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

A. 510(k) Number:

k183546

B. Purpose for Submission:

New Device

C. Measurand:

Glucose, Lactate, Hematocrit, pH, pCO2

D. Type of Test:

Quantitative, potentiometry for pH, and pCO2

Quantitative, amperometry for glucose and lactate

Quantitative, electrical conductivity for hematocrit

E. Applicant:

Instrumentation Laboratory Co.

F. Proprietary and Established Names:

GEM Premier ChemSTAT

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CGA	Class II	862.1345 Glucose Test system	Chemistry (75)
KHP	Class I	862.1450 Lactic acid test system	Chemistry (75)
GKF	Class II	864.5660 Automated hematocrit instrument	Hematology (81)
CHL	Class II	862.1120 Blood Gases (pCO_2) and Blood pH system	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use.

2. Indication(s) for use:

   The GEM Premier ChemSTAT is a portable critical care system for use by health care professionals to rapidly analyze lithium heparinized whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of Glucose (Glu), Lactate (Lac), Hematocrit (Hct), pH and partial pressure of carbon dioxide (pCO2) from arterial and venous heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status and metabolite balance.

   - Glucose (Glu) measurement is used in the diagnosis, monitoring and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

   - Lactate (Lac) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis, to monitor tissue hypoxia and strenuous physical exertion, and in the diagnosis of hyperlactatemia.

   - Hematocrit (Hct) measurements in whole blood of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

   - pH and pCO2 measurements in whole blood are used in the diagnosis and treatment of life-threatening acid-base disturbances.

3. Special conditions for use statement(s):

   For prescription use only at point-of-care and central laboratory settings.

4. Special instrument requirements:

   GEM Premier ChemSTAT analyzer

I. Device Description:

The GEM Premier ChemSTAT system is a prescription-use-only, portable system used by health care professionals to analyze arterial and venous lithium heparinized whole blood samples at point-of-care or a central laboratory. The GEM Premier ChemSTAT system contains 2 key components: GEM Premier ChemSTAT analyzer and a disposable, multiuse GEM Premier ChemSTAT PAK Cartridge/PAK (GEM PAK).

The GEM Premier ChemSTAT analyzer has the internal logic and processing power necessary to perform analysis. It employs a touch-sensitive color screen and a set of menus and buttons for user interaction.

The GEM Premier ChemSTAT PAK (or GEM PAK) is a disposable, multi-use PAK that houses all components necessary to operate the instrument. These components include the sensors, solutions, sampler, and waste bag. The GEM PAK enables analysis of 75 to 450 samples.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   GEM Premier 4000

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

   k133407

3. Comparison with predicate:

Similarities		
Item	Candidate Device GEM Premier ChemSTAT (k183546)	Predicate Device GEM Premier 4000 (k133407)
Intended Use	Quantitative measurement of glucose, lactate, hematocrit, pH and pCO_2 in arterial and venous heparinized whole blood.	Same
Intended User	Central Laboratory and Point-of-Care professionals.	Same
Measurement Principle	Amperometry (Glucose and Lactate) Potentiometry (pH and pCO2) Conductivity (Hematocrit)	Same
Measuring Range Glucose	4-685 mg/dL	Same
Measuring Range lactate	0.3 -17.0 mmol/L	Same
Measuring Range pH	7 -8.00	Same
Measuring Range Hematocrit	15 – 72%	Same
Measuring Range pCO2	6 -125 mmHg	Same
Calibration	2-point calibration	Same

Differences		
Item	Candidate Device GEM Premier ChemSTAT (k183546)	Predicate Device GEM Premier 4000 (k133407)
Sample Volume	65 to 150 µL	150 µL
Sample Type	Lithium heparinized whole blood (arterial and venous)	Lithium heparinized whole blood (arterial, venous and capillary)

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

- CLSI EP05-A3. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline, 3rd Edition.
- CLSI EP06-A. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.
- CLSI EP07. Interference Testing in Clinical Chemistry; Approved Guideline, 3rd Edition.
- CLSI EP17-A2. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, 2nd Edition.
- CLSI EP25-A. Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.
- CLSI EP37 Supplemental Tables for Interference Testing in Clinical Chemistry, 1st Edition.

