510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE AND INSTRUMENT TEMPLATE

A. 510(k) Number:

k031560

B. Analyte:

Partial pressure of carbon dioxide, Partial pressure of oxygen, pH, sodium, potassium, ionized calcium, chloride, glucose, lactate, and co-oximetry parameters (tHb, FO_2Hb, FCOHb, FMetHb, FHHb).

C. Type of Test:

Ion selective electrode – Potassium, Chloride, Sodium, Calcium, and pH
Potentiometric method – pCO2
Amperiometric method – pO2
Enzymatic – Lactic Acid, Glucose
Spectral absorbency -- CO-oximetry parameters

D. Applicant:

Bayer HealthCare, Diagnostic Division

E. Proprietary and Established Names:

Bayer Rapidlab 1200 System Series

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1120; 21 CFR 862.1145; 21 CFR 862.1170; 21 CFR 862.1600; 21 CFR 862.1665; 21 CFR 862.1345; 21 CFR 862.1450; 21 CFR 864.5620.
2. Classification:
   Class II; Class I
3. Product Code:
   Blood Gases (pCO_2, pO_2) & pH-CHL; Calcium - JFP; Chloride - CGZ; Potassium - CEM; Sodium - JGS; Glucose - CGA; Lactic Acid - KHP; Hemoglobin - GKR
4. Panel:
   75 Chemistry; 81 Hematology

G. Intended Use:

1. Intended use(s):
   Refer to Indications for Use
2. Indication(s) for use:
   The Rapidab 1200 system series is intended for in vitro diagnostic use by healthcare professionals in the quantitative testing of samples of whole blood for the following parameters:

   Partial pressure of carbon dioxide, Partial pressure of oxygen, pH, sodium, potassium, ionized calcium, chloride, glucose, lactate, and co-oximetry parameters (tHb, FO_2Hb, FCOHb, FMetHb, FHHb).

pCO_2, pO_2, pH. Measurements of blood gases (PCO2, PO2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium. Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison`s disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium. Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

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

Ionized calcium. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

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

Lactate. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Total hemoglobin. Total hemoglobin measurements are used to determine the hemoglobin content of human blood.

Oxyhemoglobin. Oxyhemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

Carboxyhemoglobin. Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

Sulfhemoglobin. Sulfhemoglobin measurements are used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison).

3. Special condition for use statement(s):
   None
4. Special instrument Requirements:
   None

H. Device Description

The Rapidlab 1200 Series system has the following features:

Compact design with self-contained reagent and wash cartridges that are easily replaced when empty.
Automatic calibration of the measurement sensors
Automatic sample aspiration that eliminates variability in sampling
Automatic QC sampling at customized intervals using the optional Automatic QC cartridge
High resolution touch screen that tilts for viewing information and making selection
Built-in removable storage media to copy patient, QC, and calibration data for storage, or for export to spreadsheet or database programs
Communication ports for connecting to external data management systems, such as the Rapidlink Data Management system or an LIS (laboratory information system)
Self-contained CO-oximetry sample chamber

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Rapidlab 800 Series Analyzers; Rapidlab 400 Series Analyzers
2. Predicate K number(s):
   K933373, K946206, K002738, K020616
3. Comparison with predicate:

Similarities & Differences

Item	Rapidlab **1200 Series**	Rapidlab **800 Series K9333731K946206**	Rapidpoint **400 Series K002738/K020616**
Measured Parameters	pH, PC02, p02, Na+, K+, CI-, Ca++, Glucose, Lactate, CO-ox CO-oximetry parameters (tHb, $F0_2Hb$, FCOHb, FMetHb, FHHb	pH, $PC0_2$, P02, Na+, K+, CI-, Ca++, Glucose, Lactate, CO-ox CO-oximetry parameters (tHb, $F0_2Hb$, FCOHb, FMetHb, FHHb	pH, PC02, $p0_2$, Na+, K+, CI-, Ca++, Glucose, Lactate, Hct, CO-ox CO-oximetry parameters (tHb, $F0_2Hb$, FCOHb, FMetHb, FHHb)
Calculated Parameters	Ca++ (7.4), 0_2 SAT(est), 50_2, Anion Gap, 0_2 CT, $p0_2$ (A-a), $p0_2$(a/A), p50, $ct0_2$(a-v), ct02([a-v]/a), $V0_2$, $D0_2$, RI(T), Qsp/Qt, Qsp/Qt(est), $HC0_3$ act, HCO_3 std, $ctC0_2$, BE(B), BE(ecf), $p0_2$/F,0_2, $Ct0_2$(a), $ct0_2$(v), Hct, p02(T), $B0_2$, pH(T), $ct0_2$ (Hb), $PC0_2$(T)	Ca++ (7.4), 0_2 SAT(est), $s0_2$, Anion Gap, 0_2CT, P02 (A-a), P02 (a/A), p50, $ct0_2$(a-v), ct02([a-v]/a), $V0_2$, $D0_2$, RI(T), Qsp/Qt, Qsp/Qt(est), $HC0_3$ act, $HC0_3$ std, $ctC0_2$, BE(B), BE(ecf), $p0_2/F_I0_2$, $Ct0_2$(a), $ct0_2$(v), Hct, p02(T), $B0_2$, pH(T), ct 0_2 (Hb), $PC0_2$(T)	Ca++ (7.4), 0_2 SAT(est), $s0_2$, Anion Gap, 0_2CT, P02 (A-a), P02 (a/A), p50, $ct0_2$(a-v), ct02([a-v]/a), $V0_2$, $D0_2$, RI(T), Qsp/Qt, Qsp/Qt(est), $HC0_3$ act, $HC0_3$ std, $ctC0_2$, BE(B), BE(ecf), p02/F,02, $Ct0_2$(a), $ct0_2$(v), Hct, $p0_2$(T), $B0_2$, pH(T), ct 0_2 (Hb), $PC0_2$(T)
Entered Parameters	Temp, tHb, Fi02, Flow, RespRate, Atm, Qt(T), Tonometry Time, Catheter Type, Sex, Patient ID, Sample	Temp, Date, Time, Sample ID, ctHb, Fi02, Qt, OBF, Flow, Resp Rate	Temp, tHb, Fi02, Flow, RespRate, Alm, Qt(T), Tonometry Time, Catheter Type, Sex, Patient ID, Sample ID,

	ID, Accession Number, Oper ID, Patient Name, Phys. ID, Date of Birth, Age, Draw Date, Draw Time, S02		Accession Number, Oper ID, Patient Name, Phys. ID, Date of Birth, Age, Draw Date, Draw Time, S02
Sample Volume	1175 ul Syringe/Cap 95 ul Microsample (Syringe/Cap) 10 ml Expired Gas	1175 ul Syringe/Cap 95 ul Microsample (Syringe/Cap) 10 ml Expired Gas	100 ul Syringe/Cap
Calibration Method	Auto and Adjustable On board, gas tonometered reagents	Auto and Adjustable On board reagents w/external gas tanks	Auto On board, gas tonometered reagents
Electrode Maintenance	READY Sensors: Maintenance Free	READY Sensors: Maintenance Free	None Required
Display	Color Passive Matrix LCD	Monochrome Passive Matrix LCD	Color Passive Matrix LCD
Print Out	Roll Printer	Roll Printer with Take-up Spool	Roll Printer
Data Management	On-board	On-board	On-board
Interface Ports	RS232C (2) 1 Parallel Port 1 USB Port Ethernet 1	RS232C (4) 1 Parallel Port	RS232C (2) Ethernet (1)
Power	100 - 240 VAC 50 - 60 Hz With Power Switch	100 - 240 VAC 50 - 60 Hz No Power Switch	100 - 240 VAC 50 - 60 Hz With Power Switch
Size	23"W x 22.5"H x 22.5"D	28"W x 19"H x 20"D	11.5"W x 21"H x 16"D
Weight	65 lbs.	82 lbs.	34 lbs.

