510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k141907

B. Purpose for Submission:

Modification of a previously cleared device (k131703) – modify the intended use of the device to include Point-of-Care use

C. Measurand:

pH, pCO2, pO2, Hematocrit (Hct), Sodium (Na+), Potassium (K+), Chloride (Cl-), Ionized calcium (iCa), Glucose (Glu), and Lactate (Lac).

D. Type of Test:

Quantitative: Traditional electrode technology to measure blood pH, pCO2, pO2;
Ion selective electrode technology to measure blood Na+, K+, Cl-, iCa;
Enzyme/Amperometric technology for glucose and lactate measurement;
Conductivity method for hematocrit measurement

E. Applicant:

Nova Biomedical Corporation

F. Proprietary and Established Names:

Stat Profile Prime CCS Analyzer System
Stat Profile Prime Auto QC Cartridge CCS
Stat Profile Prime Ampuled Control ABG/CCS
Stat Profile Prime Calibrator Cartridge CCS/CCS Comp
Nova Linearity Standard Set A

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CHL	II	862.1120, Blood Gases (pCO2, pO2) and Blood pH system	75-Chemistry
JGS	II	862.1665, Sodium Test System	75-Chemistry
CEM	II	862.1600, Potassium Test	75-Chemistry
JFP	II	862.1145, Calcium Test System	75-Chemistry

CGZ	II	862.1170, Chloride Test System	75-Chemistry
CGA	II	862.1345, Glucose Test System	75-Chemistry
KHP	I, meets limitations of exemption per 862.9(c)(9)	862.1450, Lactate Test System	75-Chemistry
GKF	II	864.5600, Automated hematocrit	81-Hematology
JIX	II	862.1150, Calibrators	75-Chemistry
JJS	I, reserved	862.1660, Quality Control Materials	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Stat Profile Prime CCS Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings and for point-of-care usage for the quantitative determination of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, Glu (Glucose), and Lac (Lactate) in heparinized whole blood.

   PCO2, PO2, pH: Whole blood measurement of certain gases in whole blood, or pH of whole blood, is used in the diagnosis and treatment of life-threatening acid-base disturbances.

   Hct: Whole blood measurements of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

   Na+: Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.

   K+: Potassium Measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.

   Cl-: Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

iCa: Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glu: Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lac: Lactate (lactic acid) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis.

The Stat Profile Prime Auto QC Cartridge CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime CCS Analyzer.

The Stat Profile Prime Ampuled Control ABG/CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime CCS Analyzer.

The Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, Glucose and Lactate using the Stat Profile Prime CCS Analyzer.

Linearity Standard Set A is intended for in vitro diagnostic use with Stat Profile Prime CCS Analyzers to verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge or analytical instrument variation.

3. Special conditions for use statement(s):

   For prescription use only.

   For clinical laboratory and point of care use.

4. Special instrument requirements:

   Stat Profile Prime CCS Analyzer

I. Device Description:

1. Stat Profile Prime CCS Analyzer
   The Stat Profile Prime CCS Analyzer is a small, automatic blood gas, metabolite and electrolyte analyzer. The sensors and flow path have been integrated into one replaceable micro-sensor card, which is replaced periodically according to usage. Whole blood specimens are aspirated into the analyzer's micro-sensor card from syringes, tubes, or capillary blood collection devices using a peristaltic pump and a sampling probe. The

disposable micro-sensor card contains the analytical flow-path and all of the measurement sensors (pH, pCO2, pO2, Hct, Na+, K+, Cl-, iCa, Glu, and Lac). Once the analysis measurement is complete, the whole blood specimen is automatically flushed out of the micro-sensor card flow-path and into a self-contained waste collection bag contained within the disposable calibrator cartridge.
The Stat Profile Prime CCS Analyzer is microprocessor-based and incorporates: Traditional electrode technology to measure blood pH, pCO2, pO2; Ion selective electrode technology to measure blood sodium, potassium, chloride, ionized calcium; Enzyme/Amperometric technology for glucose and lactate measurements; and, Conductivity method for Hematocrit. The Stat Profile Prime CCS Analyzer has multiple quality control options. Both traditional internal and external liquid QC will be available, as well as an onboard Quality Management System (QMS). The Stat Profile Prime CCS Analyzer has two primary sample modes: syringe and capillary mode. The minimum sample size for both analysis modes is 100 µL.

