i-STAT EG7+ Cartridge

NAME

i-STAT EG7+ Cartridge – REF 03P76-25

INTENDED USE

The i-STAT EG7+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of Sodium, Potassium, Ionized Calcium, Hematocrit, pH, oxygen partial pressure, and carbon dioxide partial pressure in arterial or venous whole blood.

The i-STAT EG7+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of Sodium, Hematocrit, pH, oxygen partial pressure, and carbon dioxide partial pressure in capillary whole blood.

Analyte	Intended Use
Sodium (Na)	Sodium measurements are used for monitoring electrolyte imbalances.
Potassium (K)	Potassium measurements are used for diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.
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 and tetany and disturbances related to surgical and intensive care.
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.
pH	pH, ***P***O_2, and ***P***CO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.
Oxygen Partial Pressure (***P***O_2)	
Carbon Dioxide Partial Pressure (***P***CO_2)	Bicarbonate is used in the diagnosis 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.

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.

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.

pH

pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia [1].

Oxygen Partial Pressure (***P***O_2)

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of ***P***O_2 include decreased pulmonary ventilation (e.g. airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g. bronchitis, emphysema, or pulmonary edema), and alteration in the flow of blood within the heart or lungs (e.g. congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

Carbon Dioxide Partial Pressure (***P***CO_2)

PCO_2 along with pH is used to assess acid-base balance. ***P***CO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon

dioxide dissolved in the blood. ***P***CO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in ***P***CO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in ***P***CO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased ***P***CO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

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. [2]

Measured:

Sodium (Na), Potassium (K) 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.

Hematocrit (Hct)

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

pH

pH is measured by direct potentiometry. In the calculation of results for pH, concentration is related to potential through the Nernst equation.

***P*O$_2$**

PO_2 is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

***P*CO$_2$**

PCO_2 is measured by direct potentiometry. In the calculation of results for ***P***CO_2, concentration is related to potential through the Nernst equation.

Temperature "Correction" Algorithm

pH, ***P***O_2, and ***P***CO_2 are temperature-dependent quantities and are measured at 37°C. The pH, ***P***O_2, and ***P***CO_2 readings at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. In this case, blood gas results will be displayed at both 37°C and the patient's temperature.

The pH, ***P***O_2, and ***P***CO_2 at the patient's temperature (T_p) are calculated as follows 3 :

$$pH(T_p) = pH - 0.0147(T_p - 37) + 0.0065(7.4 - pH)(T_p - 37)$$

$$PO_2(T_p) = PO_2 \times 10^{\frac{5.49\times10^{-11}\,PO_2^{\,3.88} + 0.071}{9.72\times10^{-9}\,PO_2^{\,3.88} + 2.30}(T_p - 37)}$$

$$PCO_2(T_p) = PCO_2 \times 10^{0.019(T_p - 37)}$$

Calculated:

HCO_3, TCO_2, and BE

- HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance.
- 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 $\boldsymbol{P}CO_2$) and electrolyte imbalance.
- The calculated TCO_2 provided by the i-STAT System is determined from the measured and reported values of pH and $\boldsymbol{P}CO_2$ according to a simplified and standardized form of the Henderson-Hasselbalch equation. [3]
- This calculated TCO_2 measurement is metrologically traceable to the i-STAT pH and $\boldsymbol{P}CO_2$ measurements, which are in turn traceable to primary standard reference materials for pH and $\boldsymbol{P}CO_2$. Like all calculated parameters reported by the i-STAT System, the user can independently determine TCO_2 values from the reported pH and $\boldsymbol{P}CO_2$ measurements using a combination of the equation for HCO_3 given in the $\boldsymbol{P}CO_2$.
- Base excess of the extracellular fluid (ECF) or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average ECF (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at $\boldsymbol{P}CO_2$ of 40 mmHg at 37 °C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the $\boldsymbol{P}CO_2$ and reflects only the non-respiratory component of pH-disturbances.

