PRINCIPLE

INTENDED USE

PHOSm reagent, in conjunction with SYNCHRON LX® System(s), UniCel® DxC 800 System and the SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of inorganic Phosphorus concentration in human serum, plasma or urine.

CLINICAL SIGNIFICANCE

Measurements of phosphorus (inorganic) are used to in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

METHODOLOGY

PHOSm reagent is used to measure the phosphorus concentration by a timed rate method.\(^1,2\) In the reaction, inorganic phosphorus reacts with ammonium molybdate in an acidic solution to form a colored phosphomolybdate complex.

A precise volume of sample (8 microliters) is injected in a reaction cup containing a molybdate solution. The ratio used is one part sample to 72 parts reagent. The phosphomolybdate method consists of measuring the rate change in absorbance of an acidic ammonium molybdate reagent following the addition of sample. The system monitors the change in absorbance of yellow phosphomolybdate at 365 nanometers. The rate measurement between 19 and 25 seconds after sample introduction has been shown to be directly proportional to the concentration of the inorganic phosphorus in the sample and is used by the SYNCHRON System to calculate and express the phosphorus concentration.

CHEMICAL REACTION SCHEME

\[ \text{Phosphorus} + \text{Molybdate} \xrightarrow{\text{H}_2\text{SO}_4} \text{Phosphomolybdate Complex} \]
SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum, plasma or properly collected urine (random/timed) are the preferred specimens. 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.

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. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container is to be kept in the refrigerator or on ice during the time period. Urine should be acidified with 25 mL of 6 N HCl added to the container before collection begins.

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

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” Manual.

SAMPLE PREPARATION

All urine samples, including urine controls, must be diluted one part sample with nine parts normal saline prior to analysis on SYNCHRON LX or UniCel DxC 800 Systems. These dilutions should be made according to the following table:

TABLE 1 SAMPLE DILUENT

<table>
<thead>
<tr>
<th>Sample</th>
<th>DILUTION</th>
<th>VOLUME OF SAMPLE</th>
<th>VOLUME OF DILUENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controls</td>
<td>1:10</td>
<td>50 µL</td>
<td>450 µL</td>
</tr>
<tr>
<td>Samples</td>
<td>1:10</td>
<td>50 µL</td>
<td>450 µL</td>
</tr>
</tbody>
</table>

All urine results reported by the SYNCHRON LX System or UniCel DxC 800 System must be multiplied by a correction factor of 10 (see CALCULATIONS Section of this chemistry information sheet).

SAMPLE VOLUME

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples 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 for information on unacceptable specimens.
CRITERIA FOR SAMPLE REJECTION AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” Manual.

PATIENT PREPARATION

SPECIAL INSTRUCTIONS FOR PATIENT PREPARATION AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” Manual.

SPECIMEN HANDLING

SPECIAL INSTRUCTIONS FOR SPECIMEN HANDLING AS DESIGNATED BY THIS LABORATORY:

Refer to “Sample Integrity in Chemistry” write up in “Policies and Procedures” Manual.

REAGENTS

CONTENTS

Each kit contains the following items:
Two Molybdate Reagent Bottles (2 x 200 mL)
Two Phosphorus Diluent Bottles (2 x 1800 mL)
Instruction Insert

VOLUMES PER TEST

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>8 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Reagent Volume</td>
<td>570 µL</td>
</tr>
</tbody>
</table>

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Ammonium Molybdate 3.2 mmol/L
pH < 1.0

Also non-reactive chemicals necessary for optimal system performance.

EUROPEAN HAZARD CLASSIFICATION

(Phosphorus Diluent )  Xi;R36/38  Irritating to eyes and skin.
(Molybdate Solution )  Xi;R36/38  Irritating to eyes and 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

Carefully pour 200 mL of molybdate reagent into the 1800 mL of diluent. Replace cap and mix at least ten times by gentle inversion.

NOTICE

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

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.

REAGENT STORAGE AND STABILITY

PHOSm reagent when stored unopened at room temperature will remain stable until the expiration date indicated on each bottle. The combined 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 at least 10 times.

REAGENT STORAGE LOCATION:

Chemistry department, room L568. Stored on open shelves kept at room temperature (monitored daily.)

CALIBRATION

CALIBRATOR REQUIRED

SYNCHRON® Systems AQUA CAL 1 and 2

CALIBRATOR PREPARATION

No preparation is required.

