February 16, 2019

Instrumentation Laboratory Co.
Gabriella Erdosy
Regulatory Affairs Manager
180 Hartwell Road
Bedford, MA 01730

Re: K183546
Trade/Device Name: GEM Premier ChemSTAT
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, KHP, GKF, CHL
Dated: December 19, 2018
Received: December 20, 2018

Dear Gabriella Erdosy:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k183546

Device Name
GEM Premier ChemSTAT

Indications for Use *(Describe)*
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.

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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Instrumentation Laboratory
A Werfen Company

K183546: GEM Premier ChemSTAT

510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

Submitter's Information	Instrumentation Laboratory (IL) Co. 180 Hartwell Road Bedford, MA 01730, USA

Contact Person	Gabriella Erdosy Phone: 781-861-4571 Fax: 781-861-4207 Email: gerdosy@ilww.com

Preparation Date	February 11, 2019

Device Trade Name	GEM Premier ChemSTAT

Predicate Device	GEM Premier 4000	K133407

Regulatory Information					
Analyte	**Regulation Section**	**Regulatory Description**	**Classification**	**Product Code**	**Panel**
Glucose	862.1345	Glucose test system	Class II	CGA	Chemistry (75)
Lactate	862.1450	Lactic acid test system	Class I	KHP	
Hematocrit	864.5600	Automated hematocrit instrument	Class II	GKF	Hematology (81)
pH and pCO_2	862.1120	Blood Gases (pCO_2) and Blood pH system	Class II	CHL	Chemistry (75)

Device Description	
The GEM Premier ChemSTAT is a portable system that analyzes arterial and venous lithium heparinized whole blood at the point of health care delivery in a clinical setting and in a central laboratory for Glu, Lac, Hct, pH, and pCO_2. All tests are included in a single self-contained, disposable GEM Premier ChemSTAT PAK (cartridge).	
Key Components	**Description**
Analyzer	The GEM Premier ChemSTAT analyzer has the internal logic and processing power necessary to perform analysis. It employs a unique touch-sensitive color screen and a simple set of menus and buttons for user interaction. The analyzer guides operators through the sampling process with simple, clear messages and prompts.
PAK (Cartridge)	The disposable, multi-use GEM Premier ChemSTAT PAK is a completely closed cartridge that houses all components necessary to operate the instrument once the GEM PAK is validated. These components include the sensors, Process Control (PC) Solutions, sampler, and waste bag. The values of all PC Solutions are read from the GEM PAK Electronically Erasable Programmable Read Only Memory (EEPROM) chip. The components and processes used to manufacture the PC Solutions in the GEM PAK are traceable to National Institute of Standards and Technology (NIST) standards, Clinical & Laboratory Standards Institute (CLSI) procedures or other internal standards, where available and appropriate. The GEM Premier ChemSTAT PAK has flexible menus to assist facilities in maximizing efficiency. As part of this program, GEM ChemSTAT CVP (Calibration Valuation Products) are external solutions intended to complete the calibration process and final accuracy assessment of the iQM cartridge calibration following warm-up.

Device Description (Cont.)	
Intelligent Quality Management (iQM)	Intelligent Quality Management (iQM) is used as the quality control and assessment system for the GEM Premier ChemSTAT system. iQM is an active quality process control program designed to provide continuous monitoring of the analytical process before and after sample measurement with real-time, automatic error detection, automatic correction and automatic documentation of all corrective actions. iQM performs 4 types of continuous, quality checks to monitor the performance of the GEM PAK, sensors, and reagents throughout the cartridge use-life. These checks include System, Sensor, Pattern Recognition (PR) and Stability Checks.

