March 13, 2020

Nova Biomedical Corporation
Rachel Gilbert
Regulatory Affairs Specialist II
200 Prospect Street
Waltham, Massachusetts 02454

Re: K200349
Trade/Device Name: Stat Profile Prime Plus Analyzer System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, CDS, CGL, KHP
Dated: February 5, 2020
Received: February 12, 2020

Dear Rachel Gilbert:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, M.T., Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k200349

Device Name
Stat Profile Prime Plus Analyzer System

Indications for Use *(Describe)*
The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Glucose, Lactate, Creatinine, and Blood Urea Nitrogen in heparinized arterial and venous whole blood.

Glucose (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
Lactate (Lac)	Lactate (lactic acid) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis
Creatinine (Creat)	Creatinine measurement is used in the diagnosis and treatment of certain renal conditions and for monitoring adequacy of dialysis.
Blood Urea Nitrogen (BUN)	Blood Urea Nitrogen measurement is used in the diagnosis and treatment of certain renal and metabolic diseases

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
k200349

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: Rachel Gilbert, Regulatory Affairs Specialist II
Date Prepared: February 5, 2020

Proprietary Name: Stat Profile Prime Plus Analyzer System

Common or Usual Name: Blood Analyzer

Classification Name: Multiple

Regulation section	Classification	Product code
21 CFR § 864.1345 Glucose Test System	Class II	CGA
21 CFR § 862.1225 Creatinine Test System	Class II	CGL
21 CFR § 862.1770 Urea Nitrogen Test System	Class II	CDS
21 CFR § 862.1450 Lactic Acid Test System *	Class I	KHP

* Meets Limitations to Exemptions 21 CFR § 862.9(c)(9)

Predicate Device:
k180340 – Stat Profile Prime Plus Analyzer System

Purpose:
Modification of a previously cleared device (k180340) – modify the intended use of the device to include Point-of-Care (POC) use.

Device Description:
The Stat Profile Prime Plus Analyzer System is a low cost, low maintenance analyzer for hospital laboratory and point-of-care settings. It consists of the analyzer, sensor cartridges, and thermal paper for an onboard printer. Optionally, it provides for reading of barcode labels (such as operator badges and data sheets).

The Stat Profile Prime Plus Analyzer has slots to accommodate two sensor cartridges (Primary and Auxiliary). The analyzer will determine the configuration of the system by detecting which sensor cards are installed.

Primary Sensor Card Port:
There are two options for the primary sensor card:

- **Primary Sensor Card 1** shall enable and report the following listed analytes:
  - Glu, Lactate
- **Primary Sensor Card 2** shall enable and report the following listed analytes:
  - Glu, Lactate

Auxiliary Sensor Card Port:
The reporting of Creatinine and BUN parameters (or not reporting them) shall be determined by the selection of the Auxiliary Sensor Card

- Auxiliary Sensor Card 1 shall enable Creatinine and BUN parameters
- Auxiliary Sensor Card 2 shall be a "dummy" sensor card, and will not report any parameters.

As with the predicate, the Stat Profile Prime Plus Analyzer is a blood gas, co-oximetry, electrolyte, chemistry, and hematology analyzer with an enhanced test menu and multiple quality control options. Both traditional internal and external quality control is available, as well as an on-board Quality Management System (QMS), and an electronic monitoring approach that insures the analyzer is working properly at all times.

The Stat Profile Prime Plus Analyzer accepts samples from syringes and open tubes. The minimum sample size for analysis is 135 µL.

Sample collection, preparation and application to the analyzer are the same as for the previously cleared predicate. The end user can select which analytes are to be tested in the panel.

Stat Profile Prime Plus Analyzer System Components:
The Stat Profile Prime Plus Analyzer System is comprised of the following components.

- Stat Profile Prime Plus Analyzer System
- Primary Sensor Cartridge
- Auxiliary Sensor Cartridge
- Stat Profile Prime Plus Auto-Cartridge Quality Control Pack
- Stat Profile Prime Plus Calibrator Cartridge
- Stat Profile Prime Plus External Ampuled Control
- IFU/Labeling

Sample Types:
The Stat Profile Prime Plus Analyzer System accepts lithium heparinized arterial and venous whole blood.

