December 13, 2024

Radiometer Medicals ApS
Andrea Swingle
Senior Specialist, Regulatory Affairs
Aakandevej 21
2700 Broenshoej
Denmark

Re: K240998
Trade/Device Name: ABL90 FLEX PLUS System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood Gases (PCO2, PO2) and Blood pH Test System
Regulatory Class: Class II
Product Code: CHL, GKR, GHS
Dated: November 15, 2024
Received: November 15, 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)*
K240998

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 pH, blood gas (pO2), Oximetry (sO2, ctHb, FO2Hb, FCOHb, FMetHb, and FHHb), 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.

pH and pO2: pH and pO2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

sO2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

ctHb (Total Hemoglobin): Total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

FO2Hb: Oxyhemoglobin as a fraction of total hemoglobin.

FCOHb: Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

FMetHb: Methemoglobin as a fraction of total hemoglobin.

FHHb: Reduced hemoglobin as a fraction of total hemoglobin.

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 – K240998

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: December 13, 2024

Device Information

Device Trade Name:	ABL90 FLEX PLUS System
Common Name:	Blood Gas Analyzer
Regulations:	- 21 CFR 862.1120, *Blood gases (pCO_2, pO_2) and blood pH test system* - 21 CFR 864.5620, *Automated hemoglobin system* - 21 CFR 864.7425, *Carboxyhemoglobin assay*
Product Codes:	CHL, GKR, GHS
Device Class:	Class II

Predicate Device

Device Trade Name:	ABL90 FLEX PLUS
Common Name:	Blood Gas Analyzer
510(k)	K160153
Regulations:	- 21 CFR 862.1120, *Blood gases (pCO_2, pO_2) and blood pH test system* - 21 CFR 864.5620, *Automated hemoglobin system* - 21 CFR 864.7425, *Carboxyhemoglobin assay*
Product Codes:	CHL, GKR, GHS
Device Class:	Class II
Classification Panels:	CHL Clinical Chemistry; GKR and GHS: Hematology

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 sensor cassettes, solution packs and related accessories are compatible with both analyzers. Multiple versions of the sensor cassettes are available. The sensor cassette versions vary in the maximum number of tests and availability of sensors for use. The solution pack is available in two versions, differing in the number of activities available.

Intended Use

The ABL90 FLEX PLUS System is an in vitro diagnostic, portable, automated analyzer that quantitatively measures pH, blood gas (pO2), Oximetry (sO2, ctHb, FO2Hb, FCOHb, FMetHb, and FHHb), 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.

pH and pO2: pH and pO2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

sO2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

ctHb (Total Hemoglobin): Total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

FO2Hb: Oxyhemoglobin as a fraction of total hemoglobin.

FCOHb: Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

FMetHb: Methemoglobin as a fraction of total hemoglobin.

FHHb: Reduced hemoglobin as a fraction of total hemoglobin.

Substantial Equivalence Comparison

Substantial equivalence comparison table

	ABL90 FLEX PLUS System (This 510(k))	**ABL90 FLEX PLUS (510(k) K160153)**
Manufacturer	Radiometer Medical	Radiometer Medical
Indications for Use	The ABL90 FLEX PLUS System is an In Vitro diagnostic, portable, automated analyzer that quantitatively measures, pH, blood gases (pO_2), Oximetry (sO_2, *c*tHb, FO_2Hb, *F*COHb, *F*MetHb, and *F*HHb), in heparinized arterial and venous whole blood.	The ABL90 FLEX analyzer is an In Vitro diagnostic, portable, automated analyzer that quantitatively measures, pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized whole blood, and neonatal bilirubin in heparinized capillary, venous and arterial whole blood. Bilirubin measurements on the ABL90 FLEX PLUS analyzer are intended to aid in assessing the risk of kernicterus in neonates.
Intended Use	Measurement of pH, pO_2, sO_2, *c*tHb, FO_2Hb, *F*COHb, *F*MetHb, and *F*HHb	Measurement of pH, pO_2, sO_2, *c*tHb, FO_2Hb, *F*COHb, *F*MetHb, and *F*HHb
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, capillary)
Compatible sampling devices	Radiometer samplers (in S65 mode) and non-Radiometer samplers (in S65 mode)	Radiometer samplers (in S65 mode) and non-Radiometer samplers (in S65 mode)
Sample volume	65 µL	65 µL
Sample preparation	With balanced heparin anticoagulant	With balanced heparin anticoagulant
Device design		
Operating principles	Potentiometry: pH	Potentiometry: pH
	Optical: pO_2	Optical: pO_2
	Spectrophotometry: sO_2, *c*tHb, FO_2Hb, *F*COHb, *F*MetHb, and *F*HHb	Spectrophotometry: sO_2, *c*tHb, FO_2Hb, *F*COHb, *F*MetHb, and *F*HHb
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 • Optional battery pack • Communication ports

