

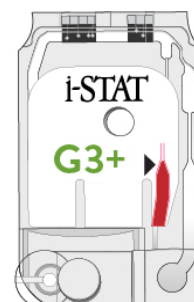


i-STAT G3+ Cartridge

Intended for US only

NAME

i-STAT G3+ Cartridge – REF 03P78-26



INTENDED USE

The i-STAT G3+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of pH, partial pressure of oxygen (PO_2) and partial pressure of carbon dioxide (PCO_2) in arterial, venous or capillary whole blood in point of care or clinical laboratory settings.

Test	Intended Use
pH	pH, PO_2 , and PCO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic and acid-base disturbances.
Partial Pressure of Oxygen (PO_2)	
Partial Pressure of Carbon Dioxide (PCO_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 (PO_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 PO_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 (PCO_2)

PCO_2 (partial pressure of carbon dioxide) along with pH is used to assess acid-base balance. PCO_2 , the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. PCO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in PCO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in PCO_2) are airway obstruction, sedatives and anesthetics,

respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased PCO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

TEST PRINCIPLE

Measured:

pH

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

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 ²:

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

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

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

Calculated:

HCO_3 , TCO_2 , and BE

- Bicarbonate (HCO_3), 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.
- Total Carbon Dioxide (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.²
- Base excess (BE) 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 , HCO_3 , TCO_2 and BE are calculated.²

$$\log \text{HCO}_3 = \text{pH} + \log \text{PCO}_2 - 7.608$$

$$\text{TCO}_2 = \text{HCO}_3 + 0.03\text{PCO}_2$$

$$\text{BE}_{\text{ecf}} = \text{HCO}_3 - 24.8 + 16.2(\text{pH} - 7.4)$$

$$\text{BE}_b = (1 - 0.014 \cdot \text{Hb}) * [\text{HCO}_3 - 24.8 + (1.43 * \text{Hb} + 7.7) * (\text{pH} - 7.4)]$$

sO₂

- Oxygen saturation (sO₂) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).
- sO₂ is calculated from measured PO_2 and pH and from HCO_3 calculated from measured PCO_2 and pH.³ 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 sO₂ value for oxygen saturation in further calculations, such as shunt fraction, or by assuming the value obtained is equivalent to fractional oxyhemoglobin.

$$\text{sO}_2 = 100 \frac{(X^3 + 150X)}{X^3 + 150X + 23400}$$

where $X = \text{PO}_2 \cdot 10^{[0.48(\text{pH} - 7.4) - 0.0013(\text{HCO}_3 - 25)]}$

REAGENTS

Contents

Each i-STAT G3+ cartridge contains a reference electrode, a ground electrode, potentiometric sensors and an amperometric sensor for the measurement of specific analytes. It also contains 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
PCO_2	Carbon Dioxide (CO ₂)	N/A	25.2 mmHg

Warnings and Precautions

- For *in vitro* diagnostic use.
- DO NOT RE-USE - cartridges are intended for single-use only.

- Although the sample is contained within the cartridge, cartridges should be disposed as biohazardous waste according to local, state, and national regulatory guidelines.
- The i-STAT 1 System automatically runs a comprehensive set of quality checks of instrument and cartridge performance each time a sample is tested. This internal quality system will suppress results by generating a Quality Check Code (QCC) if the instrument or cartridge does not meet certain specifications. To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the instrument or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. Where unavailability of results while awaiting replacement of instruments or cartridges is unacceptable, Abbott Point of Care Inc. recommends maintaining both a backup analyzer and cartridges from an alternate lot number.
- Use a puncture device that provides free-flowing blood.
- Improperly filling and/or closing the cartridges may result in Quality Check Codes and/or inability to obtain results.

For additional warnings and precautions about the i-STAT 1 System refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

Storage Conditions

- Refrigerated at 2-8°C (35-46°F) until expiration date.
- Room Temperature at 18-30°C (64-86°F). Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.

INSTRUMENTS

The i-STAT G3+ cartridge is intended for use with the i-STAT 1 analyzer.

For a detailed description of the instrument and system procedures, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Arterial, venous or capillary whole blood.

