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

A. 510(k) Number:

k151978

B. Purpose for Submission:

New Device

C. Measurand:

pH, pCO2, pO2, Hematocrit (Hct), Sodium (Na^+), Potassium (K^+), Chloride (Cl^-), and Calcium (Ca^{++})

D. Type of Test:

Potentiometric measurement: pH, PCO2, Na^+, K^+, Cl^-, and Ca^{++}

Amperometric measurement: PO2

Conductivity measurement: Hct

E. Applicant:

EDAN Instruments, Inc.

F. Proprietary and Established Names:

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

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CHL	II	862.1120, Blood Gases (pCO2, pO2) and Blood pH system	75-Chemistry
JGS	II	862.1665, Sodium Test System	75-Chemistry
CEM	II	862.1600, Potassium Test System	75-Chemistry
JFP	II	862.1145, Calcium Test System	75-Chemistry

Product Code	Classification	Regulation Section	Panel
CGZ	II	862.1170, Chloride Test System	75-Chemistry
GKF	II	864.5600, Automated hematocrit instrument	81-Hematology
JIX	II	862.1150, Calibrators	75-Chemistry
JJS	I, reserved	862.1660, Quality Control Materials	75-Chemistry
GLK	II	864.8625, Hematology Quality Control Mixture	81-Hematology

H. Intended Use:

1. Intended use(s):

   See Indication(s) for Use below

2. Indication(s) 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 (PCO2, PO2), 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, PCO2, PO2: 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, PO2, PCO2, 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 (PCO2, PO2), 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.

I. Device Description:

EDAN i15 Blood Gas and Chemistry Analysis System:
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 a panel of tests. The analyzer has a user interface module which contains the CPU and all the required electronic interfaces for external communication and data storage. The signals generated by the electrochemical sensors contained in the Test Cartridges are converted into concentration levels which are displayed on the screen of the analyzer, stored in memory, and can be transmitted by communication link or Wi-Fi to the Data Management System (DMS) or HIS/LIS. The analyzer includes a barcode scanner to scan bar codes of test cartridges, calibrant fluid packs, controls, patient and operator ID. The analyzer aspirates the sample directly from a syringe, or capillary fitted with an adaptor, and requires a minimum sample volume of 140 µL for analysis.

EDAN i15 Test Cartridge: single-use disposable cartridge into which the blood sample is introduced. The cartridge consists of fluid paths and electrochemical sensors for potentiometric measurement of pH, PCO2, Na^{+}, K^{+}, Cl^{-}, and Ca^{++}; amperometric measurement for PO2; and conductivity measurement for Hct. The cartridge is packaged into a sealed foil pouch which includes a bar-code label with calibration, lot identification and expiration dating information. The test cartridge is available in three versions with different test menus:

Cartridge Type	Measured Parameters
BG8	pH, PCO2, PO2, Na^+, K^+, Cl^-, Ca^{++}, Hct
BG3	pH, PCO2, PO2
BC4	Na^+, K^+, Cl^-, Ca^{++}, Hct

EDAN i15 Calibrant Fluid Pack

The Calibrant Fluid is contained in a replaceable cartridge and is comprised of a flexible pouch containing the calibrant standard with dissolved gases, assembled inside a rigid plastic case, with removable, protective cover. The EDAN i15 Calibrant Fluid Pack consist of one level of calibrator and is intended for the calibration of pH, pCO2, pO2, Na^+, K^+, Ca^{++}, Cl^-, and Hct as part of the EDAN i15 Blood Gas and Chemistry System. The typical target values assigned to the calibrant solutions are traceable to NIST standards and are shown in the table below:

Analyte Concentration of the EDAN i15 Calibrant Fluid Pack

Analyte	Unit of measure	Target Concentration
pH	pH units	7.342
pCO2	mmHg	41.3
pO2	mmHg	154.0
Na	mmol/L	140.0
K	mmol/L	4.80
Cl	mmol/L	100
iCa	mmol/L	1.22
Hct	%	9.5%

EDAN i15Blood Gas and Chemistry Controls

Three, single-level aqueous controls in sealed glass ampoules, packaged in 5- ampoule packages representing the normal, high, and low clinical ranges of each of the tests. Level 1: pH/Blood Gas representing respiratory acidosis with low pH and high PCO2 values and low range physiological values for PO2, Na^+, K^+, Cl^-, and elevated Ca^{++}. Level 2: Representing normal physiological values for all tests. Level3: pH/Blood Gas resenting respiratory alkalosis with elevated pH and low PCO2 values and elevated physiological values for PO2, Na^+, K^+, Cl^-, and decreased Ca^{++}.

EDAN i15 Blood Gas and Chemistry Controls

Analyte	Level 1 Target Value (Range)	Level 2 Target Value (Range)	Level 3 Target Value (Range)
pH (pH units)	7.156 (7.096-7.196)	7.411 (7.361-7.461)	7.589 (7.539-7.639)
PO2 (mmHg)	74.7 (59.7-89.7)	108.5 (91.5-125.5)	148.1 (126.1-170.1)
PCO2 (mmHg)	66.9 (58.9-74.9)	40.4 (33.4-47.4)	21.8 (15.8-27.8)
Na^+ (mmol/L)	113.5 (108.5-118.5)	131.5 (126.5-136.5)	153.6 (148-158)
K^+ (mmol/L)	1.97 (1.47-2.47)	4.37 (3.87-4.87)	6.27 (5.67-6.87)
Ca^{++} (mmol/L)	1.52 (1.32-1.72)	1.16 (1.01-1.31)	0.57 (0.47-0.67)
Cl^- (mmol/L)	73 (68.6-78.6)	94.1 (88.1-100.1)	120.5 (112.5-128.5)

EDAN i15 Hematocrit Controls
Two, single- level aqueous hematocrit controls in sealed glass ampoules representing high and low physiological range of hematocrit simulated by conductivity.

