April 9, 2020

Abbott Point of Care Inc.
Susan Tibedo
Director, Regulatory Affairs
400 College Road East
Princeton, NJ 08540

Re: K200492
Trade/Device Name: i-STAT CG4+ Cartridge with the i-STAT 1 System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood Gases (PCO2, PO2) and Blood pH Test System
Regulatory Class: Class II
Product Code: CHL, KHP
Dated: February 27, 2020
Received: February 28, 2020

Dear Susan Tibedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200492

Device Name
i-STAT CG4+ cartridge with the i-STAT 1 System

Indications for Use *(Describe)*
The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of pH, PO2, PCO2, and lactate in arterial or venous 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 disturbances and metabolic and respiratory-based acid-base disturbances.

Lactate measurements are used in (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

The information in this 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information

Owner	Abbott Point of Care Inc. 400 College Road East Princeton, NJ 08540
Contact	Primary: Susan Tibedo Director Regulatory Affairs susan.tibedo@abbott.com Phone: 609-454-9360 Secondary: Maria Figueroa Manager Regulatory Affairs maria.l.figueroa@abbott.com Phone: 609-454-9271
Date Prepared	April 7, 2020

2. Device Information

Proprietary Name	i-STAT CG4+ cartridge with the i-STAT 1 System
Common Name	Blood gas test, analyzer, handheld
510(k) Number	K200492

Product code	Device Classification name	Regulation Number	Class	Panel
CHL	Electrode, Ion Specific, pH	862.1120	II	Clinical Chemistry
CHL	Electrode, Ion Specific, pCO_2	862.1120	II	Clinical Chemistry
CHL	Electrode, Ion Specific pO_2	862.1120	II	Clinical Chemistry
KHP	Electrode, Ion Specific, Lactate	862.1450	I	Clinical Chemistry

3. Predicate Device

Proprietary Name epoc Lactate test, epoc Blood Analysis System

510(k) Number K093297

Product code	Device Classification name	Regulation Number	Class	Panel
KHP	Electrode, Ion Specific, Lactate	862.1450	I	Clinical Chemistry

Proprietary Name ABL800 FLEX blood gas, oximetry, electrolyte and metabolite analyzer

510(k) Number K041874

Product code	Device Classification name	Regulation Number	Class	Panel
CHL	Electrode, Ion Specific, pH	862.1120	II	Clinical Chemistry
CHL	Electrode, Ion Specific, PCO_2	862.1120	II	Clinical Chemistry
CHL	Electrode, Ion Specific PO_2	862.1120	II	Clinical Chemistry

4. Device Description

The i-STAT CG4+ test cartridge contains test reagents to analyze whole blood at the point of care or in the clinical laboratory for pH, PO_2 (partial pressure of oxygen), PCO_2 (partial pressure of carbon dioxide), and lactate. The test is contained in a single-use, disposable cartridge. Cartridges require two to three drops of whole blood which are typically applied to the cartridge using a transfer device.

The i-STAT 1 Analyzer is a handheld, *in vitro* diagnostic analytical device designed to run only i-STAT test cartridges. The instrument interacts with the cartridge to move fluid across the sensors and generate a quantitative result (within approximately 2 minutes).

The i-STAT 1 System is comprised of the i-STAT 1 analyzer, the i-STAT test cartridges and accessories (i-STAT 1 Downloader/Recharger, electronic simulator and portable printer). The system is designed for use by trained medical professionals at the patient point of care or in the clinical laboratory and is for prescription use only.

5. Intended Use Statement

The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of pH, PO_2, PCO_2, and lactate in arterial or venous whole blood in point of care or clinical laboratory settings.

pH, PO_2, and PCO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.

