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

## I Background Information:

### A 510(k) Number

K221900

### B Applicant

Nova Biomedical Corporation

### C Proprietary and Established Names

Stat Profile Prime Plus Analyzer System

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| CHL | Class II | 21 CFR 862.1120 - Blood Gases (PCO2, PO2) And Blood Ph Test System | CH - Clinical Chemistry |
| JPI | Class II | 21 CFR 864.6400 - Hematocrit measuring device | HE - Hematology |
| CGA | Class II | 21 CFR 862.1345 - Glucose test system | CH - Clinical Chemistry |
| KHP | Class I | 21 CFR 862.1450 - Lactic acid test system | CH - Clinical Chemistry |
| JGS | Class II | 21 CFR 862.1665 - Sodium test system | CH - Clinical Chemistry |
| CEM | Class II | 21 CFR 862.1600 - Potassium test system | CH - Clinical Chemistry |
| CGZ | Class II | 21 CFR 862.1170 - Chloride test system | CH - Clinical Chemistry |
| JFP | Class II | 21 CFR 862.1145 - Calcium test system | CH - Clinical Chemistry |

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| CFA | Class I, reserved | 21 CFR 862.1495 - Magnesium test system | CH - Clinical Chemistry |

## II Submission/Device Overview:

### A Purpose for Submission:

Addition of lithium heparinized capillary whole blood claims 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 on the Stat Profile Prime Plus Analyzer System using the capillary mode.

### B Measurand:

pH, Partial Pressure of Carbon Dioxide (pCO2), Partial Pressure of Oxygen (pO2), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate

### C Type of Test:

Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium - quantitative, potentiometric, ion selective electrode

pH and pCO2 - quantitative, potentiometry

pO2 - quantitative, amperometric technology

Hematocrit - quantitative, impedance sensor

Glucose and Lactate - quantitative, enzyme/amperometric

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for 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.

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).

### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
For clinical laboratory and point of care use.

### D Special Instrument Requirements:

Stat Profile® Prime Plus Analyzer

## IV Device/System Characteristics:

### A Device Description:

The Stat Profile Prime Plus Analyzer System is a small automatic blood gas analyzer for laboratory and point of care settings. It consists of the analyzer, sensor cartridges, calibrator packs, auto-cartridge quality control packs (internal controls), ampuled quality control materials (external controls) and thermal paper for an onboard printer. Specimens may be identified by scanning a barcode or by manually entering the information via the touchscreen.

The Stat Profile Prime Plus Analyzer was previously cleared for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of pH, pCO2, pO2, Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium,

Glucose, Lactate, Creatinine, Blood Urea Nitrogen, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood. Those claims have not changed. In this submission, the 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 is being added.

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. The reporting of CO-Oximeter parameters (or not reporting them) are determined by the selection of the Sensor Cards, for which there are two options:

• Primary Sensor Card 1 reports the following analytes: pO2, pCO2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO2, O2Hb, COHb, MetHb, HHb, tBil, HbF

• Primary Sensor Card 2 reports the following analytes: pO2, pCO2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO2

Auxiliary Sensor Card Port:
The reporting of Creatinine and BUN parameters (or not reporting them) is determined by the selection of the Auxiliary Sensor Card
• Auxiliary Sensor Card 1 enables Creatinine and BUN parameters
• Auxiliary Sensor Card 2 is a “dummy” sensor card and does not report any parameters.

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 to ensure the analyzer is working properly at all times. The Stat Profile Prime Plus Analyzer accepts samples from syringes, open blood collection tubes, and capillary tubes. The end user selects which analytes are to be tested from the test menu on the analyzer display screen.

## B Principle of Operation:

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.

pCO2 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.

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

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

Glucose measurement is based on the level of $H_2O_2$ produced during the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme. 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 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.

## C Instrument Description Information:

1. Instrument Name:

   Stat Profile Prime Plus Analyzer

2. Specimen Identification:

   Specimens may be identified by scanning a barcode or by manually entering the information via the touchscreen.

3. Specimen Sampling and Handling:

   Lithium heparin venous and arterial whole blood samples from syringes and open tubes can be used on the Stat Profile Prime Plus Analyzer. The minimum sample size for analysis when using a syringe or open blood collection tube is 135 µL. The minimum sample size for analysis when using a capillary tube is 90 µL.

4. Calibration:

The Stat Profile Prime Plus analyzer utilizes a replaceable internal Calibrator Cartridge to calibrate the Blood Gas, Electrolyte, Metabolite and CO-Ox sensors contained in the analyzer. Calibrations are initiated by the analyzer automatically but can also be started manually if necessary.

