A world of potential

510(k) Summary[1]

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(2) Device trade or proprietary name: EDAN i15 Blood Gas and Chemistry Analysis System, EDAN i15 Calibrant Fluid Pack, EDAN i15 Blood Gas and Electrolyte Control and EDAN i15 Hematocrit Control.

Device common or usual name: Blood Gases (pCO_2, PO_2) and blood pH Test System, Electrolyte Analyzer; Calibrator, multi-analyte mixture; Controls for Blood Gases, Control, Hematocrit

Classification Name: Multiple

Classification Name	Review Panel	Product Code	Regulation Number	Class
Blood gases (PCO2, PO2) and blood pH test system	Clinical Chemistry	75 CHL	862.1120	2
Sodium test system	Clinical Chemistry	75 JGS	862.1665	2
Potassium test system	Clinical Chemistry	75 CEM	862.1600	2
Chloride test system	Clinical Chemistry	75 CGZ	862.1170	2
Calcium test system	Clinical Chemistry	75 JFP	862.1145	2
Automated hematocrit instrument	Hematology	81 GKF	864.5600	2
Calibrators	Clinical Chemistry	75 JIX	862.1150	2
Controls for Blood Gases (Assayed and Unassayed)	Clinical Chemistry	75 JJS	862.1660	1
Control, Hematocrit	Hematology	81 GLK	864.8625	2

(3) Substantial Equivalence

The EDAN i15 Blood Gas and Chemistry Analysis System, including the Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, and Quality Controls) is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use as shown in the table, below.

Predicate Devices:
K002738 – Siemens (Bayer) Rapidpoint 400 System, including calibrators
K943754 – RNA Medical QC823 Blood Gas, Electrolyte, Metabolite Control
K955630 – RNA Medical QC900 Hematocrit Control

[1] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Comparison of Predicate and Candidate Devices

Predicate Device: K002738 Siemens (Bayer) Rapidpoint 400 System				**Candidate Device: EDAN i15 Blood Gas and Chemistry Analysis System**		
Characteristic						
Intended Use						
	For the measurement of pH, pCO_2, PO_2, Na^+, K^+, Ca^{++}, Cl^- and Hct in whole blood samples.			Same		
Test Principle						
	pH and pCO_2: potentiometric			Same		
	pO_2: amperometric			Same		
	Na^+, K^+, Ca^{++}, Cl^-: potentiometric, ion-selective			Same		
	Hematocrit: conductivity			Same		
Sensor Technology						
	Amperometric and potentiometric thick film microelectrodes			Same		
Sample Types						
	Heparinized whole blood			Same		
Sample Introduction						
	Syringe and capillary, by aspiration			Same		
Sample Volumes						
	100 µL (syringe and capillary)			140 µL (syringe and capillary)		
Measurement Range						
	Parameter	*Range*	*Default units*	*Parameter*	*Range*	*Default units*
	pH	6.500 – 7.800	(pH units)	pH	6.500 – 7.800	(pH units)
	pCO_2	5.0 – 200.0	mmHg	pCO_2	10 – 150	mmHg
	pO_2	10.0 – 700.0	mmHg	pO_2	10 – 700	mmHg
	Na^+	100.0 – 200.0	mmol/L	Na^+	100 – 180	mmol/L
	K^+	0.50 – 15.00	mmol/L	K^+	2.0 – 9.0	mmol/L
	Ca^{++}	0.20 – 5.00	mmol/L	Ca^{++}	0.25 – 2.50	mmol/L
	Cl^-	65 – 140	mmol/L	Cl^-	65 – 140	mmol/L
	Hct	12 – 75	%	Hct	13 - 72	%
	Glu	20 – 750	mg/dL	N/A		
User Interface, Printer						
	Menu-driven color touch screen display			Same		
	Bar-code scanner			Same		
	Thermal printer			Same		
System Operating Temperature, Humidity						
	15 - 32°C, 5% to 85% (non-condensing)			10 – 31° C, 25% to 80% (non-condensing)		

Predicate Device: K002738 Siemens (Bayer) 400 Measurement Cartridge		**Candidate Device: EDAN i15 Blood Gas and Chemistry Analysis System Calibrant Fluid Pack**
Intended Use		
	The measurement cartridge is intended to be used for the calibration of sensors used for the quantitative measurement of pH, blood gases, electrolytes and hematocrit.	Same
Configuration		
	Three solutions for the calibration of the sensors and a reference solution contained in Mylar and aluminum foil bags, housed in a protective, self-contained, molded plastic disposable container.	One solution for the calibration of the sensors contained in a Mylar and aluminum foil bag, housed in a protective, self-contained, molded plastic disposable container.

Predicate Device: K943754 RNA Medical QC823 Blood Gas, Electrolyte and Metabolite Quality Control		Candidate Device: EDAN Blood Gas and Chemistry Quality Control
Intended Use		
	To evaluate the operation of the analyzer and to monitor the measurement of pH and blood gases (pCO_2, pO_2, and electrolytes (Na+, K+, Ca++, Cl-)	Same
Configuration		
	QC 823 is provided in three (3) levels for monitoring analyzer performance at different points within the clinical range. It is packaged in sealed glass ampoules, each containing 2.5 mL of solution. Ampoules are packaged thirty (30) per box.	Same, except packaged with 5 ampoules per box.
Analytes		
	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Mg^{++}, glucose, lactate, and BUN (urea)	Same, except assay provided only for pH, pCO_2, pO_2, Na^+, K^+, Cl^- and Ca^{++}

Predicate: K955630 RNA Medical Hematocrit Controls		Candidate: EDAN Blood Gas and Chemistry System Hematocrit Controls
Intended Use		
	To evaluate the operation and to monitor the measurement of hematocrit by electrical conductivity.	Same
Configuration		
	QC 900 is provided in two (2) levels (Low and High) for monitoring analyzer performance at different points within the clinical range. It is packaged in sealed glass ampoules, each containing 1.7 mL of solution. Ampoules are packaged twenty (20) per box (10 of each level).	Same, except each single level is packaged in a convenient 5-ampoule box.
Analytes		
	Hematocrit (%)	Same
Active Ingredients		
	Salts and conductivity modifiers	Same

(4) Description of the new device.

