510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k131703

B. Purpose for Submission:

New device

C. Measurand:

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

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 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 System	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
GKF	II	864.5600, Automated hematocrit instrument	81-Hematology
JIX	II	862.1150, Calibrators	75- Chemistry
JJS	I	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 for the quantitative determination of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, and Glu (Glucose), 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.

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, and Glucose 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.

   Not for 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 Analyze 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, and Glu). 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 measurement; Conductivity method for Hematocrit. The Stat Profile Prime CCS Analyzer has multiple quality control options. Both traditional internal and external liquid QC shall be offered, 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, and Glucose (Glu). 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, 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
Control 2: Normal pH, Low-Normal Hct, Normal Electrolyte, High Glu
Control 3: Alkalosis, High Hct, Low Electrolyte, High Abnormal Glu

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

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, and Glu (Volume > 500 mL)
Calibrator B - pH, pO2, Na, K, Cl, iCa, 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 ofmeasure	Cal A ≥ 500 mL	Cal B ≥ 250 mL	Cal F ≥ 720	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	--	--

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
Ca++	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

J. Substantial Equivalence Information:

1. Predicate device name(s):

Nova Stat Profile pHOx Ultra Analyzer System

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

k110648

3. Comparison to predicate

Items	Stat Profile pHOx Ultra Analyzer **(Predicate Device, k110648)**	Stat Profile Prime CCS **(Proposed Device)**
Similarity/Differences		
Intended Use	For the quantitative determination of pH, pCO2, pO2, Hct, Na+, K+, Cl-, iCa, and Glu in heparinized whole blood samples	Same
	Clinical laboratory and POC use	Clinical laboratory use only
Sample modes	Syringe mode or capillary mode	Same
Sample volumes	100 µL for both syringe and capillary modes	Same
Measuring Range		
pH	6.500-8.000	Same
PCO2	3.0 -200 mmHg	Same
PO2	0-800 mmHg	5-765 mmHg
Hct	12%-70%	Same
Na+	80-200 mmol/L	Same
K+	1.0-20.0 mmol/L	Same
Cl-	50-200 mmol/L	Same
iCa	0.10-2.70 mmol/L	0.20-2.70 mmol/L
Glu	15-500 mg/dL	Same
Principles of Measurement		
	Hydrogen ion-selective glass sensor	Same
	Severinghaus-type sensor	Same
	Polarographic Clark-type sensor	Same
	Impedance sensor	Same
	Sodium ion-selective glass sensor	Same

	Potassium ion-selective sensor	Same
	Chloride ion-selective sensor	Same
	Calcium ion-selective sensor	Same
	Enzymatic sensor	Same
	Enzymatic sensor	Same
Sample Type	Sodium or lithium heparinized whole blood or serum/plasma samples	lithium heparinized whole blood only
Menu	Fully configurable test menu based on above sensors	Same
Bar Code Scanner	External (optional) 1D	Internal Integrated 1D/2D
Printer	2" Roll, Thermal Transfer	Same
Pump	Peristaltic Pump w/ Pressure Plate, TPE Tubing (Pharmed BPT)	Same

Items	**Predicate device:** **Stat Profile pHOx Ultra Cartridge K110648**	**Proposed device:** **Stat Profile Prime Calibrator Cartridge CCS/CCS Comp**
Intended Use	For the quantitative determination of pH, PCO2, PO2, SO2%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na+, K+, Cl-, Ca++, Mg++, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma.	The Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, *P*CO2, *P*O2, Hct, Na+, K+, Cl-, iCa, and Glucose, using the Stat Profile Prime CCS Analyzer.
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

Items	Predicate device: Stat Profile pHOx Ultra/CCX ABG and CO-Oximeter Controls (K110648)	Proposed device: Stat Profile Prime Auto QC Cartridge CCS
Intended Use	Nova STP pHOx Ultra/CCX ABG and CO-Oximeter Controls and Autocartridge QC are intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Nova STP pHOx Ultra/CCX Analyzers.	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.
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Cartridge: Solution in Mylar bags inside cardboard container. Includes a waste collection bag. Self-contained, disposable packaging.	Same

