September 11, 2023

Mojgan Soleimani
Associate Director Regulatory Affairs
Abbott Point of Care Inc.
400 College Road East
Princeton, New Jersey 08540

Re: K223755
Trade/Device Name: *i-STAT G* 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
Dated: August 8, 2023
Received: August 9, 2023

Dear Mojgan Soleimani:

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)*
K223755

Device Name
i-STAT G cartridge on the i-STAT 1 System

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: Mojgan Soleimani Associate Director Regulatory Affairs Phone: +1 613-295-0932 Secondary: Robert Gregg Director Regulatory Affairs Phone: +1 609-454-9360
Date Prepared	September 11, 2023

II. DEVICE INFORMATION

Proprietary Name	*i-STAT G* cartridge with the *i-STAT 1 System*
Common Name	Glucose test, analyzer, handheld
510(k) Number:	K223755

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 G* cartridge is used with the *i-STAT 1* analyzer as part of the *i-STAT 1 System* to measure glucose in arterial, venous, or capillary whole blood for the diagnosis, monitoring, and treatment of metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

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 G* 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 G* cartridge contains the required sensors and 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 the cartridge. The test is contained in a single-use, disposable cartridge. All the test steps and fluid movements occur within the *i-STAT G* 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 analyzer interacts with the cartridge to move fluid across the sensors and generate a quantitative result (within approximately 2 minutes).

V. INTENDED USE STATEMENT

The *i-STAT G* 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.

VI. SUMMARY COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Similarities and Differences (Test and Instrument)		
Feature or Characteristic	**Candidate Device:** **Glucose test in the *i-STAT G* cartridge with the *i-STAT 1 System***	**Predicate Device:** **Glucose test in the *i-STAT CHEM8+* cartridge with the *i-STAT 1 System*** **K210958 (K183678)**
Intended Use	The *i-STAT G* 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.	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

<table>
<tr><th colspan="3">Similarities and Differences (Test and Instrument)</th></tr>
<tr><th>Feature or Characteristic</th><th><u>Candidate Device:</u>
Glucose test in the i-STAT G cartridge with the i-STAT 1 System</th><th><u>Predicate Device:</u>
Glucose test in the i-STAT CHEM8+ cartridge with the i-STAT 1 System
K210958 (K183678)</th></tr>
<tr><td></td><td>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.</td><td>arterial or venous whole blood in point of care or clinical laboratory settings.

The glucose test in the i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of glucose 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.</td></tr>
<tr><td>Device Classification</td><td>Same</td><td>Class II</td></tr>
<tr><td>Product Code</td><td>Same</td><td>CGA</td></tr>
<tr><td>Regulation Number</td><td>Same</td><td>862.1345</td></tr>
<tr><td>Reportable Range</td><td>Same</td><td>1.1 – 38.9 mmol/L
20 – 700 mg/dL
0.20 – 7.00 g/L</td></tr>
<tr><td>Sample Type</td><td>Arterial, venous or capillary whole blood</td><td>Arterial or venous whole blood</td></tr>
<tr><td>Sample Volume</td><td>65 µL</td><td>95 µL</td></tr>
<tr><td>Sample Preparation</td><td>Same</td><td>Ready to use</td></tr>
<tr><td>Sample Collection</td><td><table><tr><td>Arterial and venous</td><td>Without anticoagulant</td></tr><tr><td>Arterial and Venous</td><td>With balanced heparin, lithium, K_2 or K_3 EDTA anticoagulant</td></tr><tr><td>Capillary</td><td>With balanced heparin or lithium anticoagulant</td></tr></table></td><td>• Without anticoagulant
• With balanced heparin anticoagulant or lithium anticoagulant</td></tr>
</table>

