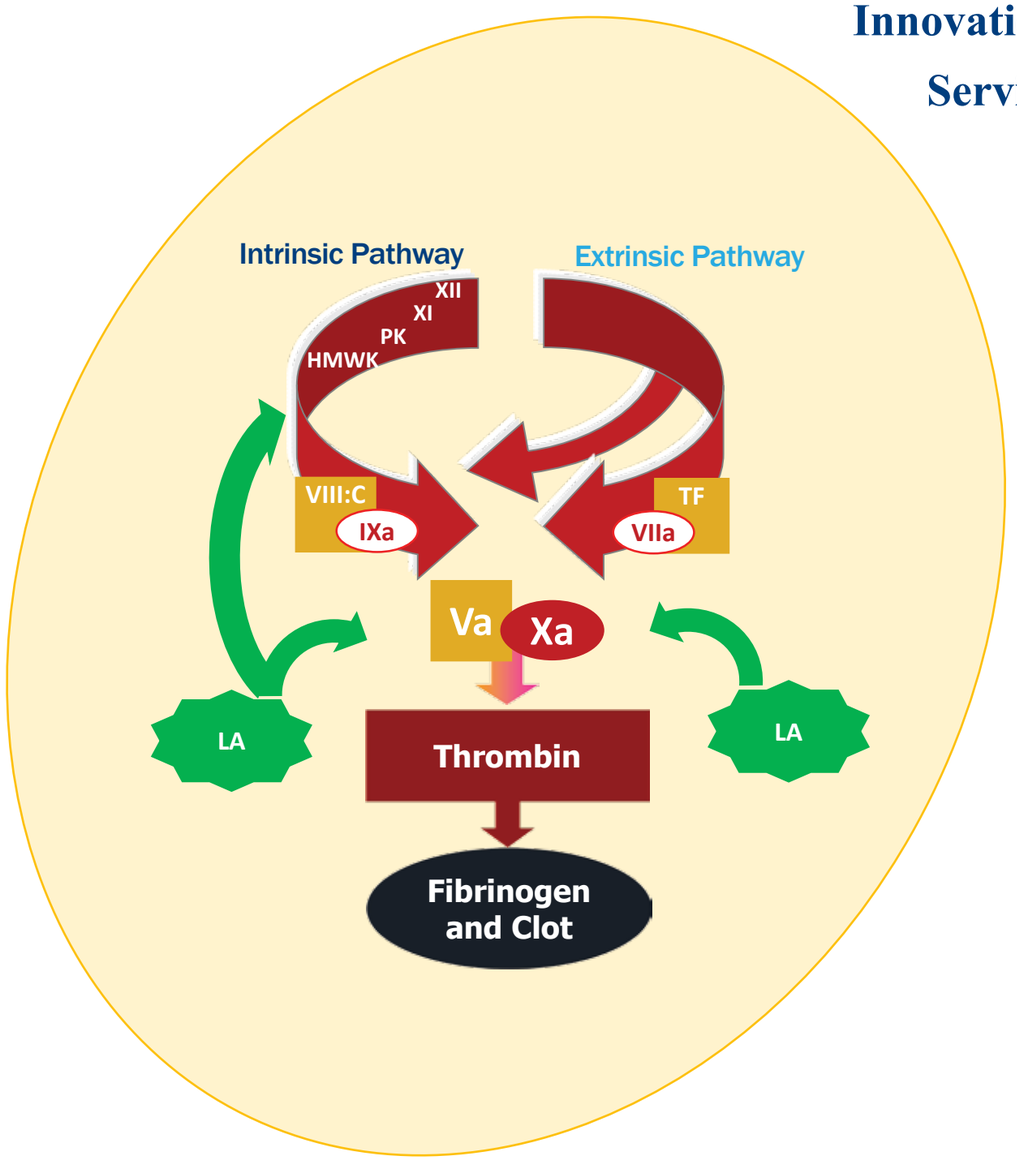
Our commitment: **Quality,**
Innovation,
Service



From the INNOVATION LEADER in Thrombosis & Hemostasis

More information on HYPHEN BioMed and product catalog is available at :
www.hyphen-biomed.com

HYPHEN BioMed S.A.S.
155 rue d'Eragny 95000 Neuville-sur-Oise, France • Tél: +33 (0)1.34.40.65.10 • info@hyphen-biomed.com • www.hyphen-biomed.com

HYPHEN BioMed

A Company of Sysmex Group

Lupus Anticoagulant (LA)