The EDAN i15 Blood Gas and Chemistry Analysis System, including the Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, and Quality Controls) is a system for *in-vitro* analysis of whole blood, delivering quantitative results for panels of tests determined by the Test Cartridge type used in the measurement. The Analyzer incorporates a large graphical user interface with a large color touch screen interfacing the analyzer electronic, Test Cartridge (containing the sensors) and Calibrant Fluid Pack. The sensors, flow path and waste are integrated into a single-use Test Cartridge. The calibration solution is contained in the Calibrant Fluid Pack which is available in versions for 50 or 100 tests. The product, consumables, installation instructions and packaging are designed for easy customer installation and operation.

The EDAN i15 Analyzer accepts lithium- or calcium-balanced heparinized whole blood samples from syringes and capillary tube. The minimum volume for samples from both syringe and capillary tube is 140 µL.

Test Cartridge

As with the predicate device, the EDAN i15 Blood Gas and Chemistry Analysis System is microprocessor-based and incorporates traditional sensor technology for measurement.

- pH, pCO_2, Na^+, K^+, Cl^-, and Ca^{++} (potentiometric measurement)
- pO_2 (amperometric measurement)
- Hct (conductivity measurement)

The Test Cartridge is available in three (3) versions, with different test panels, but with identical sample paths and calibration fluid:

Test Cartridge Type	Measured Parameters
BG8	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Hct
BG3	pH, pCO_2, pO_2
BC4	Na^+, K^+, Cl^-, Ca^{++}, Hct

The Test Cartridge aspirates the sample directly from a syringe, or capillary fitted with an adaptor, and requires a minimum sample volume of 140 µL.

Measured Parameters

The EDAN i15 Blood Gas and Chemistry Analysis System measures blood pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium and hematocrit.

Calculated Parameters

Symbol	Description
cH+	Hydrogen ion concentration
cH+(T)	Hydrogen ion concentration corrected for entered patient temperature
pH (T)	pH value corrected for entered patient temperature
pCO_2 (T)	pCO_2 corrected for entered patient
pO_2 (T)	pO_2 corrected for entered patient temperature
HCO_3^-act	Bicarbonate ion concentration
HCO_3^-std	Bicarbonate ion concentration normalized to a pCO_2 of 40mmHg
BB (B)	Buffer base
BE (B)	Base excess (B) BE (ecf) Base excess (ecf) $ctCO_2$ Total carbon dioxide
Ca^{++} (7.4)	The ionized calcium concentration of blood normalized to pH 7.4
AnGap	An approximation of the difference between measured cations and measured anions in the sample
tHb (est)	An estimation of the hemoglobin contained in the sample
sO_2 (est)	An estimation of hemoglobin oxygen saturation: a ratio of the amount of hemoglobin bound to oxygen to the total amount of hemoglobin able to bind oxygen
pO_2 (A-a)	Alveolar-arterial oxygen tension difference
pO_2 (A-a) (T)	Alveolar-arterial oxygen tension difference corrected for entered patient temperature
pO_2 (a/A)	Arterial-alveolar oxygen tension ratio
pO_2 (a/A) (T)	Arterial-alveolar oxygen tension ratio corrected for entered patient temperature
RI	Respiratory index: the ratio of the alveolar-arterial blood oxygen-pressure difference to arterial pO_2
RI (T)	Respiratory index: the ratio of the alveolar-arterial blood oxygen-pressure difference to arterial pO_2 when both values are corrected for patient temperature
pO_2/FIO_2	The ratio of arterial pO_2 to the fraction of inspired oxygen
pO_2 (T)/FIO_2	The ratio of arterial pO_2 to the fraction of inspired oxygen corrected for the entered patient temperature

Indications for Use

The i15 Blood Gas and Chemistry Analysis System (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge) is a portable, automated system that measures pH and blood gases (pCO_2, pO_2),

electrolytes (Na^+, K^+, Ca^{++}, Cl^-) and hematocrit in arterial and venous whole blood samples with lithium heparin or calcium balanced heparin. The system is intended for in-vitro diagnostic use only by trained health care professionals in a laboratory environment, near patient or point-of-care settings.

pH, pCO_2, pO_2:	Whole blood measurement of certain gases in whole blood, or pH of whole blood, is used in the diagnosis and treatment of life-threatening acid-base and/or oxygenation disturbances.
Hct:	Whole blood measurements of the packed cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red blood cells)
Na^+:	Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
K^+:	Potassium measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels
Cl^-:	Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Ca^{++}:	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

The EDAN i15 Calibrant Fluid Pack is intended for the calibration of pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-, and Hct as part of the EDAN i15 Blood Gas and Chemistry Analysis System.

The EDAN i15 Blood Gas and Electrolyte Controls are external multi-analyte quality control material intended to be used for the verification of correct operation and measurement of the EDAN i15 Blood Gas and Electrolyte Analyze, together with i15 Calibrant Fluid Pack and i15 Test Cartridge for the analysis of pH, blood gases (pCO_2 pO_2), and electrolytes (Na^+, K^+, Ca^{++}, and Cl^-).

The EDAN i15 Hematocrit Controls are intended to be used for the verification of correct operation and measurement of the EDAN i15 Blood Gas and Chemistry Analysis System, together with i15 Calibrant Fluid Pack and i15 Test Cartridge for the analysis of hematocrit.

Summary of the Technological Characteristics

The EDAN i15 Blood Gas and Chemistry Analysis System is substantially equivalent to the previously cleared Siemens RapidPoint 400 Test System in intended use. The test principle, sensor technology, sample types and mode of sample introduction are the same for these system, and measurement is shown to be equivalent in this submission. The results of software validation and performance verification testing confirmed the EDAN i15 Blood Gas and Chemistry Analysis System, including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, and Test Cartridge, is safe and effective for it intended use and the EDAN i15 Blood Gas and Chemistry Analysis system is substantially equivalent to that of the Siemens RapidPoint 400 Blood Gas Electrolyte System, including the Measurement Cartridge, K002738 (predicate device).

