ICT- SODIUM, POTASSIUM, & CHLORIDE

Intended Use

The Alinity c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

Clinical Significance

Sodium is the major cation of extracellular fluid; it plays an essential role in the normal distribution of water and in the maintenance of osmotic pressure in extracellular fluid compartments. Decreased levels of sodium may be caused by an excessive use of diuretics, prolonged vomiting, a decrease in the intake of sodium in the diet, and metabolic acidosis. Increased levels of sodium may be found in Cushing's syndrome, severe dehydration, or in high levels of salt intake without an adequate supply of water.
Potassium is the major intracellular cation. The concentration of potassium in the erythrocytes is approximately 23 times the concentration in plasma. For this reason, only unhemolyzed samples must be used. Decreased levels of extracellular potassium are characterized by weakness in the muscles, irritability, paralysis, accelerated heartbeat, and eventually cardiac arrest, and may be caused by a poor intake of potassium in the diet, by a redistribution of extracellular potassium, and by an increased loss of body fluids rich in potassium. Abnormally elevated levels of extracellular potassium produce mental confusion, general weakness, numbness, flaccid paralysis in the extremities, a slowed heart rate, and eventually collapse of the peripheral vascular system and cardiac arrest. Causes of increased potassium levels may be linked to inappropriate intravenous therapy, dehydration, shock, diabetic ketoacidosis, and severe burns.
Chloride is the major extracellular anion. Low levels of chloride are observed in the case of prolonged vomiting accompanied by the loss of hydrochloric acid (HCl), in metabolic alkalosis, in critical cases of Addison's disease, and in kidney disease resulting in loss of salt. Elevated levels of chloride are observed in metabolic acidosis associated with prolonged diarrhea and with loss of sodium bicarbonate (NaHCO3), and in the case of renal tubular diseases in which there is a decreased excretion of hydrogen ion (H+), which causes in turn a decrease in the reabsorption of bicarbonate ion (HCO3-).

Continued on next page

ICT- SODIUM, POTASSIUM, & CHLORIDE, *Continued*

Methodology

Ion-selective electrodes (ISE) for sodium, potassium, and chloride utilize membranes selective to each of these ions. An electrical potential (voltage) is developed across the membranes between the reference and measuring electrodes in accordance with the Nernst equation. The voltage is compared to previously determined calibrator voltages and converted into ion concentration. Methodology: Ion-selective electrode diluted (Indirect)

Specimen

Type of Specimen

Specimen Type	Collection Vessel
- Serum	Serum Tubes (with or without gel barrier)
- Plasma	Collection tubes Acceptable anticoagulants are: Lithium Heparin(with or without gel barrier) Sodium Heparin

Special Conditions: For Potassium, hemolyzed specimens must not be used.

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. For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation. For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets. Specimens should be free of bubbles.
3. To ensure consistency in results, recentrifuge specimens prior to testing if they contain fibrin, red blood cells, or other particulate matter. NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Continued on next page

ICT- SODIUM, POTASSIUM, & CHLORIDE, *Continued*

Maximum Storage Time			
Specimen Type: Serum/ Plasma			
Temperature	**Sodium**	**Potassium**	**Chloride**
20 to 25°C	2 weeks	1 week	7 days
2 to 8°C	2 weeks	1 week	7 days
-20°C	1 year	1 year	>1 year

Reagents

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results

Reagent Storage and Stability

	Storage Temperature	**Maximum Storage Time**	**Additional Storage Instructions**
Unopened	15 to 30°C	Until expiration date	Store in upright position
Onboard	System Temperature	28 days	

ICT- SODIUM, POTASSIUM, & CHLORIDE, *Continued*

Opened	15 to 30°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. Acetic acid odor from the diluent is normal.

Calibration

Calibration Required

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.
Calibration is stable for approximately 1 day (24 hours), but is required with each change in diluent lot. The laboratory may choose any calibration interval up to 24 hours. The use of a particular calibration time interval is dependent on individual laboratory policy or preference. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.
This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Calibration Preparation

Calibration material is the Alinity c ICT Serum Calibrator Kit. Ready to use. Prior to each use, mix by gentle inversion.

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ICT- SODIUM, POTASSIUM, & CHLORIDE, *Continued*

Calibration Storage and Stability

	Calibrator Storage	Stability Once OPEN
ICT Serum Cal (Serum L and Serum H)	Unopened: 15 to 30 (until expiration date) Protect from light.	**2 to 8 °C: 7 days**

Calibration Information

1. Verify that the correct calibrator values have been entered into the calibration file.
2. Calibration is performed by running Alinity c ICT Calibrator Kit.
3. For information on configuring calibrator data, refer to the Alinity ci-series Operations Manual, Section 2.

Quality Control

See Policy Chemistry Quality Control Policy

Sample Processing

See Policy RIV-PPP-1199

Reference Range

Test unit= mEq/L for all ages and both sexes.

Test	Age Day Low	Age Day High	Age Year Low	Age Year High	Ref Low	Ref High
Sodium	0	31			136	145
Sodium	31			250	136	145
Potassium	0	31			3.4	5
Potassium	31			19	3.4	5
Potassium			19	250	3.4	5
Chloride			0	250	98	113
Anion Gap			0	250	6	14

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ICT- SODIUM, POTASSIUM, & CHLORIDE, *Continued*

Analytic Range

Test	AMR Low	AMR High	CRR Low	CRR High
Sodium	100	200	100	200
Potassium	1	10	1	10
Chloride	50	150	50	150

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