i-STAT CG4+ Cartridge
Intended for use with the i-STAT Alinity Instrument

NAME

i-STAT CG4+ Cartridge – REF 03P85-50

INTENDED USE

The i-STAT CG4+ cartridge with the i-STAT Alinity System is intended for use in the *in vitro* quantification of pH, partial pressure of oxygen, partial pressure of carbon dioxide**,** and lactate in arterial or venous whole blood.

Analyte	Intended Use
pH	pH, PO$_2$, and PCO**$_2$** measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.
Partial Pressure of Oxygen *(P*O$_2$)	
Partial Pressure of Carbon Dioxide (*P*CO$_2$)	Bicarbonate is used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
Lactate	The i-STAT lactate test is useful for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

SUMMARY AND EXPLANATION / CLINICAL SIGNIFICANCE

Measured:
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.

Art: 765861-01 Rev. C   Rev. Date: 06-Nov-2020

Lactate (Lac)

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolemia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates. [2]

Hyperlactatemia is an indicator commonly used to detect tissue hypoperfusion, particularly in the case of sepsis, [3][4][5] but also in trauma [6][7][8] and surgical [9][10][11] settings.

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. [12]

Measured:

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

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

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

Lactate (Lac)

Lactate is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at a platinum electrode to produce a current which is proportional to the sample lactate concentration.

$$\text{L-Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Platinum electrode}} 2H^+ + O_2 + 2e^-$$
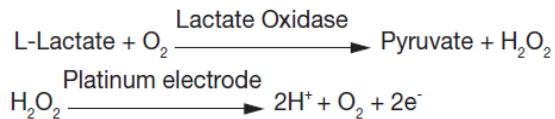
Temperature "Correction" Algorithm

pH, PO_2, and PCO_2 are temperature-dependent quantities and are measured at 37°C. The pH, PO_2, and PCO_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.

pH, PO_2, and PCO_2 at the patient's temperature (T_p) are calculated as follows : [13]

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

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

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

Calculated:
HCO₃, TCO₂, 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 PCO_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 PCO_2 according to a simplified and standardized form of the Henderson-Hasselbalch equation. [13]

- This calculated TCO_2 measurement is metrologically traceable to the i-STAT pH and PCO_2 measurements, which are in turn traceable to primary standard reference materials for pH and PCO_2. Like all calculated parameters reported by the i-STAT System, the user can independently determine TCO_2 values from the reported pH and PCO_2 measurements using a combination of the equation for HCO_3 and the equation for TCO_2 below.

- 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 PCO_2 of 40 mmHg at 37 °C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only the non-respiratory component of pH‑disturbances.

  When a cartridge includes sensors for both pH and PCO_2, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) are calculated. [13]

  $\log HCO_3 = pH + \log PCO_2 - 7.608$
  $TCO_2 = HCO_3 + 0.03 PCO_2$
  $BE_{ecf} = HCO_3 - 24.8 + 16.2(pH-7.4)$
  $BE_b = (1 - 0.014 \cdot Hb) \cdot [HCO3 - 24.8 + (1.43 \cdot Hb + 7.7) \cdot (pH - 7.4)]$

sO₂

- 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 PO_2 and pH and from HCO_3 calculated from measured PCO_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.

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

$$\text{where } X = PO_2 \cdot 10^{(0.48(pH-7.4)-0.0013(HCO_3 -25))}$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels in vivo. [14] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Art: 765861-01 Rev. C   Rev. Date: 06-Nov-2020

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 CG4+ cartridge is indicated below:

Sensor	Reactive Ingredient	Biological Source	Minimum Quantity
pH	Hydrogen Ion (H^+)	N/A	6.66 pH
PCO$_2$	Carbon Dioxide (CO_2)	N/A	25.2 mmHg
Lactate	Lactate	N/A	1.8 mmol/L
	Lactate Oxidase	*Aerococcus viridans*	0.001 IU

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 ℃ (35–46 ℉) until expiration date.
- Room Temperature at 18–30 ℃ (64–86 ℉). Refer to the cartridge box for room temperature storage requirements.

INSTRUMENTS

The i-STAT CG4+ cartridge is intended for use with the i-STAT Alinity Instrument (Model No. AN-500).

