September 29, 2023

Nova Biomedical Corporation
Bobby Zinck
Sr. Regulatory Affairs Manager
200 Prospect St.
Waltham, Massachusetts 02454

Re: K221900
Trade/Device Name: Stat Profile Prime Plus Analyzer System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood Gases (pCO2, pO2) and Blood pH Test System
Regulatory Class: Class II
Product Code: CHL, JPI, CGA, KHP, JGS, CEM, CGZ, JFP, CFA
Dated: February 17, 2023
Received: February 21, 2023

Dear Bobby Zinck:

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,

Paula V. Caposino
-S

Paula Caposino, Ph.D.
Acting Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221900

Device Name
Stat Profile Prime Plus Analyzer System

Indications for Use *(Describe)*

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 pH, Partial Pressure of Carbon Dioxide (pCO2), Partial Pressure of Oxygen (pO2), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate in heparinized capillary whole blood.

Indication for Use:
pH, pCO2, pO2 measurements are used in the diagnosis and treatment of life-threatening acid base disturbances.

Hematocrit (Hct) measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.

Glucose (Glu) 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 (lactic acid) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis.

Sodium (Na) measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.

Potassium (K) measurements are used in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.

Chloride (Cl) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ionized Calcium (iCa) 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).

Ionized Magnesium (iMg) measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

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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K221900 510(k) Summary

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: Bobby Zinck

Date Prepared: September 28, 2023

Proprietary Name:
Stat Profile Prime Plus Analyzer System

Common or Usual Name:
Blood and Blood Gas Analyzer

Classification Name: Multiple

Classification Name	Regulation #	Class	Product Code	Panel
Blood Gases and Blood pH System	862.1120	II	CHL	Chemistry (75)
Hematocrit measuring device	864.6400	II	JPI	Hematology (81)
Glucose Test System	864.1345	II	CGA	Hematology (81)
Lactic Acid Test System*	862.1450	I	KHP	Chemistry (75)
Sodium Test System	862.1665	II	JGS	Chemistry (75)
Potassium Test System	862.1600	II	CEM	Chemistry (75)
Chloride Test System	862.1170	II	CGZ	Chemistry (75)
Calcium Test System	862.1145	II	JFP	Chemistry (75)
Magnesium Test System	862.1495	Class I, reserved	CFA	Chemistry (75)

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

Predicate Device: The predicate device for this submission is the Nova Biomedical Stat Profile pHOx Ultra Analyzer which received clearance through 510(k) K110648.

Purpose for Submission:
The purpose of this submission is to expand the indication for use to include capillary whole blood specimen testing for the following analytes tested on the Stat Profile Prime Plus Analyzer System, pH, pCO2, pO2, sodium (Na^+), potassium (K^+), chloride (Cl^-), ionized calcium (Ca^{2+}), ionized magnesium (Mg^{2+}), glucose, lactate, and hematocrit. The full panel of analytes measured on the Stat Profile Prime Plus including the ones listed in this submission previously received FDA clearance for point-of-care testing with arterial and venous whole blood specimens as a part of a bundled submission under the 510(k)s: K193246, K200204, K200349, K200403.

To support the expanded claims, a point-of-care study at 2 clinical sites was conducted using capillary specimens tested on the Stat Profile Prime Plus Analyzer and compared to the predicate device, Stat Profile pHOx Ultra Analyzer.

Device Description:
Stat Profile Prime Plus Analyzer
The Stat Profile Prime Plus Analyzer System is an analyzer for use in 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:
  - PO_2, PCO_2, pH, Hct, tHb, SO_2, O_2Hb, COHb, MetHb, HHb, Glu, Lactate, Sodium, Potassium, Chloride, Calcium, Ionized Magnesium
- **Primary Sensor Card 2** shall enable and report the following listed analytes:
  - PO_2, PCO_2, pH, Hct, tHb, SO_2, Glu, Lactate, Sodium, Potassium, Chloride, Calcium, Ionized Magnesium

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 the 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 ensures the analyzer is working properly.

The Stat Profile Prime Plus Analyzer accepts samples from syringes, open tubes, and capillary tubes. The sample size for analysis is 135 µL for the complete test panel or 90 µL for the capillary panel.

