# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
ASSAY ONLY

## I Background Information:

### A 510(k) Number

K223857

### B Applicant

Abbott Point of Care Inc.

### C Proprietary and Established Names

i-STAT G3+ cartridge with the i-STAT 1 System

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| CHL | Class II | 21 CFR 862.1120 - Blood Gases (PCO2, PO2) And Blood pH Test System | CH - Clinical Chemistry |

## II Submission/Device Overview:

### A Purpose for Submission:

Modification to a previously cleared device.

### B Measurand:

pO2, pCO2, and pH

### C Type of Test:

Quantitative, amperometric for pH and pCO2

Quantitative, potentiometric for pO2

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for 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 (PO2), and partial pressure of carbon dioxide (PCO2) in arterial, venous or capillary whole blood in point of care or clinical laboratory settings.

pH, PO2, and PCO2 measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic, and acid-base disturbances.

### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For Point-of-Care or clinical laboratory setting

### D Special Instrument Requirements:

i-STAT 1 Analyzer

## IV Device/System Characteristics:

### A Device Description:

The i-STAT G3+ cartridge is used with the i-STAT 1 analyzer as part of the i-STAT 1 System.

The i-STAT G3+ (white) cartridge contains sensors for the measurement of the pH, pO2 and pCO2 tests, a fluid pouch containing aqueous calibrator, a sample entry well and snap closure, fluid channels, waste chamber, and mechanical features for controlled fluid movement within the cartridge. It is a single-use disposable unit that is self-contained. The cartridge tests a sample consisting of two to three drops of whole blood (95 µL). All the test steps and fluid movements occur within the i-STAT G3+ cartridge.

### B Principle of Operation:

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

**pO2** 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.

**pCO2** is measured by direct potentiometry. In the calculation of results for pCO2, concentration is related to potential through the Nernst equation.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
RAPIDPoint 500e Blood Gas System

### B Predicate 510(k) Number(s):
K192240

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | K223857 | K192240 |
|---|---|---|
| Device Trade Name | i-STAT G3+ cartridge with the i-STAT 1 System | RAPIDPoint 500e Blood Gas System |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | Intended to measure pH, partial pressure of oxygen (*pO2*), and partial pressure of carbon dioxide (*pCO2*) | Same |
| Reportable Range | 6.500 – 7.800 pH units | Same |
| Sample Type | Arterial, venous or capillary whole blood | Same |
| **General Device Characteristic Differences** | | |
| Reportable Range | pO2: 5 – 700 mmHg<br>pCO2: 5 – 130 mmHg | pO2: 10 – 700 mmHg<br>pCO2: 5 – 200 mmHg |
| Sample Volume | 95 µL | 100 µL |
| Time to Test/ Sample Stability (Time from collection to sample fill) | pH, pCO2, and pO2 (arterial and venous whole blood): 3 minutes without anticoagulant<br><br>pH, pCO2, and pO2 (capillary whole blood): 10 minutes with anticoagulant | pH, pCO2, and pO2 (arterial, venous, and capillary whole blood):10 minutes with anticoagulant |

## VI Standards/Guidance Documents Referenced:

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition

CLSI EP06-A2: Evaluation of Linearity of Quantitative Measurement Procedures;2nd Edition.

CLSI EP07: Interference Testing in Clinical Chemistry; 3rd ed.

CLSI EP09c: Measurement Procedure Comparison and Bias Estimation using Patient Samples, 3rd ed.

CLSI EP 17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline

CLSI EP37: Supplement Tables for Interference Testing in Clinical Chemistry; 1st ed.

CLSI EP35: Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures; 1st ed.