HEMOCLOT™ LA-S
HEMOCLOT™ LA-C

Lire attentivement les instructions figurant sur l'étiquetage et/ou la notice d'utilisation des réactifs.
HYPHEN BioMed (France) - " destination " générique " - Réf. HBM14_v4_EN - Date de création : 04/2017

HYPHEN BioMed S.A.S.
155 rue d'Eragny 95000 NEUVILLE-SUR-OISE France • Tél: +33 (0)1.34.40.65.10 • Web : www.hyphen-biomed.com

Lupus Anticoagulant (LA) Assay Pannel

HYPHEN BioMed offers Laboratory assays for complete LA profiling:

- In compliance with the SSC/ISTH guidelines
- Improved sensitivity and better specificity than current assays.
- Dedicated LA controls, weak and high positive
- No interference of factor deficiency
- Little impact of Direct Oral Anticoagulants (DOACs) or Vitamin K Antagonists (VKAs)
- No interference of Heparins (LMWH & UFH) up to 1 IU/mL
- Good stability and can be frozen

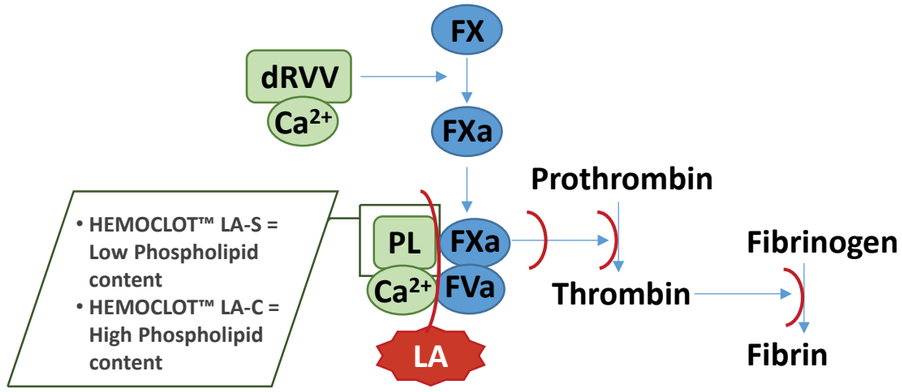
Reagent

Product name	Assay principle	Presentation	Ref. No.
HEMOCLOT™ LA-S *(CE-IVD)*	Simplified dRVV reagent to screen for the presence of LA. The assay is performed with low phospholipid concentration: LA-S clotting time is expected to be prolonged in the presence of LA	6 x 1 mL 	CK090K
HEMOCLOT™ LA-C *(CE-IVD)*	dRVV reagent to confirm the presence of LA. The reagent contains a high phospholipid concentration, expected to neutralize LA present in test plasma: clotting time is shortened	6 x 1 mL 	CK091K

Associated Controls

Product name	Assay principle	Presentation	Ref. No.
BIOPHEN™ Normal Control Plasma *(CE-IVD)*	Normal Control Plasma for coagulation assay quality control, which can be used as a negative control for LA clotting assays.	12 x 1 mL	223201
LA Control Plasma *(CE-IVD)*	A set contains 2 levels of lyophilized quality control plasmas for LA clotting assays. ▪ *C1: LA Control "Weak positive" with indicative normalized ratio of about 1.40 (±0.15).* ▪ *C2: LA Control "High positive" with indicative normalized ratio of about 2.40 (±0.60).*	C1: 6 x 0.5 mL C2: 6 x 0.5 mL	SC081K
LA Control Plasma Weak *(CE-IVD)*	Weak positive human plasma for the quality control of LA clotting assays.	C1: 6 x 0.5 mL	SC082K
LA Control Plasma High *(CE-IVD)*	High positive human plasma for the quality control of LA clotting assays.	C2: 6 x 0.5 mL	SC083K

dRVVT Assay Principle



Performance Characteristics

Precision

Product name (Ref. No.)	Precision		BIOPHEN™ Normal Control Plasma (ref. 223201)	LA Control Plasma Weak (ref. SC081K, C1 / SC082K)	LA Control Plasma Weak (ref. SC081K, C2 / SC083K)
HEMOCLOT™ LA-S (Ref. CK090K)	Within-run precision	N	30	30	30
		CV%	0.59	0.57	1.24
	Between-run precision	N	12	12	12
		CV%	2.10	4.00	1.38
HEMOCLOT™ LA-C (Ref. CK091K)	Within-run precision	N		30	30
		CV%		0.49	0.71
	Between-run precision	N		12	12
		CV%		0.68	0.89

