DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2015

NOVA BIOMEDICAL CORPORATION
PAUL MACDONALD
CHIEF QUALITY AND REGULATORY AFFAIRS OFFICER
200 PROSPECT ST
WALTHAM MA 02454

Re: K141907
Trade/Device Name: 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 and Nova Linearity Standard Set A
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, GKF, KHP, JIX, JJS
Dated: April 24, 2015
Received: April 27, 2015

Dear Mr. Paul Macdonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k141907

Device Name
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

Indications for Use *(Describe)*
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 quantitative determination of pH, PCO2, PO2, Hct, Na+. K+, Cl-, iCa, Glu (Glucose), and Lac (Lactate) in heparinized whole blood.

PC02,P02,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.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(k) Number: K141907
510(k) Owner: Nova Biomedical Corporation
Registration Number: 1219029
Address: 200 Prospect St.
Waltham, MA 02454
Phone: 781-894-0800
Fax Number: 784-891-4806
Contact Person: Paul W. MacDonald
Date Prepared: 22 May, 2015

Proprietary Name: Stat Profile® Prime CCS Analyzer System, Stat Profile Prime Auto QC cartridges CCS, Ampuled Control ABG/CCS, Calibrator Cartridge CCS/CCS Comp, and the Nova Linearity Standard Set A

Common or Usual Name: Blood Gas/Electrolyte/Metabolite/CO-Oximetry Analyzer

Classification Name: Multiple

Classification Names:	Class No.	Reg. No.	Class
Blood Gases and Blood pH system	75CHL	862.1120	II
Sodium Test System	75JGS	862.1665	II
Potassium Test System	75CEM	862.1600	II
Calcium Test System	75JFP	862.1145	II
Chloride Test System	75CGZ	862.1170	II
Glucose Test System	75CGA	862.1345	II
Instrument, Hematocrit, Automated	81GKF	864.5600	II
Lactic Acid Test System	75KHP	862.1450	I
Calibrators	75JIX	862.1150	II
Quality Control Materials	75JJS	862.1660	I

Product Codes: CHL, JGS, CEM, JFP, CGZ, CGA, GKF, JIX, JJS, KHP

Predicate Device: K131703 - Nova Stat Profile Prime CCS Analyzer System (including controls, calibrators and linearity standards)

Device Description:

The Stat Profile Prime CCS Analyzer is a small, low cost blood gas, metabolite and electrolyte analyzer for laboratory use. The sensors and flow path have been integrated into one replaceable microsensor card, which is replaced periodically according to usage. The product, consumables, installation instructions and packaging are designed for easy customer installation.

Whole blood specimens are aspirated into the analyzer's microsensor card from syringes, tubes, or capillary blood collection devices using a peristaltic pump and a sampling probe. The disposable microsensor card contains the analytical flow path and all of the measurement sensors (pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, Glu (Glucose) and Lac (Lactate). Once the analysis measurement is complete, the whole blood specimen is automatically flushed out of the microsensor card flow path and into a self-contained waste collection bag contained within the disposable calibrator cartridge.

The Stat Profile Prime CCS Analyzer will have an enhanced test menu and multiple quality control options. Both traditional Internal and External liquid QC shall be offered, as well as an on-board Quality Management System (QMS), an electronic monitoring approach that insures the analyzer is working properly.

As with the predicate, the Stat Profile Prime CCS Analyzer is microprocessor-based and incorporates:

- traditional sensor technology to measure blood pO_2
- ion selective electrode technology to measure pH, pCO_2, blood sodium, potassium, chloride, and ionized calcium
- enzyme/Amperometric technology for glucose measurements

Liquid quality control materials are available as internal auto-cartridge quality control packs and as external ampules. The sampling, calibration and quality control functions are fully automated.