The EDAN i15 Calibrator Fluid Pack is substantially equivalent to the Siemens 400 Measurement Cartridge previously cleared with the Siemens RapidPoint 400 Test System in configuration and in support for the calibration and measurement of equivalent panels of measurands.

The EDAN i15 Blood Gas and Electrolyte Control is substantially equivalent to the previously cleared RNA

Medical Blood Gas, Electrolyte and Metabolite Control K943754 (predicate device) in formulation, measurands and primary (glass ampoule) packaging, but packaged in convenient 5-ampoule packages.

The EDAN i15 Hematocrit Control is substantially equivalent to the previously cleared RNA Medical Hematocrit Control K955630 (predicate device) in formulation, measurands and primary (glass ampoule) packaging, but packaged in convenient 5-ampoule packages.

Summary of Performance Testing

Bench testing was completed to demonstrate the EDAN i15 System is substantially equivalent to the Siemens RapidPoint 400 Blood Gas and Electrolyte System in performance, safety and efficacy.
The bench testing included:

- Method Comparison Studies, Linearity and Analytical Measuring Range
- Imprecision/Reproducibility Studies
- Specificity/Interference Testing
- Detection Limit

The results of that testing confirm the performance of the EDAN i15 Blood Gas and Chemistry Analysis System, (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, and Test Cartridge), is substantially equivalent to that of the previously cleared Siemens (Bayer) RapidPoint 400 Test System, including Measurement Cartridge (predicate device).

a. Linearity Studies

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit. Criteria for acceptance is a slope between 0.95 and 1.05 and r-value ≥ 0.975. Electrolyte values were compared to those calculated from serial dilution of high and low concentration blood samples, pO_2 and pCO_2 against those determined by tonometry, pH was compared against parallel measurement on a Radiometer ABL 800, while hematocrit was compared the PCV% obtained by microhematocrit centrifuge. The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Na^+	7	100 - 180	94 - 185	114%	0.9923	-1.38	0.9983
K^+	7	2.0 - 9.0	1.7 - 10.2	120%	0.9886	0.08	0.9997
Cl^-	7	65 - 140	58 - 176	158%	1.0028	-1.59	0.9993
Ca^{++}	7	0.25 - 2.50	0.23 - 2.94	120%	0.9848	-0.05	0.9981
pH	7	6.500 - 7.800	6.455 - 7.944	115%	0.9842	0.11	0.9996
pCO_2	7	10 - 150	3 - 149	104%	0.9533	0.62	0.9969
pO_2	7	10 - 700	6 - 716	103%	0.9969	-6.16	0.9993
Hct	7	13 - 72	3 - 77	125%	0.9687	1.54	0.9981

Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Na^+	7	100 - 180	94 - 185	114%	1.0059	-3.06	0.9986
K^+	7	2.0 - 9.0	1.9 - 10.0	116%	1.0013	-0.01	0.9998
Cl^-	7	65 - 140	59 - 175	155%	0.9965	-1.59	0.9992
Ca^{++}	7	0.25 - 2.50	0.24 - 2.97	121%	0.9771	-0.06	0.9968
pH	7	6.500 - 7.800	6.464 - 7.978	116%	1.0039	-0.03	0.9995
pCO_2	7	10 - 150	2 - 150	105%	0.9999	-0.06	0.9992
pO_2	7	10 - 700	7 - 717	103%	1.0174	-5.40	0.9997
Hct	7	13 - 72	4 - 76	122%	0.9623	1.51	0.9984

Linearity across claimed measurement range in samples introduced from glass Capillary.

b . Imprecision in External Controls

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control and 2 levels of EDAN i15 Hematocrit Control in duplicate each day for a total of 20 runs on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A2, *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second edition.*

pH Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (pH units)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	7.153	80	0.012	0.17 %	0.012	0.17 %
Level 2	7.410	80	0.013	0.18 %	0.013	0.18 %
Level 3	7.598	80	0.008	0.11 %	0.009	0.12 %
pCO_2 Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmHg)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	62.8	80	2.11	3.36 %	2.40	3.82 %
Level 2	38.8	80	2.11	5.45 %	2.33	6.02 %
Level 3	20.5	80	0.80	3.91 %	0.85	4.13 %
pO_2 Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmHg)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	71.4	80	2.67	3.73 %	2.68	3.75 %
Level 2	106.2	80	1.84	1.73 %	2.50	2.35 %
Level 3	149.2	80	2.59	1.74 %	3.33	2.23 %
Na^+ Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	111.8	80	1.29	1.15 %	1.32	1.18 %
Level 2	133.0	80	0.95	0.71 %	1.14	0.86 %
Level 3	158.5	80	1.51	0.95 %	1.44	0.91 %

K^+ Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	1.91	80	0.040	2.11 %	0.040	2.07 %
Level 2	4.34	80	0.047	1.09 %	0.052	1.20 %
Level 3	6.34	80	0.073	1.16 %	0.065	1.02 %
Cl^- Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	75.9	80	0.91	1.20 %	0.93	1.22 %
Level 2	92.3	80	1.07	1.16 %	1.08	1.17 %
Level 3	121.7	80	0.66	0.54 %	0.69	0.57 %
Ca^{++} Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV%	Total Imprecision SD	Total Imprecision CV%
Level 1	1.37	80	0.04	3.09	0.05	3.47
Level 2	1.23	80	0.02	1.54	0.03	2.42
Level 3	0.61	80	0.02	3.10	0.02	3.66
Hct Precision in Aqueous Hematocrit Control						
Sample	Mean (%)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Low	19.2	80	0.57	2.97 %	0.73	3.82 %
High	46.8	80	0.58	1.24 %	0.54	1.16 %

c. *Precision in Whole Blood*

Hematocrit Venous Whole Blood Precision

An in-house with-in run precision study was performed on heparinized venous whole blood samples collected from eight volunteers. Six levels were prepared (one on each day of 6 days) in order to cover the measuring range of hematocrit. Each sample was run in replicates of 10 on 3 EDAN i15 analyzers, using 3 reagent lots, over a period of 6 days (one level run per day) for a total of 30 results per level. The with-in run precision results for of the six levels of whole blood tested from both syringe and capillary tube is presented in the table below:

Venous whole blood within-run precision for Hct

n = 30	Syringe			Capillary		
Hct Level	Mean (%)	SD	%CV	Mean (%)	SD	%CV
1	18.0	1.1	6.3	18.4	1.1	5.9
2	30.6	0.6	1.8	31.1	0.8	2.4
3	47.1	0.8	1.7	48.0	1.1	2.3
4	51.4	0.6	1.2	52.5	0.7	1.3
5	54.0	0.6	1.2	53.9	0.9	1.6
6	62.9	0.9	1.4	63.1	0.8	1.3

An in-house precision study was performed utilizing 3 EDAN i15 Blood Gas and Chemistry Analysis System with venous whole blood collected from 3 healthy volunteers. The whole blood was tonometered to nominal gas values. The remainder of the analytes were not altered. The samples were run in replicates of 10 on each of the three analyzers for a total of 30 results. The results of the combined precision data is summarized below:

Venous whole blood within-run precision

n = 30	Syringe			Capillary		
Parameter	Mean (%)	SD	%CV	Mean (%)	SD	%CV
pH	7.325	0.015	0.20	7.322	0.016	0.21
pCO_2 (mmHg)	44.3	1.1	2.6	43.7	1.2	3.8
pO_2 (mmHg)	150.8	4.5	3.0	148.7	4.1	2.8
Na^+ (mmol/L)	139.1	0.9	0.7	139.2	0.9	0.6
K^+ (mmol/L)	3.24	0.06	1.9	3.35	0.08	2.5
Ca^{++} (mmol/L)	1.19	0.03	2.7	1.17	0.03	2.3
Cl^- (mmol/L)	103.5	1.8	1.7	103.5	2.0	1.1
Hct (%)	47.1	0.8	1.7	48.1	1.1	2.2

d. Comparison of Syringe and Capillary Measurement

Whole blood venous samples from healthy volunteers were evaluated to demonstrate the measurement results from samples introduced from syringes and capillary tubes are equivalent. Six levels of blood were prepared to provide a range of measurement values for electrolytes and hematocrit, and tonometered with precision gas mixtures to attain a range of pCO_2 and PO2 values and analyzed over numerous days on three (3) EDAN i15 instruments with 10 replicates on each of six (6) levels of prepared blood samples introduced from capillary tubes as compared to introduced from syringes.

Measurand	N	sample range tested	Slope	Intercept	r-value	Bias
pH	180	7.036 - 7.689	0.9855	0.1056	0.9936	-0.001
pCO_2 (mmHg)	180	6.7 - 119.1	0.9870	0.0377	0.9953	-0.6
pO_2 (mmHg)	180	15.0 - 749.0	1.0177	-1.0704	0.9941	3.3
Na^+ (mmol/L)	180	105 - 176	0.9716	4.3119	0.9954	0.3
K^+ (mmol/L)	180	2.8 - 10.6	0.9848	0.0339	0.9981	-0.04
Ca^{++} (mmol/L)	180	0.86 - 3.16	0.9813	-0.0213	0.9928	-0.05
Cl^- (mmol/L)	180	76 - 164	0.9844	1.6184	0.9922	-0.2
Hct (%)	180	16 - 64	0.9933	0.8013	0.9968	0.5

Correlation in whole blood samples introduced from Capillary vs Syringe

e. Specificity / Interference Testing

An interference study was performed according to the CLSI guideline EP7-A2. The study used spiked and diluted human whole blood samples containing potential interferents for pH, pO2, pCO_2, sodium, potassium, chloride, calcium, and hematocrit. Seven replicates of both the spiked and the unspiked sample were tested on two i15 Blood Gas and Chemistry System with one lot of test cartridges. The results of each replicate of the spiked and unspiked samples were compared and the percent bias between the results was calculated for all analytes except for pH for which absolute difference was calculated. The acceptance criteria used to evaluate if the substances significantly interfere with each analyte is shown in the table below:

Measurand	pH	pCO_2	pO_2	Na^+	K^+	Ca^{++}	Cl^-	Hct
Evaluation Method	Absolute difference	Percent Bias	Percent bias	Percent bias	Percent bias	Percent bias	Percent bias	Percent bias
Acceptance Criteria	< 0.02 pH Units	< 8%	< 9%	< 3%	< 10%	< 10%	< 5%	< 6%

The following table represents substances that were tested without significant effects on test results:

Interfering Substance	Highest Concentration Tested	Analytes Tested
Albumin	1.5 g/dL (added)	Na^+, K^+, Ca^{++}, Cl^-, Hct
Ascorbic acid (Vitamin C)	6.02 mg/dL	pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Benzylkonium Chloride	0.80 mg/dL	Na^+, K^+, Ca^{++}, Cl^-, Hct
Bilirubin	15 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Calcium Chloride	27.75 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Hct
Cholesterol	500 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Cysteine	12.12 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Hemoglobin	500 mg/dL	pH, pCO_2, pO_2, Na^+, Ca^{++}, Cl^-, Hct
Heparin lithium salt	11.76 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Hydroxybutyrate	208 mg/dL	pCO_2, pO_2, Na^+, Ca^{++}, Cl^-, Hct
Hydroxyurea	182.52 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Ibuprofen	50 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Lactic acid	59.40 mg/dL	pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Lithium	2.24 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Ofloxacin	6 µg/mL	pH, pCO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Triglycerides	1500 mg/dL	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct

The following table represents substances that were tested that demonstrated a significant interference on test results. The table includes the range of % bias (absolute difference for pH) that was calculated between the 7 replicates spiked and unspiked samples for each analyte.

