510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k180340

B. Purpose for Submission:

New device

C. Measurand:

Glucose, blood urea nitrogen, creatinine

D. Type of Test:

Glucose and Creatinine - quantitative, enzyme/amperometric

BUN - quantitative, enzymatic potentiometric

E. Applicant:

Nova Biomedical Corporation

F. Proprietary and Established Names:

Stat Profile® Prime Plus Analyzer System

G. Regulatory Information:

Regulation section	Classification	Product code	Panel
21CFR§862.1345 Glucose test system	Class II	CGA	Chemistry (75)
21CFR§862.1770 Urea nitrogen test system		CDS	
21CFR§862.1225 Creatinine test system		CGL	

H. Intended Use:

1. Intended use(s):

   See Indication(s) for Use below

2. Indication(s) 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.

   Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell tumor.

   Creatinine measurements are used in the diagnosis and treatment of certain renal conditions and for monitoring adequacy of dialysis.

   Blood urea nitrogen (BUN) measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

3. Special conditions for use statement(s):

   Not for point-of-care use.

4. Special instrument requirements:

   Stat Profile® Prime Plus Analyzer

I. Device Description:

The Stat Profile® Prime Plus Analyzer System 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. 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. The reporting of CO-Oximeter parameters (or not reporting them) will also be determined by the selection of the Sensor Cards:
Primary Sensor Card Port: There are two options for the primary sensor card:

- Primary Sensor Card 1 shall enable and report glucose in addition to other select analytes.
- Primary Sensor Card 2 shall enable and report glucose in addition to other select analytes.

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 will not report any parameters.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Stat Profile pHOx Ultra Analyzer System

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

   k110648

3. Comparison with predicate:

Item	Candidate Device Stat Profile PRIME Plus Analyzer System (k180340)	Predicate Device Stat Profile pHOx Ultra Analyzer System (k110648)
Indications for Use	For the quantitative determination of glucose, creatinine and blood urea nitrogen, in heparinized arterial and venous whole blood.	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 with amperometric and potentiometric amplifiers, air detector circuitry and temperature control circuitry.	Same
Measuring Principle	Glucose - Enzyme sensor	Same
	BUN - Enzyme sensor	Same
	Creatinine - Impedance sensor	Same
Measuring Range	Glucose, 15.0 – 500.0 mg/dL	Same
	BUN, 3.0 – 100.0 mg/dL	Same
	Creatinine, 0.2 – 12.0 mg/dL	0.2 – 20.0 mg/dL

Item	Candidate Device Stat Profile PRIME Plus Analyzer System (k180340)	Predicate Device Stat Profile pHOx Ultra Analyzer System (k110648)
Sample Types	Lithium heparin arterial and venous whole blood from syringes, open tubes, and small cups.	Sodium or lithium heparinized whole blood, serum, or plasma samples from syringes, open tubes, small cups, and capillary tubes.
Sample Volume	135µL	60-200µL (dependent on panel selected)
Touch Screen	10.1" WXGA 1280 x 800 color touch screen	12.1" LCD, 1024x768 pixel, Resistive Touch

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

Not applicable.

L. Test Principle:

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.

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.

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 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 Creatinine concentration of the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-Run Precision:

Within-run precision testing was performed using quality control (QC) and whole blood samples from syringe analyzed in one run, with 20 replicates per run on one day. Samples were run on three analyzers. The results of one representative analyzer are shown below:

Within-run precision results using internal QC samples:

Parameter	n = 20	Internal Control Level 1	Internal Control Level 2
Glucose (mg/dL)	Mean SD CV%	86 0.6 0.7	297 3.7 1.2
BUN (mg/dL)	Mean SD CV%	16.5 0.1 0.4	47.5 0.2 0.4
Creatinine (mg/dL)	Mean SD CV%	0.8 0.0 1.3	6.7 0.2 2.3

Within-run precision results using external QC samples:

Parameter	n = 20	External Control Level 1	External Control Level 2
Glucose (mg/dL)	Mean SD CV%	77 1.1 1.4	313 2.9 0.9
BUN (mg/dL)	Mean SD CV%	16.0 0.5 2.9	51.2 0.3 0.6
Creatinine (mg/dL)	Mean SD CV%	1.1 0.1 5.6	7.4 0.0 0.6