** Example obtained with Sysmex CS-5100 (refer to the instrument specific method application)*

Stability

Product name	2-8°C	18-25°C	-20°C or below
HEMOCLOT™ LA-S (Ref. CK090K)	48 hrs	24 hrs	1 mths
HEMOCLOT™ LA-C (Ref. CK091K)			
BIOPHEN™ Normal Control Plasma (Ref. 223201)	24 hrs*	8 hrs*	
LA Control Plasma (Ref. SC081K)	24 hrs	8 hrs	7 days
LA Control Plasma Weak (Ref. SC082K)			
LA Control Plasma High (Ref. SC083K)			

** Information for LA only. For other parameters, refer to the product IFU*

Overview of ISTH recommendation[1]

Screening test

1. Perform testing on plasmas from healthy donors
2. Two tests using different principles:
   - Dilute Russell's viper venom time (dRVVT)
   - Sensitive aPTT (low phospholipids [PL] and silica as activator)
3. Take the cut-off as the value above the 99th percentile of the distribution

Mixing test

1. Perform testing on plasmas from healthy donors mixed with the pooled normal plasma (PNP) at 1:1 proportion. Testing should be performed without pre-incubation within 30 min
2. Take the cut-off as the value above the 99th percentile of the distribution

Confirmatory test

1. Perform testing on plasmas from healthy donors at low (screen) and high (confirm) phospholipid concentration
2. Take the cut-off as the value corresponding to the mean of the individual % corrections calculated as defined by the equation:
   [(screen - confirm)/screen] x 100

Other related products

Product name	Assay principle	Presentation	Ref. No.
CEPHEN * *(CE-IVD)*	Ready to use liquid aPTT reagent with a low sensitivity to LA.	6 x 1 mL	CK511K
		6 x 2.5 mL	CK512K
		8 x 5 mL	CK515K
		12 x 5 mL	CK515L
CEPHEN LS * *(CE-IVD)*	Ready to use liquid aPTT reagent, sensitive to LA.	6 x 1 mL	CK521K
		6 x 2.5 mL	CK522K
BIOPHEN™ Normalplasma *(CE-IVD)*	Lyophilized normal human citrated plasma, which can be used for diluting plasmas for the diagnosis of LA.	6 x 1 mL	223602
		8 x 5 mL	223605
ZYMUTEST™ Anti ß2 -Glycoprotein I IgG – Isotype *(CE-IVD)*	an optimized ELISA designed for measuring auto-antibodies to $ß_2$-GPI of the IgG isotype (use of human $ß_2$-GPI)	96 tests	RK014A
ZYMUTEST™ Anti ß2 -Glycoprotein I IgM – Isotype *(CE-IVD)*	an optimized ELISA designed for measuring auto-antibodies to $ß_2$-GPI of the IgM isotype (use of human $ß_2$-GPI)	96 tests	RK014B
ZYMUTEST™ Anti ß2 -Glycoprotein I IgA – Isotype *(CE-IVD)*	an optimized ELISA designed for measuring auto-antibodies to $ß_2$-GPI of the IgA isotype (use of human $ß_2$-GPI)	96 tests	RK014C
ZYMUTEST ACA-APA, IgG ** *(CE-IVD)*	an optimized ELISA designed for measuring Anti-Cardiolipin/Anti-Phospholipid Antibodies IgG isotype	96 tests	RK029A On-demand
ZYMUTEST ACA-APA, IgM ** *(CE-IVD)*	an optimized ELISA designed for measuring Anti-Cardiolipin/Anti-Phospholipid Antibodies IgM isotype	96 tests	RK029B On-demand
ZYMUTEST ACA-APA, IgA ** *(RUO)*	an optimized ELISA designed for measuring Anti-Cardiolipin/Anti-Phospholipid Antibodies IgA isotype	96 tests	RK029C On-demand

** Can be used for the aPTT ratio*
*** human $ß_2$-GPI used as phospholipid cofactor*

Reference

1. Pengo V1, Tripodi A, Reber G, Rand JH, Ortel TL, Galli M, De Groot PG; Subcommittee on Lupus Anticoagulant/Antiphospholipid Antibody of the Scientific and Standardisation Committee of the International Society on Thrombosis and Haemostasis. Update of the guidelines for lupus anticoagulant detection. J Thromb Haemost. 2009 Oct;7(10):1737-40.
2. Moore GW. Recent guidelines and recommendations for laboratory detection of lupus anticoagulants. Semin Thromb Hemost. 2014 Mar;40(2):163-71.
3. Poster "Moore G, Peyrafitte M, Dunois C, Amiral J. Evaluation of a new formulation dilute russell's viper venom time for detection of lupus anticoagulants" presented at ISTH SSC 2016