October 27, 2023

Abbott Point of Care Inc.
Jacquelyn Gesumaria
Principal Regulatory Affairs Specialist
400 College Road East
Princeton, New Jersey 08540

Re: K230285
Trade/Device Name: i-STAT CG8+ 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
Dated: September 28, 2023
Received: September 28, 2023

Dear Jacquelyn Gesumaria:

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.

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.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230285

Device Name
i-STAT CG8+ cartridge with the i-STAT 1 System

Indications for Use *(Describe)*
The i-STAT CG8+ 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.

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.

I. SUBMITTER INFORMATION

Owner	Abbott Point of Care Inc. 400 College Road East Princeton, NJ 08540
Contact	Primary: Jacquelyn Gesumaria Principal Regulatory Affairs Specialist Phone: 609-454-9384 Secondary: Mojgan Soleimani Associate Director Regulatory Affairs Phone: 613-295-0932
Date Prepared	October 27, 2023

II. DEVICE INFORMATION

Proprietary Name	*i-STAT CG8+* cartridge with the *i-STAT 1 System*
Common Name	Blood gas test, analyzer, handheld
510(k) Number	K230285

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

III. PREDICATE DEVICE

Proprietary Name	RAPIDPoint 500e Blood Gas System
510(k) Number	K192240

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

IV. DEVICE DESCRIPTION

The *i-STAT CG8+* cartridge is used with the *i-STAT 1* analyzer as part of the *i-STAT 1 System* and contains test reagents to measure pH, partial pressure of oxygen (PO_2), and partial pressure of carbon dioxide (PCO_2) in arterial, venous or capillary 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 CG8+* 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 CG8+* 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 movement occur within the *i-STAT CG8+* cartridge. 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 instrument interacts with the *i-STAT CG8+* cartridge to move fluid across the sensors and generate a quantitative result (within approximately 2 minutes).

V. INTENDED USE STATEMENT

The *i-STAT CG8+* 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.

VI. SUMMARY COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 1: Similarities and Differences (Test and Instrument): pH, *P*O_2, and *P*CO_2 in Arterial, Venous, and Capillary Whole Blood		
Feature or Characteristic	**Candidate Device:** pH, *P*O_2 and *P*CO_2 Tests in the: *i-STAT CG8+* cartridge with the *i-STAT 1 System*	**Predicate Device:** pH, *P*O_2 and *P*CO_2 Tests in the Siemens RAPIDPoint 500e Blood Gas System (K192240)
Intended Use	The *i-STAT CG8+* cartridge with the *i-STAT 1 System* is intended for use in the *in vitro* quantification of sodium, potassium, ionized calcium, glucose, hematocrit, pH, partial pressure of oxygen (*P*O_2), and partial pressure of carbon dioxide (*P*CO_2) in arterial, venous, or capillary whole blood in point of care or clinical laboratory settings. pH, *P*O_2, and *P*CO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory, metabolic and acid-base disturbances.	The RAPIDPoint 500e Blood Gas System is intended for *in vitro* diagnostic use and is designed to provide the determination in whole blood for the following parameters: • Partial pressure of carbon dioxide • Partial pressure of oxygen • pH • Sodium • Potassium • Ionized Calcium • Chloride • Glucose • Lactate • Total Hemoglobin and fractions: FO2Hb, FCOHb, FMetHb, FHHb • Neonatal Bilirubin The RAPIDPoint 500e Blood Gas System is also intended for in vitro testing of pleural fluid samples for the pH parameter. The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions. The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions and are exudative in nature. This test system is intended for use in point of care or laboratory settings. *p*CO_2, *p*O_2, pH: Measurements of blood gases (*p*CO_2, *p*O_2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.
Device Classification	Same	Class II
Product Code	Same	CHL

