DXC (NA) SODIUM

☒ St. Joseph Medical Center Tacoma, WA ☒ St. Clare Hospital Lakewood, WA ☐ St. Elizabeth Hospital Enumclaw, WA
☒ St. Francis Hospital Federal Way, WA ☒ St. Anthony Hospital Gig Harbor, WA ☐ Highline Medical Center, Burien, WA ☐ PSC

PURPOSE

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

PRINCIPLE

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1, 2 and 3, are intended for the quantitative determination of sodium concentration in human serum, plasma or urine.

BACKGROUND

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.

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

E015247L.EPS

RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC 800 Analytical Measurement Range
M-F-CH-0820	DXC 600 Controls
M-F-CH-0826	DXC 600 Calibrators
M-F-CH-1940	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 preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

3. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period. No preservative is required.

Sample Type	Volume	Sample Stability
Plasma/Serum	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.

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: (Ref#A28945)
- Two Electrolyte Buffer Reagent Bottles (2 x 2 L)
- ISE ELECTROLYTE REFERENCE REAGENT: (Ref# A28937)
- Two Electrolyte Reference Reagent Bottles (2 x 2 L)

Volume per Test	
Sample Volume	40 µL
Reagent Volume • ISE Electrolyte Buffer • ISE Electrolyte Reference (not part of sample dilution)	 1.27 mL 3.23 mL

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 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, unless the expiration date is exceeded.

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, unless the expiration date is exceeded.

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, 2 and 3

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

1. If unopened, the 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 NA 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 & M-F-CH0820 Chemistry Controls

STEPS

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

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

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operations. For detailed testing procedures, refer to 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.

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%)

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

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mmol/L)
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	+3.5

PERFORMANCE CHARACTERISTICS

Reference Range

Sample type	Range	Critical Low	Critical High
Serum / plasma	135 – 145 mmol/L	< 120 mmol/L	> 155 mmol/L
Urine, timed	27 – 287 mmol/24hr	N/A	N/A
Urine, random	N/A	N/A	N/A

For Critical Value reporting protocol, refer to FHS Critical Policy

Analytic Range

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

Sample Type	Conventional Units
Serum or Plasma	100 – 200 mmol/L
Urine	10 – 300 mmol/L

Reporting results outside of analytical range

Lower limit of detection: serum / plasma	100 mmol/L	Result below 100; Report as <100 mmol/L
Upper limit of detection: serum / plasma	200 mmol/L	**DO NOT DILUTE; Report as >200 mmol/L**
Lower limit of detection: urine	10 mmol/L	Result below 10; Report as <10 mmol/L
Upper limit of detection: urine	300 mmol/L	Results >300 should be diluted with deionized (Nerl) H_2O, reanalyzed and dilution factor applied. The maximum allowable dilution is X5. Results >1500 are reported as >1500 mmol/L.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for NA determination is 100 mmol/L for serum or plasma, and 10 mmol/L for urine.

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 sodium measurement, the potassium concentration is used in the calculation of the sodium concentration. If the potassium chemistry is not calibrated, or the potassium value is out of range for the sample type, the sodium value will be suppressed for urine samples. Serum samples will use a nominal value for potassium.

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	No Significant Interference (within ±2.0 mmol/L or 2%)
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	No Significant Interference (within ±2.0 mmol/L or 2%)
Lipemia	Intralipid[e]	320 mg/dL INDEX of 8 Airfuge Recommended	No Significant Interference (within ±2.0 mmol/L or 2%).
Lithium	Lithium Acetoacetic Acid	20 mmol/L	+5 mmol/L
Benzalkonium chloride	NA	0.5 mg/dL	-2 mmol/L
Methylbenzethonium Chloride	NA	0.2 mg/dL	-2 mmol/L

2. Lipemic samples with a Lipemia Serum Index >10, should be ultracentrifuged and the analysis performed on the infranate.
3. Refer to References (8,9,10) 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

1. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 5th Edition, W. B. Saunders, Philadelphia, PA (2005).
2. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens* Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
3. National Committee for Clinical Laboratory Standards, *Routine Urinalysis and Collection, Transportation and Preservation of Urine Specimens* Tentative Guideline, NCCLS publication GP16-T, Villanova, PA (1992).
4. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders Company, Philadelphia, PA (1995).
5. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 6th Edition, W. B. Saunders, Philadelphia, PA (2007).
6. National Committee for Clinical Laboratory Standards, *How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory* Approved Guideline, NCCLS publication C28-A, Villanova, PA (1995).
7. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 22nd Edition, W. B. Saunders Company, Philadelphia, PA (2006).

8. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 5th Edition, AACC Press, Washington, D. C. (2000).
9. Friedman, R. B., Young, D. S.,*Effects of Disease on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D.C. (2001).
10. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D. C. (2007).
11. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples* Approved Guideline, NCCLS publication EP9-A, Villanova, PA (1995).
12. National Committee for Clinical Laboratory Standards, *Evaluation of Precision Performance of Clinical Chemistry Devices*, Approved Guideline, Vol. 19, No. 2, NCCLS publication EP5-A, Villanova, PA (1999).

DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Updated formatting, added maximum dilution, updated related documents, added Index info, removed sodium heparin			
Committee Approval Date	☒ Date: 8/13/15 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 8/25/15