510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K210958

B Applicant

Abbott Point of Care Inc.

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CGA	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
CGL	Class II	21 CFR 862.1225 - Creatinine test system	CH - Clinical Chemistry
JGS	Class II	21 CFR 862.1665 - Sodium test system	CH - Clinical Chemistry
CEM	Class II	21 CFR 862.1600 - Potassium test system	CH - Clinical Chemistry
CGZ	Class II	21 CFR 862.1170 - Chloride test system	CH - Clinical Chemistry
JFP	Class II	21 CFR 862.1145 - Calcium test system	CH - Clinical Chemistry
CDS	Class II	21 CFR 862.1770 - Urea nitrogen test system	CH - Clinical Chemistry
JFL	Class II	21 CFR 862.1160 - Bicarbonate/carbon dioxide test system	CH - Clinical Chemistry
JPI	Class II	21 CFR 864.6400 - Hematocrit measuring device	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Modification to add use of anticoagulant free venous and arterial whole blood to the previously cleared i-STAT CHEM8+ (blue) cartridge with i-STAT 1 System under k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium) and k183680 (hematocrit).

B Measurand:

Glucose, creatinine, blood urea nitrogen (BUN), sodium (Na), potassium (K), chloride (Cl), ionized calcium (iCa), total carbon dioxide (TCO2), and hematocrit.

C Type of Test:

Quantitative amperometric assays for glucose and creatinine
Quantitative, Ion Specific Electrode (Potentiometric method) for Na, K, Cl, iCa, BUN and TCO2
Quantitative conductivity (electrical) measurement for hematocrit

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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.
Sodium measurements are used for monitoring electrolyte imbalances.

Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.

Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.

Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

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.

Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases.

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.

Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status that can be associated with conditions including anemia and erythrocytosis. The i-STAT Hematocrit test has not been evaluated in neonates.

Carbon dioxide measurements are used in the diagnosis, monitoring, and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
For point-of-care or clinical laboratory setting

D Special Instrument Requirements:

i-STAT 1 Analyzer

IV Device/System Characteristics:

A Device Description:

The i-STAT 1 System consists of the i-STAT 1 Analyzer and the i-STAT CHEM8+ (blue) cartridges. 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.

The i-STAT 1 Analyzer (previously cleared under k103195 as the i-STAT 1 Wireless Analyzer) is a handheld analytical device designed to run i-STAT test cartridges. The instrument interacts with the cartridge to move fluid across the sensors and generate a quantitative result.

The single-use, disposable i-STAT CHEM8+ (blue) cartridge contains test reagents to analyze venous and arterial whole blood at the point of care or in the clinical laboratory. The cartridge format allows all the tests in the cartridge to be performed simultaneously. The cartridges contain the required sensors, a fluid pouch, a sample entry well and closure, fluid channels, waste chamber, and the necessary mechanical features for controlled fluid movement within the 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.

B Principle of Operation:

Glucose on the i-STAT CHEM8+ cartridge is measured amperometrically. A voltage is applied to the cartridge electrodes with current generated by the reduction of hydrogen peroxide that was

produced by catalytic oxidation of glucose present in the sample by glucose oxidase. The current is directly proportional to the concentration of the glucose.

Creatinine on the i-STAT CHEM8+ cartridge is measured amperometrically. Creatinine in the sample is hydrolyzed to creatine by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. A voltage is applied to the cartridge electrodes with current generated by the reduction of hydrogen peroxide. The current is directly proportional to the concentration of the creatinine.

Sodium, Potassium, Chloride and ionized Calcium on the i-STAT CHEM8+ cartridge are measured by ion-selective electrode potentiometry; measurement of potential difference between the ion selective electrode and the reference electrode. In the calculation of concentration is related to potential through the Nernst equation.

BUN on the i-STAT CHEM8+ cartridge is measured by the hydrolysis of urea in the sample to ammonium ions catalyzed by the urease, and ammonium measured by ion-selective potentiometry.