CALIBRATOR STORAGE AND STABILITY

If unopened, the SYNCHRON® Systems AQUA CAL 1 and 2, may be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Opened calibrators are stable at room temperature for 30 days unless the expiration date is exceeded.

CALIBRATOR STORAGE LOCATION:

Opened Aqua Cal bottles kept at room temperature (monitored daily) in Chemistry department room L568. Unopened Aqua Cal bottles kept in Chemistry refrigerator #6 in Chemistry department room L568.

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 PHOSm 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 SYNCHRON LX Maintenance Manual and Instrument Log, or the UniCel DxC 600/800 Systems Instructions for Use (IFU) manual.

3. 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.

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 good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

<table>
<thead>
<tr>
<th>CONTROL NAME</th>
<th>SAMPLE TYPE</th>
<th>STORAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitrol levels 1 and 2 vials in use kept refrigerated after thawing. Unopened Monitrol kept frozen until just before use. Refer to “DXC 800 Control Analysis” in DXC 800 procedure manual for other control material used and storage. Control preparations and acceptance of QC results are in “Policies and Procedures” manual</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TESTING PROCEDURE(S)

1. If necessary prepare reagent as defined in the Reagent Preparation section of this chemistry information sheet and load the reagent onto the system.

2. After reagent load is completed, calibration may be 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.

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 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

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. 

**TABLE 3 REFERENCE INTERVALS**

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature</td>
<td>Serum or Plasma</td>
<td>2.7 – 4.5 mg/dL</td>
<td>0.87 – 1.46 mmol/L</td>
</tr>
<tr>
<td></td>
<td>Urine (timed)</td>
<td>0.4 – 1.3 g/24 hrs</td>
<td>12.9 – 42.0 mmol/L/24 hrs</td>
</tr>
<tr>
<td>SYNCHRON</td>
<td>Serum or Plasma</td>
<td>2.4 – 4.7 mg/dL</td>
<td>0.78 – 1.53 mmol/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory</td>
<td>Serum or Plasma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0- 30 day</td>
<td>3.9–7.7 mg/dL</td>
</tr>
<tr>
<td></td>
<td>31d- &lt;1y</td>
<td>3.5–6.6 mg/dL</td>
</tr>
<tr>
<td></td>
<td>1y- &lt;4y</td>
<td>3.1–6.0 mg/dL</td>
</tr>
<tr>
<td></td>
<td>4y- &lt;13y</td>
<td>3.0–5.7 mg/dL</td>
</tr>
<tr>
<td></td>
<td>13y- &lt;16y</td>
<td>2.9-5.1 mg/dL</td>
</tr>
<tr>
<td></td>
<td>&gt;16 y</td>
<td>2.6-4.9 mg/dL</td>
</tr>
</tbody>
</table>

2. Normal range for adults was determined by testing 271 male and female healthy blood donors at UCSF with the lower limit adjusted 0.1 mg/dL lower to compensate for MZ’s cartridge method running approximately 0.2 lower.

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

ADDITIONAL REPORTING INFORMATION AS DESIGNATED BY THIS LABORATORY:
Serum or plasma patient Phosphorus results <1.0 mg/dL are PANIC VALUES and must be called to an appropriate person and documented in the LIS. Refer to “Panic Values” section of “Policies and Procedures” manual.

Refer to “DXC800 Linearity and Reportable Range” chart in Technical notes section of DXC800 Procedure Manual.

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 4 COMPATIBLE ANTICOAGULANTS**

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL TESTED FOR IN VITRO INTERFERENCE</th>
<th>AVERAGE PLASMA-SERUM BIAS (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonium Heparin</td>
<td>14 Units/mL</td>
<td>NSI^a</td>
</tr>
</tbody>
</table>
2. The following anticoagulant was found to be incompatible with this method:

**TABLE 5 INCOMPATIBLE ANTICOAGULANTS**

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL TESTED FOR IN VITRO INTERFERENCE</th>
<th>PLASMA-SERUM BIAS (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA</td>
<td>1.5 mg/dL</td>
<td>- 0.7</td>
</tr>
<tr>
<td>Potassium Oxalate/Sodium Fluoride</td>
<td>2.0 / 2.5 mg/mL</td>
<td>- 1.2</td>
</tr>
</tbody>
</table>

**LIMITATIONS**

None identified.