<table>
<tr><th colspan="3">Similarities and Differences (Test and Instrument)</th></tr>
<tr><th>Feature or Characteristic</th><th><u>Candidate Device:</u>
Glucose test in the i-STAT G cartridge with the i-STAT 1 System</th><th><u>Predicate Device:</u>
Glucose test in the i-STAT CHEM8+ cartridge with the i-STAT 1 System
K210958 (K183678)</th></tr>
<tr><td>Traceability</td><td>Same</td><td>NIST SRM 965</td></tr>
<tr><td>Calibration</td><td>Same</td><td>1-point on-board contained within cartridge</td></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>Arterial and venous</td><td>within 3 minutes</td></tr><tr><th colspan="2">With anticoagulant:</th></tr><tr><td>Capillary</td><td>within 3 minutes</td></tr><tr><td>Arterial and venous</td><td>within 30 minutes</td></tr></table></td><td><table><tr><th colspan="2">Without anticoagulant:</th></tr><tr><td>Arterial and venous</td><td>within 3 minutes</td></tr><tr><th colspan="2">With anticoagulant:</th></tr><tr><td>Arterial and venous</td><td>within 30 minutes</td></tr></table></td></tr>
<tr><td>Principle of Measurement</td><td>Same</td><td>Amperometric measurement of oxidized hydrogen peroxide produced by glucose oxidase activity</td></tr>
<tr><td>Reagent Format</td><td>Same</td><td>Cartridge</td></tr>
<tr><td>Reagent Storage and Stability</td><td>Same</td><td>Refrigeration at 2°C to 8°C (35-46°F) until expiration date;
Room Temperature at 18°C to 30°C (64–86 °F) for 14 days</td></tr>
<tr><td>Analyzer Type</td><td>Same</td><td>Handheld</td></tr>
</table>

VII. PERFORMANCE CHARACTERISTICS

A. Analytical Performance

a. Precision/Reproducibility:

i. <u>Precision 20 days (aqueous materials)</u>

The precision of the i-STAT Glucose test in the *i-STAT G* cartridge with the *i-STAT 1 System* was evaluated using five (5) levels of aqueous material. This single-site 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 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 are shown in **Table 1.**

Table 1: Results of 20-Day precision of the i-STAT Glucose test on the i-STAT 1 analyzer using i-STAT Calibration Verification set (mg/dL)										
Fluid Level	N	Mean	Repeatability		Between-run		Between-day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
CV L1	80	25.0	0.43	1.71	0.06	0.23	0.34	1.36	0.55	2.19
CV L2	80	38.5	0.38	0.99	0.22	0.58	0.21	0.54	0.49	1.27
CV L3	80	119.1	0.69	0.58	0.21	0.18	0.31	0.26	0.78	0.66
CV L4	80	272.2	1.42	0.52	0.40	0.15	0.76	0.28	1.66	0.61
CV L5	80	565.5	4.33	0.77	2.71	0.48	1.78	0.32	5.41	0.96

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 material containing five (5) levels of glucose. At each site, testing was performed 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 G* 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 2** below.

Table 2: Results of point of care multi-day precision of i-STAT Glucose test on the i-STAT 1 analyzer using i-STAT TriControls Calibration Verification set (mg/dL)														
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
CV L1	89	573.1	2.63	0.46	1.20	0.21	0.00	0.00	2.89	0.50	0.00	0.00	2.89	0.50
CV L2	90	266.3	0.71	0.27	0.37	0.14	0.16	0.06	0.82	0.31	0.05	0.02	0.82	0.31
CV L3	90	133.7	0.57	0.43	0.12	0.09	0.18	0.13	0.61	0.46	0.00	0.00	0.61	0.46
CV L4	90	46.1	0.33	0.72	0.31	0.67	0.04	0.09	0.46	0.99	0.15	0.32	0.48	1.04
CV L5	90	33.7	0.57	1.68	0.00	0.00	0.14	0.40	0.58	1.73	0.00	0.00	0.58	1.73

iii. *Precision (whole blood)*

Whole blood precision of the i-STAT Glucose test in the *i-STAT G* 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. For each sample type, samples were grouped into subintervals based on their mean values. The results are summarized in **Table 3**.

Table 3: Whole blood precision of arterial, venous, and capillary whole blood for the i-STAT Glucose test in the i-STAT G cartridge on the i-STAT 1 analyzer						
Test (units)	Sample Type	Sample Range	N	Mean	SD	%CV
Glucose (mg/dL)	Venous whole blood	20-90	38	75.0	0.32	0.43
		>90-150	67	109.6	0.39	0.35
		>150-250	32	195.8	0.73	0.37

		>250-400	15	315.0	1.17	0.37
		>400-700	12	559.0	2.01	0.36
	Arterial whole blood	20-90	9	82.4	0.33	0.40
		>90-150	94	125.0	0.57	0.46
		>150-250	64	182.0	0.54	0.30
		>250-700	6	357.0	0.91	0.26
	Capillary whole blood	20-90	33	70.9	1.92	2.71
		>90-150	53	116.0	2.44	2.10
		>150-250	37	196.6	4.40	2.24
		>250-700	16	297.1	4.09	1.38

b. Linearity/assay reportable range:

i. Linearity

The study was designed based on CLSI EP06-Ed2: *Evaluation of Linearity of Quantitative Measurement Procedures – Second Edition*.