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 Cartridges contain 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 Calibration Cartridge aqueous solutions allow for 2 point calibration of each parameter as follows:

- Calibrator A - pH, PCO_2, Na, K, Cl, iCa, Glu and Lactate (Volume > 500 mL)
- Calibrator B - pH, PO_2, Na, K, Cl, iCa, Glu and Lactate (Volume > 250 mL)
- Calibrator F - PCO_2, PO_2 (Volume > 720 mL)
- Reference Solution - KCl (Volume > 300 mL)

The external glass ampule controls contain a buffered bicarbonate solution with a known pH and known levels of Na, K, Cl, iCa, Glucose (Glu) and Lactate. The solutions are equilibrated with known levels of O2, CO2, and N2. Each ampule contains 1.7 ml volume.

The 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. 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, Glucose (Glu) and Lactate. 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, and Lactate
- Control 3: Alkalosis, High Hct, Low Electrolyte, High Abnormal Glu, and Lactate

Linearity Standard Set A consists of ampuled buffered solutions containing Ca++, Glu, Lactate, K+, and Cl-. Each ampule contains 1.8 ml volume.

The Stat Profile Analyzer accepts Lithium heparin whole blood sample from syringes, open tubes, small cups, and capillary tubes. The minimum sample size for both syringe and capillary samples analysis is 100 µL.

Measured Parameters:

The Stat Profile Prime CCS Analyzer measures pH, *P*CO2, *P*O2, Hct, Na^+, K^+, Cl^-, iCa, Glu and Lactate (Note: Glucose and Lactate are optional).

Calculated Parameters:

- pH, PCO_2, PO_2 (corrected to patient temperature)
- Bicarbonate level (HCO_3-)
- Total Carbon Dioxide (TCO_2)
- Base Excess of the blood (BE-b)
- Base Excess of extracellular fluid (BE-ecf)
- Standard Bicarbonate Concentration (SBC)
- Oxygen Content (O_2Ct)
- Oxygen Capacity (O_2Cap)
- Alveolar Oxygen (A)
- Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)
- Arterial Alveolar Oxygen Tension Ratio (a/A)
- Respiratory Index (RI)
- P50
- PO_2/FIO_2 ratio
- Oxygen Saturation (SO_2%)
- Hemoglobin
- Anion Gap
- Normalized Calcium, nCa

Intended 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, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, Glu (Glucose), and Lac (Lactate) in heparinized whole blood.

*P*CO2, *P*O2, 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).
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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).
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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.

Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO_2, PO_2, 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.

Summary of the Technological Characteristics:

The Stat Profile Prime CCS Analyzer is substantially equivalent to the previously cleared for market Stat Profile Prime CCS Analyzer System in intended use. It uses the same sensor technology and measurement algorithms, and the formulations of the internal and external controls and the calibration cartridge are the same for the tested parameters. The linearity standards for use with the Stat Profile Prime CCS Analyzer are identical to those cleared for use with the predicate Stat Profile Prime CCS Analyzer System.

Summary of Performance Testing:

Testing was completed to demonstrate that the Stat Profile Prime CCS Analyzer is substantially equivalent in performance, safety and efficacy to the Stat Profile pHOx Ultra Analyzer System.

In this submission, only Lactate data for detection limit, linearity, and interference/specificity was reviewed and cleared. Performance data for all other analytes was presented and reviewed in the predicate device submission (K131703 - Stat Profile Prime CCS Analyzer).

Method Comparison

Method comparison studies were performed. 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.

Table 1: 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
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
Lac	182	0.4 – 17.8	0.9841	-0.0937	0.9974

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.