Items	Predicate device: K110648 Stat Profile pHOx Ultra/CCX ABG and CO-Oximeter Controls	Proposed device: Stat Profile Prime Ampuled Control ABG/CCS
Intended Use	Nova STP pHOx Ultra/CCX ABG and CO-Oximeter Controls and Autocartridge QC are intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Nova STP pHOx Ultra/CCX Analyzers.	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.
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.7 ml volume.	Same

Item	Predicate device: K110648 Stat Profile pHOx Ultra Linearity Standards	Proposed device: Linearity Standard Set A
Indication For Use	For in vitro diagnostic use to verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge or analytical instrument variation.	Same
Configuration	4 level aqueous solutions in glass ampules. Contain electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.8 ml volume	Same

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

CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition
CLSI EP6-A: Evaluation of Linearity of Quantitative Measurement Procedures, A Statistical Approach; Approved Guideline
CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition
CLSI EP9-A2-IR: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition
CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline
CLSI EP25-A: Evaluation of In Vitro Diagnostic Reagents; Approved Guideline – CLSI EP25-A

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 H_2O_2 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Quality Control Within Run Precision Performance
   The protocol consisted of 20 replicates per run for each of 3 different quality control materials on each of 3 Stat Profile Prime CCS Analyzers. The average, SD, CV%, and N for each analyzer, for each QC level and parameter was calculated. All 3 analyzers yielded similar results. The results of one representative analyzer are summarized in the table below.

Quality Control within-run results:

Within Run Precision				
Parameter	**n = 20**	**QC# 1**	**QC # 2**	**QC# 3**
pH	Mean	7.165	7.361	7.596
pH units	SD	0.001	0.002	0.002
pCO2	Mean	56.7	41.6	23.6
mmHg	SD	0.2	0.3	0.3
	CV%	0.4	0.7	1.2
pO2	Mean	70.1	108.8	142.2
mmHg	SD	0.3	0.6	0.7
	CV%	0.5	0.5	0.5
Hct	Mean	38	55	69
%	SD	0.5	0.5	0.5
	CV%	1.32	1.05	0.79
Na	Mean	158.1	140.2	120.4
mmol/L	SD	0.1	0.1	0.1
	CV%	0.1	0.1	0.1
K	Mean	5.80	3.84	1.88
mmol/L	SD	0.00	0.02	0.01
	CV%	0.08	0.43	0.64
iCa	Mean	1.51	0.97	0.52
mmol/L	SD	0.01	0.01	0.00
	CV%	0.33	0.92	0.90
Cl	Mean	131.0	102.3	84.7
mmol/L	SD	0.1	0.5	0.5
	CV%	0.1	0.4	0.6
Glu	Mean	74	200	320
mg/dL	SD	0.0	1.1	1.0
	CV%	0.0	0.5	0.3

Whole Blood Within Run Precision Performance

Estimates of the whole blood within run precision were evaluated in syringe mode and capillary mode using lithium heparinized whole blood samples. For each run, tonometered whole blood was analyzed 20 times on 3 Stat Profile Prime Analyzers for a total of 20 results per analyzer. Statistical analysis for each analyzer for both syringe mode and capillary mode was calculated. All 3 analyzers yielded similar results. The results of one representative analyzer are summarized in the table below.

Within-Run Precision Summary - Whole Blood – Capillary

Within Run Precision		
Parameter	**n = 20**	**Analyzer # 1**
pH	Mean	7.388
pH units	SD	0.004
pCO2	Mean	34.5
mmHg	SD	0.5
	CV%	1.6
pO2	Mean	119.0
mmHg	SD	0.9
	CV%	0.8
Hct	Mean	47
%	SD	0.6
	CV	1.28
Na	Mean	146.7
mmol/L	SD	0.9
	CV%	0.6
K	Mean	3.84
mmol/L	SD	0.07
	CV%	1.73
iCa	Mean	1.06
mmol/L	SD	0.02
	CV%	2.05
Cl	Mean	109.8
mmol/L	SD	0.3
	CV%	0.3
Glu	Mean	81
mg/dL	SD	1.4
	CV%	1.7

