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

A. 510(k) Number:
k051804

B. Purpose for Submission:
New device and instrument

C. Measurand:
pH, pO_2, pCO_2, Potassium (cK^+), Sodium (cNa^+), Calcium (cCa^{2+}), Chloride (cCl^-), Hematocrit (Hct), Glucose (cGlu)

D. Type of Test:
Potentiometry: pH, pCO_2 and electrolytes.
Amperometry: pO_2 and Glucose.
Conductivity: hematocrit and air-in-sample detection

E. Applicant:
SenDX Medical, Inc.

F. Proprietary and Established Names:
ABL80 FLEX

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1120 Blood gases and blood pH test system
   21 CFR 862.1600 Potassium test system
   21 CFR 862.1145 Calcium test system
   21 CFR 862.1665 Sodium test system
   21 CFR 862.1170 Chloride test system
   21 CFR 862.1345 Glucose test system
   21 CFR 864.6400 Hematocrit measuring device
   21 CFR 862.1150 Calibrator
   21 CFR §862.1660 Multi-Analyte Controls
2. Classification:
   Class I for Controls
   Class II for the others
3. Product Code:
   CHL; CEM; JFP; JGS; CGZ; CGA; JPI; JIX; JJY
4. Panel:
   75 Chemistry; 81 Hematology

H. Intended Use:

1. Intended use(s):

Refer to Indications for Use below

2. Indication(s) for use:
   The ABL80 FLEX is a portable, automated system that measures pH, blood gases, electrolytes, glucose, and hematocrit in whole blood. The ABL80 FLEX system is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physicians order:

   pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/Blood gas measurement.
   ***p*$\mathbf{O_2}$:** The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.
   ***p*$\mathbf{CO_2}$:** *p*CO_2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.
   Potassium (*c*$\mathbf{K^+}$): The potassium level is the predominant intracellular cation. It is fundamental for correct neuromuscular activity.
   Sodium (*c*$\mathbf{Na^+}$): The sodium ion is the most abundant cation in plasma. It is the foremost agent involved in maintenance of osmolality and body fluid volumes.
   Calcium (*c*$\mathbf{Ca^{2+}}$): The calcium ion is the most abundant mineral element in the human body and is involved in numerous enzymatic processes, blood coagulation, cell growth, and membrane transport mechanisms as well as plays an important role in nervous impulse conduction, neuromuscular transmission, and muscular contraction and relaxation.
   Chloride (*c*$\mathbf{Cl^-}$): The chloride ion is the main extracellular anion and plays an important role in maintaining electrical neutrality.
   Hematocrit (Hct): The hematocrit measurement is the ratio of the volume of red blood cells in whole blood in comparison to the total volume.
   Glucose (*c*Glu): The glucose measurements are used to screen for, diagnose and monitor glycemic levels in potential pre-diabetic, diabetic, hypoglycemic patients.
3. Special condition for use statement(s):
   For prescription use
4. Special instrument requirements:
   ABL 80 FLEX System

I. Device Description:

The ABL80 FLEX System consists of a modular analyzer incorporating a user interface module with a large color touch screen interfacing to analyzer electronic and fluidic modules. The user interface module contains the analyzer CPU and all of the required electronic interfaces for external communication and data storage. The system also includes a reagent cartridge for the calibration and automatic quality control of the analyzer and sensor system. The calibration and quality control reagents are packaged in sealed foil pouches, similar to the existing ABL 77 cal pack.

The analyzer and consumable incorporate "smart chip" technology for unique identification and lot specific calibration data.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ABL77, ABL700 Family, ABL800 FLEX
2. Predicate K number(s):
   k994346, k980130, k050869, k041874
3. Comparison with predicate:

Similarities & Differences		
Item	**Device**	**Predicate**
Blood Gas Measurement	pH, pCO_2, and pO_2	. pH, pCO_2, and pO_2
Electrolyte Measurement	cK^+, cNa^+, cCa^{2+}, cCl^-	cK^+, cNa^+, cCa^{2+}, cCl^-
Test Principle	Ion selective potentiometric, conductometric and amperometric sensor	Ion selective potentiometric, conductometric and amperometric sensor
Calibration Method	2 - Point	2 - Point

