

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k033063

B. Analyte:

pH, PCO₂, PO₂, Sodium, Potassium, Calcium, Chloride, Lithium

C. Type of Test:

Control materials for blood gas instruments

D. Applicant:

Diamond Diagnostics, Inc.

Mission Diagnostics is a Division of Diamond Diagnostics

E. Proprietary and Established Names:

Mission Diagnostic ISE pH/Blood Gas Controls for pH/BG &/or Electrolyte Analyzers

F. Regulatory Information:

1. Regulation section:
862.1660, Controls, Assayed and Unassayed
2. Classification:
I
3. Product Code:
JJS
4. Panel:
Chemistry (75)

G. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
The Mission Diagnostic controls are 4 levels of assayed quality control materials intended for monitoring the measurements of pH, pCO₂, PO₂ in blood gas analyzers and sodium, potassium, chloride, lithium, ionized calcium and total CO₂ in pH/blood gas and or electrolyte analyzers. They are intended to estimate test imprecision and to detect systematic deviations that may occur because of instrument or reagent variation. Ranges are provided for six test systems; AVL, Ciba-Corning (now Bayer), IL, NOVA, Radiometer, and

Medica analyzers. (Specific models of these analyzers appear on the Indications for Use form.)

The device is for in vitro diagnostic use.
The device is for prescription use.

3. Special condition for use statement(s):
None.
4. Special instrument Requirements:
Not applicable.

H. Device Description:

The product is a four level aqueous based control material.

I. Substantial Equivalence Information:

1. Predicate device name(s):
ALKOntrol Controls
2. Predicate K number(s):
k950902
3. Comparison with predicate:
Both devices are aqueous based control materials with similar constituents and have the same intended use. The manufacturers differ.

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

The sponsor did not reference any standards in their submission.

K. Test Principle:

Not applicable.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not applicable.
 - b. *Linearity/assay reportable range:*
Not applicable.
 - c. *Traceability (controls, calibrators, or method):*
The appropriate salts (chemical constituents) are gravimetrically weighed out and added to Type 1 deionized water to yield the desired control values. The controls are tonometered with the appropriate gas to yield the desired pH, pCO₂, and pO₂ levels for each control.

Representative value assignment sheets for each level are provided.

Value Assignment Procedures:

The sponsor does not establish their own ranges for each of the analyzers identified in their value assignment sheet. Instead, they analyze their material and the predicate device on a minimum of 2 analyzers. They establish the bias between the two materials by comparing both of them to a reference point. The determined bias is then applied to all of the analyte ranges posted by the predicate device.

Controls are run on a flame photometer for Na, K, and Li and via an ISE measurement for Ca, Cl, and TCO₂.

According to the sponsor, values are established by running on a minimum of two instruments in the AVL, Corning/Bayer, Radiometer, and Medica Instrument families.

Currently, the sponsor is able to utilize the following instrument models in their testing:

AVL - Compact 2, 995, 985, 9180, 9130

Corning – 238, 248, 865, 278, 288, 664, 634, 614, 654

Radiometer – 520

MEDICA – EASYLyte Na/K/Cl/Li, Na/K/Ca/pH, ILYte Na/K/Cl

Stability Studies:

Stability of the products has not yet been established, however studies are currently under way. The sponsor states the firm is targeting a three year shelf life. Stability of the product is being established on 1 lot of product in an accelerated study and is being confirmed on 3 lots of product via real time studies. Stability testing will not be performed on future lots.

Accelerated studies are based on the 2X rule. The sponsor is evaluating 20 weeks at 55°C in order to project a 3 year stability claim.

Conditions of the study include:

Storage temperatures are RmT (25°C) & 55°C.

Frequency of testing is every 3 wks for 55°C for the accelerated studies and every 12 wks for RmT for the Real Time studies.

The reference values against which measurements are compared are as follows:

For Na, K, Cl, Ca, Li, TCO₂ testing is NIST standard measurements.

- At each Accelerated time point the difference between Accelerated and RmT values are calculated.
- At each Real Time point, values are compared to T=0 (the initially measured value).

For pH, pCO₂, pO₂ a minimum of 3 ampules per temperature are tested.

- At each Accelerated time point difference between Accelerated and RmT value is calculated.
- At each Real Time point, difference between the new lot and predicate device is calculated and compared to the Time =0 bias value.

Acceptance Criteria for the study for Na, K, Cl, Ca, Li, TCO₂ is $\pm 2, 0.05, 3, 0.03, 0.03, 2$ respectively.

For pH, pCO₂, pO₂ the criteria is $\pm 0.005, 3, 5$ respectively.

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):

4. Clinical cut-off:
Not applicable.
5. Expected values/Reference range:
Representative target ranges for the control have been provided.

M. Conclusion:

I recommend that this device be found substantially equivalent to the predicate device.