July 15, 2009
		Revised Date:	02/04/2019
		Contact:	Clinical Core Lab/Cancer Center- Chemistry Management
Name & Title: Gregory J. Pomper, MD Medical Director of Pathology Laboratories		**Date:**	
Signature:			

1) General Procedure Statement:

a. **Scope:** To provide laboratory testing personnel with instructions for performing laboratory procedures as deemed appropriate by industry practices and regulatory agencies to assist in quality patient care.

b. **Responsible Department/Party/Parties:**

i.	Procedure owner:	Clinical Core Laboratory Management-Chemistry
ii.	Procedure:	Clinical Core Laboratory Personnel
iii.	Procedure prepared by:	Leigh Ann Jones / Emily Dockery
iv.	Supervision:	Clinical Core Laboratory Management-Chemistry Clinical Core Laboratory Specialist and Designees Medical Director Clinical Chemistry
v.	Implementation:	Clinical Core Laboratory Management-Chemistry Clinical Core Laboratory Specialist and Designees Medical Director Clinical Chemistry

2) Definitions: NA

3) Procedure:

This procedure is valid for the following analyzers:

- DXC600

PRINCIPLE:

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.

INTENDED USE:

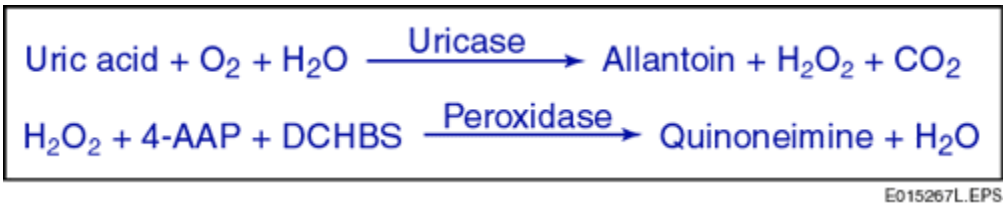
URIC reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Uric Acid concentration in human serum, plasma or urine.

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



SPECIMEN:

PATIENT PREPARATION: None required.

Additional instructions for patient preparation as designated by this laboratory: None

TYPE OF SPECIMEN:

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[2] Freshly drawn serum or plasma are the preferred specimens. Freshly collected urine may also be used for testing. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. 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.[3]

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.[3]
3. It is recommended that urine assays be performed within 2 hours of collection.[4] For timed specimens, the collection container should be kept at room temperature. Sodium hydroxide (NaOH) should be added to keep urine alkaline.

ADDITIONAL SPECIMEN STORAGE AND STABILITY CONDITIONS AS DESIGNATED BY THIS LABORATORY:

None

SAMPLE PREPARATION:

Sample preparation is not required. Urine samples are diluted (1:10) automatically by the system using the DIL1 cartridge.

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 for your system.

CRITERIA FOR UNACCEPTABLE SPECIMENS:

Refer to the PROCEDURAL NOTES section of this chemistry information sheet or the SPECIMEN REQUIREMENTS section of this manual for information on unacceptable specimens.

SPECIMEN HANDLING:

SPECIAL INSTRUCTIONS FOR SPECIMEN HANDLING AS DESIGNATED BY THIS LABORATORY:

None

REAGENTS:

CONTENTS

Each kit contains the following items:

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
Diluent Volume	180 µL
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.

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
Protective Equipment: lab coat, gloves

REAGENT PREPARATION

No preparation is required.

ACCEPTABLE REAGENT PERFORMANCE

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria, as defined in the CONTROL PROCEDURES section of this manual.

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.

REAGENT STORAGE LOCATION:

Refrigerator #2 in Cancer Center Lab.

CALIBRATION:

CALIBRATOR REQUIRED

SYNCHRON® Systems Multi Calibrator

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. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days unless the expiration date is exceeded.

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]

CALIBRATOR STORAGE LOCATION:

Refrigerator/Freezer #2 in Cancer Center Lab.

