October 1, 2020

Diamond Diagnostics Inc.
Kathy Fisher
Director, Quality Assurance
333 Fiske Street
Holliston, MA 01746

Re: k200544
Trade/Device Name: SmartLyte® Plus Electrolyte Analyzer $Na^+/K^+/Cl^-/Ca^{++}/Li^+$
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium Test System
Regulatory Class: Class II
Product Code: CEM, JGS, CGZ, JFP, JIH, JJE
Dated: August 12, 2020
Received: September 1, 2020

Dear Kathy Fisher:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez- Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
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)*
K200544

Device Name
SmartLyte® Plus Electrolyte Analyzer Na+/K+/Cl-/Ca++/Li+

Indications for Use *(Describe)*
The SmartLyte® Plus is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium in Serum, Sodium Heparin Plasma, and Venous Whole Blood, as well as measurement of sodium, potassium and chloride in pre-diluted Urine samples.

The SmartLyte® Plus Sodium Assay is intended to measure sodium in Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine on the SmartLyte® Plus Electrolyte Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute Urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The SmartLyte® Plus Potassium Assay is intended to measure potassium in Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine on the SmartLyte® Plus Electrolyte Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

The SmartLyte® Plus Chloride Assay is intended to measure the level of chloride in Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine on the SmartLyte® Plus Electrolyte Analyzer. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The SmartLyte® Plus Calcium Assay is intended to measure ionized calcium levels in Venous Whole Blood, Sodium Heparin Plasma, and Serum on the SmartLyte® Plus Electrolyte Analyzer. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

The SmartLyte® Plus Lithium Assay is intended to measure lithium (from the drug lithium carbonate) in Venous Whole Blood, Sodium Heparin Plasma, and Serum on the SmartLyte® Plus Electrolyte Analyzer. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

For in-vitro diagnostic use only.

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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510(k) 200544 Summary– SmartLyte® Plus Electrolyte Analyzer

(1) Submitted by:

Diamond Diagnostics, Inc.
333 Fiske St.
Holliston, MA 01746

(2) Contact Person:

Kathy Fisher, Director Quality Assurance
Phone: 508-429-0450 (x 358)
Fax: 866-771-9608
E-mail: kfisher@diamonddiagnostics.com

(3) Summary Prepared:

September 25, 2020

(4) Device Trade Name:

SmartLyte® Plus Electrolyte Analyzer $Na^+/K^+/Cl^-/Ca^{++}/Li^+$

(5) Regulatory Information

Description	CFR Section	Device Class	Product Code
Discrete photometric chemistry analyzer for clinical use	862.2160	Class I	JJE
Sodium Test System	862.1665	Class II	JGS
Potassium Test System	862.1600	Class II	CEM
Chloride Test System	862.1170	Class II	CGZ
Calcium Test System	862.1145	Class II	JFP
Lithium Test System	862.3560	Class II	JIH

(6) Predicate Devices:

Description	510(k)	Measurand
SmartLyte® (GEMLYTE)	K082462	Sodium, Potassium, Chloride, Calcium and Lithium

Statement of Technology Characteristics of the Device Compared to Predicate Device

Operating Principle	Predicate Device	SmartLyte® Plus
Potentiometric Na^+, K^+, Cl^-, Ca^{++}, Li^+	K082462	Same

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(7) Device Description:

The SmartLyte® Plus Na+, K+, Cl-, Ca++, Li+ Electrolyte Analyzer which can test Serum, Sodium Heparin Plasma, Venous Whole Blood, pre-diluted Urine samples, and QC materials is substantially equivalent to it's predicate SmartLyte® Na+, K+, Cl-, Ca++, Li+ Electrolyte Analyzer which tests Serum, Sodium Heparin Plasma, Venous Whole Blood, pre-diluted Urine samples, and QC materials. Both are microprocessor-controlled analyzers which utilize ion-selective electrodes for the measurement of Sodium, Potassium, Chloride, Calcium and Lithium in Serum, Sodium Heparin Plasma, Venous Whole Blood, pre-diluted Urine samples, and QC materials. The analyzer self-calibrates using Diamond Diagnostics Fluid Pack (510(k) 013850) every 4 hours throughout the day or on request. Sodium, Potassium, Chloride and Calcium are commonly measured for use in the diagnosis and management of patients with a broad range of renal, metabolic and cardiovascular disorders. Lithium is a drug used to treat mental illness. Mission controls (510 (k) 033063) are the recommended quality control material to be used daily.

The SmartLyte® Plus is intended to be a direct replacement for the SmartLyte® Electrolyte Analyzer (K082462).

The SmartLyte® Plus Electrolyte Analyzer is designed for clinical laboratory use by laboratory professionals to assess the levels of Sodium, Potassium, Chloride, Calcium and Lithium found in Venous Whole Blood, Sodium Heparin Plasma, Serum, and Urine of patients. The analysis is performed in-vitro, and neither the analyzer nor any of its components come in contact with the patient.

This analyzer is used by laboratory trained technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte imbalance and drug (lithium) regulation. These locations routinely conform to CLIA regulations and conduct daily quality control programs.

(8) Indications for Use:

The SmartLyte® Plus is an automated, microprocessor-controlled analyzer which utilizes ion-selective electrodes for the measurement of sodium, potassium, chloride, calcium and lithium in Serum, Sodium Heparin Plasma, and Venous Whole Blood, as well as measurement of sodium, potassium and chloride in pre-diluted Urine samples.

The SmartLyte® Plus Sodium Assay is intended to measure sodium in Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine on the SmartLyte® Plus Electrolyte Analyzer. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute Urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

The SmartLyte® Plus Potassium Assay is intended to measure potassium in Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine on the SmartLyte® Plus Electrolyte Analyzer. Measurements obtained by his device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

The SmartLyte® Plus Chloride Assay is intended to measure the level of chloride in Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine on the SmartLyte® Plus Electrolyte Analyzer. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The SmartLyte® Plus Calcium Assay is intended to measure ionized calcium levels in Venous Whole Blood, Sodium Heparin Plasma, and Serum on the SmartLyte® Plus Electrolyte Analyzer. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

The SmartLyte® Plus Lithium Assay is intended to measure lithium (from the drug lithium carbonate) in Venous Whole Blood, Sodium Heparin Plasma, and Serum on the SmartLyte® Plus Electrolyte Analyzer. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

For in-vitro diagnostic use only.

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Technological Characteristics of the Device:

(9) Measurement Principles:

The principles of measurements used in the SmartLyte® Plus Electrolyte Analyzer are identical to those principles existing in the current SmartLyte® electrolyte analyzer (K082462) and AVL 9180 (K961458) and are substantially equivalent to the K823480 (IL Flame Photometer) and K810615 (925 Chloridometer).

The SmartLyte® Plus measures sodium, potassium, chloride, calcium and lithium in Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine using ion selective electrode technology. The sodium electrode contains a glass tube, specially formulated to be sensitive to sodium ions. The potassium, calcium and lithium each incorporate neutral carrier ionophore membranes which are highly selective for their respective ions. The chloride contains an ionophore covalently bound to a substrate which is sensitive to negatively charged ions. The potential of each electrode is measured relative to a fixed, stable reference established by a silver/silver chloride electrode in concentrated salt solution. The measured potential varies with the concentration of the ion sensed by the electrode.

Comparison to Predicate Devices:

The SmartLyte® Plus software has been modified to measure samples within 30 seconds. In addition, the hardware was changed to allow saving of more than one sample or calibration result and increased QC storage capacity as well. The Hardware has also been modified to enable the instrument to have internet connection via LAN or WiFi. Moreover, an RFID board was added to the CPU board so that individual reagent packs can be monitored for fluid consumption. All other functionality has remained unchanged from the Predicate SmartLyte®.