L. Test Principle:

Glucose and Lactate

The Glucose and Lactate sensors are amperometric biosensors consisting of a platinum electrode operated at a positive potential with respect to the card reference electrode. Glu or Lac determination is accomplished by enzymatic reaction of Glu or Lac with oxygen in the presence of glucose oxidase or lactate oxidase and the electrochemical oxidation of the resulting hydrogen peroxide (H_2O_2) at the platinum electrode. The current flow between the platinum electrode and the ground electrode is proportional to the rate at which H2O2 molecules diffuse to the platinum and are oxidized, which in turn is directly proportional to the metabolite (Glu or Lac) concentration.

Hematocrit
Hct is measured by an electrical conductivity technique. The conductivity technique is based on the principle that because plasma is more conductive than blood cells due to the high resistance of the cell membranes, the resistivity of blood will increase as the concentration of cells increases.

pH
The pH sensors are based on the principle of ion selective electrodes in which electrical potential can be established across a membrane resulting from chemical selectivity of the membrane to a specific ion. The potential can be described by this simplified form of the Nernst equation E=E' +(S x Log C), where E is the electrode potential, E' is the standard potential for that membrane, S is the sensitivity (slope), and C is the ion activity. E' and S can be determined by the sensor response to the Process Control (PC) Solutions, and the equation can be solved for the activity of the ion of interest.

pCO2
The pCO2 sensor is a patented design that relies on generated potential of the bicarbonate sensor versus the pH sensor. The potential difference between the two sensors is related to the logarithm of pCO2 content in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

i. Internal Precision Study – Whole Blood
An internal precision study was performed at an internal site using 5 whole blood samples with different concentrations of analytes for Glucose, Lactate, pH, pCO_2, and Hematocrit. Testing was performed on 3 different GEM Premier ChemSTAT analyzers with 3 cartridges for 5 days, with 1 run per day and 8 replicates measured per run per level for a total of 120 data sets per sample.
The results are summarized in the table below:

Analyte	Level	Mean	Within Run		Between Analyzer		Total Imprecision	
			SD	%CV	SD	%CV	SD	%CV
Glucose (mg/dL)	1	24	0.5	2.3	0.0	0.0	0.5	2.3
	2	48	0.9	1.9	0.3	0.7	0.9	2.0
	3	122	1.3	1.1	1.0	0.8	1.7	1.4
	4	356	2.7	0.8	1.6	0.4	3.2	0.9
	5	620	3.2	0.5	4.3	0.7	5.4	0.9
Lactate (mmol/L)	1	0.7	0.06	8.9	0.00	0.0	0.06	8.9
	2	2.0	0.06	2.8	0.04	1.9	0.07	3.3
	3	4.9	0.05	1.1	0.10	2.1	0.11	2.3
	4	7.8	0.13	1.7	0.13	1.6	0.18	2.3
	5	14.2	0.23	1.6	0.25	1.8	0.34	2.4
Hct (%)	1	18	0.3	1.6	0.1	0.8	0.3	1.8
	2	33	0.3	0.9	0.2	0.7	0.4	1.1
	3	44	0.3	0.7	0.2	0.5	0.4	0.9
	4	57	0.3	0.5	0.2	0.4	0.4	0.7
	5	65	0.4	0.7	0.3	0.5	0.5	0.8

Analyte	Level	Mean	Within Run		Between Analyzer		Total Imprecision	
			SD	%CV	SD	%CV	SD	%CV
pH	1	7.07	0.008	0.1	0.000	0.0	0.008	0.1
	2	7.25	0.007	0.1	0.000	0.0	0.007	0.1
	3	7.34	0.008	0.1	0.002	0.0	0.008	0.1
	4	7.49	0.009	0.1	0.003	0.0	0.010	0.1
	5	7.69	0.010	0.1	0.008	0.1	0.013	0.2
pCO_2 (mmHg)	1	110	1.4	1.3	0.0	0.0	1.4	1.3
	2	71	0.9	1.2	0.0	0.0	0.9	1.2
	3	51	0.7	1.4	0.0	0.0	0.7	1.4
	4	29	0.4	1.5	0.1	0.2	0.5	1.6
	5	12	0.6	4.8	0.0	0.0	0.6	4.8

ii. External Reproducibility Study with Aqueous Controls -Point-of-Care Setting:

An external reproducibility study was performed in 3 clinical point of care sites using aqueous control solutions. Testing was performed by 9 different operators on six different GEM Premier ChemSTAT analyzers, using a single lot of GEM Premier CHEMSTAT PAK's cartridges. Each site tested quality control materials for each analyte with two levels of GEM ChemSTAT CVP and 4 to 5 levels of GEM ChemSTAT PVP. Each control was tested in triplicate, twice a day for five days for a total of 30 replicates per level with n= 90 data sets across all three sites per analyte per control level. Individual POC site statistics were analyzed by two-way nested ANOVA with factors day and run nested within day. Multisite statistics were determined via three-way nested ANOVA with the factors being site, day and nested within site and run nested within site and day.

