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

A. 510(k) Number:
k121027

B. Purpose for Submission:
New Device

C. Measurand:
Calibrator materials for sodium, potassium, chloride, carbon dioxide

D. Type of Test:
Not applicable

E. Applicant:
Diamond Diagnostics Inc.

F. Proprietary and Established Names:
Diamond Diagnostics ATAC 8000/ Envoy 500 ISE calibrators

G. Regulatory Information:
1. Regulation section:
   21 CFR § 862.1150; Calibrator
2. Classification:
   Class II
3. Product code:
   JIT
4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See Indications for use below.

2. Indication(s) for use:
   Diamond Diagnostics Calibrators for ATAC 8000 and Envoy 500 instruments are intended to provide calibration points for the Na^+, K^+, Cl^-, and CO_2 electrodes on the ATAC 8000 and Envoy 500 instruments.

3. Special conditions for use statement(s):
   For prescription use only

4. Special instrument requirements:
   For use with ATAC 8000 and Envoy 500 instruments

I. Device Description:

Diamond Diagnostics ATAC 8000/Envoy 500 ISE Calibrators consist of two calibrators, a low level and a high level. Both low and high level calibrators consist of an aqueous buffered solution of electrolytes and preservative in de-ionized water. It contains no human or animal products. It is a liquid packaged in a 22ml screw top amber vial. Each vial contains 20 ml of solution.

Each calibrator is comprised of the following concentrations of analytes:

ISE Calibrator	Na^+ mmol/L	K^+ mmol/L	Cl^- mmol/L	CO_2 mmol/L
Low	92 ± 2.0	3.05 ± 0.05	78 ± 2	11 ± 1
High	162 ± 1.0	10.2 ± 0.1	126 ± 1	34.5 ± 1

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ATAC 8000/Envoy 500 ISE Calibrators

2. Predicate k number(s):
   k945271

3. Comparison with predicate:

	Similarities and Differences	
Item	Diamond ATAC 8000/Envoy 500 ISE Calibrators (candidate device)	ATAC 8000 ISE Calibrators (predicate device-k945271)
Intended Use	For *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, Cl^- and CO_2 electrodes	same
Matrix	Aqueous buffered solution of salts & preservatives in de-ionized water. Contains no human or animal materials.	same
Packaging, Vial	Glass Vial	Same
Levels	2x20 mL	2x6x20 mL
Storage	18-25°C	same
Shelf Life	24 months	same

K. Standard/Guidance Document Referenced (if applicable):
None were referenced.

L. Test Principle:
Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Not applicable

b. Linearity/assay reportable range:
Not applicable

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

Traceability:

Sponsor claims traceability to the following materials and methods:

Analyte	Standard Used for Determination of Analyte Value	Instrument Used
Na, K,	NIST 919a, 918a	IL 943 (Flame Photometry)
Cl	NIST 919a	Corning 925, SAT-500 Salt analyzer (Titrimetric)
CO2	Clinical calibrator DD-93100	Hitachi 912, Olympus-Beckman CX-7

Value Assignment:

Commercially available salts/chemical constituents are gravimetrically weighed and added to Type 1 deionized water to yield the desired concentrations. To ensure that target values are met, multiple replicates of test samples are measured at the beginning and end of the production run on multiple analyzers and must passed the target ranges prior to release. Target values are determined by taking the mean of multiple determinations performed on randomly selected samples from each lot. In addition, calibrators are also tested on the ATAC 8000 and Envoy 500 instruments and must pass the target values specifications before release. The target values specifications are listed below:

ISE Calibrator	Na^+ mmol/L	K^+ mmol/L	Cl^- mmol/L	CO_2 mmol/L
Low	92 ± 2.0	3.05 ± 0.05	78 ± 2	11 ± 1
High	162 ± 1.0	10.2 ± 0.1	126 ± 1	34.5 ± 1

Stability:

Shelf-life stability was tested using an accelerated stability study. Real-time stability study is still on-going. The accelerated stability testing protocols and acceptance criteria were described and found to be adequated. Both calibrators low and high has an estimated shelf life of 24 months when stored at 18-25˚C. There is no open-vial claim since the calibrators are designed to be used once only.

d. Detection limit:
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off:
Not applicable

2. Comparison studies:
   a. Method comparison with predicate device:
   Not applicable

   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:
   Not applicable

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.