Lactate measurements are used in (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

6. Summary Comparison of Technological Characteristics

Similarities and Differences: System (Test and Instrument) for pH		
Feature or Characteristic	**Predicate: ABL800 FLEX pH Test (K041874)**	**Candidate: pH test in the i-STAT CG4+ cartridge with the i-STAT 1 System**
Intended Use	The ABL800 FLEX is intended for *in vitro* testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, FCOHb, FMetHb, FHHb, and FHbF). In addition the ABL800 FLEX is intended for *in vitro* testing of samples of expired air for the parameters pO_2 and pCO_2. The ABL800 FLEX includes an AutoCheck Module to perform automated analysis of quality control fluids. pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/blood gas measurement. The normal function of many metabolic processes requires a pH to be within a relatively narrow range.	The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of pH in arterial or venous whole blood in point of care or clinical laboratory settings. pH measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.
Reportable Range	Test Range:[1] 7.0 – 7.7 Measuring Range:[2] 6.300 – 8.000	Reportable Range: 7.000 – 7.700
Sample Type	Arterial, venous or capillary whole blood	Arterial or venous whole blood
Sample Volume	At least 50 – 70 µL	95 µL

[1] The **measuring range** for a parameter is the range within which the analyzer is physically capable of measuring. The measuring range corresponds to the "range of indication" as defined in the International vocabulary of basic and general terms in metrology" (VIM).

[2] The **test range** for a parameter is the range within which accuracy and precision of a measured parameter has been specified and intended to lie within specified limits. The test range corresponds to the "measuring range" as defined in the "International vocabulary of basic and general terms in metrology" (VIM).

Similarities and Differences: System (Test and Instrument) for pH		
Feature or Characteristic	**Predicate: ABL800 FLEX pH Test (K041874)**	**Candidate: pH test in the i-STAT CG4+ cartridge with the i-STAT 1 System**
Sample Preparation	Ready to Use	Ready to Use
Traceability	BMS™ Mk2	NIST SRM 186-I, 186-II, 185, and 187
Calibration	1-point intervals 30 min, 1 hour, 2 hours	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Analyze heparinized samples within 30 minutes after collection	Heparinized samples: within 10 minutes of collection
Principle of Measurement	Ion selective electrode	Ion selective electrode
Reagent Format	Reagent handling system, stored within analyzer	Cartridge
Analyzer Type	Floor Model	Handheld

Similarities and Differences: System (Test and Instrument) for PO_2		
Feature or Characteristic	**Predicate: ABL800 FLEX pO_2 Test (K041874)**	**Candidate: PO_2 test in the i-STAT CG4+ cartridge with the i-STAT 1 System**
Intended Use	The ABL800 FLEX is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, FCOHb, FMetHb, FHHb, and FHbF). In addition the ABL800 FLEX is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2. The ABL800 FLEX includes an AutoCheck Module to perform automated analysis of quality control fluids. The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.	The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of PO_2 in arterial or venous whole blood in point of care or clinical laboratory settings. PO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.
Reportable Range	Test Range:[1] 15 – 530 mmHg Measuring Range:[2] 0.0 – 800 mmHg 0.00 – 107 kPa	Reportable Range: 15 – 530 mmHg 2.00 – 70.49 kPa
Sample Type	Arterial, venous or capillary whole blood	Arterial or venous whole blood
Sample Volume	At least 50 – 70 µL	95 µL
Sample Preparation	Ready to Use	Ready to Use
Traceability	NIST certified Standard Reference Materials	NIST standard reference materials via commercially available certified specialty medical gas standards
Calibration	1-point intervals 30 min, 1 hour, 2 hours	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Analyze heparinized samples within 30 minutes after collection	Heparinized samples: within 10 minutes of collection
Principle of Measurement	Amperometric measurement of oxygen reduction current	Amperometric measurement of oxygen reduction current
Reagent Format	Reagent handling system, stored within analyzer	Cartridge
Analyzer Type	Floor Model	Handheld

[1] The **measuring range** for a parameter is the range within which the analyzer is physically capable of measuring. The measuring range corresponds to the "range of indication" as defined in the International vocabulary of basic and general terms in metrology" (VIM).

[2] The **test range** for a parameter is the range within which accuracy and precision of a measured parameter has been specified and intended to lie within specified limits. The test range corresponds to the "measuring range" as defined in the "International vocabulary of basic and general terms in metrology" (VIM).