CALIBRATION INFORMATION

1. The system must have valid calibration factors in memory before controls or patient samples can be run.
2. Under typical operating conditions the URIC reagent cartridge must be calibrated every 14 days or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the SYNCHRON LX *Maintenance Manual and Instrument Log*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

3. This assay has within-lot calibration available. For detailed calibration instructions, refer to the SYNCHRON LX *Operations Manual*, or 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 SYNCHRON LX *Diagnostics and Troubleshooting Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

DxC 600 Calibration Procedure

From the **Rgts/Cal** dialog box, check the Calibration Time Left column shown in days:hours:minutes and the Cal Status Column to see which chemistries require calibration.

1. Select **Rgts/Cal** from the menu bar.

2. Select the chemistries to be calibrated. If necessary, use the up and down arrows to select more chemistries.

3. Select **Cal F4**.

4. Select **List F5** to review the calibrator load list. Make sure the same lot number on the calibrator bottle is the same as the lot number in the screen.

5. Get the bar coded calibrator racks listed on the screen and place nesting cups into the assigned rack positions as shown on the load list.

- For Aqua Cals 1, 2, and 3, use 2mL nesting cups.
- For all other chemistries use a 0.5mL nesting cup.

6. Place calibrators into appropriate nesting cups.

7. Place the rack(s) in the autoloader with the rack bar code label to the right. Press **Run** on the analyzer.

Calibrations will print out automatically upon completion. File all printouts in the provided calibration notebook for each DxC.

Follow all passed calibrations with the appropriate quality control material for each chemistry that was calibrated.

If there is a failure during the calibration for either a modular or a chemistry calibration, there is a pop-up message which shows the chemistry that failed and the associated error code(s).

For failed calibrations refer to the DxC's IFU (on the DxC computer - **ALT F1**) *CHAPTER 12, Troubleshooting Calibration and Result Errors* for more information.

TRACEABILITY

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL:

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new bottle of reagent, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on work load and work flow.

The following controls should be prepared and used in accordance with the package inserts. Copies of these inserts can be found in the CONTROL PROCEDURES section of this manual. Discrepant quality control results should be evaluated and handled as described in the CONTROL PROCEDURES section of this manual.

TABLE 1 QUALITY CONTROL MATERIAL

CONTROL NAME	SAMPLE TYPE	STORAGE
BC SYNCHRON LIQUID COMP.CHEM CONTROL 1,2,3 REF.657365 LIS QC CODES: LEVEL 1 : C - SYN1C4 LEVEL 2 : C - SYN2C4 LEVEL 3 : C - SYN3C4	SERUM/PLASMA	UNOPENED: FREEZER OPENED: REFRIGERATOR

Running Control Samples with Auto Generation and Multiple Cartridge

This procedure is used when daily QC is run. The instrument automatically runs chemistries that are defined for the control, loaded and calibrated, and contain sufficient volume to run the controls.

1. Clear previous control orders.

    - Select **Samples** from the menu bar.
    - Select **Clear F7**.
    - Under Sample ID(s) type *From* **C-A** *To* **C-Z**.
    - Select **OK** to continue clearing. A confirmation screen appears. Select **OK**.

2. Get the bar coded quality control racks and place nesting cups into the assigned rack positions.

    - For Synchron Controls 1 and 3 use 2 mL nesting cups.
    - For all other controls use a 0.5 mL nesting cup.

3. Place controls into the appropriate nesting cups.

4. Place the rack(s) in the autoloader with the rack bar code label to the right. Press **Run** on the analyzer.

Manually Programming Control Samples

This procedure is used when only specific tests need quality control testing (i.e. post calibration)

1. Clear previous control orders.

    - Select **Samples** from the menu bar
    - Select **Clear F7**
    - Type the QC sample ID into the **Sample ID(s)** field.
    - Select **OK**.
    - Select **OK** to confirm.

2. Select **Control F5**.

3. Select the number next to the **Control name** field (by using the touch screen) to select from predetermined Control names.

4. The **Program Control** screen opens. Touch the drop down key next to the Control ID to populate the field.

5. Select chemistries to be run. To access duplicate or specific cartridges, select **Rgt Cart F8**. Then select the desired cartridges and select **OK**.

6. Select **Save F10** to save the control programming.

7. Get the bar coded quality control racks and place nesting cups into the assigned rack positions.

- Use 0.5 mL nesting cups for all chemistries.

