i-STAT G3+ Cartridge

Intended for use with the i-STAT Alinity Instrument

NAME

i-STAT G3+ Cartridge – REF 03P78-25

INTENDED USE

The i-STAT G3+ cartridge with the i-STAT Alinity System is intended for use in the *in vitro* quantification of pH, partial pressure of oxygen, and partial pressure of carbon dioxide in arterial, venous or capillary whole blood.

Analyte	Intended Use
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. 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:

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)

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

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:

pH

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

***P*O₂**

***P*O₂** 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*CO₂**

***P*CO₂** is measured by direct potentiometry. In the calculation of results for ***P*CO₂**, concentration is related to potential through the Nernst equation.

Temperature "Correction" Algorithm

pH, ***P*O₂**, and ***P*CO₂** are temperature-dependent quantities and are measured at 37°C. The pH, ***P*O₂**, and ***P*CO₂** 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, ***P*O₂**, and ***P*CO₂** at the patient's temperature (T_p) are calculated as follows: [3]

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

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

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

Calculated:

HCO_3, TCO_2, and BE

- HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance.
- TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, bicarbonate (HCO_3) or carbonate (CO_3) anions, and carbonic acid (H_2CO_3). Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and ***P*CO₂**) 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*CO₂** 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*CO₂** measurements, which are in turn traceable to primary standard reference materials for pH and ***P*CO₂**. Like all calculated parameters reported by the i-STAT System, the user can independently determine TCO2 values from the reported pH and ***P*CO₂** measurements using a combination of the equation for HCO_3 given in the ***P*CO₂**.

- 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]

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

sO_2

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

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

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

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, 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 G3+ cartridge is indicated below:

Sensor	Reactive Ingredient	Biological Source	Minimum Quantity
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 G3+ 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, 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 collections tubes and syringes to capacity, following manufacturers' instructions.

G3+ 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.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 [5]	7.31 -7.41**
PO_2	mmHg	5 - 800	80 - 105 [6]***	
	kPa	0.7 – 106.6	10.7 - 14.0 [6]***	
PCO_2	mmHg	5 - 130	35 - 45 [5]	41 – 51
	kPa	0.67 – 17.33	4.67 - 6.00	5.47 - 6.80
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) [5]	(-2) – (+3) [5]
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).

Unit Conversion:

- ***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 G3+ 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, venous or capillary whole blood (expressed as the negative logarithm of the relative molal hydrogen ion activity) for *in vitro* diagnostic use. pH values assigned to i-STAT System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference materials SRMs 186-I, 186-II, 185, and 187.

***P*O_2**

The i‑STAT System test for oxygen partial pressure 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*CO₂**

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

Precision*

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

Test	Units	Aqueous 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

*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. [7] 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

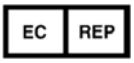
Test	Units		Comparative Method i-STAT 1W
		r	0.999
		intercept	0.075
		X_{min}	6.592
		X_{max}	8.189
PO_2	mmHg	n	192
		Slope	0.986
		r	0.998
		intercept	0.0
		X_{min}	9
		X_{max}	705
PCO_2	mmHg	n	149
		Slope	0.989
		r	0.999
		intercept	0.3
		X_{min}	5.1
		X_{max}	129.8

FACTORS AFFECTING RESULTS

Factor	Analyte	Effect
Exposing the sample to air	***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.
	PCO_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.
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	***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.
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 ***P***O_2 at a rate of 2–6 mmHg per hour. [1]
	PCO_2	Standing anaerobically at room temperature will increase ***P***CO_2 by approximately 4 mmHg per hour.
	HCO_3	Allowing blood to stand (without exposure to air) before testing allows ***P***CO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.
	TCO_2	
Under fill or partial draw	***P***CO_2	The use of partial draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g., a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended due to the potential for decreased ***P***CO_2, HCO_3 and TCO_2 values. Underfilling blood collection tubes may also cause decreased ***P***CO_2, HCO_3 and TCO_2 results. Care must be
	HCO_3	
	TCO_2	

Factor	Analyte	Effect
		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 ***P***O_2 and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement. [3]
Clinical conditions	HCO_3	Causes of primary metabolic acidosis (decrease calculated HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase calculated HCO_3) are vomiting and antacid treatment.
Propofol (Diprivan®) or thiopental sodium	***P***CO_2	The use of G3+ cartridge is recommended, which is free from clinically significant interference at all relevant therapeutic doses.
PO_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. 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. 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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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

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