

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

A. 510(k) Number: K080069

B. Purpose for Submission: Transfer of ownership of 510(k)

C. Measurand: D-Dimer

D. Type of Test: Latex Immuno Assay

E. Applicant: American Diagnostica Inc.

F. Proprietary and Established Names: DIMERTEST®

G. Regulatory Information:

1. Regulation section: 864.7320
2. Classification: II
3. Product code: DAP
4. Panel: Hematology

H. Intended Use:

1. Intended use(s): The DIMERTEST® latex kit is intended for the rapid qualitative or semi-quantitative evaluation of circulating derivatives of cross-linked fibrin degradation products (D-dimer) in human plasma.
2. Indication(s) for use: same as Intended Use.
3. Special conditions for use statement(s): N/A
4. Special instrument requirements: N/A

I. Device Description:

The kit is comprised of: latex reagent (latex beads coupled with murine anti-D-Dimer monoclonal antibody), positive control, negative control, buffer, test cards, and stirrers.

J. Substantial Equivalence Information:

1. Predicate device name(s): DIMERTEST[®]
2. Predicate K number(s): K974596
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
510(k)	Same as predicate	K974596

Differences		
Item	Device	Predicate
510(k)	No differences	K974596

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

L. Test Principle: see K974596

M. Performance Characteristics (if/when applicable):

1. Analytical performance: see K974596
 - a. *Precision/Reproducibility*:
 - b. *Linearity/assay reportable range*:
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods)*:
 - d. *Detection limit*:
 - e. *Analytical specificity*:
 - f. *Assay cut-off*:
2. Comparison studies: see K974596
 - a. *Method comparison with predicate device*:
 - b. *Matrix comparison*:
3. Clinical studies: N/A
 - a. *Clinical Sensitivity*:

b. Clinical specificity:

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off: see K974596

5. Expected values/Reference range: see K974596

N. Proposed Labeling: see K974596

O. Conclusion:

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