EDAN i15 Hematocrit Controls

Hct (%)	Target value	Range
Level 1	20	17-23
Level 2	47	43-51

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Siemens (Bayer) Rapidpoint 400 System, including calibrators
   RNA Medical QC823 Blood Gas, Electrolyte, Metabolite Control
   RNA Medical QC900 Hematocrit Control

2. Predicate 510(k) number(s):

   k002738
   k943754
   k955630

3. Comparison with predicate:

Analyzer

Similarities and Differences		
Item	Candidate Device EDAN i15 Blood Gas and Chemistry Analysis System	Predicate Device Siemens Rapidpoint 400 System (k002738)
Intended Use	For the measurement of pH and blood gases (PCO2, PO2), electrolytes (Na^+, K^+, Ca^{++}, Cl^-) ;and hematocrit in whole blood.	Same
Setting for use	Clinical laboratory and point of care settings	Same
Test Principle	pH and PCO2 and electrolytes: potentiometric PO2: Amperometric Hematocrit: conductivity	Same
Sample type	Heparinized whole blood	Same
Sample introduction	Syringe and capillary tube, by aspiration	Same
Sample volume	140 µL	100 µL
Measurement Range	pH: 6.500-7.800 pCO2: 10-150 mmHg PO2:10-700 mmHg Na^+: 100-180 mmol/L K^+: 2.0-9.0 mmol/L Cl^-: 65-140 mmol/L Ca^{++}: 0.25-2.50 mmol/L Hct: 13-72%	pH: 6.500-7.800 pCO2: 5.0-200.0 mmHg PO2: 10-700 mmHg Na^+: 100-200 mmol/L K^+: 0.5-15.0 mmol/L Cl-: 65-140 mmol/L Ca^{++}: 0.20-5.00 mmol/L Hct: 12-75%

Calibrator

Similarities and Differences		
Item	Candidate Device EDAN i15 Blood Gas and Chemistry Calibrant Fluid Pack	Predicate Device Siemens Rapidpoint 400 System (k002738)
Intended Use	For the calibration of pH and blood gases (PCO2, PO2), electrolytes (Na^+, K^+, Ca^{++}, Cl^-) ;and hematocrit on the blood gas and chemistry analyzer.	Same

Similarities and Differences		
Item	Candidate Device EDAN i15 Blood Gas and Chemistry Calibrant Fluid Pack	Predicate Device Siemens Rapidpoint 400 System (k002738)
Calibration level and packaging	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.	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.

Blood gas, pH, and electrolyte controls

Similarities and Differences		
Item	Candidate Device EDAN i15 Blood Gas and Chemistry Quality Control	Predicate Device RNA Medical QC823 Blood Gas, Electrolyte and Metabolite Quality Control (k943754)
Intended Use	Quality control material intended to monitor the measurement of pH and blood gases (PCO2, PO2), electrolytes (Na^+, K^+, Ca^{++}, Cl^-).	Same
Levels	Three	Same
Configuration	Packaged in sealed glass ampoules, each containing 2.5 mL of solution.	Same

Hematocrit controls

Similarities and Differences		
Item	Candidate Device EDAN i15 Blood Gas and Chemistry System Hematocrit Controls	Predicate Device RNA Medical Hematocrit Controls (k955630)
Intended Use	Quality control material intended to monitor the measurement of hematocrit by electrical conductivity.	Same
Levels	Three	Same
Configuration	Packaged in sealed glass ampoules, each containing 1.7 mL of solution.	Same

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

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP07-A2: Interference Testing in Clinical Testing; Approved Guideline-Second Edition

CLSI EP09-A3: Method Comparison and Bias Estimation Using Patient Samples-Approved Guideline-Second Edition

CLSI EP17-A2: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline-Second Edition

L. Test Principle:

Potentiometry is used to measure pH, PCO2 and electrolytes (Na^+, K^+, Ca^{++} and Cl^-) in the EDAN i15 System. Potentiometry is based on the measurement of the difference in electrical signal resulting from a chemical reaction between the analyte and an electrochemical sensor. The electrical signal generated by the reaction is proportional to the amount of analyte in the sample.

Amperometry is used to measure PO2 in the EDAN i15 System. PO2 is measured by applying a fixed voltage to an electrode and then measuring the current resulting in the reaction. The current is proportional to the amount of the analyte in the sample.

Conductance is used to measure hematocrit in the EDAN i15 System. Conductance is the ease with which a conducting substance transmits an electrical current. The conductance is inversely proportional to the concentration of hematocrit in the sample.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   i.) A within run and total precision study was conducted in-house by with the 3 levels of EDAN i15 blood gas and chemistry control materials by testing two samples per day in 2 runs per day for 20 days on one EDAN i15 Blood Gas and Electrolyte analyzer (n=80). Results are summarized below:

		Within-Run		Total	
Analyte	Mean (n=80)	SD	CV%	SD	CV%
pH (pH units)	7.153	0.012	0.17	0.012	0.17
	7.410	0.013	0.18	0.013	0.18
	7.598	0.008	0.11	0.009	0.12
PCO2 (mmHg)	62.8	2.11	3.36	2.40	3.82
	38.8	2.11	5.45	2.33	6.02
	20.5	0.80	3.91	0.85	4.13
pO2 (mmHg)	71.4	2.67	3.73	2.68	3.75
	106.2	1.84	1.73	2.50	2.35
	149.2	2.59	1.74	3.33	2.23
Na+ (mmol/L)	111.8	1.29	1.15	1.32	1.18
	133.0	0.95	0.71	1.14	0.86
	158.5	1.51	0.95	1.44	0.91
K+ (mmol/L)	1.91	0.040	2.11	0.040	2.07
	4.34	0.047	1.09	0.052	1.20
	6.34	0.073	1.16	0.065	1.02
Cl- (mmol/L)	75.9	0.91	1.20	0.93	1.22
	92.3	1.07	1.16	1.08	1.17
	121.7	0.66	0.54	0.69	0.57
Ca++ (mmol/L)	1.37	0.04	3.09	0.05	3.47
	1.23	0.02	1.54	0.03	2.42
	0.61	0.02	3.10	0.02	3.66
Hct (%)	19.2	0.57	2.97	0.73	3.82
	46.8	0.58	1.24	0.54	1.16

