Glucose (GLUCm) - Serum, Plasma, Urine, CSF, Fluids
Beckman UniCel DxC Systems

Technical Procedure 3130

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| Michael Inn | October, 2000 | Reformatted |

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**For *In Vitro* Diagnostic Use Only**

## Principle

### Intended Use

GLUCm reagent, when used in conjunction with UniCel® DxC System(s) and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for quantitative determination of glucose concentration in human serum, plasma, urine, CSF or fluids.

### Clinical Significance

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

### Methodology

The SYNCHRON® System(s) determines GLUCm concentration by an oxygen rate method employing a Beckman Coulter Oxygen electrode.(1,2)

A precise volume of sample (10 microliters) is injected in a reaction cup containing a glucose oxidase solution. The ratio used is one part sample to 76 parts reagent. The peak rate of oxygen consumption is directly proportional to the concentration of GLUCm in the sample.(3)

### Chemical Reaction Scheme

Oxygen is consumed at the same rate as glucose reacts to form gluconic acid.

$$\beta - D \text{ - glucose} + O_2 \xrightarrow[H_2O]{\text{Glucose Oxidase}} \text{Gluconic acid} + H_2O_2$$

Because oxygen consumption rather than peroxide formation is measured, the only requirement for peroxide is that it must be destroyed by a path not leading back to oxygen. The addition of ethanol to the reagent causes peroxide to be destroyed in the presence of catalase without yielding oxygen, according to the following reaction:

$$H_2O_2 + \text{Ethanol} \xrightarrow{\text{Catalase}} \text{Acetaldehyde} + H_2O$$

To ensure complete destruction of the peroxide, iodide and molybdate are added to the enzyme reagent, causing the following reaction:

$$H_2O_2 + 2H^+ + 2I^- \xrightarrow{\text{Molybdate}} I_2 + 2H_2O$$

The reaction is effective even after the catalase activity has diminished with length of storage.

## Specimen

### Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers, Terumo Gray Top micro containers
13 x 75 Gray Top BD tubes for fasting glucose, glucose loads & glucose tolerance samples
CSF should be submitted in the LP sterile collection tubes. Tube #1 is the preferred tube for chemistry testing.
Fluids should be received in a 13 x 75 Clear Cap BD tube
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.
Optimum volume: 0.5 mL

### Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(4) Freshly drawn serum, plasma, CSF, fluids or properly collected urine (random/timed) are the preferred specimens. **Whole blood is not recommended for use as a sample**. The use of fluoride as a glycolysis inhibitor is recommended.

### 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.(5)
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.(5)
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. No preservative is required.(6)
4. CSF specimens should be centrifuged and analyzed without delay.
5. **Urine samples aspirated by the IRIS IQ are not acceptable for urine chemistry testing.**
6. Urine collected in a BD UA Preservative Tube is not acceptable for urine chemistry testing.

### 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

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 # 472500**
Two Glucose Reagent Bottles (2 X 2 L)

### Volumes per Test

| | |
|---|---|
| Sample Volume | 10 µL |
| ORDAC Sample Volume | 5 µL |
| Total Reagent Volume | 765 µL |

### Reactive Ingredients

Reagent Constituents

| | |
|---|---|
| Glucose Oxidase | 150 U/mL |
| Denatured Ethanol | 5% |
| Potassium Iodide | 0.04 mol/L |
| Ammonium Molybdate | 0.03 mol/L |

Also non-reactive chemicals necessary for optimal system performance.

**Materials Needed But Not Supplied With Reagent Kit**

SYNCHRON® Systems AQUA CAL 1 and 2
At least two levels of control material
Saline

**Reagent Preparation**

1. Prior to use, allow the Glucose reagent to equilibrate to room temperature for at least 8 hours. A +25°C water bath may be used to warm reagent. Invert reagent 5 times to mix.
2. Inspect for crystals and if present, see instructions for frozen reagent in Reagent Storage and Stability.

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

3. Date and initial reagent container and document in reagent log before loading each new carboy.

**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**

1. GLUCm reagent stored unopened at +2°C to +8°C is stable until the expiration date indicated on each bottle. The reagent is stable on the instrument for 30 days or until the expiration date, if sooner.
2. If reagent is frozen in transit, thaw completely, warm to room temperature and mix thoroughly by gently inverting bottle at least 10 times.