<table>
<tr><th colspan="3">Table 1: Similarities and Differences (Test and Instrument): pH, PO₂, and PCO₂ in Arterial, Venous, and Capillary Whole Blood</th></tr>
<tr><th>Feature or Characteristic</th><th>Candidate Device:
pH, PO₂ and PCO₂ Tests in the:
i-STAT CG8+ cartridge
with the i-STAT 1 System</th><th>Predicate Device:
pH, PO₂ and PCO₂ Tests in the
Siemens RAPIDPoint 500e
Blood Gas System
(K192240)</th></tr>
<tr><td>Regulation No.</td><td>Same</td><td>862.1120</td></tr>
<tr><td>Reportable Range</td><td><table><tr><td>pH</td><td>Same</td></tr><tr><td>PO₂</td><td>5 – 700 mmHg
0.7 – 93.3 kPa</td></tr><tr><td>PCO₂</td><td>5 – 130 mmHg
0.67 – 17.33 kPa</td></tr></table></td><td><table><tr><td>pH</td><td>6.500 – 7.800</td></tr><tr><td>pO₂</td><td>10.0 – 700.0 mmHg
1.33 – 93.32 kPa</td></tr><tr><td>pCO₂</td><td>5.0 – 200.0 mmHg
0.66 – 26.66 kPa</td></tr></table></td></tr>
<tr><td>Sample Type</td><td>Arterial, venous or capillary whole blood</td><td>• Whole blood (Arterial, Venous and Capillary for all analytes)
• Pleural Fluid (for pH test only)</td></tr>
<tr><td>Sample Volume</td><td>95 µL</td><td>100 µL</td></tr>
<tr><td>Sample Preparation</td><td>Same</td><td>Ready to use</td></tr>
<tr><td>Sample collection</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><td>With balanced heparin anticoagulant or lithium heparin anticoagulant</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></table></td><td><table><tr><td>pH</td><td>Traceable to NIST SRM 186 reference materials via the IFCC blood reference method.</td></tr><tr><td>PO₂, PCO₂</td><td>Traceable to tonometered aqueous standards prepared using NIST traceable temperature and pressure standards and gravimetrically prepared precision gas standards.</td></tr></table></td></tr>
<tr><td>Calibration</td><td>1-point calibration using reagents contained within cartridge</td><td>1-point, 2-point and full calibration using automated on-board reagent</td></tr>
</table>

Table 1: Similarities and Differences (Test and Instrument): pH, PO_2, and PCO_2 in Arterial, Venous, and Capillary Whole Blood		
Feature or Characteristic	**Candidate Device:** pH, PO_2 and PCO_2 Tests in the: *i-STAT CG8+* cartridge with the *i-STAT 1 System*	**Predicate Device:** pH, PO_2 and PCO_2 Tests in the Siemens RAPIDPoint 500e Blood Gas System (K192240)
Principle of Measurement	pH, PCO_2: Potentiometric measurement between active working sensor and independent reference sensor PO_2: Amperometric measurement of oxygen reduction current	pH, PCO_2: Potentiometric method PO_2: Amperometric measurement
Reagent Format	Same	Cartridge
Storage Conditions	Refrigerated at 2-8°C (35-46°F) until expiration date Room Temperature at 18-30°C (64-86°F) for 2 months	Refrigerated at 2 to 8°C (35 to 46°F) until stated "install-by-date"; 28 additional days after installation on system Room Temperature for up to 1 day
Analyzer Type	Handheld	Benchtop

VII. PERFORMANCE CHARACTERISTICS

A. Analytical Performance

a. Precision/Reproducibility:

i. Precision 20 days (Aqueous materials)

The precision of the i-STAT pH, Partial Pressure of Oxygen (PO_2), and Partial Pressure of Carbon Dioxide (PCO_2) tests in the *i-STAT CG8+* cartridge on the *i-STAT 1 System* was evaluated using five (5) levels of aqueous material. This 20-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 analyzers and one (1) test cartridge lot over 20 days at one 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 CG8+* cartridge on the *i-STAT 1 System* are shown in **Table 2**.

Table 2: Results of 20-Day Precision of the i-STAT CG8+ Cartridge on the i-STAT 1 Analyzer											
Test (units)	**Fluid Level**	**N**	**Mean**	**Repeatability**		**Between-run**		**Between-day**		**Within-Laboratory**	
				SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
pH (pH units)	CV L1	80	6.5831	0.00284	0.04	0.00354	0.05	0.00162	0.02	0.00482	0.07
	CV L2	80	7.0326	0.00165	0.02	0.00121	0.02	0.00102	0.01	0.00229	0.03
	CV L3	80	7.4574	0.00118	0.02	0.00170	0.02	0.00065	0.01	0.00217	0.03
	CV L4	80	7.6365	0.00133	0.02	0.00201	0.03	0.00072	0.01	0.00251	0.03
	CV L5	80	7.9612	0.00244	0.03	0.00188	0.02	0.00090	0.01	0.00321	0.04
PO_2 (mmHg)	CV L1	80	75.7	1.93	2.54	1.45	1.92	0.77	1.02	2.53	3.35
	CV L2	80	87.3	1.81	2.07	0.46	0.53	0.55	0.63	1.94	2.23
	CV L3	80	115.0	2.40	2.08	1.76	1.53	0.47	0.41	3.01	2.62
	CV L4	80	144.1	2.74	1.90	2.62	1.82	1.02	0.70	3.92	2.72
	CV L5	80	371.6	6.25	1.68	8.29	2.23	2.97	0.80	10.80	2.91

