HEMOSIL®

LUPUS ANTICOAGULANT (LA) ASSAY PANEL



BETTER TOGETHER.

- Silica Clotting Time
- dRVVT Screen and Confirm
- LA Positive Control
- LA Negative Control

Fully automated on the ACL TOP® Family of Hemostasis Testing Systems

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Does your LA testing meet the standard?

Guidelines for Lupus Anticoagulant (LA) testing call for two types of tests, Dilute Russell Viper Venom Test (dRVVT) and an APTT-based assay with a silica activator.* Together, these tests optimize sensitivity and specificity in LA. Only IL offers both tests on a single, fully automated panel.

HemosIL LA assay panel includes Silica Clotting Time (SCT), the only silica-based APTT assay that, when combined with dRVVT, offers increased sensitivity[1] and results on one system. Meet the new standard, with HemosIL.

The only automated LA panel with both SCT and dRVVT

- Features APTT-based assay with silica activator as recommended by ISTH SSC 2009 LA testing guidelines
- SCT and dRVVT testing, together, offer enhanced detection:
  - More likely to differentiate LA from anti-FVIII inhibitors than either test alone[2,3]
  - Highest sensitivity in the detection of LA in patients who meet the clinical criteria for antiphospholipid syndrome (APS)[1]
- Combined with ACL AcuStar® Hemostasis Testing System, covers the maximum spectrum of antiphospholipid (aPL) antibody detection

Efficient and compliant

- Easy to use, fully automated on IL Hemostasis Testing Systems
- Screen and Confirm available for both methodologies
- Fully compliant with guidelines for LA detection[4]
- Results expressed as Normalized Ratio (NR)



*Recommended by ISTH SSC 2009 LA testing guidelines

Excellent stability and performance on ACL TOP Systems

HemosIL LA panel analytical performance

	Silica Clotting Time	dRVVT Screen and Confirm	LA Negative Control	LA Positive Control
Stability at 2–8° C	20 Days	15 Days	24 Hours	24 Hours
Onboard Stability†	5 Days	3 Days	24 Hours	24 Hours
Expected Values	Normalized SCT Ratio	Normalized dRVVT Ratio	Normalized SCT Ratio	Normalized dRVVT Ratio
ACL TOP 700	0.84–1.16	0.92–1.11	<1.16	≥1.40
ACL ELITE®/ ELITE PRO	0.75–1.20	0.91–1.14	<1.20	≥1.40

HemosIL LA Negative Control: ideal for mixing studies

- LA Controls prepared from human samples screened +/- according to ISTH guidelines[4]
- In-house study demonstrated similar clotting times between LA Negative Controls and Platelet Poor Normal Pooled Plasma (PPNPP) measured daily over a 7-day period using HemosIL LA and APTT assays
- LA Negative Control can replace Pooled Normal Plasma in LA mixing studies

	Silica Clotting Time	dRVVT Screen and Confirm	SynthASil	APTT-SP
PPNPP Mean Clot Time (sec)	32.8 (Screen) 35.7 (Confirm)	32.8 (Screen) 29.0 (Confirm)	32.0	30.1
LA Negative Control Mean Clot Time (sec)	33.3 (Screen) 36.9 (Confirm)	32.8 (Screen) 30.6 (Confirm)	30.1	29.1