Measured Parameters:
The Stat Profile Prime Plus Analyzer System measures:

- Glucose (Glu)
- Lactate (Lac)
- Creatinine (Creat)
- Blood Urea Nitrogen (BUN).

Calculated Parameters:
The Stat Profile Prime Plus Analyzer System also provides the following parameter results calculated based on results of the directly measured parameters:

- BUN/Creat Ratio (BUN/Creat)
- Blood Osmolality (OSM)
- Estimated Glomerular Filtration Rate (eGFR)

Intended Use:
The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Glucose, Lactate, Creatinine, and Blood Urea Nitrogen in heparinized arterial and venous whole blood.

Indications for Use:

Glucose (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
Lactate (Lac)	Lactate (lactic acid) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis
Creatinine (Creat)	Creatinine measurement is used in the diagnosis and treatment of certain renal conditions and for monitoring adequacy of dialysis.
Blood Urea Nitrogen (BUN)	Blood Urea Nitrogen measurement is used in the diagnosis and treatment of certain renal and metabolic diseases

Summary of the Technological Characteristics:
The Stat Profile Prime Plus Analyzer System is substantially equivalent to the previously cleared for market Stat Profile Prime Plus 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.

Principles of Measurement:

Glucose:
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. At a constant potential of 0.70 volts, electroactive H2O2 is oxidized at the surface of the platinum anode. The current generated by the flow of electrons at the surface of the platinum electrode is proportional to the glucose concentration of the sample.

Lactate:
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. At a constant potential of 0.70 volts, electroactive H_2O_2 is oxidized at the surface of the platinum anode. The current generated by the flow of electrons at the surface of the platinum electrode is proportional to the lactate concentration of the sample.

Creatinine:
The Prime Plus Creatinine sensor uses 3 enzymes. These 3 enzymes catalyze the conversion of Creatinine, ultimately forming formaldehyde, glycine, and hydrogen peroxide. At a constant potential of 0.70, electroactive H_2O_2 is oxidized at the surface of the platinum anode. The current generated by the flow of electrons at the surface of the platinum electrode is proportional to the Creatinine concentration of the sample.

BUN:
The Prime Plus Analyzer uses urease, which has been chemically bonded to a membrane, to catalyze the conversion of urea present in the sample to ammonia and CO_2. At the pH of the sample, ammonia converts predominantly to the ammonium ion. An ammonium ion selective electrode is used to detect the ammonium formed by the above reactions. This measurement is then related to the concentration of urea present in the original sample via the Nernst equation.

Traceability (Lactate):
The reagents and standards containing lactate are derived from reagent grade lithium lactate. In the absence of a standard reference material from NIST, the traceability is established by comparing standards made from lithium lactate to lithium reference standards made from NIST SRM ***924a***, lithium carbonate. The validation is accomplished by using a Nova analyzer using a membrane covered amperometric electrode.

Reference Values[1],[2],[3],[4],[5]:
Reference values for glucose, creatinine, BUN, and lactate on the Stat Profile Prime Plus Analyzer System are cited from literature.

Analyte	Default (US) Units of Measure	International (SI) Units of Measure
Glucose	65-95 mg/dL	3.61-5.27 mmol/L
Lactate	0.7 – 2.5 mmol/L 6.3 – 22.5 mg/dL	0.7 – 2.5 mmol/L 6.3 – 22.5 mg/dL
Creatinine	Male: 0.7 – 1.3 mg/dL	Male: 61.9 – 114.9 mmol/L; 61,900 – 114,900 µmol/L
	Female: 0.6 – 1.1 mg/dL	Female: 53.0 – 97.2 mmol/L; 53,000 – 97,200 µmol/L
BUN	7 – 14 mg/dL	5.0 – 10.0 mmol/L

Summary of Performance Testing (Lactate):

Testing was completed to show that the Stat Profile Prime Plus Analyzer System demonstrates substantial equivalence to the Stat Profile pHOx Ultra Analyzer System (K110648). In this submission, only Lactate data for detection limit, linearity, and interference/specificity was reviewed. Performance data for all other analytes was presented and reviewed in the predicate device submission (k180340 – Stat Profile Prime Plus Analyzer System).

Precision/Reproducibility – Within Run and Run to Run Study:

Within Run and Run to Run precision for lactate was evaluated by replication studies performed on three Stat Profile Prime Plus Analyzers.