8. Place controls into the appropriate nesting cups.

9. Place the rack(s) in the autoloader with the rack bar code label to the right. Press **Run** on the analyzer.

10. When Quality Control is completed it will be review by the tech manning Command Central. When QC is successful then patients can be ran on the instrument. If any Quality Control does not meet our lab's quality control policies then the failed test will have to have the QC repeated on it. It is possible that the test may have to be recalibrated before running QC. That will be determined by looking at that test's previous QC results - is QC shifting one direction or another, etc…)

TESTING PROCEDURE(S):

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 SYNCHRON LX *Operations Manual*, or the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

DxC 600 Sample Programming and Processing

Processing Bar Coded and centrifuged Samples

1. Refer to Beckman Coulter's Primary Tube Sample Template to identify which rack(s) to load samples on and to determine if nesting cups are necessary. Template is located at each DxC 600.

2. Load tube(s) into appropriate rack(s) with the bar code labels visible through the slot on the same side of the rack as the rack bar code label.

3. Place rack(s) on the autoloader with the rack bar code label to the right. Load priority samples first then routines.

5. Press **RUN** on the analyzer.

For a STAT sample:

If the system is running and there are other racks on the autoloader, press **PRIORITY**. The rack pusher moves back one space so the STAT rack can be placed in front of the other racks. Press **RUN.**

The following items require manual programming:

- Samples without bar codes and no sample programming.
- Samples with bar codes and no sample programming.
- Short / Pediatric Samples

1. Refer to Beckman Coulter's Primary Tube Sample Template to identify which rack(s) to load samples on and to determine if nesting cups are necessary. Template is located at each DxC 600.

2. Select **Samples** from the menu bar.

3. Identify samples using the list below:

    - If the sample has a readable bar code - type in the Sample ID.
    - If the sample has no bar code or bar code cannot be read - Type in the sample ID and type numbers in the **Rack** and **Pos** fields.

4. If the sample is STAT, select the **STAT** check box.

5. Select **Sample type** from the pull-down menu. Serum is the default.

6. Select each chemistry and/or select panel. It may be necessary to use the up and down arrows to access additional chemistries.

7. Select **Next F10**.

8. To program additional samples repeat steps 2-6.

9. Place samples into assigned rack postions.

10. Remove caps from sample(s).

11. Place rack(s) on the autoloader with the rack bar code label to the right. Load priority samples first then routines.

12. Press **RUN** on the analyzer.

For a STAT sample:

If the system is running and there are other racks on the autoloader, press **PRIORITY**. The rack pusher moves back one space so the STAT rack can be placed in front of the other racks. Press **RUN.**

CALCULATIONS;

SYNCHRON® System(s) 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.

REPORTING RESULTS:

Equivalency between the SYNCHRON CX, SYNCHRON LX, and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The reference intervals listed below were taken from literature and a study performed on SYNCHRON Systems.[6]

TABLE 2 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 mmoL/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

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS		S.I. UNITS
Laboratory	Serum / Plasma	>=18Y	2.5-8.0 mg/dL	
		14Y up to 18Y	3.0-6.5 mg/dL	
		7Y up to 14Y	3.0-7.0 mg/dL	
		1Y up to 7Y	2.3-6.5 mg/dL	
		1M up to 1Y	2.0-8.0 mg/dL	
		7D up to 1M	2.0-5.5 mg/dL	
		0D up to 7D	1.8-8.0 mg/dL	

Refer to References (7,8,9) for guidelines on establishing laboratory-specific reference intervals.

Procedures for reporting results to the appropriate personnel can be found in the HOW TO REPORT RESULTS section of this manual.

ADDITIONAL REPORTING INFORMATION AS DESIGNATED BY THIS LABORATORY:

Results are autoverified by the Beckman DL2000 software. Failed verify and critical values are held to be reviewed by the DL operator who will take action before results are validated. For quick help, refer to " DATALINK OPERATIONAL GUIDE ".

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:

Table 3 Acceptable 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

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

Table 4 Incompatible Anticoagulants[d]

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	PLASMA-SERUM BIAS (mg/dL)[e].
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/dL	-0.7

LIMITATIONS

None identified.

