

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

A. 510(k) Number:

k062674

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for pH, PCO₂, PO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻, glucose, lactate, tHb, % COHb, % methHb and % HHb

D. Type of Test:

Not Applicable

E. Applicant:

Diamond Diagnostics, Inc.

F. Proprietary and Established Names:

Mission Trinity B[™] Controls

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
<u>Multi-Analyte Controls, All Kinds (Assayed and Unassayed) JJY</u>	<u>Class I</u>	<u>21 CFR 862.1660</u>	<u>75 Clinical Chemistry (CH)</u>

H. Intended Use:

1. Intended use(s):

See indications(s) for use below.

2. Indication(s) for use:

Mission Trinity B™ Controls are intended to be used as a quality control material for monitoring the performance of pH, PCO₂, PO₂, Na⁺, Ca⁺⁺, Cl⁻, glucose, lactate, tHb, % O₂Hb, % CoHb, % methHb & % HHb on Bayer instrumentation.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Bayer 270/800/400 Analyzer Series Instrumentation

I. Device Description:

Mission Trinity B™ Controls are a specially formulated, three-level, aqueous material intended for use to monitor all analytes measured by the Bayer line of blood gas, electrolyte, metabolite and CO-Oximetry analyzers. This control material is provided in three (3) distinct levels of pH, pCO₂, PO₂, Na⁺, K⁺, Cl⁻, Ca⁺⁺, glucose, lactate, tHb, O₂Hb, COHb, methHb, and HHb covering the significant range of the instrument performance. It is packaged in sealed glass ampules, each containing 1.8 mL of solution.

J. Substantial Equivalence Information:

Characteristics	Mission Trinity B (New Device k062674)	Bayer Rapid QC™ Complete
PN	DD-96001, 96002, 96003, 96123	108860, 108868, 108869
Contents: Any Level	Aqueous solution of buffers, electrolytes, glucose lactate dyes, equilibrated with CO ₂ , O ₂ and N ₂ . Contains NO human or animal materials.	Aqueous solution of buffers, electrolytes, glucose lactate dyes, equilibrated with CO ₂ , O ₂ and N ₂ . Contains NO human or animal materials.
Container	Glass ampule (heat sealed, score break)	Glass ampule (heat sealed, score break)
Color	Red/ purple solution	Red/ purple solution
Package	30 X 1.8 mL (instrument only requires a fraction of an mL to make measurement)	30 X 2.5 mL
Intended Use	For in-vitro diagnostics use for quality control of pH, Blood Gas analyzers, ISE analyzers, CO-oximeters, and Metabolite Analyzers.	For in-vitro diagnostics use for quality control of pH, Blood Gas analyzers, ISE analyzers, CO-oximeters, and Metabolite Analyzers.
Storage/ Shelf Life	2-8°C (36-months) or 18-25°C 12 – months	2-8°C (36 months) or 18-25°C (until expiration date)

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

Not Applicable

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: The assigned values for the Mission Trinity Control were derived from formulated pilot lots of levels 1, 2, and 3 matching the Bayer Complete (OEM) Controls as close as possible. The bias with the predicate's assay sheet is taken into account. The established ranges are $\pm 10\%$ with some exceptions such as CO-OX fractions. The Mission Trinity Control test pilot lots and Bayer Complete were assayed on the Bayer 855 analyzer for comparison. The results are presented in the table below.

Analyte	Units	Level 1		Level 2		Level 3	
		OEM	Pilot	OEM	Pilot	OEM	Pilot
pH	-----	7.16	7.16	7.36	7.36	7.57	7.65
pCO ₂	mmHg	73	61	43	42	23	23.4
pO ₂	mmHg	142	156	99	106	29	17
Na ⁺	mmol/L	112	116	134	139	157	154
K ⁺	mmol/L	3.14	2.73	4.87	4.15	6.96	6.32
Cl ⁻	mmol/L	72	74	96	93	120	112
iCa	mmol/L	1.61	1.4	1.16	0.85	0.76	0.34
tHb	g/dL	16	18.6	12.7	11.9	7.8	6.7
O ₂ Hb	%	77.5	81.2	90.4	91.1	58.5	57
COHb	%	4.4	1.6	6.3	6.6	20.9	21.5
MetHb	%	15.5	14.3	1.5	1.4	6.3	5.4
HHb	%	2.6	2.9	1.8	1.0	15.4	16
Glucose	mg/dL	206	200	99	107	50	55
Lactate	mmol/L	12.3	12.3	0.91	0.90	3.00	3.00

Stability: The sponsor performed an accelerated stability study of the Mission Trinity B Controls stored refrigerated at (2-8°C) for 36-months, and also 12-months stability when stored at room temperature (18-25°C). Real time stability studies are on-going.

The sponsor's stability study demonstrated that the Mission Trinity Controls are stable up to 12 months when stored at 18-25°C or 36 months when stored at 2-8°C.

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 mean and ranges are provided in the labeling. The sponsor recommends in the labeling that the expected ranges are provided as a guide in evaluating analyzer performance and that each laboratory should establish its own acceptance criteria for the control materials.

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 equivalent decision.