URIC Acid
For In Vitro Diagnostic Use

ANNUAL REVIEW

Reviewed by: | Reviewed by: | Date
---|---|---
Refer to coversheet in front of method | | |

PRINCIPLE

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.

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. 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

\[
\text{Uric acid} + \text{O}_2 + \text{H}_2\text{O} \xrightarrow{\text{Uricase}} \text{Allantoin} + \text{H}_2\text{O}_2 + \text{CO}_2
\]

\[
\text{H}_2\text{O}_2 + 4\text{-AAP} + \text{DCHBS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + \text{H}_2\text{O}
\]
SPECIMEN

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:

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

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 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 URIC Reagent Cartridges (2 x 300 tests)

VOLUMES PER TEST

**Serum or Plasma**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>12 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORDAC Sample Volume</td>
<td>6 µL</td>
</tr>
<tr>
<td>Total Reagent Volume</td>
<td>300 µL</td>
</tr>
</tbody>
</table>

**Cartridge Volumes**

- A: 270 µL
- B: 30 µL
- C: —

**Urine**

**Sample Dilution Volumes**

<table>
<thead>
<tr>
<th>Sample Volume</th>
<th>20 µL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent Volume</td>
<td>180 µL</td>
</tr>
<tr>
<td>Diluted Sample Volume</td>
<td>12 µL</td>
</tr>
<tr>
<td>Total Reagent Volume</td>
<td>300 µL</td>
</tr>
</tbody>
</table>

**Cartridge Volumes**

- A: 270 µL
- B: 30 µL
REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

- 4-Aminooantipyrine 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.

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.

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

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:

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

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.

CALIBRATOR STORAGE LOCATION:

Thawed Multical vial in-use kept refrigerated in Calibrator tray. Unopened Multical kept frozen (-15°C to -20°C), Chemistry freezer 8. Refer to “DXC800 Calibrator Quick Reference” write up in DXC800 Procedures manual.

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.
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 1 QUALITY CONTROL MATERIAL

<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, 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 operations.

For detailed testing procedures, refer to the SYNCHRON LX Operations Manual, or the UniCel DxC 600/800 System Instructions For Use (IFU) manual.

CALCULATIONS
The SYNCHRON® System(s) performs 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.®
**TABLE 2 REFERENCE INTERVALS**

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS (Mg/dL)</th>
<th>S.I. UNITS (µmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature</td>
<td>Serum or Plasma (Male)</td>
<td>4.4 – 7.6</td>
<td>262 – 452</td>
</tr>
<tr>
<td></td>
<td>Serum or Plasma (Female)</td>
<td>2.3 – 6.6</td>
<td>137 – 393</td>
</tr>
<tr>
<td></td>
<td>Urine (timed)</td>
<td>250 – 750</td>
<td>1.48 – 4.43</td>
</tr>
<tr>
<td>SYNCHRON</td>
<td>Serum or Plasma (Male)</td>
<td>4.8 – 8.7</td>
<td>286 – 518</td>
</tr>
<tr>
<td></td>
<td>Serum or Plasma (Female)</td>
<td>2.6 – 8.0</td>
<td>155 – 476</td>
</tr>
</tbody>
</table>

**INTERVALS**

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>AGE</th>
<th>MALE (Mg/dL)</th>
<th>FEMALE (Mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory</td>
<td>Serum or Plasma</td>
<td>0- 30d</td>
<td>1.2-3.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>31d- &lt;1y</td>
<td>1.2-5.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1y- &lt;4y</td>
<td>2.1-5.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4y- &lt;7y</td>
<td>1.8-5.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7y- &lt;10y</td>
<td>1.8-5.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10y- &lt;13y</td>
<td>2.2-5.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13y- &lt;16y</td>
<td>3.1-7.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>16y- &lt;18y</td>
<td>2.1-7.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;18 yr</td>
<td>3.9-8.2</td>
</tr>
</tbody>
</table>

