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

A. 510(k) Number:

K062306

B. Purpose for Submission:

To obtain clearance for the PlasmaCon N, PlasmaCon L-1, and PlasmaCon L-2 coagulation control plasmas.

C. Measurand:

Prothrombin Time and Activated Partial Thromboplastin Time

D. Type of Test:

Assayed controls

E. Applicant:

R^2 Diagnostics, Inc.

F. Proprietary and Established Names:

PlasmaCon N, PlasmaCon L-1, and PlasmaCon L-2

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5425

2. Classification:

   Class II

3. Product code:

   GIZ, GGC

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

   PlasmaCon N is a human lyophilized plasma control intended for use as a normal control with citrated plasma to monitor the performance of the Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT) tests.

   PlasmaCon L-1 is a human lyophilized plasma control intended for use as a mid-level abnormal control with citrated plasma to monitor the performance of the Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT) tests.

   PlasmaCon L-2 is a human lyophilized plasma control intended for use as a high level abnormal control with citrated plasma to monitor the performance of the Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT) tests.

2. Indication(s) for use:

   Same

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

The PlasmaCon Control Plasma devices contain lyophilized citrated human plasma for use in the verification of system performance for PT and aPTT assays. The PlasmaCon Control plasmas are packages in 10 vials each containing 1 ml of reagent. Controls plasmas should only be used in an appropriate clinical laboratory by qualified laboratory professionals. The tests may be performed manually or using semi-automated and automated coagulation analyzers.

PlasmaCon N is prepared from a pool of fresh citrated plasma from donors with normal coagulation parameters. The pooled plasma is buffered with Hepes and lyophilized to maximize stability of all plasma constituents.

PlasmaCon L-1 and PlasmaCon L-2 are prepared from a pool of fresh citrated plasma from donors with normal coagulation parameters. The pooled plasma is depleted of clotting factors II, VII, IX, and X. The control plasma is buffered with Hepes and lyophilized to maximize stability of all plasma constituents.

J. Substantial Equivalence Information:

1. Predicate device name(s):

a) Trinity Biotech Normal Coagulation Control Plasma
b) Trinity Biotech Abnormal Coagulation Control Plasma Level-1
c) Trinity Biotech Abnormal Coagulation Control Plasma Level-2

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

a) K895262
b) K895260
c) K895261

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	PlasmaCon N	***Normal Coagulation Control Plasma***
Intended Use	For use as a normal control with citrated plasma to monitor the performance of the PT and (aPTT) tests.	Use as a normal control in PT, aPTT, and fibrinogen determinations.
Matrix	Citrated human plasma	Citrated human plasma
Device compatibility	Manual, semi or fully automatic processing	Manual, semi or fully automatic processing

Differences		
Item	Device	Predicate
	PlasmaCon N	***Normal Coagulation Control Plasma***
Stability (reconstituted)	Stable for 8 hours when stored at 2 – 8° C.	Stable for 8 hours stored at room temperature.

Similarities		
Item	Device	Predicate
	PlasmaCon L-1	***Abnormal Coagulation Control Plasma Level 1***
Intended Use	For use as an abnormal mid-level control with citrated plasma to monitor the performance of the PT and	Use as an abnormal control in PT, aPTT, and fibrinogen determinations.

Similarities		
Item	Device	Predicate
	(aPTT) tests.	
Matrix	Citrated human plasma	Citrated human plasma
Device compatibility	Manual, semi- or fully automatic processing	Manual, semi- or fully automatic processing

Differences		
Item	Device	Predicate
	PlasmaCon L-1	***Abnormal Coagulation Control Plasma Level 1***
Stability (reconstituted)	Stable for 8 hours when stored at 2 – 8° C.	Stable for 8 hours stored at room temperature.

