Sodium (Na) - Serum, Plasma, Urine, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3145

Prepared By	Date Adopted	Supersedes Procedure #
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06/18/2012	Added dialysate solutions as a sample type	M. Inn	06/22/2012	G. Kost

Sodium (Na) - Serum, Plasma, Urine, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3145

For *In Vitro* Diagnostic Use Only

Principle

Intended Use

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with UniCel® DxC 800 System(s) and SYNCHRON® Systems AQUA CAL 1, 2 and 3, are intended for the quantitative determination of sodium concentration in human serum, plasma, urine or dialysate solutions.

Clinical Significance

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of hormone aldosterone), diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Methodology

The SYNCHRON® System(s) determines sodium ion concentration by indirect potentiometry utilizing two glass sodium electrodes (one acts as the reference electrode).

To measure sodium concentrations, a precise volume of sample (40 microliters) is mixed with a buffered solution. The ratio used is one part sample to 33 parts buffer. The high molar strength buffer is used to establish a constant activity coefficient for sodium ions, calibrating the electrode to concentration values.

Chemical Reaction Scheme

The sodium electrode is made of lithium-sodium-aluminum-silicate glass. It is essential that the outer layer of the glass electrode is adequately hydrated. When the sample buffer mixture contacts the electrode, sodium ions in the sample undergo an ion exchange process with the sodium ions in the hydrated layer of the electrode. Changes in electrode potential occur as the ion exchange process takes place. These changes in electrode potential are referenced to the reference electrode. The "referenced potential" follows the Nernst equation and allows the calculation of sodium concentration in the sample:

$$E = \text{Constant} + (\text{slope})\ (\log[Na^+])$$

For more accurate measurement, the reference reagent containing sodium ions is introduced into the flow cell after the sample cycle, and the same ion exchange process takes place. The differential potential (voltage) between sample and reference reagent cycles is used for the calculation.

Under ideal conditions, the electrode imparts a selectivity of 300:1 over potassium and is insensitive to hydrogen ions in solutions buffered from pH 6 to 10.

Specimen

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(1) Freshly drawn serum, plasma, properly collected urine (random/timed) or dialysate solutions are the preferred specimens. Acceptable anticoagulants are listed in *Procedural Notes* section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers
Spot urines should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube
24 hour urine chloride collections are usually received in 3000 mL plastic urine collection jugs.
Dialysate solutions should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube

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.

Timed urine specimens are calculated from the following equation:

$$\text{Urine sodium X } \frac{\text{Total volume collected}}{\text{Total time of collection (hrs)}}$$

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

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.(4)

Table 2 Reference Intervals

Intervals	Sample Type	Conventional Units		S.I Units
Literature	Serum or Plasma	136 - 145 mmol/L		136 - 145 mmol/L
	Urine (timed)	40 – 220 mmoL/24 hrs		40 – 220 mmoL/24 hrs
SYNCHRON	Serum or Plasma	136 – 144 mmol/L		136 – 144 mmol/L
UCDMC	Serum or Plasma	Premature	132 - 140 mmol/L	132 - 140 mmol/L
	Serum or Plasma	Mature < 1 yr	132 - 140 mmol/L	132 - 140 mmol/L
	Serum or Plasma	1 to 12 yr	132 - 140 mmol/L	132 - 140 mmol/L
	Serum or Plasma	> 12 yr	132 - 140 mmol/L	132 - 140 mmol/L
	Urine (random)	N/A		N/A
	Urine (timed)	Infant	0.3 - 3.5 mmol/24 hrs	0.3 - 3.5 mmol/24 hrs
	Urine (timed)	Child	40 - 180 mmol/24 hrs	40 - 180 mmol/24 hrs
	Urine (timed)	Adult	40 - 220 mmol/24 hrs	40 - 220 mmol/24 hrs

Refer to References (5,6,7) for guidelines on establishing laboratory-specific reference intervals.

Pediatric and timed urine reference intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

There are no published reference intervals for dialysate solutions. These are custom solutions for each patient and results from analysis are used to verify accuracy of dialysate solution preparations.

Critical Values

Sodium results **≤ 120 mmol/L** and **≥ 160 mmol/L** are considered critical values and should be called immediately to the attending physician or charge nurse.

