January 14, 2025

Radiometer Medicals ApS
Andrea Swingle
Senior Specialist, Regulatory Affairs
Åkandevej 21
2700 Brønshøj
Denmark

Re: K241037
Trade/Device Name: ABL90 FLEX PLUS System
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium Test System
Regulatory Class: Class II
Product Code: CEM, JGS, JFP, CGA, KHP
Dated: December 10, 2024
Received: December 10, 2024

Dear Andrea Swingle:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241037

Device Name
ABL90 FLEX PLUS System

Indications for Use *(Describe)*
The ABL90 FLEX PLUS System is an in vitro diagnostic, portable, automated analyzer that quantitatively measures electrolytes (cK+, cNa+, cCa2+), glucose, and lactate in heparinized arterial and venous whole blood.

The ABL90 FLEX PLUS System is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient, or point-of-care setting.
These tests are only performed under a physician's order.

Potassium (cK+): Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa+): Sodium 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.

Calcium (cCa2+): Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Glucose (cGlu): Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (cLac): The lactate measurements measure the concentration of lactate. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

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) Summary – K240137

The information provided in this 510(k) summary are in accordance with 21 CFR 807.92

Submitter Information:

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Application Correspondent:

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Date prepared: January 14, 2024

Device Information

Device Trade Name:	ABL90 FLEX PLUS System
Common Name:	Blood Gas Analyzer
Regulations:	- 21 CFR 862.1600, Potassium test system - 21 CFR 862.1665, Sodium test system - 21 CFR 862.1145, Calcium test system - 21 CFR 862.1345, Glucose test system - 21 CFR 862.1450, Lactic acid test system
Product Codes:	CEM, JGS, JFP, CGA, KHP
Device Class:	Class I for KHP; All others: Class II
Classification Panel:	Clinical Chemistry

Predicate Device

Device Trade Name:	ABL90 FLEX
Common Name:	Blood Gas Analyzer
510(k)	K092686
Regulations:	- 21 CFR 862.1600, Potassium test system - 21 CFR 862.1665, Sodium test system - 21 CFR 862.1145, Calcium test system - 21 CFR 862.1345, Glucose test system 21 CFR 862.1450, Lactic acid test system

Product Codes:	CEM, JGS, JFP, CGA, KHP
Device Class:	Class I for KHP; All others: Class II
Classification Panels:	Clinical Chemistry

Device Description

The ABL90 FLEX PLUS System consists of the ABL90 FLEX PLUS analyzer, sensor cassette and solution pack consumables, and related accessories for the analyzers. The ABL90 FLEX PLUS is a portable, automated system intended for *in vitro* testing of samples of balanced heparinized whole blood for electrolytes (cK^+, cNa^+, cCa^{2+}), glucose, and lactate. The ABL90 FLEX PLUS System has an automated sample inlet mechanism, which can collect blood through two different measuring modes: the S65 syringe mode and the SP65 short probe mode.

Intended Use

The ABL90 FLEX PLUS System is an *in vitro* diagnostic, portable, automated analyzer that quantitatively measures electrolytes (cK^+, cNa^+, cCa^{2+}), glucose, and lactate in heparinized arterial and venous whole blood.

The ABL90 FLEX PLUS System is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient, or point-of-care setting.
These tests are only performed under a physician's order.

Potassium (cK^+): Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa^+): Sodium 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.

Calcium (cCa^{2+}): Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Glucose (cGlu): Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (cLac): The lactate measurements measure the concentration of lactate. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Substantial Equivalence Comparison