	ABL90 FLEX PLUS System (This 510(k))	ABL90 FLEX PLUS (510(k) K160153)
Consumables	• Sensor cassette • Solution pack	• Sensor cassette • Solution pack
Performance characteristics		
Reportable ranges	pH: 6.818 - 7.797	pH: 6.818 - 7.797
	pO_2: 30.1 - 488 mmHg	pO_2: 30.1 - 488 mmHg
	sO_2: 3.3 - 100.0%	sO_2: 3.3 - 100.0%
	*c*tHb: 0.1 - 24.0 g/dL	*c*tHb: 0.1 - 24.0 g/dL
	FO_2Hb: 3.3 - 98.5%	FO_2Hb: 3.3 - 98.5%
	*F*COHb: 1.00 - 92.2%	*F*COHb: 1.00 - 92.2%
	*F*MetHb: 0.5 - 91%	*F*MetHb: 1.0 - 91%
	*F*HHb: 1.5 - 98.3%	*F*HHb: 2.4 - 98.5%

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	Linearity interval
Ph	6.605-7.997
pO_2	0.81-75.41 kPa
*c*tHb	0.068-27.660 g/dL
sO_2	2.18-100.22 %
FO_2Hb	2.18-98.96 %
*F*COHb	0.54-95.79 %
*F*MetHb	0.49-95.61 %
*F*HHb	0.53-98.37 %

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	Lower LoQ	Upper LoQ
pH	-	6.754	7.843

Parameter	Unit	LoB	LoD	LoQ
pO_2	mmHg	*N/A*	*N/A*	7.7
	kPa			1.02
*c*tHb	g/dL	0.03	0.09	0.09
*F*HHb	%	0.2	0.6	1.4
	Fraction	0.002	0.006	0.014
sO_2	%	*N/A*	*N/A*	1.4
	Fraction			0.014
FO_2Hb	%	*N/A*	*N/A*	1.4
	Fraction			0.014
*F*COHb	%	*N/A*	*N/A*	0.7
	Fraction			0.007
*F*MetHb	%	*N/A*	*N/A*	0.3
	Fraction			0.003

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

				Repeatability		Within Lab Precision		Reproducibility	
Parameter	**QC ampoule**	**N**	**Mean**	**SD**	**CV%**	**SD**	**CV%**	**SD**	**CV%**
***F*COHb (%)**	QC5+ L 1	243	5.9	0.03	0.6	0.06	1.0	0.11	1.8
	QC5+ L 2	244	2.8	0.03	1.1	0.08	2.9	0.13	4.7
	QC5+ L 3	244	20.0	0.02	0.1	0.05	0.3	0.05	0.3
	QC5+ L 4	244	10.1	0.02	0.2	0.03	0.3	0.06	0.6
FMetHb (%)	QC5+ L 1	243	5.0	0.01	0.3	0.03	0.6	0.05	0.9
	QC5+ L 2	244	2.0	0.02	0.8	0.04	2.1	0.05	2.3
	QC5+ L 3	244	10.0	0.02	0.2	0.02	0.2	0.03	0.3
	QC5+ L 4	244	20.1	0.04	0.2	0.06	0.3	0.09	0.4

