i-STAT EC8+ Cartridge

Intended for use with the i-STAT Alinity Instrument

NAME

i-STAT EC8+ Cartridge – REF 03P79-25

INTENDED USE

The i-STAT EC8+ cartridge with the i-STAT Alinity System is intended for use in the *in vitro* quantification of sodium, potassium, chloride, glucose, blood urea nitrogen, hematocrit, pH and partial pressure of carbon dioxide in arterial, venous, or capillary 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.
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.
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, and ***P***CO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances. Bicarbonate is used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
Partial Pressure of Carbon Dioxide (***P***CO_2)	

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.

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.

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]

Partial Pressure of Carbon Dioxide (***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 Chloride (Cl)

The respective analyte is measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured 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.

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*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.

Calculated:

Anion Gap (AnGap)

Anion Gap is calculated in the EC8+ cartridge as follows:

$$\text{Anion Gap (EC8+)} = (Na + K) - (Cl + HCO_3)$$

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify 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.

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 ***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 ***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 ***P***CO_2 measurements, which are in turn traceable to primary standard reference materials for pH and ***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 ***P***CO_2 measurements using a combination of the equation for HCO_3 given in the ***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]

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

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels in vivo. [4] 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 EC8+ 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
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
pH	Hydrogen Ion (H^+)	N/A	6.66 pH
$\boldsymbol{P}CO_2$	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 Alinity System Operations 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 room temperature storage requirements.

INSTRUMENTS

The EC8+ cartridge is intended for use with the i-STAT Alinity Instrument (Model No. AN-500).

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types
Arterial, venous or capillary whole blood.
Sample volume: 65 µL

Blood Collection Options and Test Timing (time from collection to cartridge fill)
As higher heparin-to-blood ratios may affect results, fill blood collection tubes and syringes to capacity, following manufacturers' instructions.

EC8+ Sample Collection	
Syringe	**Without anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Mix sample immediately before filling cartridge. • Fill cartridge within 3 minutes of sample collection. **With balanced heparin anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Mix sample immediately before filling cartridge. • Fill cartridge within 10 minutes of sample collection.
Evacuated Tube	**Without anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Mix sample immediately before filling cartridge. • Fill cartridge within 3 minutes of sample collection. **With lithium heparin anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Mix sample immediately before filling cartridge. • Fill cartridge within 10 minutes of sample collection.
Capillary Tube	**With balanced heparin anticoagulant** • Mix sample immediately before filling cartridge. • Fill cartridge within 3 minutes of sample collection. **With lithium heparin anticoagulant** - If labeled for measurement of electrolytes. • Mix sample immediately before filling cartridge. • Fill cartridge within 3 minutes of sample collection.
Fill cartridge directly from skin puncture	**Not Recommended**

PROCEDURE FOR CARTRIDGE TESTING

Preparation for Use:

1. Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.
2. All cartridges should be used immediately after opening pouch.
3. If the pouch has been punctured, the cartridge should not be used.
4. Do not return cartridges to the refrigerator after bringing them to room temperature.

How to Perform Patient Testing

1. From the Home screen, touch "**Perform Patient Test**". This initiates the patient testing pathway.
2. To begin, follow instructions on the screen to "**Scan or Enter OPERATOR ID**"
3. Follow instructions on the screen to "**Scan or Enter PATIENT ID**"
4. Continue to follow prompts on the screen to proceed with patient testing. "**Scan (CARTRIDGE POUCH) Barcode**", Scanning is required. Information cannot be entered manually.
5. The screen for selecting sample type will display if more than one sample type is applicable; select sample type if applicable.
6. Follow instructions on the screen to "**Close and Insert Filled Cartridge**". The action buttons at the bottom of the screen allow forward, backward and pause functionality.
7. Once the cartridge is inserted, "**Contacting Cartridge**" will display followed by the countdown bar. The following alerts are also displayed: **"Cartridge locked in instrument. Do not attempt to remove the Cartridge**" and "**Testing - Instrument Must Remain Level**".
8. When the test is complete, the test results are displayed.