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 Ampule Control
- IFU/Labeling

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

Measured Parameters:
The Stat Profile Prime Plus Analyzer measures:

- pH
- Partial Pressure of Carbon Dioxide (pCO_2)

- Partial Pressure of Oxygen (pO_2)
- Hematocrit (Hct)
- Glucose (Glu)
- Lactate (Lac)
- Sodium (Na)
- Potassium (K)
- Chloride (Cl)
- Ionized Calcium (iCa)
- Ionized Magnesium (iMg)

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 pH, Partial Pressure of Carbon Dioxide (pCO2), Partial Pressure of Oxygen (pO2), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate in heparinized capillary whole blood.

Indication for Use:

pH, pCO2, pO2	Measurements are used in the diagnosis and treatment of life-threatening acid base disturbances.
Hct	Hematocrit (Hct) measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.
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.
Sodium (Na)	Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
Potassium (K)	Potassium measurements are used in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.
Chloride (Cl)	Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Ionized Calcium (iCa)	Ionized 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).
Ionized Magnesium (iMg)	Ionized magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

Principle of Measurement:

pH:

pH is measured using a hydrogen ion selective glass membrane. One side of the glass 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. The magnitude of the potential difference is a measure, then, of the pH of the unknown solution.

pCO_2:

PCO_2 is measured with a modified pH sensor. Carbon dioxide in the unknown solution makes contact with a gas permeable membrane mounted on a combination measuring/ reference electrode. CO_2 diffuses across the membrane into a thin layer of electrolyte solution in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure. CO_2 in the solution becomes hydrated producing carbonic acid, which results in a change in hydrogen ion activity.

pO_2:

PO_2 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:

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:

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. 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 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.

Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium:

The parameters are measured by an Ion-Selective Electrode (ISE) that selectively measures the activity of ionic species. When the ISE is contacted with a sample, potential is developed. The potential is proportional to the logarithm of the ionic activity and is measured versus a reference electrode.

Summary of Technological Characteristics:

The Stat Profile Prime Plus Analyzer System is substantially equivalent to the previously cleared for market Stat Profile pHOx Ultra Analyzer System (K110648). It uses the same sensor technology, measurement algorithms, formulations of the internal and external controls, and calibrator cartridge for the tested parameters.

Summary of Performance Testing:

Bench testing was previously completed and summarized in the following Prime Plus Analyzer System bundled 510(k)s K173797, K180186, K180340, K180428, K200349 to demonstrate that the Stat Profile Prime Plus Analyzer is substantially equivalent in performance, safety, and efficacy in the predicate submission.

The results of that testing confirmed that the performance of the Stat Profile Prime Plus Analyzer System

is substantially equivalent to that of the Nova Stat Profile pHOx Ultra Analyzer System (predicate device).

Summary of Point-of-Care Testing:
Point-of-Care testing for arterial and venous whole blood samples was previously completed and summarized in the following Prime Plus Analyzer System bundled 510(k)s K193246, K200204, K200349, K200403 to demonstrate that the system is safe and effective for use in the POC setting.

The testing included method comparison studies in 3 POC sites, including a Cardiothoracic Intensive Care Unit (CTICU), an Emergency Department (ED) and a Respiratory Therapy Lab (RT).

The results of the POC clinical performance verification testing confirmed that the Stat Profile Prime Plus Analyzer is safe and effective for its intended purpose in POC settings and that the Stat Profile Prime Plus Analyzer System is substantially equivalent to that of the predicate Stat Profile Prime Plus Analyzer System.

Summary of Capillary Mode Testing:
Method Comparison:

A separate clinical study was conducted in Point-of-Care (POC) settings to demonstrate the clinical performance of capillary whole blood specimens on the Stat Profile Prime Plus analyzers. The study was conducted to demonstrate the clinical performance of capillary whole blood specimens on the Stat Profile Prime Plus analyzers. The study compared the Stat Profile Prime Plus analyzers to the Nova Stat Profile pHOx Ultra analyzers (predicate device) to assess the equivalence of the analyzers in the measurement of pH, blood gases, hematocrit, electrolytes, and metabolites in capillary whole blood specimens. The method comparison study was performed at two (2) external POC sites. The study was conducted in the Emergency Room (ER) with five (5) POC nurses and within a Hemodialysis Unit with four (4) POC nurses over a minimum of 20 days. Each site used a single Prime Plus analyzer and a single pHOx Ultra analyzer. Some of the specimens were altered (less than 10%) to cover the full dynamic range.