Potassium (K) - Serum, Plasma, Urine, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3136

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			09/26/2006	G. Kost
			11/05/2007	G. Kost
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06/28/2011	Removed sample types fluids and feces	M. Inn	07/06/2011	G. Kost
06/18/2012	Added dialysate solutions as a sample type	M. Inn	06/22/2012	G. Kost

Potassium (K) - Serum, Plasma, Urine, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3136

For *In Vitro* Diagnostic Use Only

Principle

Intended Use

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with UniCel® DxC 800 System(s) and SYNCHRON® Systems AQUA CAL 1, 2 and 3, are intended for the quantitative determination of potassium concentration in human serum, plasma, urine or dialysate solutions.

Clinical Significance

Potassium measurements are used in the diagnosis and treatment of hypokalemia (metabolic alkalosis, metabolic acidosis or the absence of acid-base disturbances), hyperkalemia (overadministration of potassium, acidosis, or crush injuries), renal failure, Addison‘s disease or other diseases involving electrolyte imbalance.

Methodology

The SYNCHRON® System(s) determines potassium ion concentration by indirect potentiometry utilizing a potassium ion selective electrode in conjunction with a sodium reference electrode.

To measure potassium concentrations, a precise volume of sample (40 microliters) is mixed with a buffered solution. The ratio used is one part sample to 33 parts buffer. The high molar strength buffer is used to establish a constant activity coefficient for potassium ions, calibrating the electrode to concentration values.

Chemical Reaction Scheme

The potassium ion selective electrode consists of a valinomycin PVC membrane cast on a solid support. The physical structure of the valinomycin ionophore is such that its cavity is nearly equal to the diameter of the potassium ion, thus allowing potassium ions to complex with valinomycin. When sample buffer mixture contacts the electrode, changes in electrode potential occur as potassium ions react with valinomycin. These changes in potential are referenced to the sodium reference electrode. The "referenced potential" follows the Nernst equation and allows the calculation of potassium concentration in sample:

$$E = \text{Constant} + (\text{slope})\ (\log[K^+])$$

For more accurate measurement, the reference reagent containing potassium ions is introduced into the flow cell after the sample cycle, and the same ion exchange process takes place. The differential potential (voltage) between sample and reference reagent cycles is used for the calculation.(1)

Under ideal conditions, the electrode imparts a selectivity of 1000:1 over sodium ions and is insensitive to hydrogen ions in solutions buffered from pH 3 to 9.

Specimen

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(2) Freshly drawn serum, plasma or properly collected urine (random/timed) are the preferred specimens. Acceptable anticoagulants are listed in *Procedural Notes* section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers
Spot urines should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube
24 hour urine chloride collections are usually received in 3000 mL plastic urine collection jugs.
Dialysate solutions should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube

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 Uni-Cel DxC system but by Remisol.

Timed urine specimens are calculated from the following equation:

$$\text{Urine sodium X } \frac{\text{Total volume collected}}{\text{Total time of collection (hrs)}}$$

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

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.(4)

Table 2 Reference Intervals

Intervals	Sample Type	Conventional Units		S.I Units
Literature	Serum or Plasma	3.5 - 5.1 mmol/L		3.5 - 5.1 mmol/L
	Urine (timed)	25 - 125 mmoL/24 hrs		25 - 125 mmoL/24 hrs
SYNCHRON	Serum or Plasma	3.6 - 5.1 mmol/L		3.6 - 5.1 mmol/L
UCDMC	Serum or Plasma	0 - 14 days	4.0 - 6.4 mmol/L	4.0 - 6.4 mmol/L
	Serum or Plasma	14 days - 3 mos.	4.0 - 6.2 mmol/L	4.0 - 6.2 mmol/L
	Serum or Plasma	3 mos. - 1 yr	3.7 - 5.6 mmol/L	3.7 - 5.6 mmol/L
	Serum or Plasma	> 1 yr	3.5 - 5.0 mmol/L	3.5 - 5.0 mmol/L
	Urine (random)	N/A		N/A
	Urine (timed)	Pediatric	20 - 125 mmol/24 hrs	20 - 125 mmol/24 hrs
	Urine (timed)	Adult	25 - 125 mmol/24 hrs	25 - 125 mmol/24 hrs

Refer to References (5,6,7) for guidelines on establishing laboratory-specific reference intervals.

Pediatric, timed urine and fecal reference intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

There are no published reference intervals for dialysate solutions. These are custom solutions for each patient and results from analysis are used to verify accuracy of dialysate solution preparations.

