May 2, 2025

Abbott Point of Care Inc.
Brian Ma, Ph.D.
Principal Specialist, Regulatory Affairs
400 College Road East
Princeton, New Jersey 08540

Re: K244014
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: April 4, 2025
Received: April 4, 2025

Dear Brian Ma:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K244014

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, 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.

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.

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

Abbott

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: Brian Ma, PhD Principal Specialist, Regulatory Affairs Phone: 613-688-5949 Secondary: Mojgan Soleimani Director, Regulatory Strategy and Design Quality Assurance Phone: 613-295-0932
Date Prepared	May 2, 2025

2. Device Information

Proprietary Name: *i-STAT CG4+* cartridge with the *i-STAT 1 System*

Common Name: Blood gas test, lactate test, analyzer, handheld

510(k) Number: K244014

Product Code	Device Classification Name	Regulation Number	Class	Panel
CHL	Electrode measurement, blood gases (PCO_2, PO_2) and blood pH	862.1120	II	Clinical Chemistry
KHP	Acid, lactic, enzymatic method	862.1450	I	Clinical Chemistry

3. Predicate Device

Proprietary Name	*i-STAT G3+* cartridge with the *i-STAT 1 System*
510(k) Number	K223857

Product Code	Device Classification Name	Regulation Number	Class	Panel
CHL	Electrode measurement, blood gases (PCO_2, PO_2) and blood pH	862.1120	II	Clinical Chemistry

4. Device Description

The *i-STAT CG4+* cartridge is used with the *i-STAT 1* analyzer as part of the *i-STAT 1 System* to measure pH, partial pressure of oxygen (PO_2), and partial pressure of carbon dioxide (PCO_2) in arterial, venous or capillary whole blood and to measure lactate (Lac) in arterial or venous whole blood.

The *i-STAT 1 System* is an *in vitro* diagnostic (IVD) medical device intended for the quantitative determination of various clinical chemistry tests contained within i-STAT cartridges using whole blood. The *i-STAT 1 System* consists of a portable blood analyzer (*i-STAT 1* analyzer), single-use disposable test cartridges (i-STAT cartridges), liquid quality control and calibration verification materials, and accessories (*i-STAT 1* Downloader/Recharger, *i-STAT* Electronic Simulator and *i-STAT 1* Printer). The *i-STAT 1 System*, including the *i-STAT CG4+* cartridge, is designed for use by trained medical professionals in point of care or clinical laboratory settings and is for prescription use only.

The *i-STAT CG4+* cartridge contains the required sensors, a fluid pack (calibrant pouch), a sample entry well and closure, fluid channels, waste chamber, and the necessary mechanical features for controlled fluid movement within cartridge. The i-STAT cartridge format allows all the tests in the cartridge to be performed simultaneously. All the test steps and fluid movements occur within the *i STAT CG4+* cartridge. The *i-STAT 1* analyzer interacts with the *i-STAT CG4+* cartridge to move fluid across the sensors and generate a quantitative result. Cartridges require two to three drops of whole blood applied to the cartridge using a transfer device, by the trained user before the cartridge is placed within the analyzer.

The *i-STAT 1* analyzer is a handheld, *in vitro* diagnostic analytical device designed to run only i-STAT test cartridges. The analyzer functions as the main user interface and the electro-mechanical interface to the test cartridge. All within-cartridge fluid movements, as well as the timing and heating of the test cycle, are automated and controlled without user intervention by system software embedded within the analyzer.

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, partial pressure of oxygen (PO_2), and partial pressure of carbon dioxide (PCO_2) in arterial, venous, or capillary whole blood in point of care or clinical laboratory settings.

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.

pH, PO_2, and PCO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic, and 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

Table 1: **Similarities and Differences: System (Test and Instrument)**		
Feature or Characteristic	**Candidate Device: i-STAT CG4+ cartridge with the i-STAT 1 System**	**Predicate Device: i-STAT G3+ cartridge with the i-STAT 1 System (K223857)**
Intended Use	The i-STAT CG4+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of pH, partial pressure of oxygen (PO_2), and partial pressure of carbon dioxide (PCO_2) in arterial, venous, or capillary whole blood in point of care or clinical laboratory settings. 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. pH, PO_2, and PCO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic, and 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.	The i-STAT G3+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of pH, partial pressure of oxygen (PO_2), and partial pressure of carbon dioxide (PCO_2) in arterial, venous, or capillary whole blood in point of care or clinical laboratory settings. pH, PO_2, and PCO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic, and acid-base disturbances.
Device Classification(s)	Class II - PCO_2, PO_2, pH Class I - Lactate	Class II - PCO_2, PO_2, pH
Product Code(s)	CHL, KHP	CHL
Regulation Number(s)	862.1120, 862.1450	862.1120