Indications for Use / Intended 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 (pCO_2) 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 pCO_2 measurements in whole blood are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Special Conditions for Use Statement

- For prescription use only.
- For clinical laboratory and point-of-care use

Substantial Equivalency			
Item	**Candidate Device:** GEM Premier ChemSTAT		**Predicate Device:** GEM Premier 4000
510(k) No.	K183546		K133407
Manufacturer	Instrumentation Laboratory Co.		Same
Intended Use	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 (pCO_2) 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.		Same
Intended User	Central Laboratory and Point-of-Care		Same
Measurement Principle	Glu	Amperometry	Same
	Lac	Amperometry	Same
	Hct	Conductivity	Same
	pH	Potentiometry	Same
	pCO_2	Potentiometry	Same
Sample Volume	150 µL		65 to 150 µL (dependent on sample mode)
Sample Type	Lithium heparinized whole blood (arterial and venous)		Same (arterial, venous and capillary)

Substantial Equivalency (Cont.)			
Item		**Candidate Device:** GEM Premier ChemSTAT	**Predicate Device:** GEM Premier 4000
Reportable Range	Glu	4 to 685 mg/dL	Same
	Lac	0.3 to 17.0 mmol/L	Same
	Hct	15 to 72%	Same
	pH	7.00 to 8.00	Same
	pCO_2	6 to 125 mmHg	Same
PAK Storage Temperature		15-25°C	Same
Calibration		2-point calibration	Same

Performance Summary

Internal Precision Study – Whole Blood

In accordance with CLSI EP05-A3, an internal precision study was performed using five (5) different concentrations of whole blood per analyte, each run on three (3) GEM Premier ChemSTAT analyzers for five (5) days, with one (1) run per day and eight (8) replicates measured per run per level (N=120).

All results were within specification.

Analyte	Whole Blood Level	N	Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
Glucose (mg/dL)	Level 1	120	24	0.5	2.3%	0.5	2.3%
	Level 2	120	48	0.9	1.9%	0.9	1.9%
	Level 3	120	122	1.3	1.1%	1.7	1.4%
	Level 4	120	356	2.7	0.8%	3.2	0.9%
	Level 5	120	620	3.2	0.5%	5.4	0.9%
Lactate (mmol/L)	Level 1	120	0.7	0.06	8.9%	0.06	8.9%
	Level 2	120	2.0	0.06	2.8%	0.07	3.3%
	Level 3	120	4.9	0.05	1.1%	0.11	2.3%
	Level 4	120	7.8	0.13	1.7%	0.18	2.3%
	Level 5	120	14.2	0.23	1.6%	0.34	2.4%
Hct (%)	Level 1	120	18	0.3	1.6%	0.3	1.6%
	Level 2	120	33	0.3	0.9%	0.4	1.1%
	Level 3	120	44	0.3	0.7%	0.4	0.9%
	Level 4	120	57	0.3	0.5%	0.4	0.7%
	Level 5	120	65	0.4	0.7%	0.5	0.8%

Performance Summary (Cont.)

Internal Precision Study – Whole Blood (Cont.)

Analyte	Whole Blood Level	N	Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
pH	Level 1	120	7.07	0.008	0.1%	0.008	0.1%
	Level 2	120	7.25	0.007	0.1%	0.007	0.1%
	Level 3	120	7.34	0.008	0.1%	0.008	0.1%
	Level 4	120	7.49	0.009	0.1%	0.010	0.1%
	Level 5	120	7.69	0.010	0.1%	0.013	0.2%
pCO_2 (mmHg)	Level 1	120	110	1.4	1.3%	1.4	1.3%
	Level 2	120	71	0.9	1.2%	0.9	1.2%
	Level 3	120	51	0.7	1.4%	0.7	1.4%
	Level 4	120	29	0.4	1.5%	0.5	1.6%
	Level 5	120	12	0.6	4.8%	0.6	4.8%

Performance Summary (Cont.)

