February 7, 2020

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

Re: K183678
Trade/Device Name: i-STAT CHEM8+ 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, CGL
Dated: January 9, 2020
Received: January 10, 2020

Dear Susan Tibedo:

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

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

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

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

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

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

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K183678

Device Name
i-STAT CHEM8+ cartridge with the i-STAT 1 System

Indications for Use *(Describe)*
The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of glucose, and creatinine 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.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

1. Submitter Information

Owner

Abbott Point of Care Inc.
400 College Road East
Princeton, NJ 08540

Contact

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Date Prepared: February 5, 2020

510(k) Number: k183678

2. Device Information

Proprietary Name: i-STAT CHEM8+ cartridge with i-STAT 1 System

Common Name: Chemistry test, analyzer, handheld

Product code	Device Classification name	Regulation Number	Class	Panel
CGA	Glucose Oxidase, Glucose	862.1345	II	Clinical Chemistry
CGL	Electrode, Ion Based Enzymatic, Creatinine	862.1225	II	Clinical Chemistry

3. Predicate Device

Proprietary Name	SYNCHRON Systems Glucose Reagent on UniCel DxC 600/800 SYNCHRON Clinical System SYNCHRON Systems Creatinine Reagent on UniCel DxC 600/800 SYNCHRON Clinical System
510(k) Number	K042291

Product code	Device Classification name	Regulation Number	Class	Panel
CGA	Glucose Oxidase, Glucose	862.1345	II	Clinical Chemistry
CGX	Alkaline Picrate, Colorimetry, Creatinine	862.1225	II	Clinical Chemistry

4. Device Description

The i-STAT CHEM8+ test cartridge contains test reagents to analyze whole blood at the point of care or in the clinical laboratory for glucose and creatinine. The test is contained in a single-use, disposable cartridge. Cartridges require two to three drops of whole blood which are typically applied to the cartridge using a transfer device.

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

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

5. Intended Use Statement

The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of glucose and creatinine 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.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

6. Summary Comparison of Technological Characteristics

Similarities and Differences: System (Test and Instrument): Glucose		
Feature or Characteristic	**Predicate** SYNCHRON Systems Glucose Reagent on UniCel DxC 600/800 SYNCHRON Clinical System **(K042291)**	**Candidate** **Glucose Test with i-STAT 1 System**
Intended Use	The glucose test system is intended for the quantitative determination of glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF). Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including 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 glucose and creatinine 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.
Reportable Range	0.2 – 33.3 mmol/L (Serum, Plasma) 0 – 600 mg/dL up to 1200 mg/dL by sample dilution	1.1 - 38.9 mmol/L (mEq/L) 20 - 700 mg/dL 0.20 – 7.00 g/L
Sample Type	Serum, plasma, urine, CSF	Arterial or venous whole blood
Sample Volume	0.5 mL (500 µL)	95 µL
Sample Preparation	Sample tubes prepared and then processed within analyzer	Ready to Use
Traceability	NIST SRM 917	NIST SRM 965
Calibration	Must be conducted every 24 hours and with each new reagent	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Serum or plasma: Within 8 hours at room temperature, or up to 48 hours if stored at +2°C to +8°C Urine: Within 2 hours of collection	Heparinized samples: within 30 minutes of collection
Principle of Measurement	O_2 depletion by glucose oxidase activity	Amperometric measurement of oxidized hydrogen peroxide produced by glucose oxidase activity
Reagent Format	Reagent handling system, stored within analyzer	Cartridge
Reagent Storage and Stability	Room temperature	2°C to 8°C (35-46°F)
Analyzer Type	Floor Model	Handheld

Similarities and Differences: System (Test and Instrument): Creatinine (CREA)		
Feature or Characteristic	**Predicate** SYNCHRON Systems Creatinine Reagent on UniCel DxC 600/800 SYNCHRON Clinical System **(K042291)**	**Candidate CREA Test with i-STAT 1 System**
Intended Use	The creatinine test system is intended for the quantitative determination of creatinine in human serum and urine. Measurements of creatinine are used in the diagnosis and treatment of renal disease. Serum creatinine measurements prove useful in evaluation of kidney glomerular function and in monitoring renal dialysis.	The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of glucose and creatinine in arterial or venous whole blood in point of care or clinical laboratory settings. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Reportable Range	0.1 – 25.0 mg/dL (Serum)	0.2-20.0 mg/dL
Sample Type	Serum, urine	Arterial or venous whole blood
Sample Volume	0.5 mL (500 µL)	95 µL
Sample Preparation	Sample tubes prepared and then processed within analyzer	Ready to Use
Traceability	Isotope Dilution Mass Spectroscopy	NIST SRM 967
Calibration	Must be conducted every 24 hours and with each new reagent	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Serum or plasma: Within 8 hours at room temperature, or up to 48 hours if stored at +2°C to +8°C Urine: Within 2 hours of collection	Heparinized samples: within 30 minutes of collection
Principle of Measurement	Colorimetric (520 nm) measurement of creatinine-alkaline picrate complex formation	Amperometric measurement of oxidized hydrogen peroxide produced by creatinine amidinohydrolase activity
Reagent Format	Reagent handling system, stored within analyzer	Cartridge
Reagent Storage and Stability	Room temperature	2°C to 8°C (35-46°F)
Analyzer Type	Floor Model	Handheld