Sample Volume: 95 µL

Blood Collection Options and Test Timing (time from collection to cartridge fill)

Analyte	Syringes*	Test Timing	Evacuated Tubes	Test Timing	Capillary	Test Timing
pH PCO ₂ PO ₂	Without anticoagulant	3 minutes	Without anticoagulant	3 minutes	With balanced heparin	3 minutes
	With balanced heparin anticoagulant or lithium heparin	10 minutes	With lithium heparin anticoagulant (tubes must be filled to	10 minutes	anticoagulant or lithium heparin (tubes must be filled to labeled capacity)**	

Analyte	Syringes*	Test Timing	Evacuated Tubes	Test Timing	Capillary	Test Timing
	anticoagulant (syringe must be filled to labeled capacity)** <ul style="list-style-type: none"> Maintain anaerobic conditions Remix thoroughly before filling cartridge. 		labeled capacity)** <ul style="list-style-type: none"> Maintain anaerobic conditions. Remix thoroughly before filling cartridge 			

*Do Not Use Heparin lock flush solution syringes

**Fill blood collection devices to capacity. Underfilling will cause higher heparin to blood ratios which may affect results.

Note: Do not use blood collection or transfer devices that would introduce air into the sample when pH, PCO_2 or PO_2 are being measured.

PROCEDURE FOR CARTRIDGE TESTING

Each cartridge is sealed in a foil pouch for protection during storage--do not use if pouch has been punctured.

- A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). For best results, the cartridge and analyzer should be at room temperature.
- Since condensation on a cold cartridge may prevent proper contact with the analyzer, allow refrigerated cartridges to equilibrate at room temperature for 5 minutes for a single cartridge and 1 hour for an entire box before use.
- Use a cartridge immediately after removing it from its protective pouch. Prolonged exposure may cause a cartridge to fail a Quality Check.
- Do not return unopened, previously refrigerated cartridges to the refrigerator.
- Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.

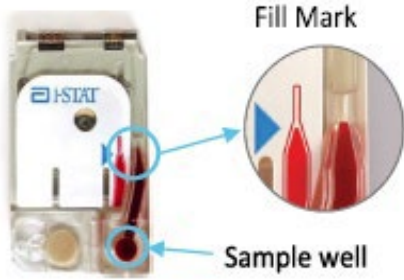


Filling and Sealing the Cartridge (after cartridge has been equilibrated and blood sample has been collected)




- Place the cartridge on a flat surface.
- Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds. The blood in the hub of the syringe will not mix, therefore expelling 2 drops before filling a cartridge is recommended. Note that it may be difficult to properly mix a sample in a 1.0 mL syringe.
- Fill the cartridge immediately. Direct the hub of syringe or tip of the transfer device (capillary tube, pipette or dispensing tip) into the sample well of the cartridge.
- Slowly dispense sample into the sample well until the sample reaches the fill mark indicated on the cartridge. Cartridge is properly filled when the sample reaches the 'fill to' mark and a

small amount of sample is in the sample well. The sample should be continuous, no bubbles or breaks (see System Manual for details).

5. Fold the snap closure of the cartridge over the sample well.

Note: Every effort should be made to fill cartridges properly before inserting into the analyzer. The illustrations below are provided for to support proper cartridge filling using representative cartridges

Properly filled cartridge	<p>The sample fills the sample chamber to the fill mark indicator</p>  <p>Full sample well, and no bubble appears in the sample pathway.</p> 
Underfilled cartridge	<p>The sample well is sufficiently filled, but the sample does not reach the fill mark indicator</p> 

	<p>The sample well is insufficiently filled, and the sample does not reach the fill mark indicator.</p> 
<p>Overfilled cartridge</p>	<p>The sample well is overfilled, the sample exceeds the fill mark indicator</p>  <p>The sample well is overfilled, there is a bubble in the sample well.</p> 

Performing Patient Analysis

1. Press the power button to turn on the analyzer.
2. Press 2 for *i-STAT Cartridge*.
3. Follow the analyzer prompts.
4. Scan the lot number on the cartridge pouch.
5. Continue normal procedures for preparing the sample, and filling and sealing the cartridge.
6. Push the sealed cartridge into the analyzer port until it clicks into place. Wait for the test to complete.
7. Review the results.