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

ISO 13485:1996 – Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001
ISO 13485:2003
IVD Directive: 98/79/EC

L. Test Principle:

There are three different measuring principles employed.
Potentiometry: A potential is recorded using a voltmeter, which relates to the concentration of the sample. A reference electrode is used to provide a stable, fixed potential against which other potential differences can be measured. This measurement technique is used for pH, pCO_2 and electrolytes.
Amperometry: The magnitude of an electrical flow of current is proportional to the concentration of the substance being oxidized or reduced at an electrode. This measurement technique is used for pO_2 and Glucose.
Conductivity: The specific impedance of a sample as measured by two conducting electrodes held at a constant voltage is directly proportional to the conductive properties of the sample. This technique is used for hematocrit and air-in-sample detection.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility

The precision study was performed using 5 ABL80 analyzers. Samples used for testing were heparinized blood samples from healthy, voluntary donors. The blood was prepared to obtain high, mid, and low concentration levels of each measured parameter. For pH, pCO_2 and pO_2, the blood was tonometered with certified gas mixtures traceable to NIST to attain test levels. For sodium, potassium, calcium, chloride, and glucose, the blood sample was spiked with concentrated stock solution of analyte or diluted to adjust analyte level. For hematocrit, the plasma volume of the sample was adjusted to attain test levels. Five replicates per level and analyte were measured on each ABL80. The test was repeated for each of 3 days. The total number of samples tested was 75 per analyte level.

Precision is a measure of the standard deviation (SD) of results from repeated measurements within a short interval of time using: the same instrument and location, the same measurement procedure, identical portions of the same sample, and one operator per instrument. The standard deviation for each level is pooled for all test instruments and test days

Below are listed tables showing SD and %CV for the parameters of the ABL80 analyzer: For comparison, SD is also shown for the ABL77 for pH, pCO_2, pO_2, Na^+, K^+, Ca^{2+}, Cl^-, and Hct and for the ABL725 for glucose.

			SD		CV%	
Parameter	Level	Unit	ABL80	ABL77/725	ABL80	ABL77/725
pH	7.0		0.004	0.004	0.06%	0.06%
pH	7.4		0.003	0.004	0.04%	0.05%
pH	7.7		0.005	0.006	0.06%	0.08%
pCO2	14	mmHg	0.39	0.36	2.8%	2.6%
pCO2	42	mmHg	0.37	0.46	0.9%	1.1%
pCO2	49	mmHg	0.31	0.59	0.6%	1.2%
pCO2	70	mmHg	0.59	0.63	0.8%	0.9%
pCO2	126	mmHg	1.00	2.10	0.8%	1.7%
pO2	14	mmHg	0.52	0.61	3.7%	4.4%
pO2	42	mmHg	0.49	0.55	1.2%	1.3%
pO2	84	mmHg	0.62	0.94	0.7%	1.1%
pO2	210	mmHg	0.84	1.60	0.4%	0.8%
pO2	420	mmHg	6.92	6.37	1.6%	1.5%
Na+	120	mmol/L	0.42	0.38	0.4%	0.3%

Na+	140	mmol/L	0.43	0.36	0.3%	0.3%
Na+	180	mmol/L	0.62	0.51	0.3%	0.3%
K+	2	mmol/L	0.04	0.04	2.0%	2.0%
K+	4	mmol/L	0.03	0.03	0.8%	0.8%
K+	8	mmol/L	0.04	0.07	0.5%	0.9%
Ca2+	0.5	mmol/L	0.008	0.009	1.6%	1.8%
Ca2+	1.25	mmol/L	0.008	0.013	0.6%	1.0%
Ca2+	2.5	mmol/L	0.026	0.009	1.0%	0.4%
Cl-	85	mmol/L	0.49	0.45	0.6%	0.5%
Cl	105	mmol/L	0.47	0.37	0.4%	0.4%
Cl	140	mmol/L	0.88	0.51	0.6%	0.4%
Glu	2	mmol/L	0.05	0.10	2.5%	5.0%
Glu	5	mmol/L	0.06	0.10	1.2%	2.0%
Glu	15	mmol/L	0.15	0.40	1.0%	2.7%
Glu	36	mg/dL	0.90	1.8	2.5%	5.0%
Glu	90	mg/dL	1.08	1.8	1.2%	2.0%
Glu	270	mg/dL	2.70	7.2	1.0%	2.7%
Hct	10	vol%	0.29	0.27	2.9%	2.7%
Hct	25	vol%	0.33	0.31	1.3%	1.2%
Hct	40	vol%	0.48	0.46	1.2%	1.2%
Hct	60	vol%	0.63	0.85	1.1%	1.4%
Hct	75	vol%	1.08	0.68	1.4%	0.9%