Table 2: Results of 20-Day Precision of the i-STAT CG8+ Cartridge on the i-STAT 1 Analyzer											
Test (units)	Fluid Level	N	Mean	Repeatability		Between-run		Between-day		Within-Laboratory	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
PCO_2 (mmHg)	CV L1	80	88.55	0.781	0.88	0.973	1.10	0.392	0.44	1.307	1.48
	CV L2	80	54.96	0.598	1.09	0.139	0.25	0.055	0.10	0.616	1.12
	CV L3	80	28.90	0.300	1.04	0.082	0.28	0.082	0.28	0.321	1.11
	CV L4	80	22.59	0.268	1.19	0.112	0.50	0.066	0.29	0.298	1.32
	CV L5	80	13.81	0.335	2.42	0.157	1.13	0.181	1.31	0.412	2.98

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

Multi-day precision testing was performed at three (3) sites using a panel of aqueous solutions containing five (5) levels of pH, PO_2, and PCO_2. At each site, each level was tested once a day by two (2) operators for five (5) days on six (6) *i-STAT 1* analyzers using *i-STAT CG8+* cartridges. Within-run, between-day, between-operator and within-site (total) variance components were calculated by site. These components were also calculated for all sites combined and provided in the **Table 3** below.

Table 3: Multi-Day Precision of the i-STAT CG8+ Cartridge on the i-STAT 1 Analyzer															
Test (units)	**Fluid Level**	**N**	**Mean**	**Within-Run**		**Between-Day**		**Between-Operator**		**Within-Site (Total)**		**Between-Site**		**Overall**	
				SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
pH (pH units)	CV L1	90	6.5829	0.00395	0.06	0.00267	0.04	0.00329	0.05	0.00579	0.09	0.00000	0.00	0.00579	0.09
	CV L2	90	7.0332	0.00317	0.05	0.00135	0.02	0.00054	0.01	0.00349	0.05	0.00000	0.00	0.00349	0.05
	CV L3	96	7.4571	0.00231	0.03	0.00080	0.01	0.00085	0.01	0.00258	0.03	0.00000	0.00	0.00258	0.03
	CV L4	90	7.6372	0.00184	0.02	0.00038	0.01	0.00116	0.02	0.00221	0.03	0.00000	0.00	0.00221	0.03
	CV L5	90	7.9627	0.00256	0.03	0.00035	0.00	0.00110	0.01	0.00281	0.04	0.00000	0.00	0.00281	0.04
PO_2 (mmHg)	CV L1	91	81.1	2.73	3.37	1.00	1.23	1.56	1.92	3.30	4.07	0.00	0.00	3.30	4.07
	CV L2	90	91.2	3.34	3.67	1.31	1.43	0.84	0.92	3.69	4.04	0.00	0.00	3.69	4.04
	CV L3	97	118.3	2.38	2.01	1.06	0.89	0.93	0.78	2.76	2.34	0.99	0.84	2.94	2.48
	CV L4	90	147.3	2.39	1.62	2.17	1.48	2.29	1.56	3.96	2.69	0.00	0.00	3.96	2.69
	CV L5	90	367.7	6.27	1.71	4.25	1.16	9.62	2.62	12.24	3.33	0.00	0.00	12.24	3.33
PCO_2 (mmHg)	CV L1	90	88.67	1.308	1.48	0.349	0.39	0.620	0.70	1.489	1.68	0.000	0.00	1.489	1.68
	CV L2	90	56.08	0.652	1.16	0.379	0.68	0.000	0.00	0.754	1.35	0.000	0.00	0.754	1.35
	CV L3	96	29.42	0.332	1.13	0.173	0.59	0.033	0.11	0.376	1.28	0.000	0.00	0.376	1.28
	CV L4	90	22.73	0.379	1.67	0.166	0.73	0.105	0.46	0.427	1.88	0.000	0.00	0.427	1.88
	CV L5	90	13.17	0.381	2.89	0.188	1.43	0.123	0.93	0.442	3.36	0.181	1.37	0.477	3.63

iii. Precision (Whole Blood)

