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

A. 510(k) Number:

K062203

B. Purpose for Submission:

Modification to the intended use and reagent formulation (a pH change of a buffer)

C. Measurand:

D-dimer

D. Type of Test:

Immunoturbidimetric

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

Tina-Quant D-dimer

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.7320

2. Classification:

   Class II

3. Product code:

   GHH

4. Panel:

   81 Hematology

H. Intended Use:

1. Intended use(s):

The Roche diagnostics Tina-Quant D-dimer assay is an immunoturbidimetric assay for the in vitro quantitative determination of fibrin degradation products including d-dimer and x-oligomers in human plasma. In conjunction with a non-high clinical probability assessment, a normal (<0.5 µg FEU/mL) result excludes deep vein thrombosis (DVT) and pulmonary embolism (PE) with high sensitivity.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

Roche automated clinical chemistry analyzers

I. Device Description:

The Roche Tina-quant D-dimer is an immunoturbidimetric assay consisting of a ready to use tris buffer and a ready to use anti-d-dimer latex suspension.

J. Substantial Equivalence Information:

1. Predicate device name(s):

a. Roche Diagnostics Tina-Quant D-Dimer Test System

b. Biomerieux Vidas D-Dimer Exclusion Assay

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

a. K030740

b. K040822

3. Comparison with predicate:

Similarities			
Item	Device	Predicate (a)	Predicate (b)
Intended Use	Quantitative d-dimer and in conjunction with PTP, exclude DVT and PE		same
Quality control	Bi-level	Same	same

Item	Device	Predicate (a)	Predicate (b)
Intended Use	Quantitative d-dimer and in conjunction with PTP, exclude DVT and PE	Quantitative d-dimer	
Technology	Immunoturbidimetric	Same	Enzyme Linked Fluorescent Assay
Sample Matrix	Citrated Plasma Lithium Heparin Plasma	Same	Citrated Plasma
Buffer	Anti-D-dimer latex suspension in Tris Buffer pH7.2	Anti-D-Dimer latex suspension in Tris buffer pH 8.2	NA

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

L. Test Principle:

The Tina-quant D-Dimer Test System is based on a particle enhanced immunoturbidimetric method. Latex particles of uniform size are coated with monoclonal antibodies (F(ab')2 fragments) to the D-dimer epitope. The antigen/antibody complexes produced by the addition of samples containing D-dimer lead to an increase in the turbidity of the test reactants, which can be determined

turbidmetrically.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

Within-run	Roche/Hitachi
0.19µg FEU/mL	7.3%
0.86 µg FEU/mL	1.7%
5.11 FEU/mL	0.8%
	COBAS Integra
0.279 µg FEU/mL	6.9%
2.88 µg FEU/mL	1.1%

   b. *Linearity/assay reportable range:*

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

   d. *Detection limit:*

Roche/Hitachi:	COBAS Integra:
0.04 µg FEU/mL	<0.08 µg FEU/mL

   e. *Analytical specificity:*

   f. *Assay cut-off:*

2. Comparison studies: N/A

   a. *Method comparison with predicate device:*

   b. *Matrix comparison:*

3. Clinical studies:

a. *Clinical Sensitivity:*

DVT Exclusion

Tina-Quant® D-dimer was used in a multicenter management study involving 812 outpatients with suspected DVT. Patient pre-test probability (PTP) was assessed following Wells probability score. Patients were classified as high (≥3) or non-high (<3), and the Tina-Quant® D-dimer test was then performed using a cutoff of 0.5 µg FEU/mL. Those patients with a normal (negative) d-dimer, and a non-high pretest probability had no further diagnostic testing and were followed for 3 months for development of DVT. 1 of 176 such patients developed DVT during the follow-up period. Sensitivity, NPV and Failure rates were determined as follows:

Sensitivity:	99.3%
NPV	99.4%
Failure Rate:	0.6%

PE Exclusion

Tina-Quant® D-Dimer was used in a management study involving 168 outpatients with suspected PE. Patient pre-test probability (PTP) was assessed following Wells probability score for PE. Patients were classified as having a low, moderate, or high pretest probability of PE, and the Tina-Quant® D-dimer test was then performed using a cutoff of 0.5 µg FEU/mL. Those patients with a normal (negative) d-dimer, and a non-high (low or moderate) pretest probability had no further diagnostic testing and were followed for 3 months for development of PE. No patients developed PE during the follow-up period. Sensitivity, NPV and Failure rates were determined as follows:

Sensitivity:	100%
NPV	100%
Failure Rate:	0%

b. *Clinical specificity:*

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

4. Clinical cut-off**:**

    N/A

5. Expected values/Reference range:

    N/A

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.