i-STAT CHEM8+ Cartridge

Intended for use with the i-STAT 1 Analyzer (REF 04P75-01 & 03P75-06)

NAME

i-STAT CHEM8+ Cartridge – REF 09P31-25

INTENDED USE

The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide in arterial or venous whole blood.

Analyte	Intended Use
Sodium (Na)	Sodium measurements are used for monitoring electrolyte imbalances.
Potassium (K)	Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.
Chloride (Cl)	Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.
Ionized Calcium (iCa)	Ionized calcium measurements are used in the diagnosis, monitoring, and treatment of conditions including, but not limited to, parathyroid disease, a variety of bone diseases, chronic renal disease, tetany, and disturbances related to surgical and intensive care.
Glucose (Glu)	Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
Blood Urea Nitrogen (BUN/Urea)	Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases.
Creatinine (Crea)	Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Hematocrit (Hct)	Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status including, but not limited to, conditions such as anemia, erythrocytosis, and blood loss related to trauma and surgery.
Total Carbon Dioxide (TCO_2)	Carbon dioxide is used in the diagnosis, monitoring, and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

SUMMARY AND EXPLANATION/CLINICAL SIGNIFICANCE

Measured:

Sodium (Na)

Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

Potassium (K)

Tests for potassium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for potassium include renal glomerular disease, adrenocortical insufficiency, diabetic ketoacidosis (DKA), sepsis and in vitro hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

Chloride (Cl)

Tests for chloride in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for chloride include prolonged diarrhea, renal tubular disease, hyperparathyroidism and dehydration. Some causes for decreased values for chloride include prolonged vomiting, burns, salt-losing renal disease, overhydration and thiazide therapy.

Ionized Calcium (iCa)

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Glucose (Glu)

Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g., Cushing’s syndrome), drugs (e.g., steroids, thyrotoxicosis), chronic renal failure, stress, or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

Blood Urea Nitrogen (BUN/Urea)

An abnormally high level of urea nitrogen in the blood is an indication of kidney function impairment or failure. Some other causes of increased values for urea nitrogen include prerenal azotemia (e.g., shock), postrenal azotemia, GI bleeding and a high protein diet. Some causes of decreased values for urea nitrogen include pregnancy, severe liver insufficiency, overhydration and malnutrition.

Creatinine (Crea)

Elevated levels of creatinine are mainly associated with abnormal renal function and occur whenever there is a significant reduction in glomerular filtration rate or when urine elimination is obstructed. The concentration of creatinine is a better indicator of renal function than urea or uric acid because it is not affected by diet, exercise, or hormones.

The creatinine level has been used in combination with BUN to differentiate between prerenal and renal causes of an elevated urea/BUN.

Hematocrit (Hct)

Hematocrit is a measurement of the fractional volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. A decreased hematocrit can be due to either overhydration, which increases the plasma volume, or a decrease in the number of red blood cells caused by anemias or blood loss. An increased hematocrit can be due to loss of fluids, such as in dehydration, diuretic therapy, and burns, or an increase in red blood cells, such as in cardiovascular and renal disorders, polycythemia vera, and impaired ventilation.

Total Carbon Dioxide (TCO_2)

TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, bicarbonate (HCO_3) or carbonate (CO_3) anions, and carbonic acid (H_2CO_3). Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and ***P***CO_2) and electrolyte imbalance.

TEST PRINCIPLE

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods. [1]

Measured:

Sodium (Na), Potassium (K), Chloride (Cl) and ionized Calcium (iCa)

The respective analyte is measured by ion-selective electrode potentiometry. In the calculation of results, concentration is related to potential through the Nernst equation.

Glucose (Glu)

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2). The liberated H_2O_2 is oxidized at the electrode to produce a current proportional to the sample glucose concentration.

$$\beta\text{-D-glucose} + H_2O + O_2 \xrightarrow{\textit{glucose oxidase}} \text{D-gluconic acid} + H_2O_2$$

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^-$$

BUN/Urea

Urea is hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease.

$$\text{Urea} + H_2O + 2H^+ \xrightarrow{\text{urease}} 2NH_4^+ + CO_2$$

The ammonium ions are measured potentiometrically by an ion-selective electrode. In the calculation of results, concentration is related to potential through the Nernst Equation.

Creatinine (Crea)

Creatinine is measured amperometrically. It is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine by creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

Hematocrit (Hct)

Hematocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

Total Carbon Dioxide (TCO_2)

The measured TCO_2 test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO_2 reference method [2] with an algorithm based on the Henderson-Hasselbalch equation, which uses pH, ***P***CO_2, and ionic strength (Na) measurements.

Calculated:

Anion Gap (AnGap)

Anion Gap is calculated in the CHEM8+ cartridge as follows:

$$\text{Anion Gap (CHEM8+)} = (Na + K) - (Cl + (TCO_2 - 1))$$

For reporting the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate the size of the anion gap reflects the unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist, but, while relatively nonspecific, anion gap as calculated is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure and in classifying metabolic acidosis into high and normal anion gap types.