Parameter	QC ampoule	N	Mean	Repeatability		Within Lab Precision		Reproducibility	
				SD	CV%	SD	CV%	SD	CV%
***F*HHb (%)**	QC5+ L 1	243	44.6	0.03	0.1	0.05	0.1	0.13	0.3
	QC5+ L 2	244	3.0	0.02	0.7	0.06	2.0	0.09	3.2
	QC5+ L 3	244	21.0	0.01	0.1	0.03	0.1	0.03	0.1
	QC5+ L 4	244	66.3	0.05	0.1	0.07	0.1	0.13	0.2
***F*O_2Hb (%)**	QC5+ L 1	243	44.6	0.03	0.1	0.05	0.1	0.05	0.1
	QC5+ L 2	244	92.2	0.04	0.0	0.06	0.1	0.06	0.1
	QC5+ L 3	244	49.0	0.02	0.1	0.05	0.1	0.05	0.1
	QC5+ L 4	244	3.5	0.01	0.3	0.03	0.7	0.03	0.8
pH	QC5+ L 1	243	7.066	0.0034	0.0	0.0034	0.0	0.0038	0.1
	QC5+ L 2	244	7.390	0.0018	0.0	0.0018	0.0	0.0019	0.0
	QC5+ L 3	244	7.582	0.0018	0.0	0.0018	0.0	0.0018	0.0
	QC5+ L 4	244	6.784	0.0037	0.1	0.0037	0.1	0.0041	0.1
***p*O_2 (mmHg)**	QC5+ L 1	243	154.3	1.91	1.2	2.87	1.9	3.13	2.0
	QC5+ L 2	244	100.3	1.13	1.1	2.01	2.0	2.01	2.0
	QC5+ L 3	244	56.1	0.95	1.7	1.33	2.4	1.33	2.4
	QC5+ L 4	244	310.0	3.00	1.0	5.51	1.8	6.95	2.2
***s*O_2 (%)**	QC5+ L 1	243	50.0	0.01	0.0	0.02	0.0	0.06	0.1
	QC5+ L 2	244	96.9	0.03	0.0	0.07	0.1	0.12	0.1
	QC5+ L 3	244	70.0	0.01	0.0	0.03	0.0	0.03	0.0
	QC5+ L 4	244	5.0	0.01	0.2	0.03	0.5	0.03	0.5
***c*tHb (g/dL)**	QC5+ L 1	243	8.1	0.02	0.2	0.03	0.4	0.04	0.6
	QC5+ L 2	244	12.9	0.03	0.2	0.04	0.3	0.06	0.5
	QC5+ L 3	244	19.3	0.03	0.2	0.06	0.3	0.09	0.5
	QC5+ L 4	244	2.7	0.01	0.4	0.02	0.6	0.02	0.6

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 summarize the results of the study.