Reproducibility Study with Aqueous Controls – Point-of-Care (POC) Setting

In accordance with CLSI EP05-A3, a reproducibility study was performed with controls at three (3) external clinical point-of-care (POC) sites. The studies were run by a total of nine (9) different operators on six (6) different GEM Premier ChemSTAT instruments, using a single lot of GEM Premier ChemSTAT PAKs (cartridges). Each site used seven (7) levels of quality control material for Glu and Lac (2 levels of GEM ChemSTAT CVP and 5 levels of GEM ChemSTAT PVP), six (6) levels for Hct (2 levels of GEM ChemSTAT CVP and 4 levels of GEM ChemSTAT critPVP) and six (6) levels for pH and pCO_2 (2 levels of GEM ChemSTAT CVP and 4 levels of GEM ChemSTAT PVP), running each control level in triplicate, twice a day for 5 days, for a total of 30 replicates per level (N=90 pooled across 3 sites).

All results at all sites were within specification.

Pooled Multi-Site POC Data													
Analyte	**Control Level**	**N**	**Mean**	**Repeatability**		**Between-Run**		**Between-Day**		**Between-Site**		**Reproducibility**	
				SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Glucose (mg/dL)	CVP Level 1	90	392	1.0	0.2%	3.9	1.0%	0.7	0.2%	4.3	1.1%	5.9	1.5%
	CVP Level 2	90	78	1.5	1.9%	0.0	0.0%	0.6	0.8%	0.0	0.0%	1.6	2.1%
	PVP Level 1	90	642	1.3	0.2%	1.4	0.2%	1.1	0.2%	6.5	1.0%	6.8	1.1%
	PVP Level 2	90	393	1.6	0.4%	1.3	0.3%	1.3	0.3%	3.3	0.8%	4.2	1.1%
	PVP Level 3	90	115	1.4	1.2%	0.6	0.5%	0.0	0.0%	0.0	0.0%	1.5	1.3%
	PVP Level 4	90	80	0.6	0.7%	0.3	0.4%	0.5	0.6%	0.3	0.3%	0.9	1.1%
	PVP Level 5	90	14	0.5	3.6%	0.0	0.0%	0.2	1.6%	1.4	9.7%	1.5	10.5%

Performance Summary (Cont.)

Reproducibility Study with Aqueous Controls – Point-of-Care (POC) Setting (Cont.)

Pooled Multi-Site POC Data													
Analyte	**Control Level**	**N**	**Mean**	**Repeatability**		**Between-Run**		**Between-Day**		**Between-Site**		**Reproducibility**	
				SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Lactate (mmol/L)	CVP Level 1	90	8.2	0.04	0.5%	0.04	0.5%	0.02	0.3%	0.03	0.3%	0.07	0.8%
	CVP Level 2	90	1.7	0.03	1.8%	0.00	0.0%	0.01	0.7%	0.04	2.4%	0.05	3.1%
	PVP Level 1	90	15.7	0.07	0.4%	0.07	0.4%	0.07	0.5%	0.09	0.6%	0.15	0.9%
	PVP Level 2	90	8.1	0.06	0.7%	0.04	0.5%	0.04	0.4%	0.07	0.9%	0.11	1.3%
	PVP Level 3	90	5.0	0.03	0.6%	0.00	0.0%	0.04	0.8%	0.03	0.6%	0.06	1.2%
	PVP Level 4	90	1.7	0.03	1.5%	0.01	0.4%	0.01	0.6%	0.01	0.9%	0.03	1.9%
	PVP Level 5	90	0.5	0.02	4.1%	0.00	0.0%	0.03	5.1%	0.03	5.6%	0.04	8.6%
Hematocrit (%)	CVP Level 1	90	42	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%
	CVP Level 2	90	22	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%
	critPVP Level 1	90	18	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%
	critPVP Level 2	90	23	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%
	critPVP Level 3	90	43	0.1	0.2%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.1	0.2%
	critPVP Level 4	90	68	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%

Performance Summary (Cont.)

Reproducibility Study with Aqueous Controls – Point-of-Care (POC) Setting (Cont.)

