

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

A. 510(k) Number:

k093384

B. Purpose for Submission:

New Device

C. Measurand:

Quality Control material for pH, pCO₂, pO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻, glucose, lactate, tHb, %COHb, %metHb and %HHb

D. Type of Test:

Not applicable

E. Applicant:

Diamond Diagnostics, Inc.

F. Proprietary and Established Names:

Mission Trinity R (Level 1, 2, 3)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I	21 CFR 862.1660	Chemistry 75

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Mission Trinity R Control is intended to be used as an assayed quality control material for monitoring the precision performance of the following analytes pH, pCO₂, pO₂,

Na⁺,K⁺, Ca⁺⁺, Cl⁻, glucose and lactate on blood gas, electrolyte and metabolite analyzers as well as tHb, %O₂Hb,%O₂Sat, %COHb, %MetHb, %O₂Ct & %HHb on CO-oximeter instrumentation.

3. Special conditions for use statement(s):

Prescription use only

4. Special instrument requirements:

Radiometer ABL Blood Gas analyzers and CO-oximeters, Radiometer OSM3 CO-oximeter, Ciba-Corning/Bayer Blood Gas analyzers

I. Device Description:

Trinity R consists of a buffered solution of electrolytes, glucose, lactate, dyes and preservative. It is equilibrated with specific levels of CO₂, O₂, and N₂. It contains no human or biological materials.

Trinity R is provided in three distinct levels of pH, pCO₂, pO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻, glucose, lactate, tHb, %O₂ Hb, %HbO₂Sat, %COHb, %MetHb, %O₂Ct & %HHb covering the significant range of the instrument performance. It is packaged in sealed glass ampules, each containing 1.8 ml of solution. Ampules are packaged in single level boxes (30 ampules of same level) or tri-level boxes (10 ampules of each level). The ampules are single use products.

J. Substantial Equivalence Information:

1. Predicate device name:

RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-Oximeter (Radiometer) Control

2. Predicate K number:

k880447

3. Comparison with predicate:

Similarities		
	Candidate Device	Predicate Device
Characteristics	Mission Trinity R	RA525 (k880447)
Intended Use	For <i>in vitro</i> diagnostics use for quality control of pH/Blood Gas analyzers,	Same

	ISE analyzers, Metabolite analyzers and CO-Oximeter instrumentation.	
Product Type	Assayed Blood Gas Control	Same
Matrix	Buffered Aqueous Solution	Same
Storage	2-8°C	Same
Color	Red/purple solution	Same
Levels	Three	Same
Analytes	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻ , glucose, lactate, tHb, %O ₂ Hb, %COHb, %metHb, %O ₂ Ct, %O ₂ Sat and %HHb	Same
Instruments	Multiple instruments	Multiple instruments

Differences		
	Candidate Device	Predicate Device
Characteristics	Mission Trinity R	RA 525 (predicate k880447)
Preservative	Present	Not present
Package	Package 30 x 1.8mL	30 x 2.5mL
Shelf Life	24 months	36 months

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

FDA Guidance for Industry and FDA Staff: Assayed and Unassayed Quality Control Materials

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

Commercially available salts/chemical constituents are gravimetrically weighed and added to deionized water to yield desired concentrations. Controls are tonometered with commercially available gas to yield the desired pH, pCO₂, pO₂, levels for each control. Commercially available dyes are also added to create clinically relevant co-oximeter values for each control. Lot to lot variation of the Mission Trinity R controls is determined by testing the new lot vs. the previous lot normalized to either an aqueous standard made with corresponding analyte NIST material or a known calibrator.

Analyte	Standard Used for Determination of Analyte Value
Na, K	NIST 919a, 918a
Ca	NIST 915a
Cl	NIST 919a
Glucose	NIST 917b
Lactate	Pointe™ Lactate Std

Value Assignment

Multiple replicates of test samples are measured at the beginning and end of the production run on various analyzers for electrolyte, metabolite, and co-oximetry values. Multiple replicates of test samples are run on two analyzers for blood gas and pH values. Values are determined by taking the mean of multiple determinations performed on randomly selected samples from each lot. Ranges are assigned using pre-determined intervals. Value assignment is performed for each lot of Mission Trinity R control.

The labeling states that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability

Real Time, Shelf-Life, Open Vial, and Transport Simulation testing protocols and acceptance criteria were described and found to be adequate. The Mission Trinity R controls are stable until the expiration date of two years printed on the vials when stored at 2-8 °C. The labeling states that for pH and blood gas values the controls should be analyzed within one minute of opening and for electrolyte measurements the controls should be analyzed within one hour of opening. This device should not be frozen.

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:

The expected values are provided in the labeling for each specific lot.

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.