Measurand	Interfering Substance	Concentration Tested	Blood Sample Value	Absolute Difference in pH Units
pH	Acetaminophen	20.01 mg/dL	pH: 7.5	-0.034
			pH: 7.3	< |0.02|
	Bromide	185.20 mg/dL	pH: 7.5	-0.027
			pH: 7.3	< |0.02|
	Calcium Chloride	27.27 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.024
	Ethanol	400 mg/dL	pH: 7.5	-0.024
			pH: 7.3	< |0.02|
	Hematocrit	20% PCV	pH: 7.5	-0.022
			pH: 7.3	< |0.02|
	Heparin	58.82 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.034
	Hydroxycarbamide (Hydroxyurea)	182.52 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.031
	Iodide	37.94 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.025
	Potassium Chloride	59.64 mg/dL	pH: 7.5	-0.036
			pH: 7.3	< |0.02|

Measurand	Interfering Substance	Concentration Tested	Blood Sample Value	Absolute Difference in pH Units
pH	Sodium Chloride	117 mg/dL	pH: 7.5	-0.024
			pH: 7.3	-0.021
	Sodium Oxalate	168 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.032
Measurand	Interfering Substance	Concentration Tested	Blood Sample Value	% Difference
pCO_2	Acetaminophen	20.01 mg/dL	pCO_2: 70 mmHg	10.15%
			pCO_2: 40 mmHg	< |8%|
	Acetylsalicylic acid	39.09 mg/dL	pCO_2: 70 mmHg	8.01%
			pCO_2: 40 mmHg	< |8%|
	Ethanol	400 mg/dL	pCO_2: 70 mmHg	9.54%
			pCO_2: 40 mmHg	< |8%|
	Iodide	37.94 mg/dL	pCO_2: 70 mmHg	-10.00%
			pCO_2: 40 mmHg	-8.69%
	Potassium Chloride	59.64 mg/dL	pCO_2: 70 mmHg	11.15%
			pCO_2: 40 mmHg	< |8%|
	Bicarbonate ($NaHCO_3$)	294 mg/dL	pCO_2: 70 mmHg	-18.40%
			pCO_2: 40 mmHg	-17.44%
pO_2	Acetylsalicylic acid	39.09 mg/dL	pO_2: 100 mg/dL	< |9%|
			pO_2: 70 mg/dL	-10.11%
	Hematocrit	20% PCV	pO_2: 100 mg/dL	< |9%|
			pO_2: 70 mg/dL	12.13%
	Lactic Acid	90 mg/dL	pO_2: 100 mg/dL	< |9%|
			pO_2: 70 mg/dL	9.74%
	pCO_2	60 mmHg	pO_2: 100 mg/dL	< |9%|
			pO_2: 70 mg/dL	9.60%
	Salicylic acid	59.94 mg/dL	pO_2: 100 mg/dL	< |9%|
			pO_2: 70 mg/dL	14.98%
	Sodium Chloride	117 mg/dL	pO_2: 100 mg/dL	< |9%|
			pO_2: 70 mg/dL	9.22%
	Bicarbonate ($NaHCO_3$)	294 mg/dL	pO_2: 100 mg/dL	-14.46%
			pO_2: 70 mg/dL	< |9%|

Measurand	Interfering Substance	Concentration Tested	Blood Sample Value	% Difference
Na^+	Calcium Chloride	55.50 mg/dL	Na^+: 150 mmol/L	3.26%
			Na^+: 130 mmol/L	4.99%
	Dobutamine hydrochloride	22.30 mg/dL	Na^+: 150 mmol/L	< |3%|
			Na^+: 130 mmol/L	5.62%
K^+	Acetylsalicylic acid	65.22 mg/dL	K^+: 5 mmol/L	17.21%
			K^+: 3 mmol/L	< |10%|
	Dobutamine hydrochloride	22.30 mg/dL	K^+: 5 mmol/L	< |10%|
			K^+: 3 mmol/L	13.97%
	Hydroxybutyrate	208 mg/dL	K^+: 5 mmol/L	12.28%
			K^+: 3 mmol/L	16.87%
	Iodide	37.94 mg/dL	K^+: 5 mmol/L	< |10%|
			K^+: 3 mmol/L	24.20%
	Lactic Acid	90 mg/dL	K^+: 5 mmol/L	13.05%
			K^+: 3 mmol/L	< |10%|
	pCO_2	60 mmHg	K^+: 5 mmol/L	10.13%
			K^+: 3 mmol/L	< |10%|
	Salicylic acid	29.97 mg/dL	K^+: 5 mmol/L	10.54%
			K^+: 3 mmol/L	< |10%|
	Bicarbonate ($NaHCO_3$)	294 mg/dL	K^+: 5 mmol/L	21.51%
			K^+: 3 mmol/L	10.31%
Ca^{++}	Halothane	14.98 mg/dL	Ca^{++}: 2 mmol/L	< |10%|
			Ca^{++}: 1 mmol/L	11.20%
	Heparin	58.82 mg/dL	Ca^{++}: 2 mmol/L	-12.68%
			Ca^{++}: 1 mmol/L	-14.06%
	Magnesium Chloride	47.61 mg/dL	Ca^{++}: 2 mmol/L	13.91%
			Ca^{++}: 1 mmol/L	16.86%
	Bicarbonate ($NaHCO_3$)	294 mg/dL	Ca^{++}: 2 mmol/L	-27.07%
			Ca^{++}: 1 mmol/L	-21.17%
	Phosphate (NaH_2PO_4)	24 mg/dL	Ca^{++}: 2 mmol/L	-12.14%
			Ca^{++}: 1 mmol/L	-12.34%
	Sodium Oxalate	168 mg/dL	Ca^{++}: 2 mmol/L	-94.16%
			Ca^{++}: 1 mmol/L	-86.21%
Cl^-	Acetylsalicylic acid	39.09 mg/dL	Cl^-: 110 mmol/L	7.72%
			Cl^-: 90 mmol/L	5.11%
	Albumin	3 g/dL (added) Approx. 8 g/dL (total)	Cl^-: 110 mmol/L	5.13%
			Cl^-: 90 mmol/L	7.19%
	Bromide (NaBr)	185.20 mg/dL	Cl^-: 110 mmol/L	< |5%|
			Cl^-: 90 mmol/L	6.38%