The results are summarized in the table below for all 3 sites POC sites.

Glucose (mg/dL)									
Control Level	Mean	Repeatability		Between Day		Between Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
CVP 1	392	1.0	0.2	0.7	0.2	4.3	1,1	5.9	1.5
CVP 2	78	1.5	1.9	0.6	0.8	0.0	0.0	1.6	2.1
PVP 1	642	1.3	0.2	1.1	0.2	6.5	1.0	6.8	1.1
PVP 2	393	1.6	0.4	1.3	0.3	3.3	0.8	4.2	1.1
PVP 3	115	1.4	1.2	0.0	0.0	0.0	0.0	1.5	1.3
PVP 4	80	0.6	0.7	0.5	0.6	0.3	0.3	0.9	1.1
PVP 5	14	0.5	3.6	0.2	1.6	1.4	9.7	1.5	10.5

Lactate (mmol/L)									
Control Level	Mean	Repeatability		Between Day		Between Site		Reproducibility	
CVP 1	8.2	0.04	0.5	0.02	0.3	0.03	0.3	0.07	0.8
CVP 2	1.7	0.03	1.8	0.01	0.7	0.04	2.4	0.05	3.1
PVP 1	15.7	0.07	0.4	0.07	0.5	0.09	0.6	0.15	0.9
PVP 2	8.1	0.06	0.7	0.04	0.4	0.07	0.9	0.11	1.3
PVP 3	5.0	0.03	0.6	0.04	0.8	0.03	0.6	0.6	1.2
PVP 4	1.7	0.03	1.5	0.01	0.6	0.01	0.9	0.03	1.9
PVP 5	0.5	0.02	4.1	0.03	5.1	0.03	5.6	0.04	8.6

Hematocrit (%)									
Control Level	Mean	Repeatability		Between Day		Between Site		Reproducibility	
CVP 1	42	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CVP 2	22	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PVP 1	18	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PVP 2	23	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PVP 3	43	0.1	0.1	0.0	0.0	0.0	0.0	0.1	0.2
PVP 4	68	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

pH									
Control Level	Mean	Repeatability		Between Day		Between Site		Reproducibility	
CVP 1	7.11	0.005	0.1	0.002	0.0	0.000	0.0	0.006	0.1
CVP 2	7.54	0.003	0.0	0.001	0.0	0.001	0.0	0.003	0.0
PVP 1	7.59	0.004	0.1	0.002	0.0	0.002	0.0	0.005	0.1
PVP 2	7.11	0.007	0.1	0.003	0.0	0.000	0.0	0.008	0.1
PVP 3	7.36	0.003	0.0	0.000	0.0	0.001	0.0	0.005	0.1
PVP 4	7.55	0.004	0.1	0.002	0.0	0.002	0.0	0.005	0.1

pCO_2 (mmHg)									
Control Level	Mean	Repeatability		Between Day		Between Site		Reproducibility	
CVP 1	92	1.2	1.4	0.0	0.0	0.2	0.2	2.0	2.2
CVP 2	16	0.3	2.0	0.1	0.6	0.3	0.3	0.4	2.8
PVP 1	60	1.1	1.9	0.2	0.3	0.5	0.5	1.3	2.1
PVP 2	92	2.1	2.3	0.8	0.9	0.8	0.8	2.5	2.7
PVP 3	38	0.6	1.6	0.0	0.0	0.3	0.3	0.7	1.9
PVP 4	16	0.4	2.4	0.1	0.5	0.2	0.2	0.4	2.8

iii. External Precision - Whole Blood

A precision study was performed at 3 external clinical point-of care (POC) sites, using 5 whole blood patient samples for over 5 days, by 6 different operators on 3 GEM Premier ChemSTAT instruments (one analyzer per site), using a single lot of GEM Premier ChemSTAT PAKs (cartridges). Reproducibility was not assessed for whole blood samples because samples at each clinical site are unique. Each whole blood patient sample was run in triplicate on a single GEM Premier ChemSTAT instrument.