<table>
<tr><th colspan="3">Table 1: Similarities and Differences: System (Test and Instrument)</th></tr>
<tr><th>Feature or Characteristic</th><th>Candidate Device:
i-STAT CG4+ cartridge with the i-STAT 1 System</th><th>Predicate Device:
i-STAT G3+ cartridge with the i-STAT 1 System
(K223857)</th></tr>
<tr><td>Reportable Range</td><td><table><tr><td>pH</td><td>6.500 – 7.800</td></tr><tr><td>PO_2</td><td>5 – 700 mmHg
0.7 – 93.3 kPa</td></tr><tr><td>PCO_2</td><td>5 – 130 mmHg
0.67 – 17.33 kPa</td></tr><tr><td>Lactate</td><td>0.30 – 20.00 mmol/L
2.7 – 180.2 mg/dL</td></tr></table></td><td><table><tr><td>pH</td><td>Same</td></tr><tr><td>PO_2</td><td>Same</td></tr><tr><td>PCO_2</td><td>Same</td></tr></table></td></tr>
<tr><td>Sample Type</td><td><table><tr><td>pH, PO_2, PCO_2</td><td>Arterial, venous or capillary whole blood</td></tr><tr><td>lactate</td><td>Arterial or venous whole blood</td></tr></table></td><td><table><tr><td>pH, PO_2, PCO_2</td><td>Same</td></tr></table></td></tr>
<tr><td>Sample Volume</td><td>95 µL</td><td>Same</td></tr>
<tr><td>Sample Preparation</td><td>Ready to Use</td><td>Same</td></tr>
<tr><td>Sample Collection</td><td><table><tr><td>pH, PO_2, PCO_2</td><td>• Without anticoagulant (for arterial and venous whole blood sample types)
• With balanced heparin anticoagulant or lithium heparin anticoagulant (for arterial, venous, and capillary whole blood sample types)</td></tr><tr><td>lactate</td><td>• Without anticoagulant (for arterial and venous whole blood sample types)
• With balanced heparin anticoagulant or lithium heparin</td></tr></table></td><td><table><tr><td>pH, PO_2, PCO_2</td><td>Same</td></tr></table></td></tr>
</table>

<table>
<tr><th colspan="3">Table 1: Similarities and Differences: System (Test and Instrument)</th></tr>
<tr><th>Feature or Characteristic</th><th>Candidate Device:
i-STAT CG4+ cartridge with the i-STAT 1 System</th><th>Predicate Device:
i-STAT G3+ cartridge with the i-STAT 1 System
(K223857)</th></tr>
<tr><td></td><td><table><tr><td></td><td>anticoagulant (for arterial and venous whole blood sample types)</td></tr></table></td><td></td></tr>
<tr><td>Traceability</td><td><table><tr><td>pH</td><td>Traceable to NIST SRMs 186-I, 186-II, 185 and 187</td></tr><tr><td>PO₂, PCO₂</td><td>Traceable to NIST SRMs via commercially available certified specialty medical gas tanks</td></tr><tr><td>Lactate</td><td>Certified Standard Reference Material not available at present; traceable to i-STAT manufacturer’s working calibrator (MWC) prepared from sodium L-lactate (Sigma-Aldrich Fluka, >99 % purity)</td></tr></table></td><td><table><tr><td>pH</td><td>Same</td></tr><tr><td>PO₂, PCO₂</td><td>Same</td></tr></table></td></tr>
<tr><td>Calibration</td><td>1-point on-board contained within cartridge</td><td>Same</td></tr>
</table>

<table>
<tr><th colspan="3">Table 1: Similarities and Differences: System (Test and Instrument)</th></tr>
<tr><th>Feature or Characteristic</th><th>Candidate Device:
i-STAT CG4+ cartridge with the i-STAT 1 System</th><th>Predicate Device:
i-STAT G3+ cartridge with the i-STAT 1 System
(K223857)</th></tr>
<tr><td>Time to Test/ Sample Stability
(Time from collection to sample fill)</td><td>
<table>
<tr><th colspan="2">Without anticoagulant:</th></tr>
<tr><td>pH, PO_2, PCO_2 (arterial and venous)</td><td>within 3 minutes</td></tr>
<tr><td>Lactate (arterial and venous)</td><td>Immediately</td></tr>
<tr><th colspan="2">With anticoagulant:</th></tr>
<tr><td>pH, PO_2, PCO_2 (arterial and venous)</td><td>within 10 minutes</td></tr>
<tr><td>pH, PO_2, PCO_2 (capillary)</td><td>within 3 minutes</td></tr>
<tr><td>Lactate (arterial and venous)</td><td>Immediately</td></tr>
</table>
</td><td>
<table>
<tr><th colspan="2">Without anticoagulant:</th></tr>
<tr><td>pH, PO_2, PCO_2 (arterial and venous)</td><td>Same</td></tr>
</table>
<table>
<tr><th colspan="2">With anticoagulant:</th></tr>
<tr><td>pH, PO_2, PCO_2 (arterial and venous)</td><td>Same</td></tr>
<tr><td>pH, PO_2, PCO_2 (capillary)</td><td>Same</td></tr>
</table>
</td></tr>
<tr><td>Principle of Measurement</td><td>pH, PCO_2: Potentiometric measurement between active working sensor and independent reference sensor.
PO_2: Amperometric measurement of oxygen reduction current.
Lactate: Amperometric measurement of oxidized hydrogen peroxide produced by lactate oxidase activity.</td><td>pH, PCO_2: Same