5. Quality Control:

The Stat Profile Prime Plus Blood Gas/CO-Oximeter Controls 1, 2, and 3 and Nova Prime Plus Chemistry Controls Levels 4, 5 are quality control material recommended for monitoring the performance of Stat Profile Prime Plus Analyzer.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
Nova Stat Profile pHOx Ultra Analyzer System

### B Predicate 510(k) Number(s):
K110648

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | K221900 | K110648 |
|---|---|---|
| Device Trade Name | Stat Profile Prime Plus Analyzer System | Nova Stat Profile pHOx Ultra Analyzer System |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | 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 | Same |
| Intended users | Healthcare professionals in clinical laboratory settings and for point-of-care usage | Same |
| Measuring Range | pH, 6.500 – 8.000<br>pO2, 5.0–765.0 mmHg | Same |

| | | |
|---|---|---|
| | pCO2, 3.0 –200 mmHg<br>Hct, 12% - 70%<br>Na, 80 – 200 mmol/L<br>K, 1.0 – 20.0 mmol/L<br>Cl, 50 – 200 mmol/L<br>iCa, 0.1 – 2.7 mmol/L<br>iMg, 0.1 – 1.5 mmol/L<br>Glu, 15 – 500 mg/dL<br>Lac, 0.3 – 20.0 mmol/L | |
| **General Device Characteristic Differences** | | |
| Sample types | Lithium heparinized arterial, venous and capillary whole blood. | Sodium or lithium heparinized whole blood, serum, or plasma samples from syringes, open tubes, small cups, and capillary tubes. |
| Sample Volumes | 135µL (Syringes and open tubes)<br>90µL (Capillary mode) | 60-200µL (dependent on panel selected) |

## VI Standards/Guidance Documents Referenced:

CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Methods; Third Edition, 2014.

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:
   Internal studies and one point-of -care (POC) external study were performed to assess precision of the Stat Profile Prime Plus analyzer for pH, pCO2, pO2, Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate.

   *i. Within-Run Precision*
   An internal study was conducted to assess within-run precision in capillary mode: 20 replicates of venous whole blood transferred to capillary tubes at 3 different targeted sample concentrations were run on two Prime Plus Analyzers using a different cartridge lot on each analyzer. The average SD and CV% for each analyzer for each sample type and level was calculated. The results are shown below.

| Prime Plus Capillary Mode | | | | |
|---|---|---|---|---|
| Whole Blood Within Run Precision | | | | |
| Analyte | 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 |
| pCO2, mmHg | Mean | 25.0 | 24.7 | 24.8 |
| | SD | 0.6 | 0.5 | 0.6 |
| | CV% | 2.4 | 1.9 | 2.2 |
| pCO2, mmHg | Mean | 54.8 | 59.6 | 57.2 |
| | SD | 1.1 | 0.8 | 2.6 |
| | CV% | 2.0 | 1.3 | 4.5 |
| pCO2, mmHg | Mean | 70.2 | 73.7 | 72.0 |
| | SD | 1.8 | 1.3 | 2.4 |
| | CV% | 2.6 | 1.8 | 3.3 |
| pO2, mmHg | Mean | 54.3 | 56.0 | 55.2 |
| | SD | 0.7 | 0.6 | 1.1 |
| | CV% | 1.3 | 1.0 | 2.0 |
| pO2, mmHg | Mean | 178.4 | 174.3 | 176.4 |
| | SD | 1.8 | 1.6 | 2.7 |
| | CV% | 1.0 | 0.9 | 1.5 |
| pO2, mmHg | Mean | 95.0 | 100.7 | 97.9 |
| | SD | 1.7 | 1.5 | 3.3 |
| | CV% | 1.7 | 1.5 | 3.4 |
| 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 |
| | 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 |

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

| Prime Plus Capillary Mode | | | | |
|---|---|---|---|---|
| Whole Blood Within Run Precision | | | | |
| Analyte | n = 20 | Analyzer 1 | Analyzer 2 | Between Analyzer |
| | 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 |

ii. *Repeatability and within lab precision with whole blood using capillary mode*
To assess within run precision, an internal precision study was performed 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 (replicates) measured per run per level. The average concentration, average SD, and %CV was calculated for each individual analyzer and is summarized below.