Similarities and Differences: System (Test and Instrument) for *P*CO_2		
Feature or Characteristic	**Predicate: ABL800 FLEX pCO_2 Test (K041874)**	**Candidate: *P*CO_2 test in the i-STAT CG4+ cartridge with the i-STAT 1 System**
Intended Use	The ABL800 FLEX is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, FCOHb, FMetHb, FHHb, and FHbF). In addition the ABL800 FLEX is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2. The ABL800 FLEX includes an AutoCheck Module to perform automated analysis of quality control fluids. pCO_2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.	The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of *P*CO_2 in arterial or venous whole blood in point of care or clinical laboratory settings. *P*CO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances.
Reportable Range	Test Range:[1] 15 – 150 mmHg Measuring Range:[2] 5.0 – 250 mmHg 0.67 – 33.3 kPa	Reportable Range: 15.0 – 130.0 mmHg 2.00 –17.29 kPa
Sample Type	Arterial, venous or capillary whole blood	Arterial or venous whole blood
Sample Volume	At least 50 – 70 µL	95 µL
Sample Preparation	Ready to Use	Ready to Use
Traceability	NIST certified Standard Reference Materials	NIST standard reference materials via commercially available certified specialty medical gas standards
Calibration	1-point intervals 30 min, 1 hour, 2 hours	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Analyze heparinized samples within 30 minutes after collection	Heparinized samples: within 10 minutes of collection
Principle of Measurement	Ion selective electrode	Ion selective electrode
Reagent Format	Reagent handling system, stored within analyzer	Cartridge
Analyzer Type	Floor Model	Handheld

[1] The **measuring range** for a parameter is the range within which the analyzer is physically capable of measuring. The measuring range corresponds to the "range of indication" as defined in the International vocabulary of basic and general terms in metrology" (VIM).

[2] The **test range** for a parameter is the range within which accuracy and precision of a measured parameter has been specified and intended to lie within specified limits. The test range corresponds to the "measuring range" as defined in the "International vocabulary of basic and general terms in metrology" (VIM).

Similarities and Differences: System (Test and Instrument) for Lactate		
Feature or Characteristic	**Predicate: epoc Lactate Test with epoc Blood Analysis System (K093297)**	**Candidate: Lactate test in the i-STAT CG4+ cartridge with the i-STAT 1 System**
Intended Use	The Lactate test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical institutions. Lactate measurements from the epoc Blood Analysis System are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)	The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of lactate in arterial or venous whole blood in point of care or clinical laboratory settings. Lactate measurements are used in (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.
Reportable Range	Reportable Range: 0.30 – 20.00 mmol/L 2.7 – 180.2 mg/dL 0.03 – 1.80 g/L	Reportable Range: 0.30 – 20.00 mmol/L 2.7 – 180.2 mg/dL
Sample Type	Arterial, venous or capillary whole blood	Arterial or venous whole blood
Sample Volume	At least 92 µL	95 µL
Sample Preparation	Ready to Use	Ready to Use
Traceability	Certified standard reference material not available at present	Certified standard reference material not available at present
Calibration	1-point on-board contained within the card	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Immediately after collection or in less than 5 minutes	Immediately after collection
Principle of Measurement	Amperometric measurement of oxidized hydrogen peroxide produced by lactate oxidase activity	Amperometric measurement of oxidized hydrogen peroxide produced by lactate oxidase activity
Reagent Format	Test card	Cartridge
Analyzer Type	Handheld	Handheld

7. Performance Characteristics

Analytical Performance

a. Precision

Precision 20 days (Aqueous Materials)

The precision of the i-STAT pH, PO_2, PCO_2, and Lactate tests in the i-STAT CG4+ blue cartridge with the i-STAT 1 System was evaluated using 5 levels of aqueous materials. This 20-day multi-day precision testing was based on CLSI document EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition.* The study was conducted using multiple instruments and one test cartridge lot over 20 days at one site. Total precision ('within-laboratory'), within-run, between-run, and between-day were estimated for each level. The results of the 20-day precision study are shown in **Table 1.**