INTERFERENCES

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

Table 5 Interferences[f]

SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT[g].
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
Hemoglobin	RBC hemolysate	300 mg/dL	≤ ± 0.7 mg/dL or 10%
Lipemia	Human	Serum Index 5	≤ ± 0.7 mg/dL or 10%
Albuminf	Human Cohn Fraction Vg	8 g/dL	-0.5 mg/dL
Ascorbate (Serum)f	SIGMAh	1.5 mg/dL	-0.3 mg/dL
Ascorbate (Urine)f	SIGMA	20 mg/dL	+3.0 mg/dL

2. 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.

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

4. N-acetyl-p-benzoquinone imine (NAPQI), a metabolite of acetaminophen (paracetamol), may generate erroneously low results in samples for patients that have taken toxic doses of acetaminophen (paracetamol).

PERFORMANCE CHARACTERISTICS:

Analytic Range

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

TABLE 6 ANALYTICAL RANGE

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma	0.5 – 12.0 mg/dL	30 – 714 µmol/L

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum or Plasma (ORDAC)	9.0 – 21.0 mg/dL	536 – 1250 µmol/L
Urine	5 – 120 mg/dL	300 – 7140 µmol/L

Samples with concentrations exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with saline and reanalyzed.

REPORTABLE RANGE (as determined on site):

TABLE 7 REPORTABLE RANGE

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum / Plasma	0.5 - 21.0 mg/dL	

SENSITIVITY

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for 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.

Serum or plasma (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 (13) for guidelines on performing equivalency testing.

PRECISION

A properly operating SYNCHRON® System(s) should exhibit precision 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.

TABLE 8 MAXIMUM PERFORMANCE LIMITS

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[l].		% 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[m]	NA	NA	NA	10.0
	Urine	1.0	60.0	33.0	1980.0	3.0

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[l].		% CV
		mg/dL	µmol/L	mg/dL	µmol/L	
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

Comparative performance data for the SYNCHRON® System(s) evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.[14] Each laboratory should characterize their own instrument performance for comparison purposes.

TABLE 9 NCCLS EP5-T2 PRECISION ESTIMATE METHOD

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points[n].	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

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 SYNCHRON LX Systems or UniCel DxC Systems, refer to the appropriate system manual.

SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

4) Review/Revision/Implementation:

a. Review Cycle: 2 years
b. Office of Record: Department of Clinical Core Laboratory-Chemistry
c. All new procedures and procedures that have major revisions must be signed by the Laboratory Director.
d. All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.

5) Related Procedures: None

6) References:

REFERENCES:

1. Fossati, P., Prencipe, L., Berti, G., *Clin. Chem.*, 26:227 (1980).

2. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1994).

3. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens*, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).

4. National Committee for Clinical Laboratory Standards, *Routine Urinalysis and Collection, Transportation and Preservation of Urine Specimens*, Tentative Guideline, NCCLS publication GP16-T, Villanova, PA (1992).

5. CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Government Printing Office, Washington, D.C. (1984).

6. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).

7. National Committee for Clinical Laboratory Standards, *How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory*, Approved Guideline, NCCLS publication C28-A, Villanova, PA (1995).

8. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1987).

9. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 18th Edition, W. B. Saunders Company, Philadelphia, PA (1991).

10. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D. C. (1995).

11. Friedman, R. B., Young, D. S., *Effects of Disease on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D.C. (1997).

12. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D. C. (1997).

13. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Approved Guideline, NCCLS publication EP9-A, Villanova, PA (1995).

14. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, Tentative Guideline, 2nd Edition, NCCLS publication EP5-T2, Villanova, PA (1992).

ENDNOTES

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%).

c Partially filled EDTA tubes may cause interference with this test.

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

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

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

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

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

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

j Pentex Diagnostic Division, Miles, Inc., Kankakee, IL.

k SIGMA-Aldrich Co., St. Louis, MO.

l 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.

m NA = Not applicable.

n The point estimate is based on the pooled 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.

7) Attachments: None

8) Revision Dates:

Review/Revision Date	Review/Revision Description	Signature
02/04/2020	Possible Tylenol interference added on pg. 14	