

**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<sup>®</sup>

**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<sup>®</sup> 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:

<b>Similarities</b>		
Item	Device	Predicate
510(k)	Same as predicate	K974596

<b>Differences</b>		
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.