Critical Values

Potassium results **≤ 2.7** mmol/L and **≥ 6.5** mmol/L are considered critical values and should be called immediately to the attending physician or charge nurse.

Hemolyzed potassium results **≤ 2.7** mmol/L and **≥ 8.0** mmol/L are considered critical values and should be called immediately to the attending physician or charge nurse.

Carbon Dioxide (CO_2) - Serum, Plasma, Dialysate Solutions — Technical Procedure 3120
Beckman UniCel DxC Systems

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			09/26/2006	G. Kost
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06/18/2012	Added dialysate solutions as a sample type	M. Inn	06/22/2012	G. Kost

Carbon Dioxide (CO_2) - Serum, Plasma, Dialysate Solutions — Technical Procedure 3120
Beckman UniCel DxC Systems

For *In Vitro* Diagnostic Use Only

Principle

Intended Use

ISE Electrolyte Buffer reagent, ISE Electrolyte Reference reagent, CO2 Alkaline Buffer and CO2 Acid Reagent, when used in conjunction with UniCel® DxC 800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 3, are intended for the quantitative determination of carbon dioxide in human serum, plasma or dialysate solutions.

Clinical Significance

Carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Methodology

The SYNCHRON® System(s) determines total carbon dioxide using a pH rate of change method utilizing a glass carbon dioxide electrode in conjunction with a glass pH reference electrode.

The electrode measures the rate of change of the pH and compares it to the reference electrode.(1)

Chemical Reaction Scheme

TA CO2 electrode is a glass pH electrode covered with a gas permeable silicone membrane, with a layer of bicarbonate solution in between. To measure CO_2 concentrations, a precise volume of sample (40 microliters) is mixed with a buffered solution. The ratio used is one part sample to 33 parts buffer. When this mixture is delivered into the flow cell, it is acidified with a fixed volume of CO_2 acid reagent which is delivered to the upper portion of the flow cell. All forms of carbon dioxide are converted to their gaseous form according to the following equation:

$$CO_2 + H_2CO_3 + HCO_3 + CO_3^{=} + RNHCOO + H^+ \longrightarrow CO_{2(g)} + H_2O$$

A portion of the liberated CO2 gas diffuses through the silicone membrane and lowers the pH of the bicarbonate solution. The rate of pH change, measured by the glass pH electrode, is directly proportional to the carbon dioxide concentration in the solution.(2)

For more accurate measurement, the reference reagent containing carbon dioxide is introduced into the flow cell after the sample cycle. The same reaction scheme and gas diffusion process take place. The ratio of the rate of pH change between sample and reference reagent cycles is used for the calculation.

Specimen

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(3) Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the *Procedural Notes* section of this chemistry information sheet. Whole blood or urine are not recommended for use as a sample.

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers
Dialysate solutions should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube

Table 1 Quality Control Material

Control	Storage
MAS ChemTrak 1	+2^{O}C to +8^{O}C*
MAS ChemTrak 3	+2^{O}C to +8^{O}C*

*Controls are received frozen and stored at –15^{O}C to –25^{O}C. Bottles of controls in use are thawed and stored at +2^{O}C to +8^{O}C and are good for 14 days.

Testing Procedure

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 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.

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.(5)

Table 2 Reference Intervals

Intervals	Sample Type	Conventional Units	S.I Units
Literature	Serum or Plasma	23 - 29 mmol/L	23 - 29 mmol/L
SYNCHRON	Serum or Plasma	22 - 32 mmol/L	22 - 32 mmol/L
UCDMC	Serum or Plasma	24 - 32 mmol/L	24 - 32 mmol/L

Refer to References (6, 7, 8) for guidelines on establishing laboratory-specific reference intervals.

There are no published reference intervals for dialysate solutions. These are custom solutions for each patient and results from analysis are used to verify accuracy of dialysate solution preparations.

Critical Values

Carbon dioxides results **≤ 10 mmol/L** and **≥ 45 mmol/L** are considered critical values and should be called immediately to the attending physician or charge nurse.

Calcium (Ca) - Serum, Plasma, Urine, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3115

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			09/26/2006	G. Kost
			11/05/2007	G. Kost
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06/18/2012	Added dialysate solutions as a sample type	M. Inn	06/22/2012	G. Kost

Calcium (Ca) - Serum, Plasma, Urine, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3115

For *In Vitro* Diagnostic Use Only

Principle

Intended Use

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with UniCel® DxC 800 System(s) and SYNCHRON® Systems AQUA CAL 1, 2 and 3, are intended for the quantitative determination of calcium concentration in human serum, plasma, urine or dialysate solutions.