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:
   *Internal within-site precision (aqueous control material)*
   A single site precision study for the i-STAT pH, pO2, and pCO2 assays was conducted following the recommendations in CLSI EP05-A3. Five concentration levels of commercially available calibration verification samples were tested using one lot of i-STAT G3+ (white) cartridges and ten i-STAT 1 Analyzers. Each sample was measured in duplicates per run, with two runs per day for 20-days by two operators resulting in a total of 80 test results per level. The results are summarized below.

| Test | Level | Mean | Repeatability | | Between-run | | Between-day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| pH (pH units) | L1 | 6.5796 | 0.00314 | 0.05 | 0.00401 | 0.06 | 0.00184 | 0.03 | 0.00541 | 0.08 |
| | L2 | 7.0335 | 0.00251 | 0.04 | 0.00320 | 0.05 | 0.00063 | 0.01 | 0.00411 | 0.06 |
| | L3 | 7.4611 | 0.00256 | 0.03 | 0.00109 | 0.01 | 0.00084 | 0.01 | 0.00291 | 0.04 |
| | L4 | 7.6425 | 0.00339 | 0.04 | 0.00103 | 0.01 | 0.00085 | 0.01 | 0.00364 | 0.05 |
| | L5 | 7.9702 | 0.00324 | 0.04 | 0.00109 | 0.01 | 0.00081 | 0.01 | 0.00351 | 0.04 |
| pO2 (mmHg) | L1 | 75.7 | 2.25 | 2.97 | 0.78 | 1.03 | 0.59 | 0.78 | 2.45 | 3.24 |
| | L2 | 87.9 | 1.69 | 1.92 | 1.10 | 1.25 | 0.84 | 0.96 | 2.18 | 2.48 |
| | L3 | 115.5 | 2.09 | 1.81 | 1.75 | 1.51 | 0.92 | 0.80 | 2.88 | 2.49 |
| | L4 | 146.0 | 2.90 | 1.99 | 2.87 | 1.97 | 1.24 | 0.85 | 4.27 | 2.92 |
| | L5 | 388.7 | 6.63 | 1.71 | 8.37 | 2.15 | 3.67 | 0.95 | 11.29 | 2.90 |
| | L1 | 89.21 | 0.792 | 0.89 | 1.161 | 1.30 | 0.538 | 0.60 | 1.505 | 1.69 |
| | L2 | 56.43 | 0.470 | 0.83 | 0.288 | 0.51 | 0.149 | 0.26 | 0.571 | 1.01 |

| Test | Level | Mean | Repeatability | | Between-run | | Between-day | | Within-Laboratory | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| pCO2 (mmHg) | L3 | 29.32 | 0.288 | 0.98 | 0.128 | 0.44 | 0.076 | 0.26 | 0.324 | 1.11 |
| | L4 | 22.48 | 0.356 | 1.58 | 0.157 | 0.70 | 0.057 | 0.25 | 0.393 | 1.75 |
| | L5 | 12.06 | 0.308 | 2.55 | 0.082 | 0.68 | 0.092 | 0.76 | 0.331 | 2.75 |

*Point of Care precision (aqueous control material)*

A multi-site precision study was conducted for pO2, pCO2, and pH using five concentration levels of commercially available calibration verification samples, and tested using one lot of i-STAT G3+ (white) cartridges and six i-STAT 1 Analyzers. Each sample was measured once per day for five days by two operators. The results of the study are summarized below:

| Test | N | Level | Mean | Between-Day | | Between-Site | | Overall | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV | SD | %CV |
| pH (pH units) | 81 | L1 | 6.5790 | 0.00224 | 0.03 | 0.00227 | 0.03 | 0.00589 | 0.09 |
| | 82 | L2 | 7.0342 | 0.00179 | 0.03 | 0.00000 | 0.00 | 0.00321 | 0.05 |
| | 85 | L3 | 7.4619 | 0.00102 | 0.01 | 0.00081 | 0.01 | 0.00308 | 0.04 |
| | 80 | L4 | 7.6414 | 0.00142 | 0.02 | 0.00000 | 0.00 | 0.00310 | 0.04 |
| | 80 | L5 | 7.9678 | 0.00000 | 0.00 | 0.00000 | 0.00 | 0.00287 | 0.04 |
| pO2 (mmHg) | 81 | L1 | 77.9 | 1.13 | 1.45 | 1.85 | 2.37 | 3.83 | 4.91 |
| | 82 | L2 | 88.1 | 1.58 | 1.79 | 1.66 | 1.88 | 3.31 | 3.76 |
| | 85 | L3 | 114.5 | 2.48 | 2.16 | 1.59 | 1.39 | 3.63 | 3.17 |
| | 80 | L4 | 144.1 | 2.86 | 1.98 | 1.57 | 1.09 | 4.61 | 3.20 |
| | 81 | L5 | 373.4 | 7.32 | 1.96 | 0.00 | 0.00 | 12.94 | 3.47 |
| pCO2 (mmHg) | 81 | L1 | 90.42 | 0.416 | 0.46 | 0.000 | 0.00 | 1.553 | 1.72 |
| | 82 | L2 | 57.40 | 0.195 | 0.34 | 0.206 | 0.36 | 0.818 | 1.43 |
| | 85 | L3 | 29.80 | 0.203 | 0.68 | 0.275 | 0.92 | 0.749 | 2.51 |
| | 80 | L4 | 22.83 | 0.168 | 0.73 | 0.189 | 0.83 | 0.464 | 2.03 |
| | 80 | L5 | 12.28 | 0.043 | 0.35 | 0.058 | 0.48 | 0.469 | 3.82 |

| Test | N | Level | Mean | Within-Run | | Within-Site (Total) | |
|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV |
| pH (pH units) | 81 | L1 | 6.5790 | 0.00465 | 0.07 | 0.00544 | 0.08 |
| | 82 | L2 | 7.0342 | 0.00228 | 0.03 | 0.00321 | 0.05 |
| | 85 | L3 | 7.4619 | 0.00274 | 0.04 | 0.00297 | 0.04 |
| | 80 | L4 | 7.6414 | 0.00236 | 0.03 | 0.0031 | 0.04 |
| | 80 | L5 | 7.9678 | 0.00247 | 0.03 | 0.00287 | 0.04 |
| pO2 (mmHg) | 81 | L1 | 77.9 | 3.16 | 4.05 | 3.35 | 4.30 |
| | 82 | L2 | 88.1 | 2.39 | 2.72 | 2.87 | 3.26 |
| | 85 | L3 | 114.5 | 2.07 | 1.81 | 3.26 | 2.85 |
| | 80 | L4 | 144.1 | 3.03 | 2.10 | 4.34 | 3.01 |
| | 81 | L5 | 373.4 | 7.32 | 1.96 | 12.94 | 3.47 |
| pCO2 | 81 | L1 | 90.42 | 1.497 | 1.66 | 1.553 | 1.72 |
| | 82 | L2 | 57.40 | 0.767 | 1.34 | 0.791 | 1.38 |

| Test | N | Level | Mean | Within-Run | | Within-Site (Total) | |
|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV |
| (mmHg) | 85 | L3 | 29.80 | 0.600 | 2.01 | 0.697 | 2.34 |
| | 80 | L4 | 22.83 | 0.344 | 1.51 | 0.424 | 1.86 |
| | 80 | L5 | 12.28 | 0.461 | 3.75 | 0.465 | 3.79 |

*Point of Care Precision (Whole Blood)*

A multi-site precision study was conducted using arterial, venous, and capillary whole blood specimens collected with lithium heparin collection devices targeted to three levels within the reportable range of pH, pO2, and pCO2 tests. The whole blood precision was assessed using the duplicate test results collected across multiple point of care sites. For each sample type, samples were grouped into subintervals based on their mean values. The precision results between sites were similar. The combined results of the whole blood precision are shown below:

| Whole Blood Precision of Arterial, Venous, and Capillary for i-STAT G3+ Cartridge on the i-STAT 1 Analyzer, *Results with 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 |
| *P*O2 (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 |
| | | 5.0-35.0 | 10 | 24.43 | 0.326 | 1.33 |