7. Performance Characteristics

Analytical Performance

a. Precision

Precision 20 days (aqueous materials)

The precision of the i-STAT Glucose and Creatinine tests on the i-STAT 1 Wireless Analyzer was evaluated using 5 levels of aqueous materials. This 20-day multi-day precision testing was based on CLSI document EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition.* The study was conducted using multiple instruments and one test cartridge lot over 20 days at one site. Total precision ('within-laboratory', S_T), within-run, (S_r), between-run, (S_{rr}) and between-day, (S_{dd}) were estimated for each level. The results of the 20-day precision study are shown in **Table 1.**

Table 1: 20-Day Precision of i-STAT Glucose and Creatinine tests on the i-STAT 1 Analyzer

i-STAT Test	Fluid Level	N	Mean	Total		Within-run		Between-run		Between-day	
				S_T	CV_T (%)	S_r	CV_r (%)	S_{rr}	CV_{rr} (%)	S_{dd}	CV_{dd} (%)
Creatinine (mg/dL)	CV L1	81	15.90	0.337	2.1	0.321	2.0	0.096	0.6	0.030	0.2
	CV L2	81	4.23	0.101	2.4	0.093	2.2	0.029	0.7	0.027	0.6
	CV L3	81	1.69	0.035	2.1	0.033	2.0	0.008	0.5	0.007	0.4
	CV L4	80	0.51	0.029	5.7	0.027	5.3	0.008	1.6	0.006	1.2
	CV L5	80	0.18	0.028	15.6	0.026	14.4	0.007	3.9	0.007	3.9
Glucose (mg/dL)	CV L1	80	26.7	0.49	1.8	0.47	1.8	0.13	0.5	0.10	0.4
	CV L2	81	40.9	0.52	1.3	0.46	1.1	0.16	0.4	0.18	0.4
	CV L3	81	123.0	0.47	0.4	0.43	0.3	0.13	0.1	0.12	0.1
	CV L4	80	286.5	1.40	0.5	1.25	0.4	0.55	0.2	0.33	0.1
	CV L5	80	608.1	5.56	0.9	5.21	0.9	1.46	0.2	1.31	0.2

Precision (Whole Blood)

The whole blood precision of the i-STAT Glucose and Creatinine Tests on the i-STAT 1 Analyzer were evaluated using venous whole blood (native or altered) samples targeted to four levels within the test reportable range.

One test cartridge lot was used across 3 point of care sites. At each site, each sample was tested 3 times on each of 7 i-STAT 1 Wireless Analyzers (total of 21 test results per sample per instrument). The results of the whole blood precision using the i-STAT 1 Wireless Analyzer are shown in **Table 2.**