ii.) A precision study was performed with the intended POC operators following CLSI EP5-A3. The precision study took place at four point-of-care (POC) locations comprised of a respiratory medical unit, two intensive care units, and an anesthesia unit. Testing was performed by 11 POC operators (2 or 3 operators per site). Within-run and total precision were performed using 3 levels of blood gas/electrolyte control material as well as 3 levels of hematocrit control material. Four EDAN i15 analyzers and 4 number of cartridge lots (one analyzer and one lot per site). The duration of testing varied between 4 and 14 days among the sites. Each of the control materials were run twice a day at each site. Each site produced similar precision results. Results of precision studies from a representative site (POC site 1) are shown below:

pH Precision			Within-Run		Total	
Sample	N	Mean (pH units)	SD	CV%	SD	CV%
Level 1	24	7.139	0.007	0.097	0.007	0.104
Level 2	24	7.399	0.006	0.081	0.005	0.072
Level 3	24	7.584	0.007	0.089	0.006	0.073
PCO2 Precision			Within-Run		Total	
Sample	N	Mean (mmHg)	SD	CV%	SD	CV%
Level 1	24	72.1	2.84	3.94	3.04	4.21
Level 2	24	43.3	1.22	2.82	1.48	3.42
Level 3	24	24.0	0.44	1.85	0.62	2.57
PO2 Precision			Within-Run		Total	
Sample	N	Mean (mmHg)	SD	CV%	SD	CV%
Level 1	24	69.9	1.83	2.62	2.32	3.32
Level 2	24	105.6	1.83	1.73	1.69	1.60
Level 3	24	148.5	2.17	1.46	1.97	1.33
Na^+ Precision			Within-Run		Total	
Sample	N	Mean (mmol/L)	SD	CV%	SD	CV%
Level 1	24	121.1	1.17	0.97	1.11	0.92
Level 2	24	142.5	0.89	0.62	1.23	0.86
Level 3	24	166.1	1.71	1.03	1.49	0.90
K^+ Precision			Within-Run		Total	
Sample	N	Mean (mmol/L)	SD	CV%	SD	CV%
Level 1	24	2.10	0.000	0.000	0.000	0.000
Level 2	24	4.59	0.029	0.629	0.028	0.614
Level 3	24	6.79	0.054	0.796	0.054	0.790
Cl^- Precision			Within-Run		Total	
Sample	N	Mean (mmol/L)	SD	CV%	SD	CV%
Level 1	24	78.3	0.65	0.82	0.64	0.81
Level 2	24	99.3	0.41	0.41	0.57	0.57
Level 3	24	127.6	0.58	0.45	0.72	0.57
Ca^{++} Precision			Within-Run		Total	
Sample	N	Mean (mmol/L)	SD	CV%	SD	CV%
Level 1	24	1.448	0.065	4.49	0.063	4.38
Level 2	24	1.108	0.022	2.02	0.027	2.47
Level 3	24	0.56	0.013	2.93	0.016	3.55
Hct Precision			Within-Run		Total	
Sample	N	Mean (%)	SD	CV%	SD	CV%
Level 1	24	21.5	0.29	1.34	0.52	2.41
Level 2	24	34.0	0.00	0.00	0.00	0.00
Level 3	24	47.0	0.00	0.00	0.00	0.00

The combined-site total imprecision results from all 4POC sites are summarized in the table below

The combined-site total imprecision from all 4 POC sites are summarized in the tables below:

Combined POC Sites Precision Level 1 Control

Analyte	N	Mean	Total SD	Total CV%
pH (pH units)	80	7.135	0.007	0.10
PCO2 (mmHg)	80	73.2	2.56	3.5
PO2 (mmHg)	80	70.9	2.3	3.2
Na^+(mmol/L)	80	121.3	0.99	0.8
K^+ (mmol/L)	80	2.23	0.03	1.3
Ca^{++}(mmol/L)	80	1.46	0.07	4.5
Cl^-(mmol/L)	80	78.1	0.8	1.0
Hct (%)	80	21.0	0.7	3.2

Combined POC Sites Precision Level 2 Control

Analyte	N	Mean	Total SD	Total CV%
pH (pH units)	80	7.399	0.006	0.08
PCO2 (mmHg)	80	43.1	1.66	3.9
PO2 (mmHg)	80	104.8	2.13	2.0
Na^+(mmol/L)	80	143.1	1.0	0.7
K^+ (mmol/L)	80	4.63	0.05	1.0
Ca^{++}(mmol/L)	80	1.10	0.04	3.3
Cl^-(mmol/L)	80	99.9	0.6	0.6
Hct (%)	80	33.7	0.3	0.9

Combined POC Sites Precision Level 3 Control

	N	Mean	Total SD	Total CV%
Analyte	80	7.583	0.006	0.08
PCO2 (mmHg)	80	24.7	0.9	3.6
PO2 (mmHg)	80	146.3	2.1	1.4
Na^+(mmol/L)	80	166.0	1.4	0.9
K^+ (mmol/L)	80	6.84	0.06	0.8
Ca^{++}(mmol/L)	80	0.48	0.02	3.7
Cl^-(mmol/L)	80	126.6	1.0	0.8
Hct (%)	80	47.0	0.22	0.5

iii.) 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 from the six

levels of whole blood tested from both syringe and capillary tube is presented in the table below.