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

• ISO 14971:2000 Medical devices - Application of risk management to medical devices

• IEC (EN) 60601-1-2:1993 (Second Edition, 2001), Medical Electrical Equipment --Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests

• ISO 13485:1996 - Quality systems - Medical Devices - Particular requirements for the application of ISO 9001

• IEEE 1012:1998 - Standard for Software Verification and Validation. (Software)

• ISO/IEC 12207:1995 - Information Technology - Software Life Cycle Processes

• AAMI/ANSI SW68:2001 - Medical device software Software life cycle processes Capability Maturity Model version 1.3

Guidance Documents:

The following FDA Guidance documents were used in preparing this Premarket 510(k) Notification:

- Recognition and Use of Consensus Standards, Final Guidance for Industry and FDA Staff
- The Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for Industry and FDA
- Guidance for Industry In Vitro Diagnostic Chloride Test System
- Guidance for Industry In Vitro Diagnostic Sodium Test System
- Guidance for Industry In Vitro Diagnostic Potassium Test System
- Guidance for Industry In Vitro Diagnostic Glucose Test System
- Guidance for Industry In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

K. Test Principle:

The Rapidlab 1200 System uses measurement technology that is based on electrochemical, biochemical and optical phenomena. The device use potentiometry and amperometry methods for blood gas, electrolytes and metabolites to convert the potential generated by the sensor to an electrical signal which the system then converts to a value that represents that concentration of a specific analyte or substances in recognizable units of measurement.

Electrodes used for measurement in the Rapidlab 1200 systems are called sensors. Each sensor has a molecular or ion-specific substance of interest in a sample.

The Rapidlab 1200 series system CO-oximetry module utilizes spectral absorption by measuring the light from whole blood at several wavelengths. The measurement module detects and quantitates total hemoglobin and other related quantities in the sample.

The Rapidlink data management system program is a system accessory that enables the user to manage patient, quality control (QC), maintenance, and calibration data for Bayer Diagnostic blood gas systems and CO-oximeters, including the Rapidlab 1200.

The Rapidlab 1200 series system will interface with the Rapidlink information management system and/or will provide connect capability to hospital LIS/HIS systems via network interface ports.

L. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>
    a. *Precision/Reproducibility:*

    Precision on manual aqueous quality control materials was established using a minimum of three instruments for each Rapidlab 1200 system. At least four runs per instrument were made over four days for pH, pCO_2, and pO_2. At least 30 runs per instrument were made over 48 days for the CO-ox fractions. Two replicates of each

control level were analyzed in each run. All assays available on the Rapidlab 1200 system were evaluated as appropriate.

b. Linearity/assay reportable range:
Linearity of the system was compared to the predicate device within the whole blood method comparison testing. Linear regression was performed for the system series. The regression graphs demonstrated equivalence to the predicate device.

c. Traceability (controls, calibrators, or method):
Quality control materials, both manual (RapidQC Complete) and automatic (AQC) were analyzed on the Rapidlab 1200 systems. Manual QC is performed by the operator based on their established laboratory QC procedures, while AQC is performed automatically by the system based on the QC frequency defined in the system software. The RapidQC Complete material is sealed in a glass ampule and was cleared under 510(k), k970956.

d. Detection limit:
Detection limits for the Rapidlab 1200 system are defined as the linear range of each assay. As part of the whole blood method comparison testing minimum and maximum test values were obtained. The minimum values obtained for each tested parameter are near the limit of detection for the system.

e. Analytical specificity:
Interference testing was performed to demonstrate the specificity of the RapidLab 1200 sensors.

The results from each of the studies were tabulated and the simple average effect was determined for each interfering compound. The effect of interference column demonstrates the apparent change in result as a function of introducing the interfering compound. In several instances multiple tests were performed on an interfering substance as well as several levels of interfering substance.
The effect of the potential interfering substance on results is summarized in the following table. The table shows the interference level tested along with the average change in blood results (test result $_{\text{spiked}}$ - control result $_{\text{unspiked}}$) for each of the sensors.