Hemoglobin (Hb)

The i-STAT System provides a calculated hemoglobin result which is determined as follows:

hemoglobin (g/dL) = hematocrit (% PCV) x 0.34

hemoglobin (g/dL) = hematocrit (decimal fraction) x 34

To convert a hemoglobin result from g/dL to mmol/L, multiply the displayed result by 0.621. The calculation of hemoglobin from hematocrit assumes a normal MCHC.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels in vivo. [3] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

REAGENTS

Contents

Each i-STAT cartridge contains one reference electrode sensor, sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. A list of reactive ingredients for the CHEM8+ cartridge is shown below:

Sensor	Reactive Ingredient	Biological Source	Minimum Quantity
Na	Sodium (Na^+)	N/A	121 mmol/L
K	Potassium (K^+)	N/A	3.6 mmol/L
Cl	Chloride (Cl^-)	N/A	91 mmol/L
iCa	Calcium (Ca^{2+})	N/A	0.9 mmol/L
Glu	Glucose	N/A	7 mmol/L
	Glucose Oxidase	*Aspergillus niger*	0.002 IU
BUN/Urea	Urea	N/A	4 mmol/L
	Urease	*Canavalia ensiformis*	0.12 IU
Crea	Creatinine	N/A	158.4 µmol/L
	Creatine Amidinohydrolase	Microbial	0.01 IU
	Creatinine Amidohydrolase	Microbial	0.02 IU
	Sarcosine Oxidase	Microbial	0.001 IU
TCO_2	Carbon Dioxide (CO_2)	N/A	25.2 mmHg

Warnings and Precautions

- For *in vitro* diagnostic use.
- DO NOT REUSE—cartridges are intended for single-use only.
- Refer to the i-STAT 1 System Manual for all warnings and precautions.

Storage Conditions

- Refrigeration at 2–8 ºC (35–46 ºF) until expiration date.
- Room Temperature at 18–30 ºC (64–86 ºF). Refer to the cartridge box for recommended shelf life.

INSTRUMENTS

The i-STAT CHEM8+ cartridge is intended for use with the i-STAT 1 analyzer REF 04P75-01 (Model 300-G) and REF 03P75-06 (Model 300W).

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Arterial or venous whole blood
Sample volume: 95 µL

Blood Collection Options and Test Timing (time from collection to cartridge fill)

Analyte	Syringes	Test Timing	Evacuated Tubes	Test Timing
Ionized Calcium TCO_2	Without anticoagulant	3 minutes	Without anticoagulant	3 minutes
	With balanced heparin anticoagulant (or lithium heparin anticoagulant for TCO_2 only) (syringe must be filled per manufacturer's recommendation) • Maintain anaerobic conditions. • Remix thoroughly before filling cartridge.	10 minutes	With lithium heparin anticoagulant (tubes must be filled per manufacturer's recommendation) • Maintain anaerobic conditions. Remix thoroughly before filling cartridge.	10 minutes
Sodium Potassium Chloride Glucose BUN/Urea Creatinine Hematocrit	Without anticoagulant	3 minutes	Without anticoagulant	3 minutes
	With balanced heparin anticoagulant or lithium heparin anticoagulant (syringe must be filled per manufacturer's recommendation) • Remix thoroughly before filling cartridge.	30 minutes	With lithium heparin anticoagulant (tubes must be filled per manufacturer's recommendation) • Remix thoroughly before filling cartridge.	30 minutes

PROCEDURE FOR CARTRIDGE TESTING

Each cartridge is sealed in a foil pouch for protection during storage--do not use if pouch has been punctured.

- A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). For best results, the cartridge and analyzer should be at room temperature.
- Since condensation on a cold cartridge may prevent proper contact with the analyzer, allow refrigerated cartridges to equilibrate at room temperature for 5 minutes for a single cartridge and 1 hour for an entire box before use.
- Use a cartridge immediately after removing it from its protective pouch. Prolonged exposure may cause a cartridge to fail a Quality Check.
- Do not return unopened, previously refrigerated cartridges to the refrigerator.
- Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.

Filling and Sealing the Cartridge (after cartridge has been equilibrated and blood sample has been collected)

1. Place the cartridge on a flat surface.
2. Mix the sample thoroughly. Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds. The blood in the hub of the syringe will not mix, therefore expelling 2 drops before filling a cartridge is desired. Note that it may be difficult to properly mix a sample in a 1.0 mL syringe.

3. Fill the cartridge immediately after mixing. Direct the hub of syringe or tip of the transfer device (pipette or dispensing tip) into the sample well of the cartridge.
4. Slowly dispense sample into the sample well until the sample reaches the fill mark indicated on the cartridge. Cartridge is properly filled when the sample reaches the 'fill to' mark and a small amount of sample is in the sample well. The sample should be continuous, no bubbles or breaks (see System Manual for details).
5. Fold the snap closure of the cartridge over the sample well.