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Arterial or venous whole blood.
Sample Volume: 95 µL

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

CG4+ Sample Collection	
Syringe	**Without anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Fill cartridge immediately after sample collection **With balanced heparin anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Fill cartridge immediately after sample collection.
Evacuated Tube	**Without anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Fill cartridge immediately after sample collection. **With lithium heparin anticoagulant** • Maintain anaerobic conditions prior to filling this cartridge. • Fill cartridge immediately after 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)*	*(venous)*
MEASURED				
pH		6.50 - 8.20	7.35 - 7.45 [15]	7.31 - 7.41**
PO$_2$	mmHg	5 - 800	80 - 105 [16***]	
	kPa	0.7 – 106.6	10.7 - 14.0 [16***]	
PCO$_2$	mmHg	5 - 130	35 - 45 [15]	41 - 51
	kPa	0.67 – 17.33	4.67 - 6.00	5.47 - 6.80
Lac	mmol/L	0.30 - 20.00	0.36 - 1.25 [2****]	0.90 - 1.70 [2****]
	mg/dL	2.7 – 180.2	3.2 - 11.3 [2****]	8.1 - 15.3 [2****]
CALCULATED				
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) [15]	(-2) – (+3) [15]
sO$_2$	%	0-100	95 - 98	

*   The i-STAT System can be configured with the preferred units. Not applicable for pH test.
**   Calculated from Siggard-Andersen nomogram. [1]
***   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).
**** The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

Unit Conversion
- **PO$_2$ and PCO$_2$:** To convert PO$_2$ and PCO$_2$ results from mmHg to kPa, multiple the mmHg value by 0.133.
- **Lactate/Lac:** To convert a Lactate result from mmol/L to mg/dL, multiply the mmol/L value by 9.01.

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 CG4+ 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.

pH

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

PO_2

The i‑STAT System test for partial pressure of oxygen measures the partial pressure of oxygen in arterial or venous whole blood (dimension kPa) for *in vitro* diagnostic use. PO_2 values assigned to the 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.

PCO_2

The i‑STAT System test for partial pressure of carbon dioxide measures the partial pressure of carbon dioxide in arterial or venous whole blood (dimension kPa) for *in vitro* diagnostic use. PCO_2 values assigned to the 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.

Lactate/Lac

The i-STAT System test for lactate measures L-lactate amount-of-substance concentration in the plasma fraction of arterial or venous whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Presently, no international conventional reference measurement procedure or international conventional calibrator for lactate is available. Lactate values assigned to the i-STAT System controls and calibration verification materials are traceable to i-STAT System working calibrator prepared from sodium L-lactate (Sigma-Aldrich Fluka, >99 % purity).

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

PERFORMANCE CHARACTERISTICS

The performance data summarized 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 (%)]
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
		Very High Abnormal	80	377.1	8.52	2.26
PCO_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
Lac	mmol/L	Very Low Abnormal	80	0.45	0.01	2.44

Test	Units	Aqueous Cal Ver	n	Mean	SD (Standard Deviation)	CV (%) [Coefficient of Variation (%)]
		Low Abnormal	80	0.86	0.01	1.16
		Normal	80	2.12	0.01	0.52
		High Abnormal	80	7.68	0.06	0.74
		Very High Abnormal	80	17.40	0.25	1.44

*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. [17] 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
pH		n	187
		Slope	0.990
		r	0.999
		intercept	0.075
		X_{min}	6.592
		X_{max}	8.189
PO_2	mmHg	n	192
		Slope	0.986
		r	0.998
		intercept	0.0
		X_{min}	9
		X_{max}	705
PCO_2	mmHg	n	149
		Slope	0.989
		r	0.999
		intercept	0.3
		X_{min}	5.1
		X_{max}	129.8
Lac	mmol/L	n	186
		Slope	0.99
		r	1.000
		intercept	0.01
		X_{min} (%PCV)	0.41
		X_{max} (%PCV)	19.54

FACTORS AFFECTING RESULTS

The following substances were evaluated in plasma for relevant analytes at the test concentrations recommended in CLSI guideline EP7-A2 [18] 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 [19]	Lactate	No	

Substance	Test Concentration (mmol/L)	Analyte	Interference (Yes/No)	Comment
Acetaminophen	1.32	Lactate	No	
Acetylcysteine	10.2	Lactate	No	
Ascorbate	0.34	Lactate	No	
Bromide	37.5	Lactate	Yes	Decreased results. Use another method.
Bromide (therapeutic)	2.5 [20] [21] [22]	Lactate	No	
Dopamine	0.006	Lactate	No	
Formaldehyde	0.133 [19]	Lactate	No	
Glycolic Acid	10.0 [19]	Lactate	Yes	Increased i-STAT lactate results. Use another method.
Hydroxyurea	0.92	Lactate	Yes	Increased i-STAT lactate results. Use another method.
β-Hydroxybuterate	6.0 [23]	Lactate	No	
Pyruvate	0.31	Lactate	No	
Salicylate	4.34	Lactate	No	
Uric Acid	1.4	Lactate	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 Bromide, Glycolic acid and Hydroxyurea are noted below:

  o 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. Bromide at a concentration of 37.5 mmol/L decreased i-STAT lactate results, while a therapeutic range of bromide (2.5 mmol/L) did not significantly interfere with i-STAT lactate results.

  o Glycolic acid is a product of ethylene glycol metabolism. Unexpected increased lactate concentrations caused by glycolic acid may be a clue to the possibility of ethylene glycol ingestion as the cause of an otherwise unknown high anion gap metabolic acidosis. [24] [25] In a study of 35 patients who had ingested ethylene glycol, initial glycolic acid concentrations of 0 to 38 mmol/L corresponded to ethylene glycol levels of 0.97 – 130.6 mmol/L. [25]

  o Hydroxyurea has been shown to interfere with Lactate. 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.