| Whole Blood Precision of Arterial, Venous, and Capillary for i-STAT G3+ Cartridge on the i-STAT 1 Analyzer, *Results with outliers excluded | | | | | | |
|---|---|---|---|---|---|---|
| Test (units) | Sample Type | Sample Range | N | Mean | SD | %CV |
| *P*CO2 (mmHg) | Venous Whole Blood | >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 |

| Whole Blood Precision of Arterial, Venous, and Capillary for i-STAT G3+ Cartridge on the i-STAT 1 Analyzer (outliers included) | | | | | | |
|---|---|---|---|---|---|---|
| Test (uUnits) | 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 |
| *P*O2 (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 |

| Whole Blood Precision of Arterial, Venous, and Capillary for i-STAT G3+ Cartridge on the i-STAT 1 Analyzer (outliers included) | | | | | | |
|---|---|---|---|---|---|---|
| | 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 |
| *P*CO2 (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

2. Linearity:

The linearity study was designed based on CLSI EP06-A2. The linearity of the i-STAT pH, pO2, and pCO2 tests in the i-STAT G3+ (white) cartridge with the i-STAT 1 System was evaluated by preparing venous whole blood samples collected in lithium heparin tubes from healthy subjects of varying analyte levels for each i-STAT test. Each sample for pO2, pCO2, and pH testing was prepared via tonometry to eleven target analyte concentrations. The number of i-STAT 1 Analyzers used varied; 15 for pO2, 15 for pCO2 and 30 for pH. Twelve cartridge lots were tested for each analyte. Each test sample was tested in replicates of 3 per cartridge lot for a total of 15 results per level.

The linearity study results support that the assays are linear across the following claimed reportable ranges:

| i-STAT Test | Reportable Range |
|---|---|
| pH | 6.500 – 7.800 pH Units |
| pO2 | 10 – 700 mmHg |
| pCO2 | 5.0 – 130.0 mmHg |

3. Analytical Specificity/Interference:

The analytical specificity of the pO2, pCO2, and pH tests in the i-STAT G3+ (white) cartridge using the i-STAT 1 system was established by conducting interference testing following the recommendations in CLSI EP07-Edition 3. Interference from certain exogenous and endogenous substances was assessed using tonometed lithium heparin venous whole blood samples. A substance was identified as an interferent if the difference in the mean between the control and test sample was outside of the predefined allowable error:

For pO2: ± greater of 5 mmHg or 10% of the control (mmHg)
For pCO2: ± greater of 5 mmHg or 8% of the control (mmHg)
For pH: ± 0.04 pH units

The following table lists the concentrations of each substance at which no significant interference was found.

pO2, pCO2 and pH

| Substance | Highest concentration at which no significant interference was observed |
|---|---|
| Acetaminophen | 1.03 mmol/L |
| Atracurium | 0.0287 mmol/L |
| Calcium | 20 mg/dL |
| Ethanol | 130 mmol/L |
| Ibuprofen | 1.06 mmol/L |
| Morphine | 0.0273 mmol/L |
| Potassium | 8 mmol/L |
| Sodium | 170 mmol/L |
| Bilirubin | 40 mg/dL |
| Hemoglobin | 10 g/L |
| Triglyceride** | 1500 mg/dL |
| Intralipid** | 2684 mg/dL |
| Thiopental | 1.66 mmol/L |

**Intralipid 20% and Triglyceride were assessed using the same data set.

4. Assay Reportable Range:

See section A.2 Linearity.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

*Traceability*
The i-STAT System for pH is traceable to NIST standard reference materials SRMs 186-I, 186-II, 185, and 187.

pO2 values are traceable to NIST standard reference materials.

pCO2 values are traceable to NIST standard reference materials.