Clinical Significance

Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms). Urinary calcium measurement is used in the differential diagnosis of absorptive hypercalciuria and hypercalciuria caused by hyperparathyroidism, hyperthyroidism, Paget's disease or "renal leak" type of calciuria as seen in renal tubular acidosis.

Methodology

The SYNCHRON® System(s) determines total calcium concentration by indirect potentiometry utilizing a calcium ion selective electrode in conjunction with a sodium reference electrode.

In principle, a calcium ion selective electrode measures un-bound free calcium ions in solution. Total calcium can only be calculated from free calcium when the molar ratio between free and total calcium concentrations is constant. This constant molar ratio is achieved by the buffered solution which contains strong calcium complexing agents.

A precise volume of sample (40 microliters) is mixed with the buffered solution. The ratio used is one part sample to 33 parts buffered solution. The high molar strength buffer is used to establish a constant activity coefficient for calcium ions, calibrating the electrode to concentration values.(1,2)

Chemical Reaction Scheme

The calcium ion selective electrode consists of a calcium ionophore membrane cast on a solid support. When sample buffer mixture contacts the electrode, changes in electrode potential occur as calcium ions react with the ionophore. These changes in potential are referenced to the sodium reference electrode. The "referenced potential" follows the Nernst equation and allows the calculation of calcium concentration:

$$E = \text{Constant} + (\text{slope})\ (\log[Ca^{2+}])$$

For more accurate measurement, the reference reagent containing calcium ions is introduced into the flow cell following the sample cycle, and the same reaction scheme takes place. The differential potential (voltage) between sample and reference reagent cycles is used for the calculation.

Under ideal conditions, the electrode imparts a selectivity of 1000:1 over sodium and potassium and is insensitive to hydrogen ions in solution buffered from pH 4 to 10.

Specimen

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(3) 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.

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers
Spot urines should be aliquoted into a 13 x 75 clear cap red cork BD tube
24 hour urine chloride collections are usually received in 3000 mL plastic urine collection jugs
Dialysate solutions should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube

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.

Timed urine specimens are calculated from the following equation:

$$\text{Urine calcium X } \frac{\text{Total volume collected}}{\text{Total time of collection (hrs)}}$$

Calculations are only performed on 24 hour collections (±15 minutes) and reported as mmol/24 hrs

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.

Dialysate results are reported in meq/L and are converted in the LIS. The conversion factor from mg/dL to meq/L is 0.4990.

Reference Intervals

The following reference intervals 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	8.6 - 10.0 mg/dL		2.15 - 2.50 mmol/L
	Urine (timed)	100 - 300 mg/24 hrs		2.50 – 7.50 mmoL/24 hrs
SYNCHRON	Serum or Plasma	8.9 – 10.3 mg/dL		2.23 – 2.58 mmol/L
UCDMC	Serum or Plasma	< 1 yr	7.3 - 12.0 mg/dL	1.82 - 2.99 mmol/L
	Serum or Plasma	1 yr to 2 yr	8.0 - 12.0 mg/dL	2.00 - 2.99 mmoL/L
	Serum or Plasma	2 yr to 16 yr	8.8 - 10.6 mg/dL	2.20 - 2.64 mmol/L
	Serum or Plasma	16 yr to adult	8.6 - 10.5 mg/dL	2.15 - 2.62 mmol/L
	Urine (timed)	50 - 400 mg/24 hrs		1.25 - 9.98 mmol/L

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

Pediatric reference intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

There are no published reference intervals for dialysate solutions. These are custom solutions for each patient and results from analysis are used to verify accuracy of dialysate solution preparations.

Critical Values

Calcium results **≤ 6.0** mg/dL and **≥13.0** mg/dL are considered critical values and should be called immediately to the attending physician or charge nurse.

Magnesium (MG) - Serum, Plasma, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3144

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			10/25/2004	S. Devaraj
			11/28/2005	G. Kost
			09/26/2006	G. Kost
			11/05/2007	G. Kost
			06/16/2008	G. Kost
			09/15/2009	G. Kost
			10/12/2010	G. Kost
05/26/2011	update	M.Inn		
06/18/2012	Added dialysate solutions as a sample type	M. Inn	06/22/2012	G. Kost

Magnesium (MG) - Serum, Plasma, Dialysate Solutions
Beckman UniCel DxC Systems

Technical Procedure 3144

For *In Vitro* Diagnostic Use Only

Principle

Intended Use

MG reagent, when used in conjunction with UniCel® DxC System(s) and SYNCHRON® Systems Multi Calibrator, is intended for quantitative determination of magnesium concentration in human serum, plasma or dialysate solutions.

