# i-STAT CG8+ Cartridge

Intended for use with the i-STAT Alinity Instrument


## NAME

i-STAT CG8+ Cartridge – REF 03P88-25

## INTENDED USE

The i-STAT CG8+ cartridge with the i-STAT Alinity System is intended for use in the *in vitro* quantification of sodium, potassium, ionized Calcium, glucose, hematocrit, pH, partial pressure of oxygen, 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. |
| 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. |
| 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.<br><br>Bicarbonate is used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. |
| Partial Pressure of Oxygen (***P***$O_2$) | |
| 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.

**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.

**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 Oxygen** (***P***$O_2$)

***P***$O_2$ (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).

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

***P***$CO_2$ 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]

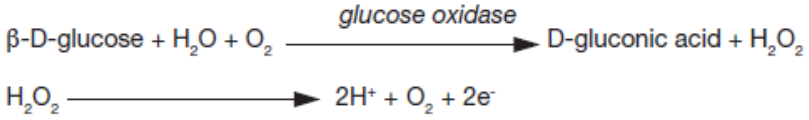
### Measured:

**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.

**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.




**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*$O_2$**

***P***$O_2$ 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$_2$**

***P*CO$_2$** 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$_2$CO$_3$). 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 ***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 ***P*CO$_2$** and reflects only the non-respiratory component of pH-disturbances.

  When a cartridge includes sensors for both pH and ***P*CO$_2$**, bicarbonate (HCO$_3$), total carbon dioxide (TCO$_2$) and base excess (BE) are calculated. [3]

  log HCO$_3$ = pH + log ***P*CO$_2$** - 7.608

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

**$sO_2$**

- $sO_2$ (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.

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

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

**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, 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 CG8+ cartridge is 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 |
| Glu | Glucose | N/A | 7 mmol/L |
| | Glucose Oxidase | *Aspergillus niger* | 0.002 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 i-STAT CG8+ 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: 95 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.**

| CG8+ Sample Collection | |
|---|---|
| Syringe | **Without anticoagulant**<br>• Maintain anaerobic conditions prior to filling this cartridge.<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 3 minutes of sample collection.<br><br>**With balanced heparin anticoagulant**<br>• Maintain anaerobic conditions prior to filling this cartridge.<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 10 minutes of sample collection. |
| Evacuated Tube | **Without anticoagulant**<br>• Maintain anaerobic conditions prior to filling this cartridge.<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 3 minutes of sample collection.<br><br>**With lithium heparin anticoagulant**<br>• Maintain anaerobic conditions prior to filling this cartridge.<br>• Mix sample immediately before filling cartridge.<br>• Fill cartridge within 10 minutes of sample collection. |
| Capillary Tube | **With balanced heparin anticoagulant**<br>• Mix sample immediately before filling cartridge.<br>• 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.pointofcare.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 [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] | |
| Glu | mmol/L | 1.1–38.9 | 3.9–5.8 [7] | |
| | mg/dL | 20–700 | 70–105 [7] | |
| | g/L | 0.20–7.00 | 0.70–1.05 [7] | |
| Hematocrit/Hct | % PCV *** | 15–75 | 38–51 [6] **** | |
| | Fraction | 0.15–0.75 | 0.38–0.51 [6] | |
| pH | | 6.50 - 8.20 | 7.35 - 7.45 [7] | 7.31 - 7.41****** |
| ***P***$O_2$ | mmHg | 5 - 800 | 80 - 105 [6] ***** | |
| | kPa | 0.7 – 106.6 | 10.7 - 14.0 [6] ***** | |
| ***P***$CO_2$ | mmHg | 5 - 130 | 35 - 45 [7] | 41 - 51 |
| | kPa | 0.67 – 17.33 | 4.67 - 6.00 | 5.47 - 6.80 |
| **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.
- **Glucose (Glu):** To convert mg/dL to mmol/L, multiply the mg/dL value by 0.055.
- **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 $K_3$EDTA or $K_2$EDTA anticoagulant. Mean cell volumes of $K_3$EDTA anticoagulated blood are approximately 2–4% less than $K_2$EDTA 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 $K_3$EDTA anticoagulant, the i-STAT System default customization is $K_3$EDTA.

- ***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.

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 CG8+ 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.