Performing Patient Analysis

1. Press the power button to turn on the handheld.
2. Press 2 for *i-STAT Cartridge*.
3. Follow the handheld prompts.
4. Scan the lot number on the cartridge pouch.
5. Continue normal procedures for preparing the sample, and filling and sealing the cartridge.
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.
7. Review the results.

For additional information for cartridge testing, refer to the i-STAT 1 System Manual located at www.pointofcare.abbott.

Analysis Time

Approximately 130–200 seconds.

Quality Control

The i-STAT quality control regimen comprises four aspects, with a system design that reduces the opportunity for error, including:

1. A series of automated, on-line quality measurements that monitors the sensors, fluidics, and instrumentation each time a test is performed.
2. A series of automated, on-line procedural checks that monitors the user each time a test is performed
3. Liquid materials are available to be used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question. The performance of this procedure is not a manufacturer's system instruction.
4. Traditional quality control measurements that verify the instrumentation using an independent device, which simulates the characteristics of the electrochemical sensors in a way that stresses the performance characteristics of the instrumentation.

For additional information on Quality Control, refer to the i-STAT 1 System Manual located at www.pointofcare.abbott.

Calibration Verification

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure is not a manufacturer's system instruction. However, it may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid-levels.

EXPECTED VALUES

TEST	UNITS *	REPORTABLE RANGE	REFERENCE RANGE *arterial*	*venous*
MEASURED				
Na	mmol/L (mEq/L)	100–180	138–146 [4]	
K	mmol/L (mEq/L)	2.0–9.0	3.5–4.9 [4] **	
Cl	mmol/L (mEq/L)	65–140	98–109 [4]	
iCa	mmol/L	0.25–2.50	1.12–1.32 [5]	
	mg/dL	1.0–10.0	4.5–5.3 [5]	
Glu	mmol/L	1.1–38.9	3.9–5.8 [5]	
	mg/dL	20–700	70–105 [5]	
	g/L	0.20–7.00	0.70–1.05 [5]	
BUN/Urea Nitrogen	mg/dL	3–140	8–26 [4]	
Urea	mmol/L	1–50	2.9–9.4 [4]	
	mg/dL	6–300	17–56 [4]	
	g/L	0.06–3.00	0.17–0.56 [4]	
Crea	mg/dL	0.2–20.0	0.6–1.3 [6]	
	µmol/L	18–1768	53–115	
Hematocrit/Hct	% PCV***	15–75	38–51 **** [4]	
	Fraction	0.15–0.75	0.38–0.51 [4]	
TCO_2	mmol/L	5–50	23–27 *****	24–29 *****
CALCULATED				
AnGap	mmol/L	(-10)–(+99)	10–20 [5]	
Hemoglobin/Hb	g/dL	5.1–25.5	12–17 [4]	
	g/L	51–255	120–170 [4]	
	mmol/L	3.2–15.8	7–11 [4]	

* The i-STAT System can be configured with the preferred units. (See "Unit Conversion" below.)

** The reference range for potassium has been reduced by 0.2 mmol/L from the range cited in Reference 4 to account for the difference in results between serum and plasma.

*** PCV, packed cell volume.

**** The reference ranges for hematocrit and hemoglobin span both female and male populations.

***** Calculated from Siggard-Andersen nomogram. [7]

Unit Conversion

- **Ionized Calcium (iCa):** To convert mmol/L to mg/dL, multiply the mmol/L value by 4. To convert mmol/L to mEq/L, multiply the mmol/L value by 2.
- **Glucose (Glu):** To convert mg/dL to mmol/L, multiply the mg/dL value by 0.055.
- **BUN/Urea**: To convert a BUN result in mg/dL to a urea result in mmol/L, multiply the BUN result by 0.357. To convert a urea result in mmol/L to a urea result in mg/dL, multiply the mmol/L result by 6. To convert a urea result in mg/dL to a urea result in g/L, divide the mg/dL result by 100.
- **Creatinine (Crea):** To convert mg/dL to µmol/L, multiply the mg/dL value by 88.4.
- **Hematocrit (Hct):** To convert a result from % PCV (packed cell volume) to fraction packed cell volume, divide the % PCV result by 100. For the measurement of hematocrit, the i-STAT System can be customized to agree with methods calibrated by the microhematocrit reference method using either K_3EDTA or K_2EDTA anticoagulant. Mean cell volumes of K_3EDTA anticoagulated

blood are approximately 2–4% less than K_2EDTA anticoagulated blood. While the choice of anticoagulant affects the microhematocrit method to which all hematocrit methods are calibrated, results from routine samples on hematology analyzers are independent of the anticoagulant used. Since most clinical hematology analyzers are calibrated by the microhematocrit method using K_3EDTA anticoagulant, the i-STAT System default customization is K_3EDTA.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

METROLOGICAL TRACEABILITY

The measured analytes in the i-STAT CHEM8+ cartridge are traceable to the following reference materials or methods. The i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods.