Table 4: Precision results using whole blood

Parameter (unit)	N	Test interval	Mean	Repeatability	
				SD	CV%
S65 Mode					
pH (pH unit)	18	6.9 - <7.2	7.141	0.003	0.04
	38	7.2 - <7.35	7.298	0.002	0.03
	130	7.35 - <7.45	7.405	0.003	0.04
	60	7.45 - <7.55	7.480	0.003	0.04
***p*O₂ (mmHg)**	48	30.1 - <60	41.904	0.252	0.60
	114	60 - <83	73.424	1.031	1.40
	42	83 - <108	90.771	1.198	1.32
	18	108 - <150	124.50	0.850	0.68
***c*tHb (g/dL)**	24	6.750 - 7.950	7.533	0.082	1.08
	184	8.050 - 13.250	10.784	0.083	0.77
	34	13.550 - 17.150	14.941	0.077	0.51
***s*O₂ (%)**	34	3.3 - <80	64.221	0.890	1.39
	36	80 - <94	91.767	0.147	0.16
	158	94 - <100	96.934	0.177	0.18
***F*O₂Hb (%)**	34	3.3 - <80	63.215	0.918	1.45
	64	80 - <94	91.677	0.146	0.16
	130	94 - <98.5	96.083	0.165	0.17
***F*MetHb (%)**	62	0.5 - <1.5	0.797	0.070	8.73
	4	1.5 - <20	1.825	0.050	2.74
	12	20 - <50	40.667	0.058	0.14
***F*COHb (%)**	162	1 - <5	1.323	0.059	4.48
	6	5 - <35	32.733	0.058	0.18
	12	35 - <50	39.492	0.065	0.16
***F*HHb (%)**	112	1.5 - <5	2.876	0.198	6.87
	34	10 - <40	30.297	0.860	2.84
	4	40 - <70	53.350	0.158	0.30
SP65 Mode					
pH (pH unit)	18	6.9 - <7.2	7.135	0.003	0.05
	33	7.2 - <7.35	7.302	0.001	0.02
	133	7.35 - <7.45	7.402	0.002	0.02
	60	7.45 - <7.55	7.482	0.001	0.01
***p*O₂ (mmHg)**	49	30.1 - <60	42.322	0.197	0.47
	96	60 - <83	73.383	0.842	1.15
	55	83 - <108	91.136	1.343	1.47
	20	108 - <150	121.85	1.204	0.99
***c*tHb (g/dL)**	16	6.5 - <8	7.456	0.066	0.89
	188	8 - <13.5	10.598	0.091	0.86
	36	13.5 - <17.5	14.931	0.069	0.46
***s*O₂ (%)**	36	3.3 - <80	62.644	0.282	0.45
	33	80 - <94	91.858	0.203	0.22
	155	94 - <100	97.126	0.234	0.24
***F*O₂Hb (%)**	36	3.3 - <80	61.633	0.306	0.50
	59	80 - <94	91.763	0.181	0.20
	131	94 - <98.5	96.327	0.185	0.19
***F*MetHb (%)**	62	0.5 - <1.5	0.777	0.070	9.04
	4	1.5 - <20	1.825	0.050	2.74
	12	20 - <50	40.575	0.050	0.12
***F*COHb (%)**	156	1 - <5	1.317	0.063	4.78
	6	5 - <35	32.683	0.041	0.12
	12	35 - <50	40.367	0.058	0.14
***F*HHb (%)**	109	1.5 - <5	3.045	0.248	8.14

Parameter (unit)	N	Test interval	Mean	Repeatability	
				SD	CV%
	30	10 - <40	31.060	0.292	0.94
	8	40 - <70	51.963	0.137	0.26

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
pO_2 (mmHg)	A	S65	222	32.7-476	0.720	0.995	0.999	83.000	0.344
		SP65	216	32.5-471	-0.065	1.002	0.998		0.119
	V	S65	191	30.1-476	0.044	0.994	0.999		-0.454
		SP65	192	30.1-471	-0.194	1.001	0.999		-0.128
pH (pH scale)	A	S65	226	6.848-7.797	0.015	0.998	0.999	7.350	-0.003
		SP65	220	6.843-7.796	0.025	0.996	0.999		-0.003
	V	S65	235	6.848-7.797	0.019	0.997	0.999		-0.003
		SP65	225	6.843-7.796	0.014	0.998	0.999		-0.003
sO_2 (%)	A	S65	213	3.3-100	-0.235	1.005	0.999	94.000	0.193
		SP65	204	3.4-100	-0.033	1.003	1.000		0.280
	V	S65	222	3.3-99.3	-0.078	1.000	0.998		-0.083
		SP65	212	3.4-99.2	-0.040	1.000	0.998		-0.003
***F*O_2Hb (%)**	A	S65	202	3.3-98.5	-0.319	1.006	0.999	94.000	0.235
		SP65	192	3.4-98.5	-0.075	1.003	0.999		0.210
	V	S65	222	3.3-98	-0.021	0.999	0.998		-0.136
		SP65	213	3.4-98.1	0.083	0.997	0.998		-0.180
***F*HHb (%)**	A	S65	131	1.4-95.8	-0.041	1.003	1.000	10.000	-0.011
		SP65	119	1.4-95.4	-0.159	1.000	1.000		-0.156
	V	S65	220	3.1-95.8	0.051	1.000	0.998		0.056
		SP65	211	2.8-95.4	0.004	1.000	0.998		0.001
***F*COHb (%)**	A	S65	133	1-87.6	-0.237	1.001	1.000	10.000	-0.223
		SP65	123	1-90.3	-0.359	0.993	0.999		-0.429
	V	S65	197	1-87.6	-0.394	1.003	0.999		-0.360
		SP65	189	1-90.3	-0.409	0.994	0.999		-0.474