Venous whole blood with-in run precision studies for Hct

	Syringe			Capillary Tube		
Hct Level	Mean (%) (n=30)	SD	%CV	Mean (%) (n=30)	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	0.7	1.3
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

iv. 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 with-in run precision studies

N=30	Syringe values			Capillary Tube values		
Parameter	Mean	SD	%CV	Mean	SD	%CV
pH	7.325	0.015	0.20	7.322	0.016	0.21
PCO2 (mm/Hg)	44.3	1.1	2.6	43.7	1.2	3.8
PO2 (mm/Hg)	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

b. Linearity/assay reportable range:

A linearity study was performed based on CLSI EP6 guidance for each analyte using lithium heparinized venous whole blood with sampling from a syringe and from a capillary tube. Samples aspirated into the instrument from a syringe or from a capillary tube require the same volume of blood (140 µL), travel through the same aspiration port and tubing, and are measured exactly the same by the analyzer. The only difference is the sample tube type and the manner in which the samples are collected. For each parameter, 7 levels were prepared by tonometry to achieve

expected concentrations and by spiking or diluting the samples to span the claimed measuring range. The target values were based on results from a reference measurement procedure; Radiometer ABL 800 (pH), microhematocrit centrifuge (HCT). Samples were tested in a single run in replicates of 3 on a single analyzer. The linearity results are summarized in the table below:

Linearity results from Lithium-heparinized whole blood samples from a syringe

Analyte	Slope	Intercept	r	Range tested
pH (pH units)	0.9842	0.11	0.9996	6.455-7.944
PO2 (mmHg)	0.9969	-6.16	0.9993	6-716
PCO2 (mmHg)	0.9533	0.62	0.9969	3-149
Na^+ (mmol/L)	0.9923	-1.38	0.9983	94-185
K^+ (mmol/L)	0.9886	0.08	0.9997	1.7-10.2
Cl^- (mmol/L)	1.0028	-1.59	0.9993	58-176
Ca^{++} (mmol/L)	0.9848	-0.05	0.9981	0.23-2.94
Hct (%)	0.9687	1.54	0.9981	3-77

Linearity results from Lithium-heparinized, whole blood samples from a capillary tube

Analyte	Slope	Intercept	r	Range tested
pH (pH units)	1.0039	-0.03	0.9995	6.464-8.00
PO2 (mmHg)	1.0174	-5.40	0.9997	7-717
PCO2 (mmHg)	0.9999	-0.06	0.9992	2-150
Na^+ (mmol/L)	1.0059	-3.06	0.9986	94-185
K^+ (mmol/L)	1.0013	-0.01	0.9998	1.9-10.0
Cl^- (mmol/L)	0.9965	-1.59	0.9992	59-175
Ca^{++} (mmol/L)	0.9771	-0.06	0.9968	0.24-2.97
Hct (%)	0.9623	1.51	0.9984	4-76

The results of the linearity study support the sponsor's claimed measuring ranges below:

pH: 6.500- 7.800
PO2: 10-700 mmHg
PCO2: 10-150 mmHg
Na^+: 100-180 mmol/L
K^+: 2-9 mmol/L
Cl^- : 65-140 mmol/L
Ca^{++}: 0.25-2.50 mmol/L
Hct: 13-72 %

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability: The traceability of the EDAN i15 Blood Gas and Chemistry Calibrant Fluid Pack are listed in the chart below:

Traceability EDAN i15 Blood Gas and Chemistry Calibrant Cartridge

Analyte	Traceability
pH	NIST HEPES SRM 2181 and 2182
PO2	NIST traceable pure gases prepared gravimetrically
PCO2	NIST traceable pure gases prepared gravimetrically
Na^+	NIST SRM 919b Sodium Chloride
K^+	NIST SRM 918b Potassium Chloride
Ca^{++}	NIST SRM 915b Calcium Carbonate
Cl^-	NIST SRM 919b Sodium Chloride
Hct	No standard reference material available. Values based on micro hematocrit centrifuge method according to CLSI H7-A3, Procedure for Determining Packed Cell Volume by the Microhematocrit Method

Value Assignment:

EDAN i15 Calibrant Fluid Pack is value assigned by testing at least 20 replicates pre analyte/per level on the EDAN i15 Blood Gas and Chemistry Analysis System and comparing the results to those obtained on the reference methods (Rapidpoint 400 and ABL 800). The analyte concentrations of the EDAN i15 calibrant fluid must meet internal specifications for acceptable bias as compared to the reference methods. The typical target values assigned to the calibrant solutions are traceable to NIST standards and are shown in the table below:

EDAN i15 Calibrant Fluid Pack Target Values

Analyte	Unit of measure	Target Concentration
pH	pH units	7.342
pCO2	mmHg	41.3
pO2	mmHg	154.0
Na^+	mmol/L	140.0
K^+	mmol/L	4.80
Cl^-	mmol/L	100
iCa^{++}	mmol/L	1.22
Hct	%	9.5%

EDAN i15 Blood Gas and Electrolyte Controls and EDAN i15 Hematocrit Controls are value assigned by testing 60 replicates per analyte/ per level on the EDAN i15 Blood Gas and Chemistry Analysis System after verification of correct measurement on traceable standard methods. The following represents an example of target values and ranges for the EDAN i15 Blood Gas and Electrolyte Control and EDAN i15 Hematocrit Controls:

EDAN i15 Blood Gas and Electrolyte Control

Level 1

Analyte	Target value	Range
pH (pH units)	7.156	7.096-7.196
PO2 (mmHg)	74.7	59.7-89.7
PCO2 (mmHg)	66.9	58.9-74.9
Na^+ (mmol/L)	113.5	108.5-118.5
K^+ (mmol/L)	1.97	1.47-2.47
Ca^{++} (mmol/L)	1.52	1.32-1.72
Cl^- (mmol/L)	73	68.6-78.6