For additional information for cartridge testing, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

Analysis Time

Approximately 130–200 seconds

Quality Control

The i-STAT quality control regimen has four aspects, with a system design that reduces the opportunity for error, including:

1. A series of automated, on-line quality measurements that monitor the sensors, fluidics and instrumentation each time a test is performed.
2. A series of automated, on-line procedural checks monitors the user each time a test is performed.
3. Liquid materials are available to be used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question.
4. Traditional quality control measurements verify the instrumentation using an independent device, which simulates the characteristics of the electrochemical sensors in a way which stresses the performance characteristics of the instrumentation.

Each laboratory should follow local, state and national regulations regarding quality control materials.

For additional information on Quality Control, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

Calibration Verification

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid-levels.

For additional information on Calibration Verification, refer to the i-STAT 1 System Manual located at www.globalpointofcare.abbott.

EXPECTED VALUES

TEST	UNITS *	REPORTABLE RANGE [†]	REFERENCE RANGE	
			arterial	venous
MEASURED				
pH	pH units	6.50 - 7.80	7.35 - 7.45 ⁴	7.31 - 7.41 **
PO ₂	mmHg	5 - 700	80 - 105 ^{5***}	–
	kPa	0.7 - 93.3	10.7 - 14.0 ^{5***}	–
PCO ₂	mmHg	5 - 130	35 – 45 ⁴	41 - 51 ⁴
	kPa	0.67 - 17.33	4.67 - 6.00	5.47 - 6.80
CALCULATED				
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**
BE	mmol/L (mEq/L)	(-30) - (+30)	(-2) - (+3) ⁴	(-2) - (+3) ⁴
sO ₂	%	0-100	95 – 98 ⁵	–

* The i-STAT 1 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

- ***PO₂* and *PCO₂***: To convert *PO₂* and *PCO₂* results from mmHg to kPa, multiply the mmHg value by 0.133.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, sex, race, and ethnicity, 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 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

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.

PO₂

PO₂ 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.

PCO₂

PCO₂ 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.

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

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

PERFORMANCE CHARACTERISTICS

The typical performance of the i-STAT G3+ cartridge with the i-STAT 1 System are shown below.

Precision

Precision data was collected in studies based on CLSI guideline EP05-A3⁶. The precision study was conducted using five (5) levels of aqueous materials for pH, *PO₂* and *PCO₂*. Duplicates of each level were tested twice a day for a minimum of 20 days.

The statistics for Mean, Standard Deviation (SD) and Coefficient of Variation (CV) are represented below. This is representative data; results in individual laboratories may vary.

Test	Units	Fluid Level	N	Mean	SD	CV (%)
pH	pH units	CV L1	81	6.5796	0.00541	0.08
		CV L2	82	7.0335	0.00411	0.06
		CV L3	85	7.4611	0.00291	0.04
		CV L4	80	7.6425	0.00364	0.05
		CV L5	80	7.9702	0.00351	0.04
PO_2	mmHg	CV L1	81	75.7	2.45	3.24
		CV L2	82	87.9	2.18	2.48
		CV L3	85	115.5	2.88	2.49
		CV L4	80	146.0	4.27	2.92
		CV L5	81	388.7	11.29	2.90
PCO_2	mmHg	CV L1	81	89.21	1.505	1.69
		CV L2	82	56.43	0.571	1.01
		CV L3	85	29.32	0.324	1.11
		CV L4	80	22.48	0.393	1.75
		CV L5	80	12.06	0.331	2.75

Whole blood precision was evaluated using arterial, venous and capillary¹ whole blood specimens collected with lithium heparin. The repeatability analysis was conducted using the data collected across multiple point of care sites. For each sample type, samples were grouped into subintervals based on their mean values. Results are summarized for data with outliers excluded and with outliers included below.

¹ The capillary whole blood clinical precision study design involved the performance of two individual fingersticks, collected independently by two operators into two separate capillary tubes and tested on two (2) i-TAT G3+ cartridges.

