510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K230300

B Applicant

Abbott Point of Care Inc.

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JFP	Class II	21 CFR 862.1145 - Calcium 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 a previously cleared device

B Measurand:

Ionized Calcium (iCa), Hematocrit (Hct)

C Type of Test:

Ionized Calcium: Quantitative Ion-selective electrode potentiometry assay
Hematocrit: Quantitative conductometric assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The i-STAT CG8+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of ionized calcium and hematocrit in arterial or venous whole blood in point of care or clinical laboratory settings.

The i-STAT CG8+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of hematocrit in capillary whole blood in point of care or clinical laboratory settings.

lonized calcium measurements are used in the diagnosis, monitoring, and treatment of conditions including, but not limited to, parathyroid disease, a variety of bone diseases, chronic renal disease, tetany, and disturbances related to surgical and intensive care.

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, erythrocytosis, and blood loss related to trauma and surgery.

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 CG8+ (white) cartridge is used with the i-STAT 1 analyzer as part of the i-STAT 1 System.

The single-use, disposable i-STAT CG8+ (white) cartridge contain 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+ (white) cartridge. Cartridges require two to three drops of whole blood (95µL) to be run on the analyzer.

The candidate device is for the calcium and hematocrit analytes on the i-STAT CG8+ (white) cartridge with the i-STAT 1 System. Additional analytes on the i-STAT CG8+ (white) cartridge

with the i-STAT 1 System were cleared in K223710 (glucose), K230285 (pH, pCO2, pO2), and K230275 (sodium and potassium).

B Principle of Operation:

Ionized Calcium (iCa) on the i-STAT CHEM8+ cartridge is 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.

Hematocrit (Hct) 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):

K191360

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230300	K191360
Device Trade Name	i-STAT CG8+ (white) cartridge with the i-STAT 1 System	i-STAT CG8+ (white) cartridge with the i-STAT 1 System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for in vitro quantification of ionized calcium	Same
Intended use settings	Point of care and clinical laboratory settings	Same
General Device Characteristic Differences		
Analytes Measured	Ionized calcium and hematocrit	Ionized calcium
Sample Type	Hct: capillary whole blood with lithium heparin anticoagulant iCa and Hct: Arterial and venous whole blood with and without lithium heparin anticoagulant	iCa: Arterial and venous whole blood with and without lithium heparin anticoagulant

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition
- CLSI EP06: Evaluation of Linearity of Quantitative Measurement Procedures; 2nd Edition.
- CLSI EP07: Interference Testing in Clinical Chemistry; 3rd ed.
- CLSI EP09c: Measurement Procedure Comparison and Bias Estimation using Patient Samples, 3rd ed.
- CLSI EP 17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline
- CLSI EP37: Supplement Tables for Interference Testing in Clinical Chemistry; 1st ed.
- CLSI EP35: Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures; 1st ed.
- CLSI H7-A3: Procedure for Determining Packed Cell Volume by the Microhematocrit Method - Second Edition; Approved Standard - Third Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Internal within-laboratory precision (aqueous control material)
A single site precision study was conducted using five concentration levels of commercially available calibration verification (CalVer) samples that were tested using one lot of the i-STAT CG8+ (white) cartridge and ten i-STAT 1 Analyzers. The precision of the i-STAT Ionized Calcium test was evaluated using five (5) levels of aqueous materials and the precision of the i-STAT Hematocrit (Hct) test was evaluated using four (4) levels of aqueous materials. Each sample was measured in duplicates per run, with two runs per day over 20-days by a minimum of two operators resulting in a total of 80 test results per level. When a cartridge generated a star-out (non-reported result) for one assay, an additional cartridge was run to replace the star-out result, which produced additional test results for other assays. The results are summarized below.