OTHER FACTORS AFFECTING RESULTS

Factor	Analyte	Effect
Exposing the sample to air	PO_2	Exposure of the sample to air will cause an increase in PO_2 when values are below 150 mmHg and a decrease in PO_2 when values are above 150 mmHg (approximate PO_2 of room air).
	pH PCO_2 HCO_3 TCO_2	Exposing the sample to air allows CO_2 to escape which causes PCO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated.
Venous stasis	pH	Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid.
Hemodilution	pH	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).
Cold temperature	PO_2	Do not ice samples before testing - PO_2 results may be falsely elevated in cold samples. Do not use a cold cartridge - PO_2 results may be falsely decreased if the cartridge is cold.
Sample collection	Lactate	Special collection procedures are necessary to prevent changes in lactate both during and after the blood is drawn. For steady state lactate concentrations, patients should be at rest for 2 hours and fasting. Venous samples should be obtained without the use of a tourniquet or immediately after the tourniquet is applied. Both venous and arterial samples may be collected into heparinized syringes.
Allowing blood to stand (without exposure to air)	pH	pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour. [1]
	PO_2	Standing anaerobically at room temperature will decrease PO_2 at a rate of 2–6 mmHg per hour. [1]
	PCO_2	Standing anaerobically at room temperature will increase PCO_2 by approximately 4 mmHg per hour.
	HCO_3 TCO_2	Allowing blood to stand (without exposure to air) before testing allows PCO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.
	Lactate	Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25 ºC as a result of glycolysis. [2]
Under fill or partial draw	PCO_2 HCO_3 TCO_2	The use of partial draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g., a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended due to the potential for decreased PCO_2, HCO_3 and TCO_2 values. Underfilling blood collection tubes may also cause decreased 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.
Method of calculation	sO_2	Calculated sO_2 values from a measured PO_2 and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement. [13]
Clinical conditions	HCO_3	Causes of primary metabolic acidosis (decrease calculated HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase calculated HCO_3) are vomiting and antacid treatment.
Propofol (Diprivan®) or thiopental sodium	PCO_2	The use of CG4+ cartridge is recommended, which is free from clinically significant interference at all relevant therapeutic doses.
PO_2 sensitivity	PCO_2	In patient samples where the PO_2 is > 100 mmHg above the normal range (80-

Factor	Analyte	Effect
		105 mmHg), an increase in PCO$_2$ of approximately 1.5 mmHg (with a range of 0.9 to 2.0 mmHg) may be observed for every 100 mmHg increase in PO$_2$. For example, if an oxygenated patient has a measured PO$_2$ of 200 mmHg, and a normal PO$_2$ is 100 mmHg, the impact to the PCO$_2$ result may be increased by approximately 1.5 mmHg.

KEY TO SYMBOLS

Symbol	Definition/Use
2 m	2 months room temperature storage at 18-30^{0}C
(hourglass symbol)	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used.
LOT	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
Σ (sufficient for tests symbol)	Sufficient for \<n\> tests
EC REP	Authorized representative for Regulatory Affairs in the European Community.
(thermometer symbol)	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
REF	Catalog number, list number, or reference
(do not reuse symbol)	Do not reuse.
(manufacturer symbol)	Manufacturer
(consult IFU symbol)	Consult instructions for use or see System Manual for instructions.
IVD	*In vitro* diagnostic medical device
CE	Compliance to the European directive on *in vitro* diagnostic devices (98/79/EC)
Rx ONLY	For prescription use only.

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

References

1. Pruden EL, Siggard-Andersen O, Tietz NW. Blood Gases and pH. In: C.A. Burtis and E.R. Ashwood, ed. *Tietz Textbook of Clinical Chemistry*. Second Edition ed. Philadelphia: W.B. Saunders Company; 1994.

2. Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, eds. *Tietz Textbook of Clinical Chemistry*. 2nd ed. Philadelphia: W.B. Saunders Company; 1994.

3. Jones AE, Puskarich MA. Sepsis-Induced Tissue Hypoperfusion. *Critical Care Clinics*. October 2009;25(4):769-779.

4. Dellinger RP, Levy MM, Carlet JM, et al. Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock: 2008. *Intensive Care Medicine*. January 2008;34(1):17-60.