Within Run Precision testing consisting of one run of each of the following sample types and levels was performed, 20 replicates per run:

- Stat Profile Prime Plus Auto QC Cartridge: Levels 4 and 5
- Stat Profile Prime Plus Quality Control Ampules: Levels 4 and 5
- Five whole bloods, sampled from syringes
    - One normal un-manipulated whole blood sample was run.
    - The other four whole blood lactate concentration were varied by spiking with a concentrated lactate solution made with saline.

Run to Run Precision was evaluated on each of the following sample types:

- Stat Profile Prime Plus Auto QC Cartridge: Levels 4 and 5 – samples were evaluated in QC mode in duplicate, two runs per day for a total of forty runs
- Whole Blood – triplicate analyses was performed on five whole blood samples in ten separate runs during a single day. The systems were recalibrated before each triplicate run.
    - One normal un-manipulated whole blood sample was run.
    - The other four whole blood lactate concentration were varied by spiking with a concentrated lactate solution made with saline.

The results are summarized below:

Table 1: Auto QC Cartridge: Levels 4 and 5 – Precision Testing Results

Parameter	n = 20	PP1	PP2	PP3	Pooled
Lac, mmol/L (Level 4)	Mean	2.0	2.0	2.0	2.0
	SD	0.00	0.00	0.00	0.00
	CV%	0.00	0.00	0.00	0.00
Lac, mmol/L (Level 5)	Mean	6.9	6.9	6.9	6.9
	SD	0.00	0.00	0.05	0.03
	CV%	0.00	0.00	0.68	0.44

[1]Statland, Bernard, Clinical Decision Levels for Lab Tests, Medical Economics Books, 1987.
[2] Burtis, Carl A. and Ashwood, Edward R., ed. 1994. Tietz Textbook of Clinical Chemistry, W. B. Saunders Co. Philadelphia, PA.
[3] Tofaletti, J., Hammes, M.E., Gray, R., Lineberry, B., and Abrams, B. 1992. "Lactate Measured in Diluted and Undiluted Whole Blood and Plasmas: Comparison of Methods and Effects of Hematocrit," Clinical Chemistry, Vol. 38, No. 12.
[4] Bernstein, W.K., Auden, J., Bhatiani, A., Kerzner, R., Davison, L., Miller, C., and Chernow, B. 1994. "Simultaneous Arterial and Venous Lactate Determinations in Critically Ill Patients," Critical Care Medicine, Vol. 22.
[5] Tietz, Norbert W., ed. 1983. Clinical Guide to Laboratory Tests, W. B. Saunders Co., Philadelphia, PA.

Table 2: Quality Control Ampules: Levels 4 and 5 – Precision Testing Results

Parameter	n = 20	PP1	PP2	PP3	Pooled
Lac, mmol/L (Level 4)	Mean	1.9	1.9	1.9	1.9
	SD	0.00	0.00	0.00	0.00
	CV%	0.00	0.00	0.00	0.00
Lac, mmol/L (Level 5)	Mean	6.6	6.4	6.5	6.5
	SD	0.1	0.1	0.1	0.1
	CV%	1.2	1.3	1.2	1.6

Table 3: Whole Bloods, Sampled from Syringes – Precision Testing Results

Parameter	n = 20	PP1	PP2	PP3	Pooled
Lac, mmol/L (Blood #1)	Mean	2.0	2.1	2.3	2.2
	SD	0.1	0.1	0.1	0.2
	CV%	6.8	6.8	5.1	8.0
Lac, mmol/L (Blood #2)	Mean	4.8	4.7	4.7	4.7
	SD	0.2	0.1	0.1	0.1
	CV%	3.2	2.6	3.0	3.1
Lac, mmol/L (Blood #3)	Mean	7.4	7.7	7.5	7.5
	SD	0.2	0.2	0.2	0.2
	CV%	3.2	2.9	2.9	3.2
Lac, mmol/L (Blood #4)	Mean	11.0	11.1	10.8	11.0
	SD	0.3	0.2	0.2	0.3
	CV%	2.7	1.9	1.8	2.4
Lac, mmol/L (Blood #5)	Mean	16.7	16.7	16.5	16.6
	SD	0.2	0.3	0.3	0.3
	CV%	1.3	1.5	1.9	1.7