When a cartridge includes sensors for both pH and $\boldsymbol{P}CO_2$, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) are calculated. [3]

$\log HCO_3 = pH + \log \boldsymbol{P}CO_2 - 7.608$
$TCO_2 = HCO_3 + 0.03\boldsymbol{P}CO_2$
$BE_{ecf} = HCO_3 - 24.8 + 16.2(pH - 7.4)$
$BE_b = (1 - 0.014*Hb) * [HCO3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)]$

sO_2

- sO_2 (oxygen saturation) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).
- sO_2 is calculated from measured $\boldsymbol{P}O_2$ and pH and from HCO_3 calculated from measured $\boldsymbol{P}CO_2$ and pH. However, this calculation assumes normal affinity of oxygen for hemoglobin. It does not take into account erythrocyte diphosphoglycerate (2,3-DPG) concentrations which affect the oxygen dissociation curve. The calculation also does not take into account the effects of fetal hemoglobin or dysfunctional hemoglobins (carboxy-, met-, and sulfhemoglobin). Clinically significant errors can result from incorporation of such an estimated sO_2 value for oxygen saturation in further calculations, such as shunt fraction, or by assuming the value obtained is equivalent to fractional oxyhemoglobin.

$$sO_2 = 100 \frac{(X^3 + 150X)}{X^3 + 150X + 23400}$$

where $X = \boldsymbol{P}O_2 \bullet 10^{(0.48(pH-7.4)-0.0013(HCO_3-25))}$

Hemoglobin

The i-STAT System provides a calculated hemoglobin result which is determined as follows [4]:

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.[5] 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 relevant for the i-STAT EG7+ cartridge are indicated 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
iCa	Calcium (Ca^{2+})	N/A	0.9 mmol/L
pH	Hydrogen Ion (H^+)	N/A	6.66 pH
PCO_2	Carbon Dioxide (CO_2)	N/A	25.2 mmHg

Warnings and Precautions

- For *in vitro* diagnostic use.
- Cartridges are intended for single-use only. Do not reuse.
- Refer to the i-STAT 1 System Manual for all warnings and precautions.

Storage Conditions

- Refrigerated at 2-8°C (35-46°F) until expiration date.
- Room Temperature at 18-30°C (64-86°F). Refer to the cartridge box for shelf life.

INSTRUMENTS

The i-STAT EG7+ cartridge is intended for use with the i-STAT 1 analyzer.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types
Arterial, venous or capillary 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	Capillary Tubes	Test Timing
Ionized Calcium pH ***P***CO_2 ***P***O_2	Without anticoagulant	3 minutes	Without anticoagulant	3 minutes	With balanced heparin anticoagulant or lithium heparin if labeled for the measurement of electrolytes	3 minutes
	With balanced heparin anticoagulant (or lithium heparin anticoagulant for pH, ***P***CO_2, and ***P***O_2 only)	10 minutes	With lithium heparin anticoagulant (tubes must be filled per manufacturer's recommendation)	10 minutes		

Analyte	Syringes	Test Timing	Evacuated Tubes	Test Timing	Capillary Tubes	Test Timing
	(syringe must be filled per manufacturer's recommendation) • Maintain anaerobic conditions. • Remix thoroughly before filling cartridge.		• Maintain anaerobic conditions. • Remix thoroughly before filling cartridge.		(for pH, ***P***CO_2, and ***P***O_2 only) **Not applicable for Ionized Calcium**	**Not applicable for Ionized Calcium**
Sodium Potassium Hematocrit	Without anticoagulant	3 minutes	Without anticoagulant	3 minutes	With balanced heparin anticoagulant or lithium heparin if labeled for the measurement of electrolytes **Not applicable for Potassium**	3 minutes **Not applicable for Potassium**
	With balanced heparin anticoagulant or lithium heparin anticoagulant (syringe must be filled per manufacturer's recommendation) • Remix thoroughly before filling cartridge.	30 minutes **Note: Do not report pH, *P*CO_2, *P*O_2, and ionized calcium results for samples run beyond 10 minutes from collection**	With lithium heparin anticoagulant (tubes must be filled per manufacturer's recommendation) • Remix thoroughly before filling cartridge,	30 minutes **Note: Do not report pH, *P*CO_2, *P*O_2, and ionized calcium results for samples run beyond 10 minutes from collection**		