Analyte(units)	Interference	Interference Level Tested	Effect of Interference (Test-control)
pH (pH units)	Acetaminophen	20 mg/dL	0.000
	Sodium Pentothal	*300* mg/dL	-0.009
	Salicylic Acid	*20* mg/dL	0.000
	Acetyl Salicylic Acid	*50* mg/dL	*-0.513*
PO_2 (mm Hg)	Isoflurane	3 %	3.48
	Halothane	3 %	0.20
	Nitrous Oxide	84%	0.25
PCO_2 (mm Hg)	Ibuprofen	40 mg/dL	0.35
	Sodium Pentothal	300 mg/dL	1.34

Analyte (units)	Interference	Interference Level Tested	Effect of Interference (Test - control)
Na^+ (mmol/L)	Acetaminophen	2 mg/dL	0.00
	Dobutamine	20 mg/dL	0.37
	Dobutamine	10 mg/dL	0.15
	Dobutamine	5 mg/dL	0.20
	Vancomycin	63 ug/dL	-0.23
	Ofloxacin	6 ug/dL	-0.14
	Perphenazine	1.25 ug/mL	0.05
	Sodium Pentothal	300 mg/dL	-0.88
K^+ (mmol/L)	Sodium Pentothal	300 mg/dL	-0.016
Cl^- (mmol/L)	Heparin	90 units/ml-	0.5
	Salicylic Acid	30 mg/dL	1.0
	Salicylic Acid	20 mg/dL	0.7
	Acetylsalicylic Acid	50 mg/dL	0.5
	Acetaminophen	2 mg/dL	0.0
	Sodium Pentothal	300 mg/dL	-1.0
Ca^{++} (mmol/L)	Acetaminophen	2 mg/dL	-0.03
	Ibuprofen	40 mg/dL	-0.03
	Salicylic Acid	20 mg/dL	-0.04
	Salicylic Acid	30 mg/dL	-0.40
	Sodium Pentothal	300 mg/dL	-0.01
	Acetyl Salicylic Acid	50 mg/dL	0.04
	Acetyl Salicylic Acid	30 mg/dL	0.01
	Acetyl Salicylic Acid	15 mg/dL	0.01
Glucose (mg /dL)	Acetaminophen	2 mg/dL	-11.8
	Heparin	90 units/ml	7.8
	Salicylic Acid	30 mg/dL	-0.5
	Salicylic Acid	20 mg/dL	-0.3
	Ethanol	350 mg/dL	-1.5
	Dopamine	10 mg/dL	-12.6
	Dopamine	5 mg/dL	12.5
	Dobutamine	20 mg/dL	-9.5
	Dobutamine	10 mg/dL	-5.5
	Dobutamine	5 mg/dL	-2.0
	Acetylsalicylic Acid	50 mg/dL	-1.5
	Sodium Pentothal	300 mg/dL	-0.9
	P02	25-85 mm Hg	-1.0
Lactate (mmol/L)	Chlorpromazine	17 mg/dL	<+/-0.3
	Dopamine	1 mg/dL	<+/-0.3
	Ethanol	350 mg/dL	<+/-0.3
	Salicylate	50 mg/dL	<+/-0.3
	Sodium Nitroprusside	70 mg/dL	<+/-0.3
	Thiocyanate	80 mg/dL	< +/-0.3
	Heparin	20,000 U/dL	<+/-0.3
	Epinephrine	2 mg/dL	<+/-0.3
	Norepinephrine	2 mg/dL	<+/-0.3
	Phenobarbital	15 mg/dL	<+/-0.3
	Glutamate	16 mg/dL	<+/-0.3
	Hetastarch	30%	<+/-0.3
	Acetoacetate	40 mg/dL	< +/-0.3
	Ascorbate	8 mg/dL	<+/-0.3

	Dilantin	14 mg/dL	<+/-0.3
	Bilirubin (Direct)	30 mg/dL	<+/-0.3
	Bilirubin (Total)	35 mg/dL	<+/-0.3
	Creatinine	30 mg/dL	<+/-0.3
	Hydroxybutyrate	200 mg/dL	<+/-0.3
	Urea	500 mg/dL	<+/-0.3
	Guaiacol	5 mg/dL	<+/-0.3
	Pyruvate	9 mg/dL	<+/-0.3
	Theophylline	9 mg/dL	<+/-0.3
	Penicillamine	25 mg/dL	<+/-0.3
	Isoniazid	2 mg/dL	<+/-0.3
	Uric Acid	10 mg/dL	<+/-0.3
	Citrate	1000 mg/dL	<+/-0.3
	Potassium Oxalate	1000 mg/dL	<+/-0.3
	EDTA	800 mg/dL	<+/-0.3
Lactate (mmol/L)	Sodium Fluoride	1000 mg/dL	1.0
	Sodium Fluoride/ Potassium Oxalate	1000 mg/dL	1.0
	Acetaminophen	2 mg/dL	0.35

