

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

A. 510(k) Number:

k093032

B. Purpose for Submission:

New devices: Triage® Total 3 Controls (TC3) and Triage® Total 3 Calibration Verification Set

C. Measurand:

Control and calibrator verification materials for CK-MB, Troponin I, and β -type natriuretic peptide (BNP)

D. Type of Test:

Quality control materials

E. Applicant:

Biosite Incorporated

F. Proprietary and Established Names:

Triage® Total 3 Controls

Triage® Total 3 Calibration Verification

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	21 CFR§862.1660	Chemistry 75

H. Intended Use:

1. Intended use(s):

See indication for use below.

2. Indication(s) for use:

The Triage® Total 3 Controls are assayed materials to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance.

The Triage® Total 3 Calibration Verification Set are assayed materials to be used with the Triage® Troponin I Test, Triage® BNP Test, Triage® Cardio2 Panel and Triage® Cardio3 Panel devices and the Triage® Meter to assist the end user in monitoring product performance

3. Special conditions for use statement(s):

Prescription Use

4. Special instrument requirements:

Triage® Meter

I. Device Description:

The Triage® Total 3 Controls consist of two levels, level 1 and level 2. The Triage® Total 3 Calibration Verification Set consists of 5 levels, Levels A, B, C, D, E. All are single-use, unit dose (approximately 0.25 ml) quality control materials prepared with concentrated purified CK-MB, troponin complex, and BNP in human EDTA plasma at defined levels. The controls are stored frozen < -20°C. Preservatives and stabilizers are added to maintain product integrity.

All human source materials used to produce this product have been tested for HbsAg, anti-HCV, HIV-1 and HIV-2 and found to be non-reactive by FDA licensed tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Triage® Total 5 Controls

Triage® Total 5 Calibration Verification Set

2. Predicate K number (s):

k072892

3. Comparison with predicate:

Similarities-Triage® Total Controls 3		
Item	Device	Predicate
Intended Use	The Triage Total 3 Controls are assayed materials to be used with the Triage Troponin I Test, BNP Test, Cardio2 panel and Cardio3 panel devices and the Triage meter to assist the end user in monitoring product performance.	The Triage Total Controls 5 are assayed materials to be used with the Triage Profiler S.O.B. Panel, Triage CardioProfiler Panel, Triage Cardiac Panel, Triage BNP Test, Triage D-Dimer Test and the Triage meters to assist in monitoring performance
Form	Liquid	Same
Analytes	CK-MB, Troponin I, BNP	CK-MB, myoglobin, Troponin I, BNP, D-dimer
Storage (Unopened)	≤ -20°C	Same
Matrix	EDTA Human Plasma	Same
Room Temp Claim	30 minutes	Same
Levels	2	Same
Packaging	Approximately 0.25 mL polystyrene unit-dose vial	Same

Differences-Triage® Total Controls 3		
Item	Device	Predicate
Packaging/Labeling	Triage ® Total Controls 3	Triage® Total Controls 5

Similarities-Triage® Total 3 Calibration Verification		
Item	Device	Predicate
Intended Use	The Triage Total 3 Calibration Verification are assayed materials to be used with the Triage Troponin I Test, Triage BNP Test, Triage Cardio2 Panel and the Triage Cardio 3 Panel devices and the Triage® meter to assist the end user in monitoring product performance.	The Triage Total Calibration Verification 5 materials are to be used with the Triage Profiler S.O.B. Panel, Triage CardioProfiler Panel, Triage Cardiac Panel, Triage BNP Test, Triage D-Dimer Test and the Triage Meters to verify the calibration of the Test Devices throughout the measurable range.
Form	Liquid	Same
Analytes	CK-MB, Troponin I, BNP	CK-MB, myoglobin, Troponin I, BNP, D-dimer

Storage (unopened)	≤ -20° C	Same
Matrix	EDTA Human Plasma	Same
Room Temp Claim	30 minutes	Same
Levels	5	Same

Differences-Triage® Total Calibration Verification 5		
Item	Device	Predicate
Packaging/Labeling	Triage® Total Calibration Verification 3	Triage® Total 5 Calibration Verification

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

FDA Guidance for Industry and FDA Staff: Assayed and Unassayed Quality Control Materials

Clinical and Laboratory Standards Institute guideline, EP5-A, Precision Performance of Quantitative Measurement Methods.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The within run precision (CV) of the CK-MB, Troponin, and BNP assay was performed by assaying the Total 3 Controls (low and high levels) for 20 days. This testing was considered to be representative of the Triage® Total 3 Calibration Verification Set. The controls were tested as they represent samples with CK-MB, Troponin I, and BNP concentrations near the clinical decision points and within the affected ranges. CLSI guideline EP5A, Evaluation of Precision Performance of Quantitative Measurement Methods was used as a guideline in performing and evaluating these studies,

Precision Study

Within Run CV			
	BNP (pg/mL)	CKMB (ng/mL)	Troponin (ng/mL)
High Sample (concentration)	2433.595 pg/mL	47.634 ng/mL	2.828 ng/ml
SD	346.993	5.643	0.2205
%CV	13.6%	11.8%	8.2%
Low sample (concentration)	104.096 pg/ml	7.632 ng/ml	0.060 ng/ml
SD	10.123	0.732	0.0106
%CV	9.5%	10.1%	15.6%
Total Precision CV			
	BNP	CKMB	Troponin
High Sample (concentration)	2433.595pg/ml	47.634 ng/ml	2.828 ng/ml
SD	355.446	5.829	0.2205
%CV	13.9%	12.2%	8.2%
Low Sample (concentration)	104.096 pg/ml	7.632 ng/ml	0.060 ng/ml
SD	10.131	0.743	0.0128
%CV	9.5%	10.3%	18.8%

b. *Linearity/assay reportable range:*

Not applicable

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

Traceability

Traceability for Troponin I, BNP and CKMB are to in-house prepared materials.

Stability

Real time closed vial stability was performed at $\leq -20^{\circ}\text{C}$. Recovery at all time points was acceptable for a stability of one month. The devices are single use products.

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 values are assigned to the Triage® Total 3 Controls and the Triage® Calibration Verification set by assaying multiple vials of Triage® Total 3 Controls (TC3) and Triage® Total 3 Calibration Verification on 20 days using multiple Triage test devices. The observed mean is used to establish the expected value range which is the mean ± 3 SD. The expected values of the Triage® Total 3 Controls (TC3) and Triage® Total 3 Calibration Verification Set are lot dependent and are listed on the Expected Values (EV) card for each level

In the labeling, the sponsor recommends that each laboratory establish their own acceptable ranges.

The following are examples for a lot specific material.

Control	Expected Values	CKMB,ng/mL	Troponin I,ng/mL	BNP, pg/mL
Control 1	Range	2.75 – 8.0	0.04 - 0.06	60.0 – 140.0
Control 2	Range	32.9 – 47.0	2.0 - 4.00	1925 – 2750

Cal Ver Level	Expected Values	CKMB,ng/ml	Troponin I,ng/ml	BNP, pg/mL
Level A	Range	1.0 - 3.0	0.013 - 0.030	10.0 - 36.5
Level B	Range	3.0 - 6.45	0.025 - 0.050	36.5 – 150
Level C	Range	20.0 - 37.1	0.50 - 2.00	1074 – 1994
Level D	Range	43.2 – 61.6	5.50 - 7.50	2300 – 3650
Level E	Range	62.6 – 80	8.00 – 10.0	3660 – 5000

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.