Test (units)	Level	N	Mean	Repeatability		Between-run		Between-day		Within-Laboratory	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
iCa (mmol/L)	L1	80	2.280	0.0129	0.57	0.0050	0.22	0.0036	0.16	0.0144	0.63
	L2	80	1.517	0.0073	0.48	0.0023	0.15	0.0020	0.13	0.0080	0.52
	L3	80	1.282	0.0080	0.63	0.0020	0.15	0.0018	0.14	0.0085	0.66
	L4	80	0.763	0.0034	0.44	0.0018	0.23	0.0010	0.13	0.0039	0.51
	L5	80	0.260	0.0018	0.68	0.0007	0.27	0.0006	0.22	0.0020	0.76
Hct (%PCV)	L1	81	22.0	0.38	1.74	0.12	0.54	0.11	0.48	0.42	1.89
	L2	80	35.0	0.41	1.17	0.14	0.40	0.11	0.32	0.45	1.27
	L3	80	56.4	0.22	0.40	0.12	0.21	0.10	0.18	0.27	0.48
	L4	82	66.3	0.24	0.35	0.02	0.03	0.06	0.09	0.24	0.37

Point of Care precision (aqueous control material)

A three-site precision study was performed using a panel of five levels of aqueous control solutions, containing different levels of each analyte. At each site, testing was performed once per day by two operators for five days and each operator performed the test on three analyzers using one lot of the i-STAT CG8+ (white) cartridge. When a cartridge generated a star-out (non-reported result) for one assay, an additional cartridge was run to replace the star-out result, which produced additional test results for other assays. 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 are provided below. Lot-to-lot and instrument-to-instrument precision was also evaluated and found to be acceptable.

Test (units)	N	Level	Mean	Between-Day		Between-Site		Overall	
				SD	%CV	SD	%CV	SD	%CV
iCa (mmol/L)	91	L1	2.323	0.0104	0.45	0.0079	0.34	0.0196	0.84
	90	L2	1.535	0.0043	0.28	0.0018	0.12	0.0091	0.59
	97	L3	1.288	0.0000	0.00	0.0000	0.00	0.0069	0.53
	90	L4	0.762	0.0000	0.00	0.0008	0.10	0.0049	0.65
	90	L5	0.260	0.0000	0.00	0.0000	0.00	0.0011	0.41
Hct (%PCV)	90	L1	12.2	0.18	1.45	0.12	0.97	0.41	3.38
	90	L2	22.1	0.00	0.00	0.20	0.92	0.42	1.90
	90	L3	35.1	0.00	0.00	0.11	0.31	0.39	1.10
	90	L4	56.3	0.09	0.16	0.27	0.48	0.53	0.95
	90	L5	66.1	0.17	0.26	0.14	0.21	0.38	0.58

Test (units)	N	Level	Mean	Within-Run		Within-Site (Total)	
				SD	%CV	SD	%CV
iCa (mmol/L)	91	L1	2.323	0.0147	0.63	0.018	0.77
	90	L2	1.535	0.0078	0.51	0.0089	0.58
	97	L3	1.288	0.0068	0.53	0.0069	0.53
	90	L4	0.762	0.0049	0.64	0.0049	0.64
	90	L5	0.260	0.0011	0.41	0.0011	0.41
Hct (%PCV)	90	L1	12.2	0.34	2.75	0.39	3.24
	90	L2	22.1	0.35	1.57	0.37	1.67
	90	L3	35.1	0.36	1.03	0.37	1.06
	90	L4	56.3	0.45	0.80	0.46	0.81
	90	L5	66.1	0.31	0.47	0.36	0.54

Point of Care Precision (Whole Blood)

Whole blood precision for the i-STAT CG8+ (white) cartridge on the i-STAT 1 System was evaluated using arterial, venous, and capillary whole blood specimens collected with lithium heparin for the hematocrit test and arterial and venous whole blood specimens collected with lithium heparin for the ionized calcium test. 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 each i-STAT test. The results are summarized below.