Table 2: Whole Blood Precision Results – i-STAT 1 System										
i-STAT Test	Level	Site	N	Mean	Within-Analyzer		Total			
					SD	%CV	SD	SD 95% CI	%CV	%CV 95% CI
Glucose (mg/dL)	30-110	01	21	95.3	0.98	1.0	0.98	0.81 to 1.39	1.0	0.8 to 1.5
		01	21	72.3	1.23	1.7	1.23	1.03 to 1.75	1.7	1.4 to 2.4
		02	21	95.1	0.90	0.9	0.90	0.75 to 1.27	0.9	0.8 to 1.3
		02	21	95.5	0.69	0.7	0.69	0.57 to 0.98	0.7	0.6 to 1.0
		02	21	80.0	0.38	0.5	0.38	0.31 to 0.63	0.5	0.4 to 0.8
		03	21	101.3	0.76	0.8	0.76	0.61 to 1.17	0.8	0.6 to 1.2
		03	21	87.8	0.58	0.7	0.58	0.47 to 0.86	0.7	0.5 to 1.0
		03	21	98.9	0.58	0.6	0.63	0.50 to 1.07	0.6	0.5 to 1.1
	111 – 150	01	21	148.2	0.62	0.4	0.62	0.51 to 0.88	0.4	0.3 to 0.6
		02	20	143.0	0.85	0.6	0.85	0.70 to 1.22	0.6	0.5 to 0.9
		02	14	143.3	1.25	0.9	1.25	1.06 to 2.03	0.9	0.7 to 1.4
		03	21	142.2	0.79	0.6	0.79	0.65 to 1.12	0.6	0.5 to 0.8
	151 – 400	01	21	385.7	2.38	0.6	2.98	2.33 to 5.40	0.8	0.6 to 1.4
		02	21	318.0	3.25	1.0	3.25	2.70 to 4.62	1.0	0.8 to 1.5
		03	21	151.8	1.02	0.7	1.02	0.83 to 1.57	0.7	0.5 to 1.0
	401 – 700	01	21	618.4	7.95	1.3	7.95	6.54 to 11.67	1.3	1.1 to 1.9
		02	21	444.2	2.23	0.5	2.23	1.85 to 3.14	0.5	0.4 to 0.7
		03	21	582.0	2.82	0.5	2.93	2.33 to 4.84	0.5	0.4 to 0.8
Creatinine (mg/dL)	<1	01	21	0.82	0.038	4.6	0.044	0.035 to 0.078	5.4	4.3 to 9.5
		01	21	0.60	0.038	6.3	0.038	0.031 to 0.053	6.3	5.2 to 8.8
		01	21	0.52	0.049	9.4	0.049	0.040 to 0.070	9.4	7.7 to 13.5
		02	20	0.96	0.049	5.1	0.051	0.041 to 0.086	5.3	4.3 to 9.0
		02	21	0.96	0.053	5.5	0.053	0.044 to 0.080	5.5	4.6 to 8.3
		02	21	0.56	0.058	10.4	0.058	0.048 to 0.082	10.4	8.6 to 14.6
		02	21	0.87	0.044	5.1	0.049	0.039 to 0.084	5.6	4.5 to 9.7
		03	21	0.81	0.031	3.8	0.031	0.025 to 0.048	3.8	3.1 to 5.9
		03	21	0.70	0.031	4.4	0.032	0.025 to 0.052	4.6	3.6 to 7.4
		03	21	0.59	0.031	5.3	0.031	0.025 to 0.048	5.3	4.2 to 8.1
	1 – 15	03	21	1.23	0.049	4.0	0.049	0.039 to 0.078	4.0	3.2 to 6.3
		03	21	1.17	0.049	4.2	0.049	0.040 to 0.074	4.2	3.4 to 6.3
	1.5 – 2.0	01	21	1.53	0.049	3.2	0.049	0.040 to 0.074	3.2	2.6 to 4.8
		02	14	1.83	0.053	2.9	0.053	0.044 to 0.090	2.9	2.4 to 4.9
		02	21	1.97	0.062	3.1	0.062	0.051 to 0.092	3.1	2.6 to 4.7
		03	21	1.70	0.058	3.4	0.058	0.047 to 0.088	3.4	2.8 to 5.2
	5.0 – 7.0	01	21	5.62	0.172	3.1	0.172	0.142 to 0.246	3.1	2.5 to 4.4
		02	21	6.31	0.246	3.9	0.246	0.202 to 0.366	3.9	3.2 to 5.8
		03	21	5.30	0.072	1.4	0.072	0.059 to 0.107	1.4	1.1 to 2.0
	7.0 – 12	02	21	9.47	0.127	1.3	0.155	0.121 to 0.277	1.6	1.3 to 2.9
	>12	01	21	14.37	0.388	2.7	0.388	0.321 to 0.561	2.7	2.2 to 3.9
		02	21	14.90	0.515	3.5	0.515	0.427 to 0.732	3.5	2.9 to 4.9
		03	21	14.30	0.558	3.9	0.558	0.462 to 0.795	3.9	3.2 to 5.6

b. Linearity

The study was designed based on CLSI EP06-A: *Evaluation of the linearity of quantitative measurement procedures.*

The linearity of the i-STAT Glucose and Creatinine tests on the i-STAT 1 Analyzer were evaluated by preparing whole blood samples of varying analyte levels that spanned the reportable range of the test. The best fitting regression model was the third order model. The absolute degree of nonlinearity results met the acceptance criteria for each of the levels tested for each analyte. Therefore, the i-STAT Glucose and Creatinine test demonstrated linearity over the reportable range as shown in **Table 3.** Regression summary of the Glucose and Creatinine response versus the concentration of the whole blood samples of varying analyte levels is also provided in **Table 3.**