PROCEDURE FOR CARTRIDGE TESTING

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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 (capillary tube, 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 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 [6]	
K	mmol/L(mEq/L)	2.0–9.0	3.5–4.9 [6] **	
iCa	mmol/L	0.25–2.50	1.12–1.32 [7]	
	mg/dL	1.0–10.0	4.5–5.3 [7]	
Hematocrit/Hct	% PCV***	15–75	38–51 [6] ****	
	Fraction	0.15–0.75	0.38–0.51 [6]	
pH		6.50 - 7.80	7.35 - 7.45 [7]	7.31 -7.41******

TEST	UNITS *	REPORTABLE RANGE	REFERENCE RANGE *(arterial)*	*(venous)*
MEASURED				
PO_2	mmHg	5 - 700	80 – 105 [6] *****	
	kPa	0.7 – 106.6	10.7 - 14.0 [6] *****	
PCO_2	mmHg	5 - 130	35 - 45 [7]	41 - 51
	kPa	0.67 – 17.33	4.67 - 6.00	5.47 - 6.80

TEST	UNITS *	REPORTABLE RANGE	REFERENCE RANGE *(arterial)*	*(venous)*
CALCULATED				
Hemoglobin/Hb	g/dL	5.1–25.5	12–17 [6] ****	
	g/L	51–255	120–170 [6]	
	mmol/L	3.2–15.8	7–11 [6]	
Bicarbonate/ HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26******	23 – 28******
TCO_2	mmol/L (mEq/L)	5 - 50	23 - 27	24 - 29
Base Excess/ BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3) [7]	(-2) – (+3) [7]
sO_2		0-100	95 - 98	

* The i-STAT System can be configured with the preferred units. Not applicable for pH test.

** The reference range for potassium has been reduced by 0.2 mmol/L from the range cited in Reference 6 to account for the difference in results between serum and plasma results.

*** PCV, packed cell volume.

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

***** The reference ranges shown are for a healthy population. Interpretation of blood gas measurements depend on the underlying condition (e.g., patient temperature, ventilation, posture and circulatory status).

****** Calculated from Siggard-Andersen nomogram [1]

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.
- **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.

- ***P*O$_2$ and *P*CO$_2$:** To convert ***P***O$_2$ and ***P***CO$_2$ results from mmHg to kPa, multiple the mmHg value by 0.133.

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 EG7+ 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) and Potassium (K) and Ionized Calcium (iCa)
The respective analyte values assigned to 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.

Hematocrit (Hct)
The i-STAT System test for hematocrit measures packed red blood cell volume fraction in arterial, venous, or capillary whole blood (expressed as the % packed cell volume) for *in vitro* diagnostic use. Hematocrit values assigned to i-STAT System 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].

pH

The i-STAT System test for pH measures the hydrogen ion amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (expressed as the negative logarithm of the relative molal hydrogen ion activity) for *in vitro* diagnostic use. pH values assigned to i-STAT System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference materials SRMs 186-I, 186-II, 185, and 187.

***P*O$_2$**

The i-STAT System test for oxygen partial pressure measures oxygen partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. *P*O$_2$ values assigned to i-STAT System controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards.

***P*CO$_2$**

The i-STAT System test for carbon dioxide partial pressure measures carbon dioxide partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. *P*CO$_2$ values assigned to i-STAT System controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards.