Test (units)	Sample Type	Sample Range	N	Mean	SD	%CV
iCa (mmol/L)	Venous Whole Blood	0.25-0.75	5	0.468	0.0045	0.96
		>0.75-1.20	95	1.123	0.0094	0.84
		>1.20-1.50	77	1.281	0.0165	1.29
		>1.50-2.50	7	2.179	0.0214	0.98
	Arterial Whole Blood	0.25-0.75	0	N/A	N/A	N/A
		>0.75-1.20	92	1.144	0.0063	0.55
		>1.20-1.50	58	1.282	0.0114	0.89
		>1.50-2.50	3	1.797	0.0100	0.56
Hct (%PCV)	Venous Whole Blood	15-35	88	27.3	0.45	1.63
		>35-50	75	39.4	2.20	5.59
		>50-75	7	60.1	0.46	0.77
	Arterial Whole Blood	15-35	104	26.3	0.55	2.08
		>35-50	45	38.9	0.48	1.24
		>50-75	2	50.0	0.00	0.00
	Capillary Whole Blood	15-35	28	29.5	1.23	4.18
		>35-50	109	41.1	1.10	2.68
		>50-75	17	53.5	0.95	1.78

2. Linearity:
The linearity of the i-STAT Ionized Calcium and Hematocrit tests in the i-STAT CG8+ (white) cartridge with the i-STAT 1 System was evaluated by preparing whole blood samples of varying HCT and iCa levels. The data demonstrated that the i-STAT Ionized Calcium and Hematocrit tests in the i-STAT CG8+ (white) cartridge are linear over the reportable range for each i-STAT test. Summary of the results are provided below:

Test	Units	Reportable Range	Range Tested	Slope	Intercept	R^2
iCa	mmol/L	0.25 – 2.50	0.204 – 2.832	1.016	0.019	0.9981
Hct	%PCV	15 – 75	12.7 – 78.3	1.031	-0.592	0.9992

3. Analytical Specificity/Interference:
The analytical specificity of the i-STAT Ionized Calcium and Hematocrit tests in the i-STAT CG8+ (white) cartridge was established following the recommendations in CLSI EP07-ED3. Interference from certain exogenous and endogenous substances was assessed using lithium heparin venous whole blood that was spiked with the analytes to two concentrations: Ionized Calcium 1.05 – 1.25 mmol/L and 1.40 – 1.60 mmol/L; Hematocrit 26.5 – 31.5 % PCV and 57 – 63% PCV. Each low and high sample was further divided into two aliquots: control (with no added interferent) and test (with added interferent). 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. A substance was identified as an interferent if the difference between the control and test samples was outside of the allowable error (±Ea) for the i-STAT test. For an identified interferent, a dose-response was performed to determine the degree of interference as a function of the substance concentration. Each sample was measured in replicates of 10 using one lot each of the i-STAT CG8+ (white) cartridge.

For Ionized Calcium the Ea was ± 0.5 mmol/L
For Hematocrit the Ea was ± 10.8% PCV

The following table lists the concentrations of each substance at which no significant interference was found:

Ionized Calcium

Substance*	Highest concentration at which no significant interference was observed
Acetaminophen	15.6 mg/dL
Acetyl Cysteine (N-Acetyl-L-Cysteine)	15 mg/dL
Ascorbic Acid (L-Ascorbic Acid)	5.25 mg/dL
β-Hydroxybutyric Acid	62.46 mg/dL
Bilirubin	40 mg/dL
Bromide (Lithium Bromide)	21.7 mg/dL
Cholesterol	400 mg/dL
Hemoglobin	1000 mg/dL
Intralipid 20%	3447 mg/dL

Substance*	Highest concentration at which no significant interference was observed
Iodide (Sodium Iodide)	44.82 mg/dL
Potassium (Potassium Chloride)	59.6 mg/dL
Salicylate (Lithium Salicylate)	2.86 mg/dL
Sodium (Sodium Chloride)	993.48 mg/dL
Triglyceride	1500 mg/dL