The results are summarized in the table below:

Analyte	Site	N	Mean	Within Sample SD or CV%
Glucose (mg/dL)	POC1	12	38	1.7
	POC2	3	23	0.6
	POC3	15	49	1.7
	Pooled	30	42	1.6
	POC1	54	122	1.0%
	POC2	63	112	0.8%
	POC3	51	115	1.0%
	Pooled	168	116	0.9%
Lactate (mmol/L)	POC1	9	1.9	0.07
	POC2	27	1.8	0.08
	POC3	9	2.2	0.07
	Pooled	45	1.9	0.08
	POC1	57	5.7	1.7%
	POC2	39	3.7	2.5%
	POC3	54	3.8	1.8%
	Pooled	150	4.5	1.9%
Hematocrit (%)	POC1	69	32	0.5
	POC2	66	40	0.4
	POC3	63	31	0.6
	Pooled	198	35	0.5
pH	POC1	63	7.26	0.008
	POC2	66	7.36	0.009
	POC3	66	7.31	0.007
	Pooled	195	7.31	0.008
pCO_2 (mmHg)	POC1	54	49	1.2
	POC2	60	40	0.7
	POC3	60	50	0.9
	Pooled	174	46	0.9
	POC1	18	74	1.4%
	POC2	6	66	1.6%
	POC3	3	78	1.5%
	Pooled	27	73	1.5%

b. Linearity/assay reportable range:

A linearity study was performed following CLSI EP06-A guidelines. Nine to ten levels per analyte were prepared by tonometry, spiking or diluting whole blood samples to challenge the claimed measuring ranges. Each level was analyzed in triplicate on six GEM Premier ChemSTAT analyzers, with three different cartridges for all analytes except for pH and pCO2 which were tested on three GEM Premier ChemSTAT analyzers and results compared to reference analyzers.

The results are summarized in the table below:

Analyte	Linear regression Equation	R^2	Sample range tested	Claimed Measuring Range
Glucose	y = 1.023x – 0.502	1.00	3-749 mg/dL	4-685 mg/dL
Lactate	y = 1.004x + 0.000	0.9998	0.2-17.8 mmol/L	0.3-17.0 mmol/L
Hct	y = 0.984x + 1.909	0.9975	13-74 %	15-72%
pH	y = 1.006x – 0.042	0.9996	6.76-8.10	7.00-8.00
pCO_2	y = 1.030x – 0.843	0.9994	2-137 mmHg	6-125 mmHg

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

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

Traceability:

Glucose is traceable by automated spectrophotometry using hexokinase method per CDC no. 77-8660 using secondary standard prepared from NIST #917.

Lactate traceability is established by automated spectrophotometry using lactate oxidase with secondary standard prepared from USP #1614308.

pCO_2 traceability is established through tonometry at 37°C using NIST traceable gas mixtures.

pH traceability is established through a direct potentiometry method which uses secondary standards prepared from NIST SRM 186I & 186II phosphate salts.

Hematocrit traceability is established by centrifugation using whole blood per CLSI H7-A3 for establishing true correlation. Maintained from lot to lot by controlling conductivity through controlling sodium level.

d. Detection limit:

The limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) were evaluated in accordance to CLSI EP17-A2 guideline, for Glu, Lac, Hct, pH, and pCO_2.

The LoB was assessed by testing blank samples on 3 days with 3 different cartridge lots (N=60/analyte/lot). After recording 60 blank sample measurements, the results were ranked from lowest to highest. LoB was independently calculated for each lot using the non-parametric method.

The LoD was determined by testing low-level samples over three days using three cartridge lots on three analyzers. The LoB used for LoD calculation is the maximum value across the three cartridge lots. The is calculated using the formula:

$$LoD = LoB + \frac{1.645}{1-\left(\frac{1}{4(L-J)}\right)} * SD_L$$

Where:

L = total number of all low-level sample results across all cartridge lots

J= number of low level samples (number of days)

The LoQ was assessed by testing low-level whole blood samples. Sixty replicates of the low-level samples were measured per day on 3 analyzers (N=60/analyte/day) using 3 reagent lots. The LoQ is defined as the lowest concentration at which measured total error is less than the pre-defined total error of ± 6 mg/dL for glucose, ± 0.4 mmol/L for lactate, ±4% for hematocrit and ±5 mmHg for pCO_2. Total error (TE) for low level sample was calculated using the following formula:

TE = |(meanGEM Premier ChemSTAT – meanPredicate Device)| + 1.96 * SDLow Level

The results are summarized in the table below

Analyte	LoB	LoD	LoQ	Claimed Measuring Range
Glucose mg/dL	0	1	1	4-685 mg/dL
Lactate(mmol/L)	0.0	0.0	0.1	0.3-17.0 mmol/L
Hematocrit (%)	2	3	10	15-72%
pCO_2(mmHg)	1	3	3	6-125 mmHg

Linearity studies were used to support the lower end of the measuring range for pH (see section M.1.b above).

e. Analytical specificity:

An interference study was performed based on CLSI EP17-A guideline. The interference testing was conducted using whole blood samples at two different analyte concentrations. Substances were considered not interfering if the difference between the test and control samples was less than or equal to the following clinically significant interference limits set for each analyte:

Analyte	Clinical non-interference limits
pH	≤± 0.02
pCO2 (mmHg)	≤± 8%
Glucose (mg/dL)	≤± 10%
Lactate (mmol/L)	≤± 0.4
Hematocrit (%)	≤± 4

Substances identified as interfering substances were further characterized to determine the concentration that produces a clinically significant interference

The results are summarized in the table below for substances that showed non-significant interference when tested at the concentrations listed.

Test substances	Tested concentrations	Tested analytes where interference was not observed
Acetaminophen	1030 µmol/L	Glucose, Lactate
Acetoacetate	2 mmol/L	Glucose, Lactate
Albumin (Human)	60 g/L	Hct
Ascorbic acid	298 µmol/L	Glucose, Lactate
Atracurium	50 mg/dL	Glucose, Lactate, Hct, pH, pCO_2
Bilirubin	40 mg/dL	Glucose, Lactate, Hct, pH, pCO_2
Ceftriaxone	1510 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Chlorpromazine	10.3 µmol/L	Glucose, Lactate
Dobutamine	0.121 mg/dL	Glucose, Lactate
Dopamine	4.06 µmol/L	Glucose, Lactate
Epinephrine	0.5 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Ethanol	130 mmol/L	Glucose, Lactate
Ethylene glycol	8.8 mmol/L	Glucose, Lactate
Etomidate	50 mg/L	Glucose, Lactate, Hct, pH, pCO_2
Fentanyl	0.03 µg/mL	Glucose, Lactate, Hct, pH, pCO_2
Fructose	1 mmol/L	Glucose
Furosemide	48.1 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Gadodiamide	1.4 mmol/L	Glucose, Lactate, Hct, pH, pCO_2
Glycolic acid	1.0 mmol/L	Glucose
Hematocrit	25%	pH, pCO_2, Glucose, Lactate
Hematocrit	60%	pH, pCO_2, Glucose, Lactate
Hemoglobin (Hemolysis)	1000 mg/dL	Glucose, Lactate, Hct, pH, pCO_2
Heparin	100,000 U/L	Glucose, Lactate
β-hydroxybutyrate	2 mmol/L	Glucose, Lactate, pH
Ibuprofen	1060 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Icodextrin	20 mg/dL	Glucose, Lactate
Isoniazid	438 µmol/L	Glucose, Lactate
Leukocytes / Platelets	24.81 / 452 (x103/µl)	Hct 30%
	27.60 / 564 ($x10^3$/µl)	Hct 60%
Maltose	360 mg/dL	Glucose, Lactate

Test substances	Tested concentrations	Tested analytes where interference was not observed
Methadone	10.3 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Midazolam	0.376 mg/dL	Glucose, Lactate, Hct, pH, pCO_2
Morphine	27.3 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
N-Acetyl-L-cysteine	920µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Phenobarbital	2970 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Piperacillin	110 mg/dL	Glucose, Lactate, Hct, pH, pCO_2
pO2	30 mmHg	Glucose, Lactate
Pralidoxime iodide	4 mg/dL	Glucose, Lactate
Propofol	4.8 mg/dL	Glucose, Lactate, Hct, pH, pCO_2
Suxamethonium	68 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Tazobactam	3.05 mg/dL	Glucose, Lactate, Hct, pH, pCO_2
Thiocyanate	898 µmol/L	Glucose, Lactate
Thiopental	1660 µmol/L	pCO_2
Triglycerides (Intralipid)	2000 mg/dL (1% Intralipid)	Glucose, Lactate, Hct, pH, pCO_2
Uric acid	1.4 mmol/L	Glucose, Lactate
Vancomycin	82.8 µmol/L	Glucose, Lactate, Hct, pH, pCO_2
Xylose	20 mg/dL	Glucose