## Equipment

This test is performed on the Beckman UniCel DxC 800 systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the UniCel DxC 800 systems *Reference Manual* for detailed instructions.

## Calibration

**Calibrator Required**

SYNCHRON® Systems AQUA CAL 1 and 2 (**Kit Reorder #s 471288 and 471291**)

**Calibrator Preparation**

No preparation is required.

**Calibrator Storage and Stability**

1. If unopened calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.
2. Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

**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 GLUCm assay must be calibrated every 48 hours or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 800

Systems *Instructions for Use* (IFU) manual. Calibration may be required if the system is powered down for more than five minutes.

3. For detailed calibration instructions, refer to the UniCel DxC 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 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**

Glucose (analyte) in this calibrator is traceable to NIST* SRM 917a.

**NIST=National Institute of Standards and Technology*

The set point values were established based upon the gravimetric addition of specific quantities of the measurand to achieve the appropriate concentration.

The values are verified using representative samples from each lot of calibrator and are specific to the assay methodlogies of the SYNCHRON systems. Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

## Quality Control

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 bottle of reagent, 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.

**NOTICE**
Do not use controls containing diethylamine HCl.

The following controls should be used in accordance with the package instructions for use inserts. Copies of these inserts can be found in the *Control IFUs* folder on the S drive (*S:\APS\ClinLab\PoliciesandProcedures\1000-8999CLINICALPATHOLOGY\3000-3999Chemistry\3000-3499AutomatedChemistry\Control IFUs*). 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* |

*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.

## Testing Procedure

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 is required.
3. Program samples and controls for analysis.
4. Due to sporadic imprecision of results, all patient samples are automatically run in duplicate. Duplicate results up to 115 mg/dL must be within 8 mg/dL. Duplicate results > 115 mg/dL must be within 12 mg/dL. Results exceeding this limit will be flagged in Remisol for repeat testing. For adult glucose critical results, the acceptable reproducible range is 491 to 509 mg/dL. For newborns to teens less than 18 years old, the critical result must be in the acceptable reproducible range between 298 to 302 mg/dL.
5. 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 hour timed urine specimens are calculated from the following equation:

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

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

**Do not round off total collection time**.

## 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.(7)

Reference Intervals

| Intervals | Sample Type | Conventional Units | | S.I Units |
|---|---|---|---|---|
| Literature | Serum or Plasma | 74 - 106 mg/dL | | 4.1 - 5.9 mmol/L |
| | Urine[a] | 1 - 15 mg/dL | | 0.06 - 0.83 mmol/L |
| | Urine (timed)[a] | < 0.5 g/24 hrs | | < 2.8 mmol/24hrs |
| | CSF | 40 - 70 mg/dL | | 2.2 - 3.9 mmol/L |
| SYNCHRON | Serum or Plasma | 74 - 118 mg/dL | | 4.1 - 6.1 mmol/L |
| UCDMC | Random Serum or Plasma | 0 days to 2 days | 60 to 110 mg/dL | 3.3 to 6.1 mmol/L |
| | Random Serum or Plasma | > 2 days to 17 yrs | 70 to 110 mg/dL | 3.9 to 6.1 mmol/L |
| | Random Serum or Plasma | ≥ 18 yrs | 70 to 110 mg/dL | 3.9 to 6.1 mmol/L |
| | Fasting Serum or Plasma | 0 days to 2 days | 60 to 99 mg/dL | 3.3 to 5.5 mmol/L |
| | Fasting Serum or Plasma | > 2 days to 17 yrs | 70 to 99 mg/dL | 3.9 to 5.5 mmol/L |
| | Fasting Serum or Plasma | ≥ 18 yrs | 70 to 99 mg/dL | 3.9 to 5.5 mmol/L |
| | CSF[b] | 40 to 80 mg/dL | | 2.2 to 4.4 mmol/L |
| | Urine (timed)[b] | < 500 mg/24hrs | | < 27.8 mmol/24hrs |