Table 1: Capillary Mode Method Comparison: ER

Capillary Mode Method Comparison						
Stat Profile Prime Plus vs pHOx Ultra (ER)						
Parameter	**N**	**Altered Samples**	**Whole Blood Range**	**Slope**	**Intercept**	**r**
pH	122	9	6.790 -7.729	0.9949	0.0321	0.9914
pO2, (mmHg)	123	10	7.5-562.2	1.0109	-1.3281	0.9965
pCO2, (mmHg)	120	7	7.4-183.0	1.0003	-0.3135	0.9958
Hct, (%)	118	5	18-54	0.9944	0.7831	0.9864
Na, (mM)	119	6	83.0-194.8	1.0158	-2.7473	0.9907
K, (mM)	120	7	1.34-18.47	0.9924	0.0461	0.9984
Cl, (mM)	119	6	64.5-191.1	0.9561	4.7910	0.9810
Ca, (mM)	121	8	0.37-2.44	0.9871	0.0222	0.9932
Mg, (mM)	122	9	0.13-1.17	0.9690	0.0187	0.9808
Glu, (mg/dL)	120	7	28.0-427.5	0.9955	0.4436	0.9959
Lac, (mM)	119	6	0.5-16.9	1.0148	-0.0108	0.9988

Table 2: Capillary Mode Method Comparison: Hemodialysis

Capillary Mode Method Comparison						
Stat Profile Prime Plus vs pHOx Ultra (Hemodialysis)						
Parameter	**N**	**Altered Samples**	**Whole Blood Range**	**Slope**	**Intercept**	**r**
pH	127	9	6.790-7.655	0.9839	0.1148	0.9971
pO2, (mmHg)	128	10	8.1-567.1	0.9936	2.3980	0.9987
pCO2, (mmHg)	125	7	7.4-183.1	1.0125	-0.8197	0.9975
Hct, (%)	123	5	18-55	0.9944	0.7831	0.9864
Na, (mM)	124	6	85.0-195.6	1.0097	-1.6583	0.9866
K, (mM)	125	7	1.43-18.53	0.9956	0.0369	0.9990
Cl, (mM)	124	6	67.2-191.6	1.0235	-3.0725	0.9897
Ca, (mM)	126	8	0.38-2.46	0.9935	0.0082	0.9935
Mg, (mM)	127	9	0.16-1.22	0.9627	0.0241	0.9813
Glu, (mg/dL)	125	7	28.5-452.0	0.9948	1.3066	0.9979
Lac, (mM)	124	6	0.4-17.6	0.9867	0.0307	0.9991

Table 3: Capillary Mode Method Comparison: Combined Results

Capillary Mode Method Comparison						
Stat Profile Prime Plus vs pHOx Ultra (Combined)						
Parameter	**N**	**Altered Samples**	**Whole Blood Range**	**Slope**	**Intercept**	**r**
pH	249	18	6.790-7.729	0.9894	0.0736	0.9942
pO2, (mmHg)	251	20	7.5-567.1	1.0006	0.8320	0.9976
pCO2, (mmHg)	245	14	7.4-183.1	1.0075	-0.5969	0.9968
Hct, (%)	241	10	18-55	0.9900	0.8011	0.9876
Na, (mM)	243	12	83.0-195.6	1.0129	-2.2244	0.9885
K, (mM)	245	14	1.34-18.53	0.9940	0.0416	0.9987
Cl, (mM)	243	12	64.5-191.6	0.9944	0.3494	0.9856
Ca, (mM)	247	16	0.37-2.46	0.9900	0.0155	0.9932
Mg, (mM)	249	18	0.13-1.22	0.9659	0.0214	0.9811
Glu, (mg/dL)	245	14	28-452	0.9950	0.9041	0.9969
Lac, (mM)	243	12	0.4-17.6	1.0001	0.0119	0.9989

Conclusion: The Nova Biomedical Stat Profile Prime Plus analyzer provided consistently reliable performance throughout the POC clinical evaluation study. The capillary blood comparison data for all test parameters for the Stat Profile Prime Plus analyzers met the clinical accuracy acceptance criteria for correlation coefficient (r) and bias at the medical decision levels.