Sodium (Na), Potassium (K), Chloride (Cl) and Ionized Calcium (iCa)
The respective analyte values assigned to the i-STAT System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956.

Glucose (Glu)

The i-STAT System test for glucose measures glucose amount-of-substance concentration in the plasma fraction of arterial, venous whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Glucose values assigned to the i-STAT System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM965.

Blood Urea Nitrogen (BUN/Urea)
The i-STAT System test for blood urea nitrogen/urea measures blood urea nitrogen/urea amount-of substance concentration in the plasma fraction of arterial, venous whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. BUN/urea values assigned to the i-STAT System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909.

Creatinine (Crea)
The i-STAT System test for creatinine measures creatinine amount-of-substance concentration in the plasma fraction of arterialor venous whole blood (dimension µmol L^{-1}) for *in vitro* diagnostic use. Creatinine values assigned to the i-STAT System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM967.

Hematocrit (Hct)
The i-STAT System test for hematocrit measures packed red blood cell volume fraction in arterialor venous whole blood (expressed as the % packed cell volume) for *in vitro* diagnostic use. Hematocrit values assigned to i-STAT's working calibrators are traceable to the Clinical and Laboratory Standards Institute (CLSI) H7-A3 procedure for determining packed cell volume by the microhematocrit method. [8]

Total carbon dioxide (TCO_2)
The i-STAT System test for total carbon dioxide (TCO2) measures the amount-of-substance total concentration of all forms of carbon dioxide in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. TCO_2 values assigned to the i-STAT System controls and calibration verification materials are traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Measurement Procedure for Substance Concentration Determination for Total Carbon Dioxide in Blood, Plasma or Serum. [2]

Additional information regarding metrological traceability is available from Abbott Point of Care Inc.

PERFORMANCE CHARACTERISTICS

The typical performance data summarized below were collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision

Precision data was collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Test	Units	Aqueous Control	Mean	SD (Standard Deviation)	CV (%) [Coefficient of Variation (%)]
Na	mmol/L or mEq/L	Level 1	120.0	0.46	0.4
		Level 3	160.0	0.53	0.3
K	mmol/L or mEq/L	Level 1	2.85	0.038	1.3
		Level 3	6.30	0.039	0.6
Cl	mmol/L or mEq/L	Level 1	76.7	0.54	0.7
		Level 3	114.0	0.56	0.5
iCa	mmol/L	Level 1	1.60	0.017	1.1
		Level 3	0.84	0.012	1.4
Glu	mg/dL	Level 1	41.8	0.68	1.6
		Level 3	289	2.4	0.8
BUN/Urea	mg/dL	Level 1	52.8	0.76	1.4
		Level 3	5.5	0.45	8.2
Crea	mg/dL	Level 1	4.33	0.131	3.0
		Level 3	0.81	0.039	4.8
Hct	% PCV	Low	30.0	0.44	1.5
	(packed cell volume)	High	49.0	0.50	1.0
TCO_2	mmol/L	Level 1	17.4	0.62	3.6
		Level 3	34.6	0.62	1.8

For the creatinine test, clinical settings vary and some may require different performance characteristics to assess renal function status than others (e.g., medication dosing, intravenous contrast use, and outpatient clinic). If deemed necessary by a healthcare facility, performance data should be obtained in specific clinical settings to assure patients' needs are met.

Method Comparison

Method comparison data were collected using CLSI guideline EP9-A. [9]

Deming regression analysis [10] was performed on the first replicate of each sample set. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site-specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid". [10] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem, and, as a guide, the range of data can be considered adequate for r >0.975.

Sodium/Na (mmol/L or mEq/L)		Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.	n	189	142	192
	Sxx	0.74	0.52	0.54
	Syy	0.53	0.58	0.53
	Slope	1.00	0.98	0.95
	Int't	-0.11	3.57	5.26
	Sy.x	1.17	1.04	1.53
	Xmin	126	120	124
	Xmax	148	148	148
	r	0.865	0.937	0.838

Potassium/K (mmol/L or mEq/L)		Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.	n	189	142	192
	Sxx	0.060	0.031	0.065
	Syy	0.055	0.059	0.055
	Slope	0.97	1.06	0.99
	Int't	0.02	-0.15	-0.01
	Sy.x	0.076	0.060	0.112
	Xmin	2.8	3.0	2.8
	Xmax	5.7	9.2	5.8
	r	0.978	0.993	0.948

