510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k041874

B. Purpose For Submission:

Notification from Radiometer Medical Aps of their intent to manufacture and market the new Radiometer ABL800 FLEX Blood gas ,Cooximetry, Electrolyte and Metabolite Analyzer.

C. Analyte:

The ABL800 FLEX is designed for use on undiluted whole human blood and expired air. The following parameters can be measured: pH(acidity), pCO_2(carbon dioxide tension), pO_2 (oxygen tension), ctHb(total hemoglobin concentration), sO_2(oxygen saturation), FO_2Hb(fraction of oxyhemoglobin in total hemoglobin), FCOHb(fraction of carboxyhemoglobin in total hemoglobin), FHHb, fraction of deoxyhemoglobin in total hemoglobin, FMetHb,(fraction of methemoglobin in total hemoglobin), FHbF(fraction of fetal hemoblobin),cK^+(potassium ion concentration, cNa^+(sodium ion concentration), cCa^{2+}(calcium ion concentration), cCl^-(chloride ion concentration), ctBil(concentration of total bilirubin in plasma)

The following samples can be measured on expired air samples:

pCO_2(carbon dioxide tension) and pO_2 (oxygen tension)

D. Type of Test:

With respect to sensor technology, the ABL800 FLEX is substantially equivalent to the predicate device ABL700 Series upgrade

	ABL800 FLEX Sensor Technology	ABL700 Series Upgrade Sensor Technology
Blood gases and pH	Electrochemical	Electrochemical
Sodium	Electrochemical	Electrochemical
Potassium	Electrochemical	Electrochemical
Calcium	Electrochemical	Electrochemical
Glucose	Electrochemical	Electrochemical
Lactate	Electrochemical	Electrochemical
Co-oximetry parameters	Optical	Optical
Bilirubin	Optical	Optical

E. Applicant: Radiometer Medical ApS

F. Proprietary and Established Names:

ABL800 FLEX blood gas, oximetry, electrolyte and metabolite analyzer.

Common Name: The analyzer is called ABL800 FLEX. There are several models of the device, all with 8xx number.

G. Regulatory Information:
Regulation section:

	CFR Section	Device Class	Product Code
Blood gases and blood pH	862.1120	II	CHL
Sodium test system	862.1665	II	JGS
Potassium test system	862.1600	II	CEM
Calcium test system	862.1145	II	JFP
Chloride test system	862.1170	II	CGZ
Glucose test system	862.1345	II	CGA
Lactic acid test system	862.1450	I	KHP
Bilirubin (total or direct test system	862.1110	II	CIG
Bilirubin in the neonate test system	862.1113	I (reserved)	MQM
Carboxyhemoglobin assay	864.7425	II	GHS
Automated hemoglobin system	864.5620	II	GKR
Fetal hemoglobin assay	864.7455	II	KQI

H. Intended use(s):

1. Intended use(s)

The ABL800 FLEX is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, FCOHb, FMetHb, FHHb, FHbF). In addition the ABL800 FLEX is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2. The ABL800 FLEX includes an AutoCheck Module to perform automated analysis of quality control fluids.

2. Indication(s) for use:

The ABL800 FLEX is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, FCOHb, FMetHb, FHHb, FHbF). In addition the ABL800 FLEX is intended for in vitro testing of samples of expired air for the parameters pO_2 and

pCO_2. The ABL800 FLEX includes an AutoChek Module to perform automated analysis of quality control fluids.

Indication for use information for the analytes measured by the ABL800 FLEX:

pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/blood gas measurement. The normal function of many metabolic processes requires a pH to be within a relatively narrow range.

***p*O$_2$:** The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

***p*CO$_2$:** *p*CO_2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.

Potassium (*c*K$^+$): The measurements of the concentration of potassium ions in plasma are used to monitor the electrolyte balance.

Sodium (*c*Na$^+$): The measurements of the concentration of sodium ions in plasma are used to monitor the electrolyte balance.

Calcium (*c*Ca^{2+}): The measurements of the concentration of calcium ions in plasma are used to monitor the electrolyte balance.

Chloride (*c*Cl$^-$): The measurements of the concentration of chloride ions in plasma are used to monitor the electrolyte balance.

Glucose (*c*Glu): The glucose measurements measure the concentration of glucose in plasma. The glucose measurements are used to screen for, diagnose and monitor diabetes, pre-diabetes, and hyper- and hypoglycemia.

Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements serve as a marker of critical imbalance between tissue oxygen demand and oxygen supply.

Bilirubin (*c*tBil): The bilirubin measurements measure the total concentration of bilirubin in plasma. *c*tBil is used to assess the risk of hyperbilirubinemia.

Total Hemoglobin (*c*tHb): *c*tHb is a measure of the potential oxygen-carrying capacity of the blood.

Oxygen Saturation (*s*O$_2$): *s*O2 is the percentage of oxygenated hemoglobin in relation to the amount of hemoglobin capable of carrying oxygen. *s*O2 allows evaluation of oxygenation.

Fraction of Oxyhemoglobin (*F*O$_2$Hb): *F*O_2Hb is a measure of the utilization of the potential oxygen transport capacity; that is the fraction of oxyhemoglobin in relation to all hemoglobins present (tHb) including dyshemoglobins.

Fraction of Carboxyhemoglobin (*FC*OHb): *F*COHb is the fraction of carboxyhemoglobin. It is incapable of transporting oxygen.

Fraction of Methemoglobin (*F*MetHb): *F*MetHb is the fraction of methemoglobin. It is incapable of transporting oxygen.

Fraction of Deoxyhemoglobin in Total Hemoglobin (*F*HHb): *F*HHb is the fraction of deoxyhemoglobin in total hemoglobin. It can bind oxygen then forming oxyhemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): Fetal hemoglobin consists of two α-chains and two β-chains, and has a higher oxygen affinity than adult Hb.