Table 4: Auto QC Cartridge: Levels 4 and 5 – Run to Run Imprecision

Sample	Pooled Mean	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 4	2.0	240	0.0	1.5	0.1	3.5
QC Level 5	7.0	240	0.1	1.0	0.1	1.4

Table 5: Whole Blood – Run to Run Precision

Parameter	n = 30	PP1	PP2	PP3	pooled
Lac, mmol/L (Blood #1)	Mean	1.4	1.4	1.4	1.4
	SD	0.2	0.2	0.2	0.2
	CV%	13.3	14.0	14.7	13.9
Lac, mmol/L (Blood #2)	Mean	4.9	4.8	4.8	4.8
	SD	0.2	0.2	0.2	0.2
	CV%	4.7	4.1	4.1	4.5
Lac, mmol/L (Blood #3)	Mean	7.1	6.9	7.4	7.1
	SD	0.3	0.5	0.2	0.4
	CV%	4.5	7.4	3.1	6.0

Parameter	n = 30	PP1	PP2	PP3	pooled
Lac, mmol/L (Blood #4)	Mean	12.1	11.2	12.2	11.8
	SD	0.6	0.5	0.4	0.7
	CV%	4.6	4.8	3.1	5.7
Lac, mmol/L (Blood #5)	Mean	17.4	17.2	17.2	17.3
	SD	0.3	0.3	0.3	0.3
	CV%	2.0	1.7	1.5	1.8

Linearity Testing Study:

A Linearity study was performed to assess the linearity of lactate to verify the Analytical Measurement Range (AMR) for the Stat Profile Prime Plus Analyzer System. The evaluation of the linear range included lower and upper limits of the AMR and medical decision limits using whole blood samples analyzed in triplicate. All Stat Profile Prime Plus results were compared to the reference analyzer and/or the product specifications defined in the Stat Profile Prime Marketing Requirements document.
The results are summarized below:

Table 6: Prime Plus Lactate Linearity

claimed measurement range	analyzer	total # of levels	specimen range	slope	intercept	r
0.3 - 20.0	PP1	9	0.2 - 23.5	0.9936	-0.0950	0.9983
	PP2	9	0.2 - 23.4	0.9965	0.1751	0.9982
	PP3	9	0.2 - 23.0	1.0011	0.0012	0.9988

The results support the claimed measurement range of 0.3 – 20.0 mmol/L.

Specificity / Interference Testing Study:

An interference testing study was performed to identify substances that may interfere with Stat Profile Prime Plus lactate sensor. A dose response study was done for glycolic acid and hydroxyurea because the difference between the test and control sample was greater than the allowed bias of ±10%. From the dose response study, it was found that glycolic acid and hydroxyurea interferes with lactate at all concentrations.
The results are summarized below:

Table 7: Prime Plus Lactate Interference

Substance Tested	Highest concentration tested that showed no significant interference
Acetaminophen	20 mg/dL
Acetoacetate	2 mmol/L (20 mg/dL)
Acetylsalicylic Acid	3.62 mmol/L (65 mg/dL)
Ammonium Chloride	107 µmol/L (0.6 mg/dL)
Ascorbic Acid	50 mg/dL
Benzalkonium Chloride	10 mg/L
Bilirubin	342 µmole/L (20 mg/dL)
B-hydroxybutyrate	2 mmol/L (20 mg/dL)
Dobutamine	2 mg/dL
Dopamine Hydrochloride	5.87 µmol/L (0.1 mg/dL)
EDTA	3 mmol/L (88 mg/dL)
Ethanol	86.8 mmol/L (400 mg/dL)
Sodium Fluoride	105 µmol/L (441 mg/dL)