PO_2: Same</td></tr>
<tr><td>Reagent Format</td><td>Cartridge</td><td>Same</td></tr>
<tr><td>Storage Conditions</td><td>Refrigerated at 2 to 8°C (35 to 46°F) until expiration date.
Room Temperature at 18-30°C (64-86°F) for 2 months.</td><td>Same</td></tr>
<tr><td>Analyzer Type</td><td>Handheld</td><td>Same</td></tr>
</table>

7. Performance Characteristics

A. Analytical Performance

a. Precision/Reproducibility:

i. Precision 20 days (Aqueous Materials)

The precision of the *i-STAT* pH, PO_2, PCO_2, and Lactate tests in the *i-STAT CG4+* cartridge with the *i-STAT 1 System* was evaluated using five (5) levels of aqueous materials. The study followed the standard single-site 20x2x2 experimental design based on guidance provided in CLSI document EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition*. The study was conducted using multiple analyzers and one (1) test cartridge lot over at least 20 days at one (1) site. Repeatability, between-run, between-day, and within-laboratory precision were estimated for each level. The results of the 20-day precision study for the *i-STAT CG4+* cartridge on the *i-STAT 1 System* are shown in **Table 2**.

Table 2: 20-Day Precision of i-STAT CG4+ Cartridge on the i-STAT 1 Analyzer

Test (units)	Fluid Level	Mean	N	Repeatability		Between-run		Between-day		Within-Laboratory	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
pH (pH units)	CV L1	6.5701	84	0.00359	0.05	0.00280	0.04	0.00034	0.01	0.00457	0.07
	CV L2	7.0259	84	0.00178	0.03	0.00105	0.01	0.00068	0.01	0.00218	0.03
	CV L3	7.4532	83	0.00231	0.03	0.00051	0.01	0.00052	0.01	0.00242	0.03
	CV L4	7.6338	84	0.00961	0.13	0.00325	0.04	0.00266	0.03	0.01049	0.14
	CV L5	7.9653	84	0.00236	0.03	0.00081	0.01	0.00165	0.02	0.00299	0.04
PO_2 (mmHg)	CV L1	71.0	84	1.71	2.41	0.65	0.92	1.03	1.45	2.10	2.96
	CV L2	82.6	84	1.74	2.11	0.58	0.70	0.45	0.54	1.89	2.29
	CV L3	108.9	83	1.86	1.71	1.00	0.91	0.67	0.62	2.22	2.03
	CV L4	138.8	84	2.52	1.82	0.90	0.65	1.12	0.81	2.90	2.09
	CV L5	372.9	84	4.66	1.25	5.29	1.42	2.07	0.56	7.35	1.97
PCO_2 (mmHg)	CV L1	89.41	84	1.251	1.40	0.626	0.70	0.354	0.40	1.443	1.61
	CV L2	56.28	84	0.621	1.10	0.338	0.60	0.165	0.29	0.726	1.29
	CV L3	29.37	83	0.365	1.24	0.128	0.43	0.141	0.48	0.412	1.40
	CV L4	22.69	84	0.707	3.11	0.196	0.86	0.191	0.84	0.758	3.34
	CV L5	12.19	84	0.377	3.10	0.131	1.07	0.123	1.01	0.418	3.43
Lactate (mmol/L)	CV L1	19.791	84	0.1827	0.92	0.0869	0.44	0.0226	0.11	0.2035	1.03
	CV L2	7.874	84	0.0592	0.75	0.0302	0.38	0.0123	0.16	0.0676	0.86
	CV L3	2.110	83	0.0128	0.61	0.0051	0.24	0.0046	0.22	0.0146	0.69
	CV L4	0.820	84	0.0135	1.64	0.0036	0.44	0.0049	0.60	0.0148	1.80
	CV L5	0.410	84	0.0128	3.13	0.0028	0.70	0.0055	1.35	0.0142	3.47

ii. Multi-site and operator-to-operator precision (Aqueous materials)

Multi-day precision testing was performed at three (3) point of care sites using a panel of aqueous material containing five (5) levels of pH, PO_2, PCO_2, and lactate. The study followed a 3x5x2x3 design based on guidance provided in CLSI EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition*. At each site, each level was tested once per day by two (2) operators for five (5) days on six (6) *i-STAT 1* analyzers using one (1) lot of *i-STAT CG4+* cartridges. Repeatability, between-day, between-operator, within-site, between-site variance components, and reproducibility were calculated for all sites combined and provided in the **Table 3** below.

