February 16, 2019

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

Re: K183549
Trade/Device Name: GEM Premier ChemSTAT
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS, CEM, JFP, CGZ, JJE
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)*
k183549

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 Sodium (Na+), Potassium (K+), Ionized Calcium (Ca++) and Chloride (Cl-) from arterial and venous heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's electrolyte balance.

Electrolytes in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes:

- Sodium (Na+) measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.
- Potassium (K+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

- Ionized calcium (Ca++) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

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

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

K183549: GEM Premier ChemSTAT with Na^+, K^+, Ca^{++} and Cl^-

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 15, 2019

Device Trade Name	GEM Premier ChemSTAT

Predicate Device	GEM Premier 4000	K133407

Regulatory Information					
Device	**Regulation Section**	**Regulatory Description**	**Classification**	**Product Code**	**Panel**
Analyzer	862.2160	Analyzer, chemistry (photometric, discrete), for clinical use	Class I (Exempt)	JJE	Chemistry (75)
Sodium	862.1665	Sodium test system	Class II	JGS	
Potassium	862.1600	Potassium test system	Class II	CEM	
Ionized Calcium	862.1145	Calcium test system	Class II	JFP	
Chloride	862.1170	Chloride test system	Class II	CGZ	

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 Na^+, K^+, Ca^{++} and Cl^-. 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 Sodium (Na^+), Potassium (K^+), Ionized Calcium (Ca^{++}) and Chloride (Cl^-) from arterial and venous heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's electrolyte balance. Electrolytes in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes: • Sodium (Na^+) measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance. • Potassium (K^+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. • Ionized calcium (Ca^{++}) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. • Chloride (Cl^-) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders, such as, cystic fibrosis and diabetic acidosis.

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.	Pending		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 Sodium (Na^+), Potassium (K^+), Ionized Calcium (Ca^{++}) and Chloride (Cl^-) from arterial and venous heparinized whole blood. These parameters, along with derived parameters, aid in the diagnosis of a patient's electrolyte balance.		Same
Intended User	Central Laboratory and Point-of-Care		Same
Measurement Principle	Na^+	Potentiometry	Same
	K^+	Potentiometry	Same
	Ca^{++}	Potentiometry	Same
	Cl^-	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)
Reportable Range	Na^+	100 to 180 mmol/L	Same
	K^+	0.3 to 19.0 mmol/L	0.2 to 19.0 mmol/L
	Ca^{++}	0.10 to 4.25 mmol/L	Same
	Cl^-	40 to 158 mmol/L	Same

Substantial Equivalency (Cont.)		
Item	**Candidate Device:** GEM Premier ChemSTAT	**Predicate Device:** GEM Premier 4000
PAK Storage Temperature	15-25°C	Same
Calibration	2-point calibration	Same
Instrument Sample Introduction	Aspiration	Same
Instrument Operating Temperature	12-32°C	Same
Software Operating System	Linux-based	Same
Instrument User Interface	Menu Driven Touch Screen	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	Analyzer-to-Analyzer SD	Analyzer-to-Analyzer %CV	Total SD	Total %CV
Na^+ (mmol/L)	Level 1	120	106	0.5	0.5%	0.4	0.3%	0.6	0.6%
	Level 2	120	118	0.4	0.4%	0.4	0.4%	0.6	0.5%
	Level 3	120	132	0.5	0.4%	0.0	0.0%	0.5	0.4%
	Level 4	120	152	0.7	0.4%	0.3	0.2%	0.8	0.5%
	Level 5	120	175	0.6	0.3%	0.6	0.3%	0.8	0.5%
K^+ (mmol/L)	Level 1	120	1.5	0.03	2.2%	0.01	0.8%	0.04	2.3%
	Level 2	120	3.4	0.03	0.9%	0.01	0.4%	0.03	0.9%
	Level 3	120	5.8	0.04	0.7%	0.02	0.4%	0.04	0.7%
	Level 4	120	7.9	0.04	0.5%	0.02	0.3%	0.05	0.6%
	Level 5	120	18.1	0.04	0.2%	0.11	0.6%	0.12	0.6%

Performance Summary (Cont.)

Internal Precision Study – Whole Blood (Cont.)