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

PERFORMANCE CHARACTERISTICS

The typical performance data summarized below was 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
iCa	mmol/L	Level 1	1.60	0.017	1.1
		Level 3	0.84	0.012	1.4
Test	**Units**	**Aqueous Control**	**Mean**	**SD (Standard Deviation)**	**CV (%) [Coefficient of Variation (%)]**
Hct	% PCV (packed cell volume)	Low	30.0	0.44	1.5
		High	49.0	0.50	1.0
pH		Level 1	7.165	0.005	0.08
		Level 3	7.656	0.003	0.04
PO_2	mmHg	Level 1	65.1	3.12	4.79
		Level 3	146.5	6.00	4.10
PCO_2	mmHg	Level 1	63.8	1.57	2.5
		Level 3	19.6	0.40	2.0

Method Comparison

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

Deming regression analysis [10] was performed on the first replicate of each sample. 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. As a guide, the range of data can be considered adequate if 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.	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

A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.	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

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

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

pH		IL BGE	Radiometer ICA 1	Nova STAT Profile 5	Radiometer ABL500
Venous blood samples were collected in evacuated tubes and arterial samples were collected in blood gas syringes with lithium heparin anticoagulant.	n	62	47	57	45
	Sxx	0.005	0.011	0.006	0.004
	Syy	0.009	0.008	0.008	0.008
	Slope	0.974	1.065	1.058	1.0265
	Int't	0.196	-0.492	-0.436	-0.1857
	Sy.x	0.012	0.008	0.010	0.0136

All sample were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 mL blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.	Xmin	7.210	7.050	7.050	----
	Xmax	7.530	7.570	7.570	----
	r	0.985	0.990	0.9920	0.986

Oxygen Partial Pressure/PO_2 (mmHg)		**Radiometer ABL500**	**Radiometer ABL700**	**Bayer 845**
Arterial blood samples were collected from hospital patients in 3 cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.	n	45	29	30
	Sxx	3.70	2.04	3.03
	Syy	2.78	2.64	3.28
	Slope	1.023	0.962	1.033
	Int't	-2.6	1.2	-2.9
	Sy.x	2.52	3.53	3.44
	Xmin	----	39	31
	Xmax	----	163	185
	r	0.996	0.990	0.996

Carbon Dioxide Partial Pressure/ PCO_2 (mmHg)		**IL BGE**	**Radiometer ABL500**
Venous blood samples were collected in blood gas syringes. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.	n	62	29
	Sxx	0.69	0.74
	Syy	1.24	0.53
	Slope	1.003	1.016
	Int't	-0.8	1.1
	Sy.x	1.65	0.32
	Xmin	30.4	28
	Xmax	99.0	91
	r	0.989	0.999

FACTORS AFFECTING RESULTS

The following substances were evaluated in plasma for relevant analytes at the test concentrations recommended in CLSI guideline EP7-A2 [11] unless otherwise noted. For those identified as an interferant the interference is described.

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
Acetaminophen	1.32	Na	No	
		K	No	
		iCa	Yes	Decreased results
Acetaminophen (therapeutic)	0.132	iCa	No	
Acetylcysteine	10.2	Na	No	
		K	No	
		iCa	Yes	Decreased results
Acetylcysteine (therapeutic)	0.30 [12 13]	iCa	No	
Ascorbate	0.34	Na	No	
		K	No	
		iCa	No	

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
Bromide	37.5	Na	Yes	Increased results. Use another method.
		K	Yes	Increased result and rate or star (***) outs. Use another method.
		iCa	Yes	Increased results. Use another method.
		Hct	Yes	Increased rate of star (***) outs
Bromide (therapeutic)	2.5 [14 15 16]	Na	No	
		K	No	
		iCa	No	
		Hct	No	
β-Hydroxybutyrate	6.0 [17]	Na	No	
		K	No	
		iCa	No	
Lactate	6.6	Na	No	
		K	No	
		iCa	Yes	Decreased results by up to 0.07 mmol/L.
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.
Nithiodote (Sodium thiosulfate)	16.7 [18]	Na	Yes	Increased results
		K	Yes	Decreased results
		iCa	Yes	Decreased results
Salicylate	4.34	Na	No	
		K	No	
		iCa	Yes	Decreased results
Salicylate (therapeutic)	0.5 [19]	iCa	Yes	Decreased results by up to 0.03 mmol/L
Thiocyanate	6.9	iCa	Yes	Decreased results. Use another method

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, Leflunomide, Nithiodote and Salicylate are noted below:
  - Acetaminophen has been shown to interfere with i-STAT ionized calcium 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 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 has been 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.