3. Special condition for use statement(s): For Prescription Use.

4. Special instrument Requirements: Radiometer ABL800 FLEX

I. Device Description:

The ABL800 FLEX will, as the predicate device ABL700 Series Upgrade, consists of several models of the same analyzer for the measurement of blood gas, electrolyte, metabolite and co-oximetry. The operator may choose a model wherein only pH and blood gases will be reported; or a model wherein only pH/blood gases. tHb and oxygen saturation will be reported; or a model wherein only pH/blood gases, electrolytes and metabolites will be reported; or a model wherein all the ABL800 FLEX parameters except the hemoglobin fractions will be reported; or a model wherein all the ABL 800 FLEX parameters except the electrolytes and metabolites parameters will be reported, etc. Each model may consist of a different model part number. The ABL 835 FLEX model includes all the possible parameter options, and is the platform on which all the other reduced parameters models are based.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   The ABL800 FLEX is substantially equivalent in features and characteristics to the predicate ABL700 Series Upgrade (k002290) manufactured by Radiometer Medical ApS. The ABL800 FLEX includes an AutoCheck module (a module for automatically performing quality control), which is identical to the ABL700 Analyzers AutoCheck Module (k992859).

2. Predicate K number(s): (k002290) ABL700 Series Upgrade
   (k992859) ABL700 Analyzers AutoCheck Module

3. Comparison with Predicate:

Technology
With respect to sensor technology, the ABL800 FLEX is substantially equivalent to the predicate device ABL700 Series upgrade

	ABL800 FLEX Sensor Technology	ABL700 Series Upgrade Sensor Technology
Blood gases and pH	Electrochemical	Electrochemical
Sodium	Electrochemical	Electrochemical
Potassium	Electrochemical	Electrochemical
Calcium	Electrochemical	Electrochemical
Glucose	Electrochemical	Electrochemical
Lactate	Electrochemical	Electrochemical
Co-oximetry parameters	Optical	Optical
Bilirubin	Optical	Optical

The sensors for pH, blood gases, electrolytes, metabolites and co-oximetry parameters are the same as in the ABL700 Series Upgrade.

Performance

With respect to performance, the ABL800 FLEX is substantially equivalent to the ABL700 Series Upgrade.

The measuring ranges for the two devices are as stated below:

Whole Blood

Parameter	ABL7800 Series low	ABL700 Series high	ABL800 FLEX low	ABL800 FLEX high	Unit
pH	6.300	8.000	6.300	8.000	
pO_2	0.0	800.0	0.0	800.0	mmHg
pCO_2	5.0	250.0	5.0	250.0	mmHg
cK^+	0.5	25.0	0.5	25.0	mmol/L
cNA^+	7	350	7	350	mmol/L
cCa^{++}	0.20	9.99	0.20	9.99	mmol/L
cCl^-	7	350	7	350	mmol/L
cGlucose	0.0	60.0	0.0	60.0	mmol/L
cLactate	0.0	30.0	0.0	30.0	mmol/L
ctHb	0.0	27.7	0.0	27.7	g/dL
ctBil	0.0	600	0.0	600	mg/L
sO_2	0.0	100.0	0.0	100.0	%
FO_2Hb	0.0	100.0	0.0	100.0	%
FCOHb	0.0	100.0	0.0	100.0	%
FMetHb	0.0	100.0	0.0	100.0	%
FHHb	0.0	100	0.0	100	%
FHbF	0.0	100	0.0	100	%

Gas

Parameter	ABL700 Series low	ABL700 Series high	ABL800 FLEX low	ABL800 FLEX high	Unit
pO_2	0.0	800	0.0	800	mmHg
pCO_2	5.0	250.0	5.0	250.0	mmHg

The test ranges for the two devices are as stated below:

Whole Blood

Parameter	ABL7800 Series low	ABL700 Series high	ABL800 FLEX low	ABL800 FLEX high	Unit
pH	7.0	7.7	7.0	7.7	
pO_2	15	530	15	530	mmHg
pCO_2	15	150	15	150	mmHg
cK^+	2	8	2	8	mmol/L
cNA^+	120	180	120	180	mmol/L
cCa^{++}	0.50	2.5	0.50	2.5	mmol/L
cCl^-	85	140	85	140	mmol/L
cGlucose	2	15	2	15	mmol/L
cLactate	0.3	10	0.3	10	mmol/L
ctHb	7	25	7	25	g/dL
ctBil	0	235	0	235	mg/L
sO_2	0	100	0	100	%
FO_2Hb	0	100	0	100	%
FCOHb	0	20	0	20	%
FMetHb	0	20	0	20	%
FHHb	0	20	0	20	%
FHbF	0	80	0	80	%

Gas

Parameter	ABL700 Series low	ABL700 Series high	ABL800 FLEX low	ABL800 FLEX high	Unit
pO_2	15	530	15	530	mmHg
pCO_2	15	150	15	150	mmHg

Measuring modes and sample volumes

As the ABL700 Series Upgrade, the ABL800 FLEX Analyzer comprises several different measuring modes. For each analyzer, the number of parameters reported depends on the model of the analyzer, and the number of parameters to be reported depends on the amount of sample available as well.

Generally for the ABL800 FLEX, the following parameters may be reported:

	Available sample volume	Measured parameters
Whole Blood	195µL and more	pH/BG/Oxi/Met/Lyte/Bil
	95-195µL	pH/BG/Met/Lyte (possibly Oxi/ctBil)
	55-95µL	pH/BG (possibly Oxi/Met/ctBil)
	35-55µL	pH (possibly Oxi/ctBil)
Gas	15 mL	pO_2/ pCO_2

In addition the ABL800 FLEX comprises an adaptive sample handling called FLEXMODE, which is described below:

The software now allows for a new adaptive sample handling called FLEXMODE. In case a too small sample volume has been introduced in the measuring mode with the largest volume, the sample will not be rejected. A measurement will be performed in FLEXMODE. Depending on the available sample volume, FLEXMODE provides the highest number of parameters as reliably possible.

Derived Parameters
For derived parameters, the ABL700 Series Upgrade and the ABL800 FLEX are identical.

Solutions and gases
The two calibration solutions, the rinse solution, the cleaning solution, the tHb calibrator and the calibration gases for the pO_2 and the pCO_2 sensors are of the same formulations as in the ABL700 Series Upgrade.

Software
The software is partly based on commercially available standard software and partly on software developed in-house, the software interfaces via serial channel or Ethernet with TCP/IP to LIS HIS systems.

User interface
Operation of the ABL800 FLEX analyzer is as the ABL700 Series Upgrade analyzer performed via a touch screen. Sample introduction is performed by aspirating the sample from the sample collection device. Both analyzers contain a hard drive and a printer. The ABL700 Series Upgrade includes also a disk drive, which in the ABL800 FLEX is substituted by a CD-R/WR ROM drive.