Table 3: Regression Summary for the i-STAT tests on the i-STAT 1 Analyzer

i-STAT Test	Reportable Range	Range Tested	Slope	Intercept	R^2
Glucose (mg/dL)	20-700	17 - 620	0.9794	-1.603	0.9991
Creatinine (mg/dL)	0.20 – 20.0	0.13 – 16.2	1.021	0.0763	0.9978

c. Limit of Quantitation (LoQ)

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

The LoQ of the i-STAT Glucose and Creatinine tests were evaluated on the i-STAT 1 Analyzer using whole blood that was altered to low glucose (< 20 mg/dL) and low creatinine (< 0.2 mg/dL) concentrations and two test cartridge lots. The LoQs for the i-STAT Glucose and Creatinine tests were determined to be 12 mg/dL and 0.10 mg/dL respectively, which is below the lower limit of the reportable range for each of the i-STAT Glucose and Creatinine tests as shown in **Table 3.**

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

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

The LoB/LoD of the i-STAT glucose and creatinine tests were evaluated on the i-STAT 1 Analyzer using whole blood that was altered to “blank” analyte (glucose or creatinine) concentration for LoB testing and two “low” analyte (glucose or creatinine) concentrations 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 i-STAT Creatinine and Glucose tests on the i-STAT 1 Analyzer were determined as shown in the **Table 4** below.

Table 4: Summary of LoB and LoD Results Per Test (mg/dL)

i-STAT Test	LoB	LoD
Creatinine	0.05	0.10
Glucose	1	2

e. Hematocrit Sensitivity to the i-STAT Glucose Test

A hematocrit sensitivity study was performed for the i-STAT Glucose test to assess the effect of hematocrit. Three hematocrit levels (low, mid and high) were evaluated across four (4) glucose levels across the reportable range of the test.

The results of the study demonstrated that the i-STAT Glucose test performs equivalently at different hematocrit levels when tested on the i-STAT 1 analyzer.

f. Oxygen Sensitivity

The effect on oxygen on the i-STAT Creatinine and Glucose tests was evaluated with high and low ranges of oxygen.

The equivalency between the high and low conditions was determined by a two-sample equivalence test using the analyte allowable error (Ea) relative to the analyte control mean/median results.

The study demonstrated that the i-STAT Creatinine and Glucose tests are insensitive to oxygen changes between 20 to >500 mmHg for creatinine and 25 to >500 mmHg for glucose.

g. Altitude

The results of the study show equivalent creatinine results at elevations up to 6367 feet and for glucose up to 9523 feet. The correlation coefficient and slope results from the Passing-Bablok regression analysis met the acceptance criteria as summarized as shown in Table below.

Table 5: Summary of Results

Test	Average Measured Altitude	Results	
Creatinine	6367 feet	r	1.00
		Slope	1.13
Glucose	9523 feet	r	1.00
		Slope	1.00

h. Interference

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

Table 6 and **Table 7** contain the lists of potentially interfering substances tested for the i-STAT Glucose and Creatinine tests and the interference results**.**

i-STAT Glucose Test

Table 6: Summary of Substance Tested and Interference Results for the i-STAT Glucose test

Substance	Test Concentration		Interference (Yes/No)	Interference Results
	mmol/L	mg/dL		
Acetaldehyde	0.045[a]	0.2	No	
Acetaminophen	1.03	15.6	No	
Lithium Acetoacetate	2.0	20	No	
N-Acetyl-L-Cysteine	0.92	15.0	No	
Ammonium Chloride	2.0[a]	10.70	No	
L-Ascorbic Acid	0.298	5.25	No	
Bilirubin	0.684	40	No	
Lithium Bromide	37.5[a]	325.69	Yes	Decreased results ≥ 11.8 mmol/L
Cholesterol	10.3	400	No	
Creatinine	1.326	15	No	
Dopamine Hydrochloride	4.06 µmol/L	0.0621	No	
Ethanol	130	600	No	
Lithium Fluoride	0.0632	0.12	No	
Formaldehyde	0.133[a]	0.399	No	
Fructose	1	18	No	
Galactose	3.33	60	No	
Gentamicin Sulfate	0.0628	3	No	
Glucosamine Hydrochloride	0.030[a]	0.647	No	
Glutathione, reduced	3	3 mEq/L	No	
Glycolic Acid	10.0[a]	76.05	No	

[a] No CLSI EP37 test concentration available. The molecular weight of the substance tested was used to convert the test concentration from mmol/L to mg/dL. The molecular weight of each substance could vary depending on the form chosen.