Table 2: Method Comparison Results – Capillary vs. Syringe

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
Lac mmol/L	100	1.1 – 18.1	1.0034	-0.0120	0.9994

Specificity / Interference Testing Protocol:

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 Lactate. The following table represents substances that were tested without demonstrating a significant interference on test results:

Table 3: Substances Tested for Lactate Interference

Interfering Substance	Highest Concentration Tested
Acetaminophen	20.0 mg/dL
Acetoacetate	2.0 mmol/L
Acetylsalicylic acid	3.62 mmol/L
Ammonium Chloride	107.0 µmol/L
Ascorbic Acid	50 mg/dL
Benzylkonium Chloride	10.0 mg/L
BetaHydroxybutyrate	2.0 mmol/L
Bilirubin	20.0 mg/dL
D-Galactose	1.0 mmol/L
Dobutamine	2.0 mg/dL
Dopamine Hydrochloride	5.87 µmol/L
EDTA	3.4 µmol/L
Ethanol	86.8 mmol/L
Fluoride	105 µmol/L
Glucose	1,000 mg/dL
Glucosamine	30.0 µmol/L
Hemoglobin	2.0 g/L
Heparin	100 IU/mL
Ibuprofen	2.4 mmol/L
Intralipid	10.0 mg/mL
Maltose	13.0 mmol/L
Mannose	1.0 mmol/L
Potassium Thiocyanate	2,064 µmol/L
Pyruvate	309 µmol/L
Salicylic Acid	4.34 mmol/L
Sodium Bromide	37.5 mmol/L
Sodium Citrate	12.0 mmol/L
Sodium Oxalate	500 mg/dL
Thiocyanate	6.8 mmol/L
Urea	40.0 mg/dL
Uric Acid	1.4 mmol/L
Xylose	25.0 mg/dL

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

Table 4: Lactate Interfering Substances

Parameter	Interfering Substance	Concentration of interfering substance	Interference
Lactate	Glycolic acid	0.0 mmol/L	No interference observed
		0.25 mmol/L	Bias of 11.7%
	Hydroxyurea	0.0 mg/dL	No interference observed
		0.2 mg/dL	Bias of 20.1%

Determination of Limit of Detection: Limit of Detection was determined by obtaining the standard deviation of sample measurements from repeated measurements of samples with a relevant low concentration. Three blood samples with low level lactate concentration were used to estimate the limit of detection.

Table 5: Lactate Limit of Detection

Limit of Detection						
	LoB	LoD	LoQ	Average Total Error	Acceptance Criteria for Total Error	Claimed Measurement Range
Lac	2.70 mg/dL 0.30 mmol/L	3.60 mg/dL 0.40 mmol/L	3.60 mg/dL 0.40 mmol/L	0.13	≤ 0.3	3.6 - 178.6 mg/dL 0.4 - 20.0 mmol/L

Lactate Linearity: Samples were prepared by tonometering, spiking or diluting whole blood to span the analytical measurement range for lactate. Each blood level sample was analyzed in triplicate on each of the three (3) test analyzers and on the pHOx Ultra analyzers. The pHOx Ultra analyzers were used to establish the target value of each blood level for lactate.

Table 6: Lactate Linearity Results

Individual Analyzer Performance Data						
Parameter	total # levels	Specimen range	Analyzer	Slope	Intercept	r
Lac	11	0.2 - 24.9 0.2 - 24.7 0.2 - 24.8	#1 #2 #3	0.9946 0.9920 0.9911	0.1178 0.1431 0.2117	0.9992 0.9994 0.9993

Point-of-Care

A Point-of-Care study was conducted to demonstrate that the system was safe and effective for use in the POC setting. The testing compared results obtained by trained Healthcare Professionals to results obtained by POC personnel on the same specimens using the same analyzer. The Stat Profile Prime CCS Analyzer was evaluated by point-of-care (POC) personnel in 3 POC sites including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU) and a trauma/neuro intensive care unit. A total of 43 respiratory therapy and 10 Nursing POC personnel participated from the 3 POC settings over the course of the study. The personnel represent trained, qualified staff found in typical POC sites where blood gas analyzers are utilized. All testing was performed using discarded blood gas specimens.

Combined data from all 3 POC settings is summarized in Tables 7 and 8.