Hardware
The ABL800 FLEX comprises a new power supply, new computer and minor modifications to the inlet section including a further liquid sensor to be used with the new feature FLEXMODE. Due to the inclusion of the further liquid sensor, the measuring conduit of the ABL800 FLEX is a bit longer than the measuring conduit of the ABL700 Series Upgrade. Further, the ABL800 FLEX is provided with an extended inlet probe for more easy aspiration of samples from test tubes.

All models of the ABL800 FLEX are provided with an AutoCheck module for automatically performing quality control. The module is identical to the AutoCheck module (k992059) for the ABL700 Series Analyzer.

K. Standard/Guidance Document Referenced (if applicable):

Electrical Safety and EMC

Approvals:	UL, CSA. In compliance with IEC 61010-1. Installation category II
EMC Emission:	the equipment complies with the emission requirements for Class B equipment in EN 61326-1: Electrical equipment for measurement, control and laboratory use – EMC requirements part 1: General requirements.
EMC Immunity:	The equipment complies with immunity requirements in EN 61326-1: Electrical equipment for measurement, control and laboratory use – EMC requirements part 1: General requirements.

L. Test Principle:

Potentiometric measuring principle
The potential of an electrode chain is recorded using a voltmeter, and related to the concentration of the sample (the Nernst equation).

An electrode chain describes an electrical circuit consisting of a sample, electrode, reference electrode, voltmeter, membranes, and electrolyte solutions. Every element in the electrode chain contributes a voltage to the total potential drop through the chain. Thus:

- When immersed in the appropriate electrolyte solution, both electrodes have separate potentials.
- The membrane junctions between the sample and electrolyte solutions also have separate potentials.

The potentiometric measuring principle is applied to pH, pCO_2, and electrolyte electrodes.

Amperometric measuring principle
The magnitude of an electrical current flowing through an electrode chain, which is in turn proportional to the concentration of the substance being oxidized or reduced at an electrode in the chain.

The electrode chain in amperometric measurements consists of the sample, the two electrodes (anode and cathode), an amperemeter, a voltage source, the membrane, and the electrolyte solution.

To simplify the description of the measuring process in an amperometric electrode, we make the following assumptions:

- There is a species **A** in the sample which is reduced at the cathode to $\mathbf{A}^-$.
- There is a species **X** in the electrolyte which is oxidized at the anode to $\mathbf{X}^+$.

The membrane is selective to the species **A**, allowing no other species but it to pass through from the sample into the electrolyte solution.

As appropriate potential is applied across the electrodes, the species **A** is reduced as the cathode according to the following reaction:

$$A + e^- \rightarrow A^-$$

The reduction of **A** produces a flow of electrons, i.e. an electrical current.

To complete the electrical circuit an oxidation reaction where electrons are released is necessary. Therefore species **X** is oxidized according to the following reaction:

$$X \rightarrow X^+ + e^-$$

The magnitude of the current flowing through the circuit is proportional to the concentration of the species being reduced, in this case species **A**. The analyzer thereby automatically calculates the concentration on **A** in the sample.

The amperometric measuring principle is applied in the pO_2, glucose, and lactate electrodes.

Optical measuring principles

The optical system of the ABL800 FLEX analyzer is designed to measure the following parameters:

Parameter	**Description**
ctHb	concentration o f total hemoglobin
sO_2	oxygen saturation
FO_2Hb	fraction of oxyhemoglobin
FCOHb	fractionation of carboxyhemoglobin
FHHb	fractionation of deoxyhemoglobin
FMetHb	fraction of methemoglobin
FHbF	fraction of fetal hemoglobin
ctBil	concentration of total bilirubin (the sum of conjugated and conjugated bilirubin) in plasma

Note: ctBil can be measured on a whole blood or plasma sample. Plasma samples provide the optimal measurement performance. To obtain optimal accuracy when following a patient trend in ctBil, use the same aspiration mode and same analyzer.

Hematocrit (Hct) is also available as a derived parameter.
The optical system is based on a 128-wavelength spectrophotometer with a measuring range of 478-672 nm. The spectrophotometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

The precision (i.e. repeatability or within-run imprecision) and reproducibility (i.e. total imprecision) results for the parameters as well as the linearity/assay reportable ranges were established from a single large-sized study.

The variation parameters of the study appears from the table below

Parameter	**(n)**
Observations	2
Days	11
Instruments	11
Operators	3
Sites	1
Runs	16

The study was performed as a large comparative in-house study using 11 ABL8xx FLEX analyzers and 5 ABL735 analyzers. The study used the average of the 5 ABL735 analyzers (adjusted for drift of the parameters in the sample) as reference values. The study was designed to comprise all measuring modes of all the configurations of the ABL8xx FLEX analyzer on all parameters. All measurements on the ABL8xx FLEX analyzers were made as doubles. Three in-house operators located at one site performed the measurements during 11 working days - from March 22, 2004 to April 6, 2004.

Below are listed tables showing the %CV for the parameters of the ABL800 FLEX analyzer:

pH	**%CV-Micromode**	**%CV-Macromode**
6.80	0.12	0.09
6.90	0.11	0.08
7.00	0.11	0.08
7.10	0.11	0.08
7.20	0.11	0.08
7.25	0.11	0.08
7.30	0.11	0.08
7.40	0.11	0.09
7.50	0.12	0.10
7.60	0.13	0.11

pCO_2(mmHg)	%CV-Micromode	%CV-Macromode
15.0	4.7	3.0
17.0	4.6	2.9
20.0	4.6	2.8
40.0	4.5	2.6
60.0	4.6	2.6
80.0	4.6	2.7
119.9	4.8	2.8
140.0	5.0	2.9
149.9	5.0	3.0
160.0	5.1	3.1

pO_2(mmHg)	%CV-Micromode	%CV-Macromode
14	1.9	4.0
15	1.8	4.0
20	1.8	4.0
25	1.8	3.9
35	1.7	3.9
45	1.7	3.9
50	1.7	3.9
65	1.7	4.0
75	1.7	4.0
80	1.7	4.1
85	1.4	3.4
120	1.4	3.3
150	1.4	3.3
180	1.4	3.3
210	1.4	3.3
250	1.4	3.3
280	1.4	3.3
310	1.4	3.4
340	1.4	3.4
390	1.4	3.5
410	1.9	4.8
420	1.8	4.6
430	1.8	4.5
440	1.8	4.4
450	1.8	4.3
460	1.7	4.3
480	1.7	4.2
510	1.7	4.1
530	1.7	4.1
550	1.7	4.1