Pooled Multi-Site POC Data													
Analyte	**Control Level**	**N**	**Mean**	**Repeatability**		**Between-Run**		**Between-Day**		**Between-Site**		**Reproducibility**	
				SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
pH	CVP Level 1	90	7.11	0.005	0.1%	0.002	0.0%	0.002	0.0%	0.000	0.0%	0.006	0.1%
	CVP Level 2	90	7.54	0.003	0.0%	0.001	0.0%	0.001	0.0%	0.001	0.0%	0.003	0.0%
	PVP Level 1	90	7.59	0.004	0.1%	0.001	0.0%	0.002	0.0%	0.002	0.0%	0.005	0.1%
	PVP Level 2	90	7.11	0.007	0.1%	0.000	0.0%	0.003	0.0%	0.000	0.0%	0.008	0.1%
	PVP Level 3	90	7.36	0.003	0.0%	0.004	0.1%	0.000	0.0%	0.001	0.0%	0.005	0.1%
	PVP Level 4	90	7.55	0.004	0.1%	0.001	0.0%	0.002	0.0%	0.002	0.0%	0.005	0.1%
pCO_2 (mmHg)	CVP Level 1	90	92	1.2	1.4%	1.6	1.7%	0.0	0.0%	0.2	0.2%	2.0	2.2%
	CVP Level 2	90	16	0.3	2.0%	0.0	0.0%	0.1	0.6%	0.3	1.9%	0.4	2.8%
	PVP Level 1	90	60	1.1	1.9%	0.0	0.0%	0.2	0.3%	0.5	0.9%	1.3	2.1%
	PVP Level 2	90	92	2.1	2.3%	0.6	0.6%	0.8	0.9%	0.8	0.8%	2.5	2.7%
	PVP Level 3	90	38	0.6	1.6%	0.2	0.5%	0.0	0.0%	0.3	0.9%	0.7	1.9%
	PVP Level 4	90	16	0.4	2.4%	0.1	0.8%	0.1	0.5%	0.2	1.2%	0.4	2.8%

Performance Summary (Cont.)

External Precision – Whole Blood

A precision study was performed with whole blood patient samples at three (3) external clinical point-of-care (POC) sites. The studies were run by six (6) different operators on three (3) different GEM Premier ChemSTAT instruments, using a single lot of GEM Premier ChemSTAT PAKs (cartridges). Less than 10% of samples included in the study were contrived.

For data analysis and acceptance criteria application, measured data for each analyte were partitioned into zones and identified as Fixed Acceptance Range (Constant SD) or Variable Acceptance Range (Constant %CV).

All results at all sites were within specification.

Analyte	Fixed or Variable Acceptance Range	Site	N	Mean	Within Sample SD of %CV
Glucose (mg/dL)	Fixed (SD)	POC 1	12	38	1.7
		POC 2	3	23	0.6
		POC 3	15	49	1.7
		Pooled	30	42	1.6
	Variable (%CV)	POC 1	54	122	1.0%
		POC 2	63	112	0.8%
		POC 3	51	115	1.0%
		Pooled	168	116	0.9%
Lactate (mmol/L)	Fixed (SD)	POC 1	9	1.9	0.07
		POC 2	27	1.8	0.08
		POC 3	9	2.2	0.07
		Pooled	45	1.9	0.08
	Variable (%CV)	POC 1	57	5.7	1.7%
		POC 2	39	3.7	2.5%
		POC 3	54	3.8	1.8%
		Pooled	150	4.5	1.9%

Performance Summary (Cont.)

External Precision – Whole Blood (Cont.)

Analyte	Fixed or Variable Acceptance Range	Site	N	Mean	Within Sample SD of %CV
Hematocrit (%)	Fixed (SD)	POC 1	69	32	0.5
		POC 2	66	40	0.4
		POC 3	63	31	0.6
		Pooled	198	35	0.5
pH	Fixed (SD)	POC 1	63	7.26	0.008
		POC 2	66	7.36	0.009
		POC 3	66	7.31	0.007
		Pooled	195	7.31	0.008
pCO_2 (mmHg)	Fixed (SD)	POC 1	54	49	1.2
		POC 2	60	40	0.7
		POC 3	60	50	0.9
		Pooled	174	46	0.9
	Variable (%CV)	POC 1	18	74	1.4%
		POC 2	6	66	1.6%
		POC 3	3	78	1.5%
		Pooled	27	73	1.5%

Performance Summary (Cont.)