[a] In a healthy patient, the normal urine glucose value is zero.
Refer to References (8, 9, 10) for guidelines on establishing laboratory-specific reference intervals.
[b] CSF and urine reference intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

- In a healthy patient, the normal urine glucose value is 0 mg/dL. However, the lowest measurable concentration which can be distinguished from zero with 95% confidence by UCDHS is 10 mg/dL.
- A reference interval for fluids has not been determined by UCDHS. This result may be less accurate than for the usual sample type, and should be interpreted in the context of the patient's clinical condition.
- Fasting blood sugar (FBS) is defined as the measurement of serum or plasma glucose after a patient has not eaten for 8 to 12 hours (usually overnight).
- Fasting glucose values between 100-125 mg/dL (5.6-6.9 mmol/L) suggest an impaired fasting glucose status. Fasting glucose results greater or equal to 126 mg/dL (7.0 mmol/L) suggest diabetes mellitus.
- Non-fasting glucose results greater than 199 mg/dL (> 11.0 mmol/L) suggest diabetes mellitus.(16)

### Critical Values

Glucose results **≤ 40** mg/dL and **≥ 300** mg/dL for newborns (**0 days to 2 days old**) are considered critical values and should be called immediately to the attending physician or charge nurse.

Glucose results **≤ 50** mg/dL and **≥ 300** mg/dL for neonates to teens (**> 2 days to 17 yrs old**) are considered critical values and should be called immediately to the attending physician or charge nurse.

Glucose results **≤ 50** mg/dL and **≥ 500** mg/dL for adults (**≥ 18 yrs old**) are considered critical values and should be called immediately to the attending physician or charge nurse.

## Procedural Notes

### Anticoagulant Test Results

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method:

Compatible Anticoagulants

| Anticoagulant | Level Tested for In Vitro Interference | Average Plasma-Serum Bias (mg/dL) |
|---|---|---|
| Ammonium Heparin | 14 Units/mL | NSI[a] |
| Lithium Heparin | 14 Units/mL | NSI |
| Sodium Heparin | 14 Units/mL | NSI |
| Potassium Oxalate/Sodium Fluoride | 2.0 / 2.5 mg/mL | NSI |

[a] NSI = No Significant Interference (within ±4.0 mg/dL or 4%).

### Limitations

1.If sodium fluoride is used as a preservative, a decrease of 9 mg/dL is seen during the first 2 hours.(7)

2.If urine or CSF samples are cloudy or turbid or if CSF samples are visibly contaminated with blood, it is recommended that they be centrifuged before transfer to a sample cup.

3.Freshly prepared D-glucose solutions or commercial controls spiked with D-glucose must be allowed to mutarotate before analysis for accurate results.

### Interferences

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

Interferences

| Substance | Source | Level Tested | Observed Effect |
|---|---|---|---|
| Bilirubin (unconjugated) | Bovine | 30 mg/dL | NSI[a] |
| Hemoglobin | RBC Hemolysate | 500 mg/dL | NSI |
| Lipemia | Intralipid[b] | 500 mg/dL | NSI |

[a] NSI = No Significant Interference (within ±4.0 mg/dL or 4%).

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

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

3. 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/Plasma/Urine/CSF/Fluids | 10 - 600 mg/dL | 0.6 - 33.3 mmol/L |
| Serum/Plasma/Urine/CSF/Fluids (ORDAC) | 300 - 1200 mg/dL | 16.6 - 66.6 mmol/L |

### Clinical Reportable Range:

Clinical Reportable Range (CRR)

| Sample Type | Conventional Units | S.I. Units |
|---|---|---|
| Serum/Plasma/Urine/CSF/Fluids | 10 - diluted result mg/dL | 0.6 - diluted result mmol/L |

Samples with concentrations below the AMR and CRR (10 mg/dL) will be reported as "**< 10 mg/dL**" (< 0.7 mmol/L). 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 GLUm determination is 10 mg/dL (0.56 mmol/L).