Chloride/Cl (mmol/L or mEq/L)		Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.	n	189	142	192
	Sxx	1.27	0.41	0.89
	Syy	0.88	0.90	0.88
	Slope	0.99	0.88	0.93
	Int't	-0.82	14.6	4.3
	Sy.x	1.65	1.84	2.33
	Xmin	93	63	96
	Xmax	114	128	117
	r	0.817	0.914	0.752

Ionized Calcium/iCa (mmol/L)		Radiometer ICA1	Nova STAT Profile
Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.	n	47	57
	Sxx	0.009	0.017
	Syy	0.017	0.017
	Slope	0.925	0.960
	Int't	0.113	0.062
	Sy.x	0.035	0.029
	Xmin	0.46	0.53
	Xmax	2.05	2.05
	r	0.982	0.982

Glucose/Glu (mg/dL)		Beckman Coulter LX20®	Bayer 860	Dade Dimension RxL-Xpand
Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.	n	35	40	32
	Sxx	2.21	4.71	0.98
	Syy	0.69	0.96	0.59
	Slope	1.03	0.99	1.01
	Int't	-3.39	-1.67	-0.85
	Sy.x	0.91	0.70	1.57
	Xmin	45	58	48
	Xmax	297	167	257
	r	0.999	0.993	0.998

BUN/Urea (mg/dL)		Beckman Coulter LX20®	Dade Dimension RxL-Xpand®	Beckman Coulter CX9®
Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.	n	39	32	26
	Sxx	0.36	0.48	0.39
	Syy	0.67	0.34	0.60
	Slope	1.03	1.05	1.00
	Int't	1.39	-0.28	-0.38
	Sy.x	0.99	0.31	0.85
	Xmin	5	5	7
	Xmax	70	38	66
	r	0.997	0.998	0.997

Creatinine/Crea (mg/dL)		Roche Integra 800	Beckman LX20®	J & J Vitros 950	Dade Dimension RxL
Venous blood samples, collected in lithium or sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. A portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.	n	30	58	31	36
	Sxx	0.029	0.141	0.04	0.04
	Syy	0.112	0.143	0.12	0.06
	Slope	0.929	0.960	0.948	0.964
	Int't	0.237	0.022	0.206	0.100
	Sy.x	0.204	0.261	0.165	0.123
	Xmin	0.4	0.7	0.5	0.5
	Xmax	10.3	20.0	7.2	5.7
	r	0.997	0.996	0.991	0.986

Hematocrit/Hct (% PCV) (% packed cell volume)		Coulter® S Plus	Nova STAT Profile® 5	Abbott Cell-Dyn 4000	Sysmex SE9500
Venous blood samples, collected in lithium heparin Vacutainer® tubes, were analyzed in duplicate on the i-STAT System and on the comparative methods for hematocrit within 20 minutes of collection.	n	142	192	29	29
	Sxx	0.50	0.46	0.41	0.53
	Syy	1.09	1.31	0.77	0.76
	Slope	0.98	1.06	1.06	1.11
	Int't	1.78	-3.98	-1.42	-4.19
	Sy.x	2.03	2.063	1.13	0.98
	Xmin	18	21	19	24
	Xmax	51	50	46	47
	r	0.952	0.932	0.993	0.980

Total Carbon Dioxide/TCO_2 (mmol/L)		TCO₂ (Measured) Beckman Coulter LX®20
Venous blood samples were collected in lithium heparin evacuated tubes from hospital patients. The whole blood samples were run in duplicate on the i-STAT System. The samples were then centrifuged and the plasma analyzed in duplicate on the comparative instrument. All samples were analyzed on both methods within 15 minutes of each other. For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and ***P***CO_2 due to loss of CO_2 during non-anaerobic handling. 11 Up to 6 mmol/L CO_2 can be lost per hour by exposure of the sample to air. 12	n	35
	Sxx	0.48
	Syy	0.60
	Slope	1.152
	Int't	-1.5
	Sy.x	0.96
	Xmin	21
	Xmax	35
	r	0.943

FACTORS AFFECTING RESULTS

The following substances were evaluated in plasma for relevant analytes at the test concentrations recommended in CLSI guideline EP7-A2 [13] unless otherwise noted. For those identified as an interferant the interference is described.

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
Acetaldehyde	0.045 [14]	Glu	No	
		Crea	No	
Acetaminophen	1.32	Na	No	
		K	No	
		Cl	No	
		iCa	Yes	Decreased results
		Glu	No	
		BUN	No	
		Crea	Yes	Increased results
Acetaminophen (therapeutic)	0.132 [14]	iCa	No	
		Glu	No	
		Crea	No	
Acetoacetate	2.0	Glu	No	
Acetylcysteine	10.2	Na	No	
		K	No	
		Cl	Yes	Increased results
		iCa	Yes	Decreased results
		Glu	Yes	Decreased results
		BUN	No	
		Crea	Yes	Increased results
Acetylcysteine (therapeutic)	0.3 [15 16]	Cl	No	
		iCa	No	