Total Imprecision Performance:

Within Run Precision:

Estimates for total imprecision for within run precision were obtained from running 20 replicates of venous blood transferred to capillary tubes at targeted sample concentrations on two Prime Plus analyzers in a Customer Simulation Laboratory at Nova Biomedical. The average SD and CV% for each analyzer for each sample type and level was calculated and compared to the defined within run imprecision specifications. The Between Analyzer mean, SD, and CV% from two (2) analyzers for each level was calculated and compared to the defined

between analyzer imprecision specifications. Within run data are summarized in Tables **3** to **5.**

Table 4: Capillary Mode Within Run Precision: Blood Gas Summary

Prime Plus Capillary Mode				
Whole Blood Within Run Precision				
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Between Analyzer**
pH	Mean	7.358	7.342	7.350
	SD	0.006	0.006	0.009
pH	Mean	7.252	7.246	7.249
	SD	0.004	0.004	0.005
pH	Mean	7.142	7.144	7.143
	SD	0.004	0.005	0.005
pCO_2, mmHg	Mean	25.0	24.7	24.8
	SD	0.6	0.5	0.6
	CV%	2.4	1.9	2.2
pCO_2, mmHg	Mean	54.8	59.6	57.2
	SD	1.1	0.8	2.6
	CV%	2.0	1.3	4.5
pCO_2, mmHg	Mean	70.2	73.7	72.0
	SD	1.8	1.3	2.4
	CV%	2.6	1.8	3.3
pO_2, mmHg	Mean	54.3	56.0	55.2
	SD	0.7	0.6	1.1
	CV%	1.3	1.0	2.0
pO_2, mmHg	Mean	178.4	174.3	176.4
	SD	1.8	1.6	2.7
	CV%	1.0	0.9	1.5
pO_2, mmHg	Mean	95.0	100.7	97.9
	SD	1.7	1.5	3.3
	CV%	1.7	1.5	3.4

Table 5: Capillary Mode Within Run Precision: Electrolytes Summary

Prime Plus Capillary Mode				
Whole Blood Within Run Precision				
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Between Analyzer**
Na+, mmol/L	Mean	87.2	86.2	86.7
	SD	0.5	0.8	0.8
	CV%	0.6	1.0	1.0
Na+, mmol/L	Mean	155.0	155.6	155.3
	SD	0.4	1.0	0.8

Prime Plus Capillary Mode				
Whole Blood Within Run Precision				
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Between Analyzer**
	CV%	0.3	0.6	0.5
Na+, mmol/L	Mean	134.5	135.9	135.2
	SD	0.4	0.6	0.9
	CV%	0.3	0.4	0.6
K+, mmol/L	Mean	1.92	1.93	1.92
	SD	0.02	0.02	0.02
	CV%	1.1	1.1	1.1
K+, mmol/L	Mean	6.17	6.11	6.14
	SD	0.11	0.11	0.11
	CV%	1.8	1.8	1.8
K+, mmol/L	Mean	4.57	4.59	4.58
	SD	0.04	0.03	0.04
	CV%	0.9	0.7	0.8
Cl-, mmol/L	Mean	72.1	71.7	71.9
	SD	0.5	0.9	0.8
	CV%	0.7	1.2	1.0
Cl-, mmol/L	Mean	130.8	131.5	131.2
	SD	1.2	1.0	1.2
	CV%	0.9	0.7	0.9
Cl-, mmol/L	Mean	102.7	102.0	102.3
	SD	0.4	0.5	0.6
	CV%	0.4	0.5	0.6
iCa, mmol/L	Mean	0.31	0.29	0.30
	SD	0.01	0.01	0.01
	CV%	2.2	3.0	3.9
iCa, mmol/L	Mean	2.59	2.62	2.61
	SD	0.03	0.06	0.05
	CV%	1.1	2.2	1.8
iCa, mmol/L	Mean	1.33	1.35	1.34
	SD	0.01	0.01	0.02
	CV%	0.6	0.7	1.3
iMg, mmol/L	Mean	0.13	0.13	0.13
	SD	0.01	0.00	0.00
	CV%	4.3	1.7	3.4
iMg, mmol/L	Mean	0.91	1.00	0.95
	SD	0.02	0.01	0.05
	CV%	1.7	1.3	5.2
iMg, mmol/L	Mean	0.58	0.60	0.59

