

**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), Baxtroxobin time, Fibrinogen, Coagulation Factors II, V, VII, VIII, vWF, IX, X, XI, XII, inhibitors: Antithrombin III, protein C, protein S, α 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, α 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:

Similarities- Control Plasma N		
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

Differences		
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

Differences		
Item	Device	Predicate
	Antithrombin III, protein C, protein S, α 2-antiplasmin, Plasminogen, Lupus anticoagulants and Factor V Leiden.	

Similarities- ProC® Control Plasma		
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

Differences		
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 that 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 form 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.