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
		Glu	No	
		Crea	No	
Ascorbate	0.34	Na	No	
		K	No	
		Cl	No	
		iCa	No	
		Glu	No	
		BUN	No	
		Crea	Yes	Increased by up to 0.3 mg/dL
Bicarbonate	35.0	Crea	No	
Bilirubin	0.342	Crea	No	
Bromide	37.5	Na	Yes	Increased results. Use another method.
		K	Yes	Increased results and rate of star (***) outs. Use another method.
		Cl	Yes	Increased results. Use another method.
		iCa	Yes	Increased results. Use another method.
		Glu	Yes	Decreased results. Use another method.
		BUN	Yes	Decreased result and increased rate of star (***) outs. Use another method.
		Hct	Yes	Increased rate of star (***) outs.
Bromide (therapeutic)	2.5 [17, 18, 19]	Na	No	
		K	No	
		Cl	Yes	Increased results. Use another method.
		iCa	No	
		Glu	Yes	Decreased results
		BUN	No	
		Crea	Yes	Increased results
		Hct	No	
Calcium Chloride	5.0	Crea	No	
Creatine	0.382	Crea	Yes	Increased by up to 0.3 mg/dL. See Other Factors Affecting Results below for Creatine.
Dopamine	0.006	Glu	No	
		Crea	No	
Formaldehyde	0.133 [14]	Glu	No	
		Crea	No	

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
β-Hydroxybutyrate	6.0 [20]	Na	No	
		K	No	
		Cl	No	
		iCa	No	
		Glu	No	
		BUN	No	
		Crea	No	
Glycolic Acid	10.0	Crea	Yes	Decreased results. Use another method.
Hydroxyurea	0.92	Glu	Yes	Increased results. Use another method.
		BUN	Yes	Increased results.
		Crea	Yes	Increased results. Use another method.
Iodide	2.99	Cl	Yes	Increased results.
	0.4	Cl	No	
Lactate	6.6	Na	No	
		K	No	
		Cl	No	
		iCa	Yes	Decreased results by up to 0.07 mmol/L.
		Glu	No	
		BUN	No	
		Crea	No	
Leflunomide	0.03	iCa	Yes	Decreased results
Magnesium Chloride	1.0	Na	No	
		K	No	
		iCa	Yes	Increased results by up to 0.04 mmol/L.
Maltose	13.3	Glu	No	
Methyldopa	0.071	Crea	No	
Nithiodote (Sodium thiosulfate)	16.7 [21]	Na	Yes	Increased results
		K	Yes	Decreased results
		Cl	Yes	Increased results
		iCa	Yes	Decreased results
		Glu	Yes	Decreased results
		BUN	Yes	Decreased results
		Crea	Yes	Increased results
Pyruvate	0.31	Glu	No	
		Crea	No	

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
Salicylate	4.34	Na	No	
		K	No	
		Cl	Yes	Increased results. Use another method.
		iCa	Yes	Decreased results
		Glu	No	
		BUN	No	
		Crea	No	
Salicylate (therapeutic)	0.5 [22]	Cl	No	
		iCa	Yes	Decreased results by up to 0.03 mmol/L
Thiocyanate	6.9	Cl	Yes	Increased results. Use another method
		iCa	Yes	Decreased results. Use another method.
		Glu	Yes	Decreased results
		BUN	No	
Thiocyanate (therapeutic)	0.5 [14]	Glu	No	
Uric Acid	1.4	Glu	No	
		Crea	No	

The degree of interference at concentrations other than those reported above might not be predictable. It is possible that interfering substances other than those tested may be encountered.

Relevant comments regarding interference of Acetaminophen, Acetylcysteine, Bromide, Hydroxyurea, Iodide, Leflunomide, Nithiodote and Salicylate and are noted below:

- Acetaminophen has been shown to interfere with i-STAT ionized calcium and creatinine results at a 1.32 mmol/L, a toxic concentration that is proscribed by the CLSI guideline. Acetaminophen at 0.132 mmol/L, which represents the upper end of the therapeutic concentration range, has been shown not to significantly interfere with i-STAT ionized calcium and creatinine results.
- Acetylcysteine has been tested at two levels: the CLSI recommended level of 10.2 mmol/L and a concentration of 0.30 mmol/L. The latter is 3 times the peak therapeutic plasma concentration associated with treatment to reverse acetaminophen poisoning. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level.
- Bromide was tested at two levels: the CLSI recommended level and a therapeutic plasma concentration level of 2.5 mmol/L. The latter is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level.
- Hydroxyurea has been shown to interfere with glucose, BUN and creatinine results at 0.92 mmol/L. Hydroxyurea is a DNA synthesis inhibitor used in the treatment sickle cell anemia, HIV infection, and various types of cancer. The malignancies that it is used to treat include melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocythemia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in a patient's blood may be sustained at approximately 100 to 500 μmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.
- Iodide has been tested at the CLSI recommended level of 2.99 mmol/L, which is close to the peak concentration after a lethal dose. A lethal dose is reported to be in the range of 2–4 grams , which equates to 3.1–6.3 mmol/L assuming the dose is fully distributed in a typical blood 23 volume of 5