Table 7: Prime CCS: POC v Trained Healthcare Professional (THP) - Syringe Mode

Parameter	Total # specimens	Whole Blood Range	Slope	Intercept	r
pH	234	6.874 - 7.665	0.983	0.116	0.997
PCO2 mmHg	230	4.1 - 195.5	1.007	0.750	0.998
PO2 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	53.0 - 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

Table 8: Prime CCS: POC v Trained Healthcare Professional (THP) - Capillary Mode

Parameter	Total # specimens	Whole Blood Range	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	0.899	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 - 484	1.004	0.036	0.999
Lac mmol/L	173	0.6 - 18.4	1.019	-0.127	0.998

Total Imprecision Performance

The total imprecision data included in the following table was obtained from different POC site personnel running 3 levels of Stat Profile Prime External Quality Control material (Levels 1-3) in duplicate each day for a total of 20 runs on 3 Stat Profile Prime CCS analyzers. The protocol was based upon methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second edition," CLSI EP5-A2. The test data is representative of the expected total imprecision between analyzer performance obtainable by POC personnel using the Stat Profile Prime CCS analyzer using external quality control materials.

Table 9: Prime CCS: Total Imprecision Results – Combined – External Controls

Combined Total Imprecision Data - Level 1						
Parameter	**Pooled Mean**	**N**	**Within Run SD (Sr)**	**Within Run %CV**	**Total Imprecision SD(St)**	**Total Imprecision %CV**
pH	7.144	120	0.004	0.06	0.007	0.10
*P*CO2	64.6	120	0.8	1.3	1.5	2.3
*P*O2	56.2	120	1.8	3.2	2.6	4.7
Hct	33	120	0.5	1.6	0.6	1.9
Na	163.6	120	0.6	0.4	1.1	0.7
K	5.69	120	0.05	0.9	0.08	1.4
Cl	128.2	120	0.3	0.2	1.3	1.0
iCa	1.56	120	0.007	0.5	0.023	1.5
Glu	81.0	120	1.1	1.4	1.4	1.8
Lac	1.0	120	0.02	2.0	0.02	2.0
Combined Total Imprecision Data - Level 2						
pH	7.368	120	0.002	0.03	0.005	0.07
*P*CO2	42.5	120	0.4	1.0	0.8	2.0
*P*O2	98.0	120	0.9	1.0	2.2	2.3
Hct	51	120	0.5	0.9	0.6	1.2
Na	139.7	120	0.5	0.3	1.0	0.7
K	3.73	120	0.02	0.5	0.05	1.3
Cl	102.1	120	0.2	0.2	0.4	0.4
iCa	1.00	120	0.005	0.5	0.009	0.9
Glu	203.0	120	2.2	1.1	4.9	2.4
Lac	2.8	120	0.05	1.8	0.06	2.1
Combined Total Imprecision Data – Level 3						
pH	7.562	120	0.008	0.11	0.009	0.12
*P*CO2	25.1	120	0.7	2.7	1.3	5.2
*P*O2	140.8	120	1.2	0.9	3.2	2.3
Hct	65	120	0.5	0.8	0.7	1.0
Na	117.6	120	0.3	0.2	0.5	0.4
K	1.87	120	0.01	0.5	0.02	1.1
Cl	87.0	120	0.4	0.5	0.9	1.1
iCa	0.55	120	0.004	0.7	0.007	1.3
Glu	318.0	120	4.2	1.3	9.0	2.8
Lac	7.1	120	0.1	0.7	0.12	1.7
Combined Total Imprecision Data - Low Hematocrit						
Hct	19	120	0.4	2.2	0.5	2.6

Table 10: Comparison of Predicate and Proposed devices

Characteristic	Predicate: K131703 Stat Profile Prime CCS Analyzer		Proposed: Stat Profile Prime CCS Analyzer
Indication 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.		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, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, Glu (Glucose), and Lac (Lactate) in heparinized whole blood.
	*P*CO2, *P*O2, pH	Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances in critically ill patients with numerous metabolic and pulmonary diseases.	Same
	Hct	Whole blood measurements of hematocrit are used to estimate that red blood cells are present in sufficient quantity to carry oxygen and carbon dioxide.	Same
	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.	Same
	K+	Potassium Measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.	Same
	Cl-	Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.	Same
	iCa	Ionized Calcium measurement is used in the diagnosis and treatment of hypertension, renal disease, and vitamin D related disorders. Also useful in the diagnosis and treatment of patients with increased total protein and/or albumin levels, as in dehydration.	Same

