Reagents and services for LA diagnostics

PRODUCT NAME	PACK.	REF.	UTILITY	STABILITY	
Reagents					
PTT-LA	6x2mL	00599	Screening testing using the APTT pathway to aid in the detection of LA (Silica activator)	8 hours on board the STA-Compact & STA-R, 24h at 20°C +/-5°C, 5 days at 2-8°C	
Staclot LA	2x5tests	00600	Integrated test system for qualitative detection of LA based on the APTT pathway using Patented Hexagonal Phospholipids	8h at 20°C +/- 5°C	
STA-Staclot DRVV Screen 2	12x2mL	00339	Screening testing for LA based on the dRVV pathway	3 days on board the STA-Compact & STA-R, 7 days at 2 - 8°C and 1 month at - 20°C	
STA-Staclot DRVV Screen 5	12x5mL	00333	Screening testing for LA based on the dRVV pathway	3 days on board the STA-Compact & STA-R, 7 days at 2-8°C and 1 month at -20°C	
STA-Staclot DRVV Confirm	12x2mL	00334	Confirmatory testing for LA based on the dRVV pathway	3 days on board the STA-Compact & STA-R, 7 days at 2-8°C and 1 month at -20°C	
Pool Normal					
Pool Norm	12x1mL	00539	A normal human plasma pool intended for differentiating between a coagulation factor deficiency and existence of circulating anticoagulants	8 hours at 20°C +/- 5°C	
Quality controls					
STA-Control LA 1+2	3x2x1mL	00201	Lupus negative & positive Quality Controls (QCs)	8 hours on board the STA-Compact & STA-R & at 20°C +/-5°C	
Quahris QC Lupus Anticoagulants	6x1mL annual subscription	01063	Unassayed plasmas for external quality assessment using the My Qualiris QC program for LA detection tests	4 hours at 20°C +/- 5°C	
Digital solutions by Stago					
Coagone STA Coag Expert					

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- 4. Pengo V. Update of the guidelines for lupus anticoagulant detection. J Thromb Haemost, 2009
- 5. Triplett DA. Hexagonal phase phospholipid neutralization of lupus anticoagulants: a specific and sensitive confirmatory procedure. XIIIth ISTH, 1991
- APS: antiphospholipid syndrome aPL antibodies: antiphospholipid antibodies LA: lupus anticoagulant

Δ: delta Staclot LA1-Staclot LA2 in seconds

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For further information, please contact:



Diagnostica Stago S.A.S. 3 allée Thérésa 92600 Asnières sur Seine - France Tel.: +33 1 46 88 20 20 Fax: +33 1 47 91 08 91 webmaster@stago.com www.stago.com

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AN INTEGRATED SOLUTION



DIAGNOSING APS⁽⁷⁾



- LA, aCL and aβ2GP1 testing is essential for the diagnosis of APS
- Conduct tests as per international guidelines
- Confirm positive results on a 2nd sample
- APS is diagnosed when the patient is positive for one or more antibodies

Patients classified according to the type and number of aPL antibodies present, confirmed at least twice, 12 weeks apart

Type I	at least two laboratory criteria present		
Type II	only one laboratory criterion present		
Type IIa	LA present alone		
Type IIb	aCL present alone		
Type IIc	anti-GP1 present alone		

AN INTEGRATED SOLUTION FOR DETECTION OF LUPUS ANTICOAGULANTS

DIAGNOSTIC TOOLS ADAPTED TO ALL CLINICAL **CONTEXTS**

Stago is proud to offer Screening, Mixing and Confirmatory testing solutions for dRVV & APTT pathways.

 \square

- Adapted to all clinical contexts & adhering to international guidelines: offering 2 products with differing LA sensitivities (low and high) within each of the dRVV and APTT ranges, with a reference plasma pool for mixing studies
- Staclot LA: demonstrating superior clinical performances^(1,6) (specificity of 100%*) thanks to the use of the well recognised Hexagonal Phospholipids

* The Staclot® LA procedure has shown a high specificity. The procedure was used to test normal plasmas (n = 35), plasmas from stabilized couradin patients (n = 29), heparinized plasmas containing up to 1 IU/ml (n = 10) and plasmas deficient in various factors (n = 21). All plasmas gave negative results with Staclot LA.

RELIABLE & SECURE

- > A full LA diagnostic solution incorporating automation, quality solutions and decisional algorithms
- CE marked*
- Internationally renowned products especially within the ISTH community⁽⁸⁾
- * My Qualiris QC is intended for Quality assessment purposes rather than diagnostic procedures and is therefore not CE marked.

EASE-OF-USE

- Optimisation of the sample volume (<400 µL)</p> required for the complete LA panel)
 - Can be used with secure sample microtubes
 - Optimised on board stabilities (e.g. 3 days on board the STA-Compact and R for STA-Staclot DRVV Screen & Confirm)
 - Convenient & easy to use for all activity levels: different packaging sizes available with dedicated QCs*
 - * PTT-LA is not provided with dedicated QCs.

ENHANCED PRODUCTIVITY WITH STAGO ANALYSERS

- Fully validated automated usage of DRVV & PTT-LA
- Full connectivity thanks to the usage of Staclot-LA with STart Max & STA Coag Expert or Coag.One
- Complete customization of results interpretation using STA Coag Expert or Coag.One or using Stago Coag Algorithm for LA* * CE pending.

DRVV Scree > G RATE RATIO SCREEN > 1,2 -S Pool Norm Mixing \mathbf{O} F S 0 Z ABSENCE OF CORRECTION G 4 or STA-Staclot CONFIRMATION AT LEAST 1 CONFIMATORY TEST TO BE POSITIVE

- A feature unique to Stago Decisional algorithm defined with the coag experts & validated by Stago in agreement with the
- Possibility to automatically launch tests, perform the associated calculations & help with the final results interpretation



STAGO COAG ALGORITHM

international recommendations⁽²⁾