Outliers excluded

Test	Units	Sample Type	Sample Range	N	Mean	SD	CV (%)
pH	pH units	Venous Whole Blood	6.500-7.300	24	7.1110	0.00593	0.08
			>7.300-7.450	108	7.3799	0.00591	0.08
			>7.450-7.800	9	7.5634	0.00856	0.11
		Arterial Whole Blood	6.500-7.300	6	7.2402	0.00877	0.12
			>7.300-7.450	104	7.3894	0.00913	0.12
			>7.450-7.800	26	7.4889	0.00701	0.09
		Capillary Whole Blood	6.500-7.300	1	7.2930	0.00000	0.00
			>7.300-7.450*	113	7.4110	0.01747	0.24
			>7.450-7.800*	43	7.4760	0.01696	0.23
PO ₂	mmHg	Venous Whole Blood	10-40	96	26.6	1.03	3.87
			>40-50	22	44.8	1.11	2.47
			>50-100	14	68.1	1.60	2.35
			>100-250	3	176.7	2.89	1.63
			>250-700	7	557.3	10.14	1.82
		Arterial Whole Blood	10-40	1	38.5	0.71	1.84
			>40-50	0	NA	NA	NA
			>50-100	64	79.8	1.35	1.70
			>100-250	70	150.8	3.67	2.43
			>250-700	4	388.0	9.55	2.46
		Capillary Whole Blood	10-40	2	38.5	2.89	7.50
			>40-50	18	45.6	3.76	8.25
			>50-100*	134	69.9	6.12	8.76
			>100-250*	3	109.8	6.79	6.19
			>250-700	0	NA	NA	NA
PCO ₂	mmHg	Venous Whole Blood	5.0-35.0	10	24.43	0.326	1.33
			>35.0-50.0	85	45.29	0.721	1.59
			>50.0-62.5	29	55.85	0.597	1.07
			>62.5-130.0	15	96.53	1.061	1.10
		Arterial Whole Blood	5.0-35.0	35	31.13	0.525	1.69
			>35.0-50.0	87	44.61	0.747	1.68
			>50.0-62.5	9	58.33	1.602	2.75
			>62.5-130.0	5	68.62	0.937	1.37
		Capillary Whole Blood	5.0-35.0*	48	32.06	1.488	4.64
			>35.0-50.0*	107	39.77	1.709	4.30
			>50.0-62.5	1	60.30	0.000	0.00
			>62.5-130.0	1	66.50	2.404	3.62

*Results with outliers excluded

Outliers included

Test	Units	Sample Type	Sample Range	N	Mean	SD	CV (%)
pH	pH units	Venous Whole Blood	6.500-7.300	24	7.1110	0.00593	0.08
			>7.300-7.450	108	7.3799	0.00591	0.08
			>7.450-7.800	9	7.5634	0.00856	0.11
		Arterial Whole Blood	6.500-7.300	6	7.2402	0.00877	0.12
			>7.300-7.450	104	7.3894	0.00913	0.12
			>7.450-7.800	26	7.4889	0.00701	0.09
		Capillary Whole Blood	6.500-7.300	1	7.2930	0.00000	0.00
			>7.300-7.450*	114	7.4112	0.01802	0.24
			>7.450-7.800*	47	7.4785	0.02613	0.35
PO ₂	mmHg	Venous	10-40	96	26.6	1.03	3.87

Test	Units	Sample Type	Sample Range	N	Mean	SD	CV (%)
		Whole Blood	>40-50	22	44.8	1.11	2.47
			>50-100	14	68.1	1.60	2.35
			>100-250	3	176.7	2.89	1.63
			>250-700	7	557.3	10.14	1.82
		Arterial Whole Blood	10-40	1	38.5	0.71	1.84
			>40-50	0	NA	NA	NA
			>50-100	64	79.8	1.35	1.70
			>100-250	70	150.8	3.67	2.43
			>250-700	4	388.0	9.55	2.46
		Capillary Whole Blood	10-40	2	38.5	2.89	7.50
			>40-50	18	45.6	3.76	8.25
			>50-100*	137	70.0	6.54	9.35
			>100-250*	5	108.2	21.14	19.54
			>250-700	0	NA	NA	NA
PCO ₂	mmHg	Venous Whole Blood	5.0-35.0	10	24.43	0.326	1.33
			>35.0-50.0	85	45.29	0.721	1.59
			>50.0-62.5	29	55.85	0.597	1.07
			>62.5-130.0	15	96.53	1.061	1.10
		Arterial Whole Blood	5.0-35.0	35	31.13	0.525	1.69
			>35.0-50.0	87	44.61	0.747	1.68
			>50.0-62.5	9	58.33	1.602	2.75
			>62.5-130.0	5	68.62	0.937	1.37
		Capillary Whole Blood	5.0-35.0*	50	32.11	1.849	5.76
			>35.0-50.0*	110	39.68	1.996	5.03
			>50.0-62.5	1	60.30	0.000	0.00
			>62.5-130.0	1	66.50	2.404	3.62

