

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

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

K062840

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Protein C

**D. Type of Test:**

Quantitative

**E. Applicant:**

Biosite Incorporated

**F. Proprietary and Established Names:**

Triage® Protein C Controls  
Triage® Protein C Calibration Verification Controls

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.5425, Multipurpose System for In-Vitro Coagulation Studies

2. Classification:

Class II

3. Product code:

GGN, Plasma, Coagulation Control

4. Panel:

Hematology (81)

**H. Intended Use:**

1. Intended use(s):

The Triage Protein C Controls are assayed material to be used with the Triage Protein C Test to assist the laboratory in monitoring test performance.

The Triage Protein C Calibration Verification Controls may be used to validate the performance of the Triage Protein C Test throughout the measurable range of the assay.

2. Indication(s) for use:

The Triage Protein C Controls are assayed material to be used with the Triage Protein C Test to assist the laboratory in monitoring test performance.

The Triage Protein C Calibration Verification Controls may be used to validate the performance of the Triage Protein C Test throughout the measurable range of the assay.

3. Special conditions for use statement(s):

To be used with the Triage Protein C Test. They are not calibrators and are not to be used to calibrate the Triage Protein C Test. The results of the quality control testing do not impact direct patient care and should not influence clinical decision making process the physician uses to make clinical diagnosis for the patient.

4. Special instrument requirements:

Not applicable.

**I. Device Description:**

The Triage Protein C Controls 1 and 2, and Triage Protein C Calibration Verification Controls Levels A, B, and C are single-use, 0.25 mL unit dose liquid external quality control materials prepared with concentrated purified Protein C in human citrated plasma at defined levels. They are supplied in 0.23 mL polypropylene vials and stored frozen at  $< -20^{\circ}\text{C}$ .

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

Triage® BNP (B-Type Natriuretic Peptide) Controls  
PrognostiX CardioMPO™ Control Kit

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

K000230, K050029

3. Comparison with predicate:

Similarities				
Item	Device		Predicate	
	<b><i>Triage® Protein C Controls</i></b>	<b><i>Triage® Protein C Calibration Verification</i></b>	<b><i>Triage® BNP</i></b>	<b><i>PrognostiX CardioMPO™</i></b>
Intended use	To assist the laboratory monitoring test performance of the Triage Protein C Test	To assist the laboratory in validating the performance of the Triage Protein C Test throughout the measurable range of the assay.	To assist the laboratory in monitoring the accuracy and precision of the Triage BNP Test.	To use as an assayed control sample to monitor and evaluate precision and accuracy of the CardioMPO Test.
Form	Liquid	Same	Same	Same
Storage (unopened)	≤ - 20°C	Same	Same	Same
RT Claim	30 minutes	Same	Same	N/A
Levels	2	3	2	3

Differences				
Item	Device		Predicate	
Analytes	Protein C	Protein C	BNP	MPO
Matrix	Citrated Human Plasma	Same	EDTA Human Plasma	Human Serum

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

EP5-A2 *Evaluation of Precision Performance of Quantitative Measurement Methods: Approved Guideline* – Second Edition, NCCLS

**L. Test Principle:**

Control samples are to be used in place of patient samples. Approximately 0.25 mL of the control material is added to the sample port on the Triage Protein C Test

Cartridge. The Control sample reacts with the Protein C antibody conjugate within the reaction chamber of the Test Cartridge. The Test Cartridge is inserted into the Triage Meter. The Meter automatically performs the Protein C analysis after the sample has reacted with reagents contained within the Protein C Test Cartridge. Total test time approximately 15 minutes. The result is displayed on the Meter screen and can be printed. Internal assay controls (positive and negative controls) and automatic endpoint detection technology is used to indicate assay completion.

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

##### **1. Analytical performance:**

###### **a. *Precision/Reproducibility:***

A study was performed using 240 control samples. The samples, consisting of the Low Level (1.4 µg/ml), Medium Level (2.4 µg /ml) and the High Level (4.0 µg /ml) were tested in duplicates, twice a day, for 20 days at each of three testing sites. Testing was conducted by one operator at each site using the same single lot of Triage Protein C test reagent and one Triage Meter. The total Coefficient of Variation varied from 11% to 17%.

###### **b. *Linearity/assay reportable range:***

Value assignment:

The concentration of bulk Protein C solution is verified. The control materials are tested twice per day over a two day period (replicates of eight using eight Triage Protein C Test lots in each assay run). The results are averaged together to yield an overall Protein C concentration for the bulk solution that must fall within a pre-defined specification.

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

An **open vial** stability study was performed using Controls 1 (Calibration Verification Control Level A) and Control 2 (Calibration Verification Control Level B) using three lots of product to support the one hour time point specified in the package insert.

A **closed vial** stability study was performed using three lots of Protein C High and Low Controls to determine shelf-life stability when stored at < 20°C. Results demonstrated that the Protein C Controls are stable for two months.

###### **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:

Results should fall within the expected ranges provided on the enclosed Expected Value Card that is specific for each lot number.

**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.