Within-Run Precision Summary - Whole Blood – Syringe

Within Run Precision		
Parameter	**n = 20**	**Analyzer # 1**
pH	Mean	7.285
pH units	SD	0.003
pCO2	Mean	48.1
mmHg	SD	0.8
	CV%	1.6
pO2	Mean	68.9
mmHg	SD	0.3
	CV%	0.5
Hct	Mean	42
%	SD	0.8
	CV%	1.9
Na	Mean	140.5
mmol/L	SD	0.3
	CV%	0.2
K	Mean	3.75
mmol/L	SD	0.02
	CV%	0.59
iCa	Mean	1.21
mmol/L	SD	0.00
	CV%	0.38
Cl	Mean	104.3
mmol/L	SD	0.6
	CV%	0.6
Glu	Mean	63
mg/dL	SD	0.9
	CV%	1.4

QC Total Precision Performance

Estimates of the total precision were evaluated for the Stat Profile Prime CCS analyzers by analyzing 3 levels of QC materials in duplicate over a period of 20 days; 2 runs per day for a total of 40 runs.

QC Total_Precision Results are summarized in the below tables.

pH Precision Data				
Sample	**Mean (pH unit)**	**N**	**Within run SD (Sr)**	**Total imprecision SD (St)**
QC Level 1	7.164	240	0.002	0.002
QC Level 2	7.362	240	0.000	0.001
QC Level 3	7.596	240	0.000	0.002

pCO_2 Precision Data						
Sample	**Mean (mmHg)**	**N**	**Within run SD (Sr)**	**Within run % CV**	**Total imprecision SD (St)**	**Total imprecision %CV**
QC Level 1	58.4	240	0.58	1.00	1.33	2.28
QC Level 2	41.9	240	0.06	0.13	0.53	1.26
QC Level 3	23.0	240	0.07	0.29	0.42	1.83

pO_2 Precision Data						
Sample	**Mean (mmHg)**	**N**	**Within run SD (Sr)**	**Within run % CV**	**Total imprecision SD (St)**	**Total imprecision %CV**
QC Level 1	70.2	240	0.84	1.19	2.02	2.88
QC Level 2	110.1	240	0.55	0.50	1.16	1.05
QC Level 3	143.8	240	0.39	0.27	1.21	0.84

Hct Precision Data						
Sample	**Mean (%)**	**N**	**Within run SD (Sr)**	**Within run % CV**	**Total imprecision SD (St)**	**Total imprecision %CV**
QC Level 1	37.9	240	0.44	1.15	0.81	2.15
QC Level 2	55.0	240	0.20	0.37	0.32	0.58
QC Level 3	68.6	240	0.18	0.26	0.43	0.63

Na Precision Data						
Sample	Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total imprecision %CV
QC Level 1	158.3	240	0.56	0.35	0.68	0.43
QC Level 2	140.1	240	0.12	0.09	0.25	0.18
QC Level 3	120.2	240	0.08	0.07	0.18	0.15

\

K Precision Data						
Sample	Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total imprecision %CV
QC Level 1	5.81	240	0.020	0.34	0.03	0.48
QC Level 2	3.81	240	0.005	0.14	0.01	0.36
QC Level 3	1.87	240	0.002	0.13	0.02	0.97

iCa Precision Data						
Sample	Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total imprecision %CV
QC Level 1	1.51	240	0.007	0.45	0.02	1.13
QC Level 2	0.97	240	0.002	0.22	0.00	0.43
QC Level 3	0.53	240	0.001	0.23	0.01	1.85

Cl Precision Data						
Sample	Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total imprecision %CV
QC Level 1	131.5	240	0.57	0.43	2.30	1.75
QC Level 2	103.0	240	0.72	0.70	1.52	1.48
QC Level 3	86.1	240	0.27	0.32	1.38	1.60