2. Stat Profile Prime Auto QC cartridge CCS
This internal auto QC cartridge consists of 3 flexible bags within a cardboard carton. Each bag contains an aqueous quality control material for monitoring the measurement of pH, pCO2, pO2, hematocrit (Hct) Na, K, Cl, iCa, Glucose (Glu), and Lactate (Lac). The aqueous quality control materials are composed of a buffered bicarbonate solution, each with a known pH and known level of Na, K, Cl, iCa, Lac and Glu. Solutions are equilibrated with known levels of O2, CO2, and N2. Each bag contains a minimum volume of 100 mL. The aqueous quality control materials are formulated at three levels:
Control 1: Acidosis, with High Electrolyte, Low-Normal Glu and Lactate.
Control 2: Normal pH, Low-Normal Hct, Normal Electrolyte, High Glu, Normal-High Lactate.
Control 3: Alkalosis, High Hct, Low Electrolyte, High Abnormal Glu and Lactate.

Control Ranges: Stat Profile Prime Auto QC Cartridge CCS				
Analyte	Units of measure	Control 1 min - max	Control 2 min - max	Control 3 min - max
pH		7.130 - 7.180	7.347 - 7.397	7.558 - 7.608
H+	nmol/L	74.13 - 66.07	44.98 - 40.09	27.67 - 24.66
PCO2	mmHg	61.9 - 71.9	39.7 - 45.7	19.7 - 25.7
PO2	mmHg	52.4 - 64.4	95.0 - 107.0	135.0 - 155.0
HCT	%	33 - 37	49 - 55	63 - 69
Na	mmol/L	159.7 - 167.7	137.5 - 145.5	115.0 - 123.0
K	mmol/L	5.48 - 6.08	3.54 - 4.04	1.67 - 2.07
Cl	mmol/L	124.1 - 133.1	97.2 - 106.2	80.6 - 90.6
iCa	mmol/L	1.48 - 1.68	.94 - 1.10	.50 - .62
Glu	mg/dL	76 - 90	196 - 226	300 - 350
Lac	mmol/L	0.5-1.1	2.3-2.9	5.7-7.1

3. Stat Profile Prime Ampuled Control ABG/CCS
The composition of this liquid control is the same as Stat Profile Prime Auto QC cartridge. The packaging is different; it is offered as external ampules each contains 1.7 ml volume.

4. Stat Profile Prime Calibrator Cartridge CCS/CCS Comp

These internal calibration standards with dissolved gases are provided in sealed pouches eliminating the need for users to calibrate the blood gas electrodes using external compressed gas cylinders. The calibration cartridge contains aqueous solutions within individual flexible bags housed in a cardboard box and a flexible waste bag. Each bag includes a fitment with septa that is pierced during the insertion of the cartridge into the analyzer. The calibrator aqueous solutions are:

Calibrator A - pH, pCO2, Na, K, Cl, iCa, Lac, and Glu (Volume: 500 mL)
Calibrator B - pH, pO2, Na, K, Cl, iCa, Lac, and Glu (Volume: 250 mL)
Calibrator F - pCO2, pO2 (Volume: 720 mL)
Reference Solution - KCI (Volume: 300 mL)

Target Values: Stat Profile Prime Calibrator Cartridge CCS/CCS Comp					
Analyte	Units of measure	Cal A 500 mL	Cal B 250 mL	Cal F 720 mL	R Solution 300 mL
pH		7.348	6.840	--	--
pCO2	mmHg	24.5	--	49.5	--
pO2	mmHg	--	--	99.7	--
Na	mmol/L	133.0	72.0	--	--
K	mmol/L	4.0	10.0	--	--
Cl	mmol/L	106.0	46.0	--	--
iCa	mmol/L	1.10	2.20	--	--
Glu	mg/dL	80	200	--	--
Lac	mmol/L	2.0	10.0	--	--

5. Nova Linearity Standard Set A

There are four levels of standards (1, 2, 3, and 4). Each ampule contains1.8 ml buffered solutions containing the following analytes.