Analyte	Whole Blood Level	N	Mean	Within Run SD	Within Run %CV	Analyzer-to-Analyzer SD	Analyzer-to-Analyzer %CV	Total SD	Total %CV
Ca^{++} (mmol/L)	Level 1	120	0.19	0.003	1.7%	0.004	2.3%	0.005	2.8%
	Level 2	120	0.38	0.004	1.1%	0.003	0.7%	0.005	1.3%
	Level 3	120	0.82	0.007	0.8%	0.3%	0.3%	0.007	0.8%
	Level 4	120	1.60	0.012	0.7%	0.010	0.7%	0.016	1.0%
	Level 5	120	3.79	0.029	0.8%	0.039	1.0%	0.048	1.3%
Cl^{-} (mmol/L)	Level 1	120	54	0.4	0.7%	0.5	0.9%	0.6	1.1%
	Level 2	120	75	0.3	0.4%	0.6	0.8%	0.7	0.9%
	Level 3	120	90	0.5	0.5%	0.8	0.9%	0.9	1.0%
	Level 4	120	118	0.6	0.5%	1.4	1.2%	1.5	1.3%
	Level 5	120	142	0.5	0.3%	2.0	1.4%	2.1	1.5%

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 each analyte (2 levels of GEM ChemSTAT CVP and 5 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**
Na^+ (mmol/L)	CVP Level 1	90	124	0.8	0.7%	0.4	0.3%	0.0	0.0%	0.5	0.4%	1.0	0.8%
	CVP Level 2	90	156	0.7	0.4%	0.4	0.2%	0.2	0.1%	0.0	0.0%	0.8	0.5%
	PVP Level 1	90	106	0.5	0.4%	0.0	0.0%	0.2	0.2%	0.3	0.3%	0.6	0.6%
	PVP Level 2	90	125	0.4	0.3%	0.3	0.2%	0.0	0.0%	0.4	0.3%	0.6	0.5%
	PVP Level 3	90	140	0.6	0.4%	0.6	0.4%	0.0	0.0%	0.1	0.1%	0.8	0.6%
	PVP Level 4	90	155	0.6	0.4%	0.3	0.2%	0.2	0.1%	0.2	0.1%	0.7	0.5%
	PVP Level 5	90	177	0.9	0.5%	0.1	0.0%	0.5	0.3%	0.7	0.4%	1.2	0.7%

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**
K^+ (mmol/L)	CVP Level 1	90	2.5	0.00	0.0%	0.02	0.7%	0.00	0.0%	0.00	0.0%	0.02	0.7%
	CVP Level 2	90	7.4	0.03	0.4%	0.05	0.7%	0.00	0.0%	0.01	0.1%	0.06	0.8%
	PVP Level 1	90	1.2	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
	PVP Level 2	90	2.5	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
	PVP Level 3	90	4.6	0.03	0.6%	0.04	0.9%	0.00	0.0%	0.02	0.5%	0.05	1.2%
	PVP Level 4	90	7.3	0.03	0.4%	0.02	0.3%	0.00	0.0%	0.02	0.2%	0.04	0.5%
	PVP Level 5	90	9.6	0.04	0.5%	0.01	0.1%	0.02	0.2%	0.06	0.6%	0.08	0.8%
Ca^{++} (mmol/L)	CVP Level 1	90	0.89	0.009	1.0%	0.001	0.1%	0.000	0.0%	0.002	0.3%	0.010	1.1%
	CVP Level 2	90	1.54	0.009	0.6%	0.007	0.4%	0.000	0.0%	0.002	0.1%	0.011	0.7%
	PVP Level 1	90	0.37	0.004	1.1%	0.003	0.9%	0.000	0.0%	0.003	0.9%	0.006	1.7%
	PVP Level 2	90	0.90	0.006	0.6%	0.005	0.5%	0.000	0.0%	0.003	0.4%	0.008	0.9%
	PVP Level 3	90	1.10	0.007	0.7%	0.008	0.7%	0.000	0.0%	0.000	0.0%	0.011	1.0%
	PVP Level 4	90	1.56	0.009	0.6%	0.006	0.4%	0.000	0.0%	0.002	0.2%	0.011	0.7%
	PVP Level 5	90	2.23	0.015	0.7%	0.011	0.5%	0.003	0.1%	0.000	0.0%	0.019	0.9%