Within-run precision results using whole blood samples:

Glucose (mg/dL) (n=20)			
Sample	**Mean**	**SD**	**%CV**
Sample 1	16	0.7	4.4
Sample 2	72	1.8	2.5
Sample 3	110	2.0	1.9
Sample 4	159	4.7	2.9
Sample 5	188	5.0	2.6
Sample 6	360	10.8	3.0

BUN (mg/dL) (n=20)			
Sample	**Mean**	**SD**	**%CV**
Sample 1	11	0.1	0.7
Sample 2	14.8	0.3	2.3
Sample 3	20.4	0.5	2.3
Sample 4	24.8	0.4	1.5
Sample 5	75.2	0.9	1.2

Creatinine (mg/dL) (n=20)			
Sample	**Mean**	**SD**	**%CV**
Sample 1	0.4	0.04	11.8
Sample 2	0.5	0.0	9.2
Sample 3	0.7	0.1	17.8
Sample 4	3.4	0.08	2.2
Sample 5	9.2	0.16	1.8

Run-to-Run Precision:
To assess run-to-run precision using QC samples, each sample was tested in duplicate per run, 2 runs per day, 3 analyzers performed over 20 days. The summary results for the three analyte test systems are shown below:

Run-to-Run precision using internal QC samples:

Glucose (mg/dL)						
Sample	Pooled Mean	N	Within run SD	Within run % CV	Total imprecision SD	Total imprecision % CV
QC 1	87	240	0.8	0.9		0.2
QC 2	116.5	240	0.2	0.2	0.3	0.3

BUN (mg/dL)						
Sample	Pooled Mean	N	Within run SD	Within run % CV	Total imprecision SD	Total imprecision % CV
QC 1	16.8	240	0.1	0.4	0.5	2.7
QC 2	48.7	240	0.4	0.7	1.7	3.6

Creatinine (mg/dL)						
Sample	Pooled Mean	N	Within run SD	Within run % CV	Total imprecision SD	Total imprecision % CV
QC 1	0.8	240	0.0	1.2	0.0	4.9
QC 2	6.7	240	0.1	0.9	0.3	4.9

Run-to-Run imprecision using whole blood samples:

To assess run-to-run precision using whole blood, triplicate analyses were performed on a single whole blood sample in ten separate runs during a single day. The systems were recalibrated before each triplicate run. Samples were analyzed on three analyzers. Representative summary results from one analyzer for the three analyte test systems are shown below:

Parameter	n = 30	Venous Blood 1	Venous Blood 2	Venous Blood 3	Venous Blood 4	Venous Blood 5
Glucose (mg/dL)	Mean	26	79	103	207	378
	SD	1.5	2.6	2.7	5.1	8.9
	CV%	5.7	3.3	2.7	2.5	2.4
BUN (mg/dL)	Mean	3.9	11.7	25	73.2	
	SD	0.1	0.3	0.3	1.3	n/a
	CV%	2.0	2.1	1.1	1.8	
Creatinine (mg/dL)	Mean	0.3	0.5	1.3	9.2	
	SD	0.06	0.0	0.12	0.34	n/a
	CV%	18.2	4.4	9.0	3.7	

b. Linearity/assay reportable range:

Linearity studies on the Stat Profile® Prime Plus analyzer were conducted to establish and verify the analytical measurement range for each test system. The studies were performed on three analyzers using Li-heparinized venous whole blood for Glucose, BUN and creatinine. Low and high concentration pools were mixed and serial dilution samples (N=10 or 11) were prepared and tested in triplicate. The results from each candidate analyzer for each parameter were compared to the average duplicate results from the comparative method on the Stat Profile pHOx Ultra analyzer. All three analyzers yielded similar results. The results of the least squares linear regression analysis from one representative analyzer are summarized below.

Analyte	Claimed measurement range	Concentration range tested	Slope	Intercept	r
Glucose (mg/dL)	15.0 – 500.0	2.0 – 519.0	1.0292	-3.8879	0.9988
BUN (mg/dL)	3.0 – 100.0	1.2 – 110.5	1.0173	-2.3235	0.9971
Creatinine (mg/dL)	0.2 – 12.0	0.1 – 12.5	1.0356	-0.0497	0.9985

The results of the linearity study support the claimed measuring ranges as described in the table above.