Table 1: 20-Day Precision of i-STAT pH, PO_2, PCO_2, and Lactate tests on the i-STAT 1 Analyzer

i-STAT Test	Fluid Level	N	Mean	Total		Within-run		Between-run		Between-day	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
pH	CV L1	80	6.5215	0.00435	0.07	0.00347	0.05	0.00228	0.03	0.00129	0.02
	CV L2	81	7.0199	0.00287	0.04	0.00252	0.04	0.00040	0.01	0.00132	0.02
	CV L3	80	7.4758	0.00279	0.04	0.00250	0.03	0.00098	0.01	0.00075	0.01
	CV L4	80	7.7551	0.00241	0.03	0.00209	0.03	0.00071	0.01	0.00097	0.01
	CV L5	80	7.9862	0.00369	0.05	0.00322	0.04	0.00118	0.01	0.00135	0.02
PO_2 (mmHg)	CV L1	80	70.2	2.45	3.5	2.08	3.0	0.70	1.0	1.08	1.5
	CV L2	81	85.7	2.69	3.1	2.40	2.8	0.76	0.9	0.93	1.1
	CV L3	80	120.4	2.66	2.2	2.25	1.9	1.18	1.0	0.81	0.7
	CV L4	80	152.9	3.02	2.0	1.88	1.2	1.78	1.2	1.55	1.0
	CV L5	80	363.4	6.98	1.9	4.15	1.1	5.07	1.4	2.40	0.7
PCO_2 (mmHg)	CV L1	80	87.08	1.349	1.5	0.916	1.1	0.872	1.0	0.470	0.5
	CV L2	81	59.48	0.921	1.5	0.872	1.5	0.228	0.4	0.190	0.3
	CV L3	80	29.24	0.675	2.3	0.617	2.1	0.227	0.8	0.151	0.5
	CV L4	80	21.14	0.552	2.6	0.521	2.5	0.141	0.7	0.118	0.6
	CV L5	80	15.05	0.506	3.4	0.473	3.1	0.138	0.9	0.114	0.8
Lactate (mmol/L)	CV L1	80	18.448	0.1655	0.9	0.1505	0.8	0.0266	0.1	0.0634	0.3
	CV L2	80	7.967	0.0495	0.6	0.0459	0.6	0.0132	0.2	0.0128	0.2
	CV L3	79	2.251	0.0082	0.4	0.0073	0.3	0.0030	0.1	0.0021	0.1
	CV L4	80	0.924	0.0122	1.3	0.0108	1.2	0.0038	0.4	0.0041	0.4
	CV L5	80	0.497	0.0133	2.7	0.0123	2.5	0.0033	0.7	0.0037	0.7

Precision (Whole Blood)

Whole blood precision was evaluated using whole blood venous and arterial specimens collected with lithium heparin. The repeatability analysis was conducted using the data collected across multiple point of care sites. The mean values for each sample were divided into subintervals for each sample type. The results are provided in **Table 2** below:

Table 2: Precision for venous and arterial whole blood

i-STAT Test	Units	Sample Type	Sample Range	N	Mean	SD	CV (%)
pH	pH units	Venous Whole Blood	<7.30	20	7.202	0.0064	0.09
			7.30 – 7.45	77	7.374	0.0060	0.08
			>7.45	7	7.585	0.0030	0.04
		Arterial Whole Blood	<7.30	22	7.259	0.0059	0.08
			7.30 – 7.45	119	7.389	0.0060	0.08
			>7.45	36	7.494	0.0047	0.06
PO_2	mmHg	Venous Whole Blood	<50	59	28.8	0.9	3.0
			50 - 100	27	58.2	2.0	3.4
			100 - 250	4	188.6	1.4	0.7
			>250	6	450.0	12.4	2.8
		Arterial Whole Blood	<50	2	40.3	0.5	1.2
			50 - 100	65	77.5	3.4	4.4
			100 - 250	78	156.6	3.7	2.4
			>250	33	355.6	8.5	2.4
PCO_2	mmHg	Venous Whole Blood	<35	6	16.83	0.29	1.7
			35 - 62.5	83	46.23	0.77	1.7
			>62.5	26	91.61	0.73	0.8
		Arterial Whole Blood	<35	33	31.23	0.51	1.6
			35 - 62.5	140	42.65	0.90	2.1
			>62.5	4	74.36	0.37	0.5
Lactate	mmol/L	Venous Whole Blood	<1.0	50	0.70	0.016	2.26
			1.0 – 5.0	62	1.83	0.021	1.14
			>5.0	11	12.88	0.200	1.55
		Arterial Whole Blood	<1.0	57	0.72	0.018	2.49
			1.0 – 5.0	42	1.87	0.020	1.08
			>5.0	8	8.55	0.036	0.42

b. Linearity

The study was designed based on CLSI EP06-A: *Evaluation of the Linearity of Quantitative Measurement Procedures.*

