July 28, 2023

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

Re: K223710
Trade/Device Name: i-STAT CG8+ cartridge with the i-STAT 1 System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, JJE
Dated: June 28, 2023
Received: June 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 (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,

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)*
k223710

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 glucose in arterial, venous, or capillary whole blood in point of care or clinical laboratory settings.

Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

The i-STAT 1 Analyzer is intended for use in the in vitro quantification of various analytes in whole blood or plasma in point of care or clinical laboratory settings. Analyzers and cartridges should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

The i-STAT System is for in vitro diagnostics use. Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

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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Abbott

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 Specialist Regulatory Affairs Phone: 609-454-9384 Secondary: Mojgan Soleimani Associate Director Regulatory Affairs Phone: 613-295-0932
Date Prepared	June 28, 2023

II. DEVICE INFORMATION

Proprietary Name	*i-STAT CG8+* cartridge with the *i-STAT 1 System*
Common Name	Chemistry test, analyzer, handheld
510(k) Number	K223710

Product Code	Device Classification Name	Regulation Number	Class	Panel
CGA	Glucose Oxidase, Glucose	862.1345	II	Clinical Chemistry

III. PREDICATE DEVICE

Proprietary Name	*i-STAT CHEM8+* cartridge with the *i-STAT 1 System*
510(k) Number	K210958 (K183678)

Product Code	Device Classification Name	Regulation Number	Class	Panel
CGA	Glucose Oxidase, Glucose	862.1345	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* to measure glucose (Glu) 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, which are typically 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 glucose in arterial, venous, or capillary whole blood in point of care or clinical laboratory settings.

Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

The i-STAT 1 Analyzer is intended for use in the *in vitro* quantification of various analytes in whole blood or plasma in point of care or clinical laboratory settings. Analyzers and cartridges should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

The i-STAT System is for *in vitro* diagnostics use. Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

VI. SUMMARY COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 1: Similarities and Differences (Test and Instrument)		
Feature or Characteristic	**Candidate Devices:** *i-STAT CG8+* cartridge with the *i-STAT 1 System,* i-STAT Glucose test	**Predicate Device:** *i-STAT CHEM8+* cartridge with the *i-STAT 1 System,* i-STAT Glucose test (K210958)
Intended Use	The *i-STAT CG8+* cartridge with the *i-STAT 1 System* is intended for use in the *in vitro* quantification of glucose in arterial, venous or capillary whole blood in point of care or clinical laboratory settings. Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.	The *i-STAT CHEM8+* cartridge with the *i-STAT 1 System* is intended for use in the in vitro quantification of sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide in arterial or venous whole blood in point of care or clinical laboratory settings. Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
Device Classification	Same	Class II
Product Code	Same	CGA
Regulation No.	Same	862.1345
Reportable Range	Same	1.1 – 38.9 mmol/L 20 – 700 mg/dL 0.20 – 7.00 g/L
Sample Type	Arterial, venous, or capillary whole blood	Arterial and venous whole blood
Sample Volume	Same	95 µL
Sample Preparation	Same	Ready to Use
Sample collection	Same	• Without anticoagulant • With balanced heparin anticoagulant or lithium heparin anticoagulant
Traceability	Same	NIST SRM965
Calibration	Same	1-point on-board contained within cartridge

Table 1: Similarities and Differences (Test and Instrument)		
Feature or Characteristic	**Candidate Devices:** *i-STAT CG8+* cartridge with the *i-STAT 1 System,* i-STAT Glucose test	**Predicate Device:** *i-STAT CHEM8+* cartridge with the *i-STAT 1 System,* i-STAT Glucose test (K210958)
Time to Test (Sample Stability)	**Without anticoagulant:** Arterial and venous: within 3 minutes **With anticoagulant:** Capillary: within 3 minutes Arterial and venous: within 30 minutes	**Without anticoagulant:** Arterial and venous: within 3 minutes **With anticoagulant:** Arterial and venous: within 30 minutes
Principle of Measurement	Same	Glu: Glucose oxidase based amperometric peroxide detection
Reagent Format	Same	Cartridge
Reagent Storage and Stability	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	Refrigerated at 2 to 8°C (35 to 46°F) until expiration date Room Temperature at 18-30°C (64-86°F) for 14 days
Analyzer Type	Same	Handheld