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

The traceability of the parameters measured by Stat Profile Prime Plus Analyzer are traceable to NIST reference standards. These are listed below:

Creatinine Test: It is traceable to NIST SRM 967a creatinine.

BUN Test: It is traceable to NIST SRM 912a urea.

Glucose Test: It is traceable to NIST SRM 917a D-glucose.

d. *Detection limit:*

The sponsor performed a study to evaluate the limit of blank (LoB), limit of detection (LoD) and limit of quantification (LoQ) for glucose, BUN and creatinine using altered whole blood samples. Study samples were prepared from heparinized venous whole blood samples. All prepared samples were measured on the reference analyzer to confirm target values.

Results from the detection limit study are summarized below:

Analyte (mg/dL)	**LoB**	**LoD**	**TE**	**LoQ**	**Acceptance Criteria for TE (</=)**	**Claimed Measurement Range**
Glucose	4.0	5.0	3.0	12.0	6.0	15.0 - 500
BUN	0.5	0.7	1.2	2.4	1.3	3.0 – 100.0
Creatinine	0.09	0.11	0.08	0.12	0.56	0.2 - 12.0

Refer to the linearity study section M.2.b. above for measuring range claims for glucose, BUN and creatinine.

e. *Analytical specificity:*

An interference study was performed using whole blood collected in lithium heparin vacutainers. The potential interfering substances were tested at two analyte concentrations. If interference was identified, then a dose response study was performed to determine the concentration where the interfering substance may alter the results.

The sponsor defined interference as a specified bias or %bias from the test concentration as shown in the following table.

Analyte	Interference Bias Specification
Glucose	± 10.0 %
BUN	± 10.0 %
Creatinine	± 0.2 mg/dL or ± 10.0 % *

* difference or percent, whichever is greater.

The sponsor determined that the following substances did not cause interference at the concentrations listed below:

Glucose

Substance	Highest concentration tested that did not cause significant interference
Acetaminophen	20 mg/dL
Acetoacetate	2 mmol/L
N-acetylcysteine	10.2 mmol/L
Acetylsalicylic Acid	3.62 mmol/L
Ammonium Chloride	107 µmol/L
Ascorbic Acid	50 mg/dL
Benzalkonium Chloride	10 mg/L
Bilirubin	342 µmol/L
Dobutamine	2 mg/dL
Dopamine Hydrochloride	5.87 µmol/L
EDTA	3 mmol/L
Ethanol	86.8 mmol/L
Fluoride	105 µmol /L
D-Galactose	1 mmol/L
Glucosamine	30 µmol/L
Glutathione	3 mmol/L
Glycolic Acid	1 mmol/L
Hemoglobin	2 g/L
Sodium Heparin	100 IU/mL
β-Hydroxybutyrate	2 mmol/L
Hydroxyurea	0.2 mg/dL

Substance	Highest concentration tested that did not cause significant interference
Ibuprofen	2.4 mmol/L
Intralipid	1.0%
Lithium Lactate	6.6 mmol/L
Lactic Acid	12 mmol/L
Maltose	13 mmol/L
Mannose	1 mmol/L
Pyruvate	309 µmol/L
Salicylic Acid	4.34 mmol/L
Sodium Citrate	12 mmol/L
Sodium Oxalate	125 mg/dL
Thiocyanate	3.4 mmol/L
Urea	43 mmol/L
Uric Acid	1.4 mmol/L
Xylose	25 mg/dL

BUN

Substance	Highest concentration tested that did not cause significant interference
Acetaminophen	20 mg/dL
Acetoacetate	2 mmol/L
Acetylsalicylic Acid	3.62 mmol/L
Ammonium Chloride	107 µmol/L
Ascorbic Acid	50 mg/dL
N-acetylcysteine	10.2 mmol/L
Benzalkonium Chloride	10 mg/L
Bilirubin	342 µmol/L
Chlorpromazine HCl	0.2 mmol/L
Sodium Citrate	12 mmol/L
Creatine	5 mg/dL
Dopamine Hydrochloride	5.87 µmol/L
EDTA	3 mmol/L
Ethanol	86.8 mmol/L
Glucose	1000 mg/dL
Glutathione	3 mmol/L
Glycolic Acid	1 mmol/L
Sodium Heparin	100 IU/mL
High Hct	63%
β-Hydroxybutyrate	2 mmol/L
Hydroxyurea	0.8 mg/dL
Ibuprofen	2.4 mmol/L
Intralipid	1.0%
Lactic Acid	12 mmol/L