Interference Testing for RapidLab 1200 CO-oximetry was performed to demonstrate the specificity of the RapidLab 1200 CO-oximtery module.

The mean effect was calculated as the spiked mean minus the control mean. The probability of the mean effect being zero was calculated, and those with less than a 5% chance ($p<0.05$) were considered statistically significant. For those effects which were statistically significant, a mean effect >0.5 g/dL for tHb or >1.0% for the CO-ox fractions was considered clinically significant. The reported effects for methylene blue at 25 and 40 mg/L are the simple mean effect (spiked mean - control mean).

For sulfhemoglobin, the mean effect was corrected using the difference observed between the spike and control from an additional reference method (gas chromatography or mass spectrophotometry depending on analyte) which was not subject to interference. That is, sample preparation differences alone, between the spiked and control

samples, accounted for some of the observed differences and by subtracting out that contribution using the reference method, the true interference can be estimated.

Interference Testing Results for tHb, $F0_2Hb$, FCOHb, FMetHb, and FHHb

Potential Interferent	Level Tested	Effect of Interference
Lipid	5 % intra-Lipid in serum	No effect
Bilirubin	40 mg/dL	No effect
Fetal Hemoglobin	20,40,85%	No effect
CyanMethemoglobin	10%	No effect
Beta-carotene	40 mg/dL	No effect
Hemolysis	10 % volume	No effect
Evans Blue	5 mg/L	No effect
Indocyanine Green	5 mg/dL	No effect
Methylene Blue	25 mg/dL	F02Hb -1.2 FCOHb +1.3
Methylene Blue	40 mg/dL	F02Hb -2.0 FCOHb +2.0
Sulfhemoglobin	10%	tHb -0.8g/dL $F0_2Hb$ -6.7 FCOHb +3.6 FMetHb +1.4 FHHb +1.7

f. Assay cut-off:

The assay cut-off is established as the linearity range of the Rapidlab 1200 System Series for each analyte.

2. Comparison studies:

a. Method comparison with predicate device:

For each of the runs performed on the Rapidlab 1200 systems, the same samples analyzed using the predicate device, the Rapidlab 800. Simple linear regression was employed to determine the method comparison statistics. The test range for each sample type is reported in the columns titled minimum and maximum. The gases were regressed against their theoretical gas values while pH used the corresponding 800 results.

Example of method comparison tests are represented as following by Rapidlab 1260: For each of the runs performed on the RapidLab 1260, the same samples were analyzed using the predicate device, the RapidLab865. Simple linear regression was employed to determine the method comparison statistics below. The test range for each sample type is reported in the columns titled Min and Max. The gasses were regressed against their theoretical gas values while pH, electrolytes, and metabolites all used the corresponding 865 results. Refer to Tables 1-9 for a summary of the method comparison results.

Table 1: 1260 Whole Blood Method Comparison – pH

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	53	0.992	0.050	0.008	0.999	6.977	7.603
Micro	53	0.960	0.286	0.007	0.999	7.015	7.594
Syringe	52	0.980	0.145	0.006	0.999	7.020	7.602
pH Only	53	0.983	0.121	0.007	0.999	7.029	7.632

Table 2: 1260 Whole Blood Method Comparison – pCO2

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	72	0.976	1.368	6.457	0.980	12.5	152.1
Micro	72	0.974	1.099	6.844	0.978	12.6	164.5
Syringe	72	0.981	1.231	4.909	0.989	13.6	154.3