TCO2 on the i-STAT CHEM8+ Cartridge is measured by potentiometric determination of both pH and pCO2, and calculated with an algorithm based on the Henderson-Hasselbalch equation, which uses pH, PCO2, and ionic strength (sodium) measurements.

Hematocrit on the i-STAT CHEM8+ cartridge is measured by the conductivity method. Conductivity of the sample is inversely proportional to the concentration of red blood cells in the sample. The hematocrit sensor first measures the electrical conductivity of the calibrant solution, followed by the conductivity of the whole blood sample. The conductivity of the sample is also a function of the plasma electrolyte concentration. The i-STAT Hematocrit test algorithm uses the sodium concentration in the calculation of the test result.

V Substantial Equivalence Information:

A Predicate Device Name(s):
i-STAT CHEM8+ cartridge with the i-STAT 1 System

B Predicate 510(k) Number(s):
k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium) and k183680 (hematocrit).

C Comparison with Predicate(s):

Device & Predicate Device:	k210958	k183678
Device Trade Name	i-STAT CHEM8+ Cartridge with the i-STAT 1 System (glucose and creatinine)	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for *in vitro* quantification of glucose and creatinine.	Same
General Device Characteristic Differences		
Specimen matrix types	Arterial or venous whole blood with heparin anticoagulant or without anticoagulant	Arterial or venous whole blood with heparin anticoagulant.
Specimen use stability time	*Whole blood without anti-coagulant:* For all analytes, up to three minutes. *Whole blood with anti-coagulant:* Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.	Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.

Device & Predicate Device:	k210958	k183688
Device Trade Name	i-STAT CHEM8+ Cartridge with the i-STAT 1 System (sodium, potassium, chloride, BUN)	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for *in vitro* quantification of sodium, potassium, chloride, and blood urea nitrogen.	Same

General Device Characteristic Differences		
Specimen matrix types	Arterial or venous whole blood with heparin anticoagulant or without anticoagulant.	Arterial or venous whole blood with heparin anticoagulant.
Specimen use stability time	*Whole blood without anti-coagulant:* For all analytes, up to three minutes. *Whole blood with anti-coagulant:* Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.	Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.

Device & Predicate Device:	k210958	k191298
Device Trade Name	i-STAT CHEM8+ Cartridge with the i-STAT 1 System (TCO2)	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for *in vitro* quantification of TCO2.	Same
General Device Characteristic Differences		
Specimen matrix types	Arterial or venous whole blood with heparin anticoagulant or without anticoagulant.	Arterial or venous whole blood with heparin anticoagulant.
Specimen use stability time	*Whole blood without anti-coagulant:* For all analytes, up to three minutes. *Whole blood with anti-coagulant:* Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.	Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.

Device & Predicate Device:	k210958	k191360
Device Trade Name	i-STAT CHEM8+ Cartridge with the i-STAT 1 System (ionized calcium)	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for *in vitro* quantification of ionized calcium.	Same
General Device Characteristic Differences		
Specimen matrix types	Arterial or venous whole blood with heparin anticoagulant or without anticoagulant	Arterial or venous whole blood with heparin anticoagulant.
Specimen use stability time	*Whole blood without anti-coagulant:* For all analytes, up to three minutes. *Whole blood with anti-coagulant:* Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.	Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.

Device & Predicate Device:	k210958	k183680
Device Trade Name	i-STAT CHEM8+ Cartridge with the i-STAT 1 System (hematocrit)	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for *in vitro* quantification of hematocrit.	Same
General Device Characteristic Differences		

Specimen matrix types	Arterial or venous whole blood with heparin anticoagulant or without anticoagulant	Arterial or venous whole blood with heparin anticoagulant.
Specimen use stability time	*Whole blood without anti-coagulant:* For all analytes, up to three minutes. *Whole blood with anti-coagulant:* Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.	Up to 30 minutes for all analytes, except TCO2 and ionized calcium - up to 10 minutes.

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) H7-A3 Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third Edition.

CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The sponsor provided information to support that the precision performance of the assays on the i-STAT CHEM8+ cartridge with the i-STAT 1 System using venous and arterial whole blood without anti-coagulant was the same as other specimen matrix types. The precision performance with other specimen types was established under studies conducted in support of k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium), and k183680 (hematocrit).

2. Linearity:

The linearity performance of the assays on the i-STAT CHEM8+ cartridge with the i-STAT 1 System was established with studies conducted in support of k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium), and k183680 (hematocrit).

3. Analytical Specificity/Interference:

The analytical specificity performance of the assays on the i-STAT CHEM8+ cartridge with the i-STAT 1 System was established with studies conducted in support of k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium), and k183680 (hematocrit).

4. Assay Reportable Range:

The assay reportable range of the assays on the i-STAT CHEM8+ cartridge with the i-STAT 1 System was established with studies conducted in support of k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium), and k183680 (hematocrit).

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability
Traceability information can be found in k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium), and k183680 (hematocrit).

Specimen stability
In support of the modification to add use of arterial and venous whole blood without anti-coagulant and testing within three minutes of collection, a specimen stability study was conducted. In the study, venous whole blood was collected without anti-coagulant from five healthy donors. Each of the whole blood samples after collection was tested immediately (control condition) and tested at four minutes (test condition). For each of the two conditions, the samples were tested in replicates of 10 using one lot of cartridges and 20 analyzers. For each analyte the specimen was considered stable if the difference between the mean results (or median) of the test and the control condition was within the sponsor's definition of allowable error. Based on an analysis of the results of the specimen stability study, the sponsor concluded that for i-STAT glucose, sodium, potassium, chloride, iCa, BUN, creatinine, hematocrit, and TCO2 tests on the i-STAT CHEM8+ cartridge when tested on the i-STAT 1 System demonstrated that whole blood samples collected without anticoagulant are stable out to four minutes, which supports the labeling claim of three minutes.

6. Detection Limit:

The detection limit performance of the assays on the i-STAT CHEM8+ cartridge with the i-STAT 1 System was established with studies conducted in support of k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium), and k183680 (hematocrit).

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   The method comparison accuracy performance of the assays on the i-STAT CHEM8+ cartridge with the i-STAT 1 System was established with studies conducted in support of k183678 (glucose and creatinine), k183688 (Na, K, Cl and BUN), k191298 (TCO2), k191360 (ionized calcium), and k183680 (hematocrit).

2. Matrix Comparison:
   A matrix equivalency assessment was conducted to support use of venous or arterial specimens collected without anticoagulant. The study was conducted at one internal site and three point of care sites (POC) sites. At the POC sites, two donor matched venous specimens with and without lithium heparin were collected, and likewise arterial specimens were collected. For the internal site, whole blood specimens from donors were collected in blood collection tubes without anticoagulant. A portion of each native or contrived non-anticoagulated sample was transferred to a lithium heparin blood collection tube to be used as the anticoagulated control condition.

   Specimens without anti-coagulant were tested with the i-STAT 1 System in duplicate with the first results used in the analysis. Specimens collected with anti-coagulant (comparator specimen) were tested in duplicate with the mean used in the analysis. The internal study tested all analytes on the cartridge, except for TCO2 using native and contrived samples (<10%). The three POC sites tested all analytes on the cartridge using only native samples. One lot of i-STAT CHEM8+ cartridges was used. Multiple different i-STAT 1 Systems were used at each site. The results were analyzed by combined data across all sites and analyzed by a Passing-Bablok linear regression. No outliers were removed from the analysis. Based on the results, as summarized below, the sponsor concluded that the samples (venous and arterial) collected without anticoagulant are equivalent to those collected with heparin anticoagulant for all analytes.

   Glucose
   8 samples were contrived representing 2.55% of the 313 specimens.

