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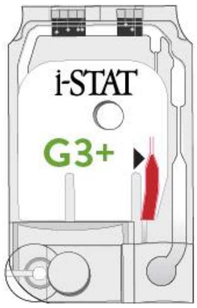
# i-STAT G3+ Cartridge




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 (***P***$O_2$) and partial pressure of carbon dioxide (***P***$CO_2$) in arterial, venous or capillary whole blood in point of care or clinical laboratory settings.

| Test | Intended Use |
|---|---|
| pH | pH, ***P***$O_2$, and ***P***$CO_2$ measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic and acid-base disturbances. |
| 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***$O_2$)

***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***$CO_2$ (partial pressure of carbon dioxide) along with pH is used to assess acid-base balance. ***P***$CO_2$, 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 $PCO_2$) 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]:

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

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

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

### Calculated:

**$HCO_3$, $TCO_2$, and BE**

- 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 $\boldsymbol{P}CO_2$) and electrolyte imbalance.

- The calculated $TCO_2$ provided by the i-STAT System is determined from the measured and reported values of pH and $\boldsymbol{P}CO_2$ 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 $\boldsymbol{P}CO_2$ 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 $\boldsymbol{P}CO_2$, $HCO_3$, $TCO_2$ and BE are calculated.[2]

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

**$sO_2$**

- Oxygen saturation ($sO_2$) 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. [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 $sO_2$ value for oxygen saturation in further calculations, such as shunt fraction, or by assuming the value obtained is equivalent to fractional oxyhemoglobin.

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

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

# 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 |
| $\boldsymbol{P}CO_2$ | 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<br>***P***$CO_2$<br>***P***$O_2$ | Without anticoagulant | 3 minutes | Without anticoagulant | 3 minutes | With balanced heparin anticoagulant or lithium heparin (tubes must be filled to labeled capacity)** | 3 minutes |
| | With balanced heparin anticoagulant or lithium heparin | 10 minutes | With lithium heparin anticoagulant (tubes must be filled to | 10 minutes | | |

| Analyte | Syringes* | Test Timing | Evacuated Tubes | Test Timing | Capillary | Test Timing |
|---|---|---|---|---|---|---|
| | anticoagulant (syringe must be filled to labeled capacity)**<br>• Maintain anaerobic conditions.<br>• Remix thoroughly before filling cartridge. | | labeled capacity)**<br>• Maintain anaerobic conditions.<br>• 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.

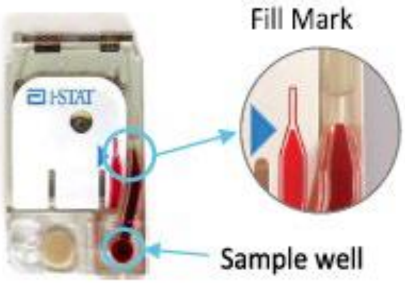
**Filling and Sealing the Cartridge** (after cartridge has been equilibrated and blood sample has been collected)

1. Place the cartridge on a flat surface.
2. 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.
3. 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.
4. 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** | The sample fills the sample chamber to the fill mark indicator   Full sample well, and no bubble appears in the sample pathway.  |
| **Underfilled cartridge** | The sample well is sufficiently filled, but the sample does not reach the fill mark indicator  |

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

## 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** |
| $\boldsymbol{P}O_2$ | mmHg | 5 - 700 | 80 - 105 [5]*** | – |
| | kPa | 0.7 - 93.3 | 10.7 - 14.0 [5]*** | – |
| $\boldsymbol{P}CO_2$ | 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

- ***P*$O_2$ and *P*$CO_2$:** To convert ***P***$O_2$ and ***P***$CO_2$ 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.