The table below compares the Candidate Device to its predicates.

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Comparison to Predicate Devices		
Item	**CANDIDATE DEVICE**	**PREDICATE 1**
Trade/proprietary name	Smartlyte Plus Electrolyte Analyzer	Smartlyte Electrolyte Analyzer
Model number	Na K Cl Ca Li	Na K Cl Ca Li
Manufacturer	Diamond Diagnostics Inc.	Diamond Diagnostics Inc.
510(k)/PMA reference number		K082462
Intended use	Sodium, Potassium, Chloride, Calcium, Lithium determination	same
Sample Type	Blood, serum, plasma, urine	same
Measurement Principle	Ion Selective Electrodes	same
Analysis time, blood	30 sec	57 sec
Analysis time, Urine	30 sec	57 sec
Measurement Range, Blood		
Na	40 - 200 mmol/L	same
K	1.7 - 15 mmol/L	same
Cl	50 - 200 mmol/L	same
Ca	0.3 - 5.0 mmol/L	same
Li	0.2 - 5.5 mmol/L	same
Measurement Range, Urine		
Na	3 - 300 mmol/L	same
K	5 - 120 mmol/L	same
Cl	15 - 300 mmol/L	same
Sodium: Blood, Plasma, Serum Precision		
Expected, within run CV	≤ 1 %	same
Expected, between run CV	≤ 2 %	same
Potassium: Blood, Plasma, Serum, Precision		
Expected, within run CV	≤ 1.5 %	same
Expected, between run CV	≤ 3 %	same
Chloride: Blood, Plasma, Serum Precision		
Expected, within run CV	≤ 1 %	same
Expected, between run CV	≤ 3 %	same
Ionized Calcium: Blood, Plasma, Serum, Precision		
Expected, within run sd	≤ 0.02	same
Expected, between run sd	≤ 0.06	same
Lithium: Blood, Plasma, Serum, Precision		
Expected, within run sd	≤ 0.03	same
Expected, between run sd	≤ 0.09	same
Sodium: Urine Precision		
Expected, within run CV	≤ 5 %	same
Expected, between run CV	≤ 5 %	same
Potassium: Urine Precision		
Expected, within run CV	≤ 5 %	same
Expected, between run CV	≤ 5 %	same
Chloride: Urine Precision		
Expected, within run CV	≤ 5 %	same
Expected, between run CV	≤ 5 %	same
Calibration	Automatic and on Demand	same
Reagent Pack	Standard A 350 ml Standards B and C 85 ml each Reference Solution 85 ml Waste Bag R/W RFID Tag for monitoring individual fluid pack consumption	same same same same same
QC storage	LEVELS 1, 2, 3 (500 each)	LEVELS 1, 2, 3 (500 each)
Sample Results Storage	10000	1000
Sample Data Recall	Recall by Date, Sample ID, Last Sample, All Daily, All Weekly, All	same
Output	5" touchscreen color display	32 character, 2 line alphanumeric display
	16 Column thermal printer	same
	RS-232 Serial port	same
	USB Ports (4)	USB Ports (2)
	RFID Board to R/W RFID Tag	same
Power Requirements	100-240V 50/60Hz 1.6 A	same
Microcontroller processor	STM32F407BG	LM3S5B91
Program Flow	Multi level menu structure	Single level menu structure

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Calibration:

The SmartLyte® Plus performs a 2-point calibration (3-point calibration if lithium) every 4 hours. The software also permits calibration on demand. A 1-point calibration is performed automatically with each measurement.