Level 2

Analyte	Target value	Range
pH (pH units)	7.411	7.361-7.461
PO2 (mmHg)	108.5	91.5-125.5
PCO2 (mmHg)	40.4	33.4-47.4
Na^+ (mmol/L)	131.5	126.5-136.5
K^+ (mmol/L)	4.37	3.87-4.87
Ca^{++} (mmol/L)	1.16	1.01-1.31
Cl^- (mmol/L)	94.1	88.1-100.1

Level 3

Analyte	Target value	Range
pH (pH units)	7.589	7.539-7.639
PO2 (mmHg)	148.1	126.1-170.1
PCO2 (mmHg)	21.8	15.8-27.8
Na^+ (mmol/L)	153.0	148-158
K^+ (mmol/L)	6.27	5.67-6.87
Ca^{++} (mmol/L)	0.57	0.47-0.67
Cl^- (mmol/L)	120.5	112.5-128.5

EDAN i15 Hematocrit Control

Hct (%)	Target value	Range
Level 1	20	17-23
Level 2	47	43-51

Stability:

The stability studies performed to support the stability claims of the EDAN i15 Blood Gas and Electrolyte Control and EDAN i15 Hematocrit Control were reviewed and the study protocol and acceptance criteria were found to be acceptable. Stability studies support EDAN's shelf life claim of 36 months when stored at 2-8^{o} C for the blood gas and electrolyte controls; and for the hematocrit controls, a 24 month shelf life when stored at 2-25^{o} C.

EDAN i15 Calibrant Fluid Pack: Real time stability studies support the sponsor's shelf life claim of 12 months when stored at 2-8^{o} C and in-use life of 30 days after installation in the analyzer. The stability study protocol and acceptance criteria were found to be acceptable.

d. Detection limit:

Refer to the linearity study above in M.2.b for the measuring range claim for all analytes except ionized calcium, for which detection limit studies were performed and are described below.

Detection limit studies were performed on the ionized calcium analyte to determine the limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ). The detection limit studies were performed according to CLSI EP17-A guidelines.

Limit of blank: Five venous whole blood samples depleted of ionized calcium were tested in replicates of 12 on two i15 systems separately to obtain a total of 60 results. Each of the two analyzers used a different lot of reagent and calibrant fluid packs. LoB was calculated using the following equation: LoB=μB +1.645ϭB. Using the highest LoB value of the two analyzers, the LoB was determined to be 0.09 mmol/L.

Limit of detection: The limit of detection was determined by testing 5 venous whole blood samples with low level calcium levels (~4 times LoB) using 2 sets of i15 systems with different lots of test cartridges and calibrant fluid over a period of 3 days for a total of 60 results. Using the following equation: LoD= μB +1.645ϭB + 1.645ϭB. The LoD was determined to be 0.11 mmol/L.

Limit of quantitation: The limit of quantitation was determined by analyzing the 60 results from the LoD study using 4 low samples. The sponsor determined that the LoQ is 0.11 mmol/L.

Ionized Calcium detection limits results:

Limit of Blank	Limit of Detection	Limit of Quantitation
0.09 mmol/L	0.11 mmol/L	0.11 mmol/L

The measuring range of Ca^{++} is 0.25-2.50 mmol/L.

e. Analytical specificity:

An interference study was performed in accordance with CLSI EP7-A2. Heparinized human venous whole blood samples containing low and high concentrations (see chart below) of each analyte were spiked with one or two levels of each potential interfering substance.

Concentrations of analytes tested

Analyte	Low test concentration	High test concentration
pH	7.300	7.500
PCO2 (mmHg)	40	70
PO2 (mmHg)	70	100
Na^+ (mmol/L)	130	150
K^+ (mmol/L)	3.0	5.0
Ca^{++} (mmol/L)	1.0	2.0
Cl^- (mmol/L)	90	110
Hct (%)	35	55

Seven replicates of both the spiked sample and the unspiked sample were tested on two i15 Blood Gas and Chemistry Systems with one lot of test cartridges. The samples containing interferent were evaluated against the same whole blood sample without the interferent. Significant interference is presented as absolute bias for pH and as percent bias for all other analytes and the sponsor's acceptance criteria for defining non-significant interference are provided below:

Measurand	Evaluation method	Definition of non-significant interference
pH	Absolute difference	< 0.02 pH units
pCO2	Percent bias	< 8%
pO2	Percent bias	< 9%
Na^+	Percent bias	< 3%
K^+	Percent bias	< 10%
Ca^{++}	Percent bias	< 10%
Cl^-	Percent bias	< 5%
Hct	Percent bias	< 6%

The table below indicates which analytes were tested with each potentially interfering substance:

Substance	Test Concentration(s)	Analyte(s) tested	Analytes not tested
Acetaminophen	20.0 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Acetylsalicylic acid	39 mg/dL 65mg/dL	PCO2, PO2, Na^+, Ca^{++}, Cl^-, Hct	pH
Albumin	+1.5 g/dl (total albumin approximately 6.5 g/dL) +3.0 g/dL (total albumin approximately 8.0 g/dL)	Na^+, K^+, Ca^{++}, Cl^-, Hct	pH, PCO2, PO2
Ascorbic acid	6.0 mg/dL	PCO2, PO2, Na^+, K^+, Cl^-, Hct	pH
Benzylkonium Chloride	0.80 mg/dL	Na^+, K^+, Ca^{++}, Cl^-, Hct	pH, PCO2, PO2
Bilirubin	15 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Sodium Bromide	185 mg/dL	pH, PCO2, PO2, K^+, Ca^{++}, Hct	Na^+
Bicarbonate (NaHCO3)	58.8 mg/dL 294 mg/dL	PCO2, PO2, K^+, Ca^{++}, Hct	pH, Na^+
Calcium Chloride	27.8 mg/dL 55.5 mg/dL	pH, PCO2, PO2, Na^+. K^+, Hct	Cl^-, Ca^{++}
Cholesterol	250 mg/dL 500 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Cysteine	12 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Dextran	3 g/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-	none
Dobutamine hydrochloride	22 mg/dL	Na^+, K^+, Ca^{++}, Cl^-, Hct	pH, PCO2, PO2
Ethanol	400 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Holothane	14.95 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none