$c\mathrm{K}^{+}$(mmol/L)	%CV-Micromode	%CV-Macromode
1.65	4.3	4.0
2.01	3.7	3.3
2.46	3.2	2.8
3.00	2.8	2.3
3.32	2.7	2.2
3.67	2.5	2.0
4.48	2.4	1.8
5.47	2.2	1.6
6.69	2.2	1.4
8.17	2.1	1.3

$c\mathrm{Na}^{++}$(mmol/L)	%CV-Micromode	%CV-Macromode
119.1	1.2	0.9
127.7	1.2	0.9
134.3	1.2	0.9
141.2	1.2	0.9
148.4	1.2	0.9
156.0	1.2	0.9
164.0	1.2	0.9
172.4	1.2	0.9
181.3	1.2	0.9
200.3	1.2	0.9

$c\mathrm{Ca}^{2++}$(mmol/L)	%CV-Micromode	%CV-Macromode
0.50	8.8	3.8
0.75	5.9	2.5
0.95	4.6	2.0
1.15	3.8	1.7
1.35	3.3	1.5
1.55	2.9	1.3
1.75	2.6	1.2
1.95	2.3	1.1
2.10	2.1	1.0
2.21	2.0	1.0

***c*Cl$^-$(mmol/L)**	**%CV-Micromode**	**%CV-Macromode**
85.63	0.3	1.3
94.63	0.2	1.3
99.48	0.2	1.4
104.58	0.2	1.4
109.95	0.2	1.4
115.58	0.2	1.4
121.51	0.2	1.4
127.74	0.3	1.4
134.29	0.3	1.4
149.90	0.3	1.5

***c*Glu**(mmol/L)	**%CV-Micromode**	**%CV-Macromode**
0.49	23.172	21.768
1.00	13.610	12.469
2.25	8.042	7.203
4.00	5.806	5.161
6.25	4.624	4.113
7.84	4.153	3.706
9.00	3.902	3.490
10.24	3.689	3.309
12.25	3.422	3.085
15.21	3.143	2.854

***c*Lac**(mmol/L)	**%CV-Micromode**	**%CV-Macromode**
0.15	36	35
0.37	18	15
1.00	13.1	9.2
2.72	12.9	8.3
4.48	13.1	8.4
5.75	13.3	8.6
7.39	13.5	8.7
9.49	13.6	8.8
12.18	13.8	9.0
15.64	14.0	9.2

***c*tHb**(mmol/L)	**%CV-Micromode**	**%CV-Macromode**
2.00	3.3	2.2
4.00	3.3	2.2
6.00	3.3	2.2
8.00	3.3	2.2
10.00	3.3	2.2
12.00	3.3	2.2
14.00	3.3	2.2
17.00	3.3	2.2
20.00	3.3	2.2
24.00	3.3	2.2

b. Linearity/assay reportable range:

The protocol used for the test of linearity is an integrated part of the experimental design for performance testing. The experimental design is basically a randomized experiment, where the measurements in the different modes of the analyzer are performed in a randomized sequence for each of the blood preparations.

Bias is defined as:

$$Bias_{Ref} = X_{ABL800Flex} - X_{Primary\ Reference\ method}$$

$$Bias_{ABL} = X_{ABL800Flex} - X_{ABL735}$$

where

$X_{ABL800Flex}$ is the mean value of the measured value for a group of ABL800Flex analyzer.

$X_{Primary\ Reference\ method}$ is the mean value of the measured value obtained with the Primary Reference method.

X_{ABL735} is the mean value of the measured value for the ABL735 analyzers used as reference analyzers.

The acceptance criteria for linearity are the maximum bias values, specified at different values of the particular parameter. These values are chosen to cover the entire test range.

The maximum bias values were specified in the design specifications for the analyzer. Requirements for the maximum bias values assure that the linearity is within acceptance criteria. The maximum bias values specified in the design specifications for the ABL800 series analyzers are given in Tables 1 and 2. The actual measured bias values from the data of the verification test are also presented in Tables 1 and 2.

From the Tables 1 and 2 it is seen that all acceptance criteria for bias, and thereby also for linearity, are met.

The concept of using bias requirements for test of linearity is illustrated in Figure 1 below.