VII. PERFORMANCE CHARACTERISTICS

A. Analytical Performance

a. Precision/Reproducibility:

i. Precision 20 days (Aqueous materials)

The precision of the i-STAT Glucose (Glu) test in the *i-STAT CG8+* cartridge on the *i-STAT 1 System* was evaluated using five (5) levels of aqueous material. 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 analyzers and two (2) test cartridge lots 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**
Glu (mg/dL)	CV L1	80	28.4	0.36	1.25	0.20	0.69	0.24	0.85	0.47	1.66
	CV L2	80	42.0	0.36	0.87	0.29	0.70	0.23	0.56	0.52	1.25
	CV L3	80	124.7	0.66	0.53	0.55	0.44	0.52	0.42	1.00	0.80
	CV L4	80	279.4	1.47	0.53	1.79	0.64	1.26	0.45	2.63	0.94
	CV L5	80	576.8	4.70	0.81	2.35	0.41	2.91	0.50	6.01	1.04

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 glucose. 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
Glu (mg/dL)	CV L1	91	28.1	0.39	1.40	0.16	0.55	0.08	0.29	0.43	1.54	0.11	0.41	0.45	1.59
	CV L2	90	41.4	0.50	1.21	0.12	0.30	0.17	0.41	0.54	1.32	0.00	0.00	0.54	1.32
	CV L3	96	124.5	0.64	0.52	0.47	0.38	0.08	0.06	0.8	0.64	0.00	0.00	0.80	0.64
	CV L4	90	280.3	1.42	0.51	0.33	0.12	0.22	0.08	1.47	0.53	0.44	0.16	1.54	0.55
	CV L5	90	578.4	4.25	0.73	1.78	0.31	0.00	0.00	4.61	0.80	0.00	0.00	4.61	0.80

iii. Precision (Whole Blood)

Whole blood precision of the i-STAT Glucose test in the *i-STAT CG8+* cartridge on the *i-STAT 1* System was evaluated using arterial, venous, and capillary 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 mean values for each sample were divided into subintervals for each sample type across the reportable range for the i-STAT Glucose test. The results are summarized in **Table 4**.

Table 4: Whole Blood Precision of arterial, venous, and capillary whole blood for the i-STAT Glucose test in the i-STAT CG8+ cartridge on the i-STAT 1 Analyzer

Test (units)	Sample Type	Sample Range	N	Mean	SD	%CV
Glu (mg/dL)	Venous Whole Blood	20-90	29	73.9	0.86	1.17
		>90-150	102	111.7	1.08	0.96
		>150-250	27	173.4	1.82	1.05
		>250-400	13	308.5	2.08	0.67
		>400-700	9	544.3	7.92	1.46
	Arterial Whole Blood	20-90	5	80.8	0.77	0.96
		>90-150	105	113.6	0.75	0.66
		>150-250	35	178.0	1.55	0.87
		>250-400	8	280.7	2.19	0.78
	Capillary Whole Blood	20-90	32	77.6	1.08	1.39
		>90-150	107	108.3	2.34	2.16
		>150-700	15	203.8	2.74	1.34

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 Glucose test in the *i-STAT CG8+* cartridge with the *i-STAT 1 System* was evaluated by preparing whole blood samples of varying glucose levels. The i-STAT Glucose test in the *i-STAT CG8+ cartridge* demonstrated linearity over the reportable range for each *i-STAT* test. Regression summary of the response for the *i-STAT Glucose* test versus the concentration of the whole blood samples of varying glucose levels is provided in **Table 5**.