L. Iodide can be used to treat thyroid disease (i.e., hyperthyroidism). A study showed serum iodide reaches mean peak concentration between 1.8 mg/L (0.014 mmol/L) and 2.2 mg/L (0.017 mmol/L) after a month of supplementation at 50 mg/day. [24] Iodide has been shown to interfere with i-STAT chloride results at 2.99 mmol/L. The lowest concentration tested at APOC of 0.4 mmol/L has been shown to not significantly interfere with i-STAT chloride results. APOC has not identified a therapeutic condition that would lead to levels consistent with the CLSI recommended level.

- Leflunomide has been shown to interfere with iCa results at 0.03 mmol/L. Leflunomide is an isoxazole immunomodulatory agent that inhibits dihydroorotate dehydrogenase, an enzyme involved in *de novo* pyrimidine synthesis, and that has antiproliferative activity. It is used in the treatment of some immune diseases. Following oral administration, leflunomide is metabolized to an active metabolite, teriflunomide, which is responsible for essentially all its *in vivo* activity. The active metabolite teriflunomide reaches a plasma concentration of 8.5 µg/mL (0.031 mmol/L) after a 100 mg loading dose and the steady state concentration is maintained at 63 µg/mL (0.23 mmol/L) after 24 weeks of maintenance dose at 25 mg/day [25] when treating inflammatory polyarthropathy.
- Nithiodote (sodium thiosulfate) has been shown to interfere with sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen and creatinine results at 16.7 mmol/L. Nithiodote (sodium thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that "the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L." [21]
- Salicylate has been shown to interfere with i-STAT chloride and ionized calcium results at 4.34 mmol/L, a toxic concentration that is proscribed by the CLSI guideline. Salicylate at 0.5 mmol/L, which represents the upper end of the therapeutic concentration range, has been shown not to significantly interfere with i-STAT chloride results and has been shown to decrease ionized calcium results by approximately 0.03 mmol/L.

OTHER FACTORS AFFECTING RESULTS

Factor	Analyte	Effect
Sodium heparin	Na	Sodium heparin may increase sodium results up to 1 mmol/L. [26]
Venous stasis	iCa	Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid. [27]
Line draw	Hct	Low hematocrit results can be caused by contamination of flush solutions in arterial or venous lines. Back flush a line with a sufficient amount of blood to remove intravenous solutions, heparin, or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors, and needle is recommended.
Heparin	iCa	Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01 mmol/L. [27] Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03 mmol/L. [27] Use only non-heparinized sample transfer devices when using i-STAT System's aqueous control and calibration verification materials.
Exposing the sample to air	iCa	Exposing the sample to air will cause an increase in pH due to loss of CO_2, which will decrease ionized calcium.

Factor	Analyte	Effect
	TCO_2	Exposing the sample to air allows CO_2 to escape, which causes TCO_2 to be underestimated.
Hemodilution	Na Cl iCa	Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride and ionized calcium results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To minimize these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g., gluconate).
Cold temperature	K	Potassium values will increase in iced specimens.
Allowing blood to stand (without exposure to air)	K	If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time.
	Glu	Glucose values will decrease in whole blood samples over time. Venous blood glucose is as much as 7 mg/dL less than capillary blood glucose as a result of tissue utilization. [28]
	TCO_2	Allowing blood samples to stand (without exposure to air) before testing causes TCO_2 to be overestimated due to metabolic processes.
Sample type	K	Serum Potassium results may be 0.1 to 0.7 mmol/L higher than Potassium results from anticoagulated samples due to the release of Potassium from platelets [1] and red blood cells during the clotting process.
Sample mixing	Hct	Samples from 1 mL syringes should not be used to determine hematocrit if testing is delayed.
Under fill or partial draw	TCO_2	The use of partial draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g., a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended due to the potential for decreased TCO_2 values. Underfilling blood collection tubes may also cause decreased TCO_2 results. Care must be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.
pH dependence	Glu	The dependence of the i-STAT glucose test with respect to pH is as follows: values below pH 7.4 at 37 °C decrease results by approximately 0.9 mg/dL (0.05 mmol/L) per 0.1 pH unit. Values above pH 7.4 at 37 °C increase results by approximately 0.8 mg/dL (0.04 mmol/L) per 0.1 pH unit.
$\boldsymbol{P}O_2$ dependence	Glu	The dependence of the i-STAT glucose test with respect to $\boldsymbol{P}O_2$ is as follows: oxygen levels of less than 20 mmHg (2.66 kPa) at 37 °C may decrease results.
Creatine	Creatinine	The normal range of creatine concentration in plasma is 0.17–0.70 mg/dL (13–53 µmol/L) in males and 0.35–0.93 mg/dL (27–71 µmol/L) in females. [14] Creatine may be elevated in patients using creatine supplements, experiencing muscle trauma or other primary or secondary myopathies, taking statins for hyperlipidemia control, or in patients with hyperthyroidism or a rare genetic defect of the creatine transporter protein.
CO_2 dependence	Creatinine	The dependence of the i-STAT creatinine test with respect to carbon dioxide (CO_2) is as follows: For creatinine results ≤ 2.0 mg/dL, no correction for $\boldsymbol{P}CO_2$ is required. For creatinine results > 2.0 mg/dL, the following correction applies: $creatinine_{corrected} = creatinine * (1 + 0.0025 * (\boldsymbol{P}CO_2 - 40))$