Hematocrit

Substance*	Highest concentration at which no significant interference was observed
Bilirubin	40 mg/dL
Bromide (Lithium Bromide)	21.7 mg/dL
Intralipid 20%	2325 mg/dL
Nithiodote (Sodium Thiosulfate)	264.04 mg/dL
Triglyceride	1500 mg/dL
White Blood Cells	50000 WBC/µL

For those substances that on initial screening were found to interfere, dose response testing was conducted. The results are summarized in the table below:

Test	Substance*	Concentration	Interference
Ionized Calcium	Lithium Bromide	≥325.7 mg/dL (≥37.5 mmol/L)	Increased results
	Lithium Lactate	≥ 54 mg/dL	Decreased results
	Leflunomide	≥ 9.322 mg/dL (≥ 0.345 mmol/L)	Decreased results
	Magnesium (Magnesium Chloride)	≥ 10 mg/dL	Increased results
	Nithiodote (Sodium Thiosulfate)	≥ 95 mg/dL (≥ 6 mmol/L)	Decreased results
	Teriflunomide	≥ 1.324 mg/dL	Decreased results
	Lithium Thiocyanate	≥ 5.22 mg/dL (≥ 0.898 mmol/L)	Decreased results
	$pH^{\pm}$	An increase of ~0.1 pH units decreases the iCa results by 0.07 mmol/L	
Hematocrit	Lithium Bromide	≥325.7 mg/dL (37.5 mmol/L)	Increased results
	Total Protein (Human Serum Albumin)	≥ 9500 mg/dL	Increased results

*The compound tested to evaluate the interfering substance is presented in parenthesis.

±The concentration of ionized calcium in blood is dependent on the pH of the specimen and therefore is considered a factor affecting results

The sponsor included the following limitations in the labeling:

- Bromide has been tested at two levels: a therapeutic plasma concentration level of 2.5 mmol/L and a toxic concentration of 37.5 mmol/L. 2.5 mmol/L is the peak plasma concentration associated with halothane anesthesia, in which bromide is released. APOC has not identified a therapeutic condition that would lead consistent with the toxic level and suggests using another method for concentrations greater than 2.5 mmol/L.
- Leflunomide is an isoxazole immunomodulatory agent that inhibits dihydroorotate dehydrogenase, an enzyme involved in de novo pyrimidine synthesis, and that has antiproliferative activity. It is used in the treatment of some immune diseases. Following oral administration, leflunomide is metabolized to an active metabolite, teriflunomide, which is responsible for essentially all its in vivo activity. The active metabolite teriflunomide reaches a plasma concentration of 8.5 µg/mL (0.031 mmol/L) after a 100 mg loading dose and the steady state concentration is maintained at 63 µg/mL [6.3 mg/dL] (0.23 mmol/L) after 24 weeks of maintenance dose at 25 mg/day when treating inflammatory polyarthropathy.
- Nithiodote (Sodium Thiosulfate) is indicated for the treatment of acute cyanide poisoning. The journal article titled "Falsely increased chloride and missed anion gap elevation during treatment with sodium thiosulfate" indicated that sodium thiosulfate could be used in the treatment of calciphylaxis indicating that the highest concentration likely to be seen in plasma [is] after infusion of a 12.5 g dose of sodium thiosulfate pentahydrate. Assuming that the 12.5 g dose of sodium thiosulfate pentahydrate is distributed in a typical blood volume of 5 L with a hematocrit of 40%, the peak sodium thiosulfate plasma concentration expected is 16.7 mmol/L.
- Thiocyanate is a major metabolite of cyanide produced in the liver. The cyanide compound sodium nitroprusside may be used in emergency medical situations to produce a rapid decrease in blood pressure in humans and most of the cyanide produced during metabolism of sodium nitroprusside is eliminated in the form of thiocyanate. Additionally, cyanide elimination is accelerated by the co-infusion of thiosulfate, thiocyanate production is increased as in the case of thiosulphate treatment of cyanide poisoning. The highest drug concentration under therapeutic treatment reported by CLSI EP37 is 0.299 mmol/L. However, concentrations in patients receiving nitroprusside and co-infusion of thiosulfate may be much higher. Thiocyanate is mildly neurotoxic (tinnitus, miosis, hyperreflexia) at serum levels of 1 mmol/L. Thiocyanate toxicity is life-threatening when levels are 3 or 4 times higher. Thiocyanate concentrations greater than 0.898 mmol/L will lead to falsely low ionized calcium results.