Table 3: Multi-Site Multi-Day Precision of i-STAT CG4+ Cartridge on the i-STAT 1 Analyzer

Test (units)	Fluid Level	N	Mean	Repeatabilty		Between-Day		Between-Operator		Within-Site		Between-Site		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
pH (pH units)	CV L1	90	6.5725	0.00404	0.06	0.00111	0.02	0.00281	0.04	0.00504	0.08	0.00147	0.02	0.00525	0.08
	CV L2	90	7.0266	0.00204	0.03	0.00133	0.02	0.00124	0.02	0.00274	0.04	0.00201	0.03	0.00340	0.05
	CV L3	90	7.4540	0.00139	0.02	0.00062	0.01	0.00119	0.02	0.00193	0.03	0.00080	0.01	0.00209	0.03
	CV L4	90	7.6373	0.00194	0.03	0.00046	0.01	0.00096	0.01	0.00222	0.03	0.00142	0.02	0.00263	0.03
	CV L5	90	7.9681	0.00194	0.02	0.00062	0.01	0.00093	0.01	0.00224	0.03	0.00107	0.01	0.00248	0.03
PO_2 (mmHg)	CV L1	91	76.9	2.80	3.64	0.95	1.23	2.63	3.42	3.96	5.15	2.20	2.87	4.53	5.89
	CV L2	90	87.4	2.02	2.31	0.86	0.98	2.13	2.44	3.06	3.50	2.56	2.93	3.99	4.57
	CV L3	90	113.4	2.34	2.06	0.57	0.50	1.57	1.38	2.87	2.53	3.08	2.71	4.21	3.71
	CV L4	90	141.4	2.63	1.86	1.50	1.06	1.15	0.82	3.24	2.29	3.47	2.45	4.74	3.35
	CV L5	90	366.0	6.26	1.71	2.92	0.80	7.53	2.06	10.21	2.79	4.66	1.27	11.23	3.07
PCO_2 (mmHg)	CV L1	90	89.41	1.365	1.53	0.501	0.56	0.710	0.79	1.618	1.81	0.000	0.00	1.618	1.81
	CV L2	90	57.20	0.508	0.89	0.287	0.50	0.311	0.54	0.661	1.16	0.000	0.00	0.661	1.16
	CV L3	90	29.99	0.289	0.96	0.169	0.56	0.063	0.21	0.341	1.14	0.140	0.47	0.368	1.23
	CV L4	90	23.03	0.336	1.46	0.092	0.40	0.000	0.00	0.348	1.51	0.054	0.24	0.353	1.53
	CV L5	90	12.18	0.361	2.96	0.000	0.00	0.000	0.00	0.361	2.96	0.000	0.00	0.361	2.96
Lactate (mmol/L)	CV L1	91	18.928	0.1905	1.01	0.0573	0.30	0.0000	0.00	0.199	1.05	0.0000	0.00	0.1990	1.05
	CV L2	90	7.636	0.0423	0.55	0.0216	0.28	0.0126	0.16	0.0491	0.64	0.0000	0.00	0.0491	0.64
	CV L3	90	2.087	0.0084	0.40	0.0033	0.16	0.0022	0.11	0.0093	0.44	0.0061	0.29	0.0111	0.53
	CV L4	90	0.838	0.0090	1.08	0.0088	1.05	0.0023	0.28	0.0128	1.53	0.0053	0.63	0.0139	1.65
	CV L5	90	0.433	0.0124	2.87	0.0056	1.29	0.0012	0.27	0.0137	3.16	0.0053	1.21	0.0146	3.39

iii. Precision (Whole Blood)

The precision of the i-STAT pH, PO_2, PCO_2 and Lactate tests in the *i-STAT CG4+* cartridge on the *i-STAT 1 System* was evaluated using anticoagulated arterial, venous, and capillary[1] whole blood specimens. The whole blood precision was assessed using duplicate test results collected across multiple point of care sites. For each sample type, the specimens were grouped into subintervals of the test reportable range for analysis. The results are summarized in **Table 4**.

Table 4: Whole blood precision of arterial, venous, and capillary whole blood for i-STAT CG4+ cartridge on the i-STAT 1 analyzer

Test (units)	Sample Type	Sample Range	N	Mean	SD	%CV
pH (pH units)	Venous Whole Blood	6.500-7.300	9	7.0265	0.00235	0.03
		>7.300 – 7.450	154	7.3745	0.00668	0.09
		>7.450-7.800	12	7.5355	0.00732	0.10
	Arterial Whole Blood	6.500-7.300	9	7.2229	0.00262	0.04
		>7.300 – 7.450	124	7.3816	0.00486	0.07
		>7.450-7.800	43	7.4763	0.00690	0.09
	Capillary Whole Blood	6.500-7.300	3	7.2477	0.01355	0.19
		7.300-7.450	121	7.4099	0.02084	0.28
		>7.450-7.800	32	7.4781	0.02609	0.35
PO_2 (mmHg)	Venous Whole Blood	10-40	125	26.2	0.91	3.49
		>40-50	21	43.1	0.98	2.26
		>50-100	24	59.3	1.32	2.23
		>100-250	3	227.7	2.65	1.16
		>250-700	8	508.4	6.96	1.37
	Arterial Whole Blood	>50-100	108	73.2	1.29	1.76
		>100-250	66	135.9	2.90	2.13
		>250-700	3	381.3	8.94	2.35
	Capillary Whole Blood	10-40	15	33.8	4.30	12.74
		>40-50	34	46.0	3.84	8.35
		>50-100	112	63.4	6.04	9.52
		>100-250*	5	166.4	12.98	7.80
		>250-700	8	489.6	8.53	1.74
PCO_2 (mmHg)	Venous Whole Blood	5.0-35.0	23	30.17	0.379	1.26
		>35.0-50.0	119	46.48	0.639	1.38
		>50.0-62.5	31	57.05	0.687	1.20
		>62.5-130.0	10	117.05	1.650	1.41
	Arterial Whole Blood	5.0-35.0	48	33.24	0.393	1.18
		>35.0-50.0	105	44.55	0.641	1.44
		>50.0-62.5	16	61.33	1.100	1.79
		>62.5-130.0	6	77.18	1.080	1.40