Whole blood precision of the i-STAT pH, *P*O2, and *P*CO2 tests in the *i-STAT CG8+* cartridge on the *i-STAT 1* System was evaluated using arterial, venous, and capillary[1] whole blood specimens collected with lithium heparin. The whole blood precision was assessed using the duplicate test results collected across multiple point of care sites. The results are summarized in **Table 4**.

Table 4: Whole Blood Precision of arterial, venous, and capillary whole blood for i-STAT CG8+ 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	14	7.0076	0.00378	0.05
		>7.300-7.450	95	7.3790	0.00605	0.08
		>7.450-7.800	9	7.5257	0.00350	0.05
	Arterial Whole Blood	6.500-7.300	7	7.2059	0.00292	0.04
		>7.300-7.450	100	7.3772	0.00574	0.08
		>7.450-7.800	41	7.4704	0.00585	0.08
	Capillary Whole Blood	6.500-7.300	0	N/A	N/A	N/A
		>7.300-7.450	108	7.4075	0.01847	0.25
		>7.450-7.800	45	7.4729	0.02508	0.34
PO_2 (mmHg)	Venous Whole Blood	10-40	72	30.5	0.98	3.21
		>40-50	15	44.7	0.68	1.53
		>50-100	20	58.9	1.17	1.99
		>100-250	5	141.1	4.72	3.35
		>250-700	6	550.1	5.35	0.97
	Arterial Whole Blood	10-40	2	37.3	1.12	3.00
		>40-50	3	48.2	1.22	2.54
		>50-100	61	76.7	1.26	1.64
		>100-250	66	161.2	3.87	2.40
		>250-700	15	323.3	7.45	2.30
	Capillary Whole Blood	10-40	5	36.3	1.52	4.18
		>40-50	13	45.5	2.49	5.47
		>50-100	136	70.4	7.50	10.65
		>100-250	0	N/A	N/A	N/A
		>250-700	0	N/A	N/A	N/A
PCO_2 (mmHg)	Venous Whole Blood	5.0-35.0	27	33.30	0.555	1.67
		>35.0-50.0	70	45.32	0.777	1.71
		>50.0-62.5	14	55.79	1.592	2.85
		>62.5-130.0	9	97.07	1.312	1.35
	Arterial Whole Blood	5.0-35.0	51	33.76	0.714	2.12
		>35.0-50.0	85	43.56	0.958	2.20
		>50.0-62.5	10	60.78	0.489	0.81
		>62.5-130.0	2	87.85	0.570	0.65
	Capillary Whole Blood	5.0-35.0	51	31.23	2.048	6.56
		>35.0-50.00	97	40.16	1.749	4.36
		>50.0-62.5	5	54.82	2.835	5.17
		>62.5-130	0	N/A	N/A	N/A

[1] The capillary whole blood clinical precision study design involved the performance of two individual fingersticks, collected independently by two operators into two separate capillary tubes and tested on two (2) i-STAT CG8+ cartridges.

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, and PCO_2 tests in the *i-STAT CG8+* 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, and PCO_2 tests in the *i-STAT CG8+ cartridge* 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 5** for *i-STAT CG8+* cartridge.

Table 5: Regression Summary for the i-STAT pH, PO_2 and PCO_2 tests in the i-STAT CG8+ Cartridge on the i-STAT 1 Analyzer

Test	Units	Reportable Range	Range Tested	Slope	Intercept	R^2
pH	pH units	6.500 – 7.800	6.4290 – 7.8522	1.011	-0.098	0.9994
PO_2	mmHg	5 – 700	4.4 – 700.0	0.977	1.062	0.9956
PCO_2	mmHg	5.0 – 130.0	2.40 – 148.38	1.029	-1.144	0.9991

c. 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 and PCO_2 tests in the *i-STAT CG8+* cartridge was evaluated on the *i-STAT 1* analyzer using two (2) *i-STAT CG8+* cartridge lots and whole blood that was altered to a low analyte level for each i-STAT test. The LoQ for the i-STAT pH, *P*O2, and *P*CO2 tests in the *i-STAT CG8+* cartridge and *i-STAT EG7+* cartridge 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 6**.

