

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

A. 510(k) Number: K032335

B. Analyte: N/A

C. Type of Test: N/A

D. Applicant: Medical Analysis Systems, Inc.

E. Proprietary and Established Names: MAS® CardioImmune® proBNP

MAS® CardioImmune® TL
Liquid Assayed Cardiac Marker Control

F. Regulatory Information:

1. Regulation section: 21 CFR §862.1660 Quality control material
(assayed and unassayed).
2. Classification: Class I, non-exempt
3. Product Code: JJY
4. Panel: 75

G. Intended Use:

1. Intended use(s):

MAS® CardioImmune® proBNP is intended for use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include CardioImmune® proBNP with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

MAS® CardioImmune® TL is intended for use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include CardioImmune® TL with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

2. Indication(s) for use:

The MAS® CardioImmune® proBNP is intended for use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include CardioImmune® proBNP with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

The MAS® CardioImmune® TL is intended for use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include CardioImmune® TL with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring constituent performance of reagent and instrument.

3. Special condition for use statement(s): None4. Special instrument Requirements: None**H. Device Description:**

The MAS® CardioImmune proBNP and MAS® CardioImmune TL products are a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from recombinant proteins, human tissue or body fluids. Preservatives and stabilizers are added to maintain product integrity.

I. Substantial Equivalence Information:1. Predicate device name(s):

MAS® CardioImmne® TL

MAS® CardioImmune® proBNP

2. Predicate K number(s):

MAS® CardioImmne® TL K013995

MAS® CardioImmune® proBNP K031364

3. Comparison with predicate:

General Information	MAS® CardioImmne® TL	MAS® CardioImmune® proBNP	MAS® CardioImmune® TL MAS® CardioImmune® proBNP
501(k) Number	K013995	K031364	K032335
Product Code	JJY	JJY	JJY
Intended Use	For use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	For use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	For use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
Product state	Liquid	Liquid	Liquid
Stability Claims	36 months unopened at - 20°C 180 days unopened at 2-8°C , 30 days opened at 2-8°C	24 months unopened at - 20°C 30 days unopened at 2-8°C , 30 days opened at 2-8°C	36 months unopened at - 20°C 90 days unopened at 2-8°C , 60 days unopened for Troponin T, 30 days opened at 2-8°C
Constituents	CK-MB, Creatinine	CK-MB, Creatinine	CK-MB, Creatinine

	Kinase-MB Isoenzyme	Kinase-MB Isoenzyme BNP	Kinase-MB Isoenzyme BNP
	CRP	CRP	CRP
	Digoxin	Digoxin	Digoxin
	Myoglobin	Myoglobin	Myoglobin
	Troponin I	Troponin I	Troponin I
			Troponin - T
Configuration	Each level sold separately Multi Pack - several vials of each level Sample Pack – one vial of each level	Each level sold separately Multi Pack - several vials of each level Sample Pack – one vial of each level	Each level sold separately Multi Pack - several vials of each level Sample Pack – one vial of each level

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

FDA guidance “Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials”.

K. Test Principle: NA**L. Performance Characteristics (if/when applicable):**1. Analytical performance:

- a. *Precision/Reproducibility:* NA
- b. *Linearity/assay reportable range:* NA
- c. *Traceability (controls, calibrators, or method):* Not Stated
- d. *Detection limit:* NA
- e. *Analytical specificity:* NA
- f. *Assay cut-off:* NA

2. Comparison studies:

- a. *Method comparison with predicate device:* NA
- b. *Matrix comparison:* NA

3. Clinical studies:

- a. *Clinical sensitivity:* NA
- b. *Clinical specificity:* NA
- c. *Other clinical supportive data (when a and b are not applicable):* NA

4. Clinical cut-off: NA

5. Expected values/Reference range:

The assigned ranges for these controls are based upon replicate assays of representative samples of the product by participating laboratories in accordance with established protocol. All values have been assigned with instruments and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these assigned ranges.

Expected values may vary slightly with different reagent and/or methodologies used. Refer to the included table for values obtained for specific systems. Values listed are specific for this lot of control only. Good laboratory practice suggests that each laboratory establish its own parameters.

M. Conclusion:

Based on the information provided, I recommend that the MAS® CardioImmune® proBNP and MAS CardioImmune® TL Liquid Assayed Cardiac Marker Control is substantially equivalent to the predicate device.