[1] The capillary whole blood clinical precision study design involved collection of capillary blood (from either two fingersticks or a single heelstick) into two (2) anticoagulated capillary tubes and each tube was used to fill a single i-STAT CG4+ cartridge.

Table 4: Whole blood precision of arterial, venous, and capillary whole blood for i-STAT CG4+ cartridge on the i-STAT 1 analyzer						
Test (units)	**Sample Type**	**Sample Range**	**N**	**Mean**	**SD**	**%CV**
Lactate (mmol/L)	Capillary Whole Blood	5.0-35.0	47	32.31	1.736	5.37
		>35.0-50.0	105	40.00	2.258	5.64
		>50.0-62.5	3	58.35	1.967	3.37
		>62.5-130.0	1	68.20	2.263	3.32
	Venous Whole Blood	0.30-1.00	100	0.639	0.0127	1.99
		>1.00-5.00	81	1.549	0.0206	1.33
		>5.00-20.00	20	12.476	0.0756	0.61
	Arterial Whole Blood	0.30-1.00	55	0.653	0.0138	2.11
		>1.00-5.00	76	1.771	0.0184	1.04
		>5.00-20.00	3	8.120	0.0252	0.31

* A potential outlier due to preanalytical handling was identified for one (1) subject; PO_2 precision for capillary whole blood in sample range 100-250 mmHg with this subject excluded (N=4) is as follows: Mean = 177.8 mmHg; SD = 5.50, %CV=3.09

iv. Precision (Within-Sample, Capillary Specimens)

Whole blood within sample precision of the i-STAT pH, PO_2, and PCO_2 tests in the *i-STAT CG4+* cartridge on the *i-STAT 1 System* was evaluated using native and contrived pooled capillary whole blood samples.

Native capillary whole blood samples collected from 30 subjects via fingerstick punctures and tested in duplicate at Abbott Point of Care were assessed for within sample precision. Results are summarized in **Table 5**.

Table 5: Whole blood precision (within sample) of native capillary whole blood for i-STAT CG4+ cartridge on the i-STAT 1 analyzer					
Test	**Units**	**N**	**Mean**	**SD**	**%CV**
pH	pH units	60	7.4848	0.01688	0.23
PO_2	mmHg	60	143.1	4.55	3.18
PCO_2	mmHg	60	30.34	1.505	4.96

Capillary whole blood samples collected from an additional 27 subjects used to prepare two levels of PO_2 (16 for low and 11 for high) at Abbott Point of Care were assessed for within sample precision by testing each sample in duplicate. Results for the contrived capillary whole blood samples are summarized in **Table 6**.

Table 6 : Whole blood precision (within sample) of contrived capillary whole blood for i-STAT CG4+ cartridge on the i-STAT 1 analyzer						
Test	**Units**	**Sample Level**	**N**	**Mean**	**SD**	**%CV**
pH	pH units	L1	32	7.3111	0.00996	0.14
		L2	22	7.3176	0.01572	0.21
PO_2	mmHg	L1	32	43.4	0.51	1.18
		L2	22	427.4	5.86	1.37
PCO_2	mmHg	L1	32	40.45	0.387	0.96
		L2	22	36.16	0.178	0.49

b. Linearity/assay reportable range:

i. Linearity

The study was designed based on CLSI EP06-Ed2: *Evaluation of the Linearity of Quantitative Measurement Procedures – Second Edition*. The linearity of the i-STAT pH, PO_2, PCO_2, and Lactate tests in the *i-STAT CG4+* cartridge with the *i-STAT 1 System* were 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 in the *i-STAT CG4+* cartridge demonstrated linearity across the reportable range for each test. The regression summary of the results from each i-STAT test versus the expected values of the whole blood samples is provided in **Table 7.**

Table 7: Regression summary for the i-STAT pH, PO_2, PCO_2, and Lactate tests in the CG4+ cartridge on the i-STAT 1 analyzer						
Test	**Units**	**Reportable Range**	**Range Tested**	**Slope**	**Intercept**	**R^2**
pH	pH units	6.500 – 7.800	6.4509 – 7.9500	1.012	-0.096	0.9996
PO_2	mmHg	5 – 700	3.5 – 723.4	0.990	0.176	0.9970
PCO_2	mmHg	5.0 – 130.0	2.59 – 145.97	1.016	-0.513	0.9986
Lactate	mmol/L	0.30 – 20.00	0.276 – 21.502	1.012	0.033	0.9991

c. Traceability, Calibration and Reference Range

i. Traceability and Calibration

The measured analytes in the *i-STAT CG4+* 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 values assigned to the *i-STAT System* controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference materials SRMs 186-I, 186-II, 185, and 187.