Technical Specifications: Analyzer tests samples for $Na^+/K^+/Cl^-/Ca^+/Li^+$

Sample Types: Venous Whole Blood, Serum, Sodium Heparin Plasma, Aqueous, Urine

Sample Size: 95µL Whole Blood, Plasma, Serum,
180µL 1:3 dilution of Urine

Measurement Range:

Parameter	Matrix	Specified range
Na+	B/P/S/Q	40 - 200 mmol/L
	U	3 - 300 mmol/L
K+	B/P/S/Q	1.7 - 15 mmol/L
	U	5 - 120 mmol/L (60 – 120 mmol/L with additional dilutions)
Cl-	B/P/S/Q	50 - 200 mmol/L
	U	15 - 300 mmol/L
iCa++	B/P/S/Q	0.3 – 5.0 mmol/L
Li+	B/P/S/Q	0.2 - 5.5 mmol/L

B = Whole Blood P = Plasma S = Serum Q = Aqueous QC U = Urine

Display Resolution:

Blood, Plasma, Serum, Aqueous QC

Na^+: 0.1 mmol/L
K^+: 0.01 mmol/L
Cl^-: 0.1 mmol/L
Ca^{++}: 0.001 mmol/L
Li^+: 0.001 mmol/L

Urine

Na^+: 0.1 mmol/L
K^+: 0.01 mmol/L
Cl^-: 0.1 mmol/L

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Precision:

Blood, Plasma, Serum

	Na^+	K^+	Cl^-	Ca^{++}	Li^+
Within Run (n=30)	C.V. ≤ 1%	C.V. ≤ 1.5%	C.V. ≤ 2%	SD ≤ 0.02	SD ≤ 0.03
Between Run (10 days)	C.V. ≤ 2%	C.V. ≤ 3%	C.V. ≤ 3%	SD ≤ 0.06	SD ≤ 0.09

Urine

	Na^+	K^+	Cl^-
Within Range (n=30)	C.V. ≤ 5%	C.V. ≤ 5%	C.V. ≤ 5%
Between Run (10 days)	C.V. ≤ 5%	C.V. ≤ 5%	C.V. ≤ 5%

Analysis Time 30 seconds

Calibration Every 4 hours, on demand
2-point calibration Na^+, K^+, Cl^-, Ca^{++}
3-point calibration Li^+

Power
120 VAC, 5 Hz, 6 A or
220-240 VAC, 24 Hz, 2 A
(Factory set)

Size and Weight
12.4” (31.5cm) W x 13.2” (33.5cm) H x 11.6” (29.5cm) D, 13 lbs. (<6 kg)

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(10) Summary of nonclinical tests submitted with the premarket notification for device.

Precision - Venous Whole Blood, Serum, Sodium Heparin Plasma and Urine.

REFERENCE

Precision was evaluated based on the following reference:

- Clinical Laboratory Standard Institute – CLSI, EP5-A3 Evaluation of Precision of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline-3rd Edition.

Precision – Within Run

Within run precision was calculated using Venous Whole Blood, Serum, Sodium Heparin Plasma, aqueous, and Urine samples for each measurand. Anticoagulant used for collecting Venous Whole Blood and Sodium Heparin Plasma samples was Sodium Heparin. The sample concentrations were at the low and high end of reference ranges and near the mid-point range. The protocol called for running 30 replicates of each sample without calibration between measurements. The replicates were run consecutively in one day.

Serum/Blood/Plasma		Urine (1:3 dilution)
Na+	C.V. ≤ 1%	C.V. ≤ 5%
K+	C.V. ≤ 1.5%	C.V. ≤ 5%
Cl-	C.V. ≤ 1%	C.V. ≤ 5%
Ca++	SD ≤ 0.02	
Li+	SD ≤ 0.03	

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Precision – Total

Total precision was calculated for all the Venous Whole Blood, Serum, Sodium Heparin Plasma, and Urine samples with concentrations spanning the reportable range. For Sodium Heparin Plasma, Serum, and Urine, each sample was tested in duplicate over a period of 20 days. Venous Whole Blood samples were tested over a 2-hour time period on 2 instruments with a calibration at the beginning and in the middle of testing. This was done since Sodium heparin Venous Whole Blood is not stable for long periods of time. A total of 20 samples were collected from 2 instruments to achieve a total of 40 replicates