Glucose Precision Data						
Sample	**Mean (mg/dL)**	**N**	**Within run SD (Sr)**	**Within run % CV**	**Total imprecision SD (St)**	**Total imprecision %CV**
QC Level 1	71.3	240	1.28	1.79	1.69	2.37
QC Level 2	196.9	240	0.81	0.41	1.33	0.67
QC Level 3	318.6	240	2.32	0.73	3.31	1.04

Whole Blood Run-to-Run Precision Performance

Estimates of the whole blood run-to-run precision were evaluated in syringe mode and capillary mode using lithium heparinized whole blood samples. For each run, tonometered whole blood was analyzed in triplicate on 3 Stat Profile Prime analyzers over 10 separate runs for a total of 30 results per analyzer. Statistical analysis for each analyzer for both syringe mode and capillary mode was calculated.

Run-to-Run Precision Summary - Whole Blood – syringe

Run-to-Run Precision		
Parameter	**n = 30**	**Analyzer # 1**
pH	Mean	7.406
pH units	SD	0.006
***P*CO2**	Mean	43.7
mmHg	SD	1.4
	CV%	3.1
***P*O2**	Mean	27.6
mmHg	SD	0.5
	CV%	1.9
Hct	Mean	48
%	SD	0.7
	CV%	1.46
Na	Mean	140.2
mmol/L	SD	0.4
	CV%	0.3
K	Mean	4.15
mmol/L	SD	0.03
	CV%	0.80

Run-to-Run Precision		
Parameter	**n = 30**	**Analyzer # 1**
iCa	Mean	1.22
mmol/L	SD	0.01
	CV%	0.60
Cl	Mean	107.5
mmol/L	SD	0.3
	CV%	0.3
Glu	Mean	106
mg/dL	SD	3.1
	CV%	2.9

Run-to-Run Precision Summary -Whole Blood – capillary

Run-to-Run Precision		
Parameter	**n = 30**	**Analyzer # 1**
pH	Mean	7.385
pH units	SD	0.010
pCO2	Mean	32.5
mmHg	SD	0.8
	CV%	2.5
pO2	Mean	97.8
mmHg	SD	1.3
	CV%	1.4
Hct	Mean	49
%	SD	1.3
	CV%	2.65
Na	Mean	144.0
mmol/L	SD	0.8
	CV%	0.6
K	Mean	4.15
mmol/L	SD	0.02
	CV%	0.58
iCa	Mean	1.12
mmol/L	SD	0.01
	CV%	1.11

Run-to-Run Precision		
Parameter	**n = 30**	**Analyzer # 1**
Cl	Mean	110.5
mmol/L	SD	0.3
	CV%	0.3
Glu	Mean	82
mg/dL	SD	2.5
	CV%	3.0

b. Linearity/assay reportable range:

A linearity study was performed using lithium heparin whole blood samples. For each parameter, 10 – 14 levels were prepared by tonometering, spiking or diluting whole blood to span the analytical measurement range for each parameter. 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 linear regression using one representative analyzer are presented in the below table.

Stat Profile Prime Whole Blood Linearity

Parameter	total # levels	Sample range	Claimed measuring range	Slope	Intercept	r
pH	12	6.542 - 8.060 pH units	6.5-8.0 pH units	0.9968	0.0295	0.9998
pCO2	14	0.6 - 220.1 mmHg	3.0-200 mmHg	1.0115	0.3674	0.9993
pO2	11	5.0 - 767.6 mmHg	5.0-765 mmHg	0.9809	-0.1638	0.9992
Hct	13	8 – 70%	12%-70%	1.0073	-1.2711	0.9991
Na	11	63.2 – 200.0 mmol/L	80-200 mmol/L	1.0125	-1.1031	0.9998
K	11	0.85 - 21.9 mmol/L	1.0-20.0 mmol/L	1.0021	0.0595	0.9999

iCa	13	0.17 - 3.06 mmol/L	0.20-2.70 mmol/L	1.0146	0.0105	0.9993
Cl	10	44.3 - 221.6 mmol/L	50-200 mmol/L	1.0160	0.0024	0.9994
Glu	11	8 – 520 mg/dL	15-500 mg/dL	1.0211	-1.5856	0.9995

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

Traceability

pH

The pH standards and reagents used for Nova's products are traceable to NIST primary pH reference material SRM 2186I and 2186II. Nova's standards and reagents are measured versus the NIST primary pH buffers using a pH glass electrode and a flowing 2M KC1 Ag/AgCl reference electrode. The measurement is done at 37°C.