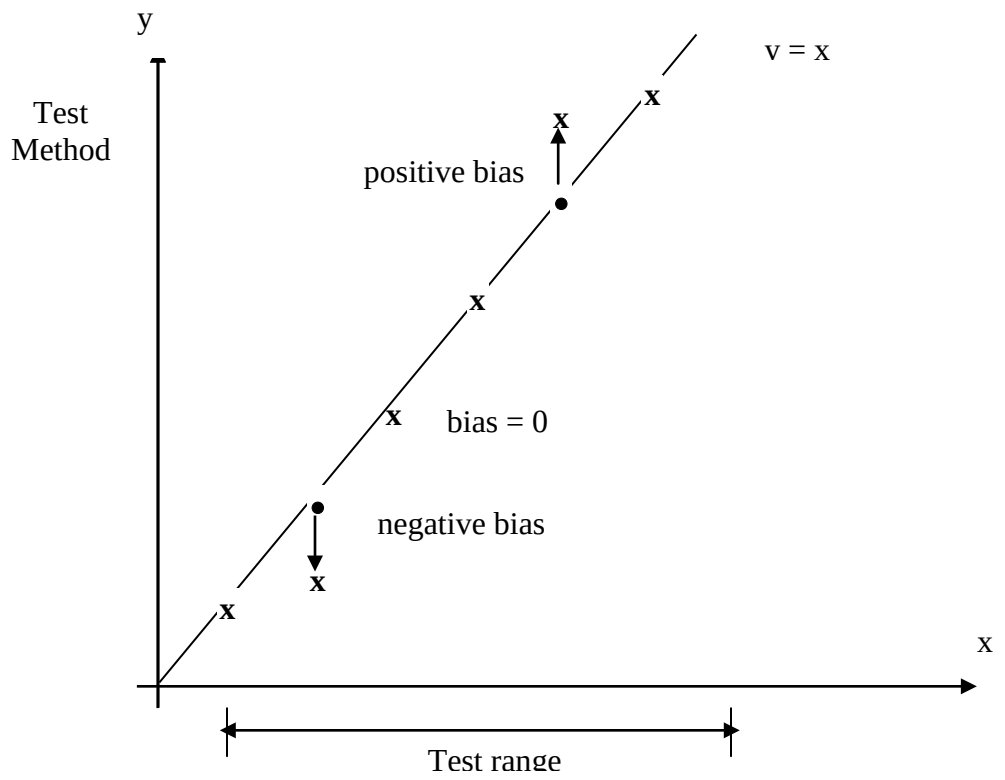

Fig. 1

Micromode

Parameter	Level	Unit	95% Confidence Intervals (in specified units)			Accepted/ not accepted
			Lower Limit	Upper Limit	Acceptance criteria	
pH	7.0		-0.009	0.006	±0.01	accepted
pH	7.4		0.003	0.005	±0.005	accepted
pH	7.6		-0.008	0.006	±0.01	accepted
pO2	15	mmHg	-0.81	0.04	±2	accepted
pO2	50	mmHg	-0.39	1.71	±2	accepted
pO2	150	mmHg	-2.17	3.38	±4	accepted
pO2	250	mmHg	-5.32	2.68	±6	accepted
pO2	530	mmHg	-39.09	17.09	±40	accepted
pCO2	15	mmHg	-0.79	0.38	±0.8	accepted
pCO2	40	mmHg	-0.87	0.61	±1	accepted
pCO2	60	mmHg	-0.42	2.28	±3	accepted
pCO2	80	mmHg	-1.25	2.99	±3	accepted
pCO2	150	mmHg	-3.15	9.90	±10	accepted

Parameter	Level	Unit	95% Confidence Intervals (in specified units)			Accepted/ not accepted
			Lower Limit	Upper Limit	Acceptance criteria	
Cl	85	mmol/L	0.15	1.00	±3.5	accepted
Cl	105	mmol/L	1.66	2.50	±3.0	accepted
Cl	140	mmol/L	2.81	1.83	±3.0	accepted
Ca	0.5	mmol/L	0.03	0.08	±0.08	accepted
Ca	1.25	mmol/L	0.03	0.06	±0.06	accepted
K	2	mmol/L	-0.07	-0.02	±0.08	accepted
K	4	mmol/L	0.20	0.24	±0.25	accepted
K	8	mmol/L	0.28	0.43	±0.45	accepted
Na	120	mmol/L	0.24	1.44	±1.5	accepted
Na	140	mmol/L	1.10	0.12	±1.5	accepted
Na	180	mmol/L	1.12	0.22	±1.5	accepted
Glu	2	mmol/L	-0.07	0.04	±0.1	accepted
Glu	5	mmol/L	-0.09	0.15	±0.2	accepted
Glu	15	mmol/L	-0.26	0.49	±0.6	accepted
Lac	0.3	mmol/L	-0.02	0.08	±0.1	accepted
Lac	2	mmol/L	0.06	0.27	±0.3	accepted
Lac	10	mmol/L	-0.30	-1.05	±1.1	accepted
tHb	7	g/dL	0.28	-0.12	±0.3	accepted
tHb	15	g/dL	0.54	0.12	±0.6	accepted
tHb	25	g/dL	1.40	0.05	±1.5	accepted

Table 1

Macromode

Parameter	Level	Unit	95% Confidence Intervals (in specified units)			Accepted/ not accepted
			Lower limit	Upper limit	Acceptance criteria	
pH	7.0		-0.005	-0.002	±0.005	accepted
pH	7.4		-0.003	-0.001	±0.005	accepted
pH	7.6		-0.005	0.000	±0.005	accepted
pO2	15	mmHg	-0.03	0.12	±1.5	accepted
pO2	50	mmHg	0.34	0.61	±1.5	accepted
pO2	150	mmHg	-1.87	-0.97	±2	accepted
pO2	250	mmHg	-2.57	-0.57	±3	accepted
pO2	530	mmHg	-12.59	-6.23	±15	accepted
pCO2	15	mmHg	-0.49	-0.30	±0.5	accepted
pCO2	40	mmHg	-0.59	-0.03	±0.6	accepted
pCO2	60	mmHg	-0.12	1.02	±1.1	accepted
pCO2	80	mmHg	-1.05	0.83	±1.5	accepted
pCO2	150	mmHg	-0.75	4.28	±6	accepted
Cl	85	mmol/L	0.15	1.34	±3.5	accepted
Cl	105	mmol/L	1.66	2.81	±3	accepted
Cl	140	mmol/L	1.41	2.95	±3	accepted
Ca	0.5	mmol/L	0.03	0.05	±0.05	accepted
Ca	1.25	mmol/L	0.01	0.03	±0.03	accepted

Parameter	Level	Unit	95% Confidence Intervals (in specified units)			Accepted/ not accepted
			Lower limit	Upper limit	Acceptance criteria	
K	2	mmol/L	-0.04	-0.01	±0.07	accepted
K	4	mmol/L	0.19	0.23	±0.25	accepted
K	8	mmol/L	0.18	0.32	±0.4	accepted
Na	120	mmol/L	-0.36	1.08	±1.1	accepted
Na	140	mmol/L	-0.44	0.75	±0.8	accepted
Na	180	mmol/L	-0.05	0.58	±1	accepted
Glu	2	mmol/L	-0.04	0.00	±0.1	accepted
Glu	5	mmol/L	0.00	0.10	±0.12	accepted
Glu	15	mmol/L	0.07	0.43	±0.5	accepted
Lac	0.3	mmol/L	-0.03	0.01	±0.1	accepted
Lac	2	mmol/L	-0.07	0.11	±0.12	accepted
Lac	10	mmol/L	-0.80	0.20	±0.9	accepted
tHb	7	g/dL	-0.01	0.11	±0.3	accepted
tHb	15	g/dL	0.29	0.44	±0.5	accepted
tHb	25	g/dL	0.90	1.23	±1.3	accepted

Table 2

c. Traceability (controls, calibrators, or method):

pH
Capillary-type glass pH electrode with a saturated calomel reference electrode and a liquid junction saturated with KCL (BMS™ Mk2) [1, 2].

pCO_2
Tonometry [3].
The gas used for tonometry are traceable to NIST certified Standard Reference Materials.

pO_2
Tonometry [3].
The gas used for tonometry are traceable to NIST certified Standard Reference Materials.

K^+
NIST certified Standard Reference Material SRM 909b (human serum).