4. Assay Reportable Range:

   See section VII. A.2 Linearity.

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

a) Traceability
The i-STAT hematocrit and ionized calcium tests on the i-STAT CG8+ (white) cartridge are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference material.

b) Sample stability
A study was conducted to verify the whole blood sample stability after sample collection for i-STAT Ionized Calcium and Hematocrit tests using the i-STAT CG8+ (white) cartridges on the i-STAT 1 Analyzer. The results support the sponsor's sample stability claims. The sample stability study results support the i-STAT Ionized Calcium labeling claims of 10 minutes for samples collected with anticoagulant and three (3) minutes for samples collected without anticoagulant, and the i-STAT Hematocrit labeling claims of 30 minutes for samples collected with anticoagulant and three (3) minutes for samples collected without anticoagulant.

6. Detection Limit:

Limit of Blank (LoB)
The LoB studies for the i-STAT Ionized Calcium (iCa) and Hematocrit (Hct) tests were conducted over four days using two lots each of the i-STAT CG8+ (white) cartridge on the i-STAT 1 analyzer. Whole blood collected in lithium heparin tubes from four unique subjects were altered to deplete ionized calcium and hematocrit levels. The LoB claim is based on the maximal LoB value obtained for the cartridge lots tested for each test.

Limit of Detection (LoD)
The LoD studies for the i-STAT Ionized Calcium (iCa) and Hematocrit (Hct) tests were conducted over four days using two lots of the i-STAT CG8+ (white) cartridge on the i-STAT 1 analyzer. Whole blood collected in lithium heparin tubes from four unique subjects were altered to create two low-level ionized calcium samples and four low-level hematocrit samples. The LoD was determined based on the maximal LoD value obtained for the cartridge lots tested for each test.

Limit of Quantitation (LoQ)
The LoQ of the i-STAT Ionized Calcium and Hematocrit tests in the i-STAT CG8+ (white) cartridge was evaluated on the i-STAT 1 analyzer using two (2) i-STAT CG8+ (white) cartridge lots, and whole blood that was altered to a low analyte level for each i-STAT test. The LoQ for the i-STAT Ionized Calcium and Hematocrit tests in the i-STAT CG8+ (white) cartridge was determined to be at or below the lower limit of the reportable range for each of the i-STAT tests.

The results are summarized in the table below.

		i-STAT CG8+ (white) cartridge		
Analyte (Unit)	Reportable Range	LoB	LoD	LoQ
Calcium (mmol/L)	0.25 – 2.50	0.119	0.125	0.15
Hematocrit (%PCV)	15 – 75	0	0.4	13

7. Assay Cut-Off:

Not Applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:
A method comparison study for the ionized calcium test (using arterial and venous whole blood specimens) and the hematocrit test (using arterial, venous, and capillary whole blood specimens) on the i-STAT CG8+ (white) cartridge with the i-STAT 1 System was conducted following the recommendations in CLSI EP09c-Ed3.

Lithium heparin whole blood specimens were collected across three point of care sites and were evaluated using i-STAT CG8+ (white) cartridges on the i-STAT 1 analyzer and were evaluated using whole blood specimens tested on the comparator methods. For ionized calcium and hematocrit, the first replicate result from the i-STAT 1 analyzer was compared to the results from the comparative method.