Analysis Time

Approximately 130–200 seconds.

Quality Control

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

1. The i-STAT Alinity System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications.
2. Aqueous-based control solutions are available for verifying the integrity of newly received cartridges.
3. In addition, the instrument performs internal electronic checks and calibration during each test cycle, and the Electronic Simulator test provides an independent check on the ability of the instrument to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. The instrument will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the instrument software.

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

Calibration Verification

Standardization is the process by which a manufacturer establishes "true" values for representative samples. A multi-point calibration is derived for each sensor by this standardization process. These calibration curves are stable over many lots.

A one-point calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors' responses to the calibrant solution are measured. This one-point calibration adjusts the offset of the stored calibration curve. Next, the instrument automatically moves the sample over the sensors and the signals produced by the sensors' responses to the sample are measured. While coefficients are used rather than graphic calibration curves, the calculation of the result is equivalent to reading the sample's concentration from an adjusted calibration curve.

EXPECTED VALUES

TEST	UNITS *	REPORTABLE RANGE	REFERENCE RANGE *arterial*	REFERENCE RANGE *venous*
MEASURED				
Na	mmol/L (mEq/L)	100–180	138–146 [5]	
K	mmol/L (mEq/L)	2.0–9.0	3.5–4.9 [5] **	
Cl	mmol/L (mEq/L)	65–140	98–109 [5]	
Glu	mmol/L	1.1–38.9	3.9–5.8 [6]	
	mg/dL	20–700	70–105 [6]	
	g/L	0.20–7.00	0.70–1.05 [6]	
BUN/Urea Nitrogen	mg/dL	3–140	8–26 [5]	
Urea	mmol/L	1–50	2.9–9.4 [5]	
	mg/dL	6–300	17–56 [5]	
	g/L	0.06–3.00	0.17–0.56 [5]	
Hematocrit/Hct	% PCV ***	15–75	38–51 [5] ****	
	Fraction	0.15–0.75	0.38–0.51 [5]	
pH		6.50 - 8.20	7.35 - 7.45 [6]	7.31 - 7.41*****
PCO_2	mmHg	5 – 130	35 - 45 [6]	41 - 51
	kPa	0.67 – 17.33	4.67 - 6.00	5.47 - 6.80
CALCULATED				
AnGap	mmol/L	(-10)–(+99)	10–20 [6]	
Hemoglobin/Hb	g/dL	5.1–25.5	12–17 [5] ****	
	g/L	51–255	120–170 [5]	
	mmol/L	3.2–15.8	7–11 [5]	
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) [6]	(-2) – (+3) [6]

* 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 5 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. [1]

Unit Conversion

- **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.
- **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*CO$_2$:** To convert ***P***CO_2 results from mmHg to kPa, multiple the mmHg value by 0.133.

i-STAT Alinity does not have default reference ranges programmed into the instrument. The reference ranges 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 EC8+ 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) and Chloride (Cl)
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.

Glucose (Glu)
The i‑STAT System test for glucose measures glucose amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Glucose 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 SRM965. 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.

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, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. BUN/urea 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 SRM909. 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.

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.[7]

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*CO$_2$**

The i‑STAT System test for partial pressure of carbon dioxide measures the partial pressure of carbon dioxide in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. ***P***CO2 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 performance data summarized for Sodium, Glucose and Hematocrit was collected by professionals trained in the use of the i‑STAT Alinity System and comparative methods. The performance data summarized for all other tests listed below was collected at Abbott Point of Care. Representative cartridges were used to collect the data.

Precision*

A multiday precision study was performed with aqueous calibration verification materials in representative cartridges. Duplicates of each aqueous fluid were tested twice a day for 20 days.