Precision results for the ABL80 are comparable to the ABL77 and ABL725, both of which are currently marketed.

b. Linearity/assay reportable range:

The linearity/reportable range study was performed using 5 ABL80 analyzers. The study was performed as a comparative in-house study against the reference method.

- Reference method comparison for pH, sodium, potassium, calcium, and chloride was against ABL725 analyzers.
- Reference method comparison for blood gases (pCO_2 and pO_2) was against tonometry. Blood gas target values were calculated from certified tonometry gas mixtures traceable to NIST.
- Reference method comparison for glucose was against serum standard per CLSI Publication RS1-A.
- Reference method comparison for hematocrit was against the microhematocrit method using centrifugation per CLSI standard H7-A3. The blood samples used for testing are heparinized blood samples from healthy, voluntary donors.
- Blood samples were prepared to obtain the different concentration levels of each measured parameter. Measurements of every parameter were taken on the analyzers with 5 samples tested per level. Each sample was split between the ABL80 and

reference/method. The total number of measurements per level was 75.

For each analyte and level, bias and the 95% confidence interval of the bias was calculated. This confidence interval indicates the expected minimum and maximum deviation of a sample result when tested on the ABL80 vs reference method. The results are summarized below.

Below are listed tables showing the ABL80 bias lower and upper limits compared to reference method.

Parameter	Level	Unit	Lower Limit	Upper Limit
PH	7.0		7.010	7.016
PH	7.4		7.403	7.411
PH	7.7		7.697	7.706
PCO2	14	mmHg	13.0	13.5
PCO2	42	mmHg	42.1	42.6
PCO2	49	mmHg	48.8	49.2
PCO2	70	mmHg	70.5	71.6
PCO2	126	mmHg	123.8	126.8
pO2	14	mmHg	12.6	13.9
pO2	42	mmHg	41.7	43.0
pO2	84	mmHg	84.0	85.5
pO2	210	mmHg	207.2	211.9
pO2	420	mmHg	405.2	437.1
Na+	120	mmol/L	120.0	120.7
Na+	140	mmol/L	139.1	139.6
Na+	180	mmol/L	179.6	180.6
K+	2	mmol/L	1.99	2.07
K+	4	mmol/L	3.93	3.99
K+	8	mmol/L	7.97	8.05
Ca2+	0.5	mmol/L	0.53	0.54
Ca2+	1.25	mmol/L	1.21	1.22
Ca2+	2.5	mmol/L	2.51	2.54
Cl-	85	mmol/L	84.5	86.2
Cl	105	mmol/L	104.0	105.1
Cl	140	mmol/L	139.1	141.1

Glu	2	mmol/L	1.83	1.95
Glu	5	mmol/L	4.64	4.93
Glu	15	mmol/L	13.14	15.15
Glu	36	Mg/dL	32.97	35.13
Glu	90	Mg/dL	83.59	88.82
Glu	270	Mg/dL	236.73	272.94
Hct	10	vol%	8.74	9.39
Hct	25	vol%	23.66	24.55
Hct	40	vol%	38.66	39.79
Hct	60	vol%	58.75	60.03
Hct	75	vol%	74.08	75.49

The ABL80 demonstrated bias equivalent to that of currently marketed instruments, the ABL77 and ABL725.

The assay reportable range was chosen to include high, normal and low values for each parameter based on clinical decision points. To achieve these levels, blood from normal human donors was adjusted per internal standard operating procedures. These procedures include tonometry with reference gas mixtures to obtain varying blood levels for pH, pCO2 and pO2, and plasma spiking to obtain varying hematocrit, glucose and electrolyte levels. Results for the assay reportable range are summarized below.