Table 3: 1260 Whole Blood Method Comparison – pO2

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	72	1.025	-0.837	19.950	0.992	27.5	797.3
Micro	71	0.987	3.474	16.420	0.994	27.5	737.0
Syringe	72	1.000	3.470	16.520	0.994	27.3	749.4

Table 4: 1260 Whole Blood Method Comparison – Na

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	43	1.039	-2.800	2.315	0.991	106.6	184.5
Micro	54	0.995	0.733	1.655	0.995	106.2	180.3
Syringe	54	0.967	3.696	1.296	0.997	107.7	177.5

Table 5: 1260 Whole Blood Method Comparison – K

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	54	1.009	0.010	0.106	0.999	1.11	9.60
Micro	53	0.986	0.093	0.142	0.998	1.21	9.82
Syringe	54	0.992	0.024	0.126	0.998	1.03	9.51

Table 6: 1260 Whole Blood Method Comparison – Ca

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	53	1.054	-0.083	0.127	0.991	0.42	4.98
Micro	53	1.098	-0.146	0.150	0.988	0.42	5.16
Syringe	52	1.059	-0.084	0.122	0.991	0.51	5.02

Table 7: 1260 Whole Blood Method Comparison – Cl

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	43	0.979	3.706	2.790	0.985	76	150
Micro	52	1.020	-2.110	2.354	0.989	75	150
Syringe	52	1.001	-0.354	2.700	0.985	77	143

Table 8: 1260 Whole Blood Method Comparison – Glucose

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	44	1.049	-3.028	20.957	0.991	30	710
Micro	54	1.021	-4.840	17.521	0.994	37	698
Syringe	54	1.015	-8.892	16.097	0.995	38	688

Table 9: 1260 Whole Blood Method Comparison – Lactate

						Test Range	
Mode	**N**	**Slope**	**Intercept**	**RMSE**	**R_Square**	**Min**	**Max**
Capillary	54	1.123	-0.570	1.401	0.970	1.5	29.3
Micro	54	1.145	-0.643	2.081	0.939	1.4	31.6
Syringe	54	1.000	-0.256	1.393	0.968	1.4	28.9

b. Matrix comparison:
NA

3. Clinical studies:
   a. Clinical sensitivity:
   None stated
   b. Clinical specificity:
   None stated
   c. Other clinical supportive data (when a and b are not applicable):
   None
4. Clinical cut-off:
   None stated
5. Expected values/Reference range:
   The expected values of each parameter are within reportable range for the various measured and calculated parameters are provided in the Operator's Manual.

M. Instrument Name:

Bayer Rapidlab 1200 System Series

N. System Descriptions:

1. Modes of Operation:
   The system will use a reagent cartridge, wash cartridge, automatic QC cartridge and Rapidlab 800 sensor.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
Yes ___X_____ or No _____

3. Sample Identification:
   Bar code
4. Specimen Sampling and Handling:
   Automatic sample aspiration, Self-contained CO-oximetry sample chamber
5. Assay Types:
   The Rapidlab 1200 System uses measurement technology that is based on electrochemical, biochemical and optical phenomena. The device use potentiometry and amperometry methods for blood gas, electrolytes and metabolites to convert the potential generated by the sensor to an electrical signal which the system then converts to a value that represents that

concentration of a specific analyte or substances in recognizable units of measurement.

6. Reaction Types:
   Ion selective electrode – Potassium, Chloride, Sodium, Calcium, and pH
   Potentiometric – pCO2
   Amperiometric – pO2
   Enzymatic – Lactic Acid, Glucose
   Spectral absorbency -- CO-oximetry parameters
7. Calibration:
   Calibration of the Rapidlab 1200 Series systems occurs automatically at defined integrals and requires no operator action.
8. Quality Control:
   The Rapidlab 1200 system offers three options for quality control (QC) analysis: required QC analysis, automatic QC analysis, and unscheduled QC analysis. The RapidQC Complete material is sealed in a glass sample ampule and was cleared under K970956.

O. Other Supportive Instrument Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Determination Decision Summary.

N/A

P. Conclusion:

Based upon the information provided, I recommend that the Rapidlab 1200 System be found substantially equivalent to the respective predicate devices.