*Sample stability*
A study was conducted to verify the whole blood sample stability after sample collection with anticoagulant for the i-STAT pO2, pCO2, and pH tests using the i-STAT G3+ (white) cartridge on the i-STAT 1 Analyzer. The results support the sponsor's sample stability claims. The sample stability claims for pO2, pCO2, and pH are 10 minutes for (arterial, venous, capillary) samples with anticoagulant and 3 minutes for samples without anticoagulant (arterial and venous).

The device performed adequately at an altitude of approximately 10,000 feet.

6. Detection Limit:
Linearity studies were used to support the lower end of the measuring range for pH, pO2, and pCO2 (see section VII.A.2. above). In addition, to support the limit of quantitation (LoQ) a study was performed according to CLSI EP17-A2. The LoQ of the i-STAT pH, PO2, and PCO2 tests in the i-STAT G3+ cartridge was evaluated on the i-STAT 1 analyzer using two i-STAT G3+ cartridge lots, and whole blood that was altered using tonometry to low pH (≤ 6.5 pH units), pO2 (≤ 10.00 mmHg), pCO2 (≤5.000 mmHg). The LoQ for each of the i-STAT pH, pO2, and pCO2 tests for the i-STAT tests is shown below.

| Analyte | Reportable range | LoQ |
|---|---|---|
| pH (pH units) | 6.5 – 7.8 | 6.439 |
| pO2 (mmHg) | 5 – 700 | 4 |
| pCO2 (mmHg) | 5.0 – 130.0 | 2.3 |

7. Assay Cut-Off:

Not applicable.

**B Comparison Studies:**

Method Comparison:

Method comparison for arterial, venous, and capillary whole blood specimens on the i-*STAT G3+* cartridge with the i-STAT 1 System was performed based on CLSI EP09c-ED3. Lithium heparin arterial and venous whole blood specimens collected across point of care sites were evaluated using i-STAT G3+ cartridges on the i-STAT 1 analyzer and compared to whole blood specimens tested on a comparative method. For pH, pO2, and pCO2, a Passing Bablok linear regression analysis was performed using the first replicate result from the i-STAT 1 analyzer versus the singlicate result from the comparative method. The regression analysis results for venous, arterial, and capillary whole blood samples are described below:

| Whole Blood Method Comparison Results for i-STAT G3+ Cartridge with i-STAT 1 System | | | | | | |
|---|---|---|---|---|---|---|
| Test (Units) | N | Slope | Intercept | r | Medical Decision Level | Bias at Medical Decision Level |
| pH (pH units) | 487 | 0.98 | 0.13 | 0.99 | 7.30 | 0.0042 |
| | | | | | 7.35 | 0.0033 |
| | | | | | 7.45 | 0.0024 |
| *P*O2 (mmHg) | 487 | 1.05 | -2.08 | 1.00 | 30 | -0.4 |
| | | | | | 45 | 0.4 |
| | | | | | 60 | 1.2 |
| *P*CO2 (mmHg) | 480 | 1.05 | -0.44 | 0.98 | 35.0 | 1.41 |
| | | | | | 45.0 | 1.94 |
| | | | | | 50.0 | 2.20 |
| | | | | | 70.0 | 3.26 |

Summary data for the capillary samples is described in the tables below:

| Results for i-STAT G3+ Cartridge with i-STAT 1 System- Native and Contrived Capillary Specimens | | | | | |
|---|---|---|---|---|---|
| Test (Units) | N | Slope | Intercept | r | Sample Range |
| pH (pH units) | 206 | 1.02 | -0.12 | 0.98 | 6.734 - 7.779 |
| *P*O2 (mmHg) | 204 | 1.09 | -5.13 | 0.99 | 9 - 680 |
| *P*CO2 (mmHg) | 199 | 1.07 | -0.95 | 0.96 | 5.4 - 120.0 |