Test	Units	Aqueous Cal Ver	n	Mean	SD (Standard Deviation)	CV (%) [Coefficient of Variation (%)]
Na	mmol/L or mEq/L	Very Low Abnormal	80	99.5	0.32	0.3
		Low Abnormal	80	121.2	0.32	0.3
		Normal	80	133.7	0.34	0.3
		High Abnormal	80	160.8	0.38	0.2
		Very High Abnormal	80	180.2	0.56	0.3
K	mmol/L	Very Low Abnormal	80	2.31	0.010	0.4
		Low Abnormal	80	2.90	0.015	0.5
		Normal	80	3.81	0.023	0.6
		High Abnormal	80	6.16	0.026	0.4
		Very High Abnormal	80	7.81	0.039	0.5
Cl	mmol/L	Very Low Abnormal	80	63.3	0.59	0.9
		Low Abnormal	80	72.9	0.71	1.0
		Normal	80	91.7	0.75	0.8
		High Abnormal	80	112.4	0.90	0.8
		Very High Abnormal	80	124.1	1.08	0.9
Glu	mg/dL	Very Low Abnormal	80	26.9	0.42	1.6
		Low Abnormal	80	41.0	0.34	0.8
		High Abnormal	80	125.0	0.32	0.3
		Very High Abnormal	80	286.7	0.77	0.3
		Highest Abnormal	80	600.6	3.47	0.6
BUN	mg/dL	Very Low Abnormal	80	4.6	0.19	4.1
		Low Abnormal	80	6.6	0.15	2.3

Test	Units	Aqueous Cal Ver	n	Mean	SD (Standard Deviation)	CV (%) [Coefficient of Variation (%)]
		Normal	80	11.5	0.19	1.6
		High Abnormal	80	54.3	0.66	1.2
		Very High Abnormal	80	108.4	1.07	1.0
Hct	%PCV	Very Low Abnormal	80	16.9	0.46	2.7
		Low Abnormal	80	33.9	0.51	1.5
		High Abnormal	80	55.2	0.49	0.9
		Very High Abnormal	80	65.0	0.39	0.6
pH		Very Low Abnormal	80	6.562	0.005	0.08
		Low Abnormal	80	7.031	0.004	0.06
		Normal	80	7.469	0.003	0.04
		High Abnormal	80	7.769	0.003	0.04
		Very High Abnormal	80	7.986	0.004	0.05
$\boldsymbol{P}CO_2$	mmHg	Very Low Abnormal	80	17.4	0.43	2.5
		Low Abnormal	80	21.7	0.40	1.8
		Normal	80	28.7	0.57	2.0
		High Abnormal	80	56.2	1.18	2.1
		Very High Abnormal	80	84.5	1.93	2.3

*Note: Representative data, individual laboratories may vary from these data.

Method Comparison

Method comparison was demonstrated in a study comparing the i-STAT Alinity to the i-STAT 1 Wireless (i-STAT 1W) using representative cartridges. The studies were based on CLSI guideline EP9-A3.[8] Whole blood samples anticoagulated with lithium heparin were evaluated. Samples were analyzed in duplicate on both systems. A weighted Deming regression analysis was performed using the first replicate result from the i-STAT Alinity versus the mean of the duplicates from the i-STAT 1W.

In the method comparison table, n is the number of specimens, and r is the correlation coefficient.

Test	Units		Comparative Method i-STAT 1W
Na	mmol/L	n	174
		Slope	1.0
		r	0.999
		intercept	-1
		X_{min}	115
		X_{max}	173
K	mmol/L	n	195
		Slope	1.00
		r	1.00
		intercept	-0.01
		X_{min}	2.0
		X_{max}	9.0