PCO2/PO2 Gases

Nova's CO2/O2 gases are gravimetrically prepared and are traceable to NIST SRM 1700a, (PCO2) and 1702a (PCO2 and PO2)

PCO2/PO2 Reagents

Nova's PCO2/PO2 controls and reagents are measured against Nova's CO2/O2 gases traceable to NIST SRMs. The Severinghaus PCO2 electrode is used to measure these reagents versus the Nova CO2/O2 gases. These reagents are stored either in a glass ampoule or a gas-impermeable laminated foil pouch.

Na+

The reagents and standards containing sodium ion are derived from analytical reagent grade sodium chloride. This reagent is then validated using NIST SRM 2201. The validation is accomplished by using a sodium glass electrode with a 2M KC1 flowing reference electrode or a Na/K/Li flame photometer.

K+

The reagents and standards containing potassium ion are derived from analytical reagent grade potassium chloride. This reagent is then validated using NIST SRM 2202. The validation is accomplished by using a valinomycin potassium electrode

with a 2M KC1 flowing reference electrode or a Na/K/Li flame photometer.

Cl-

The reagents and standards containing chloride ion are derived from analytical grade sodium chloride. The reagent is then validated using NIST SRM 2201. The validation is accomplished by using a Nova analyzer employing a neutral carrier membrane electrode with a 2 M KC1 flowing reference electrode.

Ca++

The reagents and standards containing calcium ion are derived from analytical reagent grade calcium carbonate. The reagent is then validated using NIST SRM 915a. The validation is accomplished by using a Nova analyzer employing a neutral carrier membrane electrode with a 2 M KC1 flowing reference electrode.

Glucose

Reagents containing Glucose are traceable to NIST SRM 917a. Nova Biomedical Glucose standards and reagents are measured versus the NIST primary reference using a membrane covered Amperometric electrode at 37^{o}C.

Hct

Traceable to a commercially available reference method, which is a microhematocrit method.

Shelf-life Stability

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

Nova Linearity Standard Set A for use with the Stat Profile Prime CCS Analyzer is identical to those cleared for use with the predicate Nova Stat Profile pHOx Ultra Analyzer System (K110648). The packaging and formulation are unchanged.

On-board stability

Real time stability study support up to 300 quality control tests for the Stat Profile prime CCS Auto-QC Cartridge; and up to 600 tests for the Stat Profile prime CCS Auto-calibrator Cartridge.

Value assignment:

The Stat Profile Prime Calibrator Cartridge CCS (Calibrators)-

Values are assigned by analyzing 12 samples from the test lot and 6 samples from the reference lot on three calibrated analyzers. Each sample was assayed in triplicate. The calculated calibrator value=reference lot assigned value+ (test lot mean-reference lot mean).

The Stat Profile Prime Auto QC Cartridge CCS and Stat Profile Prime Ampuled Control ABG/CCS (Controls)-

Values are assigned by analyzing 8 samples from the test lot and 8 samples of the reference lot over 2 days on two calibrated analyzers. Each sample was assayed in triplicate. The calculated control value=reference lot assigned value+ (test lot mean-reference lot mean).

d. Detection limit:

Refer to the linearity study data above in M. 2.b. for the measuring range claim of all analytes. In addition, the sponsor conducted a Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) for iCa, and Glucose according to the CLSI EP-17A guideline using whole blood samples.

Limit of Blank (LoB) – 100 replicates of zero level samples were measured on multiple test analyzers.