Parameter	Unit	Assay Reportable Range
pH		7.00 – 7.70
pCO_2	mmHg	115 – 125 mmHg
pO_2	mmHg	14 – 420 mmHg
cNa^+	mmol/L	120 – 180 mmol/L
cK^+	mmol/L	2.0 - 8.0 mmol/L
cCa^{2+}	mmol/L	0.50 – 2.50 mmol/L
cCl^-	mmol/L	85 – 140 mmol/L
cGlu	mg/dL	36 – 270 mg/dL
Hct	%	10 – 75 %

c. *Traceability (controls, calibrators, or method):*
External quality control samples were tested on ABL80 FLEX each test day. In addition, internal quality control solutions were tested. These internal quality control solutions are part of the system's auto calibration/QC cycle. This cycle occurs at user defined frequency, but at least every 8 hours. The solutions are contained in a multi-

solution calibration/QC pack similar to the cal pack currently used in the ABL77 analyzer. This new cal pack contains four pouches of liquid solutions, each from an independent manufacturing lot. Each of the four solutions contains varying concentrations of each measured analyte. The exact formulations are chosen and the measurements analyzed in a coordinated system to provide a low, normal, and high clinical value for each measured parameter. The range of values is similar to commercially available external QC ampoule systems.

During each automatic cycle, all four solutions are analyzed. The results of these measurements are used to calculate calibration values and QC results for all parameters. For each parameter, two of the solution measurement results are used to calculate a value for that parameter. This value is then used to calculate a quality control result from the measurement of a third solution analyzed in the same cycle. This QC result is compared to acceptable ranges established at the time of manufacturing of the solution pouch.

At manufacture, the pouch solutions are tested on a reference analyzer to obtain the known values for each solution and analyte. These target values and acceptance range spans are stored on a cal pack smart chip and are read into ABL80 analyzer memory at the time of cal pack installation. The acceptance range for each solution is calculated by the system software from the values read from the smart chip. In use, the four solutions are pumped into the sensor flow cell in succession such as L4 – L3 – L2 – L 1. After each solution is pumped, stability endpoints are saved and then the next solution is pumped. From known solution analyte concentrations and stability endpoints, calibration and QC results are calculated using different combinations of solution endpoints. All levels of QC are calculated at each calibration/QC interval. Calibration and quality control reagents package, Calpack, shelf life is 3 months from date of manufacture.

d. Detection limit:

Detection limits for the ABL80 FLEX 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:

The following gives an outline of the interfering substances and the results of interference tests on the ABL80 analyzer.

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

The following interference results are found on the electrolyte and metabolite electrodes:

Substance	Test Conc.	*c*K^+ mmol/L	*c*Na^+ mmol/L	*c*Ca^{2+} mmol/L	*c*Cl^- mmol/L	*c*Glu mmol/L
Li^+	4 mmol/L	0	0	0.04		
K^+	12 mmol/L		0	0.01		
Na^+	175 mmol/L	0				
NH_4^+	1 mmol/L	0.1	0			
Ca^{2+}	5 mmol/L		3			
Mg^{2+}	5 mmol/L	0.1	3	0.17		
Br^-	10 mmol/L				27	
F^-	1 mmol/L				0	
F^-	50 mmol/L					-0.5
I^-	3.0 mmol/L				26	
ClO_4^-	1.5 mmol/L				18	
HCO_3^-	40 mmol/L				4	
Lactic acid	10 mmol/L				-3	0.1
Acetyl-salicylic acid	3 mmol/L				3	0.0
Ascorbic Acid	1 mmol/L				-1	0.0
Ascorbic Acid	2 mmol/L					
Acetaminophen	2 mmol/L					0.2
pH ≤ 7.2	7.2	0	0	0.01	-1	
pH ≥ 7.6	7.6	0	0	-0.01	2	

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Method comparison study was performed as a comparative in-house study using one ABL80 analyzer tested against the comparative method.

- The method comparison for pH, sodium, potassium, calcium, and chloride was against ABL725 analyzers.
- The method comparison for blood gases (pCO_2 and pO_2) was against tonometry. Blood gas target values were calculated from certified tonometry gas mixtures traceable to NIST.
- The method comparison for glucose was against serum standard per CLSI Publication RS1-A.
- The method comparison for hematocrit was against the microhematocrit method using centrifugation per CLSI standard H7-A3. The blood samples used for testing are heparinized blood samples from healthy, voluntary donors.