The linearity of the i-STAT Glucose test in the *i-STAT G* cartridge with the *i-STAT 1 System* was evaluated by preparing whole blood samples of varying glucose levels across the reportable range for the test. The i-STAT Glucose test in the *i-STAT G* cartridge on the *i-STAT 1 System* demonstrated linearity over the reportable range of 20 – 700 mg/dL. 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 4**.

Table 4: Regression summary for the i-STAT G cartridge on the i-STAT 1 analyzer

Test	Units	Reportable Range	Range Tested	Slope	Intercept	R^2
Glucose	mg/dL	20-700	15.3 – 793.3	1.002	-1.258	0.999

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 G* cartridge was evaluated on the *i-STAT 1* analyzer using two (2) cartridge lots and whole blood that was altered to a low glucose level. The LoQ for the i-STAT Glucose test was determined to be 14 mg/dL, which is below the lower limit of the reportable range for the i-STAT Glucose test as shown in **Table 5**.

Table 5: LoQ result for the i-STAT Glu test in the i-STAT G cartridge

Test	Lower limit of the reportable range	LoQ
Glucose	20 mg/dL	14 mg/dL

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 test in the *i-STAT G* cartridge were evaluated on the *i-STAT 1* analyzer using two (2) cartridge lots. Whole blood was altered to a blank glucose level for LoB testing and two (2) low glucose levels for LoD testing. The LoB and LoD were determined based on the maximal LoB or LoD value obtained for each lot tested. The LoB and LoD for the i-STAT Glucose test on the *i-STAT 1* analyzer was determined as shown in the **Table 6** below.

Table 6: Summary of LoB and LoD results for the *i-STAT G* cartridge		
Test	**LoB**	**LoD**
Glucose	0 mg/dL	0.7 mg/dL

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 G* cartridge on the *i STAT 1* analyzer with the *i-STAT 1 System* was evaluated using whole blood samples at low and high glucose levels for all substances. The effect of each substance was evaluated by comparing the test results 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 or 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 glucose allowable error (±Ea). For an identified interferent, a dose-response analysis was performed to determine the degree of interference as a function of the substance concentration.

Table 7 contain the lists of potentially interfering substances tested for the i-STAT Glucose test and the interference results.

Table 7: Potentially interfering substances and test concentrations for the i-STAT Glucose test in the i-STAT G cartridge					
Substance	**Substance Concentration (mmol/L)**	**Substance Concentration (mg/dL)**	**Test**	**Interference (Yes/No)**	**Comment**
Acetaldehyde	0.045	0.2	Glu	No	
Acetaminophen	1.03	15.6	Glu	No	
Acetoacetate (Lithium Acetoacetate)	2.0	20	Glu	No	

Table 7: Potentially interfering substances and test concentrations for the i-STAT Glucose test in the i-STAT G cartridge					
Substance	**Substance Concentration (mmol/L)**	**Substance Concentration (mg/dL)**	**Test**	**Interference (Yes/No)**	**Comment**
Acetyl Cysteine (N-Acetyl-L-Cysteine)	0.92	15.0	Glu	No	
Ammonium (Ammonium Chloride)	2.0	10.7	Glu	No	
Ascorbic Acid (L-Ascorbic Acid)	0.298	5.25	Glu	No	
β-Hydroxybutyric Acid	6.0	62.46	Glu	No	
Bilirubin	0.684	40	Glu	No	
Bromide (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	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)	0.030	0.647	Glu	No	
Glutathione, reduced	3	3 mEq/L	Glu	No	
Glycolic Acid	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	
Intralipid 20%	N/A	3151	Glu	No	

Table 7: Potentially interfering substances and test concentrations for the i-STAT Glucose test in the i-STAT G cartridge					
Substance	**Substance Concentration (mmol/L)**	**Substance Concentration (mg/dL)**	**Test**	**Interference (Yes/No)**	**Comment**
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	1	18.02	Glu	No	
Nithiodote (Sodium Thiosulfate)	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	3	45.04	Glu	No	

ii. *Other sensitivity studies*

1) Oxygen Sensitivity

The effect of oxygen on the i-STAT Glucose test in the *i-STAT G* 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 across 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 i-STAT Glucose test in the *i-STAT G* cartridge with the *i-STAT 1 System* is insensitive to oxygen levels between 21 and 515 mmHg.