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

2. Normal range for adults was determined by testing 137 male and 129 female healthy blood donors at UCSF.

**ADDITIONAL REPORTING INFORMATION AS DESIGNATED BY THIS LABORATORY:**

Refer to “DXC 800 Linearity and Reportable Range” chart in Technical Notes section of DXC 800 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 3 Acceptable 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</td>
</tr>
<tr>
<td>Lithium Heparin</td>
<td>14 Units/mL</td>
<td>NSI</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>14 Units/mL</td>
<td>NSI</td>
</tr>
</tbody>
</table>

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

Table 4 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>Potassium Oxalate/Sodium Fluoride</td>
<td>2.0 / 2.5 mg/dL</td>
<td>-0.7</td>
</tr>
</tbody>
</table>

**LIMITATIONS**

None identified.
INTERFERENCES

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

Table 5 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>10 mg/dL</td>
<td>+0.5 @ 2.3 mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-1.0 @ 10.0 mg/dL</td>
</tr>
<tr>
<td>Dilauro Bilirubin</td>
<td>Synthetic</td>
<td>5 mg/dL</td>
<td>-0.42 @ 3.1 mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-1.25 @ 8.6 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>RBC hemolysate</td>
<td>200 mg/dL</td>
<td>+0.3 mg/dL</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Intralipid</td>
<td>500 mg/dL</td>
<td>NSI</td>
</tr>
<tr>
<td>Albumin</td>
<td>Human Cohn Fraction V</td>
<td>8 g/dL</td>
<td>-0.5 mg/dL</td>
</tr>
<tr>
<td>Ascorbate (Serum)</td>
<td>SIGMA</td>
<td>1.5 mg/dL</td>
<td>-0.3 mg/dL</td>
</tr>
<tr>
<td>Ascorbate (Urine)</td>
<td>SIGMA</td>
<td>20 mg/dL</td>
<td>+3.0 mg/dL</td>
</tr>
</tbody>
</table>

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.

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 |
| 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 or Plasma (ORDAC)  | 0.5 – 21.0 mg/dL   | n/a         |
| Urine                    | 5 – 120 mg/dL      | n/a         |

Refer to “DXC 800 Linearity and Reportable Range” chart in Technical Notes section of DXC 800 Procedure manual.
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):

- \[ Y \text{ (SYNCHRON LX Systems)} = 0.977X - 0.02 \]
- \[ N = 79 \]
- 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):

- \[ Y \text{ (SYNCHRON LX Systems)} = 0.996X + 0.12 \]
- \[ N = 78 \]
- 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>
<thead>
<tr>
<th>TABLE 8 MAXIMUM PERFORMANCE LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TYPE OF PRECISION</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Within-run</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Comparative performance data for the SYNCHRON® System(s) 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 9 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</td>
<td>Control 1</td>
<td>1</td>
<td>80</td>
<td>2.42</td>
</tr>
<tr>
<td></td>
<td>Serum</td>
<td>Control 2</td>
<td>1</td>
<td>80</td>
<td>10.48</td>
</tr>
<tr>
<td></td>
<td>Urine</td>
<td>Control 1</td>
<td>1</td>
<td>80</td>
<td>41.57</td>
</tr>
<tr>
<td></td>
<td>Urine</td>
<td>Control 2</td>
<td>1</td>
<td>80</td>
<td>14.12</td>
</tr>
<tr>
<td>Total</td>
<td>Serum</td>
<td>Control 1</td>
<td>1</td>
<td>80</td>
<td>2.42</td>
</tr>
<tr>
<td></td>
<td>Serum</td>
<td>Control 2</td>
<td>1</td>
<td>80</td>
<td>10.48</td>
</tr>
<tr>
<td></td>
<td>Urine</td>
<td>Control 1</td>
<td>1</td>
<td>80</td>
<td>41.57</td>
</tr>
<tr>
<td></td>
<td>Urine</td>
<td>Control 2</td>
<td>1</td>
<td>80</td>
<td>14.12</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., 250 South Kraemer Blvd., Brea, CA 92821
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 Data shown was collected using SYNCHRON CX Systems. Equivalency between SYNCHRON LX Systems has been established by Deming regression analysis to SYNCHRON CX Systems.

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

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

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

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

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

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

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

k 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.

l NA = Not applicable.

m 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.