

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

A. 510(k) Number:

K052124

B. Purpose for Submission:

Clearance of a new device

C. Analyte:

Lupus Anticoagulant

D. Type of Test:

Clotting

E. Applicant:

American Diagnostica

F. Proprietary and Established Names:

Acticlot® dPT™

G. Regulatory Information:

1. Regulation section:
21 CFR 864.7750
2. Classification:
Class II
3. Product Code:
GJS
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
The ACTICLOT® dPT® is an *in vitro* diagnostic assay intended for the qualitative determination of Lupus Anticoagulants (LA) in human plasma.
2. Indication(s) for use:
3. Special condition for use statement(s):
4. Special instrument Requirements:

I. Device Description:

The ACTICLOT® dPT™ is a reagent kit. It has three reagents that are used selectively for a screening protocol and a confirmatory protocol. LA Buffer™ is used with dPT™ Activator for the screening protocol. LA Phospholipid™ is used with dPT™ Activator for the confirmatory protocol.

J. Substantial Equivalence Information:

1. Predicate device name(s):
DVVtest® and DVVconfirm®
2. Predicate K number(s):
K940490

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For the qualitative determination of lupus anticoagulants (LA) in human plasma.	Same
Sample Requirements	Citrated plasma	Same
Differences		
Item	Device	Predicate
Methodology	Clotting assay (PT)	Clotting assay (PTT)
Test Principle	In the screening protocol, dPT™ Activator (recombinant tissue factor) and calcium is mixed with LA Buffer™ to initiate clotting. Instrumentation is used to measure the clot time. IN the confirmatory protocol, the dPT™ Activator is mixed with the LA Phospholipids™ reagent, and instrumentation is used to determine the clot time.	Russell's Viper Venom reagent in the DVVtest is used to initiate clotting in plasma and then instrumentation is used to measure the clot time. For the confirmation assay, Russell's Viper Venom Reagent and phospholipids in the DVVconfirm is used to initiate clotting and then instrumentation is used to measure clot time.

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

The ACTICLOT dPT is a coagulation assay that identifies the presence of LA in plasma. Clotting is initiated by activating the tissue factor (extrinsic) coagulation pathway with tissue factor in the presence of calcium ions. Tissue Factor binds to Factor VIIa resulting in the activation of Factor IX and Factor X. Factor Xa converts prothrombin to thrombin which initiates clot formation by cleaving fibrinogen to fibrin. Activation of the tissue factor pathway bypasses the activation of the contact intrinsic pathway and excludes any interference from deficiencies of Factors XI and XII.

In the Screening Protocol, the patient plasma is mixed with the ACTICLOT LA Buffer" and ACTICLOT dPT Activator". The clot time is determined by semi-automated or automated methods. A positive result is indicated by a prolonged clot time relative to an established normal range, In the Confirmatory Protocol, the patient plasma is mixed with the ACTICLOT LA Phospholipids" and ACTICLOT dPT Activator. A positive result is indicated by a significant reduction of the clot time relative to the clot time in the screening protocol.

Plasmas are identified as possessing LA when both the Screening and Confirmatory Protocols are performed and both tests are positive.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

ACTICLOT dPT reagent precision studies were performed on two sites using LATrol Normal Control, LATrol™ Abnormal Control, and various coagulation analyzers: ACL® 300R centrifugal analyzer, BCT®, MLA® 900C coagulation analyzer, and the STA Compact®. Testing involved multiple runs over several days. Results are as follows:

TABLE 2. Precision Study Results with ACTICLOT* dPT™

Coagulation Analyzer	Control	dPT Screening mean (sec)	Intra-Assay CV (%)	Inter-Assay CV (%)	dPT Confirmatory mean (sec)	Intra-Assay CV (%)	Inter-Assay CV (%)
ACL® 300R	Normal	32.8	2.5	5.1	30.2	3.8	5.3
	Abnormal	63.8	1.9	7.1	36.9	3.2	3.8
BCT®	Normal	47.5	0.5	3.2	51.6	1.7	4.5
	Abnormal	89.2	0.6	5.2	61.9	1.2	3.7
MLA® 900C	Normal	27.9	2.5	3.7	27.2	2.8	4.1
	Abnormal	51.6	2.4	8.6	30.5	1.5	3.7
STA Compact®	Normal	40.2	0.8	3.4	39.7	0.9	4.3
	Abnormal	77.9	1.1	7.2	46.0	1.0	4.8

b. Linearity/assay reportable range

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

d. Detection limit:

e. Analytical specificity:

Testing demonstrated interference with lipemic, icteric and hemolysed samples.

Testing demonstrated no interference from unfractionated heparin up to and including 1.0 U/mL.

The ACTICLOT® dPT™ screening time may be prolonged in patients with congenital or acquired factor deficiencies. Eighteen known Factor Deficiency patient plasmas were tested with ACTICLOT^ dPT

and none tested positive for LA "neat" and/or with a 1:1 mix with pooled normal plasma.

Plasmas from patients treated with Coumadin and other oral anticoagulants may have prolonged ACTICLOT® dPT™ screening and confirmatory clot times.

f. Assay cut-off:

2. Comparison studies:

a. A. Method comparison with predicate device:

ACTICLOT® dPT™ Method comparison studies were performed two sites. Patient samples were tested using ACTICLOT® dPT™ and *DVVtest®* and *DVVconfirm®*.

Site 1

	#samples LA pos with <i>DVVtest®</i> and <i>DVVconfirm®</i>	#samples LA neg with <i>DVVtest®</i> and <i>DVVconfirm</i>
#samples LA pos with ACTICLOT® dPT™	17	5
#samples LA pos with ACTICLOT® dPT™	0	32

49 out of 54 samples were in agreement (90.7%)

Site 2

	#samples LA pos with <i>DVVtest®</i> and <i>DVVconfirm®</i>	#samples LA neg with <i>DVVtest®</i> and <i>DVVconfirm</i>
#samples LA pos with ACTICLOT® dPT™	31	8
#samples LA pos with ACTICLOT® dPT™	3	47

78 out of 89 samples were in agreement (87.6%)

b. Matrix comparison:

3. Clinical studies:
 a. *Clinical sensitivity:*

23 prescreened LA positive samples were tested at two sites with the predicate device, the subject device, and a third commercially available aPTT sensitive LA test.

Percent LA Positive Test Results from each of Three LA Tests

	ACTICLOT® dPT™ ^a	DVVtest®/DVVconfirm ^b	aPTT reagent ^b
Number of Samples that Tested LA Positive with One LA Test / Number of LA Positive Plasmas	18/23	18/23	19/23
Percent LA Positive	78.3%	78.3%	82.6%

(a) Assays were performed using the ACL 300R coagulation analyzer,

(b) Assays were performed using the Sysmex*CA-1500 coagulation analyzer.

b. *Clinical specificity:*

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

4. Clinical cut-off:

5. Expected values/Reference range:

Coagulation Analyzer	ACL® 300R (n=25)	BCT® (n=32)	CA7000 (n=20)	MLA® 900C <n=93)	ST4 (n=25)	STA Compact® (n=25)
Screening Time (sec)	34.4 + 4.5	51.2 + 7.8	38.8 + 8.8	26.7 + 4.8	38.4 + 4.2	36.6 + 5.9
Confirmatory Time(sec)	29.2 + 4.8	50.5 + 11.0	35.8±4.0	26.2 + 5.2	34.9 + 8.5	35.7 + 3.1
S/C Ratio	1.18 + 0.12	1.02 + 0.12	1.08 ±0.26	1.02 + 0.16	1.11 + 0.19	1.03 ±0.09

Conclusion:

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