Clinical Significance

Determination of magnesium is useful in assessing several diseases and conditions. High magnesium is associated with uremia, dehydration, diabetic acidosis, Addison's disease, and increased medicinal intake of magnesium, such as in the treatment of preeclampsia (hypertension induced by pregnancy). Low magnesium is associated with malabsorption syndrome, acute pancreatitis, hypoparathyroidism, chronic alcoholism and delirium tremens, chronic glomerulonephritis, aldosteronism, digitalis intoxication, and protracted I. V. feeding.

Methodology

MG reagent is used to measure the MG concentration by a timed endpoint method.(1,2) In the reaction, MG combines with calmagite to form a stable chromogen. The product is formed rapidly giving reproducible results with a minimum of interferences.

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 103 parts reagent for serum or plasma and one part diluted sample to 103 parts reagent for urine. The system monitors the change in absorbance at 520 nm (nanometers). This change in absorbance is directly proportional to the concentration of magnesium in the sample and is used by the System to calculate and express the magnesium concentration.

Chemical Reaction Scheme

$$\text{Calmagite} + Mg^{++} \longrightarrow Mg^{++} \text{ - Calmagite Complex}$$

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(3) Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in *Procedural Notes* section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers
Dialysate solutions should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube

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.(4)
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.(4)

Traceability

The measurand (MG) in this calibrator is traceable to each reference material for each analyte. The traceability process is based on prEN ISO 17511. The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the UniCel DxC reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Quality Control

At least two levels of control material should be analyzed each shift. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the UniCel DxC 800 System *Instructions For Use* manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on workload and workflow or laboratory accreditation requirements and applicable laws.

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 the Beckman UniCel DxC *Chemistry Information Manual*. 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.

Table 1 Quality Control Material

Control	Storage
MAS ChemTrak 1	+2^{O}C to +8^{O}C*
MAS ChemTrak 3	+2^{O}C to +8^{O}C*

*Controls are received frozen and stored at –15^{O}C to –25^{O}C. Bottles of controls in use are thawed and stored at +2^{O}C to +8^{O}C and are good for 14 days.

Testing Procedure

1. If necessary, load reagent onto the system.
2. After reagent load is completed, calibration is required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operation.

For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calculations

UniCel DxC Systems perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

If the dilution was programmed in Remisol, the final calculated result from a dilution will not be calculated by the UniCel DxC system but by Remisol.

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.

Dialysate results are reported in meq/L and are converted in the LIS. The conversion factor from mg/dL to meq/L is 0.8229.

Reference Intervals

The following reference intervals were taken from literature and a study performed on SYNCHRON Systems.(8)

Table 3 Reference Intervals

Intervals	Sample Type	Conventional Units	S.I Units
Literature	Serum or Plasma	1.6 - 2.6 mg/dL	0.66 - 1.07 mmol/L
SYNCHRON	Serum or Plasma	1.8 - 2.5 mg/dL	0.74 - 1.03 mmol/L
UCDMC	Serum or Plasma	1.5 - 2.6 mg/dL	0.62 - 1.06 mmol/L

Refer to References (9,10,11) for guidelines on establishing laboratory-specific reference intervals.

There are no published reference intervals for dialysate solutions. These are custom solutions for each patient and results from analysis are used to verify accuracy of dialysate solution preparations.

Critical Values

A magnesium result **≥ 8.0 mg/dL** is considered a critical value and should be called immediately to the attending physician or charge nurse.

Procedural Notes

Anticoagulant Test Results

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 3.0 Compatible Anticoagulants[a]

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

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

[b] NSI = No Significant Interference (within ±0.16 mg/dL or 4%).