Test	Units		Comparative Method i-STAT 1W
Cl	mmol/L	n	189
		Slope	1.01
		r	0.999
		intercept	-0.76
		X_{min}	66
		X_{max}	140
Glu	mg/dL	n	188
		Slope	1.00
		r	1.000
		intercept	1.17
		X_{min}	24
		X_{max}	671
BUN/Urea	mg/dL	n	194
		Slope	1.01
		r	0.999
		intercept	-0.02
		X_{min}	3
		X_{max}	137
Hct	%PCV	n	229
		Slope	1.02
		r	0.993
		intercept	-0.36
		X_{min}	18
		X_{max}	70
pH		n	187
		Slope	0.990
		r	0.999
		intercept	0.075
		X_{min}	6.592
		X_{max}	8.189
$\boldsymbol{P}CO_2$	mmHg	n	149
		Slope	0.989
		r	0.999
		intercept	0.3
		X_{min}	5.1
		X_{max}	129.8

FACTORS AFFECTING RESULTS

The following substances were evaluated in plasma for relevant analytes at the test concentrations recommended in CLSI guideline EP7-A2 [9] 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 [10]	Glu	No	
Acetaminophen	1.32	Na	No	
		K	No	
		Cl	No	
		Glu	Yes	Increased results
		BUN	No	
Acetaminophen (therapeutic)	0.132 [10]	Glu	No	
Acetoacetate	2.0	Glu	No	
Acetylcysteine	10.2	Na	No	
		K	No	
		Cl	Yes	Increased results
		Glu	Yes	Decreased results
		BUN	No	
Acetylcysteine (therapeutic)	0.30 [11 12]	Cl	No	
		Glu	No	
Ascorbate	0.34	Na	No	
		K	No	
		Cl	No	
		Glu	No	
		BUN	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.
		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 [13 14 15]	Na	No	
		K	No	
		Cl	Yes	Increased results. Use another method.
		Glu	Yes	Decreased results
		BUN	No	
		Hct	No	
Dopamine	0.006	Glu	No	
Formaldehyde	0.133 [10]	Glu	No	
β-Hydroxybutyrate	6.0 [16]	Na	No	
		K	No	
		Cl	No	
		Glu	No	
		BUN	No	
Hydroxyurea	0.92	Glu	Yes	Increased results. Use another method.
		BUN	Yes	Increased results
Iodide	2.99	Cl	Yes	Increased results

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
	0.4	Cl	No	
Lactate	6.6	Na	No	
		K	No	
		Cl	No	
		Glu	No	
		BUN	No	
Magnesium Chloride	1.0	Na	No	
		K	No	
Maltose	13.3	Glu	No	
Nithiodote (Sodium thiosulfate)	16.7 [17]	Na	Yes	Increased results
		K	Yes	Decreased results
		Cl	Yes	Increased results
		Glu	Yes	Decreased results
		BUN	Yes	Decreased results
Pyruvate	0.31	Glu	No	
Salicylate	4.34	Na	No	
		K	No	
		Cl	Yes	Increased results. Use another method.
		Glu	No	
		BUN	No	
Salicylate (therapeutic)	0.5 [18]	Cl	No	
Thiocyanate	6.9	Cl	Yes	Increased results. Use another method
		Glu	Yes	Decreased results
		BUN	No	
Thiocyanate (therapeutic)	0.5 [10]	Glu	No	
Uric Acid	1.4	Glu	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, Nithiodote and Salicylate are noted below:

- Acetaminophen has been shown to interfere with i-STAT glucose results at a concentration proscribed by the CLSI guideline, 1.32 mmol/L, which represents a toxic concentration. Acetaminophen at 0.132 mmol/L, which represents the upper end of the therapeutic concentration, has been shown not to significantly interfere with i-STAT glucose 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.
- Hydroxyurea has been shown to interfere with glucose and BUN 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 [19], which equates to 3.1–6.3 mmol/L assuming the dose is fully distributed in a typical blood 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. [20] 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.
- Nithiodote (sodium thiosulfate) has been shown to interfere with sodium, potassium, chloride, glucose and BUN 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." [17]
- Salicylate has been shown to interfere with i-STAT chloride result 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.

