

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

A. 510(k) Number:

K061805

B. Purpose for Submission:

New assay

C. Measurand:

Lupus Anticoagulant

D. Type of Test:

Clotting

E. Applicant:

Diagnostica Stago

F. Proprietary and Established Names:

Staclot® DRVV Screen

Staclot® DRVV Confirm

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8950

2. Classification:

Class I

3. Product code:

GIR

4. Panel:

H. Intended Use:

1. Intended use(s):

The STA®-Staclot® dRVV Screen and Confirm are intended for the detection of lupus anticoagulants (LA) in plasma by the dilute Russell's viper venom method.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

Analyzers of the STA® line

I. Device Description:

The STA®-Staclot® dRVV Screen and Confirm assay Kit consists of freeze-dried Russell's viper venom, phospholipids, calcium and heparin inhibitor (UHF). The STA®-Staclot® dRVV Screen is available in 2ml and 5 ml vials. The STA®-Staclot® dRVV Confirm is available in 2 ml vials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

HemosIL LAC Screen and Confirm

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

K990302

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Detection of lupus anticoagulant in plasma by the dilute Russell's viper venom method	Same
Sample Requirements	Citrated plasma	same
Storage requirement	2-8 °C	same

Differences		
Item	Device	Predicate
Reconstituted reagent stability	72 hours	48 hours

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

L. Test Principle:

Lupus anticoagulants are antibodies directed against phospholipid/protein complexes.

Staclot® dRVV Screen test is performed with a low phospholipids concentration reagent to screen samples. If lupus anticoagulants are present, the clotting time will be prolonged.

The Staclot® dRVV Confirm Reagent contains a higher phospholipids concentration to neutralize the LA present in the plasma to be tested. The clotting time obtained with the Staclot® dRVV Confirm Reagent will be shorter than the one observed with the Staclot® dRVV Screen reagent.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

3 lots of Staclot® dRVV Screen and Confirm were used to determine within-run precision using LA positive and negative control plasmas. Each control was assayed 21 times on each lot. A CV of less than 1.0% was obtained for all lots.

Inter-assay precision was assessed using lyophilized positive and negative LA samples on 1 lot of Staclot® dRVV Screen and Confirm. Positive and negative samples were assayed on the Staclot® dRVV Screen, and a positive sample was assayed on the Staclot® dRVV Confirm. Samples were assayed in 10 runs over 6 days. CV's $\leq 4.1\%$ was obtained for the Screen and Confirm reagents.

b. *Linearity/assay reportable range:*

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Stability data supported the reagent shelf life.

d. *Detection limit:*

e. *Analytical specificity:*

Samples from patients on heparin may give a falsely elevated clotting time using the Staclot® dRVV Screen and Confirm assays. The Staclot® dRVV Screen and Confirm Assay contains a heparin inhibitor that will neutralize the effects of heparin up to 0.8 IU/mL. To verify this claim a normal plasma pool and a LA positive plasma were spiked with known quantities of UF. The plasmas were then tested with three lots of Staclot® dRVV Screen and Confirm reagents. No significant difference was seen in the Screen, Confirm, and Normalized ratios up to 0.8 IU/mL.

To assess the effect of LMWH on the Staclot® dRVV Screen and Confirm assays, a normal plasma pool and a LA positive plasma were spiked with known quantities of Fragmin. The plasmas were then tested with three lots of Staclot® dRVV Screen and Confirm reagents. No significant difference was seen in the Screen, Confirm, and Normalized ratios up to 0.8 anti-Xa IU/mL fragmin.

f. *Assay cut-off:*

2. Comparison studies:

a. *Method comparison with predicate device:*

The device was compared to the predicate at a 2 site study. At site one samples were collected from several hospitals in France, and assayed at Diagnostica Stago. Site 2 testing was performed at a hospital reference

laboratory in Canada. Results demonstrated 92% agreement with the predicate device.

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:

27 normal plasmas were tested with the Staclot® dRVV Screen and Confirm assays. A normal reference sample was also tested with each batch of test plasmas. Testing was performed over multiple days on the STA-R. The mean Staclot Screen and Confirm ratio was 1.04 and 1.08.

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.