**INTERFERENCES**

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

**TABLE 6 INTERFERENCES**

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>SOURCE</th>
<th>LEVEL TESTED</th>
<th>OBSERVED EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>Bovine</td>
<td>30 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Ditauro Bilirubin</td>
<td>Synthetic</td>
<td>20 mg/dL</td>
<td>+ 0.99 @ 2.1 mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>+ 1.84 @ 8.9 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>RBC hemolysate</td>
<td>250 mg/dL</td>
<td>+ 0.24 mg/dL</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Intralipid&lt;sup&gt;a&lt;/sup&gt;</td>
<td>500 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>Human</td>
<td></td>
<td>NSI</td>
</tr>
<tr>
<td></td>
<td>Serum Index 8</td>
<td></td>
<td>NSI</td>
</tr>
<tr>
<td>Cefotaxime</td>
<td>Cefotaxime sodium salt</td>
<td>500 µg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>L-Ascorbic Acid</td>
<td>20 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Fluorescein</td>
<td>Fluorescein Disodium Salt</td>
<td>300 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Nafcillin</td>
<td>NA&lt;sup&gt;1&lt;/sup&gt;</td>
<td>50 mg/L</td>
<td>+ 0.3 mg/dL</td>
</tr>
<tr>
<td>Methylbenzethonium Chloride</td>
<td>NA</td>
<td>2.0 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Rifampin</td>
<td>NA</td>
<td>2.5 mg/dL</td>
<td>- 0.3 mg/dL</td>
</tr>
</tbody>
</table>

2. Interference may occur with serum samples from patients diagnosed as having plasma cell dyscrasias and lymphoreticular malignancies associated with abnormal immunoglobulin synthesis, such as multiple myeloma, Waldenstöm’s macroglobulinemia, and heavy chain disease. Some of these samples may precipitate when mixed with reagent. Results for these samples will be suppressed due to "rxn noise". An accurate result may be obtained as follows.

A. Prepare a 0.9% sodium chloride (NaCl) solution or use a commercial preparation.

B. Combine one part of the original patient sample with one part of the prepared NaCl solution and mix well.

C. Analyze the solution. Multiply the result by 2.
If the NaCl dilution still gives a suppressed result due to "rxn noise", an accurate result may be obtained using a protein free filtrate prepared with trichloroacetic acid (TCA), as follows.

A. Prepare a 12% aqueous solution of trichloroacetic acid (TCA).

B. Combine one part of the original patient sample with one part of the prepared TCA solution and mix well.

C. Centrifuge for 10 minutes at 1200 x g at room temperature.

D. Analyze the supernatant. Multiply the result by 2.

3. Phosphorous determinations made in plasma are frequently subject to nonspecific interferences.8

4. Lipemic samples with visual turbidity >3+, or with a Lipemia Serum Index >10, should be ultracentrifuged and the analysis performed on the infranate.

5. Patients being treated with high dosages of drugs that use a phospholipid bilayer in a liposomal envelope as a delivery system may exhibit elevated serum/plasma results (e.g., AmBisome®) 109

6. Refer to References (11,12,13) for other interferences caused by drugs, disease and preanalytical variables.

**PERFORMANCE CHARACTERISTICS**

**Analytic Range**

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

**TABLE 7 ANALYTICAL RANGE**

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or Plasma</td>
<td>0.5 – 12.0 mg/dL</td>
<td>0.2 – 3.9 mmol/L</td>
</tr>
<tr>
<td>Urine</td>
<td>5 – 140 mg/dL</td>
<td>1.6 – 45.5 mmol/L</td>
</tr>
</tbody>
</table>

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

**REPORTABLE RANGE (as determined on site):**

**TABLE 8 REPORTABLE RANGE**

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum or Plasma</td>
<td>0.5 – 12.0 mg/dL</td>
<td>n/a</td>
</tr>
<tr>
<td>Urine</td>
<td>5 – dilute 1:10 to final result mg/dL</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Refer to “DXC800 Linearity and Reportable Range” chart in Technical notes section of DXC800 Procedure Manual

**SENSITIVITY**

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for the phosphorus determination is 0.5 mg/dL (0.2 mmol/L) for serum or plasma and 5 mg/dL (1.6 mmol/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 0.9 to 12.3 mg/dL):

\[
Y \text{ (SYNCHRON LX Systems)} = 0.970X + 0.29
\]

\[
\text{N} = 96
\]

\[
\text{MEAN (SYNCHRON LX Systems)} = 5.63
\]

\[
\text{MEAN (SYNCHRON CX®  7 DELTA)} = 5.51
\]

\[
\text{CORRELATION COEFFICIENT (r)} = 0.9979
\]