OTHER FACTORS AFFECTING RESULTS

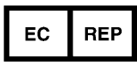
Factor	Analyte	Effect
Sodium heparin	Na	Sodium heparin may increase sodium results up to 1 mmol/L. [21]
Exposing the sample to air	pH	Exposing the sample to air allows CO_2 to escape which causes ***P*****C**O_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated.
	P**C**O_2	
	HCO_3	
	TCO_2	
Venous stasis	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.
Hemodilution	Na	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, 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).
	Cl	
	pH	
Cold temperature	K	Potassium values will increase in iced specimens.
Allowing blood to stand (without	K	If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time.

<table>
<tr><th>Factor</th><th>Analyte</th><th>Effect</th></tr>
<tr><td rowspan="5">exposure to air)</td><td>Glu</td><td>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. [22]</td></tr>
<tr><td>pH</td><td>pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour. [1]</td></tr>
<tr><td>$\boldsymbol{PCO_2}$</td><td>Standing anaerobically at room temperature will increase $\boldsymbol{PCO_2}$ by approximately 4 mmHg per hour.</td></tr>
<tr><td>HCO_3</td><td rowspan="2">Allowing blood to stand (without exposure to air) before testing allows $\boldsymbol{PCO_2}$ to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.</td></tr>
<tr><td>TCO_2</td></tr>
<tr><td>Sample type</td><td>K</td><td>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.</td></tr>
<tr><td>Sample mixing</td><td>Hct</td><td>Samples from 1 mL syringes should not be used to determine hematocrit if testing is delayed.</td></tr>
<tr><td>Hemolysis</td><td>K</td><td>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.</td></tr>
<tr><td rowspan="3">Under fill or partial draw</td><td>$\boldsymbol{PCO_2}$</td><td rowspan="3">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 $\boldsymbol{PCO_2}$, HCO_3 and TCO_2 values. Underfilling blood collection tubes may also cause decreased $\boldsymbol{PCO_2}$, 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.</td></tr>
<tr><td>HCO_3</td></tr>
<tr><td>TCO_2</td></tr>
<tr><td>pH dependence</td><td>Glu</td><td>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.</td></tr>
<tr><td>$\boldsymbol{PO_2}$ dependence</td><td>Glu</td><td>The dependence of the i-STAT glucose test with respect to $\boldsymbol{PO_2}$ is as follows: oxygen levels of less than 20 mmHg (2.66 kPa) at 37 °C may decrease results.</td></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>
</table></td></tr>
</table>

Factor	Analyte	Effect
		<table><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. [5] 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.
Sodium	Hct	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.
Clinical Conditions	Anion Gap	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, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.
	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.
Propofol (Diprivan®) or thiopental sodium	$\boldsymbol{P}CO_2$	The use of EC8+ cartridges is not recommended for patients administered propofol (Diprivan®) or thiopental sodium (syn. thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium [23]).
$\boldsymbol{P}O_2$ sensitivity	$\boldsymbol{P}CO_2$	In patient samples where the $\boldsymbol{P}O_2$ is > 100 mmHg above the normal range (80-105 mmHg), an increase in $\boldsymbol{P}CO_2$ of approximately 1.5 mmHg (with a range of 0.9 to 2.0 mmHg) may be observed for every 100 mmHg increase in $\boldsymbol{P}O_2$. For example, if an oxygenated patient has a measured $\boldsymbol{P}O_2$ of 200 mmHg, and a normal $\boldsymbol{P}O_2$ is 100 mmHg, the impact to the $\boldsymbol{P}CO_2$ result may be increased by approximately 1.5 mmHg.

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

KEY TO SYMBOLS

Symbol	Definition/Use
	14 days room temperature storage at 18–30 ^{0}C.
	Use by or expiration date. The expiration date, expressed as YYYY-MM-DD, indicates the last day the product may be used.
	Manufacturer's lot number or batch code. The lot number or batch code appears adjacent to this symbol.
	Sufficient for <n> tests.
	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.
	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 Abbott company website at www.globalpointofcare.abbott.

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