Serum/Blood/Plasma		Urine (1:3 dilution)
Na+	C.V. ≤ 2%	C.V. ≤ 5%
K+	C.V. ≤ 3%	C.V. ≤ 5%
Cl-	C.V. ≤ 3%	C.V. ≤ 5%
Ca++	SD ≤ 0.06	
Li+	SD ≤ 0.09	

Precision Serum, mmol/L

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	115.13	2.610	76.24	0.4503	0.5612
SD	0.95	0.031	0.47	0.0033	0.0050
%CV	0.82	1.20	0.62	0.74	0.89
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	132.48	4.167	103.41	1.0923	1.1763
SD	0.20	0.011	0.33	0.0041	0.0101
%CV	0.15	0.27	0.32	0.37	0.86
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	162.35	6.859	131.02	1.5722	2.2646
SD	0.44	0.035	0.38	0.0068	0.0220
%CV	0.27	0.51	0.29	0.43	0.97
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	115.20	2.52	76.81	0.45	0.56
SD	1.15	0.04	1.10	0.00	0.00
%CV	1.00	1.63	1.44	0.59	0.88
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	132.43	4.95	104.70	1.09	1.18
SD	0.80	0.06	0.66	0.00	0.01
%CV	0.60	1.20	0.63	0.27	0.89
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	161.91	6.82	132.18	1.57	2.27
SD	1.42	0.18	1.41	0.01	0.02
%CV	0.87	2.69	1.07	0.33	0.88
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

Precision Plasma, mmol/L

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	108.63	2.533	83.20	0.5028	0.4120
SD	0.32	0.016	0.28	0.0021	0.0033
%CV	0.29	0.62	0.33	0.42	0.79
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	135.42	3.327	107.73	1.3297	1.0684
SD	0.43	0.015	0.38	0.0040	0.0194
%CV	0.32	0.46	0.35	0.30	1.81
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	167.73	6.885	140.93	1.6685	1.7837
SD	0.72	0.037	0.73	0.0077	0.0157
%CV	0.43	0.54	0.52	0.46	0.88
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	108.54	2.54	84.19	0.50	0.41
SD	0.72	0.03	1.20	0.00	0.00
%CV	0.66	1.36	1.42	0.43	0.84
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	135.15	4.10	108.83	1.33	1.06
SD	0.88	0.06	0.92	0.00	0.02
%CV	0.65	1.53	0.85	0.24	1.67
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	167.16	6.88	142.60	1.67	1.79
SD	1.58	0.26	1.66	0.01	0.01
%CV	0.94	3.78	1.17	0.54	0.73
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

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Precision Whole Blood, mmol/L

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	103.35	2.717	81.15	0.6546	0.5242
SD	0.48	0.032	0.71	0.0029	0.0036
%CV	0.47	1.19	0.88	0.45	0.69
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	139.28	3.575	105.22	1.0664	0.9842
SD	0.66	0.049	0.76	0.0157	0.0122
%CV	0.47	1.38	0.72	1.47	1.24
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-	Ca++	Li+
Mean	163.33	7.177	139.91	1.6935	1.5573
SD	0.96	0.025	0.85	0.0197	0.0285
%CV	0.59	0.35	0.61	1.16	1.83
N	30	30	30	30	30
Criteria	≤1	≤1.5	≤1	≤0.02	≤0.03
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl	Ca++	Li+
Mean	103.10	2.72	81.75	0.65	0.52
SD	0.37	0.02	0.86	0.01	0.01
%CV	0.36	0.63	1.05	1.05	1.60
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	139.34	4.36	106.57	1.07	0.97
SD	0.53	0.03	0.84	0.02	0.01
%CV	0.38	0.75	0.78	1.83	1.52
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	0.09
Status	Pass	Pass	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-	Ca++	Li+
Mean	163.18	7.15	141.54	1.67	1.52
SD	0.63	0.17	1.16	0.03	0.05
%CV	0.38	2.44	0.82	1.57	3.33
N	40	40	40	40	40
Criteria	≤2	≤3	≤3	≤0.06	≤0.09
Status	Pass	Pass	Pass	Pass	Pass