Parameter	Blood type	Mode	n	Min-max	Intercept	Slope	R^2	Medical decision point	Bias at MD
***F*MetHb (%)**	A	S65	32	0.5-86	-0.239	1.008	1.000	1.500	-0.227
		SP65	26	0.5-86	-0.316	1.012	1.000		-0.298
	V	S65	28	0.5-86	-0.209	1.007	1.000		-0.198
		SP65	27	0.5-86	-0.222	1.010	1.000		-0.206

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 Mode						
COHb (%)	322	-0.332	1.002	0.999	10.000	-0.307
					25.000	-0.271
					200.00	-2.028
HHb (%)	338	-0.023	1.003	0.999	10.000	0.005
					5.000	-0.009
					36.000	0.013
MetHb (%)	49	-0.229	1.008	1.000	1.500	-0.217
					20.000	-0.075
					146.00	0.290
O2Hb (%)	411	-0.492	1.007	0.999	94.000	0.160
					80.000	0.063
pH (pH scale)	442	0.018	0.997	0.998	7.350	-0.003
					7.450	-0.003
pO2 (mmHg)	401	0.111	0.999	0.999	83.000	0.002
					108.00	-0.031
sO2 (%)	422	-0.441	1.006	0.999	94.000	0.134
					80.000	0.048
tHb (g/dL)	427	0.015	1.006	0.994	8.400	0.068
					17.500	0.126
SP65 Mode						
COHb (%)	305	-0.394	0.993	0.999	10.000	-0.462
					25.000	-0.564
					200.00	-2.045
HHb (%)	318	-0.117	1.003	0.999	10.000	-0.089
					5.000	-0.103
					36.000	-0.169
MetHb (%)	42	-0.290	1.012	1.000	1.500	-0.272
					20.000	-0.055
					146.00	0.259

Parameter	n	Intercept	Slope	R2	Medical decision point	Bias at MD
O2Hb (%)	393	-0.381	1.005	0.999	94.000	0.123
					80.000	0.048
pH (pH scale)	427	0.023	0.996	0.999	7.350	-0.003
					7.450	-0.003
pO2 (mmHg)	396	-0.166	1.003	0.999	83.000	0.042
					108.00	0.105
sO2 (%)	404	-0.395	1.006	0.999	94.000	0.212
					80.000	0.122
tHb (g/dL)	412	0.069	1.001	0.996	8.400	0.076
					17.500	0.084

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	pH	pO_2	tHb	sO_2	FO_2Hb	FHHb	FCOHb	FMetHb
Intralipid	-	-	x	x	x	x	x	x
Hemolysis	-	-	-	-	-	-	-	-
Bilirubin (unconj)	-	-	-	-	-	x	-	-
Bilirubin (conj)	-	-	-	-	-	x	-	-
Biotin	-	-	-	-	-	-	-	-
Propofol	-	-	-	-	-	-	-	-
Potassium @ high level	-							
Sodium @ high level	-							
Calcium @ high level	-							
pH @ low level			-	-	-	-	-	x
pH @ high level			-	-	-	-	-	x
Betacarotene			-	-	-	-	-	-
Cardio green = indocyanine green			-	-	-	x	-	x
Cyanocobalamin			x	-	x	-	x	x
Evans Blue			-	-	-	-	-	-
HiCN			x	x	x	x	x	x
Hydroxo-cobalamine hydrochloride			x	-	x	x	x	x