Urine (in the range of 6.5 to 116 mg/dL):

\[
Y \text{ (SYNCHRON LX Systems)} = 0.935X + 0.75
\]

\[
\text{N} = 75
\]

\[
\text{MEAN (SYNCHRON LX Systems)} = 48.6
\]

\[
\text{MEAN (SYNCHRON CX® 7 DELTA)} = 51.1
\]

\[
\text{CORRELATION COEFFICIENT (r)} = 0.9983
\]

Serum or Plasma (in the range of 0.5 to 11.6 mg/dL):

\[
Y \text{ (UniCel DxC Systems)} = 1.004X + 0.02
\]

\[
\text{N} = 198
\]

\[
\text{MEAN (UniCel DxC Systems)} = 4.7
\]

\[
\text{MEAN (SYNCHRON LX Systems)} = 4.7
\]

\[
\text{CORRELATION COEFFICIENT (r)} = 0.999
\]

Diluted Urine (in the range of 5.5 to 136.1 mg/dL):

\[
Y \text{ (UniCel DxC Systems)} = 1.009X + 0.02
\]

\[
\text{N} = 80
\]

\[
\text{MEAN (UniCel DxC Systems)} = 45.6
\]

\[
\text{MEAN (SYNCHRON LX Systems)} = 45.2
\]

\[
\text{CORRELATION COEFFICIENT (r)} = 0.999
\]

Refer to References (14) 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 9 MAXIMUM PERFORMANCE LIMITS**

<table>
<thead>
<tr>
<th>TYPE OF PRECISION</th>
<th>SAMPLE TYPE</th>
<th>1 SD</th>
<th>CHANGEOVER VALUE&lt;sup&gt;b&lt;/sup&gt;</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mg/dL</td>
<td>mmol/L</td>
<td>mg/dL</td>
</tr>
</tbody>
</table>

PHOSm
12/01/2011
<table>
<thead>
<tr>
<th>TYPE OF PRECISION</th>
<th>SAMPLE TYPE</th>
<th>1 SD</th>
<th>CHANGEOVER VALUE*</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mg/dL</td>
<td>mmol/L</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Within-run</td>
<td>Serum/Plasma</td>
<td>0.15</td>
<td>0.05</td>
<td>7.5</td>
</tr>
<tr>
<td></td>
<td>Urine</td>
<td>2.0</td>
<td>0.60</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>Serum/Plasma</td>
<td>0.23</td>
<td>0.07</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td>Urine</td>
<td>3.0</td>
<td>0.96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

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

**TABLE 10 NCCLS EP5-T2 PRECISION ESTIMATE METHOD**

<table>
<thead>
<tr>
<th>TYPE OF IMPRECISION</th>
<th>SAMPLE TYPE</th>
<th>No. Systems</th>
<th>No. Data Points</th>
<th>Test Mean Value (mg/dL)</th>
<th>EP5-T2 Calculated Point Estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SD</td>
</tr>
<tr>
<td>Within-run</td>
<td>Serum Control 1</td>
<td>1</td>
<td>80</td>
<td>1.84</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Serum Control 2</td>
<td>1</td>
<td>80</td>
<td>7.00</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>Urine Control 1</td>
<td>1</td>
<td>80</td>
<td>40.33</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>Urine Control 2</td>
<td>1</td>
<td>80</td>
<td>79.63</td>
<td>0.39</td>
</tr>
<tr>
<td>Total</td>
<td>Serum Control 1</td>
<td>1</td>
<td>80</td>
<td>1.84</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Serum Control 2</td>
<td>1</td>
<td>80</td>
<td>7.00</td>
<td>0.07</td>
</tr>
<tr>
<td></td>
<td>Urine Control 1</td>
<td>1</td>
<td>80</td>
<td>40.33</td>
<td>1.09</td>
</tr>
<tr>
<td></td>
<td>Urine Control 2</td>
<td>1</td>
<td>80</td>
<td>79.63</td>
<td>0.95</td>
</tr>
</tbody>
</table>

**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.
REFERENCES


Beckman Coulter, Inc., 4300 N. Harbor Blvd., Fullerton, CA 92835
ENDNOTES

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

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

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

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

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

f  NA = Not applicable.

g  AmBisome is a registered trademark of Gilead Sciences, Inc.

h  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.

i  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.