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

Table 4.0 Incompatible Anticoagulants[a]

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (mg/dL)[b]
EDTA	1.5 mg/mL	-2.4
Potassium Oxalate/ Sodium Fluoride	2.0 / 2.5 mg/mL	-1.0

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

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

Phosphorus (PHOSm) - Serum, Plasma, Urine, Dialysate Solutions Technical Procedure 3150
Beckman SYNCHRON UniCel DxC Systems

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

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
			11/27/2000	G. Kost
			12/28/2001	G. Kost
			10/16/2002	G. Kost
			10/10/2003	S. Devaraj
			10/25/2004	S. Devaraj
			11/28/2005	G. Kost
			09/26/2006	G. Kost
			11/05/2007	G. Kost
03/11/2008	Revised dilution procedure	M.Inn		
05/26/2008	Amphotericin B Therapy	M.Inn		
			06/16/2008	G. Kost
01/08/2009	General update	M.Inn		
			09/15/2009	G. Kost
			10/12/2010	G. Kost
12/2010	update	M. Inn		
06/18/2012	Added dialysate solutions as a sample type	M. Inn	06/22/2012	G. Kost

Phosphorus (PHOSm) - Serum, Plasma, Urine, Dialysate Solutions — Technical Procedure 3150
Beckman SYNCHRON UniCel DxC Systems

For In Vitro Diagnostic Use Only

Principle

Intended Use

PHOSm reagent, in conjunction with 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, urine or dialysate solutions.

Clinical Significance

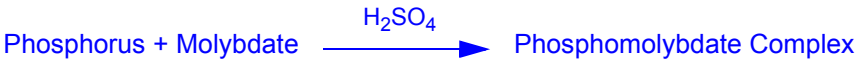
Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

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



Specimen

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.(3) Freshly drawn serum, plasma or properly collected urine (random/timed) are the preferred specimens. Acceptable anticoagulants are listed in *Procedural Notes* section of this chemistry information sheet. **Whole blood is not recommended for use as a sample**.

Acceptable Sample Containers

13 x 75 PST, SST and Red Top BD tubes
PST, SST and Red Top BD microtainers
Spot urines should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube
24 hour urine chloride collections are usually received in 3000 ml plastic urine collection jugs
Dialysate solutions should be aliquoted into a 13 x 75 Clear Cap Red Cork BD tube

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.(4)
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.

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 LX20 or UniCel DxC system but by Remisol.

Timed urine specimens are calculated from the following equation:

$$\text{urine phosphorus} \times \frac{\text{Total volume collected}}{\text{Total time of collection (hrs)}}$$

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

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.
The referenceintervals listed below were taken from literature and a study performed on SYNCHRON Systems.(6)

Table 2 Reference Intervals

Interval	Sample Type	Conventional Units			S.I. Units
Literature	Serum or Plasma	2.7 - 4.5 mg/dL			0.87 - 1.46 mmol/L
	Urine (timed)	400 - 1300 mg/24hrs			12.9 - 42.0 mmol/24hrs
SYNCHRON	Serum or Plasma	2.4 - 4.7 mg/dL			0.78 - 1.53 mmol/L
UCDMC	Serum or Plasma	Premature	At birth	5.6 - 8.0 mg/dL	1.81 - 2.58 mmol/L
	Serum or Plasma		6 - 10 d	6.1 - 11.7 mg/dL	1.97 - 3.78 mmol/L
	Serum or Plasma		20 - 25 d	6.6 - 9.4 mg/dL	2.13 - 3.04 mmol/L
	Serum or Plasma	Mature	< 3 d	5.0 - 7.8 mg/dL	1.61 - 2.52 mmol/L
	Serum or Plasma		3 - 6 d	5.8 - 9.0 mg/dL	1.87 - 2.91 mmol/L
	Serum or Plasma		6 days - 4 m	5.0 - 9.0 mg/dL	1.61 - 2.91 mmol/L
	Serum or Plasma		4 m - 1 yr	4.8 - 8.1 mg/dL	1.55 - 2.62 mmol/L
	Serum or Plasma		1 - 5 yrs	3.6 - 6.8 mg/dL	1.16 - 2.20 mmol/L
	Serum or Plasma		5 - 10 yrs	3.4 - 5.9 mg/dL	1.10 - 1.91 mmol/L
	Serum or Plasma		> 10 yrs	2.4 - 5.0 mg/dl	0.77 - 1.61 mmolL
	Urine (timed)	400 - 1300 mg/24hrs			12.9 - 42.0 mmol/24hrs

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

UCDMC Pediatric Reference Intervals are cited from literature. No in-house studies were performed. This information should serve as a general guideline.

There are no published reference intervals for dialysate solutions. These are custom solutions for each patient and results from analysis are used to verify accuracy of dialysate solution preparations.