Substance	Test Concentration(s)	Analyte(s) tested	Analytes not tested
Hydroxbutyrate	104 mg/dL 208 mg/dL	PCO2, PO2, Na^+, Ca^{++}, Cl^-, Hct	pH
Hydroxyurea	183 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Hematocrit	10%PCV 20% PCV	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-	Hct
Hemolysis	100 mg/dL 500mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Heparin	11.8 mg/dL 58.8 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Ibuprofen	50 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Iodine	38 mg/dL	pH, PO2, PO2,Na^+, K+, Cl-,Ca^{++}, Hct	none
Lactic acid	59 mg/dL 90 mg/dL	PCO2, PO2, Na^+, Ca^{++}, Cl^-, Hct	pH
Lithium	2.22 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
Magnesium Chloride	47.6 mg/dL	Na^+, K,$^+$ Ca^{++}, Cl^-, Hct	pH, PCO2, PO2
Ofloxacin	6 µg/L	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	none
PCO2	60 mm/Hg PCO2	PO2, Na^+, K^+, Ca^{++} Cl-, Hct	pH, PCO2
Phosphate	24mg/dL 48 mg/mL	PCO2, PO2, K^+, Ca^{++}, Hct	pH, Na^+
Potassium Chloride	60 mg/dL	pH, PCO2, PO2, Na^+, Ca^{++}, Hct	K^+, Cl^-
Potassium thiocynate	20 mg/dL	Na^+, Ca^{++}, Cl^-, Hct	pH, PCO2, PO2, K^+
Salicylic Acid	30 mg/dL 60 mg/dL	PCO2, PO2, Na^+, Cl^-,Ca^{++},Hct	pH
Sodium Chloride	117 mg/dL	pH, PCO2, PO2, K^+, Ca^{++}, Hct	Na^+, Cl^-

Substance	Test Concentration(s)	Analyte(s) tested	Analytes not tested
Sodium Oxalate	168 mg/dL	pH, PCO2, PO2, K^+, Cl^-,Ca^{++}, Hct	Na^+
Triglyceride	1500 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct	None
Triglyceride	358 mg/dL	Na^+, Ca^{++}, Cl^-, Hct	pH, PCO2, PO2, K^+
WBC	$50x10^9$ /L	Hct	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-,

The following table indicates the lowest concentration of substance tested that resulted in significant interference on the results of either one or both levels of analyte. An asterisk in the result column indicates that the result was not significantly affected by the concentration of substance tested.

Measurand	Interfering Substance	Concentration of substance tested	Blood Sample Value	Absolute Difference in pH Units
pH	Acetaminophen	20.01 mg/dL	pH: 7.5	-0.034
			pH: 7.3	*
	Bromide	185.20 mg/dL	pH: 7.5	-0.027
			pH: 7.3	*
	Calcium Chloride	27.27 mg/dL	pH: 7.5	*
			pH: 7.3	-0.024
	Ethanol	400 mg/dL	pH: 7.5	-0.024
			pH: 7.3	*
	Hematocrit	20%	pH: 7.5	-0.022
			pH: 7.3	*
	Hemoglobin	500 mg/dL	pH: 7.5	0.029
			pH: 7.3	0.036
	Heparin	58.82 mg/dL	pH: 7.5	*
			pH: 7.3	-0.034
	Hydroxycarbamide (Hydroxyurea)	182.52 mg/dL	pH: 7.5	*
			pH: 7.3	-0.031
	Iodide	37.94 mg/dL	pH: 7.5	*
			pH: 7.3	-0.025
	Potassium Chloride	59.64 mg/dL	pH: 7.5	-0.036
			pH: 7.3	*

	Sodium Chloride	117 mg/dL	pH: 7.5	-0.024
			pH: 7.3	-0.021
	Sodium Oxalate	168 mg/dL	pH: 7.5	*
			pH: 7.3	-0.032
Measurand	Interfering Substance	Concentration of Substance Tested	Blood Sample Value	Percent Bias
PCO_2	Acetaminophen	20.01 mg/dL	PCO_2: 70 mmHg	10.15%
			PCO_2: 40 mmHg	*
	Acetylsalicylic acid	39.09 mg/dL	PCO_2: 70 mmHg	8.01%
			PCO_2: 40 mmHg	*
	Ethanol	400 mg/dL	PCO_2: 70 mmHg	9.54%
			PCO_2: 40 mmHg	*
	Hydroxybutyrate	104 mg/dL	PCO_2: 70 mmHg	8.49%
			PCO_2: 40 mmHg	*
	Iodide	37.94 mg/dL	PCO_2: 70 mmHg	-10.00%
			PCO_2: 40 mmHg	-8.69%
	Lactic Acid	59.40 mg/dL	PCO_2: 70 mmHg	8.67%
			PCO_2: 40 mmHg	*
	Potassium Chloride	59.64 mg/dL	PCO_2: 70 mmHg	11.15%
			PCO_2: 40 mmHg	*
	Bicarbonate ($NaHCO3$)	294 mg/dL	PCO_2: 70 mmHg	-14.46%
			PCO_2: 40 mmHg	-17.44%
Measurand	Interfering Substance	Concentration of Substance Tested	Blood Sample Value	Percent Bias
PO_2	Acetylsalicylic acid	39.09 mg/dL	PO2: 100 mg/dL	*
			PO2: 70 mg/dL	-10.11%
	Hematocrit	20% PCV	PO2: 100 mg/dL	*
			PO2: 70 mg/dL	12.13%
	Lactic Acid	90 mg/dL	PO2: 100 mg/dL	*
			PO2: 70 mg/dL	9.74%
	PCO2	60 mmHg	PO2: 100 mg/dL	*
			PO2: 70 mg/dL	9.60%
	Salicylic acid	59.94 mg/dL	PO2: 100 mg/dL	*
			PO2: 70 mg/dL	14.98%
	Sodium Chloride	117 mg/dL	PO2: 100 mg/dL	*
			PO2: 70 mg/dL	9.22%