Linearity Standard Set A ranges: Nova Linearity Standards Set A					
Analyte	Units of measure	Level 1 min - max	Level 2 min - max	Level 3 min - max	Level 4 min - max
pH		7.113 - 7.173	7.260 - 7.340	7.392 - 7.472	7.509 - 7.589
H+	nmol/L	77.09 - 67.14	54.95 - 45.71	40.55 - 33.73	30.97 - 25.76
Na+	mmol/L	95.0 - 103.0	105.0 - 113.0	133.0 - 141.0	183.8 - 193.8
K+	mmol/L	1.79 - 2.39	3.61 - 4.21	5.38 - 6.18	7.41 - 8.21
Cl-	mmol/L	67.3 - 75.3	85.5 - 95.5	101.9 - 111.9	143.0 - 153.0
iCa	mmol/L	0.43 - 0.73	0.99 - 1.29	1.79 - 2.19	2.09 - 2.59
Glu	mg/dL	475 - 555	285 - 335	91 - 107	31 - 45
Lac	mmol/	15.0-21.0	8.3-11.3	1.7-2.3	0.3-0.7

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nova Stat Profile Prime CCS Analyzer System (including controls, calibrators and linearity standards)

2. Predicate 510(k) number(s):

   k131703

3. Comparison with predicate:

Analyzer

Similarities and Differences		
Item	Predicate Device Stat Profile Prime CCS Analyzer (k131703)	Candidate Device Stat Profile Prime CCS Analyzer
Intended use	For in vitro diagnostic use for the determination of pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, Glucose and Lactate in heparinized whole blood	Same
Sample type	Lithium heparinized whole blood from syringes, open tubes, small cups, and capillary tubes	Same
Sample volume	100 µL	Same
Settings for use	Clinical laboratories	Clinical laboratories and point-of-care settings.

Stat Profile Prime Calibrator Cartridge CCS/CCS Comp

Similarities and Differences		
Item	Predicate Device Stat Profile Prime Calibrator Cartridge CCS/CCS Comp (k131703)	Candidate Device Stat Profile Prime Calibrator Cartridge CCS/CCS Comp
Intended use	For the calibration of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, and Glucose, using the Stat Profile Prime CCS Analyzer	Same with the addition of the lactate analyte

Similarities and Differences		
Item	Predicate Device Stat Profile Prime Calibrator Cartridge CCS/CCS Comp (k131703)	Candidate Device Stat Profile Prime Calibrator Cartridge CCS/CCS Comp
Configuration	2 level calibration standards per analyte, and reference solution	Same
Packaging	Liquid in Mylar bags inside cardboard container. Includes a waste collection bag. Self-contained, disposable packaging.	Same
Settings for use	Clinical laboratories	Clinical laboratories and point-of-care settings.

Stat Profile Prime Auto QC Cartridge CCS

Similarities and Differences		
Item	Predicate Device Stat Profile Prime Auto QC Cartridge CCS (k131703)	Candidate Device Stat Profile Prime Auto QC Cartridge CCS
Intended use	Quality control material intended for in vitro diagnostic use for monitoring the performance of the Stat Profile Prime CCS analyzer.	Same
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Solution in Mylar bags inside cardboard container. Includes a waste collection bag. Self-contained, disposable packaging.	Same
Settings for use	Clinical laboratories	Clinical laboratories and point-of-care settings.

Stat Profile Prime Ampuled Control ABG/CCS

Similarities and Differences		
Item	Predicate Device Stat Profile Prime Ampuled Control ABG/CCS (k131703)	Candidate Device Stat Profile Prime Ampuled Control ABG/CCS
Intended use	Quality control material intended for in vitro diagnostic use for monitoring the performance of the Stat Profile Prime CCS analyzer.	Same
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.7 ml volume.	Same
Settings for use	Clinical laboratories	Clinical laboratories and point-of-care settings.

Nova Linearity Standard Set A

Similarities and Differences		
Item	Predicate Device Nova Linearity Standard Set A (k131703)	Candidate Device Nova Linearity Standard Set A
Intended use	To verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge of analytical instrument variation.	Same
Configuration	4 level aqueous solutions in glass ampules. Contains electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.8 ml volume.	Same
Settings for use	Clinical laboratories	Clinical laboratories and point-of-care settings.

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition

CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition.

CLSI EP 25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

L. Test Principle:

pH is measured using a hydrogen ion selective membrane. One side of the membrane is in contact with a solution of constant pH. The other side is in contact with a solution of unknown pH. A change in potential develops which is proportional to the pH difference of these solutions. This change in potential is measured against a reference electrode of constant potential.

pCO2 is measured with a modified pH sensor. Carbon dioxide in the unknown solution makes contact with a hydrogen ion selective membrane CO2 diffuses across the membrane into a thin layer of bicarbonate buffer in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure of the fluid in contact with the outer surface of the membrane. CO2 in the solution becomes hydrated producing carbonic acid which results in a change in hydrogen ion activity. The measured potential is related to the logarithm of *P*CO2 content of the sample after compensation of the measured potential of the pH sensor.

pO2 is measured amperometrically by the generation of a current at the sensor surface. As oxygen diffuses through a gas permeable membrane, the oxygen molecules are reduced at the cathode, consuming 4 electrons for every molecule of oxygen reduced. This flow of electrons is then measured by the sensor and is directly proportional to the partial pressure of oxygen.

