

**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:

<b>Similarities</b>		
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

<b>Differences</b>		
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.