Measurand	Interfering Substance	Concentration of Substance Tested	Blood Sample Value	Percent Bias
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	*
			Na^+: 130 mmol/L	5.62%
Measurand	Interfering Substance	Concentration of Substance Tested	Blood Sample Value	Percent Bias
K^+	Acetylsalicylic acid	65.22 mg/dL	K^+: 5 mmol/L	17.21%
			K^+: 3 mmol/L	*
	Dobutamine hydrochloride	22.30 mg/dL	K^+: 5 mmol/L	*
			K^+: 3 mmol/L	13.97%
	Hemoglobin	100 mg/dL	K^+: 5 mmol/L	30.10%
			K^+: 3 mmol/L	28.16%
	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	*
			K^+: 3 mmol/L	24.20%
	Lactic Acid	90 mg/dL	K^+: 5 mmol/L	13.05%
			K^+: 3 mmol/L	*
	PCO2	60 mmHg	K^+: 5 mmol/L	10.13%
			K^+: 3 mmol/L	*
	Salicylic acid	29.97 mg/dL	K^+: 5 mmol/L	10.54%
			K^+: 3 mmol/L	*
	Bicarbonate (NaHCO3)	294 mg/dL	K^+: 5 mmol/L	21.51%
			K^+: 3 mmol/L	10.31%

Measurand	Interfering Substance	Concentration of Substance Tested	Blood Sample Value	Percent Bias
iCa^{++}	Halothane	14.98 mg/dL	Ca^{++}: 2 mmol/L	*
			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 (NaHCO3)	294 mg/dL	Ca^{++}: 2 mmol/L	-27.07%
			Ca^{++}: 1 mmol/L	-21.17%
	Phosphate (NaH2PO4)	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%
Measurand	Interfering Substance	Concentration of Substance Tested	Blood Sample Value	Percent Bias
Cl^-	Acetylsalicylic acid	39.09 mg/dL	Cl^-: 110 mmol/L	7.72%
			Cl^-: 90 mmol/L	5.11%
	Albumin	+3 g/dL (added to whole blood sample for a total albumin concentration of approx. 8.0 g/dL)	Cl^-: 110 mmol/L	5.13%
			Cl^-: 90 mmol/L	7.19%
	Bromide (NaBr)	185.20 mg/dL	Cl^-: 110 mmol/L	*
			Cl^-: 90 mmol/L	6.38%
	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 (NaHCO3)	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%
Measurand	Interfering Substance	Concentration of Substance Tested	Blood Sample Value	Percent Bias
Hct	Albumin	+3 g/dL (added to whole blood sample for a total albumin concentration of approx. 8.0 g/dL)	Hct: 55%	* 10.29%
			Hct: 35%	6.03%
	Bromide (NaBr)	185.20 mg/dL	Hct: 55%	* 13.65%
			Hct: 35%	-6.98%
	Calcium Chloride	55.50 mg/dL	Hct: 55%	-6.11%
			Hct: 35%	*
	Dextran	3 g/dL	Hct: 55%	*
			Hct: 35%	10.24%.
	Dobutamine hydrochloride	22.30 mg/dL	Hct: 55%	*
			Hct: 35%	7.76%
	Ethanol	400 mg/dL	Hct: 55%	*
			Hct: 35%	-6.61%
	Magnesium Chloride	47.61 mg/dL	Hct: 55%	-6.40%
			Hct: 35%	-9.39%
	Potassium Chloride	59.64 mg/dL	Hct: 55%	-6.27%
			Hct: 35%	*
	Sodium Chloride	117 mg/dL	Hct: 55%	*
			Hct: 35%	-6.36%
	Bicarbonate (NaHCO3)	58.8 mg/dL	Hct: 55%	*
			Hct: 35%	-7.72%

*indicates that no significant interference was observed at the concentration of substance tested.

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

Interfering substance	Highest concentration tested that did not demonstrate significant interference	Analytes tested
Albumin	+ 1.5 g/dL (for a total albumin concentration of approx. 6.5 g/dL)	Na^+, K^+, Ca^{++}, Cl^-, Hct
Ascorbic acid	6.02 mg/dL	PCO2, PO2, Na+, K+, Ca++, Cl-, Hct
Benzylkonium Chloride	0.80 mg/dL	Na^+, K^+, Ca^{++}, Cl^-, Hct
Bilirubin	15 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Cysteine	12.12 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Lithium	2.24 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Ofloxacin	6 ug/mL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Glyceryl tridodecanoate	358 mg/dL	Na^+, K^+, Ca^{++}, Cl^-, Hct
Hydroxycarbamide	182.52 mg/dL	PCO2, PO2, Na+, K+, Ca++, Cl-, Hct
Cholesterol	500 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct
Triglycerides	1500 mg/dL	pH, PCO2, PO2, Na^+, K^+, Ca^{++}, Cl^-, Hct

The sponsor included the following limitation in the labeling regarding interference of hemolysis on the potassium results:
"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 in 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%."

Interference of Elevated WBC count on Hematocrit:

The sponsor performed a study to evaluate the effects of an elevated WBC count on the devices hematocrit measurement. Whole blood collected from a single healthy adult volunteer in lithium heparin, was processed to obtain an elevated WBC count as determined by analysis on Siemens XP-300 by centrifuging to allow collection of WBC and platelets. This WBC concentrate was added to otherwise untreated, heparinized whole blood to achieve a bias between the treated and untreated whole blood of approximately 50,000 WBC cu/mm. The study demonstrated that the

addition of 50,000 WBC cu/mL results in an increase in HCT %PCV measured by the EDAN i15 relative to spun hematocrit %PCV by 4.43% PCV (absolute) or 11% (relative).