Precision Urine, mmol/L

Within Run	Na^+	K+	Cl-
Mean	62.61	28.811	90.38
SD	1.03	0.147	0.96
%CV	1.64	0.51	1.06
N	30	30	30
Criteria	≤5	≤5	≤5
Status	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-
Mean	108.92	46.644	139.83
SD	0.94	0.121	0.96
%CV	0.87	0.26	0.69
N	30	30	30
Criteria	≤5	≤5	≤5
Status	Pass	Pass	Pass

Within Run	Na^+	K+	Cl-
Mean	248.66	171.262	151.70
SD	1.62	0.967	0.92
%CV	0.65	0.56	0.61
N	30	30	30
Criteria	≤5	≤5	≤5
Status	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-
Mean	67.87	31.01	90.97
SD	2.69	1.00	2.44
%CV	3.97	3.23	2.68
N	40	40	40
Criteria	≤5	≤5	≤5
Status	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-
Mean	108.77	46.30	137.34
SD	1.85	0.77	2.05
%CV	1.70	1.66	1.49
N	40	40	40
Criteria	≤5	≤5	≤5
Status	Pass	Pass	Pass

Run to Run	Na^+	K+	Cl-
Mean	250.10	169.93	152.85
SD	2.18	1.44	1.87
%CV	0.87	0.85	1.22
N	40	40	40
Criteria	≤5	≤5	≤5
Status	Pass	Pass	Pass

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Linearity - Venous Whole Blood, Serum, Sodium Heparin Plasma and Urine.

REFERENCE

Linearity was evaluated based on the following reference:

- Clinical Laboratory Standard Institute – CLSI, EP6-A Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

Linearity was evaluated by preparing stock solutions with high concentrations of Na^+, K^+, Cl and Ca^{++} in pooled Venous Whole Blood, Serum, Sodium Heparin Plasma and Urine solutions. These stocks were diluted to concentrations across the measuring ranges of each analyte and matrix. Linear regression was performed on the results using expected values based on the stock sample dilution. The results are shown below.

Serum, measured compared to Expected Values, mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.01	2.60	0.9990	40 – 200	1.82	48
Potassium	1.02	0.03	0.9992	1.7 – 15	0.12	75
Chloride	1.00	1.89	0.9991	50 – 200	1.73	45
Calcium	0.98	-0.22	0.9939	0.3 – 5.0	0.12	72
Lithium	1.03	-0.05	0.9995	0.2 – 5.5	0.04	70

Plasma, measured compared to Expected Values, mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.00	5.29	0.9988	40 – 200	1.99	75
Potassium	1.01	0.07	0.9993	1.7 – 15	0.12	75
Chloride	0.97	6.29	0.9997	50 – 200	0.71	39
Calcium	1.01	0.06	0.9970	0.3 – 5.0	0.08	42
Lithium	1.00	-0.08	0.9983	0.2 – 5.5	0.06	42

Whole Blood, measured compared to Expected Values, mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.02	-4.52	0.9986	40 – 200	2.00	54
Potassium	1.02	-0.15	0.9990	1.7 – 15	0.14	69
Chloride	0.97	12.07	0.9974	50 – 200	2.61	42
Calcium	1.00	-0.09	0.9983	0.3 – 5.0	0.07	52
Lithium	0.97	0.13	0.9977	0.2 – 5.5	0.07	39

Urine, measured compared to Expected Values, mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.00	2.83	0.9988	3 – 300	3.43	19
Potassium	1.00	-0.48	0.9984	5 – 120	1.71	19
Chloride	1.03	-7.24	0.9987	15 – 300	4.00	19

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The linearity studies support the following reportable range.