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**
Cl^- (mmol/L)	CVP Level 1	90	91	0.6	0.6%	0.3	0.3%	0.2	0.2%	0.3	0.3%	0.7	0.8%
	CVP Level 2	90	135	0.4	0.3%	0.1	0.1%	0.1	0.1%	2.1	1.5%	2.1	1.6%
	PVP Level 1	90	72	0.3	0.5%	0.0	0.0%	0.3	0.4%	2.3	3.2%	2.3	3.3%
	PVP Level 2	90	92	0.5	0.6%	0.2	0.2%	0.2	0.2%	0.3	0.3%	0.7	0.8%
	PVP Level 3	90	106	0.5	0.4%	0.3	0.3%	0.0	0.0%	0.7	0.7%	0.9	0.9%
	PVP Level 4	90	135	0.6	0.4%	0.4	0.3%	0.1	0.1%	2.1	1.5%	2.2	1.6%
	PVP Level 5	90	152	0.8	0.5%	0.0	0.0%	0.4	0.3%	2.7	1.8%	2.9	1.9%

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
Na^+ (mmol/L)	Fixed (SD)	POC 1	69	139	1.0
		POC 2	63	140	1.0
		POC 3	63	140	1.3
		Pooled	195	140	1.1
	Fixed (SD)	POC 1	3	106	0.6
		POC 2	3	106	0.0
		POC 3	3	103	0.6
		Pooled	9	105	0.5
K^+ (mmol/L)	Fixed (SD)	POC 1	69	4.1	0.12
		POC 2	63	4.0	0.03
		POC 3	63	3.6	0.04
		Pooled	195	3.9	0.08
	Variable (%CV)	POC 1	3	8.2	0.7%
		POC 2	3	7.3	0.0%
		POC 3	3	7.9	0.7%
		Pooled	9	7.8	0.5%

Performance Summary (Cont.)

External Precision – Whole Blood (Cont.)

Analyte	Fixed or Variable Acceptance Range	Site	N	Mean	Within Sample SD of %CV
Ca^{++} (mmol/L)	Fixed (SD)	POC 1	3	0.34	0.006
		POC 2	3	0.38	0.006
		POC 3	3	0.41	0.006
		Pooled	9	0.38	0.006
	Variable (%CV)	POC 1	69	1.20	1.1%
		POC 2	63	1.22	1.4%
		POC 3	63	1.22	1.8%
		Pooled	195	1.21	1.4%
Cl^- (mmol/L)	Fixed (SD)	POC 1	3	73	0.0
		POC 2	3	40	0.0
		POC 3	3	44	0.0
		Pooled	9	52	0.0
	Variable (%CV)	POC 1	69	102	0.5%
		POC 2	63	105	0.7%
		POC 3	63	105	0.5%
		Pooled	195	104	0.6%

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 Na^+, K^+, Ca^{++} and Cl^-, 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
Na^+ (mmol/L)	69	70	88
K^+ (mmol/L)	0.0	0.1	0.3
Ca^{++} (mmol/L)	0.00	0.01	0.05
Cl^- (mmol/L)	4	4	36

Linearity

In accordance with CLSI EP06-A, nine (9) levels per analyte were prepared by spiking or diluting whole blood to challenge the claimed reportable range for Na^+, K^+, Ca^{++} and Cl^-. Each blood level was analyzed in triplicate on six (6) GEM Premier ChemSTAT test 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
Na^+ (mmol/L)	9	18	1.023	-1.189	0.9997	92 to 200	100 to 180
K^+ (mmol/L)	9	18	0.995	0.057	0.9998	0.2 to 19.6	0.3 to 19.0
Ca^{++} (mmol/L)	9	18	0.986	0.019	0.9984	0.04 to 4.27	0.10 to 4.25
Cl^- (mmol/L)	9	18	1.011	-1.909	0.9998	34 to 177	40 to 158

Performance Summary (Cont.)

Analytical Specificity

In accordance with EP07 3rd Edition, an interference study was conducted on the GEM Premier ChemSTAT for Na^+, K^+, Ca^{++} and Cl^-.