Measurand	Interfering Substance	Concentration Tested	Blood Sample Value	% Difference
Cl^-	Iodide	37.94 mg/dL	Cl^-: 110 mmol/L	-7.60%
			Cl^-: 90 mmol/L	-11.76%
	Potassium Thiocyanate	20.06 mg/dL	Cl^-: 110 mmol/L	10.81%
			Cl^-: 90 mmol/L	13.41%
	Salicylic acid	29.97 mg/dL	Cl^-: 110 mmol/L	11.28%
			Cl^-: 90 mmol/L	9.88%
	Bicarbonate ($NaHCO_3$)	294 mg/dL	Cl^-: 110 mmol/L	7.72%
			Cl^-: 90 mmol/L	8.79%
	Sodium Oxalate	168 mg/dL	Cl^-: 110 mmol/L	5.01%
			Cl^-: 90 mmol/L	6.47%
Hct	Albumin	3 g/dL (added) approx. 8 g/dL (total)	Hct: 55% PCV	10.29%
			Hct: 35% PCV	13.65%
	Bromide (NaBr)	185.20 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	-6.98%
	Calcium Chloride	55.50 mg/dL	Hct: 55% PCV	-7.23%
			Hct: 35% PCV	-6.13%
	Dextran	3 g/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	10.24%.
	Dobutamine hydrochloride	22.30 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	7.76%
	Ethanol	400 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	-6.61%
	Magnesium Chloride	47.61 mg/dL	Hct: 55% PCV	-6.40%
			Hct: 35% PCV	-9.39%
	Potassium Chloride	59.64 mg/dL	Hct: 55% PCV	-6.27%
			Hct: 35% PCV	< |6%|
	Sodium Chloride	117 mg/dL	55% PCV	< |6%|
			35% PCV	-6.36%
	Bicarbonate ($NaHCO_3$)	58.8 mg/dL	55% PCV	< |6%|
			35% PCV	-7.72%

NOTES:

The addition of 50,000 WBC cu/mL to a blood sample with 6.1 x 10^9 WBC cu/mL causes an increase in Hct %PCV measured by the EDAN i15 relative to spun hematocrit %PCV by 4.43 %PCV (absolute) or 11% (relative) exceeding the Total Allowable Error defined in CLIA'88.

Hemolysis will increase the potassium measurement on i15 system due to release of potassium from the red blood cells. When the amount of hemoglobin in plasma is increased by 500 mg/dL, the increase in K+ measurement tested on i15 system is about 36%； when the amount of hemoglobin in plasma is increased by 100 mg/dL, the increase in K+ measurement tested on i15 system is about 29%.

f. Determination of Detection Limits for ionized Calcium

Detection limits were determined by obtaining the standard deviation of sample measurements from repeated measurements of samples with a relevant low concentration. To determine LoB, zero level samples were prepared and measured on two EDAN i15 instruments with different lots of Test Cartridges and Calibrator Fluid Packs to obtain blank measurements (N=120). To determine the LoD and LoQ, whole blood samples with low levels of analyte (approximately 1 to 4 x LoB) were measured on two instruments (N=120). The LoQ was determined based on the inter-assay precision (%CV). The limit of quantitation (LoQ) is based on an accuracy goal of 0.125 mmol/L. The accuracy goal was met and therefore, the LoQ is equal to the LoD of 0.11 mmol/L. Results of the study are presented in the following table:

Measurand	LoB	LoD	LoQ	Claimed Measurement Range
Ionized Calcium	0.09 mmol/L	0.11 mmol/L	0.11 mmol/L	0.25 – 2.50 mmol/L

Summary of Clinical Site Testing

Studies were conducted at 4 Point-of-Care (POC) sites and 3 laboratory sites to demonstrate equivalence of performance of the EDAN i15 System in comparison to previously cleared test systems cleared for the same intended use. The POC sites included a respiratory medical care unit, two medical intensive care units, an anesthesia unit and a rapid-response (STAT) lab, and employed tested by 11 persons fulfilling the minimum requirements for education and training to perform moderately complex testing in accordance with CLIA. Of these 11 persons, 10 had no prior blood gas testing experience. All testing was performed using quality control materials or discarded blood gas specimens.

a. Imprecision/Reproducibility in Aqueous Quality Control Materials

Each clinical site used to collect method comparison data, performed analysis of quality control (Blood Gas and Electrolyte Controls, and Hematocrit Controls) at the beginning and end of each testing day. The summary of imprecision from each site is provided in the table, below and demonstrate equivalence between POC and Laboratory test sites.

	Test	N	Mean	Within-Run SD	Within-Run CV%	Between-Day SD	Between Day CV%	Total SD	Total CV%
LEVEL 1	Average of Four Point-of-Care Test Sites								
Blood Gas and Electrolyte Control	pH	80	7.135	0.006	0.08%	0.004	0.05%	0.007	0.10%
	pCO_2	80	73.2	2.20	3.0%	1.32	1.8%	2.56	3.5%
	pO_2	80	70.9	1.71	2.4%	1.52	2.1%	2.29	3.2%
	Na^+	80	121.3	0.81	0.7%	0.63	0.5%	0.99	0.8%
	K^+	80	2.23	0.02	0.9%	0.02	1.0%	0.03	1.3%
	Cl^-	80	78.1	0.74	0.9%	0.30	0.4%	0.80	1.0%
	Ca^{++}	80	1.46	0.06	4.0%	0.04	2.7%	0.07	4.5%
Hct Control	Hct	80	21.0	0.67	3.2%	0.42	2.0%	0.68	3.2%
LEVEL 1	Average of Three Laboratory Test Sites								
Blood Gas and Electrolyte Control	pH	104	0.006	0.09%	0.004	0.06%	0.007	0.10%	0.006
	pCO_2	104	70.4	1.76	2.5%	1.19	1.7%	2.08	2.9%
	pO_2	104	72.3	2.12	2.9%	1.69	2.3%	2.41	3.3%
	Na^+	104	118.1	1.12	0.9%	0.49	0.4%	1.19	1.0%
	K^+	104	2.24	0.03	1.5%	0.05	2.1%	0.06	2.6%
	Cl^-	104	77.3	0.71	0.9%	0.37	0.5%	0.59	0.8%
	Ca^{++}	104	1.48	0.05	3.4%	0.04	2.9%	0.06	4.3%
Hct Control	Hct	104	20.3	0.64	3.2%	0.37	1.8%	0.69	3.4%

