

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

**A. 510(k) Number:**

K050817

**B. Purpose for Submission:**

Seek clearance of a new device

**C. Analyte:**

Thrombin

**D. Type of Test:**

Quantitative clotting assay

**E. Applicant:**

R2 Diagnostics

**F. Proprietary and Established Names:**

T-Tek Thrombin Time Test

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.7875

2. Classification:

Class II

3. Product Code:

GJA

4. Panel:

81 Hematology

**H. Intended Use:**

1. Intended use(s):

The T-Tek thrombin time reagent is intended for use in the quantitative determination of Thrombin Time (TT) in citrated human plasma in the general population. T-Tek should be used in the clinical laboratory by qualified laboratory professionals. The test may be performed using manual, semi-automated, or automated coagulation analyzers.

2. Indication(s) for use:

3. Special condition for use statement(s):

4. Special instrument Requirements:

**I. Device Description:**

The T-Tek Thrombin Time Reagent is a lyophilized preparation of human thrombin packaged in 10 x 1 mL vials of approximately 10 NIH units per mL.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

American Bioproducts, Diagnostica Stago Thrombin-PREST

2. Predicate K number(s):  
K884384
3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended use	Quantitative determination of thrombin time	same
Sample requirement	Citrated plasma	same
Design	Single component	same
Source Material	Human Thrombin	same
<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Preparation	Lyophilized	Freeze-dried
Reagent Potency	~10 NIH units/mL	~1.5 NIH units/mL

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

NCCLS EP-5-A Approved Guidelines; *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline*,  
 NCCLS EP-7-A Approved Guidelines; *Interference Testing in Clinical Chemistry; Proposed Guideline*,  
 NCCLS EP-9-A Approved Guidelines; *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*,

**L. Test Principle:**

Thrombin is a coagulation enzyme that acts on soluble fibrinogen converting it to an insoluble fibrin clot. Low plasma fibrinogen levels, abnormal fibrinogen molecules and substances such as heparin or fibrin degradation products, will prolong the thrombin clotting time.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-Run: 10 vials of 3 levels of lyophilized controls were pooled, and tested in duplicate with the T-Tek Thrombin Time assay on the ACL 3000 and STA Compact. CV's < 7%.

Between-Run: 2 vials of each sample was pooled and tested in duplicate for 5 days with the T-Tek Thrombin Time assay on the ACL 3000 and STA Compact. CV's <4%.

b. *Linearity/assay reportable range:*

c. *Traceability (controls, calibrators, or method):*

d. *Detection limit:*

e. *Analytical specificity:*

A set of samples containing potential interfering substances from clinical samples was tested in duplicate on the ACL 3000 and STA Compact. Results demonstrate interference from hemolysis, lipemia, bilirubin, heparin, and direct thrombin inhibitors. The device labeling carries a warning against the use of these types of samples.

*f. Assay cut-off:*

2. Comparison studies:

*a. Method comparison with predicate device:*

A 2 site comparison study was performed using frozen samples. Site 1 performed testing on the STA Compact (n= 125,  $y = 1.2043x - 4.904$ ,  $r=0.894$ ). Site two was an in-house site, and testing was performed on the ACL3000 (n=128,  $y=0.848x + 3.466$ ,  $r=0.895$ ).

*b. Matrix comparison:*

3. Clinical studies:

*a. Clinical sensitivity:*

*b. Clinical specificity:*

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

4. Clinical cut-off:

5. Expected values/Reference range:

120 normal donor plasma samples were tested in duplicate with the T-Tek on the ACL3000 and STA Compact. Normal reference interval determined at the 10<sup>th</sup> and 90<sup>th</sup> percentile is 13-15 secs on the ACL3000, and 16-18 secs on the STA Compact.

**N. Conclusion:**

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