The table below lists substances that demonstrated interference with Glu, Lac, Hct, pH and/or pCO_2 and the concentration of the interfering substance, as well as the bias observed and its direction (positive / negative):

Interfering Substance	Affected Analytes	Analyte Conc.	Interfering Conc. Tested	Bias Observed (Mean)	Lowest Interfering Conc. with Analyte Impact	Bias Observed at the Lowest Concentration
Galactose	Glucose	40 mg/dL	3.33 mmol/L	+13 %	2.77 mmol/L	+10 %
		220 mg/dL		No interference Observed		
Glycolic acid	Lactate	1.0 mmol/L	1.0 mmol/L	+1.5 mmol/L	0.3 mmol/L	+0.4 mmol/L
		1.7 mmol/L		+1.6 mmol/L	0.3 mmol/L	+0.4 mmol/L
Hydroxyurea	Glucose	40 mg/dL	3.08 mg/dL	+207 %	0.15 mg/dL	+10 %
		220 mg/dL		+34 %	0.90 mg/dL	+10 %
Hydroxyurea	Lactate	1.0 mmol/L	3.08 mg/dL	+3.8 mmol/L	0.30 mg/dL	+0.4 mmol/L
		1.7 mmol/L		+3.5 mmol/L	0.33 mg/dL	+0.4 mmol/L
Mannose	Glucose	40 mg/dL	20 mg/dL	+12 %	19 mg/dL	+10 %
		220 mg/dL		No Interference Observed		
Thiopental	pH	7.40	1660 µmol/L	+0.04	789 µmol/L	+0.02
		7.25		+0.03	1175 µmol/L	+0.02

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed at 3 external POC sites using lithium heparinized arterial and venous whole blood samples. Each sample was analyzed in singlicate on the GEM Premier ChemSTAT and on the GEM Premier 4000. To span the reportable range for each analyte, < 10% of contrived samples were spiked for each analyte.

The results are summarized in the table below:

Analyte	**N**	Slope	Intercept	R	Sample Range
Glucose (mg/dL)	432	1.019	-0.558	0.999	35 to 684
Lactate (mmol/L)	432	1.000	-0.100	0.997	0.6 to 16.0
Hematocrit (%)	431	1.032	-0.626	0.997	16 to 71
pH	552	1.006	-0.038	0.995	7.03 to 7.87
pCO_2 (mmHg)	559	1.000	0.000	0.996	7 to 120

b. Matrix comparison:

Not applicable. The glucose, lactate, hematocrit, pH and pCO_2 assays are 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:

The following are the reference ranges from published literature:

Analyte	Reference Range	Unit
Glu*	65 to 95	mg/dL
	3.6 to 5.3	mmol/L
Lac*	0.36 to 0.75 (arterial at rest)	mmol/L
	2.24 to 6.76 (arterial at rest)	mg/dL
	0.56 to 1.39 (venous at rest)	mmol/L
	5.0 to 12.5 (venous at rest)	mg/dL
Hct*	39-51 (male) and 35-47 (female)	%
pH* cH* cH* pH* cH* cH*	7.35 to 7.45 44.7 to 35.5 44.7 to 35.5 7.32 to 7.43 (venous) 47.9 to 37.2 (venous) 47.9 to 37.2 (venous)	pH nmol/L nEq/L pH nmol/L nEq/L
pCO_2**	35 to 48 (male) and 32 to 45 (female) 4.6 to 6.4 (male) and 4.3 to 6.0 (female) 6 to 7 mmHg (0.80 to 0.93 kPa) higher than arterial pCO_2 (venous blood, right atrium)	mmHg kPa

The sponsor recommends that each laboratory establish their own reference ranges applicable to their patient population.

References:

* Burtis, Carl and David Bruns, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Elsevier Saunders, 7th Edition, 2015, pages 952-982.

** Wu, A., Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Co., St. Louis MO, 4th Edition, 2006, pages 216.

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.