

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

A. 510(k) Number:

k041194

B. Purpose of Submission:

Modified device - Removal of all analytes except for Troponin I from the reagent formulation of the previously cleared MAS® CardioImmune® TL, (k032335).

C. Analyte:

Troponin I

D. Type of Test:

Quality Control Material

E. Applicant:

Medical Analysis Systems, Inc.

F. Proprietary and Established Names:

Abbott ARCHITECT STAT Troponin I, Liquid Assayed Cardiac Marker Control, Level L, M and H

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:
JJX
4. Panel:
75

H. Intended Use:

1. Intended use(s):

The intended use is for an Abbott instrument with the ARCHITECT STAT Troponin-I reagent and calibrator. The ARCHITECT® Troponin-I Controls are for verification of the accuracy and precision of the ARCHITECT i2000_{SR} System when used for the quantitative determination of cardiac Troponin-I in human serum and plasma. Refer to the ARCHITECT STAT Troponin-I reagent package insert for additional information.

2. Indication(s) for use:

The ARCHITECT[®] Troponin-I Controls are for verification of the accuracy and precision of the ARCHITECT i2000_{SR} System when used for the quantitative determination of cardiac Troponin-I in human serum and plasma. Refer to the ARCHITECT STAT Troponin-I reagent package insert for additional information.

3. Special condition for use statement(s):

Prescription use

4. Special instrument Requirements:

Abbott ARCHITECT i2000_{SR} System

I. Device Description:

The Abbott ARCHITECT STAT Troponin-I Controls contain a recombinant human cardiac troponin-IC complex in BES buffer with protein (human and fish) stabilizers. Human donor units have been tested and found to be non reactive for HBsAg, HIV-1 Ag, anti-HCV, and anti-HIV-1/HIV-2. Preservatives include antimicrobial and antifungal agents.

The controls are stable for 12 months from the date of manufacture when stored at -10 °C. Unopened and opened vials, when stored tightly capped, are stable for 30 days when stored at 2-8 °C.

This product will be sold in a kit with 2 vials of level L, M and H, in 3 mL vials.

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

MAS[®] CardioImmune[®] TL Cardiac Marker Control

2. Predicate K number(s):

MAS[®] CardioImmune[®] TL k032335

3. Comparison with predicate:

General Information	MAS [®] CardioImmune [®] TL	Abbott ARCHITECT STAT Troponin-I
501(k) Number	k032335	K041194
Product Code	JJY/JJX	JJX
Intended Use	For use in the clinical laboratory as an assayed control serum suitable for monitoring assay conditions in specific cardiac marker determinations. Include with patient serum specimens when assaying for any of the listed	The ARCHITECT [®] Troponin-I Controls are for verification of the accuracy and precision of the ARCHITECT i2000 _{SR} System when used for the quantitative determination of cardiac Troponin-I in human serum and plasma.

	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.	Refer to the ARCHITECT <i>STAT</i> Troponin-I reagent package insert for additional information.
Product state at purchase	Frozen	Frozen
Stability Claims	36 months unopened at -20 °C 180 days unopened at 2-8 °C 30 days opened at 2-8 °C	12 months unopened at -10 °C 30 days unopened at 2-8 °C 30 days opened at 2-8 °C
Constituents	CK-MB, Creatinine Kinase-MB Isoenzyme	
	CRP	
	Digoxin	
	Myoglobin	
	Troponin-I	Troponin-I
	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
Preservatives	Sodium Azide	Proclin 5000

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:* NA

b. *Linearity/assay reportable range:* NA

c. *Traceability (controls, calibrators, or method):*

Control target ranges were established using two Architect systems with the In-house Master Lot Calibrator and two lots of reagent. 140 replicates per control were run on each analyzer for four runs. Calibration replicates must fall within allowed range for the appropriate general specification. Total CV% for all replicates for each On-Test control for each system/reagent combination or run may not exceed

10%. Grubs Test at a 95% Confidence is used to evaluate the data. A grand mean is calculated using all accepted values from the four runs (N=140). An interval of +/- 30% is calculated for the grand mean of each control. The published value of each control grand mean and range are reported to 2 decimal places.

Stability studies were performed using three lots on opened vials at 2-8 °C for 30 days on Levels L, M and H. The 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 4 °C

Analyte	Unit	Level L			Level M			Level H		
		Fresh	30 days	% Change	Fresh	30 days	% Change	Fresh	30 days	% Change
Troponin-I	ng/mL	0.136	0.139	1.9	0.557	0.554	-0.5	14.896	14.567	-2.3

Table 2. Real Time Data, **Closed Vial Data**, 30 days at 4 °C

Analyte	Unit	Level L			Level M			Level H		
		Fresh	30 days	% Change	Fresh	30 days	% Change	Fresh	30 days	% Change
Troponin-I	ng/mL	0.146	0.138	-5.8	0.556	0.560	0.7	14.608	14.710	0.8

Arrhenius studies were performed to establish shelf life (12 months) 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 30 days at 4 °C. Results are tabulated in Table 3 for Level L, M and Level H.

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

Analyte	Unit	Level L			Level M			Level H		
		Fresh	30 days	% Change	Fresh	30 days	% Change	Fresh	30 days	% Change
Troponin-I	ng/mL	0.146	0.138	-5.8	0.556	0.560	0.7	14.608	14.710	0.8

The following concentration ranges may be used for individual replicate control specifications on the ARCHITECT i2000_{SR}:

Control	Target Concentration		Range	
	Ng/mL	µg/L	ng/mL	µg/L
Control L	0.13	0.13	0.09 – 0.17	0.09 – 0.17
Control M	0.56	0.56	0.39 – 0.73	0.39 – 0.73
Control H	15.77	15.77	11.04 – 20.50	11.04 – 20.50

The manufacturer recommends that each laboratory should establish its own concentration ranges for new control lots at each control level.

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: See the target ranges provided above in traceability.

N. Conclusion:

The submitted material in this premarket is complete and supports a substantially equivalence decision.