	N	Range Tested (mg/dL), without anticoagulant	Regression Equation	r
Venous	182	29 - 663	y = -0.44 + 1.004x	0.999
Arterial	131	61 - 648	y = -0.37 + 1.004x	0.998

   Creatinine
   8 samples were contrived representing 2.56% of the 312 specimens.

	N	Range Tested (mg/dL), without anticoagulant	Regression Equation	r
Venous	182	0.3 – 19.4	y = 0.00 + 1.00x	0.999
Arterial	130	0.2 – 18.1	y = 0.00 + 1.00x	0.999

Sodium

8 samples were contrived representing 2.54% of the 314 specimens.

	N	Range Tested (mmol/L), without anticoagulant	Regression Equation	r
Venous	183	110-173	y = 0.565 + 1.00x	0.99
Arterial	131	127-171	y = 0.00 + 1.00x	0.98

Potassium

8 samples were contrived representing 2.55% of the 313 specimens.

	N	Range Tested (mmol/L), without anticoagulant	Regression Equation	r
Venous	182	2.2 – 6.9	y = 0.018 + 1.00x	0.99
Arterial	131	2.9 – 7.7	y = 0.00 + 1.00x	0.93

Chloride

8 samples were contrived representing 2.54% of the 314 specimens.

	N	Range Tested (mmol/L), without anticoagulant	Regression Equation	r
Venous	183	76 - 136	y = 0.55 + 1.00x	0.98
Arterial	131	87 - 129	y = -0.50 + 1.00x	0.98

Ionized calcium

8 samples were contrived representing 2.54% of the 314 specimens.

	N	Range Tested (mmol/L), without anticoagulant	Regression Equation	r
Venous	183	0.41 – 2.33	y = -0.014 + 1.036x	0.93
Arterial	131	0.92 – 2.48	y = 0.00 + 1.00x	0.57

BUN

8 samples were contrived representing 2.58% of the 310 specimens.

	N	Range Tested (mg/dL), without anticoagulant	Regression Equation	r
Venous	182	4 - 120	y = 0.00 + 1.00x	0.997
Arterial	128	4 - 101	y = 0.00 + 1.00x	0.995

TCO2

	N	Range Tested (mmol/L), without anticoagulant	Regression Equation	r
Venous	142	9 – 42	y = 0.00 + 1.00x	0.96
Arterial	131	12 – 40	y = 0.00 + 1.00x	0.94

Hematocrit
32 samples were contrived representing 10.29% of the 311 specimens.

	N	Range Tested (%PCV), without anticoagulant	Regression Equation	r
Venous	180	16 - 75	y = 0.34 + 1.00x	0.993
Arterial	131	19 - 50	y = 0.50 + 1.00x	0.965

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable.

2. Clinical Specificity:
   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Expected values for the analytes on the i-STAT CHEM8+ (blue) cartridge are cited from literature:

Analyte	Units	Reference Range
Glucose (fasting)	mg/dL	70 - 105
Creatinine	mg/dL	0.6 - 1.3

Source: Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th Edition. CA Burtis, ER Ashwood, DE Bruns, ed., Elsevier Saunders Inc., 2006.

Analyte	Units	Reference Range
Sodium	mmol/L	138-146
Potassium	mmol/L	3.5-4.9
Chloride	mmol/L	98-109
BUN/Urea	mg/dL	8-26

Source: B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economics Books, 1987).

Analyte	Unit	Reference Range	
Total Carbon Dioxide (TCO2)	mmol/L	arterial	venous
		23−27	24−29

Source: Calculated from Siggard-Andersen nomogram: E.L. Pruden, O. Siggard-Andersen, and N.W. Tietz, Blood Gases and pH, in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994).

Analyte	Unit	Reference Range
Ionized calcium	mmol/L	1.12 – 1.32

Source: P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

Analyte	Unit	Adult Reference Ranges, Arterial and Venous	
Hematocrit	%PCV (packed cell volume)	Female	Male
		38−46	43−51
	Fraction	0.38−0.46	0.43−0.51

Source: B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economics Books, 1987).

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.