### Equivalency

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

As determined by Beckman

Serum or Plasma (in the range of 26 to 568 mg/dL):

| | |
|---|---|
| Y (SYNCHRON LX Systems) | = 0.991X - 0.25 |
| N | = 87 |
| MEAN (SYNCHRON LX Systems) | = 193.7 |
| MEAN (SYNCHRON CX7 DELTA) | = 195.8 |
| CORRELATION COEFFICIENT (r) | = 0.9957 |

Urine (in the range of 7 to 463 mg/dL):

| | |
|---|---|
| Y (SYNCHRON LX Systems) | = 0.990X - 3.08 |
| N | = 58 |
| MEAN (SYNCHRON LX Systems) | = 197.9 |
| MEAN (SYNCHRON CX7 DELTA) | = 203.0 |
| CORRELATION COEFFICIENT (r) | = 0.9986 |

CSF (in the range of 24 to 554 mg/dL):

| | |
|---|---|
| Y (SYNCHRON LX Systems) | = 0.970X + 1.81 |
| N | = 93 |
| MEAN (SYNCHRON LX Systems) | = 182.1 |
| MEAN (SYNCHRON CX7 DELTA) | = 185.8 |
| CORRELATION COEFFICIENT (r) | = 0.9977 |

Serum or Plasma (in the range of 3 to 571 mg/dL):

| | |
|---|---|
| Y (UniCel DxC Systems) | = 1.006X - 0.11 |
| N | = 199 |
| MEAN (UniCel DxC Systems) | = 113 |
| MEAN (SYNCHRON LX Systems) | = 112 |
| CORRELATION COEFFICIENT (r) | = 1.000 |

Urine (in the range of 3 to 600 mg/dL):

| | |
|---|---|
| Y (UniCel DxC Systems) | = 1.008X + 0.00 |
| N | = 99 |
| MEAN (UniCel DxC Systems) | = 154 |
| MEAN (SYNCHRON LX Systems) | = 152 |
| CORRELATION COEFFICIENT (r) | = 1.000 |

CSF (in the range of 22 to 552 mg/dL):

| | |
|---|---|
| Y (UniCel DxC Systems) | = 0.982X + 0.43 |
| N | = 93 |
| MEAN (UniCel DxC Systems) | = 215 |
| MEAN (SYNCHRON LX Systems) | = 219 |
| CORRELATION COEFFICIENT (r) | = 1.000 |

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

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

As determined at UCDMC

Serum or Plasma (in the range of 22 to 577 mg/dL):

| | |
|---|---|
| Y (UniCel DxC800-4118) | = 1.025X - 7.9 |
| N | = 28 |
| MEAN (UniCel DxC800-4118) | = 159.4 |
| MEAN (UniCel DxC800-1805) | = 163.2 |
| CORRELATION COEFFICIENT (r) | = 0.9986 |

Serum or Plasma (in the range of 22 to 577 mg/dL):

| | |
|---|---|
| Y (UniCel DxC800-4427) | = 1.048X - 11.9 |
| N | = 28 |
| MEAN (UniCel DxC800-4427) | = 159.0 |
| MEAN (UniCel DxC800-1805) | = 163.2 |
| CORRELATION COEFFICIENT (r) | = 0.9986 |

Serum or Plasma (in the range of 22 to 429 mg/dL):

| | |
|---|---|
| Y (UniCel DxC800-4449) | = 1.047X - 11.5 |
| N | = 27 |
| MEAN (UniCel DxC800-4449) | = 143.3 |
| MEAN (UniCel DxC800-1805) | = 147.9 |
| CORRELATION COEFFICIENT (r) | = 0.9975 |

Serum or Plasma (in the range of 25 to 444 mg/dL):

| | |
|---|---|
| Y (UniCel DxC800-4427) | = 0.981X + 3.1 |
| N | = 29 |
| MEAN (UniCel DxC800-4427) | = 162.8 |
| MEAN (UniCel DxC800-4118) | = 162.8 |
| CORRELATION COEFFICIENT (r) | = 0.9996 |

Serum or Plasma (in the range of 25 to 431 mg/dL):

| | |
|---|---|
| Y (UniCel DxC800-4449) | = 1.020X - 3.3 |
| N | = 27 |
| MEAN (UniCel DxC800-4449) | = 143.3 |
| MEAN (UniCel DxC800-4118) | = 143.7 |
| CORRELATION COEFFICIENT (r) | = 0.9995 |