Limit of Detection (LoD) –Three blood samples with low analyte concentration were measured in 100 replicates each on multiple test analyzers.
LoD=LoB+1.6494 SD

Limit of Quantitation (LoQ) – was defined according to the following criteria.

iCa: Lowest concentration where the absolute error (bias) is less than 0.10 mmol/L.
Glucose: Lowest concentration where the absolute error (bias) is less than 5.0 mg/dL.

Summary: Detection limit for iCa and Glu

	LoB	LoD	LoQ	Claimed Measurement Range
Ca	0.18 mmol/L	0.20 mmol//L	0.20 mmol/L	0.2 - 2.7 mmol/L
Glu	8.0 mg/dL	10.4 mg/dL	10.4 mg/dL	15.0 - 500.0 mg/dL

e. Analytical specificity:

Li-heparin whole blood samples were used in the interference study. For the initial testing, each interferent was spiked at 20 times the recommended concentration by CLSI EP-7 A2. Each sample containing interferent was evaluated against the same whole blood sample without the interferent. If interference was observed, a dose response study was performed at two analytes concentrations (low and high) to determine the highest substance concentration where no interference was observed. The sponsor's definition of significant interference is ±10% bias for pH, pO2, pCO2, Na, K, Ca, Cl, glucose, and Hct, +/- 0.020 for pH. The following table represents substances that were tested without demonstrating a significant interference on test results:

Interfering Substance	**Highest Concentration Tested**	**Analyte(s) Tested**
Acetaminophen	20.0 mg/dL	Glu
Acetoacetate	2.0 mmol/L	pH, Na, K, iCa, Cl, Glu,
Acetylsalicylic acid	3.62 mmol/L	Na, K, Cl, Glu
Ammonium Chloride	107.0 µmol/L	Na, K, Cl, iCa, Glu
Ascorbic Acid	50 mg/dL	Cl, Glu
Benzylkonium Chloride	10.0 mg/L	pH, Na, K, Cl, iCa, Glu
Beta-Hydroxybutyrate	2.0 mmol/L	Glu
Bilirubin	20.0 mg/dL	Hct, pH, *P*CO2, *P*O2, Na, K, Cl, iCa, Glu
Calcium Chloride	2.0 mmol/L	pH, *P*CO2, *P*O2, Na, K
D-Galactose	1.0 mmol/L	Glu
Dobutamine	2.0 mg/dL	pH, Na, K ,iCa, Glu
Dopamine Hydrochloride	5.87 µmol/L	Glu
EDTA	3.4 umol/L	Glu
Ethanol	86.8 mmol/L	Glu, pH, *P*CO2, *P*O2
Fluorescein	1.0 mmol/L	*P*CO2, *P*O2
Fluoride	105 µmol/L	Glu

Interfering Substance	Highest Concentration Tested	Analyte(s) Tested
Glycolic Acid	1 mmol/L	Glu
Glucosamine	30.0 µmol/L	Glu
Hemoglobin	2.0 g/L	Hct, pH, *P*CO2, *P*O2, Na, K, Cl, iCa, Glu
Heparin	100 IU/mL	Glu, Hct
Ibuprofen	2.4 mmol/L	Na, K, iCa, Cl, Glu
Intralipid	1000 mg/dL	Hct, pH, *P*CO2, *P*O2, Na, K, Cl, iCa, Glu
Lithium Lactate	6.6 mmol/L	Na, K, iCa, Glu
Magnesium Chloride	15.0 mmol/L	Na, Cl
Maltose	13.0 mmol/L	Glu
Mannose	1.0 mmol/L	Glu
Perchlorate	1.0 mmol/L	iCa
Potassium Chloride	5.0 mmol/L	pH, *P*CO2, *P*O2, iCa
Potassium Thiocyanate	2,064 µmol/L	Cl, Glu
Pyruvate	309 µmol/L	Glu
Salicylic Acid	4.34 mmol/L	Na, K, Cl, Glu
Sodium Bromide	37.5 mmol/L	pH, K, iCa
Sodium Chloride	10.0 mmol/L	pH, *P*CO2, *P*O2, iCa
Sodium Citrate	12.0 mmol/L	Cl, Glu
Sodium Oxalate	500 mg/dL	Cl, Glu
Sodium Salicylate	50.0 mg/dL	Glu
Xylose	25.0 mg/dL	Glu
Zinc Chloride	1.3 mg/dL	Na, K, iCa,