2) Hematocrit Sensitivity

The effect of hematocrit on the i-STAT Glucose test in the *i-STAT G* cartridge with the i-STAT 1 System was assessed. 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 G* 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 G* 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 G* cartridge on the *i-STAT 1* analyzer was evaluated at an altitude of approximately 10,000 feet above sea level using whole blood samples across the reportable range. The glucose test results obtained from the i-STAT G cartridges (candidate device) were compared to the glucose test results obtained from the *i-STAT CHEM8+* cartridges on the *i-STAT 1* analyzer (comparator device). Passing-Bablok regression analyses between the 1st replicate of the candidate device (y-axis) and mean of the comparator device (x-axis) were performed based on the CLSI cc: *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 8** below.

Table 8: Summary of altitude study results for the i-STAT G cartridge

Test	Correlation Coefficient (r)		Slope	
	r	95% CI	Slope	95% CI
Glucose	1.00	1.000 to 1.000	0.97	0.964 to 0.972

B. Comparison Studies

a. Method Comparison with Comparator Device

Method comparison was demonstrated in studies based on CLSI EP09c-ED3: *Measurement Procedure Comparison and Bias Estimation Using Patient Samples – Third Edition*. Lithium heparin arterial and venous whole blood specimens collected across multiple point of care sites were evaluated using the first replicate result from the *i-STAT G* cartridge on the *i-STAT 1* analyzer versus the mean result from the *i-STAT CHEM8+* cartridge on the *i-STAT 1* analyzer.

In addition, two (2) capillary whole blood specimens collected from skin punctures with balanced heparin capillary tubes from each study subject across multiple point of care sites were evaluated using the singlicate result from the i-STAT G cartridge on the *i-STAT 1* analyzer versus the singlicate result from the epoc Blood Analysis System.

The arterial, venous, and capillary whole blood data were pooled, and a Passing-Bablok linear regression analysis was performed using the results from the *i-STAT G* 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 G cartridge with i-STAT 1 System

Test	Comparative Method		N	Slope	Intercept	r
	Arterial/Venous	Capillary				
Glu	i-STAT CHEM8+	epoc Blood Analysis System	571	1.00	1.85	1.00

A Passing-Bablok linear regression analysis was performed using the results of each sample from the *i-STAT G* 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 G cartridge with i-STAT 1 System by sample type

Test	Sample Type	Comparative Method	N	Slope	Intercept	r
Glu	Arterial	i-STAT CHEM8+	173	1.00	1.00	1.00
	Venous	i-STAT CHEM8+	164	1.00	1.50	1.00
	Capillary	epoc Blood Analysis System	234	1.00	2.00	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 G* cartridge on the *i-STAT 1* analyzer using non-anticoagulated arterial or venous whole blood specimens compared to heparinized whole blood specimens. The study design and analysis method were based on CLSI EP35: *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures – First Edition*. The matrix equivalence was assessed by comparing arterial or venous 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 G* 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

N	Candidate Specimen Range (mg/dL)	Primary Specimen Range (mg/dL)	r	Slope	Intercept
158	42-679	42-681	1.00	1.00	0.00

c. EDTA Matrix Equivalence

A study was conducted to evaluate matrix equivalency between whole blood sample collected in lithium heparin (primary specimen type) and ethylenediaminetetraacetic acid (K_2EDTA and K_3EDTA) anticoagulants (candidate specimen types) and tested with the i-STAT Glucose test in the i-*STAT G* cartridge on the *i-STAT 1* analyzer. The

study design was based on CLSI EP35: *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures – First Edition*. Each specimen was tested in duplicate using two (2) *i-STAT G* cartridges with *i-STAT* 1 analyzers. A Passing-Bablok regression analysis was performed using the first valid result of the K_2EDTA and K_3EDTA anticoagulated specimen types versus the first valid result of the specimens with lithium heparin. The regression analysis results are summarized in **Table 12** and **Table 13**.

Table 12: Passing-Bablok regression summary for K_2EDTA vs lithium heparin

N	K_2EDTA Candidate Specimen Range (mg/dL)	LiHep Primary Specimen Range (mg/dL)	r	Slope	Intercept
43	30.3 – 522.9	29.5 – 510.9	1.00	1.03	-1.037

Table 13: Passing-Bablok regression summary for K_3EDTA vs lithium heparin

N	K_3EDTA Candidate Specimen Range (mg/dL)	LiHep Primary Specimen Range (mg/dL)	r	Slope	Intercept
43	30.4 – 520.6	29.5 – 510.9	1.00	1.03	0.015

VIII. CONCLUSION

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