Prime Plus Capillary Mode				
Whole Blood Within Run Precision				
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Between Analyzer**
	SD	0.01	0.01	0.01
	CV%	1.3	1.2	2.4

Table 6: Capillary Mode Within Run Precision: Hematology and Chemistry Summary

Prime Plus Capillary Mode				
Whole Blood Within Run Precision				
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Between Analyzer**
Hct, %	Mean	28	28	28
	SD	0.7	0.6	0.6
Hct, %	Mean	60	63	61
	SD	0.3	1.3	1.6
Hct, %	Mean	42	43	42
	SD	0.9	0.7	0.9
Glu, mg/dL	Mean	91	93	92.4
	SD	2.3	2.2	2.4
	CV%	2.5	2.4	2.5
Glu, mg/dL	Mean	282	279	280.5
	SD	4.2	2.6	3.8
	CV%	1.5	0.9	1.3
Glu, mg/dL	Mean	36	36	36.1
	SD	0.4	0.4	0.4
	CV%	1.0	1.1	1.1
Lac, mmol/L	Mean	1.8	1.8	1.79
	SD	0.1	0.1	0.07
	CV%	3.8	4.3	4.0
Lac, mmol/L	Mean	4.2	4.4	4.3
	SD	0.1	0.1	0.1
	CV%	3.4	2.0	3.2
Lac, mmol/L	Mean	9.6	9.7	9.6
	SD	0.3	0.3	0.3
	CV%	2.7	2.7	2.7

Within Sample Precision:
Sample within run precision in capillary mode was assessed for whole blood by measuring two replicates of capillary whole blood from thirty (30) different donors in a Customer Simulation Laboratory at Nova Biomedical. The mean, SD, and CV% for all samples were calculated and compared to the defined within-run imprecision specifications. Sample within run data is summarized in Table **7**.

Table 7: Capillary Mode Within Sample Precision: Summary

Prime Plus Capillary Mode					
Whole Blood Within Sample Precision					
Analyte	**SD %CV**	**n**	**Mean**	**SD**	**%CV**
pH	0.010	60	7.322	0.003	-------
pCO2 (mmHg)	1.0 3.0	60	31.0	0.7	2.1
pO2 (mmHg)	2.0 3.0	60	127.9	0.8	0.6
Hct (%)	1.0	60	32	0.4	-------
Na^+ (mM)	1.0 1.0	60	137.9	0.1	0.1
K^+ (mM)	0.2 1.5	60	4.03	0.01	0.21
Cl^- (mM)	1.5 2.0	60	109.5	0.5	0.5
iCa (mM)	0.07 2.5	60	1.11	0.00	0.44
iMg (mM)	0.03 2.0	60	0.63	0.01	1.58
Glu (mg/dL)	2.0 3.0	60	108	0.5	0.5
Lac (mM)	0.3 3.0	60	4.1	0.0	0.6

Conclusion: The precision data for all samples in capillary mode met the within run and between analyzer imprecision specifications for the Prime Plus analyzers. Each Prime Plus analyzer provided a consistently reliable performance throughout the evaluation study. The analyzers used for this evaluation met all performance criteria for precision.

Within-Run Imprecision - Capillary Mode Fingerstick (External POC):
A precision study was performed at an external site using discarded specimens transferred from a lithium heparin syringe to a capillary tube by POC (Point-of-Care) operators. The study used one Stat Profile Prime Plus Analyzer, and de-identified and discarded arterial blood specimens.

Sample Analysis
Each whole blood specimen was transferred from a syringe to three balanced heparin capillary tubes and analyzed in Capillary Micro mode on the Stat Profile Prime Plus Analyzer by one POC operator.

Data Analysis
The mean, SD, and CV% of the triplicate results of each analyte in each sample were calculated.