The following table represents substances that were tested that demonstrated a significant interference on test results:

Parameter	Interfering Substance	Concentration of interfering substance	Interference
Chloride	Bromide	2.5 mmol/L	No interference observed
		5.0 mmol/L	Bias of 12.7%
	Thiocyanate	3.4 mmol/L	No interference observed
		5.1 mmol/L	Bias of 15.2%
Ionized Calcium	$MgCl_2$	3.75 mmol/L	No interference observed
		7.50 mmol/L	Bias of 13.5%
Glucose	Hydroxyurea	0.2 mg/dL	No interference observed
		0.4 mg/dL	Bias of 19.2%
	Oxalate	125 mg/dL	No interference observed
		250 mg/dL	Bias of -10.9%
	Thiocyanate	1.7 mmol/L	No interference observed
		3.4 mmol/L	Bias of 10.0%
Hct	Albumin	2.8 g/dL	No interference observed
		5.7 g/dL	Bias of 12.7%
	Hemolysis	5%	No interference observed
		10%	Bias of -10.7%
	Triglycerides	986.4 mg/dL	No interference observed
		1233 mg/dL	Bias of 12.9%

Because of the known limitations, the sponsor has the following limitation statements in the labeling:

For Potassium**:** Correct sample handling is critical to ensure whole blood potassium values obtained accurately reflect the *in vivo* state. For example, a hemolyzed specimen of 50 mg/dL hemoglobin will increase the potassium blood concentration by 3%.

For the calculated hemoglobin: The hemoglobin calculation is an estimation based on a normal mean corpuscular hemoglobin concentration of 33.3% and a nominal male Hct of 39 to 49% or female Hct of 35 to 45%. Hemoglobin estimations made from samples with red cell dyscrasia or hemoglobinopathies may vary significantly from hemoglobin measured by cyanmethemoglobin method. The estimated hemoglobin may vary significantly in cases of abnormal blood composition or disease states such as anemia in which abnormal values may not be reported. These conditions should warrant repeat testing by conventional laboratory methods

For hematocrit: White Blood Count (WBC) greater than 50,000 WBC/µL may increase the hematocrit value.

Burtis, Carl A. and Ashwood, Edward R., ed. 1999. *Tietz Textbook of Clinical Chemistry*, 3rd Edition. Philadelphia, PA: W.B. Saunders Co. p.1058.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:
Method comparison studies were performed internally. A minimum of 150 whole blood specimens were analyzed for each parameter in syringe collection devices. Some samples were altered in order to achieve the hard-to-find sample range. The samples were analyzed on each of the Stat Profile Prime CCS analyzers and on each of the pHOx Ultra analyzers. The Stat Profile Prime CCS results for each analyzer were compared to the average of the 2 results from the pHOx Ultra comparative method.

Syringe method comparison study results *vs.* the predicate device (Stat Profile pHOx Ultra)

Test Parameter	Total # samples	Sample range tested	Slope	Intercept	r
pH	172	6.523 - 7.862 pH units	0.9976	0.0099	0.9985
pCO2	179	3.4 - 200.0 mmHg	0.9854	0.9344	0.9977
pO2	167	29.5 - 593.2 mmHg	0.9897	1.4508	0.9988
Hct	174	12 – 70%	1.0445	-1.9271	0.9889
Na	180	85.5 - 195.7 mmol/L	1.0189	-2.2841	0.9955
K	179	1.11 - 19.75 mmol/L	1.0163	-0.0371	0.9996
iCa	181	0.25 - 2.48 mmol/L	0.9880	0.0457	0.9974