Substantial equivalence comparison table

	ABL90 FLEX PLUS System (This 510(k))	**ABL90 FLEX (510(k) K092686)**
Manufacturer	Radiometer Medical ApS	Radiometer Medical ApS
Indications for Use	The ABL90 FLEX PLUS System is an *in vitro* diagnostic, portable, automated analyzer that quantitatively measures electrolytes (cK^+, cNa^+, cCa^{2+}), glucose, and lactate in heparinized arterial and venous whole blood.	The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized whole blood. The ABL90 FLEX is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.
Intended Use	Measurement of cK^+, cNa^+, cCa^{2+}, *c*Glu and *c*Lac	Measurement of cK^+, cNa^+, cCa^{2+}, *c*Glu and *c*Lac
Intended use environment	Laboratory environment, near patient or point-of-care setting	Laboratory environment, near patient or point-of-care setting
Prescription/OTC Use	Prescription	Prescription
Sample requirements		
Sample type	Heparinized whole blood (arterial, venous)	Heparinized whole blood (arterial, venous)
Compatible sampling devices	Radiometer samplers (in S65 mode) and non-Radiometer samplers (in SP65 mode)	Radiometer samplers and non-Radiometer samplers
Sample volume	65 µL	65 µL
Sample preparation	With balanced heparin anticoagulant	With balanced heparin anticoagulant
Device design		
Operating principles	Potentiometry: cK^+, cNa^+, cCa^{2+}	Potentiometry: cK^+, cNa^+, cCa^{2+}
	Amperometry: *c*Glu and *c*Lac	Amperometry: *c*Glu and *c*Lac
Major components	• Touch screen • Barcode reader • Sample mixer • Inlet module • Fluid transport system • Oximetry module • Electronics • Software • Printer • Optional battery pack • Communication ports	• Touch screen • Barcode reader • Sample mixer • Inlet module • Fluid transport system • Oximetry module • Electronics • Software • Printer • Communication ports
Consumables	• Sensor cassette • Solution pack	• Sensor cassette • Solution pack
Performance characteristics		

	ABL90 FLEX PLUS System (This 510(k))	ABL90 FLEX (510(k) K092686)
Reportable ranges	*c*K^+: 2.1 - 10.5 mEq/L	*c*K^+: 2.1 - 10.5 mEq/L
	cCa^{2+}: 2.00 - 9.94 mg/dL	*c*Ca^{2+}: 2.00 - 9.92 mg/dL
	cNa^+: 116 - 180 mEq/L	*c*Na^+: 116 - 180 mEq/L
	*c*Glu: 18 - 738 mg/dL	*c*Glu: 9 - 738 mg/dL
	*c*Lac: 4 - 216 mg/dL	*c*Lac: 4 - 216 mg/dL

Analytical Performance Testing Summary

The ABL90 FLEX PLUS System has been tested for analytical performance, including tests for linearity, limit of blank, detection and quantification, precision, bias, interference, stability. The tests were conducted in general accordance with Clinical Laboratory Standards Institute (CLSI) guidelines, all of which are FDA-recognized consensus standards.

Linearity

Linearity testing was conducted in general accordance with CLSI EP06, *Evaluation of the Linearity of Quantitative Measurement Procedures*, 2nd Edition and EP39, *A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests*, 1st Edition. The resulting linearity intervals are listed in Table 1.

Table 1: Linearity results

Parameter (unit)	Reportable Range	Tested Range	Slope	Intercept	R2
cCa^{2+} (mg/dL)	2.00–9.94	1.896-11.146	0.883	0.445	1.000
cK^+ (mEq/L)	2.1–10.5	0.99-11.99	1.001	0.027	1.000
cNa^+ (mEq/L)	116–180	90.0-194.9	1.001	-0.642	1.000
*c*Glu (mg/dL)	18–738	17.5-926.1	1.032	-1.073	1.000
*c*Lac (mg/dL)	4–216	1.9-252.9	0.971	-0.433	1.000

Detection

Detection capability testing in terms of limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) was conducted. in general accordance with CLSI EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures*, and EP39, *A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests*, 1st Edition. Table 2 shows the results of the detection testing.

Table 2: Detection results

Parameter	Unit	LoB	LoD	LoQ
cCa^{2+}	mg/dL	*N/A*	*N/A*	1.26
cK^+	mEq/L	*N/A*	*N/A*	1.6
cNa^+	mEq/L	*N/A*	*N/A*	99
*c*Glu	mg/dL	-0.023	5	5

Parameter	Unit	LoB	LoD	LoQ
*c*Lac	mg/dL	-0.7	-0.3	2

N/A: Not applicable

Precision

Two precision studies were performed; both were in general accordance with CLSI EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures*.