<table>
<tr><th>Factor</th><th>Analyte</th><th>Effect</th></tr>
<tr><td>Erythrocyte sedimentation rate</td><td>Hct</td><td>The measurement of certain blood samples with high erythrocyte sedimentation rates (ESR) may be affected by analyzer angle. While testing blood samples, beginning 90 seconds after the cartridge is inserted, the analyzer should remain level until a result is obtained. A level surface includes running the handheld in the downloader/ recharger.
Hematocrit results can be affected by the settling of red blood cells in the collection device. The best way to avoid the effect of settling is to test the sample immediately. If there is a delay in testing of a minute or more, the sample must be remixed thoroughly.</td></tr>
<tr><td>White Blood Cell Count (WBC)</td><td>Hct</td><td>Grossly elevated white blood cell counts may increase results.</td></tr>
<tr><td>Lipids</td><td>Hct</td><td>Abnormally high lipids may increase results. Interference from lipids will be about two thirds the size of the interference from protein.</td></tr>
<tr><td>Total Protein</td><td>Hct</td><td>Hematocrit results are affected by the level of total protein as follows:
<table>
<tr><th>Displayed Result</th><th>Total Protein (TP) < 6.5 g/dL</th><th>Total Protein (TP) > 8.0 g/dL</th></tr>
<tr><td>HCT < 40 %PCV</td><td>Hct decreased by ~1% PCV for each decrease of 1 g/dL TP</td><td>Hct increased by ~1% PCV for each increase of 1 g/dL TP</td></tr>
<tr><td>HCT > 40 %PCV</td><td>Hct decreased by ~0.75 % PCV for each decrease of 1 g/dL TP</td><td>Hct increased by ~0.75 % PCV for each increase of 1 g/dL TP</td></tr>
</table>
Total protein levels may be low in neonatal and burn patient populations, as well as in additional clinical populations listed in Statland. [4] Total protein levels may also be decreased in patients undergoing cardiopulmonary bypass (CPB) or extracorporeal membrane oxygenation (ECMO) and with patients receiving large volumes of saline-based intravenous (IV) fluids. Care should be taken when using hematocrit results from patients with total protein levels below the adult reference range (6.5 to 8 g/dL).
The CPB sample type can be used to correct the hematocrit result for the dilutional effect of the pump prime in cardiovascular surgery. The CPB algorithm assumes that cells and plasma are diluted equally and that the pump priming solution has no added albumin or other colloid or packed red blood cells. Since perfusion practices vary, it is recommended that each practice verify the use of the CPB sample type and the length of time in which the CPB sample type should be used during the recovery period. Note that for hematocrit values above 30% PCV, the CPB correction is ≤1.5% PCV; the size of the correction at this level should not impact transfusion decisions.</td></tr>
<tr><td>Sodium</td><td>Hct</td><td>The sample electrolyte concentration is used to correct the measured conductivity prior to reporting hematocrit results. Factors that affect sodium will therefore also affect hematocrit.</td></tr>
<tr><td>Clinical Condition</td><td>Anion Gap</td><td>The calculated anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.</td></tr>
</table>

For BUN/Urea, endogenous ammonium ions will not affect results.

KEY TO SYMBOLS

Symbol	Definition/Use
14	14 days room temperature storage at 18–30 °C.
	Use by or expiration date. The expiration date, expressed as YYYY-MM-DD, indicates the last day the product may be used.
LOT	Manufacturer's lot number or batch code. The lot number or batch code appears adjacent to this symbol.
Σ	Sufficient for <n> tests.
EC REP	Authorized representative for Regulatory Affairs in the European Community.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
REF	Catalog number, list number, or reference.
	Do not reuse.
	Manufacturer.
	Consult instructions for use or see System Manual for instructions.
IVD	*In vitro* diagnostic medical device.
CE	Compliance to the European directive on *in vitro* diagnostic devices (98/79/EC)
Rx ONLY	For prescription use only.

Additional Information: to obtain additional product information and technical support, refer to the Abbott company website at www.pointofcare.abbott.

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