*Results with outliers included

Method Comparison

Method comparison was demonstrated in a study based on CLSI guideline EP09c ED3.⁷

Lithium heparin arterial and venous whole blood specimens collected across multiple point of care sites were evaluated using *i-STAT G3+* cartridges on the i-STAT 1 analyzer against whole blood specimens tested on a comparative method. For pH, *PO*₂, and *PCO*₂ the first replicate result from the i-STAT 1 analyzer was compared to the singlicate result from the comparative method.

Two (2) capillary specimens collected from skin puncture with balanced heparin capillary tubes from each study subject across multiple point of care sites were evaluated and analyzed in singlicate on both the i-STAT 1 analyzer and the comparative method. For pH, *PO*₂, *PCO*₂ the singlicate result from the i-STAT 1 analyzer was compared to the singlicate result from the comparative method.

The arterial, venous, and capillary data were pooled, and a Passing-Bablok linear regression analysis was performed using the results from the *i-STAT G3+* cartridges on the i-STAT 1 analyzer versus the comparative method results.

In the method comparison table, N is the number of specimens in the data set, and r is the correlation coefficient.

Method comparison results comparing the i-STAT pH, *PO*₂ and *PCO*₂ performance on the

i-STAT 1 analyzer to the comparative method for arterial, venous, and capillary are shown in the table below.

Test (units)	Comparative Method	N	Slope	Intercept	r	Xmin	Xmax	Medical Decision Level	Bias at Medical Decision Level
pH (pH units)	RAPIDPoint 500/500e	487	0.98	0.13	0.99	6.580	7.781	7.30	0.0042
								7.35	0.0033
								7.45	0.0024
PO ₂ (mmHg)	RAPIDPoint 500/500e	487	1.05	-2.08	1.00	11.4	671.2	30	-0.4
								45	0.4
								60	1.2
PCO ₂ (mmHg)	RAPIDPoint 500/500e	480	1.05	-0.44	0.98	8.6	129.7	35.0	1.41
								45.0	1.94
								50.0	2.20
								70.0	3.26

Method comparison results comparing the i-STAT pH, PO₂ and PCO₂ performance on the i-STAT 1 analyzer to the comparative method for capillary whole blood are shown in the table below.

Test (units)	Comparative Method	N	Slope	Intercept	r	Xmin	Xmax
pH (pH units)	RAPIDPoint 500/500e	206	1.02	-0.12	0.98	6.734	7.779
PO ₂ (mmHg)	RAPIDPoint 500/500e	204	1.09	-5.13	0.99	9	680
PCO ₂ (mmHg)	RAPIDPoint 500/500e	199	1.07	-0.95	0.96	5.4	120.0

The bias at the medical decision levels for native capillary whole blood specimens only are shown in the table below.

Test (units)	N	Min	Max	Medical Decision Points	Estimate	Bias 95% CI
pH (pH units)	190	7.315	7.576	7.300	-0.0079	(-0.0219, 0.0040)
				7.350	-0.0026	(-0.0110, 0.0050)
				7.400	0.0028	(-0.0018, 0.0077)
PO ₂ (mmHg)	189	37	105	30	-4.3	(-8.1, -1.5)
				45	-2.2	(-4.5, -0.5)
				60	0.0	(-1.5, 0.9)
PCO ₂	190	27.7	52.4	35.0	1.61	(0.80, 2.25)

Test (units)	N	Min	Max	Medical Decision Points	Estimate	Bias 95% CI
(mmHg)				45.0	1.94	(0.60, 3.36)
				50.0	2.10	(0.28, 4.17)

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site-specific variables.

