DXC (CA) CALCIUM

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PURPOSE

To provide instructions for the quantitative determination of calcium on the DXC 600/800.

PRINCIPLE

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 2, are intended for the quantitative determination of Calcium concentration in human serum, plasma or urine.

BACKGROUND

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.

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

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
J-F-CH0826	DXC 800 Calibrators
J-F-CH1940	DXC 800 Analytical Measurement Range

M-F-CH0820 Chemistry Controls

M-F-CH0826 Chemistry Calibrators
M-F-CH1940 DXC 600 Analytical Measurement Range

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 specimens of choice. 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 timed period. Urine should be acidified with 10 mL of 6N HCl added to the container before collection begins.

Sample Type	Volume	Sample Stability
Serum/Plasma	0.5mL	• Separate serum from cells within 2 hours. • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months.
Urine		• Urine: Analyze within 2 hours or keep on ice; no preservative required • Timed Urine: Add 25 mL of 6N HCl to container before collection

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

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.

REAGENTS

Contents

Each kit contains the following items:
ISE ELECTROLYTE BUFFER REAGENT:
Two Electrolyte Buffer Reagent Bottles (2 x 2 L) Kit reorder #A28945

ISE ELECTROLYTE REFERENCE REAGENT:
Two Electrolyte Reference Reagent Bottles (2 x 2 L) Kit reorder # A28937

Volume per Test	
Sample Volume	40 uL
Reagent Volume	
ISE Electrolyte Buffer	1.27mL
ISE Electrolyte Reference	3.23 mL

(not part of sample dilution)

Reactive Ingredients	
ISE ELECTROLYTE BUFFER REAGENT:	
Tris	230 mmol/L
ISE ELECTROLYTE REFERENCE REAGENT:	
Sodium	7 mmol/L
Potassium	0.2 mmol/L
Chloride	5 mmol/L
Carbon Dioxide	1.5 mmol/L
Calcium	0.1 mmol/L

Also non-reactive chemicals necessary for optimal system performance. Avoid skin contact with reagent. Use water to wash reagent from skin.

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

1. ISE Electrolyte Reference reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days. Do not use beyond the manufacturer's expiration date.

2. ISE Electrolyte Buffer reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days. Do not use beyond the manufacturer's expiration date.

3. For any electrolyte reagents frozen in transit, completely warm to room temperature and mix thoroughly by gently inverting bottle at least 20 times to redissolve salts into solution.

CALIBRATION

Calibrator Required

SYNCHRON® Systems AQUA CAL 1 and 2

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

1. 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 CALC assay must be calibrated every 24 hours or with each new bottle of reagent and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions for Use* (IFU) manual.

3. For detailed calibration instructions, refer to 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 UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls and M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration is required.

3. Program quality control for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to 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.

ANTICOAGULANT TEST RESULTS

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:

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Ammonium Heparin	14 Units/mL	No Significant Interference (within ±0.4 g/dL or 4%)
Lithium Heparin	14 Units/mL	No Significant Interference (within ±0.4 g/dL or 4%)
Sodium Heparin	14 Units/mL	No Significant Interference (within ±0.4 g/dL or 4%)

PERFORMANCE CHARACTERISTICS

Reference Ranges

Sample Type	Range	Critical Low	Critical High
Serum / plasma	8.5-10.2 mg/dL	<6.5 mg/dL	>12.0 mg/dL
Urine 24 hours	100-300 mg/24 hrs	N/A	N/A
Urine random	N/A	N/A	N/A

For Critical Value reporting protocol, refer to the FHS Critical Value Policy

Analytic Range

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

Sample Type	Conventional Units
Serum or Plasma	2.0 – 20.0 mg/dL
Urine	2.0 – 30.0 mg/dL

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

Reporting results outside of analytical range

Lower limit of detection: serum / plasma	2 mg/dL	Results below 2, are reported as <2mg/dL
Upper limit of range: serum / plasma	20.0 mg/dL	Results >20 should be diluted with Nerl H20, reanalyzed and dilution factor applied. The maximum allowable dilution is x2. Results >40 are reported as >40 mg/dL.
Lower limit of detection: urine	2 mg/dL	Results below 2, are reported as <2mg/dL
Upper limit of range: urine	30.0 mg/dL	Results >30 should be diluted with Nerl H20, reanalyzed and dilution factor applied. The maximum allowable dilution is x5. Results >150 are reported as >150 mg/dL

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for CALC determination is 2.0 mg/dL (0.5 mmol/L).

LIMITATIONS

1. If urine samples are cloudy or turbid, it is recommended that they be centrifuged before transfer to a sample cup.

2. For each serum calcium measurement, the sodium concentration is used in the calculation. If sodium is not calibrated or the result is suppressed, a nominal value for sodium is used.

3. For each urine calcium measurement, the sodium and potassium concentrations are used in the calculation of the calcium concentration. If the sodium or potassium chemistries are not calibrated or the sodium or potassium results are suppressed, the calcium value will be suppressed when a urine sample is analyzed.

4. Recovery of aqueous calibrators or linearity standards, may exhibit a recovery bias since the calcium algorithms have been optimized to compute recovery of patient samples.

5. Urine Proficiency Survey samples should not be acidified.

Interferences

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

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX of 20	NSI
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	NSI
Lipemia	Intralipid[d]	320 mg/dL INDEX of 8 Airfuge recommended	NSI
Aluminum	Aluminum Nitrate	20 mg/dL	-0.2 mg/dL
Bromide	Lithium bromide	1 mmol/L	+1.5 mg/dL
Methicillin	NA[e]	10,000 µg/mL	-0.2 mg/dL
Methylbenzethonium	NA	0.2 mg/dL	-0.2 mg/dL

2. Serum or plasma from patients receiving EDTA therapy may yield depressed calcium values.

3. Flint glass containers contain calcium and should not be used to store samples.

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

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

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