DXC (K) POTASSIUM

☒ 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 ☐ PSC

PURPOSE

To provide instruction for the quantitative determination of potassium 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 potassium concentration in human serum, plasma or urine.

BACKGROUND

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 (over administration 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.

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

E015237L.EPS

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
M-F-CH0820	Chemistry Controls
J-F-CH0826	DXC 800 Calibrators
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH1940	DXC 800 (AMR) 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) is the preferred specimen. 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 Urine	0.5mL	• Separate serum from cells within 2 hours • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months • 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:
Two Electrolyte Buffer Reagent Bottles (2 x 2 L)
ISE ELECTROLYTE REFERENCE REAGENT:
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. 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, 2 and 3

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems AQUA CAL 1 and 2 are stable until the expiration date printed on the calibrator bottles if stored capped in the original containers at +2°C to +8°C. Once opened, calibrators are stable for 30 days stored at room temperature. Do not use beyond the manufacturer's expiration date.

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 K 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. 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

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
Ammonium Heparin	14 Units/mL	No Significant Interference (within ±0.2 mmol/L or 4%)
Lithium Heparin	14 Units/mL	No Significant Interference (within ±0.2 mmol/L or 4%)
Sodium Heparin	14 Units/mL	No Significant Interference (within ±0.2 mmol/L 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)[b]
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	-0.61

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Age	Reference Range	Critical Low	Critical High
Serum / Plasma	0 – 1 month	3.9 – 6.9 mmol/L	< 3.0 mmol/L	>7.5 mmol/L
Serum / Plasma	1 month – 12 months	3.6 – 6.8 mmol/L		>6.8 mmol/L
Serum / Plasma	12 months – 5 years	3.2 – 5.7 mmol/L		>5.8 mmol/L
Serum / Plasma	5 years – 9 years	3.4 – 5.4 mmol/L		>5.8 mmol/L
Serum / Plasma	>9 years	3.5 – 5.0 mmol/L		>6.0 mmol/L
Urine, Timed	N/A	25 – 125 mmol/24hr	N/A	N/A
Urine, Random	N/A	N/A	N/A	N/A

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	1.0 – 15.0 mmol/L
Urine	2 – 300 mmol/L

Reporting results outside of analytical range

Lower limit of detection: serum / plasma	1.0 mmol/L	Results below 1.0; Report as <1.0 mmol/L
Upper limit of detection: serum / plasma	15.0 mmol/L	**DO NOT DILUTE.** Results >15.0 should be reported as >15.0 mmol/L
Lower limit of detection: urine	2.0 mmol/L	Results below 2.0; Report as <2.0 mmol/L
Upper limit of detection: urine	300 mmol/L	Results >300 should be diluted with deionized (Nerl) H_2O and reanalyzed with dilution factor applied. The maximum allowable dilution is X2. Results >600 should be reported as >600 mmol/L.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for K determination is 1.0 mmol/L for serum or plasma, and 2.0 mmol/L for urine.

LIMITATIONS

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

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[e]
Hemoglobin	RBC hemolysate	50 mg/dL INDEX of 2	+0.2 mmol/L
Lipemia	Intralipid[f]	500 mg/dL INDEX of 10	NSI
Ammonium Nitrate	NA[g]	5 mmol/L	+0.16 mmol/L
Benzalkonium chloride	NA	1 mg/dL	-0.15 mmol/L
Cesium Chloride	NA	0.5 mg/dL	+0.15 mmol/L

2. Benzalkonium heparin demonstrates a positive interference with the potassium assay.

3. Lipemic samples with a Lipemia Serum Index >10, should be ultracentrifuged and the analysis performed on the infranate.

ADDITIONAL INFORMATION

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

REFERENCES

1. Janz, G. J., Taniguchi, H., "The Silver-Silver-Halide Electrodes", *Clinical Reviews* , Vol. 52, 53:397-437 (1953).
2. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1986).
3. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens*, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
4. 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).
5. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1987).
6. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
7. 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).
8. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 18th Edition, W. B. Saunders Company, Philadelphia, PA (1991).
9. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 4th Edition, AACC Press, Washington, D. C. (1995).
10. Friedman, R. B., Young, D. S.,*Effects of Disease on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D.C. (1997).
11. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D. C. (1997).

12. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Approved Guideline, NCCLS publication EP9-A, Villanova, PA (1995).
13. 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 allowable dilution, added Index to interfering substances, updated reference range age ranges to match LIS (5-9 yrs and >9 yrs changed from 5-10 yrs and >10 yrs).			
Committee Approval Date	☒ Date: 7/2/15 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 7/30/15