Characteristic	Predicate: K131703 Stat Profile Prime CCS Analyzer		Proposed: Stat Profile Prime CCS Analyzer
	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.	Same
	Lac	Lactate (lactic acid) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis.	Same
Acceptable Samples	Lithium heparinized whole blood from syringes, open tubes, small cups, and capillary tubes.		Same
Sample Volumes	100µL (syringe and capillary)		Same
Measurement Range			
pH	6.500-8.000		Same
PCO_2	3.0 -200 mmHg		Same
PO_2	5-765 mmHg		Same
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 (Ca^{++})	0.20-2.70 mmol/L		Same
Glu	15-500 mg/dL		Same
Lac	0.3-20.0 mmol/L		Same
Principles of Measurement			
pH	Hydrogen ion-selective sensor		Same

Characteristic	Predicate: K131703 Stat Profile Prime CCS Analyzer	Proposed: Stat Profile Prime CCS Analyzer
PCO_2	Severinghaus-type sensor	Same
PO_2	Polarographic Clark-type sensor	Same
Hct	Impedance sensor	Same
Na^+	Sodium ion-selective sensor	Same
K^+	Potassium ion-selective sensor	Same
Cl^-	Chloride ion-selective sensor	Same
iCa (Ca^{++})	Calcium ion-selective sensor	Same
Glu	Glucose Oxidase Enzymatic sensor	Same
Lac	Lactate Oxidase Enzymatic sensor	Same
Touch Screen	5.7" VGA full color display with LED backlight and integrated touch panel	Same
Menu	Fully configurable test menu based on above sensors	Same
Bar Code Scanner	Internal Integrated 1D/2D	Same
Printer	2" Roll, Thermal Transfer	Same
Pump	Peristaltic Pump w/ Pressure Plate, TPE Tubing (Pharmed BPT)	Same
Analog Board	Precision low level analog front end w/ amperometric and potentiometric amplifiers, air detector circuitry and temperature control circuitry	Same

Characteristic	Predicate: K131703 Stat Profile Prime Calibrator Cartridge CCS	Proposed: Stat Profile Prime Calibrator Cartridge CCS
Indication For Use	The Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, and Glucose using the Stat Profile Prime CCS Analyzer.	The Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, Glucose (Glu), and Lactate (Lac) using the Stat Profile Prime CCS Analyzer.
Settings	Clinical Laboratories	Clinical Laboratories and/or Point Of Care
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

Characteristic	Predicate: K131703 Stat Profile Prime Auto QC Cartridge CCS	Proposed: Stat Profile Prime Auto QC Cartridge CCS
Indication For Use	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.	Same
Settings	Clinical Laboratories	Clinical Laboratories and/or Point Of Care
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

Characteristic	Predicate: K131703 Stat Profile Prime Ampuled Control ABG/CCS	Proposed: Stat Profile Prime Ampuled Control ABG/CCS
Indication For Use	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.	Same
Settings	Clinical Laboratories	Clinical Laboratories and/or Point Of Care
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.7 ml volume.	Same

Characteristic	Predicate: K131703 Linearity Standard Set A	Proposed: Linearity Standard Set A
Indication For Use	The 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.	Same
Settings	Clinical Laboratories	Clinical Laboratories and/or Point Of Care
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

Conclusion:

The results of software validation and performance verification testing confirmed that the Stat Profile Prime CCS Analyzer is safe and effective for its intended purpose and that the Stat Profile Prime CCS Analyzer System is substantially equivalent to the predicate device Stat Profile Prime CCS Analyzer System (K131703).