

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

**A. 510(k) Number:**

k062593

**B. Purpose for Submission:**

New Device

**C. Measurand:**

CK-MB, Troponin I, Myoglobin and BNP

**D. Type of Test:**

Quality control materials

**E. Applicant:**

Compass Bioscience

**F. Proprietary and Established Names:**

Cardiac Markers Control

Cardiac Markers Calibration Verification Control Set

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1660 - Quality Control Material

2. Classification:

Class I

3. Product code:

JJY

4. Panel:

Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See indications for use statement below.

2. Indication(s) for use:

The Compass Bioscience Cardiac Markers Controls are to be used as a quality control material to assess the accuracy and precision of laboratory test methods used to measure the antigens and enzymes contained in the control. It is intended to validate the measurement of these analytes in patient samples.

Three levels of control are provided to allow the performance of the analyte test methods to be monitored within the clinically significant range.

The Compass Bioscience Cardiac Marker Calibration Verification Control Set is used to verify the calibration of various test methods over the measurable range of the test.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Biosite Triage® MeterPlus, Abbott AxSYM® and Bayer ADVIA Centaur®

**I. Device Description:**

The Compass Bioscience Cardiac Markers Controls is a frozen tri-level human (2 vials per level) plasma based control containing preservatives, stabilizers and sodium azide.

The Compass Cardiac Markers Calibration Verification Control Set is frozen 4-level (2 vials per level) liquid human EDTA plasma based control set containing preservatives, stabilizers and sodium azide.

The four level calibration verification set includes a zero level as level 1. Levels 2-4 of the calibration verifiers are targeted at the same levels as levels 1-3 of the control.

All donor units used in the controls and calibrators have been tested using FDA

accepted methods and have been found non-reactive for Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C, HIV ½ and syphilis, and for HIV-1 and HCV RNA.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Liquid Cardiac Markers 1,2,3

Triage Profiler SOB Controls and Triage Profiler SOB Calibration Verification Controls

2. Predicate 510(k) number(s):

k050537

k040459

3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicate
Intended Use	Monitor the precision of test methods established in individual laboratories and to verify the calibration.	Monitor the precision of test methods established in individual laboratories and to verify the calibration.
Matrix	Human EDTA Plasma Liquid, Frozen	Human EDTA Plasma Liquid, Frozen
Type	Multi-analyte	Multi-analyte
Levels	Controls:3 Calibration verification materials:4	Controls:2 Calibrators:5

<b>Differences</b>		
Item	Device	Predicate
Analyte	CK-MB, Troponin I, Myoglobin, BNP	Ck-MB, Troponin I, Myoglobin, BNP, D-Dimer
Stability	-20°C Twelve months	-20°C Twenty-four months

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

NCCLS C24-A2 Statistical Quality Control for Quantitative Measurements

**L. Test Principle:**

N/A

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

N/A

b. *Linearity/assay reportable range:*

N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The Compass Bioscience Cardiac Marker Controls and Calibration Verification Controls are prepared from human plasma separated from whole blood drawn in EDTA anticoagulant at FDA inspected blood center from traceable donors. The materials are formulated to target concentrations for each analyte. The control ranges were established from in-house and interlaboratory data, based on replicate assays on the instruments listed in the package insert. Ranges were determined based on 2SD – 3SD of the overall mean values. The sponsor makes the recommendation in the labeling that each laboratory should establish its own parameters for the controls for each method.

*Stability*

Accelerated closed and real-time open stability studies were conducted with the Compass Bioscience Cardiac Marker Controls and Calibration Verification Control using the Kennon stability prediction models. The analytes studied were CK-MB, myoglobin, Troponin-I and BNP. Testing at the Compass Bioscience laboratory used the Triage MeterPlus with the Profiler SOB Panel, Triage CardioProfiler Panel and the Triage Cardiac Panel. Tested at an outside laboratories was conducted with the Abbott AxSYM and the Bayer ADVIA Centaur. Frozen control samples were allowed to that at room temperature (or incubation at refrigerated temperature for accelerated stability studies). Closed stability represents storage from -20 C. Open/closed vial stability represents storage at 2-8 C between uses. The

results from the accelerated studies support the sponsors' claims for open stability of 14 or 30 days and closed stability of 1 or 2 years depending on the analyte. Please see the following table for exact specifics.

The four level calibration verification set includes a zero level as level 1. Levels 2-4 of the calibration verifiers are targeted at the same levels as levels 1-3 of the control.

Compass Bioscience Cardiac Marker Controls			
		Open Closed	Closed
Level 1	CK-MB	30 days	2 years
	Myoglobin	30 days	2 years
	Troponin I	14 days	1 year
	BNP	14 days	1 year
Levels 2 & 3	CK-MB	30 days	2 years
	Myoglobin	30 days	2 years
	Troponin I	14 days	2 years
	BNP	14 days	2 years
Compass Cardiac Markers Calibration Verification Control Set			
		Open Closed	Closed
Level 2	CK-MB	30 days	2 years
	Myoglobin	30 days	2 years
	Troponin I	14 days	1 years
	BNP	14 days	1 years
Levels 3 & 4	CK-MB	30 days	2 years
	Myoglobin	30 days	2 years
	Troponin I	14 days	2 year
	BNP	14 days	2 year

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. *Assay cut-off:*

N/A

## 2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

*b. Matrix comparison:*

N/A

3. Clinical studies:

*a. Clinical Sensitivity:*

N/A

*b. Clinical specificity:*

N/A

*c. Other clinical supportive data (when a. and b. are not applicable):*

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Expected values for the materials are provided in the package insert. The sponsor makes the recommendation in the labeling that each laboratory should establish its own parameters for the controls for each method.

**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.