

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

A. 510(k) Number: #K042209

B. Purpose for Submission: Bundled 510(k) for device modification

C. Measurand: Multiple coagulation analytes, Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (FIB) and Plasminogen; Inhibitors, Protein C/S, Antithrombin (ATIII) and a2-antiplasmin; Factors, II, V, VII, VIII, vWF, IX, X, XI, and XII. Control Plasma N has additional analytes, Thrombin Time (TT), Batroxobin Time and Lupus anticoagulants.

D. Type of Test: Quantitative; clotting and chromogenic tests.

E. Applicant: Dade Behring, Inc.

F. Proprietary and Established Names: Dade Behring Control Plasma N and Dade Behring Control Plasma P

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 (Both controls); GIZ (Control Plasma N); GGC (Control Plasma P)
4. Panel: Hematology (81)

H. Intended Use:

1. Intended use(s): Control Plasma N and Control Plasma P are assayed controls used to monitor the performance of parameters in the normal and pathological ranges.
2. Indication(s) for use: Same as Intended Use.
3. Special conditions for use statement(s): N/A
4. Special instrument requirements: Mechanical and photo-optical instrumentation such as the Dade Behring BCS, BCT and Sysmex CA instruments.

I. Device Description:

Control Plasma N and P are prepared from pooled human plasma that is collected from healthy blood donors and stabilized with HEPES buffer. Control Plasma P is additionally adjusted to defined factor concentrations. Both plasmas are then lyophilized and supplied in 10 x 1 ml siliconized vials.

J. Substantial Equivalence Information:

1. Predicate device name(s): Dade Behring Control Plasma N; Dade Behring Control Plasma P
2. Predicate 510(k) number(s): #K023309; #K023312
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Configuration	Pooled human plasma in HEPES buffer	Same
Stability (reconstituted)	(4) hours at 2° – 15° C.; (4) weeks at -20° C.	Same
Instrumentation	Mechanical and photo-optical instruments	Same
Calibration	WHO based and in-house standards	Same

Differences		
Item	Device	Predicate
Value assignment process	Values declared from the mean \pm 2SD of previous lots of control	Values assigned on (2) lots of control, from duplicates run on (3) different instruments.

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

L. Test Principle:

The Dade Behring BCT, BCS and Sysmex CA analyzers are examples of mechanical and photo-optical coagulation systems, on which the control plasmas may be used.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

- a. Precision/Reproducibility:* Retrospective data from Control Plasma N (N = 68) and Control Plasma P (N = 54) were applied to determine value assignment.

For Control Plasma N, all parameters generated mean values that fell within 2.1 – 4.5 % CV.

For Control Plasma P, all parameters generated mean values that fell within 3.0 – 8.1% CV.

- b. Linearity/assay reportable range:* N/A
- c. Traceability, Stability, Expected values (controls, calibrators, or methods):* World Health Organization (WHO) based reference preparations and 2° in-house standards.
- d. Detection limit:* N/A
- e. Analytical specificity:* N/A
- f. Assay cut-off:* N/A

2. Comparison studies:

- a. Method comparison with predicate device:* N/A
- b. Matrix comparison:* N/A

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): N/A
- 4. Clinical cut-off: N/A
- 5. Expected values/Reference range: Control Plasma N generates values within the normal range for monitored parameters. Control Plasma P generates values within the pathological range for monitored parameters.

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.