	Test	Days	Mean	Within-Run SD	Within-Run CV%	Between-Day SD	Between Day CV%	Total SD	Total CV%
LEVEL 2	Average of Four Point-of-Care Test Sites								
Blood Gas and Electrolyte Control	pH	80	7.399	0.006	0.07%	0.002	0.03%	0.006	0.08%
	pCO_2	80	43.1	1.32	3.1%	1.01	2.3%	1.66	3.9%
	pO_2	80	104.8	1.83	1.7%	1.39	1.3%	2.13	2.0%
	Na^+	80	143.1	0.65	0.5%	0.76	0.5%	1.00	0.7%
	K^+	80	4.63	0.04	0.9%	0.03	0.6%	0.05	1.0%
	Cl^-	80	99.9	0.43	0.4%	0.40	0.4%	0.58	0.6%
	Ca^{++}	80	1.10	0.02	2.1%	0.03	2.6%	0.04	3.3%
Hct Control	Hct	80	33.7	0.33	1.0%	0.12	0.3%	0.31	0.9%
LEVEL 2	Average of Three Laboratory Test Sites								
Blood Gas and Electrolyte Control	pH	104	7.402	0.004	0.05%	0.004	0.06%	0.006	0.08%
	pCO_2	104	41.0	1.76	4.3%	1.19	2.9%	2.08	5.1%
	pO_2	104	104.2	1.84	1.8%	2.14	2.1%	2.82	2.7%
	Na^+	104	139.1	0.76	0.5%	0.87	0.6%	1.15	0.8%
	K^+	104	4.59	0.04	0.8%	0.03	0.6%	0.05	1.0%
	Cl^-	104	97.61	0.71	0.7%	0.73	0.8%	0.87	0.9%
	Ca^{++}	104	1.11	0.03	2.3%	0.03	2.7%	0.04	3.5%
Hct Control	Hct	104	33.1	0.65	2.0%	0.33	1.0%	0.63	1.9%

	Test	Days	Mean	Within-Run SD	Within-Run CV%	Between-Day SD	Between Day CV%	Total SD	Total CV%
LEVEL 3	Average of Four Point-of-Care Test Sites								
Blood Gas and Electrolyte Control	pH	80	7.583	0.006	0.08%	0.002	0.03%	0.006	0.08%
	pCO_2	80	24.7	0.69	2.8%	0.56	2.3%	0.88	3.6%
	pO_2	80	146.3	1.80	1.2%	1.18	0.8%	2.05	1.4%
	Na^+	80	166.0	1.43	0.9%	0.91	0.6%	1.41	0.9%
	K^+	80	6.84	0.06	0.8%	0.02	0.3%	0.06	0.8%
	Cl^-	80	126.6	0.70	0.6%	0.82	0.6%	1.00	0.8%
	Ca^{++}	80	0.48	0.01	3.0%	0.01	2.3%	0.02	3.7%
Hct Control	Hct	80	47.0	0.22	0.5%	0.03	0.1%	0.22	0.5%
LEVEL 3	Average of Three Laboratory Test Sites								
Blood Gas and Electrolyte Control	pH	104	7.580	0.005	0.06%	0.006	0.08%	0.008	0.10%
	pCO_2	104	24.0	0.73	3.0%	0.49	2.0%	0.88	3.7%
	pO_2	104	144.9	1.89	1.3%	1.57	1.1%	2.45	1.7%
	Na^+	104	162.8	1.14	0.7%	0.91	0.6%	1.39	0.9%
	K^+	104	6.69	0.05	0.7%	0.04	0.7%	0.06	1.0%
	Cl^-	104	123.9	1.12	0.9%	1.08	0.9%	1.41	1.1%
	Ca^{++}	104	0.49	0.01	2.6%	0.02	3.2%	0.02	4.1%
Hct Control	Hct	104	46.9	0.61	1.3%	0.39	0.8%	0.68	1.5%

b. Method Comparison

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09-A3 Method Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. Up to 4 data pairs for a single measurand were eliminated from this method comparison because values were outside claimed measurement range.