Substance Tested	Highest concentration tested that showed no significant interference
D-Galactose	1 mmol/L (18 mg/dL)
Glucosamine	30 µmol/L (0.5 mg/dL)
Glucose	1000 mg/dL
Hemoglobin	2 g/dL
Heparin	100 IU/mL
Ibuprofen	2.4 mmol/L (50 mg/dL)
Intralipid	1000 mg/dL
Maltose	13 mmol/L (445 mg/dL)
Mannose	1 mmol/L (18 mg/dL)
Sodium Bromide	37.5 mmol/L (386 mg/dL)
Sodium Pyruvate	309 µmol/L (3.4 mg/dL)
Salicylic Acid	4.34 mmol/L (60 mg/dL)
Sodium Citrate	12 mmol/L (310 mg/dL)
Sodium Oxalate	500 mg/dL
Sodium Thiocyanate	6.8 mmol/L (55 mg/dL)
Urea	40 mg/dL
Uric Acid	1.4 mmol/L (24 mg/dL)
Xylose	25 mg/dL

Detection Limit Testing Study:
A study was performed to assess the low level test performance for lactate using altered blood samples for determining Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ). The studies were performed following the recommendations in Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition, CLSI EP17-A2.

LoB: Blank samples were run five times on two analyzers with different lots of reagent calibrator pack. The LoB was estimated non-parametrically by sorting the samples from low to high and averaging the 57th and 58th sample using the typical Type I error risk of α=0.05. The greater LoB of the two reagent lot is reported as the LoB.

LoD: The low level samples were run four times on two analyzers with different lots of reagent calibrator pack. Five different low level samples were run over three day, giving a total of 60 replicates per reagent lot. The LoD was calculated following the recommendations in CLSI guidance. The greater LoD of the two reagent lot is reported as the LoD.

LoQ: The low level samples were run three times on two analyzers with different lots of reagent calibrator pack. Four different low level samples were run over three days, giving a total of 36 replicates per reagent lot. The calculated TE (total error) for all samples by each reagent lot met the accuracy goal of TE ≤ 0.3.

The LoB, LoD and LoQ were all below the lower limit of the claimed lactate measurement range of 0.3 mmol/L for the Stat Profile Prime Plus Analyzer. The results are summarized in **Table 8**:

Table 8: Prime Plus Lactate Detection Limit Summary

LoB	LoD	LoQ
0.0 mmol/L	0.1 mmol/L	0.1 mmol/L

Summary of Point-of-Care Testing:

A Point-of-Care (POC) study was conducted to show that the Stat Profile Prime Plus Analyzer System for glucose, creatinine, BUN, and lactate demonstrates substantial equivalence to the predicate submission. 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 Plus Analyzer was evaluated by point-of-care (POC) personnel in 3 POC sites including a Cardiothoracic Intensive Care Unit (CTICU), an Emergency Department (ED) and a Respiratory Therapy Lab (RT). A total of 61 Respiratory Care, 12 Nursing, and 1 Exercise Physiology 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 quality control materials or discarded blood gas specimens.

Method Comparison Studies:

Method Comparison studies on venous and arterial whole blood specimens were conducted using methods described in CLSI "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition", CLSI EP9-A2. Combined method comparison data from all 3 POC settings is summarized below.

Table 9: Venous and Arterial Whole Blood Method Comparison Results – Point of Care vs Lab (ED, RT and CTICU)

								95% Confidence Interval of Bias	
analyte	**N**	**# altered samples**	**range**	**Slope**	**Intercept**	**r**	**MDL**	**Lower Limit**	**Upper Limit**
Glu	419	8	16 - 493	1.0102	-0.9232	0.9988	**40**	39	40
							120	120	121
Lac	413	0	0.5 - 16.5	1.0181	-0.0796	0.9975	**2**	1.9	2.0
							6	6.0	6.1
BUN	413	0	4.0 - 100.0	0.9969	0.0674	0.9990	**12**	11.9	12.1
							50	49.8	50.1
Creat	429	16	0.2 - 11.3	0.9984	-0.0025	0.9987	**1.6**	1.6	1.6
							6.0	6.0	6.0

Total Imprecision Performance:

The estimates for total impression were obtained from different POC personnel running 3 levels of Stat Profile Prime Plus Quality Control/Linearity Materials in duplicate each day for a total of 20 runs on 3 Stat Profile Prime Plus analyzers. The protocol was based upon methods described in CLSI Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition, CLSI EP5-A2T. The total imprecision data from one representative POC site is shown in **Table 10** and is representative of the expected total imprecision performance obtainable by POC personnel using the Stat Profile Prime Plus analyzer using external quality control and linearity materials.