Table 6: Summary of Substance Tested and Interference Results for the i-STAT Glucose test				
Substance	**Test Concentration**		**Interference (Yes/No)**	**Interference Results**
	mmol/L	**mg/dL**		
Guaifenesin	0.0227	0.45	No	
Hemoglobin	10 g/L	1000	No	
Sodium Heparin	3.30 U/mL	330 U/dL	No	
β-Hydroxybutyric Acid	6.0[aa]	62.47	No	
Hydroxyurea	0.405	3.08	Yes	Increased results ≥ 0.08 mmol/L
Ibuprofen	1.06	21.9	No	
Isoniazid	0.438	6	No	
Lithium Lactate	10	90	No	
Mannose	1.0[a]	18.02	No	
Maltose	10.5	360	No	
pH	8.0 pH units	N/A	No	
Lithium Pyruvate	0.570	5	No	
Lithium Salicylate	0.207	2.86	No	
Lithium Thiocyanate	0.898	5.22	No	
Sodium Thiosulfate	16.7[a]	264.04	No	
Triglyceride	16.94	1500	No	
Uric Acid	1.4	23.5	No	
Xylose	3[a]	45.04	No	
Gentisic Acid	0.0973	1.50	No	

i-STAT Creatinine Test

Table 7: Summary of Substance Tested and Interference Results for the i-STAT Creatinine test				
Substance	**Test Concentration**		**Interference (Yes/No)**	**Interference Results**
	mmol/L	**mg/dL**		
Acetaldehyde	0.045[a]	0.2	No	
Acetaminophen	1.03	15.6	No	
N-Acetyl-L-Cysteine	0.92	15.0	No	
L-Ascorbic Acid	0.298	5.25	No	
β-Hydroxybutyric Acid	6.0[a]	62.47	No	
Bicarbonate	35.0	294.0	No	
Bilirubin	0.684	40	No	
Lithium Bromide	37.5[a]	325.69	Yes	Increased results ≥ 18.3 mmol/L
Calcium Chloride	5.0	20	No	
Creatine	0.382[a]	5.01	No	
Dopamine Hydrochloride	4.06 µmol/L	0.0621	No	
Formaldehyde	0.133[a]	0.399	No	

[a] No CLSI EP37 test concentration available. The molecular weight of the substance tested was used to convert the test concentration from mmol/L to mg/dL. The molecular weight of each substance could vary depending on the form chosen.

Table 7: Summary of Substance Tested and Interference Results for the i-STAT Creatinine test				
Substance	**Test Concentration**		**Interference (Yes/No)**	**Interference Results**
	mmol/L	**mg/dL**		
Glycolic Acid	10.0[a]	76.05	No	
Hemoglobin	10 g/L	1000	No	
Hydroxyurea	0.405	3.08	Yes	Increased results ≥ 0.03 mmol/L
Lithium Lactate	10	90	No	
Methyldopa	107 µmol/L	2.25	No	
pH	8.0 pH units	N/A	No	
Lithium Pyruvate	0.570	5	No	
Lithium Salicylate	0.207	2.86	No	
Sodium Thiosulfate	16.7[a]	264.04	No	
Triglyceride	16.94	1500	No	
Uric Acid	1.4	23.5	No	

Comparison Study

i. Method Comparison with Predicate Device

Method comparison was demonstrated in a study comparing the i-STAT Glucose and Creatinine test performance on the i-STAT 1 to the Beckman DxC. The study was based on CLSI guideline EP09c-ED3. Venous and arterial blood specimens were evaluated and analyzed on the i-STAT 1 against plasma specimens on the Beckman DxC. A Passing-Bablok linear regression analysis was performed using the first replicate result from the i-STAT 1 versus the singlicate result of the comparative method.

The i-STAT System automatically runs a comprehensive set of quality checks of both the analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results by generating a Quality Check Code (QCC) if the analyzer, cartridge or sample does not meet certain internal specifications. When a QCC occurs, a single code number, the type of problem and the next step to be taken will be displayed on the i-STAT Analyzer. The failure rate for a single cartridge due to QCCs may be as high as 4%. The rate of failure for two consecutive cartridges due to QCCs may be as high as 1.7%.

Table 5: Method Comparison Results				
i-STAT Test	**N**	**Slope**	**Intercept**	**r**
Glucose	185	0.98	0.00	1.00
Creatinine	180	1.043	-0.062	1.00

8. Conclusion

The results of these studies demonstrate that performance of the i-STAT CHEM8+ Glucose and Creatinine tests with the i-STAT 1 System are substantially equivalent to the comparative method.