Precision using stable, aqueous ampoule-based QC material

The primary endpoints of the study were repeatability and within laboratory precision for pooled across several sites. The secondary endpoint was reproducibility between sites. The sample material was Radiometer QUALICHECK5+ QC ampoules, a QC material that comes in four "levels". Testing occurred at three external sites. Table 3 presents the data on the primary and secondary endpoints.

Table 3: Precision results using QC materials

Parameter	QC ampoule	N	Mean	Repeatability		Within Lab Precision		Reproducibility	
				SD	CV%	SD	CV%	SD	CV%
***c*Ca²⁺ (mg/dL)**	QC5+ L 1	243	3.99	0.010	0.3	0.018	0.5	0.019	0.5
	QC5+ L 2	244	2.11	0.003	0.1	0.012	0.6	0.013	0.6
	QC5+ L 3	244	1.52	0.003	0.2	0.015	1.0	0.015	1.0
	QC5+ L 4	244	6.34	0.014	0.2	0.030	0.5	0.036	0.6
***c*Glu (mg/dL)**	QC5+ L 1	243	28	0.3	1.1	0.5	2.0	0.6	2.1
	QC5+ L 2	244	101	0.6	0.6	1.2	1.2	1.2	1.2
	QC5+ L 3	244	247	1.3	0.5	5.4	2.2	6.3	2.5
***c*K⁺ (meq/L)**	QC5+ L 1	243	1.7	0.00	0.2	0.02	1.0	0.02	1.1
	QC5+ L 2	244	3.7	0.00	0.1	0.01	0.2	0.01	0.2
	QC5+ L 3	244	5.4	0.01	0.1	0.01	0.2	0.01	0.2
	QC5+ L 4	244	6.1	0.01	0.1	0.02	0.3	0.02	0.3
***c*Lac (mg/dL)**	QC5+ L 1	243	39	0.3	0.8	0.5	1.3	0.5	1.3
	QC5+ L 2	244	15	0.2	1.1	0.2	1.5	0.2	1.6
	QC5+ L 3	244	97	0.3	0.3	1.2	1.3	1.2	1.3
***c*Na⁺ (meq/L)**	QC5+ L 1	243	162	0.2	0.1	0.2	0.1	0.3	0.2
	QC5+ L 2	244	141	0.1	0.1	0.1	0.1	0.1	0.1
	QC5+ L 3	244	126	0.1	0.1	0.2	0.1	0.2	0.1
	QC5+ L 4	244	119	0.1	0.1	0.3	0.3	0.3	0.3

N: Number of data points for analysis
SD: Standard Deviation
CV%: %Coefficient of Variation
QC5+ L **X:** QUALICHECK5+ Level **X**

Precision using blood

The primary endpoint of the study was repeatability, designated *SD*, pooled across sites. Two levels of concentration were covered for all parameters. Testing was conducted in both samples collection modes: syringe/S65 mode and short probe/SP65 mode. Table 4 summarizes the results of the study.

Table 4: Precision results using whole blood

Parameter	N	Test interval	Mean	Repeatability	
				SD	CV (%)
S65 Mode					
Ca^{2+} (mg/dL)	18	2.605 - <3.407	3.165	0.007	0.23
	70	3.407 - <4.609	4.403	0.016	0.37
	154	4.609 - <5.17	4.826	0.022	0.45
	4	5.17 - <5.812	5.313	0.003	0.06
K^+ (mEq/L)	18	2.5 - <3	2.682	0.009	0.35
	4	3 - <3.4	3.185	0.007	0.22
	202	3.4 - <4.5	3.908	0.010	0.25
	22	4.5 - <6	5.090	0.007	0.14