Interferent	pH	pO_2	tHb	sO_2	FO_2Hb	FHHb	FCOHb	FMetHb
Methylene Blue			x	x	x	x	x	x
Patent Blue V = sulphan Blue			-	-	-	x	-	-
Rifampicin			-	-	-	-	-	-
SHb			x	x	x	x	x	x
Sodium Nitroprusside dihydrate			-	-	-	x	-	-
Triglyceride			-	-	-	x	-	x
HbF (fetal hemoglobin)				-	-	-	-	-
Fluoroescein		-	x	x	x	x	x	x

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
ctHb (test level: 10 g/dL)			
Cyanocobalamin	200 mg/dL	25 mg/dL	1.44 g/dL *
Fluorescein	40 mg/dL	30 mg/dL	-0.72 g/dL *
HiCN	30%	12%	1.2 g/dL *
Hydroxo-cobalamine hydrochloride	200 mg/dL	25 mg/dL	2.66 g/dL *
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	0.38 mg/dL	-3.94 g/dL *
SHb	10%	5%	-0.86 g/dL **
ctHb (test level: 20 g/dL)			
Cyanocobalamin	200 mg/dL	150 mg/dL	0.81 g/dL *
Fluorescein	40 mg/dL	30 mg/dL	-1.95 g/dL *
HiCN	30%	10%	2.4 g/dL *
Hydroxo-cobalamine hydrochloride	200 mg/dL	50 mg/dL	2.66 g/dL *
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	0.75 mg/dL	-4.15 g/dL *
SHb	10%	2.5%	-1.38 g/dL **
sO_2 (test level: 90%)			
Fluorescein	40 mg/dL	20 mg/dL	-5.62%*

Interferent	Maximum test concentration	Highest concentration level where interference was not significant	Impact on result for maximum test concentration
HiCN	30%	6.7%	-13%*
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	0.75 mg/dL	3.36%*
sO_2 (test level: 100%)			
Fluorescein	40 mg/dL	10 mg/dL	-6.58%*
HiCN	30%	6.3%	-14%*
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	1.5 mg/dL	4.40%*
***F*O_2Hb (test level: 90%)**			
Cyanocobalamin	200 mg/dL	150 mg/dL	-7.1%*
Fluorescein	40 mg/dL	No interference	2.4%*
HiCN	30%	3.1%	-37%*
Hydroxo-cobalamine hydrochloride	200 mg/dL	38 mg/dL	-14.7%*
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	1.5 mg/dL	27.0%*
SHb	10%	5%	-7.9%**
***F*O_2Hb (test level: 100%)**			
Cyanocobalamin	200 mg/dL	100 mg/dL	-8.5%*
Fluorescein	40 mg/dL	20 mg/dL	9.16%*
HiCN	30%	3.2%	-40%*
Hydroxo-cobalamine hydrochloride	200 mg/dL	38 mg/dL	-16.7%*
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	1.1 mg/dL	34.3%*
SHb	10%	5%	-14.6%**
***F*HHb (test level: 2.4%)**			
Bilirubin (unconj)	0.684 mmol/L 40 mg/dL	No interference	-0.26%
Bilirubin (conj)	0.475 mmol/L 40 mg/dL	No interference	-0.44%
Cardio green (indocyanine green)	3 mg/dL	0.75 mg/dL	-1.16%
Fluorescein	40 mg/dL	10 mg/dL	7.68%*
HiCN	30%	3.6%	8.9%*