Test Parameter	Total # samples	Sample range tested	Slope	Intercept	r
Cl	186	52.8 - 189.3 mmol/L	1.0003	1.0158	0.9955
Glu	185	39 – 474 mg/dL	1.0007	-2.6844	0.9892

Whole blood patient samples were evaluated to demonstrate that syringe sample mode and capillary sample mode are equivalent. The syringe sample was analyzed directly using the syringe mode. After the measurement, samples were transferred from the syringe into the capillary tube and then analyzed using the capillary mode. Approximately 100 whole blood samples were analyzed for each parameter. The capillary test result was compared to the syringe test result and linear regression analysis was performed. Results are summarized in the table below.

Parameter	total # samples	sample range tested	Slope	Intercept	r
pH pH units	100	6.787 - 7.683	1.0094	-0.0721	0.9988
pCO2 mmHg	100	17.7 - 111.0	1.0026	-0.4347	0.9989
pO2 mmHg	100	25.5 - 435.2	0.9942	2.1791	0.9996
Hct %	100	14 - 69	1.0013	0.0485	0.9963
Na mmol/L	100	85.0 - 198.1	0.9995	-0.1711	0.9978
K mmol/L	100	2.70 - 19.37	0.9966	0.0934	0.9996
iCa mmol/L	98	0.33 - 2.51	1.0228	-0.0603	0.9855
Cl mmol/L	100	55.8 - 197.1	0.9897	0.1776	0.9997
Glu mg/dL	100	17 - 488	0.9855	-0.4734	0.9998

b. Matrix Comparison:

Not applicable. The only sample type acceptable 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:

The sponsor has provided the following Expected Values in the Manual:
pH[1, 2, 4]: 7.35 - 7.45
*P*CO2[1, 2, 4]: 35 - 45 mmHg
*P*O2[1, 2, 4]: 83 - 108 mmHg

Hematocrit (Hct)[1, 2, 4]
(Male) 39 - 49%
(Female) 35 - 45%

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
Ionized Calcium[3]: 1.09 - 1.30 mmol/L

References:

1. Statland, Bernard. 1987. *Clinical Decisions Levels for Lab Tests*, Medical Economics Books.
2. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry*. Philadelphia, PA: W. B. Saunders Co.

3. Kost, G.T. 1993. The Significance of Ionized Calcium in Cardiac and Critical Care. *Arch. Pathol.* Lab Med. Vol. 117: pp 890-896.
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.

N. Instrument Name:

Stat Profile Prime CCS Analyzer

O. System Descriptions:

1. Modes of Operation:

   Fully automated

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____x____ or No _____

3. Specimen Identification:

   Bar code

4. Specimen Sampling and Handling:

   Lithium heparinized whole blood from syringes, open tubes, small cups, and capillary tubes.

   Analyzer will accept 3 sample types, namely, heparinized syringe, heparinized capillary tube, and heparinized blood collection tube (open tube). In addition, small cups (for quality control testing) will also be acceptable.

5. Calibration:

   The Stat Profile Prime CCS analyzer performs a 2-point calibration 30 minutes after being powered on and regularly thereafter to maintain optimal micro sensor card and air detector performance. A 1-point calibration is performed at regular intervals to monitor the Micro Sensor Card's performance between each 2-point calibration. A manually initiated 2-point calibration can be performed whenever the analyzer displays Ready or Not Ready on the header bar. A Not Ready (Not Calibrated) status is displayed after powering the analyzer on, after replacing some consumable items or as a result of a system error.

6. Quality Control:

   QC consists of the following materials:

   Stat Profile Prime Auto QC Cartridge CCS (on-board internal control), and Stat Profile Prime Ampuled Control ABG/CCS (external control, same composition as the on-board internal control)

   Nova Linearity Standard Set A

   User should follow federal, state and local guidelines for testing quality control materials.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not Applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10, and 21 CFR 801.109(b)(1) to indicate For In Vitro Diagnostic Use and Prescription use Only.

R. Conclusion:

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