EDAN vs Predicate								
Measurand	Site	Nr.	range	claimed range	slope	intercept	std error	r-value
pH	POC 1-4	257	6.826 - 7.675		1.0130	-0.0961	0.0218	0.9909
	all LAB	228	6.531 - 7.791	6.500 - 7.800	1.0085	-0.0640	0.0208	0.9940
	all Sites	488	6.531 - 7.791	97%	1.0105	-0.0778	0.0213	0.9933
pCO_2	POC 1-4	257	18.0 - 144.8		1.0285	-1.5528	3.6695	0.9841
mmHg	all LAB	226	10.9 - 144.9	10 - 150	0.9523	1.0417	3.3262	0.9916
	all Sites	483	10.9 - 144.9	96%	0.9843	0.1813	3.6383	0.9879
pO_2	POC 1-4	257	17 - 585		1.0368	-4.1355	6.5734	0.9974
mmHg	all LAB	229	10 - 661	10 - 700	1.0018	0.2151	6.9117	0.9989
	all Sites	486	10 - 661	94%	1.0119	-1.0639	6.9830	0.9983
Na^+	POC 1-4	257	110 - 170		0.9787	2.5631	1.6065	0.9802
mmol/L	all LAB	229	101 - 180	100 - 180	0.9909	0.8032	1.5810	0.9952
	all Sites	486	101 - 180	99%	0.9886	1.1358	1.5927	0.9923
K^+	POC 1-4	257	2.4 - 9.0		0.9838	0.0250	0.0791	0.9968
mmol/L	all LAB	230	2.6 - 8.2	2.0 - 9.0	0.9868	0.0450	0.1181	0.9963
	all Sites	487	2.4 - 9.0	94%	0.9895	0.0164	0.1005	0.9968
Cl^-	POC 1-4	257	77 - 137		1.0188	-2.2648	1.7342	0.9821
mmol/L	all LAB	227	66 - 139	65 - 140	1.0000	0.2599	2.0765	0.9899
	all Sites	484	66 - 139	97%	1.0012	-0.1469	1.9205	0.9875
Ca^{++}	POC 1-4	257	0.47 - 1.82		0.9568	0.0428	0.0457	0.9695
mmol/L	all LAB	228	0.30 - 2.42	0.25 - 2.50	0.9919	0.0228	0.0416	0.9921
	all Sites	485	0.30 - 2.42	94%	0.9848	0.0200	0.0453	0.9854
Hct	POC 1-4	257	21 - 60		0.9853	0.8173	1.2295	0.9891
%	all LAB	230	13 - 72	13 - 72	0.9842	0.6787	1.0990	0.9933
	all Sites	487	13 - 72	100%	0.9827	0.8306	1.1707	0.9917

Traceability

The parameters measured and reported by the EDAN i15 Blood Gas and Chemistry Analysis System, including the Calibrant Fluid Pack are calibrated and tested for release using primary and secondary standards traceable to NIST or other recognized standards (where no NIST standard is available or practical) as summarized below:

Analyte	Traceability
pH	Buffer solution made with NIST HEPES SRM 2181 and 2182
pCO_2, pO_2	NIST traceable pure gases gravimetrically prepared
Na, Cl	NIST SRM 919b
K	NIST SRM 918b

Ca	NIST SRM 915b
Hct	CLSI H7-A3 Procedure for Determining Packed Cell Volume by the Microhematocrit Method

Stability and Value Assignment for Controls and Calibrant Fluid Pack

Stability / Shelf Life:

- EDAN i15 Calibrant Fluid Pack – 12 month shelf-life when stored unopened at 2-8°C (35-46°F) (avoid freezing) and 30 days after installation on the instrument or until expiration date is reached.
- EDAN i15 Blood Gas and Electrolyte Controls – 36 months when stored at 2-8°C (35-46°F) (avoid freezing) including up to 9 months at 2-25°C (35-77°C) or until expiration date is reached.
- EDAN i15 Hematocrit Controls – 24 months when stored at 2-25°C (35-77°C) or until expiration date is reached.

Value Assignment

- EDAN i15 Calibrant Fluid Pack
  Value assignment of the Calibrant Fluid Pack is performed by determination of measurement bias between the test lot and traceable reference standards or methods using reference instrumentation and three Calibrant Fluid Packs from the production batch. The bias for each measurand is applied to the value of the reference standard to determine the value assignment for the test lot.

Parameter	Target Value	Parameter	Target Value
pH	7.342	*p*O2 (mmHg)	154.0
*p*CO2 (mmHg)	41.3	Na^+ (mmol/L)	140.0
K^+ (mmol/L)	4.80	Ca^{++} (mmol/L)	1.22
Cl^- (mmol/L)	100	Hct (%PCV)	9.5%

NOTE: These values are for example only. Actual values for each parameter are programmed in the bar code of a Calibrant Fluid Pack and may vary with the lot number of a Calibrant Fluid Pack.

- EDAN i15 Blood Gas and Electrolyte Control
  Value assignment for each new lot of control solution is performed by parallel testing on existing and new lots to determine bias for each measurand. This bias is applied to the value assigned to the existing lot to determine acceptable values for the new lot. Control solution testing is integrated into final release testing for all i15 instruments to ensure consistent performance across Calibrant Fluid Pack and Test Cartridge Lots.

	Blood Gas and Electrolyte Control		
	Level 1	Level 2	Level 3
	Lot 41526	Lot 41625	Lot 41726
Parameter	Acceptable Range	Acceptable Range	Acceptable Range
pH	7.096 - 7.196	7.361 – 7.461	7.539 – 7.639
*p*CO2 (mmHg)	58.9 – 74.9	33.4 – 47.4	15.8 – 27.8
*p*O2 (mmHg)	59.7 – 89.7	91.5 – 125.5	126.1 – 170.1
Na^+ (mmol/L)	108.5 – 118.5	126.5 – 136.5	148.0 – 158.0
K^+ (mmol/L)	1.47 – 2.47	3.87 – 4.87	5.67 – 6.87
Ca^{++} (mmol/L)	1.32 – 1.72	1.01 – 1.31	0.47 – 0.67
Cl^- (mmol/L)	68.6 – 78.6	88.1 – 100.1	112.5 – 128.5

- EDAN i15 Hematocrit Control
  Value assignment for each new lot of control solution is performed by parallel testing on existing

and new lots to determine bias for each measurand. This bias is applied to the value assigned to the existing lot to determine acceptable values for the new lot. Control solution testing is integrated into final release testing for all i15 instruments to ensure consistent performance across Calibrant Fluid Pack and Test Cartridge Lots.

	Hematocrit Control	
	Low Level	High Level
	Lot 43933	Lot 43931
Parameter	Acceptable Range	Acceptable Range
Hct, PCV%	17 - 23	43 – 51

Conclusion

The information provided in this Premarket Notification [510(k)] supports a determination of substantial equivalence for the EDAN i15 Blood Gas and Chemistry Analysis System, including the EDAN i15 Blood Gas and Chemistry Analyzer, EDAN i15 Calibrator Fluid Pack, EDAN i15 Blood Gas and Electrolyte Control, and EDAN i15 Hematocrit Control.