Hematocrit is defined as the percentage of red blood cells to the total blood volume and can be obtained by measuring electrical resistance of the blood sample. Two standard solutions are used to calibrate the hematocrit sensor and to obtain the slope. The analyzer then measures the electrical resistance of the blood sample to obtain the hematocrit value. The hematocrit value obtained is corrected for the concentration of the sodium ion.

Glucose measurement is based on the level of H2O2 produced during the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme. The

current generated by the flow of electrons at the surface of the platinum sensor is proportional to the glucose concentration of the sample.

Na+, K+, Cl-, iCa are measured by ion selective electrodes. An electrical potential is developed according the Nernst Equation for a specific ion. When compared to a reference, this electrical potential is translated into voltage and then in to the ion concentration of the sample.

Lactate measurement is based on the level of H_2O_2 produced during the enzymatic reaction between lactate and oxygen molecules in the presence of the lactate oxidase enzyme. The current generated by the flow of electrons generated from oxidation at the surface of a platinum sensor is proportional to the lactate concentration of the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   A within run precision study was performed at three point-of-care (POC) sites on three Stat Profile Prime CCS Analyzers (one at each site) by a total of 13 POC personnel, comprised of 4 cardiovascular intensive care unit operators, 6 medical intensive care operators, and 3 trauma/neuro intensive care unit operators. The study was performed by analyzing 20 replicates of 3 levels of Stat Profile Prime External Quality Control material (levels 1-3) and 1 level low hematocrit linearity material in duplicate each day for a total of 20 measurements on each of the three Stat Profile Prime CCS analyzers. All three sites produced similar results. Representative within run precision results from one site are summarized in the table below:

One representative POC (site 1): Within Run Precision with Controls (n=20)

Within Run Precision - Level 1			
Parameter	Mean	SD	CV%
pH	7.152	0.004	0.05
PCO2 (mmHg)	63.9	0.9	1.3
PO2(mmHg)	56.4	1.3	2.3
Hct (%)	33	0.51	1.6
Na (mmol/L)	163.2	0.3	0.2
K(mmol/L)	5.67	0.03	0.6
Cl(mmol/L)	130.0	0.2	0.1
iCa(mmol/L	1.54	0.02	1.3
Glu (mg/dL)	82	1.0	2.0
Lac(mg/dL)	1.0	0.0	0.0
Within Run Precision - Level 2			
pH	7.371	0.003	0.04
PCO2 (mmHg)	41.4	0.3	0.8
PO2(mmHg)	99.2	1.9	1.9
Hct (%)	51	0.89	1.8
Na (mmol/L)	139.8	0.2	0.2
K(mmol/L)	3.70	0.03	0.7
Cl(mmol/L)	101.9	0.1	0.1
iCa(mmol/L)	1.01	0.003	0.3
Glu (mg/dL)	201	3.0	1.0
Lac(mg/dL)	2.8	0.1	1.7
Within Run Precision - Level 3			
pH	7.562	0.003	0.05
PCO2 (mmHg)	23.6	0.4	1.9
PO2(mmHg)	141.5	1.5	1.0
Hct (%)	65	0.47	0.7
Na (mmol/L)	117.7	0.2	0.2
K(mmol/L)	1.87	0.00	0.2
Cl(mmol/L)	87.4	0.1	0.2
iCa(mmol/L)	0.56	0.000	0.0
Glu (mg/dL)	301	3.0	1.0
Lac(mg/dL)	7.0	0.1	1.0
Within Run Precision-Low Hematocrit			
Hct (%)	20	0.49	2.5

A total imprecision study was performed at three different point-of-care (POC) sites by 13 different POC personnel by analyzing 3 levels of Stat Profile Prime External Quality Control material (levels 1-3) in duplicate for 20 days for a total of 40 measurements on each of three Stat Profile Prime CCS Analyzers . The total imprecision data from one representative POC site is shown in the table below:

Total Imprecision from One Representative POC Site (n=40)