Substance	Highest concentration tested that did not cause significant interference
Low Hct	22%
Low pH	6.8
Nithiodote	5.12 g/dL
Paracentamol-4-acetamidopenol	2 mmol/L
Pyruvate	309 µmol/L
Salicylic Acid	4.34 mmol/L
Thiocyanate	6.8 mmol/L
Uric Acid	1.4 mmol/L

Creatinine

Substance	Highest concentration tested that did not cause significant interference
Acetaminophen	20 mg/dL
Acetoacetate	2 mmol/L
Acetylsalicylic Acid	3.62 mmol/L
Ascorbic Acid	50 mg/dL
N-acetylcysteine	10.2 mmol/L
Bilirubin	342 µmol/L
Sodium Bromide	37.5 mmol/L
Chlorpromazine HCl	0.2 mmol/L
Sodium Citrate	12 mmol/L
Creatine	5 mg/dL
Dopamine Hydrochloride	5.87 µmol/L
EDTA	3 mmol/L
Ethanol	86.8 mmol/L
Fluoride	105 µmol/L
Glucose	1000 mg/dL
Glycolic Acid	1 mmol/L
Sodium Heparin	100 IU/mL
High Hct	64%
High Protein	60 g/L
β-Hydroxybutyrate	2 mmol/L
Hydroxyurea	0.06 mg/dL
Ibuprofen	2.4 mmol/L
Intralipid	1.0%
Sodium Iodide	2.99 mmol/L
Lithium Lactate	6.6 mmol/L
Lactic Acid	12 mmol/L
Low Hct	26%
Low pH	6.8
Paracentamol-4-	2 mmol/L

Substance	Highest concentration tested that did not cause significant interference
acetamidopenol	
Proline	0.5 mmol/L
Pyruvate	309 µmol/L
Salicylic Acid	4.34 mmol/L
Thiocyanate	1.7 mmol/L
Urea	43 mmol/L
Uric Acid	1.4 mmol/L

The sponsor lists the following interferents in the labeling:

Parameter	Interferent	Interference Observed at Concentrations Above:
Glucose	Hydroxyurea	0.2 mg/dL
	Oxalate	125 mg/dL
	Thiocyanate	3.4 mmol/L
Creatinine	Hydroxyurea	0.06 mg/dL
	Thiocyanate	1.7 mmol/L

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A minimum of 200 lithium heparinized arterial and venous whole blood specimens from hospital patients were analyzed in syringe format in singlet on three Stat Profile® Prime Plus analyzers and two pHOx Ultra analyzers for each parameter. In order to cover the hard to find sample range, venous whole blood specimens from consenting donors were spiked or diluted to cover the analytical measurement ranges for all three analytes, glucose, BUN and creatinine. The singlet result from each test analyzer was compared to the average of the results from each comparative method. Representative summary result from one analyzer for the three analyte tests are listed in the below table.

Analyte	N	Sample concentration range	Slope	Intercept	r
Glucose (mg/dL)	224	23 – 479	0.9860	2.1406	0.9932
BUN (mg/dL)	209	2.0 – 98.0	0.9993	0.2195	0.9968
Creatinine (mg/dL)	216	0.4 – 11.0	0.9643	0.0222	0.9888

b. Matrix comparison:

Not applicable. For use with lithium heparinized whole blood only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Reference ranges for glucose, BUN and creatinine are cited from the literature.

Glucose: 65 – 95 mg/dL
BUN: 7 – 18 mg/dL
Creatinine: Female: 0.6 – 1.1 mg/dL and Male: 0.7 – 1.3 mg/dL

References cited:

Statland, Bernard, "Clinical Decision Levels for Lab Tests," Medical Economics Books, 1987.

Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry*, W. B. Saunders Co. Philadelphia, PA.

Tietz, Norbert W., ed. 1983. *Clinical Guide to Laboratory Tests*, W. B. Saunders Co., Philadelphia, PA.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

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