The table below and on the next page lists the substances that were screened with no observed interference on Na^+, K^+, Ca^{++} and/or Cl^-:

Test Substance	Test Concentration	Tested analytes where interference was not observed
Atracurium	50 mg/L	Sodium, Potassium, Ionized Calcium, Chloride
Benzalkonium (Chloride)	5 mg/L	Sodium, Potassium, Ionized Calcium, Chloride
Bilirubin	40 mg/dL	Sodium, Potassium, Ionized Calcium, Chloride
Ceftriaxone	1510 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Epinephrine	0.5 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Etomidate	50 mg/L	Sodium, Potassium, Ionized Calcium, Chloride
Fentanyl	0.03 µg/mL	Sodium, Potassium, Ionized Calcium, Chloride
Furosemide	48.1 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Gadodiamide	1.4 mmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Hemoglobin (Hemolysis)	1000 mg/dL	Sodium, Ionized Calcium, Chloride
Heparin	100,000 U/L	Sodium, Potassium, Ionized Calcium, Chloride
Ibuprofen	1060 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Leflunomide	100 µg/mL	Sodium, Potassium, Ionized Calcium, Chloride
Lithium	3.2 mmol/L	Sodium, Potassium
Methadone	10.3 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Midazolam	0.376 mg/dL	Sodium, Potassium, Ionized Calcium, Chloride
Morphine	27.3 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
N-Acetyl-L-cysteine	920µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Perchlorate	20 mg/dL	Sodium, Potassium, Ionized Calcium
Phenobarbital	2970 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride

Performance Summary (Cont.)

Analytical Specificity (Cont.)

Test Substance	Test Concentration	Tested analytes where interference was not observed
Piperacillin	110 mg/dL	Sodium, Potassium, Ionized Calcium, Chloride
Propofol	4.8 mg/dL	Sodium, Potassium, Ionized Calcium, Chloride
Salicylic acid	0.207 mmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Suxamethonium	68 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Tazobactam	3.05 mg/dL	Sodium, Potassium, Ionized Calcium, Chloride
Teriflunomide	100 µg/mL	Sodium, Potassium, Ionized Calcium, Chloride
Thiocyanate	898 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Thiopental	1660 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride
Triglycerides (Intralipid)	2000 mg/dL (1% Intralipid)	Sodium, Chloride, Ionized Calcium
Vancomycin	82.8 µmol/L	Sodium, Potassium, Ionized Calcium, Chloride

The table below lists substances that demonstrated interference with Na^+, K^+, Ca^{++} and/or Cl^- 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
Hemoglobin (Hemolysis)	Potassium	3.5 mmol/L	1000 mg/dL	+16 %	155 mg/dL	+7%
		5.0 mmol/L		+15 %	228 mg/dL	+7%
Perchlorate	Chloride	100 mmol/L	20 mg/dL	+6 %	18 mg/dL	+5%
		110 mmol/L		+5 %	17 mg/dL	+5%
Triglyceride (Intralipid)	Potassium	3.5 mmol/L	2000 mg/dL (1 % Intralipid)	+11 %	689 mg/dL (0.34 %)	+7%
		5.0 mmol/L		No Interference Observed		

Performance Summary (Cont.)

Reference Ranges

Analyte	Reference Range	Unit
Na^+	136 to 145	mmol/L
	136 to 145	mEq/L
K^+	3.5 to 5.1	mmol/L
	3.5 to 5.1	mEq/L
Ca^{++}	1.15 to 1.33	mmol/L
	2.30 to 2.66	mEq/L
	4.60 to 5.32	mg/dL
	1.16 to 1.32 (venous)	mmol/L
	2.32 to 2.64 (venous)	mEq/L
	4.64 to 5.28 (venous)	mg/dL
Cl^-	98 to 107	mmol/L
	98 to 107	mEq/L

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

Performance Summary (Cont.)

Clinical Testing

In accordance with EP09c, a method comparison study was conducted at three (3) point-of-care (POC) sites 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.

The pooled results from the POC sites are presented below.

Pooled Point-of-Care Sites					
Analyte	**N**	**Slope**	**Intercept**	**R**	**Sample Range**
Na^+ (mmol/L)	436	1.021	-2.157	0.987	100 to 170
K^+ (mmol/L)	442	1.000	0.100	0.999	0.5 to 18.2
Ca^{++} (mmol/L)	444	1.000	0.015	0.999	0.26 to 4.08
Cl^- (mmol/L)	435	1.000	1.000	0.994	45 to 154

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 Sodium, Potassium, Ionized Calcium and Chloride. 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).