The sponsor included the following limitation in the labeling:

"NOTE:
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%PVC (absolute) (4.02 to 4.84%PCV) or 11% (relative) exceeding the Total Allowable Error defined in CLIA'88."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study was performed at 4 point-of-care (POC) sites by 11 POC personnel, and three clinical laboratory sites to compare the results obtained from the candidate device to those obtained with the predicate device, Siemens Rapidpoint 400 Systems. At least 50 patient samples were selected from venous whole blood and arterial whole blood left over from clinical analysis were tested at each of the 4 POC sites. In order to cover the claimed measuring range, 8% of the specimens were altered. Calcium balanced heparin was used as the anticoagulant in the arterial whole blood samples and lithium heparin was used in the whole blood venous samples. The tables below shows the data from the 4 POC sites, the three clinical lab sites, and the combined POC and clinical lab data.

EDAN i15 vs Siemens Rapidpoint 400 Method Comparison Data

Analyte	Site	N	Range	Slope	Intercept	r-value
pH	POC 1-4	257	6.826 - 7.675	1.0130	-0.0961	0.9909
	all Lab	228	6.531 - 7.791	1.0085	-0.640	0.9940
	all Sites	488	6.531 - 7.791	1.0105	-0.0778	0.9933
PCO2 (mmHg)	POC 1-4	257	18.0 - 144.8	1.0285	-1.5528	0.9841
	all Lab	226	10.9 - 144.9	0.9523	1.0417	0.9916
	all Sites	483	10.9 - 144.9	0.9843	0.1813	0.9879

Analyte	Site	N	Range	Slope	Intercept	r-value
PO2 (mmHg)	POC 1-4 all Lab all Sites	257 229 486	17 - 585 10 - 661 10 - 661	1.0368 1.0018 1.0119	-4.1355 0.2151 -1.0639	0.9974 0.9989 0.9983
Na^+ (mmol/L)	POC 1-4 all Lab all Sites	257 229 486	110 - 170 101 - 180 101 - 180	0.9787 0.9909 0.9886	2.5631 0.8032 1.1358	0.9802 0.9952 0.9923
K^+ (mmol/L)	POC 1-4 all Lab all Sites	257 230 487	2.4 - 9.0 2.6 - 8.2 2.4 - 9.0	0.9838 0.9868 0.9895	0.0250 0.0450 0.0164	0.9968 0.9963 0.9968
Cl^- (mmol/L)	POC 1-4 all Lab all Sites	257 227 484	77 - 137 66 - 139 66 - 139	1.0188 1.0000 1.0012	-2.2648 0.2599 -0.1469	0.9821 0.9899 0.9875
Ca^{++} (mmol/L)	POC 1-4 all Lab all Sites	257 228 485	0.47 - 1.82 0.30 - 2.42 0.30 - 2.42	0.9568 0.9919 0.9848	0.0428 0.0228 0.0200	0.9695 0.9921 0.9854
Hct (%)	POC 1-4 all Lab all Sites	257 230 487	21 - 60 13 - 72 13 - 72	0.9853 0.9842 0.9827	0.8173 0.6787 0.8306	0.9891 0.9933 0.9917

b. Matrix comparison:

Not applicable. For use with heparinized whole blood only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

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:

The reference range values included in the labeling are cited from literature and are shown in the table below.

Parameter	Reference Range			
	Arterial		Venous	
pH	7.35 - 7.45[1]		7.31 – 7.41[1]	
*p*O2(mmHg)	80 - 105[1]		35 – 40[1]	
*p*CO2(mmHg)	35 - 45[1]		41 – 51[1]	
Na^+(mmol/L)	138 - 146[1]		138 - 146[1]	
K^+(mmol/L)	3.5 - 4.9[1]		3.5 – 4.9[1]	
Cl^-(mmol/L)	98 - 109[1]		98 - 109[1]	
Ca^{++}(mmol/L)	1.12 - 1.32[1]		1.12 – 1.32[1]	
Parameter	Reference Range			
	Male	Female	Male	Female
Hct (%)	41- 53[2]	36 - 46[2]	41- 53[2]	36 - 46[2]

References:

1. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.
2. Reference Ranges Table in Laboratory Medicine: the selection and interpretation of clinical laboratory studies, D.A. Noe and R.C. Rock, eds., William & Wilkins, Baltimore, 1994, pg. 878.

N. Instrument Name:

EDAN i15 Blood Gas and Chemistry Analyzer

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ___X___ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes __ X_____ or No __ _

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __X_____ or No _____

3. Specimen Identification:

   Bar code

4. Specimen Sampling and Handling:

   Lithium heparinized and calcium balanced heparinized whole blood from syringes and capillary tubes.

5. Calibration:

   Each lot of EDAN i15 Test Cartridge is calibrated during the manufacturing process, and bar coded with relevant calibration information as well as product identification, lot number and expiration date. Prior to running a sample, the cartridge's bar code is read into the analyzer by scanning the cartridge bar code label. Once inserted into the analyzer, a calibration of all electrochemical sensors is performed using the precision buffer solution contained in the EDAN i15 Calibrator Fluid Pack. During the calibration and measurement processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cartridge. These tests include automatic checks of the cartridge for packaging integrity, proper cartridge temperature control, and proper equilibration behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample during aspiration.

6. Quality Control:

   EDAN i15 Blood Gas and Electrolyte Control: an ampouled, three level aqueous quality control solutions.

   EDAN i15 Hematocrit control: Two, single- level aqueous hematocrit controls in sealed glass ampoules representing high and low physiological range of hematocrit simulated by conductivity.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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