Blood samples were prepared to obtain the different concentration levels of each measured parameter. Measurements of every parameter were taken on the analyzers with 5 samples tested per level. Each sample was split between the ABL80 and reference/method. The results from these tests are summarized as following:

- pH, ABL 80 / ABL725: y = 0.998x + 0.023 R = 1.00 n = 25
- pCO_2, ABL80 / Target Value: y = 0.995x+ 0.229, R = 1.00 n = 25
- pO_2, ABL80 / Target Value: y = 1.030x – 4.004 R = 1.000 n = 25
- cNa^+ ABL 80 / ABL 725: y = 1.016x - 2.461 R = 0.999 n = 15
- cK^+, ABL 90 / ABL 725: y = 1.014x + 0.111 R = 1.000 n = 15
- cCa^{2+}, ABL80/ABL725: y = 1.001x - 0.008 R= 0.999 n = 15
- cCl^-, ABL 80 / ABL 725: y = 1.010x - 1.484 R = 0.999 n = 15
- Glu, ABL 80 / Serum Standard : y = 0.9994x - 0.013 R = 1.000 n = 15
- Hct, ABL 80 / Spun: y = 1.021x – 0.489 R = 0.999 n = 25

The table below summarizes the linearity regression statistics for each parameter.

	Range	n	Slope	Offset	R
pH	7.0-7.4	25	0.998	0.023	1.000
*p*CO2	14-126	25	0.995	0.229	1.000
*p*O2	14-420	25	1.030	-4.003	1.000
*c*Na+	120-180	15	1.016	-2.461	0.999
*c*K+	2-4	15	1.014	-0.111	1.000
*c*Ca2+	0.5-2.5	15	1.001	-0.008	0.999
*c*Cl-	85-140	15	1.010	-1.484	0.999
*c*Glu	36-270	15	0.994	-0.013	1.000
Hct%	10-75	25	1.021	-0.489	0.999

Method comparison shows good agreement between the ABL80 and comparative method. Results from linear regression analysis of the data show slopes ranging from 0.994 – 1.030 and correlation ranging from 0.999 – 1.000.

b. Matrix comparison:
The ABL 80 FLEX utilizes the same sample types as the previously cleared on the predicate device.

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):
   Point-of-care studies were conducted to assess the reproducibility of sample measurement in the ABL80 when samples are performed by end-users in the point-of-care area.

   The method used for this study was repeat measurements on several levels of aqueous samples in analysis mode. There were 20 samples of unlabeled ampoules consisting of 5 ampoules of each of 4 levels. Each ampoule was chosen at random and analyzed once.

   This study was performed in-house at SenDx Medical Inc. and at three field sites. The in-house user was experienced with performing sample measurements on the ABL80. The field site users had no previous experience with the ABL80.

   Results from each site were tabulated separately. The mean, standard deviation (SD) and coefficient of variance (% CV) were calculated for each test level and parameter. The data were not pooled due to small biases between sites. The biases are largely due to the nature of the test samples. The test samples were aqueous quality control materials packaged in glass ampoules with an included gas phase. The gas phase produces a temperature dependency of the gas tensions and pH which, if not equilibrated to the same temperature at each site, will produce small biases of the gas and pH measurements between sites due to the temperature differences at the test sites. Also, because the test samples were aqueous control materials run in the sample analysis mode of the analyzer, small carry over effects were noted between sites which contributed to the inter-site biases. Results from the Point-of-care study are summarized in the following tables:

Results – Site 1:

	Level mean	SD	%CV
pH	6.98	0.005	0.08
pH	7.40	0.000	0.00
pH	7.61	0.000	0.00
pCO$_2$ mmHg	66.2	0.44	0.7
pCO$_2$ mmHg	42.0	0.00	0.0
pCO$_2$ mmHg	19.0	0.00	0.0
pO$_2$ mmHg	57.8	2.49	4.3
pO$_2$ mmHg	117.6	1.52	1.3
pO$_2$ mmHg	192.0	1.23	0.6
cNa$^+$ mmol/L	161.0	0.00	0.0
cNa$^+$ mmol/L	139.2	0.45	0.3
cNa$^+$ mmol/L	127.0	0.00	0.0
cK$^+$ mmol/L	4.82	0.045	0.9
cK$^+$ mmol/L	3.86	0.055	1.4
cK$^+$ mmol/L	2.20	0.000	0.0
cCa^{2+} mmol/L	1.20	0.000	0.0
cCa^{2+} mmol/L	0.64	0.004	0.7
cCa^{2+} mmol/L	0.44	0.000	0.0
cCl$^-$ mmol/L	121.0	0.71	0.6
cCl$^-$ mmol/L	95.8	0.45	0.5
cCl$^-$ mmol/L	82.6	0.55	0.7
cGlu mmol/L	11.44	0.182	1.6
cGlu mmol/L	4.10	0.122	3.0
cGlu mmol/L	1.44	0.055	3.8
Hct vol%	15.6	1.52	9.7%

Results – Site 2:

	Level mean	SD	%CV
pH	6.96	0.000	0.00
pH	7.39	0.005	0.07
pH	7.62	0.007	0.09

pCO_2 mmHg	69.4	0.55	0.8
pCO_2 mmHg	42.0	0.00	0.0
pCO_2 mmHg	16.2	0.84	5.2
pO_2 mmHg	52.6	1.82	3.5
pO_2 mmHg	107.3	1.26	1.2
pO_2 mmHg	184.8	1.64	0.9
cNa^+ mmol/L	161.0	0.00	0.0
cNa^+ mmol/L	138.5	1.00	0.7
cNa^+ mmol/L	125.6	1.14	0.9
cK^+ mmol/L	5.00	0.000	0.0
cK^+ mmol/L	3.93	0.050	1.3
cK^+ mmol/L	2.14	0.134	6.3
cCa^{2+} mmol/L	1.18	0.000	0.0
cCa^{2+} mmol/L	0.59	0.019	3.2
cCa^{2+} mmol/L	0.38	0.025	6.6
cCl^- mmol/L	121.4	0.55	0.5
cCl^- mmol/L	96.8	0.50	0.5
cCl^- mmol/L	84.2	0.84	1.0
*c*Glu mmol/L	13.78	0.192	1.4
*c*Glu mmol/L	6.28	0.171	2.7
*c*Glu mmol/L	2.38	0.130	5.5
Hct vol%	26.2	0.45	1.7

Results – Site 3:

	Level mean	SD	%CV
pH	6.97	0.004	0.06
pH	7.41	0.000	0.00
pH	7.63	0.005	0.07
pCO_2 mmHg	65.2	0.84	1.3
pCO_2 mmHg	41.0	0.00	0.0
pCO_2 mmHg	17.6	0.55	3.1
pO_2 mmHg	49.6	0.89	1.8
pO_2 mmHg	108.8	2.17	2.0

pO_2 mmHg	190.6	1.95	1.0
cNa$^+$ mmol/L	161.0	0.00	0.0
cNa$^+$ mmol/L	138.6	0.55	0.4
cNa$^+$ mmol/L	125.0	0.00	0.0
cK$^+$ mmol/L	4.90	0.000	0.0
cK$^+$ mmol/L	4.10	0.000	0.0
cK$^+$ mmol/L	1.98	0.045	2.3
cCa^{2+} mmol/L	1.21	0.000	0.0
cCa^{2+} mmol/L	0.62	0.008	1.4
cCa^{2+} mmol/L	0.37	0.004	1.2
cCl$^-$ mmol/L	120.2	0.45	0.4
cCl$^-$ mmol/L	95.4	0.55	0.6
cCl$^-$ mmol/L	80.4	0.55	0.7
cGlu mmol/L	11.72	0.705	6.0
cGlu mmol/L	5.54	0.288	5.2
cGlu mmol/L	1.46	0.114	7.8
Hct vol%	30.0	0.71	2.4

Results – SenDx Medical, Inc.:

	Level mean	SD	CV%
pH	6.98	0.000	0.00
pH	7.40	0.000	0.00
pH	7.62	0.005	0.07
pCO_2 mmHg	65.0	0.71	1.1
pCO_2 mmHg	42.0	0.00	0.0
pCO_2 mmHg	19.0	0.00	0.0
pO_2 mmHg	56.2	1.10	1.9
pO_2 mmHg	114.6	2.41	2.1
pO_2 mmHg	190.4	3.21	1.7
cNa$^+$ mmol/L	160.4	0.89	0.6
cNa$^+$ mmol/L	138.0	0.71	0.5
cNa$^+$ mmol/L	126.0	0.00	0.0
cK$^+$ mmol/L	4.86	0.055	1.1

cK^+ mmol/L	3.80	0.000	0.0
cK^+ mmol/L	2.04	0.055	2.7
cCa^{2+} mmol/L	1.20	0.007	0.6
cCa^{2+} mmol/L	0.61	0.022	3.6
cCa^{2+} mmol/L	0.41	0.008	2.0
cCl^- mmol/L	119.0	0.00	0.0
cCl^- mmol/L	95.4	1.34	1.4
cCl^- mmol/L	84.4	0.55	0.6
*c*Glu mmol/L	10.88	0.512	4.7
*c*Glu mmol/L	4.58	0.342	7.5
*c*Glu mmol/L	1.76	0.089	5.1
Hct vol%	22.8	0.96	4.2

4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:

   In the labeling the sponsor states: "Reference ranges are valuable guidelines for the clinician, but they should not be regarded as absolute indicators of health and disease. Reference ranges should be used with caution since values for 'healthy' individuals often overlap significantly with values for persons afflicted with disease. In addition, laboratory values may vary significantly due to methodological differences and mode of standardization" Reference: Siggaard-Andersen O, Thode J, Wandrup JH. The concentration of free calcium ions in the blood plasma ionized calcium. In: Siggaard-Andersen O, ed. Proceedings of the IFCC expert panel on pH and blood gases held at Herlev Hospital 1980. Copenhagen: Radiometer Medical A/S, 1981: 163-90.".

   The reference ranges given in this section are mainly taken from above reference. In some cases the values are taken from other sources marked by their reference number.

   "When possible the reference ranges for arterial blood have been listed. Reference ranges must be used with caution as they depend on a number of factors, such as sex, age, and normal physiological condition."

Symbol	**Unit**	For adults' arterial blood at 37 °C	
		Reference range	**Sex**
pH	–	7.35 – 7.45	m, f

pCO_2	mmHg	35 – 48 32 – 45	m f
	kPa	4.67 – 6.40 4.27 – 6.00	m f
pO_2	MmHg kPa	83 – 108 11.07 – 14.40	m, f m, f
cK^+	mmol/L meq/L	3.5 – 5.0	m, f
cNa^+	mmol/L meq/L	135 – 146	m, f
cCa^{2+}	mmol/L	1.15 – 1.29	m, f [12]
	meq/L	2.30 – 2.58	m, f
	mg/dL	4.61 – 5.17	m, f
cCl^-	mmol/L meq/L	98 – 106	m, f
cGlu	mmol/L mg/dL	3.89 – 5.83 70.08-105.03	m, f
Hct	%	41 – 53 36 – 46	m [14] f [14]

N. Instrument Name:
ABL ™ 80 FLEX

O. System Descriptions:

1. Modes of Operation:
   Discrete, Single line random access, multi-tests analysis
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
5. Assay Types:
   The ABL 80 FLEX System uses measurement technology that is based on electrochemical phenomena. The device use potentiometry, amperometry, and conductance methods for electrolytes 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:
   Amperometric : pO_2, glucose
   Potentiometric: pH, cNa^+, cK^+, Ca^{++}, cCl^-, pCO_2
   Conductance: Hematocrit
4. Calibration:
   The ABL 80 analyzer is equipped with solution pack which contains tonometered fluids. A 2-point calibration is performed at preset intervals using solution 1 and solution 2 from the solution pack. The precise vales for these solutions ae recorded in the smart chip on the solution pack.
5. Quality Control:
   External quality control samples were tested on ABL80 FLEX each test day. In addition, internal quality control solutions were tested. These internal quality control solutions are part of the system's auto calibration/QC cycle. This cycle occurs at user defined frequency, but at least every 8 hours.

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

N/A

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.