LoB, LoD and LoQ

In accordance with CLSI EP17-A2, Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ) were established for Glu, Lac, Hct, pH, and pCO_2, using three (3) lots of GEM Premier ChemSTAT PAKs (cartridges).

Following are the combined data results for LoB, LoD and LoQ:

Analyte	LoB	LoD	LoQ
Glucose (mg/dL)	0	1	1
Lactate (mmol/L)	0.0	0.0	0.1
Hematocrit (%)	2	3	10
pH	8.69	8.62	8.06
pCO_2 (mmHg)	1	3	3

Linearity

In accordance with CLSI EP06-A, a minimum of nine (9) levels per analyte were prepared by spiking or diluting whole blood to challenge the claimed reportable range for Glu, Lac, Hct, pH, and pCO_2. Each blood level was analyzed in triplicate on six (6) GEM Premier ChemSTAT test analyzers (except pH and pCO_2, which were tested on 3 analyzers) and results compared to the reference analyzer.

Combined data from limit of quantitation (LoQ) and linearity were used to support the lower limits of the claimed reportable ranges.

Analyte	# of Levels	N per Level	Slope	Intercept	R^2	Tested Range	Reportable Range
Glucose (mg/dL)	9	18	1.023	-0.502	1.0000	3 to 749	4 to 685
Lactate (mmol/L)	9	18	1.004	0.000	0.9998	0.2 to 17.8	0.3 to 17.0
Hematocrit (%)	9	18	0.984	1.909	0.9975	13 to 74	15 to 72
pH	10	9	1.006	-0.042	0.9996	6.76 to 8.10	7.00 to 8.00
pCO_2 (mmHg)	9	9	1.030	-0.843	0.9994	2 to 137	6 to 125

Performance Summary (Cont.)

Analytical Specificity

In accordance with EP07 3rd Edition, an interference study was conducted on the GEM Premier ChemSTAT for Glu, Lac, Hct, pH, and pCO_2.

The table below and on the next two pages lists the substances that were screened with no observed interference on Glu, Lac, Hct, pH, and/or pCO_2:

Test Substance	Test Concentration	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/L	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

Performance Summary (Cont.)

Analytical Specificity (Cont.)

Test Substance	Test Concentration	Tested analytes where interference was not observed
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 ($x10^3$/µl)	Hct 30%
	27.60 / 564 ($x10^3$/µl)	Hct 60%
Maltose	360 mg/dL	Glucose, Lactate
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

Performance Summary (Cont.)

Analytical Specificity (Cont.)

Test Substance	Test Concentration	Tested analytes where interference was not observed
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 Concentration	Interfering Concentration Tested	Bias Observed (Mean)	Lowest Interfering Concentration 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

Performance Summary (Cont.)

Reference Ranges

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

* 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.

Performance Summary (Cont.)

Clinical Testing

In accordance with EP09c, a method comparison study was conducted on the GEM Premier ChemSTAT compared to the predicate device, the GEM Premier 4000 (K133407), using lithium heparinized whole blood patient samples from the intended use population. Less than 10% of samples included in the study were contrived.

- Study Design:
  - Three (3) external point-of-care (POC) sites
  - For pH and pCO_2 only, internal Customer Simulation Laboratory (CSL) at IL, where multiple intended POC users were brought on site to run spiked samples to cover the reportable ranges.

The pooled results from the POC sites and the IL internal Customer Simulation Laboratory (CSL) are presented below.

Pooled Point-of-Care Sites and CSL Data					
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

Conclusion	The technological and functional characteristics of the new GEM Premier ChemSTAT as described above are substantially equivalent to that of the predicate device (GEM Premier 4000) for Glucose, Lactate, Hematocrit, pH and pCO_2. The analytical and clinical study results demonstrate that the GEM Premier ChemSTAT is safe and effective for its intended purpose and equivalent in performance to the predicate device (K133407).