Linearity

Linearity studies were performed based on guidance from CLSI EP06-Ed2⁸. The results using lithium heparin whole blood samples demonstrated linearity across the reportable range of the analytes described in the “Expected Values” section above.

LIMITATIONS OF THE PROCEDURE

The analyte results should be assessed in conjunction with the patient's medical history, clinical examination, and other findings. If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Interference Testing

Interference studies were based on CLSI guideline EP07 3rd edition⁹. The substances listed were evaluated in lithium heparin whole blood for relevant analytes. For those identified as an interferent the interference is described.

Substance*	Substance Concentration		Test	Interference (Yes/No)	Comment
	mmol/L	mg/dL			
Acetaminophen	1.03 ¹⁰	15.6	pH	No	
			PO ₂	No	
			PCO ₂	No	
Atracurium (Atracurium Besylate) ^a	0.0287	3.57	pH	No	
			PO ₂	No	
			PCO ₂	No	
Bilirubin	0.684	40	pH	No	
			PO ₂	No	
			PCO ₂	No	
Calcium (Calcium Chloride)	5.0	20	pH	No	
			PO ₂	No	
			PCO ₂	No	
Ethanol	130	600	pH	No	
			PO ₂	No	
			PCO ₂	No	
Hemoglobin	10 g/L	1000	pH	No	
			PO ₂	No	
			PCO ₂	No	

Substance*	Substance Concentration		Test	Interference (Yes/No)	Comment
	mmol/L	mg/dL			
Ibuprofen	1.06	21.9	pH	No	
			PO ₂	No	
			PCO ₂	No	
Intralipid 20%	N/A	2684	pH	No	
			PO ₂	No	
			PCO ₂	No	
Morphine (Morphine Sodium Salt)	0.0273	0.78	pH	No	
			PO ₂	No	
			PCO ₂	No	
Potassium (Potassium Chloride)	8	59.6	pH	No	
			PO ₂	No	
			PCO ₂	No	
Sodium (Sodium Chloride)	170	993.48	pH	No	
			PO ₂	No	
			PCO ₂	No	
Thiopental	1.66	40.2	pH	No	
			PO ₂	No	
			PCO ₂	No	
Triglyceride	16.94	1500	pH	No	
			PO ₂	No	
			PCO ₂	No	

^a The test concentration for this substance is not included in CLSI guideline EP37 1st edition.¹¹

*The compound tested to evaluate the interfering substance is presented in parenthesis.














This is representative data and results may vary from study to study due to matrix effects. Viscosity, surface tension, turbidity, ionic strength and pH are common causes of matrix effects. It is possible that interfering substances other than those tested may be encountered. The degree of interference at concentrations other than those listed might not be predictable.

Factors Affecting Results

Note: The calculated values are affected when the factor affecting results impacts the analyte used in the calculations. See calculated value equations in EXPECTED RESULTS section.

Factor	Test	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	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.
	PCO_2	
Partially filling a blood collection device	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	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.
	PCO_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 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	PO_2	Use a puncture device that provides free-flowing blood. Inadequate blood flow may produce erroneous results.
	pH	
	PCO_2	
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	Allowing blood to stand (without exposure to air) before testing will increase PCO_2 by approximately 4 mmHg per hour. ¹ Calculated HCO_3 and TCO_2 results are over-estimated, if blood is allowed to stand (without exposure to air), due to metabolic processes.
Under fill or partial draw	PCO_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. ²
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.

KEY TO SYMBOLS

Symbol	Definition/Use
	2 months room temperature storage at 18-30°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.
	Contains sufficient for <n> tests
	Authorized representative in the European Community.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Catalog number, list number, or reference
	Do not re-use.
	Manufacturer
	Consult instructions for use or see System Manual for instructions.
	<i>In vitro</i> diagnostic medical device
	Device for near-patient testing
	For prescription use only.

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

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