Additionally for the hematocrit test, 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 with the i-STAT CG8+ (white) cartridges on the i-STAT 1 analyzer and on the comparator method. A Passing-Bablok linear regression analysis for hematocrit was performed using the singlicate result from the i-STAT 1 analyzer versus the singlicate result of the comparator method.

The venous and arterial data were pooled, and a Passing-Bablok linear regression analysis was performed using the i-STAT Ionized Calcium results from the i-STAT CG8+ (white) cartridges on the i-STAT 1 analyzer versus the comparative method results. Accuracy results for arterial and venous whole blood specimens for ionized calcium are shown in the table below.

Test (units)	Comparative Method Arterial/ Venous	N	Concentration Range by Comparator (mmol/L)	Slope	Intercept	r	MDL	Bias at MDL
iCa (mmol/L)	i-STAT CHEM8+	343	0.30 – 2.47	1.02	-0.02	0.99	0.37	-0.009
							0.82	0.003

The venous, arterial, and capillary whole blood data were pooled, and a Passing-Bablok linear regression analysis was performed using the i-STAT Hematocrit results from the i-STAT CG8+ (white) cartridges on the i-STAT 1 analyzer versus the comparative method results. Accuracy results for arterial, venous, and capillary whole blood specimens for hematocrit are shown in the table below.

Test (units)	Comparative Method		N	Concentration Range by Comparator (%PCV)	Slope	Intercept	r	MDL	Bias at MDL
	Arterial/ Venous	Capillary							
Hct (%PCV	i-STAT CHEM8+	Epoc Blood Analysis System	535	Venous/Arterial: 16 -75	1.000	-1.00	0.98	33	-1.0
								53	-1.0
				Capillary: 18 - 73				56	-1.0
								70	-1.0

The method comparison results for capillary whole blood specimens only for the i-STAT Hematocrit test are shown below.

Test (units)	N	Slope	Intercept	r	Range
Hct (%PCV)	208	1.000	0.00	0.97	18-73

2. Matrix Comparison:

A matrix comparison study was conducted following the recommendations in CLSI EP35 to evaluate the performance of the i-STAT ionized Calcium and Hematocrit tests in the i-STAT CG8+ (white) cartridge (white) on the i-STAT 1 System using non-anticoagulated venous and arterial whole blood specimens. The matrix equivalence of each test in the i-STAT CG8+ (white) 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+ (white) 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).

Tests (units)	N	Candidate Specimen Range	Primary Specimen Range	R	Slope	Intercept
iCa (mmol/L)	298	0.44-2.43	0.45-2.42	0.99	1.00	0.01
Hct (%PCV)	293	15-73	15-73	0.99	1.00	0.00

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 Ionized Calcium and Hematocrit assay on the i-STAT CG8+ (white) cartridge are cited from literature:

Analyte	Units	Reference Range *
Ionized Calcium	mmol/L mg/dL	1.12-1.32 4.5-5.3
Hematocrit/Hct**	%PCV (packed cell volume) Fraction	Female: 38-46 Male: 43-51 Female: 0.38-0.46 Male: 0.43-0.51

** Hematocrit reference ranges by age and sex are provided in the table below.
Hematocrit (Hct): To convert a result from %PCV (packed cell volume) to fraction packed cell volume, divide the %PCV result by 100.
**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).*

Hematocrit reference range by age and sex (where applicable)*

Age	Reference Range (%PCV)
1 month	33-55
2 months	28-42
4 months	32-44
6 months	31-41
9 months	32-40
12 months	33-41
1-2 years	32-40
3-5 years	32-42
6-8 years	33-41
9-11 years	34-43
12-14 years	35-45 (male) 34-44 (female)
15-17 years	37-48 (male) 34-44 (female)

*Wu, Alan H.B., "Tietz Clinical Guide to Laboratory Tests", Fourth Edition, 2006. W.B. Saunders Company.

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.