Na^+
NIST certified Standard Reference Material SRM 909b (human serum) and Radiometer specified standard serum material (specified using flame photometry).

Cl^-
NIST certified Standard Reference Material SRM 909b (human serum)

Ca^{2+}

The calcium transfer standards were used. These are traceable to NIST SRM915 and have an ionic strength of 160.0 mmol per kg of water and pH 7.40 at 37 °C, using 1 mmol/L (37 °C) HEPES buffer. The standards were produced as indicated in [4].

Glu
Spectrophotometry, using the hexokinase (HK) method recommended by NCCLS [5], measured on serum.

Lac
Spectrophotometry using lactate dehydrogenase (LDH) method, measured on serum [10].

Hb
HiCN method recommended by NCCLS [6].

Oximetry
The optical system is unchanged in the ABL800 FLEX analyzers compared to the ABL700 Series. Tests of ctHb on the ABL800 FLEX analyzer have been conducted. As the other oximetry parameters (sO_2, FO_2Hb, FCOHb, FMetHb, FHHB, FHbF) are derived from ctHb, these parameters have not been re-tested; the information and results below are from the ABL700 Series.

The reference method established for the oximetry parameters used modified ABL520 analyzers as the reference instruments. The ABL520 analyzers have been validated and their performance specifications determined according to primary reference methods.

The modified ABL520 analyzers are used in accordance with IFCC's recommendations for traceability of reference methods.

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List of references

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d. Detection limit:

16 different mixtures of heparinized whole blood samples were used in the test. The mixtures were prepared to have the parameter levels indicated in the table below:

Target Concentrations of Test Sample Mixtures

Mix No.	K^+ mMol/L	Na^+ mMol/L	Cl^- mMol/L	Ca^{2+} mMol/L	Glu mMol/L	Lac mMol/L	tHb g/dL	pH pH	pO_2 mmHg	pCO_2 mmHg	Sat %	Bili µMol/L
1	8	120	98	1.99	3.15	5.04	15.598	7.538	493	10		5
2							15	7.58	545	10	100	
3	3.44	187.5	138	0.56	1.01	6.24	9.656	7.061	31.8	80		20
4	7						15	7.13	130	80	98	
5	2.26	191.7	144	0.57	2.61	2.97	15.503	6.892	22.5	150		0
6	7						15	7	15	150	10	
7	5.6	154.7	121	1.32	1.5	2.89	14.626	7.223	37.7	55.7		0
8	7						15	7.22	40	60	70	
9	4	183.4	133	0.42	2.25	9.01	4.481	7.499	198	26.9		48
10	7						15	7.36	230	30	100	
11	4	177.5	134	0.56	0.95	0.29	2.446	7.32	211	44		0
12	4	140	111	1.05	14.64	5.18	24.227	7.352	76.5	38.6		645
13	7	133.7	109	1.47	7.02	3.66	19.046	7.454	54.8	20		170
14	5.38	156.2	117	0.92	0.76	7.51	10.524	7.49	362	20		19
15	4	166.7	123	0.59	6.67	7.1	14.172	7.375	90.6	35.7		188
16	3.7	168.3	127	0.71	6.94	2.2	18.222	7.18	33.8	77.1		159

During a day of test, the levels of the parameters of each mixture drifted somewhat away from the initial level. However, this did not influence the quality of the study as each double measurement on an ABL8xx FLEX analyzer was complemented by corresponding measurements on the five ABL 735 analyzers. The concentrations of the measured mixtures represent the entire test/reportable range of all the parameters.

e. Analytical specificity:

pH/blood gas the following interference results are found for the pH and blood gas electrodes:

Substance	**Test Conc.**	**Interference on *p*O_2 Electrode**
Halothane	3%	5 % increased sensitivity

Intralipid (20 % solution) in a concentration greater than 4 % (the final Intralipid level being 0.8 %) will give interference on pH measurements.

Electrolytes The following interference results are found for the electrolyte electrodes:

Substance Test Concentration		Interference on			
		cK^+ (4 mmol/L level)	cNa^+ (150 mmol/L level)	cCa^{2+} (1.25 mmol/L level)	cCl^- (110 mmol/L level)
Li^+	4 mmol/L	0	0	0	
K^+	12 mmol/L		-1	-0.01	
Na^+	100-180 mmol/L	0.1 to -0.1			
NH_4	1 mmol/L	0	0		
Ca^{2+}	5 mmol/L		0		
Mg^{2+}	5 mmol/L	0	0	0.05	
Br^-	10 mmol/L				41
F^-	1 mmol/L				0
I^-	3.0 mmol/L				30–90
ClO_4^-	1.5 mmol/L				8-30
HCO_3^-	25-50 mmol/L				0.1 mmol/L Cl^- per mmol/L HCO_3^-
Lactate	10 mmol/L				0
Acetyl-salicylic acid	3.0 mmol/L				2
Ascorbic acid	1.0 mmol/L				0
pH ≤ 7.2		0	0	0.01	-1
pH≥ 7.6		0	0	-0.01	1

Sulphide will give erroneously high cCl^- results.

Metabolites

The following interference results are found for the metabolite electrodes:

Substance	**Test Conc. (mmol/L)**	**Interference on**	
		cGlucose (4.0 mmol/L level)	cLactate (1.5 mmol/L level)
Acetylsalicylic acid	3	< 0.1	< 0.1
Ascorbic acid	2	< 0.1	< 0.1
Chlorpromazine HCl	0.2	< 0.1	< 0.1
Dopamine HCl	1.0	< 0.1	< 0.1
Ethanol	79	< 0.1	< 0.1
Salicylic acid	4	< 0.1	< 0.1
Ibuprofen	2	< 0.1	< 0.1

Substance	**Test Conc. (mmol/L)**	**Interference on**	
		cGlucose (4.0 mmol/L level)	cLactate (1.5 mmol/L level)
Thiocyanic acid	24	Interference	Interference
Paracentamol-4-acetamidopenol	2	< 0.1	< 0.1
Acetoacetic acid	2	< 0.1	< 0.1
Bilirubin (unconjugated)	0.34	< 0.1	< 0.1
Bilirubin (conjugated)	0.46	< 0.1	< 0.1
Creatinine	3	< 0.1	< 0.1
Urea	84	< 0.1	< 0.1
Uric acid	1.5	< 0.1	< 0.1
Lactic acid	12	< 0.1	
Pyruvate	2	< 0.1	< 0.1
Glycolic acid	1	< 0.1	Interference
D-glucose	67		<0.1
Citrate	50	-0.37	0.19
Oxalate	90	-0.47	0.14
Heparin	8000 IU/dL	< 0.1	< 0.1
EDTA	3	< 0.1	< 0.1
Fluoride	50	-0.36	<0.1
Maltose	13.3	0.75-4.2*	<0.1

cGlu level measure on Cal 1 (10 mmol/L) and Cal 2 (0 mmol/L).