Similarities		
Item	Device	Predicate
	PlasmaCon L-2	***Abnormal Coagulation Control Plasma Level 2***
Intended Use	For use as an abnormal high control with citrated plasma to monitor the performance of the PT and (aPTT) tests.	Use as an abnormal control in PT, aPTT, and fibrinogen determinations.
Matrix	Citrated human plasma	Citrated human plasma
Device compatibility	Manual, semi- or fully automatic processing	Manual, semi- or fully automatic processing

Differences		
Item	Device	Predicate
	PlasmaCon L-2	***Abnormal Coagulation Control Plasma Level 2***
Stability (reconstituted)	Stable for 8 hours when stored at 2 – 8° C.	Stable for 8 hours stored at room temperature.

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

Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material, February 3, 1999.

L. Test Principle:

PlasmaCon Control reagents can be used in all testing in the same manner as may citrated plasma sample. Tests may be performed manually or using semi-automated and automated coagulation analyzers.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Data was collected for within run and between run precision using three levels of lyophilized controls according to procedures developed under CLSI EP15-A approved guidelines. Within run and between run precision studies obtained CV values of less than 15%.

For within run, 10 vials of each sample were pooled, tested in duplicate and recorded in duplicate or triplicate.

For between run, 2 vials of each sample were pooled, tested in duplicate and recorded each day for 5 days.

In comparison studies, normal and abnormal control plasma controls were tested using PT and aPTT reagents from multiple manufacturers on multiple instrument types to include:

- r^2 Diagnostics Phospholin ES on the ACL3000+, MLA1000c and ACL Advance
- r^2 Diagnostics Phosphoplastin RL on the ACL3000+, MLA1000c and ACL Advance
- Dade Behring Thromborel S on the Dade BCS
- Dade Behring Pathromtin SL on the Dade BCS
- Diagnostica Stago Neoplastine CI+ on the Stago STA
- Diagnostica Stago Auto PTT on the Stago STA

The %CV ranges for all instrument and reagent combinations are:

Control	Within run PT	Between run PT	Within run APTT	Between run APTT
PlasmaCon N	0.5 – 1.05	0.4 – 2.5	0.51 – 4.1	0.7 – 2.9
PlasmaCon L-1	0.6 – 1.31	0.4 – 7.0	0.4 – 5.4	0.4 – 3.9
PlasmaCon L-2	0.44 – 5.3	0.8 – 13.5	0.4 – 8.0	0.2 – 4.0

b. Linearity/assay reportable range:

Not applicable.

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

The value assignment protocol was determined by testing the PlasmaCon N reagent, the ACL3000+, and the Phosphoplastin RL (PT) reagent and Phospholin ES (APTT) reagent in the prothrombin time (PT) and activated partial thromboplastin time (APTT) assays. Ranges were determined based on a 97.5% confidence interval; thus 3SD ranges around the mean were calculated. The manufacturer recommends that each laboratory establish the mean values and expected control ranges for their particular laboratory's instrument-reagent system.

Open vial and closed vial real time stability tests were performed. Results are determined by pass/fail criteria.

Open vial stability studies were conducted PlasmaCon N, PlasmaCon L-1 and PlasmaCon L-2. Seven vials of test control plasma was stored at room temperature was run at the following intervals: 0, 4, 5, 6, 7, 8, and 9 hours (or until three consecutive failed tests) in a PT and APTT assay.

Closed vial stability studies were conducted PlasmaCon N, PlasmaCon L-1 and PlasmaCon L-2. One vial of test control plasma was stored at 2-8° C was run monthly for 3 months, once on months 6, 12, 18, 24, 30 and 36 (or until three consecutive failed tests) in a PT and APTT assay. Data was provided through month 7.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable.

   b. Clinical specificity:

   Not applicable.

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

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   Expected values were determined PT and APTT using the Phosphoplastin RL reagent for PT and the Phospholin ES reagent for APTT. Results for the r^2 Diagnostics reagents on the ACL3000+ are:

Control	Expected Value	
	PT	**APTT**
PlasmaCon N	12.4 – 13.0	28.9 – 31.1
PlasmaCon L-1	17.7 – 18.9	43.3 – 45.7
PlasmaCon L-2	46.8 – 58.2	73.1 – 73.7

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.