Measuring Range Serum	Na: 40 - 200 mmol/L K: 1.7 - 15 mmol/L Cl: 50 - 200 mmol/L Ca: 0.3 - 5.0 mmol/L Li: 0.2 - 5.5 mmol/L
Measuring Range Plasma	Na: 40 - 200 mmol/L K: 1.7 - 15 mmol/L Cl: 50 - 200 mmol/L Ca: 0.3 - 5.0 mmol/L Li: 0.2 - 5.5 mmol/L
Measuring Range Whole Blood	Na: 40 - 200 mmol/L K: 1.7 - 15 mmol/L Cl: 50 - 200 mmol/L Ca: 0.3 - 5.0 mmol/L Li: 0.2 - 5.5 mmol/L
Measuring Range Urine	Na: 3 - 300 mmol/L K: 5 - 120 mmol/L Cl: 15 - 300 mmol/L

Interference –

Please refer to previous investigation carried out on predicate device SmartLyte® 510k 082462.

Traceability -

The SmartLyte® Plus Na assay is traceable to a flame emission spectrophotometry reference method, which uses reference materials from the National Institute of Standards and Technology (NIST).

The SmartLyte® Plus K assay is traceable to a flame emission spectrophotometry reference method, which uses reference materials from the NIST.

The SmartLyte® Plus Cl assay is traceable to a coulometric reference method, which uses reference materials from the NIST.

The SmartLyte® Plus Ca++ assay is traceable to a flame emission spectrophotometry reference method, which uses reference materials from the NIST.

The SmartLyte® Plus Li+ assay is traceable flame emission spectrophotometry reference method, which uses reference materials from the NIST.

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Detection Limit –

The sponsor performed a study to evaluate the limit of blank (LoB), limit of detection (LoD) and limit of quantification for ionized calcium and ionized lithium using altered Serum, Sodium Heparin Plasma, and Venous Whole Blood samples. Study samples were prepared from Serum and heparinized (sodium heparin) Venous Whole Blood and Sodium Heparin Plasma samples. Varying amounts of sodium citrate were added to some samples to bind the ionized calcium and create blank and low level samples for Ca++. Blank samples for Li+ were made by spiking (using 1M LiCl solution) or dilution of the various sample types using saline solution. All the prepared samples were analyzed on the reference analyzer (Flame Photometer SN 86011421) to obtain the target values.

Analyte	Units	LoB	LoD	%TE	LoQ	Acceptance Criteria for %TE	Claimed Measurement Range
Serum – Ca++	mmol/L	0.047	0.089	5.541	0.299	21.6%	0.3 – 5.0
Serum – Li+	mmol/L	0.041	0.079	8.501	0.199	21.6%	0.2 – 6.0
Plasma – Ca++	mmol/L	0.035	0.072	11.868	0.302	21.6%	0.3 – 5.0
Plasma – Li+	mmol/L	0.040	0.053	14.085	0.174	21.6%	0.2 – 5.5
Whole Blood – Ca++	mmol/L	0.043	0.094	7.393	0.295	21.6%	0.3 – 5.0
Whole Blood – Li+	mmol/L	0.029	0.077	6.208	0.204	21.6%	0.2 – 5.5

The performance at the lower end of the measuring range for calcium and lithium is supported by the linearity studies.

(11) Summary of clinical tests

Method Comparison - Venous Whole Blood, Serum, Sodium Heparin Plasma and Urine.

REFERENCE

Method Comparison for Serum was evaluated based on the following reference:

- Clinical Laboratory Standard Institute – CLSI, EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline 3rd Edition.

