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

A. 510(k) Number:

k151639

B. Purpose for Submission:

To modify the software to incorporate limitations of reporting glucose results when pO_2 value is low.

C. Measurand:

Whole Blood Glucose

D. Type of Test:

Amperometric Test

E. Applicant:

SenDx Medical, Inc.

F. Proprietary and Established Names:

ABL80 FLEX and ABL80 FLEX CO-OX

G. Regulatory Information:

1. Regulation section:

   862.1345

2. Classification:

   Class II

3. Product code:

   CGA

4. Panel:

   Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   The ABL80 FLEX analyzer is a portable, automated analyzer that measures glucose, in whole blood. The ABL80 FLEX analyzer 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.

   The ABL80 FLEX CO-OX analyzer is a portable, automated analyzer that measures glucose, in whole blood. The ABL80 FLEX CO-OX analyzer 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.

   For in vitro diagnostic use.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   ABL80 FLEX and ABL80 FLEX CO-OX Analyzers

I. Device Description:

The ABL80 FLEX and ABL80 FLEX CO-OX analyzers are portable, automated systems intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, hematocrit (ABL80 FLEX analyzer only) and the oximetry parameters (ABL80 FLEX CO-OX only) total hemoglobin, oxygen saturation, FO2Hb, FCOHb, FMetHb, and FHHb.

The ABL80 FLEX and ABL80 FLEX CO-OX analyzers each exist in two different software configurations differing in the number of parameters available.

The ABL80 FLEX and ABL80 FLEX CO-OX analyzers consist of an instrument with a sensor cassette and a solution pack as the main accessories. Multiple models of sensor cassettes are available. The various sensor cassette models include models for different

parameter combinations. For each parameter combination, models allowing for different test loads are available. The solution pack is available in four models, one model for each of the four different configurations of the analyzer.

The ABL80 FLEX and ABL80 FLEX CO-OX analyzers were previously cleared in k051804 and k080370. The current modification to the glucose measurement software is to automatically handle certain glucose results depending on the pO_2 value in the sample. This will allow incorporating limitations of reporting glucose results when the pO_2 value of the sample is low.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ABL800 FLEX

2. Predicate 510(k) number(s):
   k043218

3. Comparison with predicate:

Item	Candidate Device ABL80 FLEX and ABL80 FLEX CO-OX	Predicate ABL800 FLEX (k043218)
Intended Use	The ABL80 FLEX and ABL80 FLEX CO-OX analyzers are portable, automated analyzer that measures glucose in whole blood.	Same, plus the following parameters: pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, $FCOHb$, $FMetHb$, $FHHb$ and $FHbF$)
Intended Use Site	Laboratory and Point of Care	Laboratory
Measuring Method	Amperometric	Same
Calibration Method	Two-point liquid calibration	Same
Glucose measuring range	36-180 mg/dL (pO_2 between 20 - 40 mmHg); 36-270 mg/dL ($pO_2 \geq 41$ mmHg).	36-270 mg/dL

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

CLSI EP7-A2: Interference testing in clinical chemistry; Approved Guideline – Second Edition (2005).

CSLI EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition (2004).

CSLI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).

CLSI EP09-A3: Measurement procedure comparison and bias estimation using patient samples; Approved Guideline - Third Edition (2013).

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition (2012).

L. Test Principle:

The amperometric test principle is used for the measurement of both pO_2 and glucose because glucose measurement is dependent upon enough pO_2 in the sample; therefore, pO_2 and glucose are measured simultaneously. The magnitude of an electric flow of current is proportional to the concentration of the substance being oxidized or reduced at an electrode.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   See k051804 and k080370.

   b. Linearity/assay reportable range:

   See k051804 and k080370.

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

   See k051804 and k080370.

   d. Detection limit:

   See k051804 and k080370.

   e. Analytical specificity:

Analytical Specificity for glucose measurement was reviewed and cleared in k051804 and k080370. However, additional studies were conducted to further characterize the impact of, or interference from, limitations on the amounts of oxygen in the sample. The cause of this interference effect is that the enzymatic conversion of glucose in the sensor is oxygen consuming, the oxygen coming from the sample. The interference study was performed according to the CLSI "Interference testing in clinical chemistry; Approved Guideline – Second Edition", CLSI document EP7-A2. Testing was performed on three ABL80 FLEX and three ABL80 FLEX CO-OX instruments with five levels of glucose and four levels of pO_2. Base pools of whole blood were prepared for each glucose level and split into two samples with one being tonometered to 100 mmHg pO_2 (control sample) and the other to the pO_2 level being tested (test sample). Each sample was tested on the ABL80 FLEX and ABL80 FLEX CO-OX analyzers, and the glucose bias for each test sample vs. the control sample was calculated. The bias for the test sample was calculated and should be less than or equal to the acceptance criterion which was set to 10% of the control value. Results are summarized below:

ABL80 FLEX:

Glucose Concentration (mg/dL)	pO_2 mmHg			
	< 20	20	40	80
270	-67%	-17%	-5%	1%
180	-51%	-3%	9%	-1%
90	-37%	-7%	-6%	0%
54	-26%	-10%	6%	1%
36	Not needed	-7%	-4%	2%

ABL80 FLEX CO-OX:

Glucose Concentration (mg/dL)	pO_2 mmHg			
	< 20	20	40	80
270	-69%	-20%	3%	0%
180	-55%	-4%	8%	0%
90	-42%	-8%	-7%	-2%
54	-31%	-9%	6%	0%
36	Not needed	-9%	-4%	2%

The interference study test results support the glucose linearity ranges shown below and documented in the labeling:

Glucose linearity versus pO_2 level

pO_2 (mmHg) range	Glucose concentration (mg/dL) linearity range
20 – 40	36 – 180
≥ 41	36 – 270

The labeling (reference manual and owner's manual) highlights awareness of dependency of glucose measurement on sample pO_2 levels and includes the following description for flagging glucose results outside the validated glucose linear range and the pO_2 level of the sample:

- All glucose results at pO_2 level <20 mmHg are suppressed and flagged by the symbol ">" with a message "Glu not usable. pO_2 too low for reliable cGlucose measurement".
- All glucose results >180 mg/dL at pO_2 level between 20 – 40 mmHg will be suppressed and flagged by the symbol ">" with a message "Glu not usable. pO_2 too low for reliable cGlucose measurement".
- When the measured value of pO_2 is not numeric (Not Reportable (N/R)) or pO_2 parameter is Lockout (P/L) or Not Derived (N/D) or Inactive (I/A) or QC Lockout (L/O), then the results for glucose measurement will not be displayed and the symbol "N/R" is displayed.
- If the results are outside the test range of the analyzer for glucose measurement (see table above), the results are highlighted in red and flagged with "↟ or ↡".

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

See k051804 and k080370.

b. Matrix comparison:

Not applicable

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 glucose reference range for adults' arterial blood at 37 °C is 70.02 – 104.9 mg/dL (3.89 – 5.83 mmol/L)

   Reference: Tietz NW, Logan NM. Reference ranges. In: Tietz NW, ed. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders Company, 1987: 944-75.

N. Proposed Labeling:

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

O. Conclusion:

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