

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

A. 510(k) Number:

k040459

B. Purpose for Submission:

New device

C. Analyte:

CK-MB, Troponin I, Myoglobin, B-type natriuretic peptide (BNP), D-dimer

D. Type of Test:

Quality Control Material

E. Applicant:

Biosite Incorporated

F. Proprietary and Established Names:

Triage® Profiler S.O.B. (Shortness of Breath) Calibration Verification Controls
Triage® Profiler S.O.B. (Shortness of Breath) Controls

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1660
2. Classification:
Class I
3. Product Code:
JJY
4. Panel:
75

H. Intended Use:

1. Intended use(s):
The Triage® Profiler S.O.B. (Shortness of Breath) Calibration Verification Controls are to be used with the Triage® Profiler S.O.B. Panel and Triage® Meter Plus to verify the calibration of the Triage® Profiler S.O.B. Panel throughout the measurable range.

The Triage® Profiler S.O.B. (Shortness of Breath) Controls are to be used with the Triage® Profiler S.O.B. Panel and Triage® Meter Plus to assist the laboratory in monitoring test performance.

2. Indication(s) for use:
See Intended Use above

3. Special condition for use statement(s):

Prescription Use

4. Special instrument Requirements:

Triage® Meter Plus

I. Device Description:

The Triage® Profiler S.O.B. Calibration Verification Controls are supplied as five 0.5 mL vials at levels A, B, C, D, and E and are composed of EDTA human plasma containing < 0.1% sodium azide and CK-MB, Troponin I, Myoglobin, B-type natriuretic peptide (BNP), and D-dimer. The vials should be stored frozen at -20 °C or colder in a non-defrosting freezer and are stable until the date stamped on the box. The Calibration Verification Controls should be thawed at room temperature and mixed by vortexing prior to testing. Once thawed, the Calibration Verification Controls should be tested as soon as possible and should not be re-frozen. It is recommended that each vial be used once and discarded. The concentrations and standard deviations are printed on the enclosed insert.

The Triage® Profiler S.O.B. (Shortness of Breath) Controls are supplied as two 0.5 mL vials each of Control 1 and Control 2 and are composed of EDTA human plasma containing < 0.1% sodium azide and CK-MB, Troponin I, Myoglobin, B-type natriuretic peptide (BNP), and D-dimer. The vials should be stored frozen at -20 °C or colder in a non-defrosting freezer and are stable until the date stamped on the box. The controls should be thawed at room temperature and mixed by vortexing prior to testing. Once thawed, the controls should be tested as soon as possible and should not be re-frozen. It is recommended that each vial be used once and discarded. The concentrations and standard deviations are printed on the enclosed insert.

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

Triage® Cardio Profiler Calibration Verification Controls

Triage® Cardio Profiler Controls

2. Predicate K number(s):

k030088, k030089

3. Comparison with predicate:

| Similarities | | |
|---------------------|------------------------------------------------------------------|---------------------------------------------------------------------------|
| Item | S.O.B. Controls/Calibration Verification Controls | Cardio Profiler Controls/Calibration Verification Controls |
| Intended Use | Assayed control for monitoring test performance | Same |
| Matrix | EDTA plasma | Same |
| Form | Liquid | Same |
| Storage | -20°C or colder | Same |
| Differences | | |
| Item | S.O.B. | Cardio Profiler |

| | Controls/Calibration Verification Controls | Controls/Calibration Verification Controls |
|----------|--------------------------------------------|--------------------------------------------|
| Analytes | CK-MB, Troponin I, Myoglobin, BNP, D-dimer | CK-MB, Troponin I, Myoglobin, BNP |

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

None referenced

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):*

The Triage® Profiler S.O.B. (Shortness of Breath) Calibration Verification Controls and Triage® Profiler S.O.B. (Shortness of Breath) Controls have been standardized using purified protein preparations of D-dimer, CK-MB, Troponin I, myoglobin, and BNP based on mass (concentration) of analyte present in EDTA plasma.

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):*4. Clinical cut-off:

NA

5. Expected values/Reference range:

NA

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.