Method Comparison testing was conducted to demonstrate the correlation of Diamond Diagnostics SmartLyte® Plus Analyzer to predicate devices operated by trained personnel. Venous Whole Blood, Serum, Sodium Heparin Plasma and Urine samples were collected for testing on the SmartLyte® Plus and the predicate device, the SmartLyte®. The anticoagulant used for all the samples was Sodium Heparin. Some samples were spiked or diluted to fully span the claimed measuring ranges. The results are summarized below. Regression analysis show good correlation to predicate with correlation coefficients typically greater than 0.99 and slope values between 0.97 and 1.03.

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Serum Comparison SmartLyte® Plus versus SmartLyte® (K082462), mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.01	-0.98	0.9960	42.5 - 200.7	1.33	117
Potassium	1.02	-0.23	0.9972	1.7 – 14.9	0.09	118
Chloride	1.01	-1.60	0.9958	50.1 – 198.5	1.08	125
Calcium	1.01	-0.02	0.9963	0.3 – 5.0	0.04	117
Lithium	1.00	0.08	0.9939	0.2 – 5.3	0.06	109

Plasma Comparison SmartLyte® Plus versus SmartLyte® (K082462), mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.02	-3.04	0.9962	40.6 – 198.5	1.40	110
Potassium	1.00	-0.13	0.9945	1.8 – 14.8	0.13	125
Chloride	0.99	0.33	0.9954	52.7 – 200.1	1.24	118
Calcium	1.03	-0.04	0.9982	0.3 – 4.6	0.03	113
Lithium	0.98	0.12	0.9940	0.2 – 5.3	0.05	122

Whole Blood Comparison SmartLyte® Plus versus SmartLyte® (K082462), mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.00	0.77	0.9987	43.7 – 198.6	0.67	109
Potassium	0.97	-0.08	0.9953	2.1 – 14.9	0.10	109
Chloride	1.03	-5.35	0.9952	51.4 – 197.8	1.16	108
Calcium	1.00	0.03	0.9983	0.3 – 5.1	0.02	112
Lithium	1.01	0.09	0.9960	0.2 – 5.4	0.05	110

Urine Comparison SmartLyte® Plus versus SmartLyte® (K082462), mmol/L

Parameter	Slope	Intercept	R^2	Range	Ste_{yx}	n
Sodium	1.01	-2.48	0.9985	5.0 – 290.0	1.91	117
Potassium	1.03	-0.49	0.9984	5.4 – 119.5	0.83	115
Chloride	1.00	2.42	0.9977	17.0 – 297.2	2.18	118

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The method comparison study supports correlation in the following reportable range.

Measuring Range Serum	Na: 40 - 200 mmol/L
	K: 1.7 - 15 mmol/L
	Cl: 50 - 200 mmol/L
	Ca: 0.3 - 5.0 mmol/L
	Li: 0.2 - 5.5 mmol/L
Measuring Range Plasma	Na: 40 - 200 mmol/L
	K: 1.7 - 15 mmol/L
	Cl: 50 - 200 mmol/L
	Ca: 0.3 - 5.0 mmol/L
	Li: 0.2 - 5.5 mmol/L
Measuring Range Whole Blood	Na: 40 - 200 mmol/L
	K: 1.7 - 15 mmol/L
	Cl: 50 - 200 mmol/L
	Ca: 0.3 - 5.0 mmol/L
	Li: 0.2 - 5.5 mmol/L
Measuring Range Urine	Na: 3 - 300 mmol/L
	K: 5 - 120 mmol/L
	Cl: 15 - 300 mmol/L

(12) Conclusions drawn from the clinical and non-clinical testing.

Analysis of the Venous Whole Blood, Serum, Sodium Heparin Plasma and Urine comparative measurements presented in the 510(k) for this device, together with the linearity and precision data collected during these clinical and non-clinical trials demonstrates that the Diamond Diagnostics SmartLyte® Plus Electrolyte Analyzer (with Na^+, K^+, Cl^-, Ca^{++}, Li^+) is safe, effective and substantially equivalent to the predicate devices, SmartLyte® ISE Analyzer (K082462).