5. Shapiro NI, Fisher C, Donnino M, et al. The Feasibility and Accuracy of Point-of-Care Lactate Measurement in Emergency Department Patients with Suspected Infection. *Journal of Emergency Medicine*. July 2010;39(1):89-94.

6. Crowl ACM, Young JSM, Kahler DMM, Claridge JAM, Chrzanowski DSB, Pomphrey MR. Occult Hypoperfusion Is Associated with Increased Morbidity in Patients Undergoing Early Femur Fracture Fixation. *J Trauma*. 2000;48(2):260-267.

7. Paladino L, Sinert R, Wallace D, Anderson T, Yadav K, Zehtabchi S. The utility of base deficit and arterial lactate in differentiating major from minor injury in trauma patients with normal vital signs. *Resuscitation*. June 2008;77(3):363-368.

8. Blow, Osbert MD P, Magliore LB, Claridge JAM, Butler KR, Young JSM. The Golden Hour and the Silver Day: Detection and Correction of occult hypoperfusion within 24 hours improves outcome from major trauma. *Journal of Trauma and Acute Care Surgery*. 1999;47(5):964.

9. Bakker J, De Lima AP. Increased blood lacate levels: An important warning signal in surgical practice

10. Husain FA, Martin MJ, Mullenix PS, Steele SR, Elliott DC. Serum lactate and base deficit as predictors of mortality and morbidity. Paper presented at: American Journal of Surgery, 2003.

11. Rossi AF, Khan DM, Hannan R, Bolivar J, Zaidenweber M, Burke R. Goal-directed medical therapy and point-of-care testing improve outcomes after congenital heart surgery. *Intensive Care Med.* 2005;31(1):98-104.

12. Tietz NW, Pruden EL, Siggaard-Andersen O. Electrolytes. In: C.A. Burtis and E.R. Ashwood, ed. *Tietz Textbook of Clinical Chemistry*. Second Edition ed. Philadelphia: W.B. Saunders Company; 1994.

13. CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guideline. *CLSI document C46-A*. 2001.

14. Young DS. *Effects of Drugs on Clinical Laboratory Tests*. 3rd ed. ed. Washington, DC: American Association of Clinical Chemistry; 1990.

15. Painter PC, Cope JY, Smith JL. Reference Ranges, Table 41–20. In: C.A. Burtis and E.R. Ashwood, ed. *Tietz Textbook of Clinical Chemistry*. Second Edition ed. Philadelphia: W.B. Saunders Company; 1994.

16. Statland BE. *Clinical Decision Levels for Lab Tests*. Oradell, NJ: Medical Economic Books; 1987.

17. Clinical and Laboratory Standards Institute (CLSI). Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition. *CLSI document EP09-A3*. 2013.

18. Clinical and Laboratory Standards Institute. Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition. *CLSI document EP7-A2*. 2005.

19. Wu AHB. *Tietz Clinical Guide to Laboratory Tests*: Elsevier Health Sciences; 2006.

20. Hankins DC, Kharasch ED. Determination of the halothane metabolites trifluoroacetic acid and bromide in plasma and urine by ion chromatography. *Journal of Chromatography B: Biomedical Applications*. May 1997;692(2):413-418.

21. Kharasch ED, Hankins D, Mautz D, Thummel KE. Identification of the enzyme responsible for oxidative halothane metabolism: Implications for prevention of halothane hepatitis. *Lancet*. May 1996;347(9012):1367-1371.

22. Morrison JE, Friesen RH. Elevated serum bromide concentrations following repeated halothane anaesthesia in a child. *Canadian Journal of Anaesthesia*. October 1990;37(7):801-803.

23. Charles RA, Bee YM, Eng PHK, Goh SY. Point-of-care blood ketone testing: Screening for diabetic ketoacidosis at the emergency department. *Singapore Medical Journal*. November 2007;48(11):986-989.

24. Morgan TJ, Clark C, Clague A. Artifactual elevation of measured plasma L-lactate concentration in the presence of glycolate. *Crit Care Med*. 1999;27(10):2177-2179.

25. Porter WH, Crellin M, Rutter PW, Oeltgen P. Interference by Glycolic Acid in the Beckman Synchron Method for Lactate: A Useful Clue for Unsuspected Ethylene Glycol Intoxication. *Clin Chem*. 2000;46(6):874-875.

i-STAT is a trademark of the Abbott Group of companies.

Diprivan is a registered trademark of the AstraZeneca group of companies.

Abbott Point of Care Inc.
100 and 200 Abbott Park Road
Abbott Park, IL 60064 • USA

| EC | REP | EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands |

CE IVD

Rx ONLY

©2019 Abbott Point of Care Inc. All rights reserved. Printed in USA.

Abbott