PO₂ values assigned to the *i-STAT System* controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards.

PCO₂ 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.

Lactate: Presently, no international conventional reference measurement procedure or international conventional calibrator for lactate is available. Lactate values assigned to the *i-STAT System* controls and calibration verification materials are traceable to *i-STAT System* working calibrator prepared from sodium L-lactate (Sigma-Aldrich Fluka, >99 % purity).

ii. Reference Range

Reference ranges for the *i-STAT CG4+* cartridge are based on literature reference and are listed in **Table 8** below.

Table 8: Reference Ranges

Test	Units	Reportable Range	Reference Range	
			Arterial	Venous
pH	pH units	6.50 – 7.80	7.35 – 7.45 [1]	7.31 – 7.41*
PO_2	mmHg	5 – 700	80 – 105 [2]**	–
	kPa	0.7 – 93.3	10.7 – 14.0 [2]**	–
PCO_2	mmHg	5 – 130	35 – 45 [1]	41 – 51[1]
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
Lactate	mmol/L	0.30 – 20.00	0.36 – 1.25 [3]***	0.90 – 1.70 [3]***
	mg/dL	2.7 – 180.2	3.2 – 11.3 [3]***	8.1 – 15.3 [3]***

* 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).

***The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

[1] Painter, P. C., Cope, J. Y., and Smith, J. L. (1994) "Reference Ranges, Table 41-20" In *Teitz Textbook of Clinical Chemistry*, 2nd Ed. Burtis CA, Ashwood ER, eds. W.B. Saunders, Philidelphia.

[2] Statland, B. E. (1987) *Clinical Decision Levels for Lab Tests*, 2nd Ed., Medical Economics Books, Oradell, N.J.

[3] Sacks, D. B. (1994) Carbohydrates In *Teitz Textbook of Clinical Chemistry*, 2nd Ed. Burtis CA, Ashwood ER, eds. W.B. Saunders, Philidelphia.

d. Detection Limit

i. 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+* cartridge were evaluated on the *i-STAT 1* analyzer using two (2) *i-STAT CG4+* cartridge lots, and whole blood that was altered to a low analyte level for each i-STAT test. The LoQ for each of the i-STAT tests was determined to be at or below the lower limit of the reportable range for each of the i-STAT tests as shown in **Table 9**.

Table 9: Summary of LoQ results for the pH, PO_2, PCO_2, and lactate tests in the i-STAT CG4+ cartridge on the i-STAT 1 analyzer			
Test	**Units**	**Lower limit of the reportable range**	**LoQ**
pH	pH units	6.500	6.471
PO_2	mmHg	5	5
PCO_2	mmHg	5.0	3.0
Lactate	mmol/L	0.30	0.18

ii. 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+* cartridge were evaluated on the *i-STAT 1* analyzer using two (2) *i-STAT CG4+* cartridge lots. Whole blood was altered to achieve a blank lactate level for LoB testing and two (2) low lactate levels 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 10** below.

Table 10: Summary of LoB and LoD results for the lactate test in the i-STAT CG4+ cartridge on the i-STAT 1 analyzer			
Test	**Units**	**LoB**	**LoD**
Lactate	mmol/L	0	0.026

e. Analytical Specificity

i. Interference

The interference performance of the i-STAT pH, PO_2, PCO_2, and Lactate tests in the *i-STAT CG4+* cartridge on the *i STAT 1* analyzer with the *i-STAT 1 System* 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 test 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 in means (or medians) between the control and test samples was outside of the allowed error (±Ea) for the i-STAT test. For an identified interferent, a dose-response was performed to determine the degree of interference as a function of the substance concentration. **Table 11** contains the lists of potentially interfering substances tested and the interference results for the *i-STAT CG4+* cartridge.

Table 11: Potentially Interfering Substances and Test Concentrations for the pH, *P*O$_2$, *P*CO$_2$, and Lactate Tests in the i-STAT CG4+ Cartridge on the i-STAT 1 Analyzer					
Substance [2]	**Substance Concentration**		**i-STAT Test**	**Interference (Yes/No)**	**Comments**
	mmol/L (unless specified)	**mg/dL (unless specified)**			
Acetaldehyde [3]	0.045	0.2	Lactate	No	
Acetaminophen	1.03	15.6	pH	No	
			*P*O$_2$	No	
			*P*CO$_2$	No	
			Lactate	No	
Acetyl Cysteine (N-Acetyl-Cysteine)	0.92	15.0	Lactate	No	
Ascorbic Acid (L-Ascorbic Acid)	0.298	5.25	Lactate	No	
Atracurium (Atracurium Besylate)[3]	0.0287	3.57	pH	No	
			*P*O$_2$	No	
			*P*CO$_2$	No	
β-Hydroxybutyric Acid [3]	6.0	62.46	Lactate	No	
Bilirubin	0.684	40	pH	No	
			*P*O$_2$	No	
			*P*CO$_2$	No	
			Lactate	No	
Bromide [3] (Lithium Bromide)	2.5	21.7	Lactate	No	
	37.5	325.7	Lactate	Yes	Use another method. Decreased results >10.0 mmol/L bromide.
Calcium (Calcium Chloride)	5.0	20	pH	No	
			*P*O$_2$	No	
			*P*CO$_2$	No	
Dopamine (Dopamine Hydrochloride)	4.06 µmol/L	0.0621	Lactate	No	
Ethanol	130	600	pH	No	
			*P*O$_2$	No	
			*P*CO$_2$	No	
Formaldehyde [3]	0.133	0.399	Lactate	No	
Glycolic Acid [3]	10.0	76.05	Lactate	Yes	Increased results >0.8 mmol/L glycolic acid.