### *P*$O_2$

***P***O2 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.

### *P*$CO_2$

***P***CO2 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-A3[6]. The precision study was conducted using five (5) levels of aqueous materials for pH, ***P***$O_2$ and ***P***$CO_2$. 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 |
| $\boldsymbol{P}O_2$ | 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 |
| $\boldsymbol{P}CO_2$ | 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 capillary[1] 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, $\boldsymbol{P}O_2$, and $\boldsymbol{P}CO_2$ 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, $\boldsymbol{P}O_2$, $\boldsymbol{P}CO_2$ 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, $\boldsymbol{P}O_2$ and $\boldsymbol{P}CO_2$ 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 |
| *P*$O_2$ (mmHg) | RAPIDPoint 500/500e | 487 | 1.05 | -2.08 | 1.00 | 11.4 | 671.2 | 30 | -0.4 |
| | | | | | | | | 45 | 0.4 |
| | | | | | | | | 60 | 1.2 |
| *P*$CO_2$ (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, ***P***$O_2$ and ***P***$CO_2$ 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 |
| *P*$O_2$ (mmHg) | RAPIDPoint 500/500e | 204 | 1.09 | -5.13 | 0.99 | 9 | 680 |
| *P*$CO_2$ (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 | Bias | |
|---|---|---|---|---|---|---|
| | | | | | Estimate | 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) |
| *P*$O_2$ (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) |
| *P*$CO_2$ | 190 | 27.7 | 52.4 | 35.0 | 1.61 | (0.80, 2.25) |

| Test (units) | N | Min | Max | Medical Decision Points | Bias | |
|---|---|---|---|---|---|---|
| | | | | | Estimate | 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-Ed2 [8]. 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 edition [9]. 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.

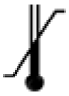
This is representative data and results may vary from study to study due to matrix effects. Viscosity, surface tension, turbidity, ionic strength and pH are common causes of matrix effects. It is possible that interfering substances other than those tested may be encountered. The degree of interference 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 | ***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, ***P***$CO_2$ | 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. |
| Partially filling a blood collection device | ***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, ***P***$CO_2$ | 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. |
| 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 | ***P***$O_2$ | Do not ice samples before testing - ***P***$O_2$ results may be falsely elevated in cold samples. Do not use a cold cartridge - ***P***$O_2$ results may be falsely decreased if the cartridge is cold. |
| Sample collection | ***P***$O_2$, pH, ***P***$CO_2$ | Use a puncture device that provides free-flowing blood. Inadequate blood flow may produce erroneous results. |
| 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] |
| | ***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. [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 | ***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 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. [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.<br>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. |
|  | Contains sufficient for <n> tests |
| EC REP | Authorized representative in the European Community. |
|  | 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 re-use. |
|  | Manufacturer |
|  | Consult instructions for use or see System Manual for instructions. |
| IVD | *In vitro* diagnostic medical device |
|  | Device for near-patient testing |
| Rx ONLY | For prescription use only. |

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

## REFERENCES


1 E.L. Pruden, O. Siggard-Andersen, and N.W. Tietz, Blood Gases and pH, in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994).

2 CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guideline. CLSI document C46-A [ISBN 1-56238-444-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

3 Severinghaus JW. Simple, accurate equations for human blood O2 dissociation computations. J Appl Physiol Respir Environ Exerc Physiol. 1979;46:599-602

4 P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry - Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

5 B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economics Books, 1987).

6 CLSI. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition. CLSI document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

7 Clinical and Laboratory Standards Institute (CLSI). Measurement Procedure Comparison and Bias Estimation Using Patient Samples – Third Edition. CLSI document EP09c ED3. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania, 19087, USA, June 2018.

8 CLSI. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd ed. CLSI guideline EP06. Clinical and Laboratory Standards Institute, 2020

9 Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry – Third Edition. CLSI guideline EP07. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA; 2018.

10 Wu, Alan H.B. Tietz Clinical Guide to Laboratory Tests (Fourth Edition). W. B. Saunders Elsevier (2006).

11 Clinical and Laboratory Standards Institute (CLSI). Supplemental Tables for Interference Testing in Clinical Chemistry - First Edition. CLSI supplement EP37. Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA; 2018.

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