| Analyte | Level | Mean | N | Between Instrument/ Lot | |
|---|---|---|---|---|---|
| | | | | SD | %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 |

| Analyte | Level | Mean | N | Between Instrument/ Lot | |
|---|---|---|---|---|---|
| | | | | SD | %CV |
| | 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 (mmol/L) | 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 |
| K (mmol/L) | 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 (mmol/L) | 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 |
| iCa (mmol/L) | 1 | 0.95 | 120 | 0.01 | 1.4 |
| | 2 | 1.5 | 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 |
| iMg (mmol/L) | 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 (mmol/L) | 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 |

*iii. Within Sample Precision - Capillary Mode Fingerstick*

To assess sample within run precision in capillary mode, an internal study was conducted using capillary whole blood collected from 30 donors via finger stick puncture from two (2) fingers into 2 balanced heparin capillary tubes per donor. Blood from each capillary pair was analyzed in singlet in capillary mode on one Prime Plus Analyzer and the results compared. The results are summarized below:

| Analyte | N | Mean | Range Min | Range Max | Within Sample (SD) | Within Sample (%CV) |
|---|---|---|---|---|---|---|
| pH | 60 | 7.322 | 7.166 | 7.472 | 0.003 | N/A |
| pO2 (mmHg) | 60 | 127.9 | 33.0 | 225.4 | 0.8 | 0.6 |
| pCO2 (mmHg) | 60 | 31.0 | 18.0 | 51.8 | 0.7 | 2.1 |
| Hct (%) | 60 | 32 | 17 | 50 | 0.4 | N/A |
| Na (mmol/L) | 60 | 137.9 | 133.6 | 142.9 | 0.1 | 0.1 |
| K (mmol/L) | 60 | 4.03 | 3.07 | 5.12 | 0.01 | 0.21 |
| Cl (mmol/L) | 60 | 109.5 | 101.9 | 114.3 | 0.5 | 0.5 |
| iCa (mmol/L) | 60 | 1.11 | 0.98 | 1.22 | 0.00 | 0.44 |
| iMg (mmol/L) | 60 | 0.63 | 0.35 | 1.11 | 0.01 | 1.58 |
| Glu (mmol/L) | 60 | 108 | 62 | 240 | 0.5 | 0.5 |
| Lac (mmol/L) | 60 | 4.1 | 2.7 | 8.0 | 0.0 | 0.6 |

*iv. Within-Sample Imprecision - Capillary Mode Fingerstick (internal POC)*

To assess within-sample imprecision, an internal capillary precision study was performed. Capillary whole blood was collected from thirty (30) consenting subjects via finger stick puncture into two (2) capillary tubes per donor and each pair was run on a single Stat Profile Prime Plus Analyzer by two (2) point-of-care (POC) operators. The results are summarized below:

| Analyte | N | Mean | Range Min | Range Max | Within Sample (SD) | Within Sample (%CV) |
|---|---|---|---|---|---|---|
| pH | 60 | 7.403 | 7.343 | 7.457 | 0.008 | N/A |
| pO2 (mmHg) | 60 | 81.8 | 67.1 | 98.5 | 2.2 | 2.7 |
| pCO2 (mmHg) | 60 | 32.0 | 26.8 | 38.3 | 1.0 | 3.0 |
| Hct (%) | 60 | 41 | 29 | 49 | 1.0 | N/A |
| Na (mmol/L) | 60 | 139.5 | 134.2 | 143.8 | 0.8 | 0.6 |
| K (mmol/L) | 60 | 4.75 | 3.87 | 5.89 | 0.17 | 3.5 |
| Cl (mmol/L) | 60 | 109.9 | 103.6 | 113.7 | 0.6 | 0.6 |
| iCa (mmol/L) | 60 | 1.20 | 1.14 | 1.36 | 0.01 | 0.9 |
| iMg (mmol/L) | 60 | 0.54 | 0.43 | 0.64 | 0.01 | 1.1 |
| Glu (mmol/L) | 60 | 109 | 78 | 225 | 1.6 | 1.5 |
| Lac (mmol/L) | 60 | 1.7 | 0.7 | 5.1 | 0.2 | 12.4 |