Total Imprecision Data - Level 1					
Parameter	Pooled Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
pH	7.140	0.004	0.06	0.007	0.10
PCO2 (mm/Hg)	64.3	0.6	0.9	0.4	2.2
PO2 (mm/Hg)	56.3	2.2	3.9	2.7	4.8
Hct (%)	33	0.6	1.8	0.7	2.1
Na (mmol/L)	163.3	0.4	0.2	0.4	0.3
K (mmol/L)	5.73	0.04	0.7	0.05	0.9
Cl (mmol/L)	127.3	0.2	0.2	1.0	0.8
Ca (mmol/L)	1.58	0.007	0.4	0.012	0.8
Glu (mg/dL)	81.0	1.3	1.6	1.4	1.7
Lac (mg/dL)	1.0	0.03	3.0	0.03	3.0
Total Imprecision Data - Level 2					
pH	7.365	0.002	0.03	0.005	0.07
PCO2 (mm/Hg)	42.7	0.3	0.7	0.5	1.2
PO2 (mm/Hg)	98.0	0.8	0.8	2.1	2.1
Hct (%)	51	0.5	1.0	0.7	1.4
Na (mmol/L)	140.3	0.5	0.3	1.0	0.7
K (mmol/L)	3.75	0.01	0.3	0.01	0.3
Cl (mmol/L)	101.9	0.2	0.2	0.30	0.3
Ca (mmol/L)	1.01	0.004	0.4	0.005	0.5
Glu (mg/dL)	201.0	2.1	1.1	3.6	1.8
Lac (mg/dL)	2.8	0.04	1.4	0.04	1.4
Total Imprecision Data - Level 3					
pH	7.560	0.004	0.05	0.008	0.11
PCO2 (mm/Hg)	25.9	0.7	2.5	0.9	3.6
PO2 (mm/Hg)	140.5	1.3	0.9	2.2	1.6
Hct (%)	65	0.5	0.7	0.6	0.9
Na (mmol/L)	117.9	0.2	0.1	0.2	0.1
K (mmol/L)	1.86	0.00	0.0	0.01	0.5
Cl (mmol/L)	87.1	0.2	0.2	1.0	1.1
Ca (mmol/L)	0.55	0.003	0.6	0.005	0.9
Glu (mg/dL)	315.0	3.5	1.1	6.8	2.2
Lac (mg/dL)	7.1	0.04	0.7	0.08	1.1
Total Precision-Low Hematocrit					
Hct (%)	19	0.3	1.7	0.5	2.7

The combined-site total imprecision results from all 3 sites are summarized in the tables below:

Total impression with external quality control materials (n=120)

Combined Total Imprecision Data Level 1					
Parameter	Pooled Mean	Within Run SD	Within Run	Total SD	Total %CV
pH	7.144	0.004	0.06	0.007	0.10
PCO2 (mm/Hg)	64.6	0.8	1.3	1.5	2.3
PO2 (mm/Hg)	56.2	1.8	3.2	2.6	4.7
Hct (%)	33	0.5	1.6	0.6	1.9
Na (mmol/L)	163.3	0.6	0.4	1.1	0.7
K (mmol/L)	5.69	0.05	0.9	0.08	1.4
Cl (mmol/L)	128.2	0.3	0.2	1.3	1.0
Ca (mmol/L)	1.56	0.007	0.5	0.023	1.5
Glu (mg/dL)	81.0	1.1	1.4	1.4	1.8
Lac (mg/dL)	1.0	0.02	2.0	0.02	2.0
Combined Total Imprecision Data - Level 2					
pH	7.368	0.002	0.03	0.005	0.07
PCO2 (mm/Hg)	42.5	0.4	1.0	0.8	2.0
PO2 (mm/Hg)	98.0	0.9	1.0	2.2	2.3
Hct (%)	51	0.5	0.9	0.6	1.2
Na (mmol/L)	139.7	0.5	0.3	1.0	0.7
K (mmol/L)	3.73	0.02	0.5	0.05	1.3
Cl (mmol/L)	102.1	0.2	0.2	0.4	0.4
Ca (mmol/L)	1.00	0.005	0.5	0.009	0.9
Glu (mg/dL)	203.0	2.2	1.1	4.9	2.4
Lac (mg/dL)	2.8	0.05	1.8	0.06	2.1
Combined Total Imprecision Data - Level 3					
pH	7.562	0.008	0.11	0.009	0.12
PCO2 (mm/Hg)	25.1	0.7	2.0	1.3	5.2
PO2 (mm/Hg)	140.8	1.2	0.9	3.2	2.3
Hct (%)	65	0.5	0.8	0.7	1.0
Na (mmol/L)	117.6	0.3	0.2	0.5	0.4
K (mmol/L)	1.87	0.01	0.5	0.02	1.1
Cl (mmol/L)	87.0	0.4	0.5	0.9	1.1
Ca (mmol/L)	0.55	0.004	0.7	0.007	1.3
Glu (mg/dL)	318.0	4.2	1.3	9.0	2.8
Lac (mg/dL)	7.1	0.4	0.7	0.12	1.7
Combined Total Precision-Low Hematocrit					
Hct (%)	19	0.4	2.2	0.5	2.6