Table 5: Regression Summary for the i-STAT Glucose test in the i-STAT CG8+ Cartridge on the i-STAT 1 Analyzer

Test	Units	Reportable Range	Range Tested	Slope	Intercept	R^2
Glu	mg/dL	20 – 700	17.1 – 795.4	0.994	-1.385	0.9993

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 Glucose test 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 glucose level. The LoQ for the *i-STAT* Glucose test in the *i-STAT CG8+* cartridge was determined to be at or below the lower limit of the reportable range for the *i-STAT Glucose* test as shown in **Table 6**.

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

Test (units)	Lower limit of the reportable range	Determined LoQ
Glu (mg/dL)	20	17

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 Glucose (Glu) test in the *i-STAT CG8+* cartridge was evaluated on the *i-STAT 1* analyzer using two (2) *i-STAT CG8+* cartridge lots. Whole blood was altered to a blank glucose level for LoB testing. Whole blood was altered to two (2) low levels of glucose 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 Glucose test in the *i-STAT CG8+* cartridge on the *i-STAT 1* analyzer is shown in the **Table 7**.

Table 7: Summary of LoB and LoD Results

Test (units)	LoB	LoD
Glu (mg/dL)	0.2	0.9

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 Glucose test 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 Glucose test. For an identified interferent, a dose-response was performed to determine the degree of interference as a function of the substance concentration.

Table 8 contains the lists of potentially interfering substances tested and the interference results for the *i-STAT CG8+* cartridge.

Table 8: Potentially Interfering Substances and Test Concentrations for the i-STAT Glucose test in the i-STAT CG8+ Cartridge					
Substance [1]	**Test Concentration**		**i-STAT Test**	**Interference (Yes/No)**	**Comments**
	mmol/L (unless specified)	**mg/dL (unless specified)**			
Acetaldehyde [2]	0.045	0.2	Glu	No	
Acetaminophen	1.03	15.6	Glu	No	
Acetoacetate (Lithium Acetoacetate)	2.0	20	Glu	No	
Acetyl Cysteine (N-Acetyl-L-Cysteine)	0.92	15	Glu	No	
Ammonium (Ammonium Chloride) [2]	2.0	10.7	Glu	No	
Ascorbic Acid (L-Ascorbic Acid)	0.298	5.25	Glu	No	
β-Hydroxybutyric Acid [2]	6.0	62.46	Glu	No	
Bilirubin	0.684	40	Glu	No	
Bromide [2] (Lithium Bromide)	2.5	21.7	Glu	No	
	37.5	325.7	Glu	Yes	Use Another Method
Cholesterol	10.3	400	Glu	No	
Creatinine	1.326	15	Glu	No	
Dopamine (Dopamine Hydrochloride)	4.06 µmol/L	0.0621	Glu	No	
Ethanol	130	600	Glu	No	
Fluoride (Lithium Fluoride)	0.0632	0.12	Glu	No	
Formaldehyde [2]	0.133	0.399	Glu	No	
Fructose	1	18	Glu	No	
Galactose	3.33	60	Glu	No	
Gentamicin (Gentamicin Sulfate)	0.0628	3	Glu	No	
Gentisic Acid	0.0973	1.5	Glu	No	
Glucosamine (Glucosamine Hydrochloride) [2]	0.030	0.647	Glu	No	
Glutathione, reduced	3	3 mEq/L	Glu	No	
Glycolic Acid [2]	10.0	76.05	Glu	No	
Guaifenesin	0.0227	0.45	Glu	No	
Hemoglobin	10 g/L	1000	Glu	No	
Heparin (Sodium Heparin)	3.30 U/mL	330 U/dL	Glu	No	
Hydroxyurea	0.405	3.08	Glu	Yes	Increased results ≥ 0.08 mmol/L
Ibuprofen	1.06	21.9	Glu	No	