Parameter	N	Test interval	Mean	Repeatability	
				SD	CV (%)
Na^+ (mEq/L)	18	116 - <120	117.54	0.118	0.10
	24	120 - <136	133.56	0.194	0.14
	164	136 - <146	140.95	0.194	0.14
	40	146 - <155	150.02	0.161	0.11
Glu (mg/dL)	16	23 - <47	40.275	0.316	0.79
	2	47 - <65	49.150	0.354	0.72
	200	65 - <200	140.29	1.018	0.73
	28	200 - <595	262.32	2.221	0.85
Lac (mg/dL)	178	4 - <20	10.264	0.231	2.25
	14	20 - <27	22.686	0.177	0.78
	14	27 - <36	30.236	0.379	1.25
SP65 Mode					
Ca^{2+} (mg/dL)	18	2.605 - <3.407	3.171	0.005	0.16
	66	3.407 - <4.609	4.389	0.013	0.31
	156	4.609 - <5.17	4.823	0.012	0.24
	4	5.17 - <5.812	5.258	0.008	0.14
K^+ (mEq/L)	18	2.5 - <3	2.673	0.026	0.96
	8	3 - <3.4	3.280	0.005	0.15
	198	3.4 - <4.5	3.899	0.009	0.22
	20	4.5 - <6	5.031	0.007	0.14
Na^+ (mEq/L)	16	116 - <120	118.04	0.061	0.05
	24	120 - <136	133.48	0.094	0.07
	160	136 - <146	140.93	0.083	0.06
	42	146 - <155	149.79	0.091	0.06
Glu (mg/dL)	18	23 - <65	39.583	0.207	0.52
	194	65 - <200	138.79	1.098	0.79
	32	200 - <595	263.24	0.912	0.35
Lac (mg/dL)	178	4 - <20	10.222	0.200	1.96
	14	20 - <27	22.818	0.235	1.03
	14	27 - <36	30.813	0.231	0.75

N: Number of data points for analysis
Test interval: Range of values studied
SD: Standard Deviation
CV%: %Coefficient of Variation

Method comparison

Bias was determined by conducting a method comparison study in general accordance with CLSI EP09c, 3rd Edition, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples.* The comparator device was the ABL90 FLEX PLUS analyzer as it was designed at the time of the clearance of K160153, in terms of its characteristics related to analytical performance. Testing was conducted using both arterial and venous blood, and in both samples collection modes: syringe/S65 mode and short probe/SP65 mode. Analysis was performed by linear regression over the reportable range. Results are presented in Table 5 and Table 6.

Table 5: Method comparison results using reportable ranges specified in the protocol

Parameter	Blood type	Mode	n	Min-max	Intercept	Slope	R^2	Medical decision point	Bias at MD
cNa^+ (meq/L)	A	S65	225	117.2-179.5	0.039	1.002	0.999	136.00	0.287
		SP65	218	116.8-179.7	-0.227	1.003	0.999		0.223
	V	S65	234	117.2-179.5	-0.012	1.002	0.999		0.242
		SP65	224	116.8-179.7	-0.276	1.004	0.999		0.220
cK^+ (meq/L)	A	S65	222	2.12-10.4	0.018	0.996	0.999	3.400	0.004
		SP65	218	2.11-10.45	0.033	0.993	0.997		0.008
	V	S65	233	2.12-10.4	0.014	0.996	0.999		0.000
		SP65	225	2.11-10.45	0.033	0.992	0.997		0.007
cCa^{2+} (mg/dL)	A	S65	222	2.114-9.791	-0.014	1.003	0.999	4.600	0.001
		SP65	214	2.127-9.651	-0.046	1.011	0.999		0.003
	V	S65	231	2.114-9.791	-0.019	1.004	0.999		0.000
		SP65	220	2.127-9.651	-0.049	1.011	0.999		0.003
***c*Glu (mg/dL)**	A	S65	224	20.5-728.1	0.425	0.988	0.999	65.000	-0.337
		SP65	215	20.1-712.7	-0.024	0.990	0.999		-0.664
	V	S65	232	20.5-728.1	0.184	0.989	0.999		-0.558
		SP65	219	20.1-712.7	-0.045	0.990	0.999		-0.696
***c*Lac (mg/dL)**	A	S65	221	4.1-209.7	-0.182	1.007	0.995	18.000	-0.053
		SP65	216	4-209.9	-0.093	0.999	0.995		-0.119
	V	S65	233	4.3-209.7	-0.333	1.008	0.994		-0.181
		SP65	223	4.3-209.9	-0.202	1.000	0.995		-0.208