[2] The compound tested to evaluate the interfering substance is presented in parenthesis.
[3] The test concentration for this substance is not included in CLSI guideline EP37 1st edition.

Table 11: Potentially Interfering Substances and Test Concentrations for the pH, PO_2, PCO_2, and Lactate Tests in the i-STAT CG4+ Cartridge on the i-STAT 1 Analyzer					
Substance [2]	**Substance Concentration**		**i-STAT Test**	**Interference (Yes/No)**	**Comments**
	mmol/L (unless specified)	**mg/dL (unless specified)**			
Hemoglobin	10 g/L	1000	pH	No	
			PO_2	No	
			PCO_2	No	
			Lactate	No	
Hydroxyurea	0.405	3.08	Lactate	No	
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	
		3579	Lactate	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	
Pyruvate (Lithium Pyruvate)	0.570	5	Lactate	No	
Salicylate (Lithium Salicylate)	0.207	2.86	Lactate	No	
Sodium (Sodium Chloride)	170	993.48	pH	No	
			PO_2	No	
			PCO_2	No	
Thiocyanate (Lithium Thiocyanate)	0.898	5.22	Lactate	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	
			Lactate	No	
Uric Acid	1.4	23.5	Lactate	No	

ii. Other sensitivity studies

1) Oxygen Sensitivity for the i-STAT Lactate Test

The effect of oxygen on the i-STAT Lactate test in the *i-STAT CG4+* cartridge on the *i-STAT 1 System* was evaluated with low and high oxygen levels using whole blood samples altered to four (4) lactate levels across the test reportable range. The equivalency between the high and low oxygen conditions was determined if the 95% confidence interval (CI) of the difference in means (or medians) was within the allowable error (±Ea). The study demonstrated that the *i-STAT* Lactate test in the *i-STAT CG4+* cartridge on the *i-STAT 1 System* perform is insensitive to oxygen levels between 28 and 521 mmHg.

2) Altitude

The performance of the *i-STAT* pH, PO_2, PCO_2, and Lactate tests in the *i-STAT CG4+* cartridge on the *i STAT 1* analyzer at an altitude of approximately 10,000 feet above sea level was evaluated using whole blood samples at relevant analyte levels across the reportable range for each test. The pH, PO_2, PCO_2 and lactate results obtained from the *i-STAT CG4+* cartridges (candidate device) were compared to the results obtained from the *i-STAT CG4+* cartridges (blue) on the *i-STAT 1* analyzer (K200492; comparator device) condition. Passing-Bablok regression analyses between the first replicate of the candidate device (y-axis) and mean of the comparator device (x-axis) were performed based on the CLSI EP09c-ED3: *Measurement Procedure Comparison and Bias Estimation using Patient Samples– Third Edition*. The results of the correlation coefficient and slope met acceptance criteria and demonstrate equivalent performance between the candidate and comparator condition at approximately 10,000 feet above sea level. The results are summarized in **Table 12** below.

Table 12: Summary of Altitude Study Results

Test	Correlation Coefficient (r)		Slope	
	r	95% CI	Slope	95% CI
pH	1.00	0.999 to 1.000	1.00	0.995 to 1.005
PO_2	1.00	0.997 to 0.999	1.03	1.014 to 1.049
PCO_2	1.00	0.999 to 0.999	0.96	0.949 to 0.967
Lactate	1.00	0.999 to 1.000	1.00	0.992 to 1.003

B. Comparison Studies

a. Method Comparison

Method comparison for arterial, venous, and capillary whole blood specimens on the i-*STAT CG4+* cartridge with the *i-STAT 1 System* was demonstrated in studies based on CLSI EP09c-ED3: *Measurement Procedure Comparison and Bias Estimation Using Patient Samples – Third Edition*.

Heparinized arterial and venous whole blood specimens collected across multiple point of care sites were evaluated using *i-STAT CG4+* cartridges on the *i-STAT 1* analyzer against whole blood specimens tested on a comparative method. For pH and PO_2, 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. For PCO_2 and lactate, the

first replicate result from the *i-STAT 1* analyzer was compared to the mean 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. One (1) tube was used to test in singlicate on the *i-STAT 1* analyzer and the other tube was used to test in singlicate on the comparative method.