The linearity of the i-STAT pH, PO_2, PCO_2, and Lactate tests in the i-STAT CG4+ blue cartridge with the i-STAT 1 System was evaluated by preparing whole blood samples of varying analyte levels for each i-STAT test. The i-STAT pH, PO_2, PCO_2, and Lactate tests demonstrated linearity over the reportable range for each i-STAT test. Regression summary of the response for each i-STAT test versus the concentration of the whole blood samples of varying analyte levels is provided in **Table 3**.

Table 3: Regression Summary for the i-STAT PO_2, PCO_2, pH and Lactate tests on the i-STAT 1 Analyzer						
i-STAT Test	**Units**	**Reportable Range**	**Range Tested**	**Slope**	**Intercept**	**r^2**
pH	pH units	7.0 – 7.7	6.889 – 7.979	0.966	0.246	0.9983
PO_2	mmHg	15 – 530	10.69 – 608.49	1.005	-0.196	0.9988
PCO_2	mmHg	15 – 130	10.75 – 151.02	1.027	-1.084	0.9978
Lactate	mmol/L	0.30 – 20.00	0.222 – 21.742	1.128	0.104	0.9966

c. Limit of Quantitation (LoQ)

The study was based on the CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition.*

The LoQ of the i-STAT pH, PO_2, PCO_2, and Lactate tests in the i-STAT CG4+ blue cartridge were evaluated on the i-STAT 1 analyzer using whole blood that was altered to low pH (< 7 pH units), PO_2 (< 15 mmHg), PCO_2 (< 15 mmHg), and lactate (0.22 – 0.29 mmol/L) concentrations and two cartridge lots for each test. The LoQ for each of the i-STAT pH, PO_2, PCO_2, and Lactate tests was determined to be below the lower limit of the reportable range for each of the i-STAT tests as shown in **Table 4**.

Table 4: LoQ Results for the i-STAT PO_2, PCO_2, pH and Lactate tests on the i-STAT 1 Analyzer		
i-STAT Test	**Lower limit of the range**	**Determined LoQ**
pH (pH units)	≤ 7.000 pH units	6.716
PO_2 (mmHg)	≤ 15 mmHg	10
PCO_2 (mmHg)	≤ 15.0 mmHg	9.7
Lactate (mmol/L)	≤ 0.30 mmol/L	0.27

d. Limit of Blank and Detection (LoB/LoD)

The study was based on CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition.*

The LoB and LoD of the i-STAT Lactate test in the i-STAT CG4+ blue cartridge were evaluated on the i-STAT 1 analyzer using whole blood that was altered to a "blank" lactate concentration for LoB testing and two "low" lactate concentrations for LoD testing. The LoB and LoD were determined based on the maximal LoB or LoD value obtained for each lot tested. The determined LoB and LoD for the i-STAT Lactate test on the i-STAT 1 Analyzer are shown in the **Table 5** below.

Table 5: Summary of LoB and LoD Results for the i-STAT Lactate test on the i-STAT 1 Analyzer		
i-STAT Test	**LoB**	**LoD**
Lactate	0.15 mmol/L	0.19 mmol/L

e. Oxygen Sensitivity for the Lactate Test

The effect on oxygen on the i-STAT Lactate test in the i-STAT CG4+ blue cartridge was evaluated with high and low ranges of oxygen. The equivalency between the high and low conditions was determined by a two-sample equivalence test using the analyte allowable error (Ea) relative to the analyte control mean/median results.

The study demonstrated that the i-STAT Lactate test in the i-STAT CG4+ blue cartridge is insensitive to oxygen changes between 20 to >500 mmHg.

f. Interference

The interference performance of the i-STAT pH, PO_2, PCO_2, and Lactate tests in the i-STAT CG4+ blue cartridge on the i-STAT 1 analyzer was evaluated using whole blood samples based on CLSI EP07 ED3: *Interference Testing in Clinical Chemistry, Third Edition*. The effect of each substance was evaluated by comparing the performance of a control sample, spiked with blank solvent solution, with the test results from a sample spiked with the potentially interfering substance at the toxic/pathological concentration based on CLSI EP37 ED1: *Supplemental Tables for Interference Testing in Clinical Chemistry, First Edition*, as applicable. A substance was identified as an interferent if the difference between the control and test samples was outside of the allowed error (Ea) for the i-STAT test.