A: Arterial
V: Venous
Min-max: Range of values measured

Table 6: Method comparison results, arterial and venous combined, additional medical decision levels

Parameter	n	Intercept	Slope	R2	Medical decision point	Bias at MD
S65						
Ca (mg/dL)	437	-0.018	1.004	0.998	4.600	0.001
					5.170	0.003
Glu (mg/dL)	439	0.295	0.988	0.999	65.000	-0.460
					200.00	-2.028
K (mEq/L)	438	0.015	0.996	0.998	3.400	0.002
					4.500	-0.002
Lac (mg/dL)	436	-0.245	1.007	0.995	18.000	-0.116
					36.000	0.013
Na (mEq/L)	441	-0.077	1.003	0.999	136.00	0.265
					146.00	0.290
SP65						
Ca (mg/dL)	420	-0.047	1.011	0.998	4.600	0.003
					5.170	0.009

Parameter	n	Intercept	Slope	R2	Medical decision point	Bias at MD
Glu (mg/dL)	420	0.002	0.990	0.999	65.000	-0.663
					200.00	-2.045
K (mEq/L)	425	0.029	0.993	0.997	3.400	0.004
					4.500	-0.004
Lac (mg/dL)	422	-0.143	0.999	0.995	18.000	-0.156
					36.000	-0.169
Na (mEq/L)	425	-0.302	1.004	0.999	136.00	0.221
					146.00	0.259

Interference

Interfering substances were evaluated based on testing conducted in general accordance with CLSI, EP07, *Interference Testing in Clinical Chemistry*, 3rd Edition, and CLSI EP37, *Supplemental Tables for Interference Testing in Clinical Chemistry,* 1st Edition*.* The interference testing consists of two parts: paired-difference and dose-response studies. The paired-difference study was conducted on a large panel of likely interferents, using clinically significant amount of the interferents. Dose-response studies were only conducted in cases where a clinically significant interferent effect was noted during the paired different study. Table 7 summarizes the testing that was performed. Specific values for level of interference are described in Table 8.

Table 7: Interference testing

Interferent	*c*Ca^{2+}	*c*K^{+}	*c*Na^{+}	*c*Glu	*c*Lac
Intralipid	-	-	x	-	-
Hemolysis	x	x	x	-	-
Bilirubin (unconj)	-	-	-	-	-
Bilirubin (conj)	-	-	-	-	-
Biotin	-	-	-	-	-
Propofol	-	-	-	-	-
Fluoride				x	x
Potassium @ low level					-
Potassium @ high level	-		-		-
Sodium @ low level					-
Sodium @ high level	-	-			-
Calcium @ low level					-
Calcium @ high level		-	-		-
Lithium	-	-	-		
Ammoniumchloride		-	-		
Ascorbate	-	-	-	-	-
Benzalkonium chloride	x	x	x		
Leflunomide	x	-	-		
Nortriptyline	-	-	-		

Interferent	*c*Glu	*c*Lac
Lactate	-	
Thiocyanate	x	x
Acetaminophen	-	-
Acetoacetate	-	-
Chlorpromazine HCl	-	-
Creatinine	-	-
2-deoxy Glucose	x	-
EDTA	-	x
Formaldehyde	-	-
Formic acid	-	x
Galactose	x	-
Glucosamine HCl	-	-
Glycolic acid	-	x
Heparin	-	-
Ibuprofen	-	-
Maltose	-	-
Mannose	-	-
Methanol	-	-
N-acetylcystein	-	x

Interferent	*c*Ca²⁺	*c*K⁺	*c*Na⁺	*c*Glu	*c*Lac
Teriflunomide	x	x	x		
Thiopental			-		
Magnesium	x		-		
pH @ low level	x				
pH @ high level	x				
Perchlorate	-				
Strontium	-				
Oxalate				-	-
Salicylic acid				-	-
Acetylsalicylic acid				-	-
Citrate				-	x
Zinc	x	-	-		