b. *Linearity/assay reportable range:*

The linearity of all other Stat Profile Prime CCS analytes previously reviewed in k131703.

Lactate:
A linearity study was performed using lithium heparin whole blood samples. For lactate, 11 levels were prepared by spiking a whole blood sample with lactate to achieve a concentration near 20 mmol/L and then diluting with a whole blood sample with a 0.2 mmol/L lactate concentration to span the analytical measurement range. Each blood level was analyzed in triplicate on each of the three Stat Profile Prime CCS analyzers and on the predicate, the pHOx Ultra analyzers. The pHOx Ultra analyzers were used to establish the target value of each blood level for each parameter. Results of the linear regression analysis of one representative analyzer are shown below.

y=0.9946x + 0.1178, R=0.9992

The linearity study results support lactate claimed measuring range of 0.4-20.0 mmol/L.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The traceability of the other Stat Profile Prime CCS analytes were previously reviewed in k131703.

Traceability: Lactate

Nova standards are made from lithium lactate and lithium reference standards were made from NIST SRM 924A (Lithium Carbonate) and mV ratio was used as means in establishing the traceability.

Shelf-life Stability:

The real time stability study protocol and acceptance criteria was reviewed and found acceptable. The results support a shelf-life of 18 months for the Stat Profile Prime Calibrator Cartridge CCS, Stat Profile Prime Auto QC Cartridge CCS, Stat Profile Prime Ampuled Control ABG/CCS; and a 24 month shelf-life for the Linearity Standard Set A when stored at 2-8^{o} C.

Open vial stability:

The controls and calibrators are designed to be used immediately after opening.

Value assignment:

The control and calibrator value assignment of the other Stat Profile Prime CCS analytes were previously reviewed in k131703.

Lactate:

Prime Cal Cartridge: The calibrator value assignment for lactate was performed over 2 days on three analyzers using 12 samples from the test lot and 6 samples of the reference lot. The samples were run in replicates of 3. The calibrator range is based on an internal

procedure and acceptance criteria. Calibrator lactate target values are listed below:

Cal A: 2.0 mmol/L
Cal B: 10.0 mmol/L

Control Value assignment: The lactate control value assignment was performed over 2 days on two analyzers using 8 samples from the test lot and 8 samples of the reference lot. The samples were run in replicates of 3. The control range is based on an internal procedure and acceptance criteria. Control lactate ranges are listed below:

Stat Profile Prime CCS Control Ranges for Lactate

Prime Auto –QC Cartridge	Range (mmol/L)
Level 1	0.5-1.1
Level 2	2.3-2.9
Level 3	5.7-7.1
Prime Ampuled QC	
Level 1	0.7-1.3
Level 2	2.5-3.1
Level 3	6.4-7.8

Linearity Set A Value Assignment: The linearity set concentrations are kept identical to the reference lot and must pass in-house specifications. The concentrations are verified by running the linearity set controls in triplicate on two analyzers. The linearity set lactate ranges are listed below:

Nova Linearity Standard Set A Ranges for Lactate

Linearity Set A	Range (mmol/L)
Level 1	15.0-21.0
Level 2	8.3-11.3
Level 3	1.7-2.3
Level 4	0.3-0.7

d. Detection limit:

The detection limits of the other Stat Profile Prime CCS analytes were previously reviewed in k131703.

Lactate:

Limit of Detection studies were performed according to the CLSI EP-17A guideline.

Limit of Blank (LoB): Blank (zero level) human whole blood samples were measured 25 times of 4 different analyzers for a total of 100 measurements. The LoB was estimated non-parametrically as the 95^{th} percentile of the measurement. Linear interpolation between the 95^{th} and 96^{th} result yielded a LoB estimate of 0.30 mmol/L.

Limit of Detection (LoD): Three low level human whole blood samples ranging from 0.36 to 0.59 mmol/L were measured in replicates of 25 on 4 analyzers. LoD was determined based on the following equation: LoD= LoB + 1.6494 * SD. The LoD was determined to be 0.40 mmol/L.