Table 8: Within-Run Imprecision - Capillary Mode Fingerstick Data Summary

Analyte	Unit	Grand Mean	Grand SD	Grand CV%
pH	pH units	7.357	0.008	N/A
pCO2	mmHg	37.2	0.7	1.9
pO2	mmHg	145.6	2.1	1.5
Hct	%	31.5	1.2	N/A
Na+	mmol/L	135.1	0.8	0.6
K+	mmol/L	3.94	0.04	0.9
Cl-	mmol/L	110.1	0.8	0.8
Ca2+	mmol/L	1.14	0.01	1.2
Mg2+	mmol/L	0.51	0.01	2.5
Glu	mg/dL	128	1.8	1.4
Lac	mmol/L	3.1	0.1	4.6

Conclusion
This study demonstrates the Stat Profile Prime Plus analyzer exhibits clinically acceptable imprecision specifications for pH, pCO2, pO2, sodium (Na+), chloride (Cl-), potassium (K+), ionized calcium (Ca2+), ionized magnesium (Mg2+), glucose, lactate, and hematocrit measured by the Stat Profile Prime Plus Analyzer System in Capillary mode.

Within-Sample Imprecision - Capillary Mode Fingerstick (Internal POC):
An internal precision study was performed in the Nova Customer Simulation Laboratory using a single Stat Profile Prime Plus analyzer. Capillary whole blood was collected via fingerstick puncture and run on the Stat Profile Prime Plus Analyzer in capillary mode by two (2) point-of-care (POC) operators (Nurse and Respiratory Therapist) in duplicate.

The mean, SD, and CV% for all sample pairs was calculated and compared to the defined imprecision specifications.

Table 9: Within-Sample Imprecision - Capillary Mode Fingerstick Data Summary

Analyte	Mean	N	Within Sample (SD)	Within Sample (%CV)
pH	7.403	60	0.008	N/A
pO2 (mmHg)	81.8	60	2.2	2.7
pCO2 (mmHg)	32.0	60	1.0	3.0
Hct (%)	41	60	1.0	N/A
Na (mM)	139.5	60	0.8	0.6
K (mM)	4.75	60	0.17	3.5
Cl (mM)	109.9	60	0.6	0.6
Ca (mM)	1.20	60	0.01	0.9
Mg (mM)	0.54	60	0.01	1.1
Glu (mg/dl)	109	60	1.6	1.5
Lac (mM)	1.7	60	0.2	12.4

Conclusion

The Stat Profile Prime Plus analyzer provided a consistently reliable performance throughout the evaluation study. The analyzer used for this evaluation met the performance criteria for within sample precision on capillary fingerstick specimens run by POC operators.

Within-Run Imprecision - Capillary Samples (Internal Study)

An internal precision study was performed in the Nova Customer Simulation Laboratory using five (5) different concentrations of deidentified venous whole blood specimens per analyte, each run on three (3) Stat Profile Prime Plus analyzers, for five (5) days, with one (1) run performed each day and eight (8) replicates measured per run per level.

The mean, SD, and CV% for all samples were calculated and compared to the defined within-run imprecision specifications.

Table 10: Within-Run Imprecision - Capillary Mode

Analyte	Level	Mean	N	Within Run (SD)	Within Run (%CV)
pH	1	7.133	120	0.003	N/A
	2	7.341	120	0.003	N/A
	3	7.465	120	0.004	N/A
	4	6.933	120	0.004	N/A
	5	7.652	120	0.009	N/A
pO2 (mmHg)	1	47.9	120	0.4	0.9%
	2	205.4	120	0.8	0.4%
	3	415.4	120	2.5	0.6%
	4	146.6	120	0.7	0.5%
	5	521.6	120	3.3	0.6%
pCO2 (mmHg)	1	84.0	120	1.3	1.5%
	2	39.5	120	0.7	1.7%
	3	21.9	120	0.2	0.9%
	4	161.0	120	2.3	1.4%
	5	117.9	120	1.6	1.3%
Hct (%)	1	40	120	0.8	N/A
	2	64	120	0.7	N/A
	3	20	120	0.6	N/A
	4	30	120	0.7	N/A
	5	57	120	0.8	N/A
Na (mM)	1	107.7	120	0.8	0.7%
	2	167.3	120	1.1	0.7%
	3	181.2	120	1.5	0.8%
	4	152.2	120	0.6	0.4%
	5	128.9	120	0.6	0.5%

Table 10: Within-Run Imprecision - Capillary Mode (continued)

