

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

A. 510(k) Number:

K050928

B. Purpose for Submission:

To obtain clearance for Dade[®] Thrombin Reagent and Dade[®] Owren's Veronal Buffer for use in the measurement of fibrinogen. Dade Behring is modifying the packaging configuration of the Dade[®] Fibrinogen Determination kits so that the kit components Dade[®] Thrombin Reagent and Dade[®] Owren's Veronal Buffer may be sold separately. No changes are being made to the operating principle or reagent composition.

C. Measurand:

Fibrinogen

D. Type of Test:

Fibrinogen determination

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dade[®] Thrombin Reagent

G. Regulatory Information:

1. Regulation section:

21 CFR 864.7340

2. Classification:

Class II

3. Product code:

KQJ

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

For use in the quantitative determination of fibrinogen in plasma and to accelerate coagulation of anticoagulated samples for immunohematology.

2. Indication(s) for use:

For use in the quantitative determination of fibrinogen in plasma and to accelerate coagulation of anticoagulated samples for immunohematology.

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

A quantitative assay for fibrinogen (Clauss method) is performed by measuring the clotting time of dilute plasma when excess thrombin is added. The clotting time obtained is then compared with that of a standardized fibrinogen preparation.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dade[®] Fibrinogen Determination Reagents (pre-1976)

Dade[®] Thrombin Reagent

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

BK 860038

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Reagent Composition	Lyophilized preparation of bovine thrombin (approximately 100 NIH units) with stabilizers and buffers	Same

Differences		
Item	Device	Predicate
Assay components	Dade [®] Thrombin Reagent Dade [®] Owren's Veronal Buffer. Individually packaged and sold separately	Dade [®] Thrombin Reagent Dade [®] Fibrinogen Standard Dade [®] Owren's Veronal Buffer

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

Not applicable

L. Test Principle:

The enzyme thrombin converts the soluble plasma protein fibrinogen into its insoluble polymer fibrin. The clotting time for diluted plasma is inversely proportional to the fibrinogen concentration of the plasma. By using this principle, Clauss developed a simple procedure for determining fibrinogen based on measuring the clotting time of diluted plasma after the addition of thrombin. The clotting time obtained in this manner is then compared with that of a standardized fibrinogen preparation.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The Dade[®] Thrombin Reagent assay was used to measure fibrinogen concentrations ranging from 0.89 to 2.8 g/L in Control Plasma N (K045333), Control Plasma P (K042209), low plasma pool (PPL), normal plasma pool (PPN) and Dade Data Fi[®] abnormal fibrinogen control (aFCP) (K811069). Eight determination per day over 5 days (n=40) were performed using a Sysmex[®] CA-1500 analyzer. The following is a summary of precision data:

	Mean value (g/L)	Within run (% CV)	Between run (% CV)	Total (%CV)
Control Plasma N	2.6	5.9	0.0	5.9
Control Plasma P	0.89	4.8	0.0	4.8
Low Plasma Pool	0.95	7.1	2.3	7.4
Normal Plasma Pool	2.8	3.5	0.0	3.5
Data Fi [®] Abnormal Control	1.1	3.8	2.4	4.5

b. Linearity/assay reportable range:

Not applicable

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

Not applicable

d. Detection limit:

Not applicable

e. Analytical specificity:

Interference testing was performed to determine the effect of icterus, lipemia, hemolysis, and heparin on the Dade[®] Thrombin Reagent assay. Normal and abnormal plasma sample preparations were spiked with increasing concentrations of each interferent. For each spiked level, the % recovery was determined [% Recovery = (Test result / Baseline) x 100]. The acceptance criterion was established as 0.25 g/L relative deviation from the base pool.

Material	No interference up to:
Bilirubin	60 mg/dL
Hemoglobin	600 mg/dL
Triglycerides	728.6 mg/dL
Heparin (low molecular wt.)	0.4 U/mL
Heparin (unfractionated)	0.6 U/mL

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The Dade® Fibrinogen Determination Reagent kit was compared to the modified Dade® Thrombin Reagent assay by evaluating 80 plasma samples with concentrations ranging from 0.50 to 8.6 g/L using reference curves generated with two lots of Standard Human Plasma (SHP). Regression analysis yielded the following results:

SHP lot # 502587 - $r = 0.995$

SHP lot # 502589 - $r = 0.993$

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:

1.8 – 3.5 g/L

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.