

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

A. 510(k) Number:

K050799

B. Purpose for Submission:

To obtain clearance for the Triage® D-Dimer Calibration Verification Controls and the Triage® D-Dimer Controls

C. Measurand:

D-dimer

D. Type of Test:

Quality Control

E. Applicant:

Biosite Incorporated

F. Proprietary and Established Names:

Triage® D-Dimer Calibration Verification Controls

Triage® D-Dimer Controls

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5425

2. Classification:

Class II

3. Product code:

GGN

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

The Triage D-Dimer Calibration Verification Controls are to be used with the Triage D-Dimer Test and Triage MeterPlus to verify the calibration of the Triage D-Dimer Test throughout the measurable range.

The Triage D-Dimer Controls are assayed materials to be used with the Triage D-Dimer Test and Triage Meter Plus to assist the laboratory in monitoring test performance.

2. Indication(s) for use:

The Triage D-Dimer Calibration Verification Controls are to be used with the Triage D-Dimer Test and Triage MeterPlus to verify the calibration of the Triage D-Dimer Test throughout the measurable range.

The Triage D-Dimer Controls are assayed materials to be used with the Triage D-Dimer Test and Triage Meter Plus to assist the laboratory in monitoring test performance.

3. Special conditions for use statement(s):

4. Special instrument requirements:

Triage MeterPlus

I. Device Description:

The Triage D-Dimer Calibration Verification Controls are supplied as five 0.25 mL vials at levels A, B, C, D, and E. Each vial is composed of EDTA human plasma containing preservatives and D-dimer. The concentrations and standard deviations are on the enclosed card.

The Triage D-Dimer Controls are supplied as five 0.25 mL vials at two levels (1 and 2). The vials are composed of EDTA human plasma containing preservatives and D-dimer.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Liquichek™ D-dimer Control Levels 1, 2 and 3

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

K032017

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analytes	D-dimer	Same
Form	Liquid	Same

Differences		
Item	Device	Predicate
Intended Use	Assayed control for monitoring test performance	Assayed quality control to monitor the precision of D-dimer procedures
Matrix	EDTA human plasma containing preservative and D-dimer	Processed human plasma with added constituents of human and animal origin and preservatives
Storage (unopened)	-20 °C or colder	2-8 °C until expiration date

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

None referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The Triage D-Dimer Calibration Verification Controls and Triage D-Dimer Controls were prepared using EDTA plasma at various concentrations. The Level 1 and Level 2 Controls were tested 8 times each at 10 different time

points using the Triage D-Dimer Controls. The % CV for the Level 1 control is 8.6% and the Level 2 control is 8.2%.

b. Linearity/assay reportable range:

Not applicable

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

An open vial stability study was conducted to determine the stability of the control material once removed from frozen storage. Samples were thawed on a bench top with an ambient room temperature of 22 °C. Samples were tested on the same lot of randomized Triage devices at 10, 15, 20, 30, 60, 90 and 120 minutes. Samples were tested on 6 devices at each time point. Acceptance criterion for the study was defined as D-dimer values being within the expected range ± 2 standard deviations. Acceptable performance was obtained when the controls were thawed between 10-120 minutes with 30 minutes being the recommended time point for a thawed vial.

Closed-vial stability studies are continual and are used to determine product expiration dating. The Triage D-Dimer Calibration Verification Controls and the Triage D-Dimer Controls were stored at -20 °C and data generated over the initial 9 months indicated that D-dimer present in the Triage D-Dimer Calibration Verification Controls and the Triage D-Dimer Controls are stable for at least 9 months at -20 °C.

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:

Lot specific

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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