

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

A. 510(k) Number: K040880

B. Purpose of Submission: Removal of Digoxin and the addition of Digitoxin to the reagent formulation of the previously cleared MAS® CardioImmune® TL, (K032335)

C. Analyte: N/A

D. Type of Test: N/A

E. Applicant: Medical Analysis Systems, Inc.

F. Proprietary and Established Names: MAS® CardioImmune® TL
Liquid Assayed Cardiac Marker Control
Level 1, 2 and 3

G. 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 / JJX
4. Panel: 75

H. Intended Use:

1. Intended use(s):

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® 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 this product 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): None

4. Special instrument Requirements: The intended instruments are stated in the package insert.

I. Device Description:

The MAS® CardioImmune TL is 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.

This product will be sold in a kit with 2 vials of level 1, 2 and 3, in 3 mL vials, or as a single level kit of 6 vials. These controls may be distributed with various combinations of the cleared analytes and the lot specific analytes claimed will be reflected by the lot specific package insert. The product may be sold as a single analyte cardiac marker.

J. Substantial Equivalence Information:

1. Predicate device name(s):

MAS® CardioImmne® TL Cardiac Marker Control

2. Predicate K number(s):

MAS® CardioImmne® TL K032335

2. Comparison with predicate:

General Information	MAS® CardioImmne® TL MAS® CardioImmune® proBNP	MAS® CardioImmune® TL
501(k) Number	K032335	K040880
Product Code	JJY	JJY / JJX
Intended Use	For use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac	For use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac

General Information	MAS® CardioImmune® TL MAS® CardioImmune® proBNP	MAS® CardioImmune® TL
	marker determinations. Include 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.	marker determinations. Include 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.
Product state at purchase	Frozen	Frozen
Stability Claims	36 months unopened at -20 °C 30 days opened at 2-8 °C 180 days unopened at 2-8 °C except for, proBNP, 90 days unopened at 2-8 °C Troponin T, 60 days unopened at 2-8 °C	36 months unopened at -20 °C 30 days opened at 2-8 °C 180 days unopened at 2-8 °C except for, Digitoxin, 30 days, unopened at 2-8 °C proBNP, 90 days unopened at 2-8 °C Troponin T, 60 days opened at 2-8 °C
Constituents	Brain Natriuretic Peptide, BNP	Brain Natriuretic Peptide, BNP
	CK-MB, Creatinine Kinase-MB Isoenzyme	CK-MB, Creatinine Kinase-MB Isoenzyme
	CRP	CRP
		*Digitoxin
	Digoxin	
	Myoglobin	Myoglobin
	Troponin-I	Troponin I
	Troponin-T	Troponin-T
Levels available	Three	Three
Configuration	6 x 3 mL vials each level 2 x 3 x 3 mL, 2 vials of each level	6 x 3 mL vials each level 2 x 3 x 3 mL, 2 vials of each level

*Addition in bold.

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

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

L. Test Principle: NA

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:* NAb. *Linearity/assay reportable range:* NAc. *Traceability (controls, calibrators, or method):* Material (digitoxin) was purchased by the sponsor based on the manufacturer's certificate of analysis.

Stability studies performed using three lots on opened and unopened vials at 2-8 °C for 30 days resulted in no significant decline in performance. Studies were performed on Levels 1 and 3 only since Level 2 is a combination of the other two levels, for both opened and unopened vials. Results are listed below in Table 1 (Open Vial) and Table 2 (Closed Vial).

Table 1. Real Time Stability Data, **Open Vial**, 30 days at 2-8 °C

Analyte	Unit	Level 1			Level 3		
		Fresh	30 days	% Change	Fresh	30 days	% Change
Digitoxin	ng/mL	11.23	11.30	0.02	39.53	40.80	0.03

Table 2. Real Time Data, **Closed Vial Data**, 30 days at 2-8 °C

Analyte	Unit	Level 1			Level 3		
		Fresh	30 days	% of Day 0	Fresh	30 days	% of Day 0
Digitoxin	ng/mL	10.10	10.10	0.00	38.65	40.20	0.04

Arrhenius studies were performed to establish shelf life dating for this product. The analyte levels of three lots were based on the targeted high and low ranges for the product. The lots were stressed for 7 days at 37 °C. Results are tabulated in Table 3 for Level 1 and Level 3.

Table 3. Accelerated Stress Stability Data, 7 days at 37 °C

Analyte	Unit	Level 1			Level 3		
		Fresh	7 days	% Change	Fresh	7 days	% Change
Digitoxin	ng/mL	11.57	11.63	0.01	38.87	37.13	-0.04

The Arrhenius data demonstrate that the shelf life for this product is greater than 3 years when stored at or below -20 °C.

d. Detection limit: NA

e. Analytical specificity: NA

f. Assay cut-off: NA

2. Comparison studies:

g. Method comparison with predicate device: NA

h. 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. The proposed range and mean for digitoxin is listed below in Table 4.

Table 4. Proposed Mean and Ranges

Analyte	Unit	Level 1 Mean (Range)	Level 2 Mean (Range)	Level 3 Mean (Range)
Digitoxin	ng/mL	11 (9-13)	21.5 (19-24)	47 (35-50)

N. Conclusion:

The submitted material in this premarket notification for MAS CardioImmune® TL Liquid Assayed Cardiac Marker Control is complete and supports a substantially equivalence decision.