Interferent	Maximum test concentration	Highest concentration level where interference was not significant	Impact on result for maximum test concentration
Hydroxo-cobalamine hydrochloride	200 mg/dL	No interference	-0.88%*
Intralipid	2000 mg/dL	800 mg/dL; No measurement result reported above 1600 mg/dL.	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	0.38 mg/dL	-4.44%*
Patent Blue V (sulphan Blue)	1 mg/dL	0.06 mg/dL	-1.78%
SHb	10%	0.5%	34.5%**
Sodium nitroprusside dihydrate	87 µg/L	No interference	-0.08%
Triglyceride	1600 mg/dL	800 mg/dL	1.42%
***F*HHb (test level: 10%)**			
Bilirubin (unconj)	0.684 mmol/L 40 mg/dL	0.17 mmol/L 10 mg/dL	-0.82%*
Bilirubin (conj)	0.475 mmol/L 40 mg/dL	0.06 mmol/L 5 mg/dL	-0.88%*
Cardio green (indocyanine green)	3 mg/dL	0.75 mg/dL	-2.0%
Fluorescein	40 mg/dL	5 mg/dL	7.34%*
HiCN	30%	4.5%	6.1%*
Hydroxo-cobalamine hydrochloride	200 mg/dL	150 mg/dL	-1.26%*
Intralipid	2000 mg/dL	1200 mg/dL; No measurement result reported above 1600 mg/dL.	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	0.38 mg/dL	-1.58%*
Patent Blue V (sulphan Blue)	1 mg/dL	0.006 mg/dL	-0.98%
SHb	10%	2.5%	17.2%**
Sodium nitroprusside dihydrate	87 µg/L	22 µg/L	-0.52%
Triglyceride	1600 mg/dL	1200 mg/dL	1.20%
***F*COHb (test level: 1%)**			
Cyanocobalamin	200 mg/dL	50 mg/dL	1.7%*
Fluorescein	40 mg/dL	2.5 mg/dL	-10.64%*
HiCN	30%	3.4%	6.3%*
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	No interference	0.64%*
SHb	10%	1.25%	1.08%**
***F*COHb (test level: 10%)**			
Cyanocobalamin	200 mg/dL	100 mg/dL	1.1%*
Fluorescein	40 mg/dL	3.75 mg/dL	-10.84%*
HiCN	30%	9.6%	2.9%*

Interferent	Maximum test concentration	Highest concentration level where interference was not significant	Impact on result for maximum test concentration
Intralipid	2000 mg/dL	1600 mg/d;L No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	1.5 mg/dL	1.88%*
SHb	10%	2.5%	1.58%**
***F*MetHb (test level: 1.0%)**			
Cardio green (indocyanine green)	3 mg/dL	1.5 mg/dL	-1.48%
Cyanocobalamin	200 mg/dL	12.5 mg/dL	5.44%*
Fluorescein	40 mg/dL	30 mg/dL	-9.88%*
HiCN	30%	1.1%	24%*
Hydroxo-cobalamine hydrochloride	200 mg/dL	8 mg/dL	13.1%*
Intralipid	2000 mg/dL	1200 mg/dL No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	0.08 mg/dL	-33%*
pH low	6.8	No interference	0.96%
pH high	8.0	No interference	-0.76%
SHb	10%	No interference	-0.7%**
Triglyceride	1600 mg/dL	1200 mg/dL	0.96%
***F*MetHb (test level: 10%)**			
Cardio green (indocyanine green)	3 mg/dL	1.5 mg/dL	-1.26%
Cyanocobalamin	200 mg/dL	12.5 mg/dL	4.28%*
Fluorescein	40 mg/dL	30 mg/dL	-11.2%*
HiCN	30%	1.3%	20%*
Hydroxo-cobalamine hydrochloride	200 mg/dL	9 mg/dL	13.3%*
Intralipid	2000 mg/dL	1600 mg/dL; No measurement result reported above 1600 mg/dL	Error message "Turbidity too high."
Methylene Blue	6 mg/dL	0.08 mg/dL	-35%*
pH low	6.8	Interference below 7.0	1.3%
pH high	8.0	Interference above 7.7	-1.52%
SHb	10%	0.5%	-5.8%**
Triglyceride	1600 mg/dL	No interference	0.82%

* The result at maximum test concentration is marked with error message "OXI spectrum mismatch"

** The result at maximum test concentration is marked with error message "Warning, SHb detected"

Conclusion

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