Table 6: Summary of LoQ Results for i-STAT Tests in the i-STAT CG8+ Cartridge

Test (units)	Lower limit of the reportable range	Determined LoQ
		i-STAT CG8+ Cartridge
pH (pH Units)	6.500	6.464
PO_2 (mmHg)	5	5
PCO_2 (mmHg)	5.0	3.2

d. Analytical Specificity

i. Interference

The study was based on CLSI EP07-ED3: *Interference Testing in Clinical Chemistry, Third Edition.*

The interference performance of the i-STAT pH, PO_2, and PCO_2 tests in the *i-STAT CG8+* 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 between the control and test samples was outside of the allowable 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 7 contains the lists of potentially interfering substances tested and the interference results for the *i-STAT CG8+* cartridge.

Table 7: Potentially Interfering Substances and Test Concentrations for the i-STAT pH, PO_2, and PCO_2 tests in the i-STAT CG8+ Cartridge

Substance [2]	Test Concentration		i-STAT Test	Interference (Yes/No)	Comments
	mmol/L (unless specified)	mg/dL (unless specified)			
Acetaminophen	1.03	15.6	pH	No	
			PO_2	No	
			PCO_2	No	
Atracurium (Atracurium Besylate)	0.0287	3.57	pH	No	
			PO_2	No	
			PCO_2	No	
Bilirubin	0.684	40	pH	No	
			PO_2	No	
			PCO_2	No	
Calcium (Calcium Chloride)	5.0	20	pH	No	
			PO_2	No	
			PCO_2	No	
Ethanol	130	600	pH	No	
			PO_2	No	
			PCO_2	No	
Hemoglobin	10 g/L	1000	pH	No	
			PO_2	No	
			PCO_2	No	
Ibuprofen	1.06	21.9	pH	No	
			PO_2	No	
			PCO_2	No	
Intralipid 20%	N/A	2684	pH	No	
			PO_2	No	
			PCO_2	No	
Morphine (Morphine Sodium Salt)	0.0273	0.78	pH	No	
			PO_2	No	
			PCO_2	No	
Potassium (Potassium Chloride)	8	59.6	pH	No	
			PO_2	No	
			PCO_2	No	
Sodium (Sodium Chloride)	170	993.48	pH	No	
			PO_2	No	
			PCO_2	No	
Thiopental	1.66	40.2	pH	No	
			PO_2	No	
			PCO_2	No	

[2] The compound tested to evaluate the interfering substance is presented in parenthesis.

Table 7: Potentially Interfering Substances and Test Concentrations for the i-STAT pH, PO_2, and PCO_2 tests in the i-STAT CG8+ Cartridge					
Substance [2]	Test Concentration		i-STAT Test	Interference (Yes/No)	Comments
	mmol/L (unless specified)	mg/dL (unless specified)			
Triglyceride	16.94	1500	pH	No	
			PO_2	No	
			PCO_2	No	

ii. *Other sensitivity studies*

1) Altitude

The performance of the i-STAT pH, PO_2 and PCO_2 tests in the *i-STAT CG8+* 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, and PCO_2 results obtained from the *i-STAT CG8+* cartridge on the *i-STAT 1* analyzer were compared to the pH, PO_2, and PCO_2 results obtained from the *i-STAT CG4+* (blue) cartridges on the *i-STAT 1* analyzer (comparator device). 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: *Measurement Procedure Comparison and Bias Estimation using Patient Samples, 3rd ed*. The results of the correlation coefficient and slope met acceptance criteria and demonstrated equivalent performance between the candidate and comparator conditions at approximately 10,000 feet above sea level. The results are summarized in **Table 8**.

Table 8: Summary of Altitude Study Results for the i-STAT CG8+ Cartridge				
Test	Correlation Coefficient (r)		Slope	
	r	95% CI	Slope	95% CI
pH	1.00	0.999 to 0.999	0.99	0.984 to 0.998
PO_2	1.00	0.994 to 0.998	1.02	1.000 to 1.037
PCO_2	1.00	0.997 to 0.999	0.98	0.969 to 0.989

B. Comparison Studies

a. Method Comparison with Comparator Device

Method comparison for arterial, venous, and capillary whole blood specimens on the *i-STAT CG8+* 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*.