Table 6 and **Table 7** contain the lists of potentially interfering substances tested for the i-STAT pH, PO_2, PCO_2, and Lactate tests and the interference results.

Table 6: Potentially Interfering Substances and Test Concentration for pH, PO_2, and PCO_2

i-STAT Test	Substance	Test Concentration		Interference (Yes/No)	Interference Results
		mmol/L	mg/dL		
PO_2 PCO_2 pH	Acetaminophen	1.03	15.6	No	
	Atracurium[1]	0.0287	3.57	No	
	Calcium	5.0	20	No	
	Ethanol	130	600	No	
	Ibuprofen	1.06	21.9	No	
	Morphine	0.0273	0.78	No	
	Potassium	8	59.6	No	
	Sodium	170	993.48	No	
	Bilirubin	0.684	40	No	
	Hemoglobin	10 g/L	1000	No	
	Triglyceride	16.94	1500	No	
	Intralipid	N/A	2493	No	
	Thiopental	1660	40.2	No	

[1] The test concentration for this substance is not included in CLSI guideline EP37 1st edition.

Table 7: Potentially Interfering Substances and Test Concentration for Lactate					
i-STAT Test	**Substance**	**Test Concentration**		**Interference (Yes/No)**	**Interference Results**
		mmol/L	**mg/dL**		
Lactate	Acetaldehyde[1]	45 µmol/L	0.20	No	
	Acetaminophen	1.03	15.6	No	
	N-Acetyl-Cysteine	0.92	15.0	No	
	Ascorbic Acid	0.298	5.25	No	
	β-Hydroxybutyric Acid[1]	6	62	No	
	Bilirubin	0.684	40	No	
	Bromide[1]	40.7	325.7	Yes	Decreased results ≥ 40.7 mmol/L
	Dopamine	4.06 µmol/L	0.0621	No	
	Formaldehyde[1]	0.133	0.399	No	
	Glycolic Acid[1]	10.0	76.1	Yes	Increased results ≥ 1.18 mmol/L
	Hemoglobin	10 g/L	1000	No	
	Hydroxyurea	0.405	3.08	No	
	Pyruvate	0.570	5	No	
	Salicylate	0.207	2.86	No	
	Thiocyanate	0.898	5.22	No	
	Triglyceride	16.94	1500	No	
	Intralipid	N/A	3423	No	
	Uric Acid	1.4	23.5	No	

Comparison Study

g. Method Comparison with Predicate Device

Method comparison data was demonstrated in a study based on CLSI guideline EP09c-ED3. Lithium heparin venous and arterial blood specimens were evaluated and analyzed on the i-STAT 1 analyzer against whole blood specimens tested on the comparative method. For pH, PO_2, and PCO_2, a Passing Bablok linear regression analysis was performed using the first replicate result from the i-STAT CG4+ cartridge with the i-STAT 1 System versus the singlicate result of Radiometer ABL800 FLEX. For lactate, the first replicate result from the i-STAT CG4+ cartridge with the i-STAT 1 System was compared to the mean result of epoc® Blood Analysis System.

The results of the method comparison of venous whole blood and arterial whole blood samples is presented in **Table 8**.

Table 8: Method Comparison Results for venous and arterial whole blood				
i-STAT Test	**N**	**Slope**	**Intercept**	**r**
pH	316	1.05	-0.34	0.97
$\boldsymbol{PO_2}$	308	1.03	-3.96	0.99
$\boldsymbol{PCO_2}$	327	1.01	-1.29	0.99
Lactate	246	0.96	0.08	1.00

8. Conclusion

The results of these studies demonstrate that performance of the i-STAT pH, PO_2, PCO_2, and Lactate tests in the i-STAT CG4+ blue cartridge with the i-STAT 1 System are substantially equivalent to the comparative method.