The arterial, venous, and capillary data were pooled, and a Passing-Bablok linear regression analysis for pH, PO_2, and PCO_2 was performed using the singlicate result from the *i-STAT CG4+* cartridge versus the result from the comparative method.

The method comparison results for arterial, venous, and capillary whole blood specimens are shown in **Table 13**. In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Table 13: Method Comparison Results for the pH, PO_2, and PCO_2 tests on the i-STAT CG4+ Cartridge with i-STAT 1 System

Test (units)	Comparative Method		N	Slope	Intercept	r	Medical Decision Level	Bias at Medical Decision Level
	Arterial/ Venous	Capillary						
pH (pH units)	RAPIDPoint 500/500e	RAPIDPoint 500/500e	551	1.00	-0.01	0.98	7.30	-0.0080
							7.35	-0.0080
							7.40	-0.0080
PO_2 (mmHg)	RAPIDPoint 500/500e	RAPIDPoint 500/500e	557	1.01	-1.29	0.99	30	-0.9
							45	-0.7
							60	-0.6
PCO_2 (mmHg)	i-STAT G3+	i-STAT G3+	475	1.03	-0.30	0.99	35.0	0.67
							45.0	0.95
							50.0	1.08
							70.0	1.64

The arterial and venous data were pooled, and a Passing-Bablok linear regression analysis for Lactate was performed using the singlicate result from the *i-STAT CG4+* cartridge versus the result from the comparative method. The method comparison results for arterial and venous whole blood specimens are shown in **Table 14**.

Table 14: Method Comparison Results for the Lactate test on the i-STAT CG4+ Cartridge with i-STAT 1 System							
Test (units)	**Comparative Method**	**N**	**Slope**	**Intercept**	**r**	**Medical Decision Level**	**Bias at Medical Decision Level**
Lactate (mmol/L)	i-STAT CG4+ (K200492)	345	1.00	0.00	1.00	5.00	-0.140

The method comparison results for capillary whole blood specimens only for pH, PO_2, and PCO_2 are shown in **Table 14**.

Table 15: Results for i-STAT CG4+ Cartridge with i-STAT 1 System- Native and Contrived Capillary Specimens						
Test (units)	**N**	**Slope**	**Intercept**	**r**	**Xmin**	**Xmax**
pH (pH units)	193	1.01	-0.08	0.97	6.607	7.709
PO_2 (mmHg)	192	1.08	-5.47	0.99	14.0	554.0
PCO_2 (mmHg)	184	1.05	-0.54	0.98	8.9	125.8

Bias at the medical decision levels for native capillary whole blood specimens only for pH, PO_2, and PCO_2 are shown in **Table 15.**

Table 16: Results for i-STAT CG4+ 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)	178	7.259	7.531	7.30	-0.0166	(-0.0341, 0.0007)
				7.35	-0.0104	(-0.0207, 0.0000)
				7.40	-0.0041	(-0.0095, 0.0013)
PO_2 (mmHg)	178	31	139	30	-3.3	(-6.1, -0.4)
				45	-2.1	(-3.7, -0.4)
				60	-0.9	(-2.1, 0.0)
PCO_2 (mmHg)	175	23.1	78.6	35.0	1.18	(0.48, 1.75)
				45.0	1.84	(1.04, 2.46)
				50.0	2.17	(1.15, 3.03)
				70.0	3.49	(1.40, 5.49)

b. Matrix Equivalence

A matrix equivalence study was conducted to evaluate the performance of the *i-STAT* pH, PO_2, PCO_2 and Lactate tests in the *i STAT CG4+* cartridge on the *i STAT 1 System* using non-

anticoagulated arterial and venous whole blood specimens. The study design and analysis method were based on recommendations from CLSI EP35: *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, First Edition*. The matrix equivalence of each test in the *i-STAT CG4+* cartridge was assessed by comparing arterial or venous whole blood specimens collected without anticoagulant (candidate specimen type) to samples collected with balanced heparin or lithium heparin anticoagulant (primary specimen type). Each specimen was tested in duplicate using two (2) *i-STAT CG4+* cartridges with two (2) *i-STAT 1* analyzers. A Passing-Bablok linear regression analysis was performed using the first replicate result from the candidate (y-axis) versus the first replicate result from the primary specimen (x-axis). The regression analysis results are summarized in **Table 16.** In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Table 17: Matrix Equivalence Results

Test (units)	N	Candidate Specimen Range	Primary Specimen Range	r	Slope	Intercept
pH (pH units)	228	7.176-7.567	7.192-7.549	0.96	1.00	0.00
PO_2 (mmHg)	228	15-197	15-197	0.99	1.01	-0.53
PCO_2 (mmHg)	228	26.3-77.4	26.8-77.0	0.97	1.03	-1.58
Lactate (mmol/L)	289	0.31-19.42	0.30-19.43	1.00	1.00	-0.02

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+* cartridge with the *i-STAT 1 System* are substantially equivalent to the predicate device.