Table 10: Total Imprecision from ED Site

Total Imprecision Data-Level 4					
	Mean	**Within Run SD**	**Within Run %CV**	**Total SD**	**Total %CV**
Glu (mg/dL)	81	1.1	1.4	1.1	1.3
Lac (mmol/L)	1.8	0.1	2.8	0.1	3.2
BUN (mg/dL)	15.7	0.6	3.6	0.8	4.8
Creat (mg/dL)	1.1	0.04	3.5	0.1	5.5
Total Imprecision Data-Level 5					
Glu (mg/dL)	298	4.4	1.5	5.2	1.7
Lac (mmol/L)	6.7	0.2	3.1	0.2	3.4
BUN (mg/dL)	49.8	2.2	4.4	2.5	5.1
Creat (mg/dL)	7.4	0.1	1.8	0.4	5.2
Total Imprecision Data-Linearity Level 4					
Glu (mg/dL)	32	0.7	2.2	0.8	2.4
Lac (mmol/L)	16.5	0.2	1.0	0.4	2.2
Total Imprecision Data-Linearity Level 3					
BUN (mg/dL)	24.3	0.2	0.7	0.6	2.4
Creat (mg/dL)	4.9	0.1	1.1	0.3	6.4

Within-Run Whole Blood Precision:

Whole blood with-run precision of the Stat Profile Prime Plus Analyzer System in the hands of point-of- care operators was assessed by a minimum of two (2) point-of-care operators at each of the three (3) POC sites for a total of nine (9) operators across the 3 testing locations. Each precision run consisted of ten (10) replicate measurements using both fresh, native and altered whole blood samples. A total of five (5) different native samples and two (2) altered samples were evaluated at each site. Each whole blood specimen was maintained in a syringe. The POC operator performed all sample analysis steps including sample analysis, removal of resultant air bubble(s) from the syringe, recapping of the syringe and mixing prior to the next sample analysis. The whole blood within-run precision data from one representative POC site is shown below and is representative of the expected within-run precision obtainable by POC personnel using the Stat Profile Prime Plus analyzer using whole blood samples.

Table 11: Within Run Precision with Whole Blood Samples (n=10) – ED Site

	Mean	**SD**	**%CV**	**95% CI**
Sample 1				
Glu (mg/dL)	140.8	2.97	2.11	135 - 147
Lac (mmol/L)	3.30	0.22	6.55	2.9 - 3.7
BUN (mg/dL)	13.9	0.32	2.28	13 - 15
Creat (mg/dL)	1.42	0.06	4.45	1.3 - 1.5
Sample 2				
Glu (mg/dL)	60.0	0.47	0.79	59 - 61
Lac (mmol/L)	1.43	0.07	4.72	1.3 - 1.6
BUN (mg/dL)	7.5	0.53	7.03	6.0 - 9
Creat (mg/dL)	0.60	0.00	0.00	0.6 - 0.6
Sample 3				
Glu (mg/dL)	86.5	2.17	2.51	82 - 91
Lac (mmol/L)	2.47	0.13	5.41	2.2 - 2.7
BUN (mg/dL)	21.0	0.00	0.00	21 - 21
Creat (mg/dL)	1.68	0.04	2.51	1.6 - 1.8

	Mean	SD	%CV	95% CI
Sample 4				
Glu (mg/dL)	83.3	2.26	2.72	79 - 88
Lac (mmol/L)	2.49	0.17	6.68	2.2 - 2.8
BUN (mg/dL)	21.3	0.48	2.27	20 - 22
Creat (mg/dL)	1.56	0.05	3.31	1.5 - 1.7
Sample 5				
Glu (mg/dL)	71.3	0.82	1.15	70 - 73
Lac (mmol/L)	1.24	0.05	4.16	1.1 - 1.3
BUN (mg/dL)	19.0	0.00	0.00	19 - 19
Creat (mg/dL)	3.30	0.05	1.43	3.2 - 3.4
Sample 6 (Altered)				
Glu (mg/dL)	349.4	8.57	2.45	332 - 367
Lac (mmol/L)	4.69	0.19	4.08	4.3 - 5.1
BUN (mg/dL)	57.8	1.23	2.13	55 - 60
Creat (mg/dL)	5.94	0.22	3.65	5.5 - 6.4
Sample 7 (Altered)				
Glu (mg/dL)	109.0	5.72	5.24	98 - 120
Lac (mmol/L)	11.4	0.45	3.98	10.5 - 12.3
BUN (mg/dL)	82.7	1.16	1.40	80 - 85
Creat (mg/dL)	10.03	0.46	4.61	9.1 - 11.0