- 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 [20] when treating inflammatory polyarthropathy.
- Nithiodote (sodium thiosulfate) has been shown to interfere with sodium, potassium and iCa 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." [19]
- Salicylate has been shown to significantly decrease ionized calcium results at a concentration proscribed by the CLSI guideline, 4.34 mmol/L, which represents a toxic concentration. Salicylate at 0.5 mmol/L, which represents the upper end of the therapeutic concentration, has been shown to decrease ionized calcium results by approximately 0.03 mmol/L.

OTHER FACTORS AFFECTING RESULTS

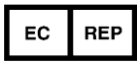
Factor	Analyte	Effect
Sodium heparin	Na	Sodium heparin may increase sodium results up to 1 mmol/L. [21]
Venous stasis	iCa	Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid. [22]
	pH	Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid.
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. [22] 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. [22] Use only non-heparinized sample transfer devices when using i-STAT 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.
	PO_2	Exposure of the sample to air will cause an increase in ***P***O_2 when values are below 150 mmHg and a decrease in ***P***O_2 when values are above 150 mmHg (approximate ***P***O_2 of room air).
	pH	Exposing the sample to air allows CO_2 to escape which causes ***P***CO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated.
	PCO_2	
	HCO_3	
	TCO_2	
Hemodilution	Na	Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion
	iCa	

Factor	Analyte	Effect
	pH	or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH 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	***P***O_2	Do not ice samples before testing as ***P***O_2 results may be falsely elevated in cold samples. Do not use a cold cartridge as ***P***O_2 results may be falsely decreased if the cartridge is cold.
	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.
	pH	pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour. [1]
	PO_2	Standing anaerobically at room temperature will decrease ***P***O_2 at a rate of 2–6 mmHg per hour. [1]
	PCO_2	Allowing blood to stand (without exposure to air) before testing will increase ***P***CO_2
	HCO_3	Allowing blood to stand (without exposure to air) before testing allows PCO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.
	TCO_2	
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 [2] 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.
Hemolysis	K	Potassium values obtained from skin puncture samples may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.
Under fill or partial draw	***P***CO_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 ***P***CO_2, HCO_3 and TCO_2 values. Underfilling blood collection tubes may also cause decreased ***P***CO_2, HCO_3 and 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.
	HCO_3	
	TCO_2	
Method of calculation	sO_2	Calculated sO_2 values from a measured *P*O_2 and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement [3].
Clinical conditions	HCO_3	Causes of primary metabolic acidosis (decrease calculated HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase calculated HCO_3) are vomiting and antacid treatment.
Erythrocyte sedimentation rate	Hct	• 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.

<table>
<tr><th>Factor</th><th>Analyte</th><th>Effect</th></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.[6] 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>Propofol (Diprivan®) or thiopental sodium</td><td>$\boldsymbol{P}CO_2$</td><td>The use of EG7+ cartridge is recommended, which is free from clinically significant interference at all relevant therapeutic doses.</td></tr>
</table>

KEY TO SYMBOLS

Symbol	Definition/Use
	2 months room temperature storage at 18-30ºC
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used.
	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
	Sufficient for <n> tests
	The authorized representative in the European Community.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Catalog number, list number, or reference
	Do not reuse.
	Manufacturer
	Consult instructions for use or see System Manual for instructions.
	*In vitro* diagnostic medical device
	Compliance to the European directive on *in vitro* diagnostic devices (98/79/EC)
	For prescription use only.

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

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