Hematocrit %	ΔcLactate % at:	
	5 mmol/L	15 mmol/L
0	0.7 %	0.7 %
45	0.0 %	0.0 %
60	-0.5 %	-2.0 %
75	-2.2 %	-5.0 %

Oximetry Parameters

The substances against which the oximetry parameters (cHb, sO_2, FO_2Hb, FCOHb, FMetHb, FHHb, FHbF) and ctBil were tested for interference given in the table below:

(SAT100 blood reference test sample: ctHb = 15 g/dL, sO_2 = 100 %, FO_2Hb = 0.7%, FMetHb = 0.5 %, ctBil = 0, pH = 7.4. Parameters sensitivity from the influence on the absorbance spectrum from various substances.)

Substance	Test conc.	Change on							
		ctHb (g/dL)	sO_2 (%)	FO_2Hb (%)	FCOHb (%)	FMetHb (%)	FHHb (%)	FHbF (%)	ctBil (µmol/L)
Intralipid	4Vol % [e]	-0.5	0.1	-1.3	0.5	0.9	-0.1	11	0 4 [b]
Intralipid	2 Vol % [f]	-0.4	0.1	-0.3	0.3	0.1	-0.1	11	7 2 [b]
HbF [a, c]	20 %	-0.02	1.17	0.04	0.73	0.37	-1.14	0	-14
SHb	10 %	0	-1.0	0.9	-0.1	0.1	-0.9	Not Tested	
pH	7.1 7.9	-0.5 -0.6	-0.5 0.6	-0.2 -0.5	-0.4 1.0	0.1 0.1	0.5 -0.6	-19 13	0 -5
Cardio Green [c]	5 mg/L	-0.16	0.29	1.14	0.07	-0.93	-0.29	-5	-20
Evans Blue [c]	5 mg/L	-0.04	0.14	0.28	-0.20	-0.20	0.14	-5	5
Betacarotene in plasma [c]	3.7 µmol/L	0.0	-0.02	0.03	-0.01	-0.04	0.02	0.1	-0.2
Patent Blue [c]	10 mg/L	-0.16	0.39	0.86	-0.47	0.00	-0.38	-21	38
Methylene Blue [c]	30 mg/L	-0.7	-3.4	5.6	-3.0	-6.2	3.6	-37	-25
HiCN [c]	0.11 mmol/L	0.26	-1.5	-3.0	-0.5	0.5	1.5	24	47
MCHC [c, d] newborn range	320 g/L 350 g/L	No Interference							-12 17
Sedimentation rate	100 arb. Units	< ± 0.5	No Interference						Not Tested

Notes:

a) If function "Correction for HbF levels less than 20%" is activated, the change is 0 for all parameters.

b) Plasma sample.

c) Calculated value from mathematical superposition of measured pure interference spectrum on measured reference spectrum.

d) ctBil = 400 µmol/L

e) Intralipid (20 % solution) at 4 Vol % gives final test level of 0.8 %.

f) Intralipid (20 % solution) at 2 Vol % gives final test level of 0.4 %.

There is no interference from fetal hemoglobin (HbF when the analyzer applies HbF correction.

There is no interference from bilirubin (conjugated/unconjugated) up to 1000 µmol/L.

Known interfering substances

The following substances are known to affect or interfere with measurements on the ABL 800 FLEX analyzers.

Substance	Interference
Halothane (anesthetic)	May give unreliable pO_2 results.
Liquid therapy, protamine sulphate treatment	In OXI measurements. After measurement on blood from a patient who has received liquid therapy of protamine sulphate it may be necessary to clan the analyzer using the Cleaning program.
Methylene Blue HiCN (medication)	In Oxi measurements.
Anions: Br^-, I^-, S^{2-} and ClO^-_4 (drugs)	Erroneously high cCL^- results
Anticoagulant (sampling)	Anticoagulants that contain sodium salts will give erroneously high cNa^+ results. Sodium fluoride with or without EDTA and oxalate (di Na) influence cGlu results. Sodium fluoride gives erroneously high cNA^+ and low cCa^{2+}, cGlucose, and cLactate results. Tri sodium citrate influences cNA^+,cK^+ and cGlu results. Thus radiometer recommends the exclusive use of heparin as anticoagulant. Solutions containing organic preservatives may damage the ion-selective membranes of the K and Glu electrodes when introduced into the analyzer.
Thiocyanic Acid (degradation product from treatment with Nitroprusside. Also produced in thiosulphate treatment of cyanide poisoning)	Erroneously high cGlu and CLac measurements.
Glycolic Acid (ethylene glycol degradation product)	Erroneously high cLac measurements

Substance	Interference
Insufficiently stabilized blood. Caustic fluids (e.g. strong acids or bases, detergents, etc.). Fluids that precipitate. Fluids that affect the sensor enzymes. Fluids that form complexes with the analyzer solutions (calcium). High viscosity fluids. Hydrophobic fluids. Reactive fluids.	Other fluids mode allows you to measure on fluids other than heparinized human blood. **Warning/Caution**: Be aware that some substances, such as listed in the left column, measured in the Other fluids, mode may damage the instrument or the electrodes. This can affect the subsequent measurement on human blood or quality control solutions.
Carboxymethyl cellulose (CMC)	Some auto-venting arterial blood samplers contain carboxymethyl cellulose (CMC) in the porous vent. CMC can dissolve into the sample and give erroneously low cCa^{2+} results. Therefore we recommend Radiometer accessories together with our analyzers, e.g., PICO 70 arterial blood sampler which is specifically designed to minimize sample contamination with CMC.
Glucosamine	Interference on cGlu up to 1.06 mmol/L
Galactose, maltose, mannose, xylose	Interference – see Interference Tests in chapter 5 of the ABL800 FLEX Reference Manual.

d. Assay cut-off:

Not applicable

2. Comparison studies:
   a. Method comparison with predicate device:

Sample Types

The study was performed on samples of whole blood. The samples included syringe samples having volumes of 20 ml and 50 ml and capillary samples having volumes of 224 µl, 104 µl, 94 µl, 83 µl, 57 µl, 50 µl and 35µl.