Within-Run Control and Linearity Material:

Typical within-run precision of the Stat Profile Prime Plus Analyzer System in the hands of point-of-care operators was assessed using methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelines – Second Edition", CLSI EP5-A2 as guidance. A total of three (3) Stat Profile Prime Plus analyzers and four (4) different lots of calibrator cartridges were used in the study. One analyzer was used at each testing site and calibrator cartridges from 3 of the 4 calibrator cartridge lots were used at the ED site, 2 at the CTICU site, and 2 at the RT site.

Using test materials consisting of a combination of available quality Control and Linearity materials to cover the analytes measurement ranges (Low, Normal and High) precision runs were performed by POC Staff members within each of the testing locations. Each run consisted of 20 replicate measurements. Representative within-run precision results from one site are summarized in the table below:

Table 12: Within Run Precision with Controls and Linearity Material (n=20) – ED

Within Run Precision-Level 4				
	Mean	**SD**	**%CV**	**95% CI**
Glu (mg/dL)	81	1.4	1.7	78.1-83.5
Lac (mmol/L)	1.7	0.05	2.9	1.6-1.8
BUN (mg/dL)	16.5	0.5	3.1	15.4-17.5
Creat (mg/dL)	1.2	0.04	3.1	1.1-1.3
Within Run Precision-Linearity Level 1				
Glu (mg/dL)	446	5.5	1.2	434.6-456.8
Lac (mmol/L)	0.4	0.04	9.5	0.3-0.5
Within Run Precision-Linearity Level 4				
Glu (mg/dL)	34	0.5	1.5	32.8-34.8
Lac (mmol/L)	16.9	0.1	0.8	16.6-17.2
Within Run Precision- Linearity Level 2				
BUN (mg/dL)	49.2	0.9	1.8	47.4-51
Creat (mg/dL)	7.5	0.08	1.1	7.4-7.7

Within Run Precision- Linearity Level 3				
BUN (mg/dL)	24.5	0.5	2.1	23.4-25.5
Creat (mg/dL)	4.8	0.05	1.0	4.7-4.9

Conclusion:

The results of the POC clinical performance verification testing confirmed that the Stat Profile Prime Plus Analyzer is substantially equivalent to the predicate Stat Profile Prime Plus Analyzer System (k180340).

Table 13: Comparison of Predicate and Proposed Devices (Glucose, Creatinine, BUN)

Characteristic	Predicate (k180340):	Proposed:
Indication For Use	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings for quantitative determination of Glucose, Creatinine, and Blood Urea Nitrogen, in heparinized arterial and venous whole blood	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of care usage for quantitative determination of Glucose, Creatinine, and Blood Urea Nitrogen in heparinized arterial and venous whole blood.
Acceptable Samples		
Sample Types	Lithium heparin whole blood from syringes and open tubes	Same
Sample Volumes	135µL	Same
Measurement Range		
Glu	15-500 mg/dL	Same
Creat	0.2-12.0 mg/dL	Same
BUN	3-100 mg/dL	Same
Principles of Measurement		
Glu	Enzymatic sensor	Same
Creat	Enzymatic sensor	Same
BUN	Enzymatic sensor	Same
Touch Screen	10.1” WXGA 1280 x 800 color touch screen	Same
Menu	Fully configurable test menu based on available 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

Table 14: Comparison of Predicate and Proposed Device (Lactate)

Characteristic	Predicate (k110648):	Proposed:
Indication For Use	The Nova Stat Profile pHOx Ultra Analyzer is intended for in vitro diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of Lactate in heparinized whole blood, serum, or plasma.	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of care usage for quantitative determination of Lactate in heparinized arterial and venous whole blood.
Sample Types	Syringe, capillary tube	Lithium heparin whole blood from syringes and open collection tubes
Sample Volume	150µL / 60µL (micro)	135µL
Measurement Range	0.3-20 mmol/L	Same
Principles of Measurement	Enzymatic sensor	Same