**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.

**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 partial pressure of oxygen measures the partial pressure of oxygen 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 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***$CO_2$ 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 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 |
| iCa | mmol/L | Very Low Abnormal | 80 | 0.32 | 0.006 | 2.0 |
| | | Low Abnormal | 80 | 0.82 | 0.008 | 1.0 |
| | | Normal | 80 | 1.29 | 0.012 | 1.0 |
| | | High Abnormal | 80 | 1.56 | 0.015 | 1.0 |
| | | Very High Abnormal | 80 | 2.38 | 0.027 | 1.1 |
| 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 |
| 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 |
| $PO_2$ | mmHg | Very Low Abnormal | 80 | 72.1 | 2.02 | 2.80 |
| | | Low Abnormal | 80 | 84.2 | 1.60 | 1.90 |
| | | Normal | 80 | 118.8 | 2.10 | 1.77 |
| | | High Abnormal | 80 | 152.1 | 3.49 | 2.29 |

| Test | Units | Aqueous Cal Ver | n | Mean | SD (Standard Deviation) | CV (%) [Coefficient of Variation (%)] |
|---|---|---|---|---|---|---|
| | | Very High Abnormal | 80 | 377.1 | 8.52 | 2.26 |
| ***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.[9] 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 |
| iCa | mmol/L | n | 194 |
| | | Slope | 1.005 |
| | | r | 1.000 |
| | | intercept | -0.001 |
| | | $X_{min}$ | 0.40 |
| | | $X_{max}$ | 2.44 |
| Glu | mg/dL | n | 188 |
| | | Slope | 1.00 |
| | | r | 1.000 |
| | | intercept | 1.17 |
| | | $X_{min}$ | 24 |
| | | $X_{max}$ | 671 |
| Hct | %PCV | n | 229 |
| | | Slope | 1.02 |
| | | r | 0.993 |
| | | intercept | -0.36 |
| | | $X_{min}$ (%PCV) | 18 |

| Test | Units | | Comparative Method i-STAT 1W |
|---|---|---|---|
| | | $X_{max}$ (%PCV) | 70 |
| pH | | n | 187 |
| | | Slope | 0.990 |
| | | r | 0.999 |
| | | intercept | 0.075 |
| | | $X_{min}$ | 6.592 |
| | | $X_{max}$ | 8.189 |
| ***P***$O_2$ | mmHg | n | 192 |
| | | Slope | 0.986 |
| | | r | 0.998 |
| | | intercept | 0.0 |
| | | $X_{min}$ | 9 |
| | | $X_{max}$ | 705 |
| ***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 [10] 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 [11] | Glu | No | |
| Acetaminophen | 1.32 | Na | No | |
| | | K | No | |
| | | iCa | Yes | Decreased results |
| | | Glu | No | |
| Acetaminophen (therapeutic) | 0.132 [11] | iCa | No | |
| | | Glu | No | |
| Acetylcysteine | 10.2 | Na | No | |
| | | K | No | |
| | | iCa | Yes | Decreased results |
| | | Glu | Yes | Decreased results |
| Acetylcysteine (therapeutic) | 0.3 [12 13] | iCa | No | |
| | | Glu | No | |
| Acetoacetate | 2.0 | Glu | No | |
| Ascorbate | 0.34 | Na | No | |
| | | K | No | |
| | | iCa | No | |
| | | Glu | No | |
| Bromide | 37.5 | Na | Yes | Increased results. Use another method. |

| Substance | Test Concentration (mmol/L) | Analyte | Interference (Yes/No) | Comment |
|---|---|---|---|---|
| | | K | Yes | Increased results and rate of star (***) outs. Use another method. |
| | | iCa | Yes | Increased results. Use another method. |
| | | Glu | Yes | Decreased results. Use another method. |
| | | Hct | Yes | Increased rate of star (***) outs |
| Bromide (therapeutic) | 2.5 [14 15 16] | Na | No | |
| | | K | No | |
| | | iCa | No | |
| | | Glu | Yes | Decreased results |
| | | Hct | No | |
| β-Hydroxybutyrate | 6.0 [17] | Na | No | |
| | | K | No | |
| | | iCa | No | |
| | | Glu | No | |
| Dopamine | 0.006 | Glu | No | |
| Formaldehyde | 0.133 [11] | Glu | No | |
| Hydroxyurea | 0.92 | Glu | Yes | Increased results. Use another method. |
| Lactate | 6.6 | Na | No | |
| | | K | No | |
| | | iCa | Yes | Decreased results by up to 0.07 mmol/L. |
| | | Glu | 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 | |
| Nithiodote (sodium thiosulfate) | 16.7 [18] | Na | Yes | Increased results |
| | | K | Yes | Decreased results |
| | | iCa | Yes | Decreased results |
| | | Glu | Yes | Decreased results |
| Pyruvate | 0.31 | Glu | No | |
| Salicylate | 4.34 | Na | No | |
| | | K | No | |
| | | iCa | Yes | Decreased results |
| | | Glu | No | |
| 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 |
| | | Glu | Yes | Decreased results |
| Thiocyanate (therapeutic) | 0.5 [11] | 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, Leflunomide, Nithiodote, and Salicylate are noted below:

    - Acetaminophen has been shown to interfere with i-STAT ionized calcium 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 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.
    - Hydroxyurea has been shown to interfere with glucose results at 0.92 mmol/L. Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including 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 patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.
    - Leflunomide has been shown to interfere with ionized calcium 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, ionized calcium and glucose 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." [18]
    - 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**

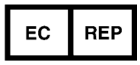
| Factor | Analyte | Effect |
|---|---|---|
| Sodium heparin | Na | Sodium heparin may increase sodium results up to 1 mmol/L. [21] |
| Venous stasis | iCa | Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid. [22] |
| | pH | Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid. |

| Factor | Analyte | Effect |
|---|---|---|
| Line draw | Hct | Low hematocrit results can be caused by contamination of flush solutions in arterial or venous lines.<br>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 the i-STAT system 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. |
| | ***P***$O_2$ | 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. |
| | ***P***$CO_2$ | |
| | $HCO_3$ | |
| | $TCO_2$ | |
| 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). |
| | iCa | |
| | pH | |
| 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. |
| | 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.[23] |
| | pH | pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour.[1] |
| | ***P***$O_2$ | Standing anaerobically at room temperature will decrease ***P***$O_2$ at a rate of 2–6 mmHg per hour.[1] |
| | ***P***$CO_2$ | Allowing blood to stand (without exposure to air) before testing will increase ***P***$CO_2$ by approximately 4 mmHg per hour. |
| | $HCO_3$ | Calculated $HCO_3$ and $TCO_2$ results are over-estimated, if blood is allowed to stand (without exposure to air), 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. |

<table>
<tr><th>Factor</th><th>Analyte</th><th>Effect</th></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>$\boldsymbol{P}CO_2$</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 $\boldsymbol{P}CO_2$, $HCO_3$ and $TCO_2$ values. Underfilling blood collection tubes may also cause decreased $\boldsymbol{P}CO_2$, $HCO_3$ 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.</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>$\boldsymbol{P}O_2$ dependence</td><td>Glu</td><td>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.</td></tr>
<tr><td>Method of calculation</td><td>$sO_2$</td><td>Calculated $sO_2$ values from a measured $\boldsymbol{P}O_2$ and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement. [3]</td></tr>
<tr><td>Clinical conditions</td><td>$HCO_3$</td><td>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.</td></tr>
<tr><td>Erythrocyte sedimentation</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.<br>• 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. [6] Total protein levels may also be decreased in patients undergoing cardiopulmonary bypass (CPB) or extracorporeal membrane oxygenation (ECMO) and with patients receiving large</td></tr>
</table>

| Factor | Analyte | Effect |
|---|---|---|
| | | 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).<br>• 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. |
| Propofol (Diprivan®) or thiopental sodium | ***P***$CO_2$ | The use of CG8+ cartridge is recommended, which is free from clinically significant interference at all relevant therapeutic doses. |
| ***P***$O_2$ sensitivity | ***P***$CO_2$ | In patient samples where the ***P***$O_2$ is > 100 mmHg above the normal range (80-105 mmHg), an increase in ***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 ***P***$O_2$.<br><br>For example, if an oxygenated patient has a measured ***P***$O_2$ of 200 mmHg, and a normal ***P***$O_2$ is 100 mmHg, the impact to the ***P***$CO_2$ result may be increased by approximately 1.5 mmHg. |

**KEY TO SYMBOLS**

| Symbol | Definition/Use |
|---|---|
|  | 2 months room temperature storage at 18-30$^0$C |
|  | Use by or expiration date.<br>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 |
|  | 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 company website at www.pointofcare.abbott.

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