Limit of Quantitation (LoQ): The sponsor claims that LoQ is the same as the LoD because the measurement accuracy relative to the reference method is less than 20% bias. LoQ was determined to be 0.40 mmol/L.

Stat Profile Prime CCS Analyzer System Lactate Assay Detection Limits

LoB	LoD	LoQ
0.30 mmol/L	0.40 mmol/L	0.4 mmol/L

The claimed measuring range of lactate is 0.40 to 20 mmol/L.

e. *Analytical specificity:*

The specificity of the other Stat Profile Prime CCS analytes was previously reviewed in k131703.

Lactate:

Interference testing was performed according to CLSI EP7-A2 guidelines. The study used spiked and diluted whole blood samples with lactate concentrations of approximately 3.0 to 5.5 mmol/L containing potential interferents at normal physiological levels. The bias or percent difference between the mean test value and the mean control value were calculated. The sponsor defines significant interference as ≥ 10% bias.

Lactate interference study results

Substance Tested	Highest concentration tested that showed no significant interference
Acetaminophen	20 mg/dL
Ibuprofen	2.4 mmol/L
Dopamine Hydrochloride	5.87 umol/L
Ethanol	86.8 mmol/L
Glucosamine	30 umol/L
Glycolic Acid	1.0 mmol/L
Maltose	13 mmol/L
Mannose	10 mmol/L
Xylose	25 mg/dL
D-Galactose	1 mmol/L
Glucose	1000 mg/dL
Hemoglobin	2 g/dL
Heparin	100 IU/mL

Pyruvate	309 umol/L
Salicylic Acid	4.34 mmol/L
Sodium Bromide	37.5 mmol/L
Urea	40 mg/dL
Uric Acid	1.4 mmol/L
Thiocyanate	6.8 mmol/L
EDTA	3.4 umol/L
Sodium Citrate	12 mmol/L
Sodium Oxalate	500 mg/dL
Acetylsalicylic Acid	3.62 mmol/L
Acetoacetate	2 mmol/L
Ammonium Chloride	107 umol/L
Bilirubin	20 mg/dL
Benzalkonium Chloride	10 mg/L
B-hydroxybutyrate	2 mmol/L
Dobutamine	2 mg/dL
Fluoride	105 umol/L
Ascorbic Acid	50 mg/dL
Intralipid	1000 mg/dL

The sponsor includes a boxed warning of the Stat Profile Prime CCS Instructions for Use Manual which reads as follows:

INTERFERENCE WARNING: Do not perform glucose and lactate testing on patients taking the drug hydroxyurea.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison study for all analytes (except for lactate) was previously cleared in k131703 for clinical laboratory use only. In order to add Point-of-Care claim, sponsor has conducted POC study using the intended POC operators at the intended use environment to demonstrate that POC operators could generate equivalent results as the clinical laboratory professionals. A method comparison study was performed at 3 POC sites by a total of 53 different POC personnel (respiratory therapist and nurses) using the analyzer's syringe mode method. Approximately 230 Lithium heparin whole blood gas specimens from syringes were analyzed to compare the whole blood results obtained by trained laboratory personnel vs respiratory therapy POC personnel on the same specimens. Less than 10% of samples for each analyte were altered in order to adequately span the measuring range. Each of the three sites

produced similar method comparison data. Syringe Mode Method comparison study data is shown below from one representative POC site and the three combined POC sites:

Syringe Mode: POC vs. Laboratory Professionals, one representative POC site

Parameter	n	Whole Blood Range tested	Slope	Intercept	r
pH	74	7.015 - 7.654	0.977	0.163	0.995
*P*CO2 mmHg	73	5.7– 188.5	1.000	1.074	0.998
*P*O2 mmHg	74	20.0 – 714.5	0.991	1.329	0.999
Hct %	69	12-59	0.984	0.676	0.986
Na mmol/L	72	91.9 – 188.4	1.013	-1.583	0.998
K mmol/L	73	1.15 – 17.08	0.950	0.213	0.999
iCa mmol/L	74	0.45 - 2.42	1.002	0.002	0.998
Cl mmol/L	74	53.5 – 188.7	0.992	0.938	0.999
Glu mg/dL	74	17– 477	1.005	0.449	0.998
Lac mmol/L	74	0.7 – 19.5	1.021	-0.092	0.997