| Results for i-STAT G3+ Cartridge with i-STAT 1 System- Native and Contrived Capillary Specimens Bias at Medical Decision Levels | | | | | | |
|---|---|---|---|---|---|---|
| Test (Units) | N | Range Min | Range Max | Medical Decision Level | Bias | |
| | | | | | Estimate | 95% CI |
| pH (pH units) | 206 | 7.315 | 7.576 | 7.300 | 0.0023 | (-0.0048, 0.0079) |
| | | | | 7.350 | 0.0032 | (-0.0024, 0.0076) |
| | | | | 7.400 | 0.0041 | (-0.0006, 0.0080) |
| *P*O2 (mmHg) | 204 | 37 | 105 | 30 | -2.5 | (-4.7, -1.1) |
| | | | | 45 | -1.1 | (-2.8, -0.1) |
| | | | | 60 | 0.2 | (-1.2, 0.9) |
| *P*CO2 (mmHg) | 199 | 27.7 | 52.4 | 35.0 | 1.42 | (0.72, 2.16) |
| | | | | 45.0 | 2.10 | (1.05, 3.28) |
| | | | | 50.0 | 2.44 | (1.03, 4.10) |

| Results for i-STAT G3+ Cartridge with i-STAT 1 System- Native Capillary Specimens Bias at Medical Decision Levels | | | | | | |
|---|---|---|---|---|---|---|
| Test (Units) | N | Range Min | Range Max | Medical Decision Level | 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*O2 (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*CO2 (mmHg) | 190 | 27.7 | 52.4 | 35.0 | 1.61 | (0.80, 2.25) |
| | | | | 45.0 | 1.94 | (0.60, 3.36) |
| | | | | 50.0 | 2.10 | (0.28, 4.17) |

Matrix Comparison:

A matrix comparison study was conducted following the recommendations in CLSI EP35 to evaluate the performance of the i-STAT pH, pCO2, and pO2 tests in the i-STAT G3+ cartridge on the i-STAT 1 System comparing arterial or venous whole blood specimens collected without anticoagulant to samples collected with balanced heparin or lithium heparin anticoagulant. A total of 221 matched whole blood samples were tested and include, native venous (n=114) and native arterial (n=107) specimens. Each specimen was tested in duplicate using two i-STAT G3+ cartridges with two i-STAT 1 analyzers. A Passing-Bablok linear regression analysis was performed using the first replicate result from the candidate (y-axis) versus the mean result from the primary specimen (x-axis). Venous and arterial samples performed similarly and were combined in the analysis. The regression analysis results for these samples are summarized below:

| Test | N | Specimen Range Without Anticoagulant | Specimen Range With Anticoagulant | r | Slope | Intercept |
|---|---|---|---|---|---|---|
| pH (pH units) | 221 | 7.211-7.550 | 7.209-7.539 | 0.96 | 1.03 | -0.24 |
| pO2 (mmHg) | 221 | 15-206 | 14-205 | 0.99 | 1.01 | -0.62 |
| pCO2 (mmHg) | 221 | 26.1-73.8 | 26.0-75.2 | 0.97 | 1.02 | -0.98 |

## C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

## D Clinical Cut-Off:

Not applicable.

## E Expected Values/Reference Range:

Expected values for the pH, pO2, pCO2 and lactate assays on the i-STAT C3G3+ (white) cartridge are cited from literature:

| Analyte | Units* | Reference Range | |
|---|---|---|---|
| | | arterial | venous |
| pH | pH units | 7.35 - 7.45 [4] | 7.31 – 7.41** |
| pO2 | mmHg<br>kPa | 80 – 105 [5]***<br>10.7 - 14.0 [5]*** | N/A |
| pCO2 | mmHg<br>kPa | 35 - 45 [4]<br>4.67 - 6.00 | 41 – 51[4]<br>5.47 - 6.80 |

** Calculated from Siggard-Andersen nomogram

*** 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).

[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).

## VIII Proposed Labeling:

The labeling does support the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and does support a substantial equivalence decision.