Interferent	*c*Glu	*c*Lac
Pralidoxime chloride	-	-
Pyruvate	-	-
Urea	-	-
Uric acid	-	-
Xylose	-	-
Dopamine Hydrochloride	-	-
Ethanol	-	-
Povidone-iodine	x	
D-Glucose		-

Key

No clinically significant interference	-
Clinically significant interference	X
Interferent not relevant to be tested for this parameter	

Table 8: Interference values

Interferent	Maximum test concentration	Highest concentration level where interference was not significant	Impact on result for maximum test concentration
***c*Ca²⁺ (test level: 4.6 mg/dL)**			
Benzalkonium chloride	2.4 mg/dL	0.6 mg/dL	1.94 mg/dL
Hemolysis	20%	5%	-1.43 mg/dL
Leflunomide	30 mg/dL	15 mg/dL	-0.73 mg/dL
Magnesium (-nitrate) (test matrix: Plasma)	385 mg/dL	96 mg/dL	1.13 mg/dL
pH @ low level (test matrix: Plasma[a])	6.8	Interference for pH < 7.2	1.58 mg/dL
pH @ high level (test matrix: Plasma[a])	8.0	Interference for pH > 7.6	-1.20 mg/dL
Zn+ (Zinc chloride)	2.3 mg/dL	1.7 mg/dL	0.58 mg/dL
***c*Ca²⁺ (test level: 6.0 mg/dL)**			
Benzalkonium chloride	2.4 mg/dL	0.45 mg/dL	2.54 mg/dL
Hemolysis	20%	5%	-1.69 mg/dL
Leflunomide	30 mg/dL	22.5 mg/dL	-0.85 mg/dL
Magnesium (-nitrate) (test matrix: Plasma)	385 mg/dL	72 mg/dL	1.53 mg/dL
pH @ low level (test matrix: Plasma[a])	6.8	Interference for pH < 7.2	2.35 mg/dL
pH @ high level (test matrix: Plasma[a])	8.0	Interference for pH > 7.7	-0.84 mg/dL
Teriflunomide	30 mg/dL	22.5 mg/dL	-0.79 mg/dL

Interferent	Maximum test concentration	Highest concentration level where interference was not significant	Impact on result for maximum test concentration
Notes for Calcium: [a)] A change in the pH of blood has the physiological effect of changing the concentrations of ionized calcium. An increase of 1 pH unit results in a decrease of approximately 2 mg/dL *c*Ca^{2+}.			
cK^+ (test level: 3.5 mEq/L)			
Benzalkonium chloride	2.4 mg/dL	0.6 mg/dL	1.11 mEq/L
Hemolysis	20%	0.25%	13.1 mEq/L
Teriflunomide	30 mg/dL	15 mg/dL	-0.53 mEq/L
cK^+ (test level: 5.0 mEq/L)			
Benzalkonium chloride	2.4 mg/dL	0.6 mg/dL	1.27 mEq/L
Hemolysis	20%	0.40%	14.3 mEq/L
Teriflunomide	30 mg/dL	15 mg/dL	-0.88 mEq/L
cNa^+ (test level: 135 mEq/L)			
Benzalkonium chloride	2.4 mg/dL	0.12 mg/dL	28.0 mEq/L
Hemolysis	20%	2.5%	-15.3 mEq/L
Intralipid	2000 mg/dL	1000 mg/dL	5.0 mEq/L
Teriflunomide	30 mg/dL	22.5 mg/dL	-4.3 mEq/L
cNa^+ (test level: 145 mEq/L)			
Benzalkonium chloride	2.4 mg/dL	0.11 mg/dL	29.6 mEq/L
Hemolysis	20%	2.5%	-14.8 mEq/L
Intralipid	2000 mg/dL	1000 mg/dL	4.8 mEq/L
Teriflunomide	30 mg/dL	22.5 mg/dL	-4.8 mEq/L
cGlu (test level: 39.6 mg/dL)			
2-deoxy glucose	164 mg/dL	3.3 mg/dL	158 mg/dL
Bromide (sodium-) [a)]	391 mg/dL	49 mg/dL	-5.81 mg/dL
Fluoride (sodium-) [b)]	210 mg/dL	105 mg/dL	-5.6 mg/dL
Galactose	59 mg/dL	44 mg/dL	3.5 mg/dL
Povidone-iodine	1000 mg/dL	500 mg/dL	6.9 mg/dL
Thiocyanate (sodium-)	195 mg/dL	1.2 mg/dL	94 mg/dL
cGlu (test level: 220 mg/dL)			
2-deoxy glucose	164 mg/dL	25 mg/dL	165 mg/dL
Thiocyanate (sodium-)	195 mg/dL	10 mg/dL	99 mg/dL
Notes for Glucose: [a)] Paired-difference cGlu test level: 101 mg/dL. Dose-Response cGlu test level: 88 mg/dL. [b)] Do not use samples collected in fluorinated sampling tubes as exposure to high concentrations of fluoride causes falsely low cGlu results and may cause falsely low cGlu results in subsequent sample measurements.”			
cLac (test level:9.0 mg/dL)			
Bromide (sodium-) [a), b)]	391 mg/dL	49 mg/dL	-3.4 mg/dL
EDTA (edetate disodium 2H2O)	112 mg/dL	84 mg/dL	-1.67 mg/dL
Formic acid [e)]	115 mg/dL	29 mg/dL	-1.36 mg/dL
Glycolic acid [d)]	7.6 mg/dL	0.2 mg/dL	10 mg/dL