†Onboard ACL TOP Family Systems

Screening for LA

LA diagnosis is a complex procedure

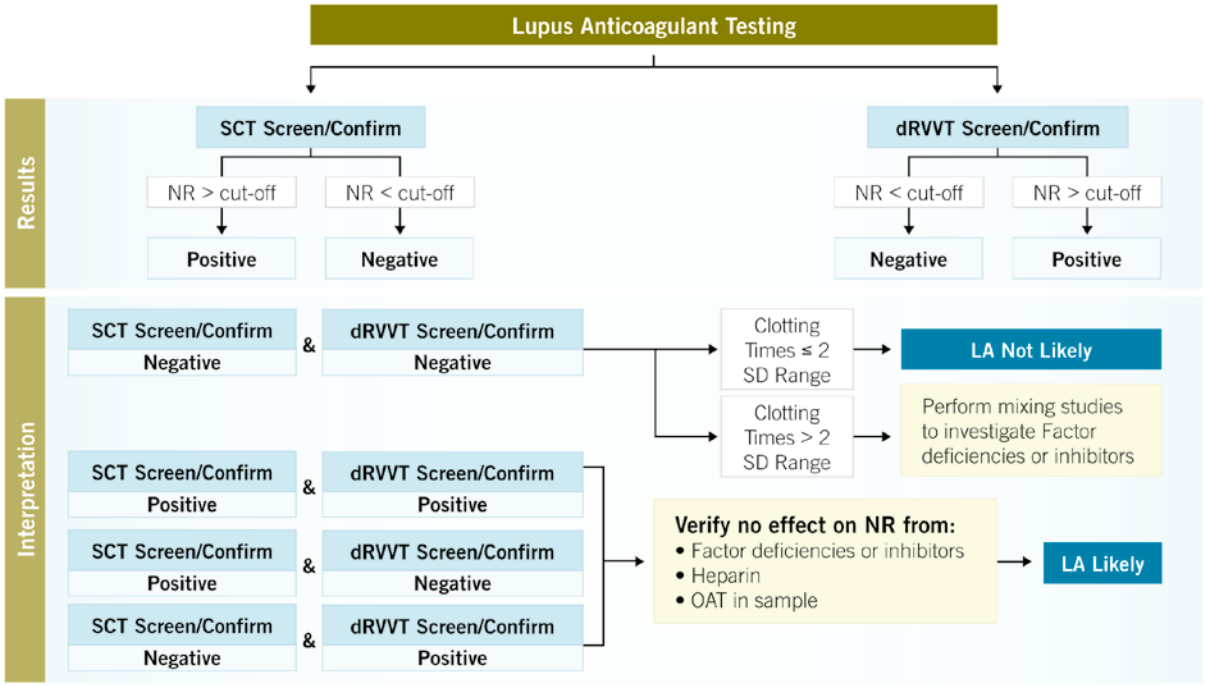
ISTH SSC 2009 LA testing guidelines[4]

- Recommends two phospholipid-dependent clotting assays based on different methodologies to demonstrate phospholipid dependence
- Only HemosIL includes both assays in one panel, and more

LA Testing Recommendations[4]	HemosIL Solution
dRVVT Assay Specific for LA in patients at high risk for thrombosis	**HemosIL dRVVT Screen/Confirm**
Silica-based APTT Assay Low in phospholipid concentration, selected for its sensitivity	**HemosIL Silica Clotting Time**
Established +/- Controls Must be used	**HemosIL LA Positive/Negative Controls**
Mixing Test Pooled Normal Plasma (fresh or lyophilized)	**LA Negative Control**

Laboratory criteria

- Prolongation of phospholipid-dependent assays
- Exclusion of interfering factors (factor deficiencies, factor inhibitors, heparin and oral anticoagulants)
- Determination of phospholipid dependence

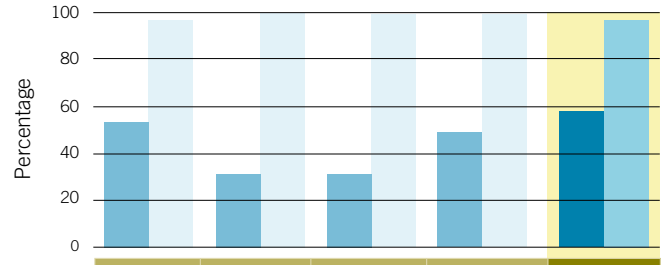


One standard. One solution.

Enhanced LA testing sensitivity

- dRVVT and SCT enhance the identification of LA with different sensitivities to LA antibodies
- dRVVT and SCT combined broadens the detection capability, resulting in the highest sensitivity

