

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

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

K042333

**B. Purpose for Submission:**

To seek the clearance of a new device, and the modification of a currently cleared device.

**C. Measurand:**

The ProC® Control Plasma controls the Factor V Leiden assay. The Control Plasma N controls for the Prothrombin time (PT), Activated partial thromboplastin time (APTT), Thrombin Time (TT), Bactroxobin time, Fibrinogen, Coagulation Factors II, V, VII, VIII, vWF, IX, X, XI, XII, inhibitors: Antithrombin III, protein C, protein S,  $\alpha$ 2-antiplasmin, Plasminogen, Lupus anticoagulants and Factor V Leiden.

**D. Type of Test:**

Quantitative

**E. Applicant:**

Dade Behring, INC

**F. Proprietary and Established Names:**

ProC® Control Plasma

Control Plasma N

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.5425 Multipurpose Systems for In Vitro Coagulation Studies

2. Classification:

Class II

3. Product code:

GGN

4. Panel:

81

**H. Intended Use:**

1. Intended use(s):

The Control Plasma N is an assayed control used to monitor the performance of the following parameters in the normal range: Prothrombin time (PT), Activated partial thromboplastin time (APTT), Thrombin Time (TT), Baxtroxobin time, Fibrinogen, Coagulation Factors II, V, VII, VIII, vWF, IX, X, XI, XII, inhibitors: Antithrombin III, protein C, protein S,  $\alpha$ 2-antiplasmin, Plasminogen, Lupus anticoagulants and Factor V Leiden.

The ProC® Control Plasma is an assayed control intended to monitor the performance of Factor V Leiden assay in the pathological range.

2. Indication(s) for use:

Same

3. Special conditions for use statement(s):

Not Applicable

4. Special instrument requirements:

Not Applicable

**I. Device Description:**

Control Plasma N is a lyophilized control prepared from pooled human plasma, stabilized with HEPES buffer solution.

The ProC® Control Plasma is a lyophilized control prepared from pooled plasma

from selected health donors which is adjusted to a defined sensitivity value by the addition of rabbit plasma. Rabbit Factor V, like human Factor V Leiden, is not rapidly degraded by Activated Protein C (APC), thus reducing the coagulation time in APC dependent tests. The control is stabilized with HEPES buffer solution.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Control Plasma N

Chromogenix Control Plasma Level 2

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

K023309

K963111

3. Comparison with predicate:

<b>Similarities- Control Plasma N</b>		
Item	Device	Predicate
Matrix	Stabilized reagent prepared from pooled human plasma	same
Intended Use	To provide quality control in the normal range	same
Form	Lyophilized	same
Instrumentation	Mechanical and photo-optical	same

<b>Differences</b>		
Item	Device	Predicate
Analytes	PT, APTT, TT, Baxtroxobin time, Fibrinogen, Coagulation Factors II, V, VII, VIII, vWF, IX, X, XI, XII, inhibitors:	All except Factor V Leiden

<b>Differences</b>		
Item	Device	Predicate
	Antithrombin III, protein C, protein S, $\alpha$ 2-antiplasmin, Plasminogen, Lupus anticoagulants and Factor V Leiden.	

<b>Similarities- ProC® Control Plasma</b>		
Item	Device	Predicate
Intended Use	To monitor the performance of Factor V Leiden assay in the pathological range	same
Analyte	Factor V Leiden	same
Form	Lyophilized	same

<b>Differences</b>		
Item	Device	Predicate
Matrix	Pooled plasma from healthy human donors adjusted with rabbit plasma	Citrated human plasma from selected donors
Instrumentation	For use on photo-optical coagulation systems	For use on turbidimetric, photometric and electro-mechanical coagulation systems

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

Not Applicable

**L. Test Principle:**

Not Applicable

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

1. Analytical performance:

*a. Precision/Reproducibility:*

Not Applicable

*b. Linearity/assay reportable range:*

Not Applicable

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

Real time stability studies were performed on two lots of control material using at least duplicate determinations. Results were within  $\pm 10\%$  of the initial reconstituted value for the following claims: 4 hours @ 15 to 25°C, 8 hours @ 2 to 8°C, and 4 weeks @ -20°C or below (10 Min thawing @ 37°C), and support a support-life expiration of more than 3 months.

Values for the Factor V Leiden for both the ProC® Control Plasma and Control Plasma N are calculated using the mean of at least 12 single determinations on multiple analyzers with multiple reagent lots. Separate assigned values are reported for Dade Behring BCS® analyzer and Sysmex® CA analyzers (CA-1500 and CA-7000).

Sensitivity of ProC® Control Plasma as a quality control material for Factor V Leiden assay was verified during studies conducted for performance evaluation of Dade Behring Factor V Leiden assay with the BCS® analyzer. In those studies, a total of 42 specimens from individuals who were previously diagnosed as Factor V Leiden deficient were divided and tested in three different runs. For each run, ProC® Control Plasma was tested twice as positive control material. All specimens were found to be positive for Factor V Leiden by the screening reagent and the control recovered within the expected range.

*d. Detection limit:*

Not Applicable

*e. Analytical specificity:*

Not Applicable

*f. Assay cut-off:*

- g. 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:  
Not Applicable

**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.