Lithium heparin venous and arterial whole blood specimens collected across multiple point of care sites were evaluated using *i-STAT CG8+* cartridges on the *i-STAT 1* analyzer against whole blood specimens tested on a 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 1* analyzer versus the singlicate result from the comparative method.

Two (2) capillary whole blood specimens collected from skin puncture with balanced heparin capillary tubes from each study subject across multiple point of care sites were evaluated and analyzed in singlicate on the *i-STAT 1* analyzer against the comparative method. A Passing-Bablok linear regression analysis for pH, PO_2, and PCO_2 was

performed using the singlicate result from the *i-STAT 1* analyzer versus the singlicate result of the comparative method.

The venous, arterial, and capillary whole blood data were pooled, and a Passing-Bablok linear regression analysis was performed using the results from the *i-STAT CG8+* cartridges on the *i-STAT 1* analyzer versus the comparative method results.

Method comparison results for arterial, venous, and capillary whole blood specimens are shown in **Table 9**. In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Table 9: Method Comparison Results for i-STAT CG8+ Cartridge with i-STAT 1 System

Test (units)	Comparative Method: Arterial/Venous/Capillary	N	Slope	Intercept	r	Medical Decision Level	Bias at Medical Decision Level
pH (pH units)	RAPIDPoint 500/500e	468	1.00	0.00	0.99	7.300	-0.0040
						7.350	-0.0040
						7.400	-0.0040
PO_2 (mmHg)	RAPIDPoint 500/500e	461	1.03	-0.72	0.99	30	0.1
						45	0.5
						60	0.9
PCO_2 (mmHg)	RAPIDPoint 500/500e	465	1.08	-1.13	0.97	35.0	1.79
						45.0	2.63
						50.0	3.04
						70.0	4.71

The method comparison results for capillary whole blood specimens only are shown in **Table 10**.

Table 10: Results for i-STAT CG8+ Cartridge with i-STAT 1 System – Native and Contrived Capillary Specimens

Test (units)	N	Slope	Intercept	r	Range
pH (pH units)	195	1.02	-0.11	0.98	6.619 - 7.772
PO_2 (mmHg)	190	1.02	-1.75	0.99	12.8 - 652.6
PCO_2 (mmHg)	189	1.09	-1.90	0.97	9.1 - 124.9

Bias at the medical decision levels for native capillary whole blood specimens only are shown in **Table 11**.

Table 11: Results for i-STAT CG8+ 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)	179	7.289	7.531	7.300	-0.0160	(-0.0352, 0.0020)
				7.350	-0.0101	(-0.0211, 0.0010)
				7.400	-0.0041	(-0.0083, 0.0008)
PO_2 (mmHg)	175	32	108	30	-1.8	(-4.7, 0.9)
				45	-1.3	(-3.0, 0.2)
				60	-0.7	(-1.9, 0.1)

Table 11: Results for i-STAT CG8+ 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
PCO_2 (mmHg)	179	26.9	59.3	35.0	1.17	(0.66, 1.75)
				45.0	1.79	(0.68, 3.05)
				50.0	2.11	(0.48, 3.86)
				70.0	3.36	(-0.26, 7.08)

b. Matrix Equivalence

A matrix equivalence study was conducted to evaluate the performance of the i-STAT pH, PO_2 and PCO_2 tests in the *i-STAT CG8+* cartridge on the *i-STAT 1* System using non-anticoagulated venous and arterial whole blood specimens. The study design and analysis method were based on recommendations from the Clinical and Laboratory Standards Institute (CLSI) guideline EP35: *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 1st ed.* The matrix equivalence of each test in the *i-STAT CG8+* 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 CG8+* 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 mean result from the primary specimen (x-axis). The regression analysis results are summarized in **Table 12**. In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Table 12: Matrix Equivalence Results						
Test (units)	N	Candidate Specimen Range	Primary Specimen Range	R	Slope	Intercept
pH (pH units)	241	7.126-7.585	7.130-7.607	0.98	0.97	0.19
PO_2 (mmHg)	241	13-606	14-555	0.98	0.94	1.28
PCO_2 (mmHg)	241	22.0-87.7	22.4-85.2	0.96	1.02	-0.23

VIII. CONCLUSION

The results of these studies demonstrate that performance of the i-STAT pH, PO_2, and PCO_2 tests in the *i-STAT CG8+* cartridge with the *i-STAT 1 System* are substantially equivalent to the predicate device.