*v. Within-Run Imprecision - Capillary Mode (External POC):*

To assess within-run imprecision, a POC precision study was performed at an external hospital site on a single Stat Profile Prime Plus Analyzer. Each of twenty-nine (29) de-

identified and discarded whole blood specimens were transferred from a lithium heparin syringe to three capillary tubes by POC operators and tested in triplicate across five (5) days by one of twenty-seven (27) different POC operators. The results are summarized below:

| Analyte | Mean (GRAND) | Range Min | Range Max | SD (GRAND) | CV% (GRAND) |
|---|---|---|---|---|---|
| pH | 7.357 | 7.029 | 7.512 | 0.008 | N/A |
| pO2(mmHg) | 145.6 | 56.5 | 249.0 | 2.1 | 1.5 |
| pCO2 (mmHg) | 37.2 | 22.6 | 58.3 | 0.7 | 1.9 |
| Hct (%) | 31.5 | 14 | 54 | 1.2 | N/A |
| Na (mmol/L) | 135.1 | 123.7 | 147.0 | 0.8 | 0.6 |
| K (mmol/L) | 3.94 | 3.32 | 5.68 | 0.04 | 0.9 |
| Cl (mmol/L) | 110.1 | 97.1 | 118.5 | 0.8 | 0.8 |
| iCa (mmol/L) | 1.14 | 0.9 | 1.29 | 0.01 | 1.2 |
| iMg (mmol/L) | 0.51 | 0.27 | 0.75 | 0.01 | 2.5 |
| Glu (mmol/L) | 128 | 35 | 330 | 1.8 | 1.4 |
| Lac (mmol/L) | 3.1 | 0.3 | 13.9 | 0.1 | 4.6 |

2. Linearity:

   Previously established in K173797, K180186, K180340, K180428 and K200349.

3. Analytical Specificity/Interference:

   Previously established in K173797, K180186, K180340, K180428 and K200349.

4. Assay Reportable Range:

   Previously established in K173797, K180186, K180340, K180428 and K200349.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Previously established in K173797, K180186, K180340, K180428 and K200349.

6. Detection Limit:

   Previously established in K173797, K180186, K180340, K180428 and K200349.

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   Refer to Section B1 Method Comparison Study

9. Carry-Over:

Not applicable

## B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study for capillary whole blood was performed at two external POC sites with 5 POC operators at site 1 and 4 POC operators at site 2 over a minimum of 20 days. Capillary blood samples were collected via finger-stick and analyzed in singlet on the Stat Profile Prime Plus in capillary mode and on the Stat Profile pHOx Ultra in capillary mode. Stat Profile Prime Plus test results were compared to the Stat Profile pHOx Ultra test results for each parameter. To span the reportable range for each analyte, <10% of total samples were contrived, transferred into capillary tubes and run in singlicate on the Stat Profile Prime Plus and Stat Profile pHOx Ultra. A least squares linear regression analysis of the samples was performed for contrived and native sample combined and native samples only. The results from both sites were similar and combined results are shown below for native and contrived samples.

**Combined Sites** (native and contrived samples)

| Analyte | N | Altered Samples | Slope | Intercept | r | Sample range |
|---|---|---|---|---|---|---|
| pH | 249 | 18 | 0.989 | 0.074 | 0.994 | 6.790-7.729 |
| pO2, (mmHg) | 251 | 20 | 1.001 | 0.832 | 0.998 | 7.5-567.1 |
| pCO2, (mmHg) | 245 | 14 | 1.008 | -0.597 | 0.997 | 7.4-183.1 |
| Hct, (%) | 243 | 12 | 1.003 | 0.256 | 0.999 | 12-55 |
| Na+(mmol/L) | 243 | 12 | 1.013 | -2.224 | 0.989 | 83.0-195.6 |
| K+ (mmol/L) | 245 | 14 | 0.994 | 0.042 | 0.999 | 1.34-18.53 |
| Cl- (mmol/L) | 243 | 12 | 0.994 | 0.349 | 0.986 | 64.5-191.6 |
| iCa (mmol/L) | 247 | 16 | 0.990 | 0.016 | 0.993 | 0.37-2.46 |
| iMg (mmol/L) | 249 | 18 | 0.966 | 0.021 | 0.981 | 0.13-1.22 |
| Glucose (mg/dL) | 245 | 14 | 0.995 | 0.904 | 0.997 | 28-452 |
| Lactate (mmol/L) | 243 | 12 | 1.000 | 0.012 | 0.999 | 0.4-17.6 |

The performance of native samples was reviewed and demonstrates substantial equivalence based on regression analyses and bias observed at medical decision levels.

2. Matrix Comparison:

For use with lithium heparinized whole blood only.

**C Clinical Studies:**

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

**D Clinical Cut-Off:**

Not applicable

**E Expected Values/Reference Range:**

Previously established in K173797, K180186, K180340, K180428 and K200349.

**F Other Supportive Instrument Performance Characteristics Data:**

Not applicable

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

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