

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

A. 510(k) Number:

K040296

B. Purpose for Submission:

New device

C. Analyte:

Prothrombin Time (PT)

D. Type of Test:

Quantitative

E. Applicant:

R2 Diagnostics, Inc.

F. Proprietary and Established Names:

Phosphoplastin RL; Prothrombin Time Test

G. Regulatory Information:

1. Regulation section:
CFR 864.7750 – Prothrombin Time Test
2. Classification:
Class II
3. Product Code:
GJS
4. Panel:
Hematology (81)

H. Intended Use:

1. Intended use(s):
R2 Diagnostics Phosphoplastin RL Prothrombin Time (PT) Test Reagent is intended for in vitro diagnostic use in a one-stage prothrombin time (PT) test on citrated human plasma. The PT Test is a quantitative assay used in the general patient population for routine screening to detect deficiencies in the extrinsic pathway of coagulation. The PT test is also used to monitor oral anticoagulant (OAC) therapy and should be used in a clinical laboratory by qualified laboratory personnel.
2. Indication(s) for use:
Same as above

3. Special condition for use statement(s):
N/A
4. Special instrument Requirements:
Mechanical and photo-optical coagulation analyzers

I. Device Description:

The Phosphoplastin RL PT Test Reagent is a quantitative, one-stage prothrombin time assay for routine screening to detect disorders of the extrinsic coagulation pathway and to monitor OAC therapy. The reagent consists of a liquid saline extract of rabbit brain, calcium ions, preservatives and stabilizers.

J. Substantial Equivalence Information:

1. Predicate device name(s):
R2 Diagnostics Phosphoplastin R
2. Predicate K number(s):
#K940082
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Ingredients	Rabbit brain thromboplastin with calcium ions	Same
Methods	Manual, automated, semi-automated	Same
Factor sensitivity	Factors II, V, VII and X	Same
Differences		
Item	Device	Predicate
Format	Liquid	Lyophilized
Normal range (ACL 3000+)	9.7 – 14.9 seconds	8.9 – 12.1 seconds

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

NCCLS documents: EP7-A, Interference Testing in Clinical Chemistry, Approved Guideline (2002); EP9-A2, Method Comparison and Bias Estimation Using Patient Samples, Approved Guideline-2nd Ed. (2002); EP10-A2, Preliminary Evaluation of Quantitative Clinical Laboratory Methods, Approved Guideline-2nd Ed. (2002); EP15-A, User Demonstration of Performance for Precision and Accuracy, Approved Guideline (2001); H21-A2, Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays, Approved Guideline (2001); and H47-A, One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test, Approved Guideline (1996).

L. Test Principle:

When Phosphoplastin RL PT Test Reagent is added to normal citrated plasma, the clotting mechanism is initiated to form a clot within a specified time. That time will be prolonged in instances of extrinsic pathway deficiencies. The degree of prolongation is proportional to the severity of the deficiency.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Three levels of quality controls were run in triplicate on the ACL 3000+ and STA Compact instruments. Within-run precision was performed on (10) vials to yield a range of 0.1 – 2.9% CV. Between-run precision was performed on (2) vials over (5) days to yield a range of 0.54 – 1.31%CV.

b. *Linearity/assay reportable range:*

N/A

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

The Hemostasis Reference Laboratory official protocol, used to assign the International Sensitivity Index (ISI), is based upon WHO thromboplastin reference material, CRM 149 S, which was calibrated against the RBT/90 international reference preparation (IRP).

d. *Detection limit:*

N/A

e. *Analytical specificity:*

A comparative interference study was performed on samples containing several levels of bilirubin, hemoglobin and lipids. Results demonstrated no significant difference between the predicate device, Phosphoplastin R, and the proposed Phosphoplastin RL PT Test reagents.

f. *Assay cut-off:*

N/A

2. Comparison studies:a. *Method comparison with predicate device:*

Patient samples (N= 105), normal and abnormal, were tested in triplicate and compared on the ACL 3000+ and STA Compact. The studies yielded the following regression statistics:

$$\text{ACL} - y = 0.6648x + 5.1833; R^2 = 0.9833 \text{ (Seconds)}$$

$$y = 1.0650x - 0.1245; R^2 = 0.9813 \text{ (INR)}$$

$$\text{STA} - y = 0.6441x + 5.2105; R^2 = 0.9405 \text{ (Seconds)}$$

$$y = 1.0590x - 0.1140; R^2 = 0.9200 \text{ (INR)}$$

Method comparison studies included oral anticoagulant, low and

high fibrinogen, normal, Factor deficient (II, V, VII, X), liver disease, heparinized, and normal patient samples.

b. Matrix comparison:
N/A

3. Clinical studies:

a. Clinical sensitivity:
N/A

b. Clinical specificity:
N/A

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

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Normal donors (N=120) were tested and compared on the ACL 3000+ and STA Compact analyzers. The studies yielded the following results:

	ACL 3000+	STA Compact
Mean	12.3 seconds	12.6 seconds
Range	9.68 – 14.92 seconds (Mean ± 2SD)	11.1 – 14.1 seconds (Mean ± 2SD)

N. Conclusion:

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