Syringe Mode: Combined all 3 POC sites

Parameter	n	Whole Blood Range tested	Slope	Intercept	r
pH	234	6.874 - 7.664	0.983	0.116	0.997
*P*CO2 mmHg	230	4.1– 195.5	1.007	0.750	0.998
*P*O2 mmHg	234	15.2– 714.5	1.005	-0.094	0.999
Hct %	222	12-70	0.997	0.395	0.985
Na mmol/L	229	83.2 – 192.3	1.020	-2.540	0.998
K mmol/L	231	1.10 – 18.80	0.974	0.110	0.999
iCa mmol/L	234	0.26- 2.55	1.001	0.004	0.999
Cl mmol/L	234	53.5 – 188.7	1.000	-0.020	0.999
Glu mg/dL	233	17– 478	0.989	1.517	0.998
Lac mmol/L	233	0.6 – 19.5	1.018	-0.093	0.998

Another method comparison study was performed at 3 POC sites by a total of 53 different POC personnel (respiratory therapists and nurses) using the analyzer's capillary mode method. Approximately 170 heparinized blood gas specimens from capillary tubes were run to compare the whole blood results obtained by trained laboratory personnel vs POC personnel on the same specimens. Less than 10% of samples for each analyte were altered in order to adequately span the measuring range. Each of the three sites produced similar method comparison data. The capillary mode method comparison study data from one representative POC site and data from the three combined POC sites is shown in the tables below:

Capillary Mode: POC vs Laboratory Professionals, one representative POC site

Parameter	n	Whole Blood Range tested	Slope	Intercept	r
pH	64	6.912 - 7.770	0.959	0.297	0.997
*P*CO2 mmHg	63	5.3– 181.4	0.995	0.872	0.998
*P*O2 mmHg	64	22.8– 531.1	0.993	1.218	1.000
Hct %	59	13-68	0.998	-0.134	0.986
Na mmol/L	63	83.2– 191.2	1.013	-1.574	0.998
K mmol/L	62	1.15– 16.34	0.979	0.084	0.998
iCa mmol/L	64	0.58 – 2.45	1.001	0.004	0.998
Cl mmol/L	64	57.2– 175.1	0.997	0.510	0.997
Glu mg/dL	64	15 – 462	0.991	1.475	0.999
Lac mmol/L	64	0.6– 18.4	1.036	-0.179	0.999

Capillary Mode: Combined all 3 POC sites

Parameter	n	Whole Blood Range tested	Slope	Intercept	r
pH	173	6.881 - 7.780	0.962	0.275	0.997
*P*CO2 mmHg	170	3.2 – 181.4	0.989	0.889	0.998
*P*O2 mmHg	173	22.8-597.3	0.979	3.141	0.999
Hct %	157	13-68	0.978	0.399	0.984
Na mmol/L	169	83.2-197.0	1.010	-1.258	0.997
K mmol/L	168	1.15-19.47	1.006	-0.025	0.998
iCa mmol/L	173	0.32 - 2.45	0.977	0.029	0.996
Cl mmol/L	173	55.9 – 188.1	1.007	-0.710	0.997
Glu mg/dL	173	15.0 - 484	1.004	0.036	0.999
Lac mmol/L	173	0.6 – 18.4	1.019	-0.127	0.998

b. Matrix comparison:

Not applicable. The only acceptable sample type for this device is lithium heparin whole blood.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

Parameter	Reference Range
pH[1,2,4]	7.35-7.45
PCO2[1,2,4]	35-45 mmHg
PO2[1,2,4]	83-108 mmHg
Sodium[2]	136-146 mmol/L
Potassium[2]	3.5-5.1 mmol/L
Chloride[2]	98-106 mmol/L
Glucose[2]	65-95 mg/dL
Lactate[4,5]	0.7-2.5 mmol/L
Ionized Calcium[3]	1.09-1.30 mmol/L
Hematocrit[1,2,4]	Male: 39-49% Female: 35-45%

References:

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4. Burtis, Carl A. Ashwood, Edward R., Burns, David R., 2011. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 5th ed,* Philadelphia, PA: W. B. Saunders Co.
5. Bernstein, W.K, Aduen, J.,Bhatiani, A., Kerzner, R, Davison, L, Miller, C., and Chernow, B. 1194. Simultaneous Arterial and Venous Lactate Determinations in Critically ill Patients. Critical Care Medicine, Vol. 22

N. Proposed Labeling:

The labeling is sufficient and it satisfies requirements of 21 CFR Part 809.10.

O. Conclusion:

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