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

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

Table 8: Potentially Interfering Substances and Test Concentrations for the i-STAT Glucose test in the i-STAT CG8+ Cartridge					
Substance [1]	**Test Concentration**		**i-STAT Test**	**Interference (Yes/No)**	**Comments**
	mmol/L (unless specified)	**mg/dL (unless specified)**			
Intralipid 20%	N/A	2891	Glu	No	
Isoniazid	0.438	6	Glu	Yes	Increased results ≥ 0.29 mmol/L
Lactate (Lithium Lactate)	10	90	Glu	No	
Maltose	10.5	360	Glu	No	
Mannose [2]	1	18.02	Glu	No	
Nithiodote (Sodium Thiosulfate) [2]	16.7	264.04	Glu	No	
pH	8.0 pH units	N/A	Glu	No	
Pyruvate (Lithium Pyruvate)	0.570	5	Glu	No	
Salicylate (Lithium Salicylate)	0.207	2.86	Glu	No	
Thiocyanate (Lithium Thiocyanate)	0.898	5.22	Glu	No	
Triglyceride	16.94	1500	Glu	No	
Uric Acid	1.4	23.5	Glu	No	
Xylose [2]	3	45.04	Glu	No	

ii. *Other sensitivity studies*

1) Oxygen Sensitivity Study

The effect of oxygen on the i-STAT Glucose test in the *i-STAT CG8+* cartridge on the *i-STAT 1 System* was evaluated with low and high oxygen levels using whole blood samples altered to four (4) glucose levels the reportable range of the i-STAT Glucose test. 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* Glucose test in the *i-STAT CG8+* cartridge on the *i-STAT 1 System* perform is insensitive to oxygen levels between 20 and 503 mmHg.

2) Hematocrit Sensitivity

A hematocrit sensitivity study was conducted to evaluate the performance of the i-STAT Glucose test in the *i-STAT CG8+* cartridge with the *i-STAT 1 System* to assess the effect of hematocrit. Three (3) hematocrit levels (low, mid and high) were evaluated at four (4) glucose levels across the reportable range of the i-STAT Glucose test in the *i-STAT CG8+* cartridge. The hematocrit sensitivity at each glucose level was assessed by comparing the results at the low and high hematocrit level to the mid hematocrit level. Equivalency was assessed by determining whether the difference between the low and high hematocrit level and the mid hematocrit level was within the allowable error (±Ea). The study demonstrated that i-STAT Glucose test in the *i-STAT CG8+* cartridge with the *i-STAT 1 System* is insensitive to hematocrit levels between 15% to 75% packed cell volume (PCV).

3) Altitude

The performance of the i-STAT Glucose test 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 glucose levels across the reportable range for the i-STAT Glucose test. The glucose test results obtained from the *i-STAT CG8+* cartridges (candidate device) were compared to the glucose test results obtained from the *i-STAT CHEM8+* (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 9**.

Table 9: Summary of Altitude Study Results for the i-STAT CG8+ Cartridge

Test	Correlation Coefficient (r)		Slope	
	r	95% CI	Slope	95% CI
Glu	1.00	1.000 to 1.000	0.96	0.957 to 0.971

B. Comparison Studies

a. Method Comparison with predicate 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. The first replicate glucose result from the *i-STAT 1* analyzer was compared to the mean glucose 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 glucose 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 10**. In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Table 10: Method Comparison Results for i-STAT CG8+ Cartridge with i-STAT 1 System

Test	Comparative Method		N	Slope	Intercept	r
	Arterial/Venous	Capillary				
Glu	i-STAT CHEM8+	epoc Blood Analysis System	547	0.98	1.62	1.00

b. Matrix Equivalence

A matrix equivalence study was conducted to evaluate the performance of the *i-STAT* Glucose test 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 the i-STAT Glucose 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 11**. In the table, N is the number of specimens in the data set, and r is the correlation coefficient.

Table 11: Matrix Equivalence Results

Test (units)	N	Candidate Specimen Range	Primary Specimen Range	r	Slope	Intercept
Glu (mg/dL)	297	39-688	39-671	1.00	1.00	0.00

VIII. CONCLUSION

The results of these studies demonstrate that performance of the i-STAT Glucose test in the *i-STAT CG8+* cartridge with the *i-STAT 1 System* are substantially equivalent to the predicate device.