Number of measurements

The number of measurements in macro- and micromodes, and the total number of measurements during the test are listed below:

Parameter	Nmacro	Nmicro	Total
pH	3334	421	3755
*p*CO2	2768	397	3165
*p*O2	282	2912	3194
*c*K+	22	1364	1786
*c*Na+	423	1362	1785
*c*Ca2+	407	1148	1555
*c*Cl–	426	1360	1786
*c*Glu	423	1825	2248
*c*Lac	412	1829	2241
*c*tHb	415	032	447

In the study, a total of approx. 4,700 measurements were performed on the ABL8xx FLEX with corresponding ABL735 reference values. As not all parameters are relevant for all measuring modes or ABL8xx versions, the values in the table shown above differ according to parameter.

S = Syringe Mode sampling
C = Capillary Mode sampling

pH
Bias on the ABL800 FLEX analyzers:

pH	ABL835/25/15 FLEX. Capillary – FLEXMODE							
	S195	C195	S95	C95	S55	C55	S35	C35
7.0	-0.0023	-0.0003	-0.006	-0.006	-0.002	-0.003	0.011	0.011
7.4	-0.0008	0.0004	-0.002	-0.002	0.006	0.005	0.008	0.008
7.7	0.0015	0.0024	0.001	-0.002	0.001	0.003	0.005	0.005

pCO_2
Bias on the ABL800 FLEX analyzers:

pCO_2 mmHg	ABL835/25/15 FLEX, Capillary – FLEXMODE					
	S195	C195	S95	C95	S55	C55
15	-0.03	-0.2	0.1	0.1	-0.5	-0.7
40	-0.01	-0.3	0.3	0.3	0.2	-0.4
60	0.4	0	0.4	0.3	2.3	0.6
80	0.4	0.1	0.8	0.5	2.5	-0.8
150	1.1	0.2	2.2	0.7	4.6	-4.7

pCO_2 (expired air samples)
Bias for the ABL800 FLEX analyzers (expired air samples)

pCO_2 mmHg	Bias
15	0.2
40	-0.2
60	-0.4
80	-0.2
150	1.6

pO_2

Bias on the ABL800 FLEX analyzers:

pO_2 mmHg	ABL835/25/15 FLEX, Capillary – FLEXMODE					
	S195	C195	S95	C95	S55	C55
15	-0.379	-0.28	-0.8	-0.7	-0.4	-0.9
50	-0.1	-0.23	0.3	0.3	-3.2	-2.0
150	0.3	-0.07	5.3	4.0	5.0	3.2
250	1.47	0.09	2.7	1.4	7.2	-1.2
530	1.44	-0.03	-16.5	-28.6	17.3	-39.5

pO_2 (expired air samples)

Bias for the ABL800 FLEX analyzers (expired air samples)

pO_2 mmHg	Bias
15	-1.3
50	-1.0
150	0.5
250	-1.4
530	7.8

cK^+ NIST certified Standard Reference Material SRM 909b (human serum).

Bias $_{REF}$

The FLEXMODE on the ABL 805/35 analyzers was tested using SRM 909b

c K^+ (mmol/L)	**Bias $_{REF}$**	**N**
3.424	-0.03	20
6.278	0.23	20

cNa^+ NIST certified Standard Reference Material SRM 909b (human serum) and Radiometer specified standard serum material (specified using flame photometry).

Bias $_{REF}$

The FLEXMODE on the ABL 805/35 analyzers was tested using SRM 909b:

cCl^- (mmol/L)	**Bias $_{REF}$**	**N**
120.76*	-0.25	20
138.5	-0.28	20

N = number of measurements on several analyzers used for the test

(*NIST certified Standard Reference Material ** Serum (Radiometer specified).

cCl^+ NIST certified Standard Reference Material SRM 909b (human serum).

Bias $_{REF}$

The FLEXMODE on the ABL 805/35 analyzers was tested using SRM 909b:

cCl^- (mmol/L)	**Bias $_{REF}$**	**N**
89.11	0.6	20
119.43	2.4	20

N = number of measurements on several analyzers used for the test

cCa^{2+} The calcium transfer standards were used. These are traceable to NIST SRM915 and have an ionic strength of 160.0 mmol per kg of water and pH 7.40 at 37 °C, using 1 mmol/L (37 °C) HEPES buffer.

Bias $_{REF}$

The FLEXMODE on the ABL 805/35 analyzer was tested using SRM915:

cCa^{2+} mmol/L	Bias $_{Ref}$	N
0.4879	0.038	150
1.2700	0.025	150
2.5657	0.052	150

N = number of measurements on several analyzers used for the test

cGLU Spectrophotometry, using the hexokinase (HK) method recommended by NCCLS [5], measured on serum

Bias $_{REF}$

The FLEXMODE on the ABL 805/35 analyzers was tested:

cGLU (mmol/L)	**Bias $_{REF}$**	**N**
0.08	0.03	30
2.09	0.06	30
5.08	0.12	30
14.73	-0.02	30

N = number of measurements on several analyzers used for the test.

cLac Spectrophotometry using lactate dehydrogenase (LDH) method, measured on serum [10].

Bias $_{REF}$

The FLEXMODE on the ABL 805/35 analyzers was tested:

cLac (mmol/L)	**Bias $_{REF}$**	**N**
0.08	0.03	30
2.09	0.06	30
5.08	0.12	30
14.73	-0.02	30

N = number of measurements on several analyzers used for the test.

ctHb HiCN method recommended by NCCLS [6].

Bias $_{REF}$

The FLEXMODE on the ABL 830/35 analyzers was tested:

ctHb (mmol/L)	Bias $_{REF}$	N
15 (SAT0)	0.32	145
7 (SAT100)	0.04	145
15 (SAT100)	0.37	145
25 (SAT100)	0.97	145

N = number of measurements on several analyzers used for the test.

b. Matrix comparison:

The ABL800 FLEX is designed for use on undiluted whole human blood and expired air.

3. Clinical studies:

a. Clinical sensitivity:

Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Clinical studies are not typically submitted for this device type.

c. Other clinical supportive data (when a and b are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

None provided

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.