

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

**A. 510(k) Number:** #K042890

**B. Purpose for Submission:** Device modification

**C. Measurand:** D-dimer

**D. Type of Test:** Quantitative

**E. Applicant:** Biosite, Inc.

**F. Proprietary and Established Names:** Triage® D-Dimer Test; Fibrin Split Products

**G. Regulatory Information:**

1. Regulation section: 21 CFR 864.7320 – Fibrin(ogen) Degradation Products
2. Classification: Class II
3. Product code: DAP, GHH
4. Panel: Hematology (81)

**H. Intended Use:**

1. Intended use(s): The Triage® D-Dimer Test is a fluorescence immunoassay to be used with the Triage® Meter Plus for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens. The test is used as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism.
2. Indication(s) for use: Same as Intended Use.
3. Special conditions for use statement(s): For professional and laboratory use.
4. Special instrument requirements: Biosite Triage® Meter Plus

**I. Device Description:** The Triage® D-Dimer Test is identical in principle, reagents and procedure to the Biosite Triage® Profiler S.O.B. Panel, which contains an assay for the D-dimer analyte. The D-Dimer Test consists of a murine monoclonal antibody (MAB) against D-dimer. The MAB is labeled with a fluorescent dye and immobilized on

a solid phase with stabilizers. The Kit contains (25), each, tests and transfer pipettes; and (1), each, reagent code chip and roll of printer paper.

**J. Substantial Equivalence Information:**

1. Predicate device name(s): Biosite Triage® Profiler S.O.B. Test; Dade Behring STRATUS CS DDMR Test
2. Predicate 510(k) number(s): #K040437; #K022976
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	D-dimer	Same
Principle	Fluorescence immuno-assay	Same
Instrumentation	Triage® Meter Plus	Same

Differences		
Item	Device	Predicate
Analyte(s)	Single	Multiple

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

**L. Test Principle:** When a whole blood sample is added to the sample port of the Triage® D-Dimer Test, the blood cells are separated from the plasma via a filter in the device. The plasma reacts with the fluorescent antibody conjugates in the reaction chamber. Following incubation, the reaction mixture flows down the detection lane. Analyte and antibody conjugate are captured in a binding assay. Analyte concentration in the sample is directly proportional to the detected fluorescence. Results are read on the Triage® Meter Plus instrument (#K973547).

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

1. Analytical performance:
  - a. *Precision/Reproducibility*: Three levels of controls were tested x (10)/day, over a 10-day period. Average within-day precision ranged from 6.0 – 14.4% CV. The average total precision ranged from 6.1 – 15.4% CV.

- b. *Linearity/assay reportable range:* Four donor plasmas were spiked with purified D-dimer, and diluted with unspiked plasma to cover the measuring range of 100 – 5000 ng/mL.

Actual vs expected results yielded a recovery between 80 – 115%, with an observed measuring range of 0.10 – 4.61 ug/mL. Regression statistics yielded slopes that ranged 0.95 – 1.03; and ‘R’ values of 0.99 – 1.00.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*  
The calibrator is traced to an in-house purified protein preparation of D-dimer, based upon the mass (concentration) of analyte present in plasma.
- d. *Detection limit:* A ‘zero’ calibrator was tested (20) times on (3) lots of reagent, using (2) different meters, over a 5-day period. The lower limit of detection (LLOD) was established as <100 ng/mL, with 95% confidence.
- e. *Analytical specificity:* A multiplicity of common pharmaceuticals, proteins and biologics were tested for interference. The following limits for interference were established for hemoglobin (5 mg/mL); lipids (30 mg/mL); bilirubin (0.15 mg/mL); fibrinogen (1 mg/mL); Fragment D (20 ug/mL); Fragment E (20 ug/mL); and hematocrit (<30% or >55%).
- f. *Assay cut-off:* N/A

## 2. Comparison studies:

- a. *Method comparison with predicate device:* The Triage® D-Dimer Test was compared to the Dade Behring STRATUS CS DDMR Test on patient samples (N = 180). Samples included: Healthy (N = 111), PE (N = 17), MI (N = 32), Angina (N = 11), CHF (N = 4), and Chest pain (N = 5), with values ranging from < 100 ng/mL to > 5000 ng/mL .

The study yielded these regression statistics:

$$\text{Slope} = 0.999 \qquad \text{Intercept} = (-) 85.89 \qquad \text{cc} = 0.92$$

A bias plot of the difference between methods vs the mean of all methods, demonstrated several outliers ( > ± 1000).

- b. *Matrix comparison:* A matrix comparison study was performed using samples (N = 22), in triplicate, of whole blood and plasma (EDTA). Samples ranged in value from 157 – 2997 ng/mL. The regression statistics from the study were:

$$y = 0.91x + 54.32; R^2 = 0.98. \text{ The ‘p’ value} = >0.05.$$

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):

4. Clinical cut-off: N/A

5. Expected values/Reference range: A reference range study was performed on healthy donors (N = 208), ranging in value from 10 – 1850 ng/mL. Donor samples were from males (N = 131) and females (N = 77), who ranged 19-79 years of age. The 90<sup>th</sup> % = 400 ng/mL; and the 95<sup>th</sup> % = 600 ng/mL.

**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.