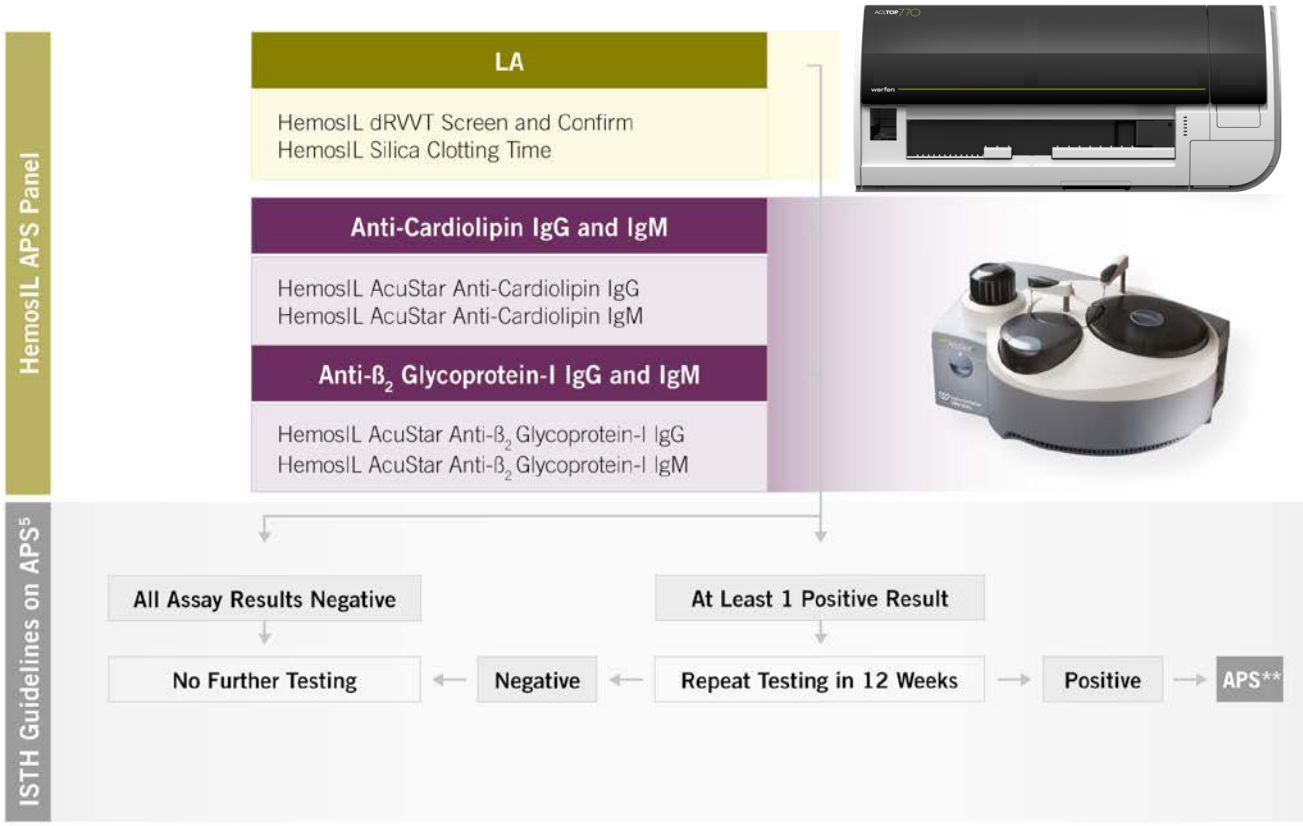
Sensitivity and specificity in LA testing[1]



	SCT	APTT-LA	DRVVT	DRVVT/APTT-LA	DRVVT/SCT
Sensitivity	53.3	31	31	48.8	57.7
Specificity	96.6	100	98.9	98.9	96.6

With APL testing, a complete APS diagnostic assessment

LA testing on the ACL TOP® together with APL testing on ACL AcuStar meets ISTH guidelines[5] for a complete APS diagnosis.



** Both clinical and laboratory criteria must be met in order to diagnose APS. Refer to ISTH Guidelines on APS Diagnosis 2006.

HemosIL Lupus Anticoagulant Assay Panel

Product	Part Number	Kit Configuration
Silica Clotting Time	0020004800	SCT Screen 3 x 5 mL (liq) SCT Confirm 3 x 5 mL (liq) SCT $CaCl_2$ 3 x 10 mL (liq)
dRVVT Screen	0020301500	10 x 2 mL (lyo)
dRVVT Confirm	0020301600	10 x 2 mL (lyo)
LA Positive Control	0020012500	10 x 1 mL (lyo)
LA Negative Control	0020012600	10 x 1 mL (lyo)

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