Analyte	Level	Mean	N	Within Run (SD)	Within Run (%CV)
K (mM)	1	3.34	120	0.04	1.2%
	2	8.80	120	0.13	1.4%
	3	1.79	120	0.05	2.7%
	4	14.95	120	0.17	1.1%
	5	6.10	120	0.05	0.8%
Cl (mM)	1	95.9	120	0.7	0.8%
	2	161.2	120	1.8	1.1%
	3	186.3	120	2.0	1.1%
	4	81.2	120	0.9	1.1%
	5	131.7	120	1.2	0.0%
Ca (mM)	1	0.95	120	0.01	1.4%
	2	1.50	120	0.02	1.3%
	3	1.82	120	0.02	1.4%
	4	0.78	120	0.01	1.1%
	5	2.22	120	0.03	1.3%
Mg (mM)	1	0.80	120	0.01	1.7%
	2	1.13	120	0.02	1.4%
	3	0.30	120	0.01	2.1%
	4	0.56	120	0.01	1.9%
	5	1.38	120	0.02	1.6%
Glu (mg/dl)	1	87	120	0.9	1.0%
	2	198	120	3.5	1.8%
	3	429	120	3.9	0.9%
	4	117	120	1.6	1.4%
	5	34	120	0.7	2.0%
Lac (mM)	1	10.8	120	0.2	2.3%
	2	2.1	120	0.1	5.4%
	3	5.9	120	0.1	2.4%
	4	13.6	120	0.3	2.5%
	5	16.1	120	0.3	1.9%

Conclusion

The Stat Profile Prime Plus analyzers provided consistently reliable performance throughout the evaluation study. The analyzers used for this evaluation met the acceptance criteria for precision.

Table 11: Comparison of Predicate and Proposed Devices

Characteristic	Predicate:	Proposed:
Indication For Use	The Stat Profile pHOx Ultra Analyzer without CO-Oximeter is intended for in vitro diagnostic use by health care professionals and/or point-of-care usage in 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 (Great) in heparinized whole blood, serum, or plasma. The Stat Profile pHOx Ultra Analyzer with CO-Oximeter is intended for in vitro diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of pH, PCO2, PO2, SO2%, Hematocrit (Hct), total Hemoglobin (tHb), Oxyhemoglobin (O2Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in heparinized whole blood; Nat, K'-, Cl-, Ca++, Mg++, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in Heparinized whole blood, serum, or plasma. Total Bilirubin (tBil) was not evaluated on neonatal samples.	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 pH, Partial Pressure of Carbon Dioxide (pCO2), Partial Pressure of Oxygen (pO2), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate in heparinized capillary whole blood.
Acceptable Samples		
Sample Types	Sodium or lithium heparinized whole blood, serum, or plasma samples from syringes, open tubes, small cups, and capillary tubes.	Lithium heparin whole blood from syringes, open tubes, and capillary tubes.
Sample Volumes	60-200µL (dependent on panel selected)	135µL (Syringes and open tubes) 90µL (Capillary tubes)
Measurement Range		
pH	6.500 - 8.000	Same
PCO_2	3.0 – 200 mmHg	Same
PO_2	0 – 800 mmHg	5.0 – 765.0 mmHg
Hct	12% - 70%	Same
Glu	15 – 500 mg/dL	Same
Lac	0.3 – 20.0 mmol/L	Same
Sodium	80 – 200 mmol/L	Same
Potassium	1.0 – 20.0 mmol/L	Same
Chloride	50 – 200 mmol/L	Same
Ionized Calcium	0.1 – 2.7 mmol/L	Same
Ionized Magnesium	0.1 – 1.5 mmol/L	Same
Principles of Measurement		
pH	Hydrogen ion-selective glass sensor	Same
PCO2	Severinghaus-type sensor	Same
PO2	Polarographic Clark-type sensor	Same

Hct	Impedance sensor	Same
Glu	Enzymatic sensor	Same
Lac	Enzymatic sensor	Same
Sodium	Ion-Selective Electrode	Same
Potassium	Ion-Selective Electrode	Same
Chloride	Ion-Selective Electrode	Same
Ionized Calcium	Ion-Selective Electrode	Same
Ionized Magnesium	Ion-Selective Electrode	Same
Touch Screen	12.1" LCD, 1024x768 pixel, Resistive Touch	10.1” WXGA 1280 x 800 color touch screen
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

Conclusion

The performance of pH, Partial Pressure of Carbon Dioxide (pCO2), Partial Pressure of Oxygen (pO2), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate in heparinized capillary whole blood on the Stat Profile Prime Plus Analyzer System is substantially equivalent to the performance on the Stat Profile pHOx Ultra Analyzer.