DXC (CL) CHLORIDE

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PURPOSE

To provide instructions for the quantitative determination of chloride 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 and 2, are intended for the quantitative determination of chloride concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

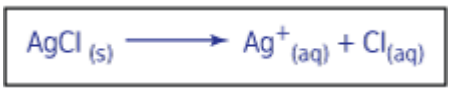
BACKGROUND

Clinical Significance

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Methodology

The SYNCHRON® System(s) determines chloride ion concentration by indirect potentiometry utilizing a solid state chloride electrode in conjunction with a glass sodium reference electrode.
To measure chloride ion 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 of chloride ions, calibrating the electrode to concentration values.



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, CSF or properly collected urine (random/timed) is 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.

4. CSF specimens should be centrifuged and analyzed without delay. Specimens may be refrigerated or frozen for 7 to 10 days for repeat determinations.

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/CSF		Urine: Analyze within 2 hours or keep on ice; no preservative required CSF – Analyze immediately CSF- 7 – 10 days at -20- +8°C.

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 uL
Reagent Volume ISE Electrolyte Buffer ISE Electrolyte Reference	 1.27mL 3.23 mL

Reactive Ingredients	
ISE ELECTROLYTE BUFFER REAGENT: Tris	 230 mmol/L
ISE ELECTROLYTE REFERENCE REAGENT: Sodium Potassium Chloride Carbon Dioxide Calcium	 7 mmol/L 0.2 mmol/L 5 mmol/L 1.5 mmol/L 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 CL 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-CH-0820 DXC 800 Controls and M-F-CH-0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.

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 operations..To load samples manually refer to the FHS 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 (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%)
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/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)[b]
EDTA	1.5 mg/mL	-5.3

PERFORMANCE CHARACTERISTICS

Reference Range

Serum/Plasma	CSF	Urine
99 – 109 mmol/L	119 – 132 mmol/L	110 – 250 mmol/24hr Random 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/Plasma/CSF	50 – 200 mmol/L
Urine	15 – 300 mmol/L

Do not dilute serum, plasma, or CSF samples. Urine 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 / CSF	50 mmol/L	Results below 50; Report as <50 mmol/L
Upper limit of range: Serum / plasma / CSF	200 mmol/L	**DO NOT DILUTE.** Results >200 mmol/L are reported as >200 mmol/L.
Lower limit of detection: Urine	15 mmol/L	Results below 15; Report as <15 mmol/l
Upper limit of range: Urine	300 mmol/L	Results >300 mmol/L should be diluted, starting at X2, using Nerl H20 and reanalyzed. 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 to 95% confidence. Sensitivity for the chloride determination is 50 mmol/L for serum, plasma or CSF and 15 mmol/L for urine.

LIMITATIONS

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 analysis.

Interferences

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

Substance	Source	Level Tested	Interferences
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX of 20	NSI
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	NSI
Lipemia	Intralipid	320 mg/dL INDEX of 8 Airfuge recommended	NSI
Acetylsalicylic Acid	NA	60 mg/dL	NSI
Ammonium Nitrate	NA	40 mmol/L	NSI
Cefotaxime	Cefotaxime sodium salt	500 µg/mL	NSI
Cefoxitin	Cefoxitin sodium salt	200 µg/mL	NSI
Sulfobromophthalein	Sulfobromophthalein sodium salt	2.0 mg/dL	NSI
N-Acetyl Cysteine	NA	2 mmol/L	+3 mmol/L
Bromide	Lithium bromide	1 mmol/L	+8 mmol/L
Iodide	Sodium Iodide	4 mmol/L	+2 mmol/L
L-Dopa	NA	40 µg/mL	-3 mmol/L

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

3. Refer to References (9,10,11) 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.

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