Serum or Plasma (in the range of 25 to 439 mg/dL):

| | |
|---|---|
| Y (UniCel DxC800-4449) | = 1.003X + 0.0 |
| N | = 27 |
| MEAN (UniCel DxC800-4449) | = 143.3 |
| MEAN (UniCel DxC800-4427) | = 142.9 |
| CORRELATION COEFFICIENT (r) | = 0.9997 |

**Precision**

A properly operating SYNCHRON® 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 | mmol/L | mg/dL | mmol/L | |
| Within-run | Serum/Plasma/Urine/CSF/Fluids | 2.0 | 0.1 | 100.0 | 5.6 | 2.0 |
| Total | Serum/Plasma/Urine/CSF/Fluids | 3.0 | 0.2 | 100.0 | 5.6 | 3.0 |
| Within-run | Serum/Plasma/Urine/CSF/Fluids (ORDAC) | NA[b] | NA | NA | NA | 5.0 |
| Total | Serum/Plasma/Urine/CSF/Fluids (ORDAC) | NA | NA | NA | NA | 7.5 |

[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 | 44.8 | 0.6 | 1.2 |
| | SYNCHRON 3 | 20 | 399.8 | 4.3 | 1.1 |
| DxC800-4427 Within-run | SYNCHRON 1 | 20 | 44.4 | 0.7 | 1.5 |
| | SYNCHRON 3 | 20 | 397.9 | 3.5 | 0.9 |
| DxC800-4449 Within-run | SYNCHRON 1 | 20 | 45.1 | 0.6 | 1.4 |
| | SYNCHRON 3 | 20 | 403.8 | 3.1 | 0.8 |

| Type of Imprecision | Sample Type | n | Mean (mg/dL) | SD | %CV |
|---|---|---|---|---|---|
| DxC800-4118 Day to Day | MAS ChemTrak 1 | 1345 | 57 | 2.8 | 4.9 |
| | MAS ChemTrak 3 | 1376 | 340 | 7.5 | 2.2 |
| DxC800-4427 Day to Day | MAS ChemTrak 1 | 1339 | 57 | 2.6 | 4.6 |
| | MAS ChemTrak 3 | 1376 | 338 | 7.5 | 2.2 |
| DxC800-4449 Day to Day | MAS ChemTrak 1 | 1352 | 58 | 2.7 | 4.7 |
| | MAS ChemTrak 3 | 1412 | 339 | 8.6 | 2.5 |

**Comparative Performance**

Data for a SYNCHRON LX® System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.(15)

As determined by Beckman

NCCLS EP5-T2 Precision Estimate Method

| Type of Imprecision | Sample Type | No. Systems | No. Data Points[a] | Test Mean Value (mg/dL) | EP5-T2 Calculated Point Estimates | |
|---|---|---|---|---|---|---|
| | | | | | SD | %CV |
| Within-run | Serum Control 1 | 1 | 80 | 43.7 | 1.3 | 2.9 |
| | Serum Control 2 | 1 | 80 | 397.1 | 1.7 | 0.4 |
| | Urine Control 1 | 1 | 80 | 37.1 | 1.0 | 2.8 |
| | Urine Control 2 | 1 | 80 | 289.7 | 1.8 | 0.6 |
| | CSF Control 1 | 1 | 80 | 35.6 | 0.8 | 2.2 |
| | CSF Control 2 | 1 | 80 | 111.4 | 1.1 | 1.0 |
| Total | Serum Control 1 | 1 | 80 | 43.7 | 1.7 | 3.9 |
| | Serum Control 2 | 1 | 80 | 397.1 | 4.7 | 1.2 |
| | Urine Control 1 | 1 | 80 | 37.1 | 1.5 | 4.0 |
| | Urine Control 2 | 1 | 80 | 289.7 | 8.2 | 2.8 |
| | CSF Control 1 | 1 | 80 | 35.6 | 1.3 | 3.6 |
| | CSF Control 2 | 1 | 80 | 111.4 | 1.9 | 1.7 |

[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.

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