Interferent	Maximum test concentration	Highest concentration level where interference was not significant	Impact on result for maximum test concentration
N-acetylcysteine	166 mg/dL	125 mg/dL	-1.07 mg/dL
Thiocyanate (sodium-)	195 mg/dL	1.2 mg/dL	16 mg/dL
cLac (test level: 15.3 mg/dL)			
Citrate (trisodium citrate 2H2O)	1176 mg/dL	882 mg/dL	-1.9 mg/dL
EDTA (edetate disodium 2H2O)	112 mg/dL	56 mg/dL	-1.9 mg/dL
Fluoride (sodium-) [c)]	210 mg/dL	52.5 mg/dL	-1.5 mg/dL
Formic acid [e)]	115 mg/dL	86 mg/dL	-1.7 mg/dL
Glycolic acid [d)]	7.6 mg/dL	0.2 mg/dL	27 mg/dL
N-acetylcysteine	166 mg/dL	83 mg/dL	-1.40 mg/dL
Thiocyanate (sodium-)	195 mg/dL	2.4 mg/dL	21 mg/dL

Notes for Lactate:

[a)] Paired-difference cLac test level: 10.7 mg/dL. Dose-Response cLac test level: 28.6 mg/dL.

[b)] Normal physiological levels of bromide do not interfere. Exposure to high concentrations of Bromide causes falsely low cLac results and may cause falsely low cLac results on any subsequent samples measured within 5 minutes.

[c)] Do not use samples collected in fluorinated sampling tubes as exposure to high concentrations of fluoride causes falsely low cLac results and may cause falsely low cLac results in subsequent sample measurements."

[d)] Healthy patients have a glycolic acid concentration of 0.034 to 0.093 mg/dL. Ethylene glycol poisoning is a rare condition affecting about 20 people per million annually in the USA. Ethylene glycol poisoning may exhibit very high levels of glycolic acid. Levels up to 289 mg/dL have been reported. A glycolic acid level of 289 mg/dL may interfere with the lactate sensor for up to 5 minutes. If ethylene glycol poisoning is suspected or confirmed, do not use lactate for that sample or any subsequent samples measured within 5 minutes."

[e)] Healthy patients have a formic acid concentration of 0.1 to 0.9 mg/dL. Higher levels of formic acid may occur with methanol poisoning, which is a rare condition affecting about 6.4 persons per million annually in the USA.

Conclusion

The results above demonstrate the acceptable analytical performance of the ABL90 FLEX PLUS System and its substantial equivalence to its predicate.