

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

A. 510(k) Number:

k060206

B. Purpose for Submission:

Clearance to market quality control material

C. Measurand:

Quality control material for pH, pCO₂, pO₂, Na⁺, K⁺, Cl⁻, Ca⁺², glucose, and lactate.

D. Type of Test:

Quality control material

E. Applicant:

Diamond Diagnostics

F. Proprietary and Established Names:

Mission Complete™ Linearity Controls

G. Regulatory Information:

1. Regulation section:

21CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class I (reserved)

3. Product code:

JJY

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

Please see indications for use.

2. Indication(s) for use:

Mission Complete™ Linearity Controls are intended to be used for confirming the calibration and linearity of instruments measuring pH, pCO₂, pO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻, Glucose, and Lactate.

3. Special conditions for use statement(s):

For Prescription Use only

4. Special instrument requirements:

The labeling states the specific instruments for use with this device.

I. Device Description:

The Mission Complete™ Linearity Control are assayed materials used for confirming the calibration and linearity of blood gas, electrolyte, and metabolite instruments measuring pH, pCO₂, pO₂, Na⁺, K⁺, Cl⁻, Ca⁺⁺, glucose, and lactate. The device is intended to confirm the calibration of an instrument. The device is not intended for use as a calibrator.

The control material is provided in 5 levels of control chosen to cover the clinically relevant range of each analyte. The control material is packaged in sealed glass ampules. Each ampule contains 1.8 ml of solution. The material is stable for 3 years if stored at 2-8 °C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Blood gas, electrolyte, lactate, and BUN controls

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

k943754

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Common Analytes	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺² , glucose, and lactate	Same
Storage	2-8 °C	Same
Reagent format	Aqueous liquid	Same

Differences		
Item	Device	Predicate
Lithium	Not present	Present
Levels of Control	5	3
BUN	Not present	Present
Shelf Life	3 years	1.5 years

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

None referenced.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable of a device of this type.

b. Linearity/assay reportable range:

Not applicable of a device of this type.

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

The control material is prepared gravimetrically from analytic grade material. CO₂ and O₂ are introduced into the solute by bubbling. Confirmation of the analyte concentration is obtained through comparison to a NIST standard. The company uses NIST 919a as reference material for Na⁺ and Cl⁻. For K⁺,

the company compares to NIST 918a. For Ca^{+2} , the company compares to NIST 915a. The company confirms the glucose concentration of their controls by comparison to NIST 917b. The concentration of lactate is obtained via comparison to a Pointe Lactate standard.

The company substantiated their claim for a 3 year shelf life via accelerated aging studies. Samples demonstrated a change in concentration of less than $\pm 5\%$, the acceptance criteria used by the company. The data supplied by the company supports the 36 month shelf life if stored at 2-8 °C.

d. Detection limit:

Not applicable of a device of this type.

e. Analytical specificity:

Not applicable of a device of this type.

f. Assay cut-off:

Not applicable of a device of this type.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable of a device of this type.

b. Matrix comparison:

Not applicable of a device of this type.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable of a device of this type.

b. Clinical specificity:

Not applicable of a device of this type.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable of a device of this type.

4. Clinical cut-off:

Not applicable of a device of this type.

5. Expected values/Reference range:

Not applicable of a device of this type.

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.