



LIAISON® Cardiolipin IgG, IgM

■ Anti-cardiolipin antibodies

The presence of anti-cardiolipin antibodies (aCL) is one of the laboratory criteria for the diagnosis of Anti-Phospholipid Syndrome (APS), an autoimmune systemic disease, characterized by thrombophilic state and by obstetrical complications.

Furthermore, anti-cardiolipin antibodies are also one of the criteria for the diagnosis of Systemic Lupus Erythematosus of the American College of Rheumatology. aCL antibodies are present in around 90% of APS patient serum, alone or together with antibodies against Beta₂ Glycoprotein.

They have been associated with the pathogenesis of APS, either as thrombotic co-factor and as co-factor that can induce foetal loss. aCL normally recognize the Cardiolipin molecule bound to Beta₂ Glycoprotein (the so-called "Beta₂GPI-dependent aCL"), a protein found in the serum in high concentration, which shows anti-coagulant properties. The antibodies that recognize cardiolipin alone, are normally associated with infectious diseases, and not with autoimmune conditions.

According to the International Classification Criteria for APS, elevated level of aCL IgG or IgM have diagnostic value if found positive on two or more occasions at least 12 weeks apart, measured by a standardized test.

■ LIAISON® Anti-Cardiolipin test, the true automation of the APS testing

It is the first fully-automated, walk-away, random-access chemiluminescent test, that allows results to be obtained by simply loading the primary tubes in the LIAISON® instrument. From this simple step to the first results, it

takes less than 40 minutes. This short processing time and the high loading capacity of the LIAISON®, result in optimization of your laboratory workload. The test is based on microparticles coated with Cardiolipin first, and then with human Beta₂ Glycoprotein. A stringent purification protocol, coupled with our QC procedures, ensure that the purified protein does not carry mutations known to decrease the link of the auto-antibodies. The test is optimized against an internal standard, with results expressed in GPL or MPL, enabling easy interpretation of results. Internal data showed good correlation against the Sapporo standard in a serial dilution experiment, proving reproducibility and reliability of the LIAISON® Cardiolipin test.

■ Clinical performance

We analyzed seventy sera of patients with well-characterized APS with the LIAISON® Cardiolipin IgG and IgM kits, and with two CE- and FDA-approved ACA IgG and IgM ELISA kits.

The results showed a sensitivity of 97.1%, when the results of the IgG and IgM isoforms were combined (**Table 1**). The distribution of the positive samples for aCL IgG, as shown in **Fig. 1**, allows very clear discrimination of the high positive results, giving a valid aid in the classification of patients that have medium- or high-titre of aCL (greater than 40 GPL U/mL), associated with clinical manifestations, according to last international consensus statement on the classification criteria for definite antiphospholipid syndrome.

The results of a test in 120 normal blood donors showed that all samples were below the positive threshold of 20 GPL U/mL. In the case of IgM, only one sample was above the positive threshold of 15 MPL U/mL. It is noteworthy

Table 1

	LIAISON® aCL			ELISA aCL		
	IgG n (%)	IgM n (%)	IgG + IgM n (%)	IgG n (%)	IgM n (%)	IgG + IgM n (%)
Negative	4/70 (5.7%)	47/70 (67.4%)	2/70 (2.9%)	8/70 (11.4%)	33/70 (47.1%)	4/70 (5.7%)
Equivocal	-	2/70 (2.9%)	-	3/70 (4.3%)	12/70 (17.1%)	1/70 (1.4%)
Positive	66/70 (94.3%)	21/70 (30.0%)	68/70 (97.1%)	55/70 (84.3%)	25/70 (35.7%)	65/70 (92.9%)

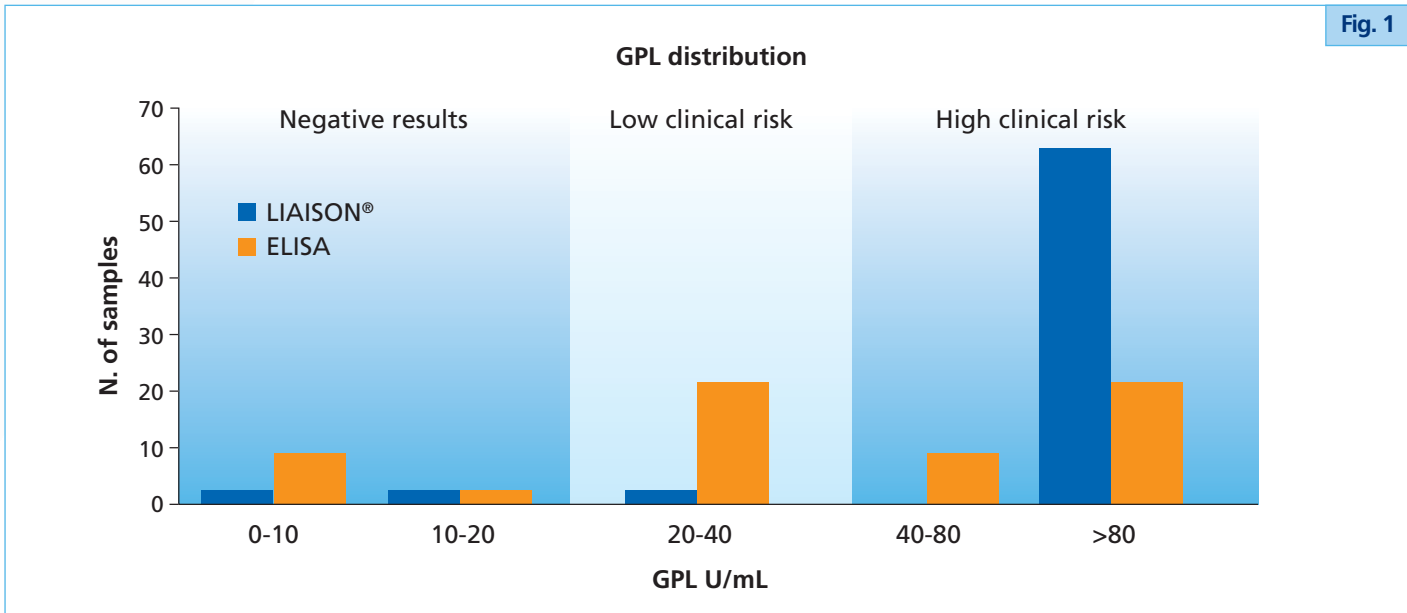


Fig. 1

that this sample was positive in all the three CE-marked ELISA kits used as a comparative method. The distribution in normal blood donors are shown in Fig. 2. In another experiment, 200 sera of patients from a rheumatology centre with suspected symptoms of APS were tested using both the LIAISON® Cardiolipin IgG and

IgM kits, and two CE- and FDA-approved ACA IgG and IgM ELISA kits. After resolving the discrepant results with two CE-marked aCL kits, the overall agreement was 97.4% for IgG and 96.1% for IgM.

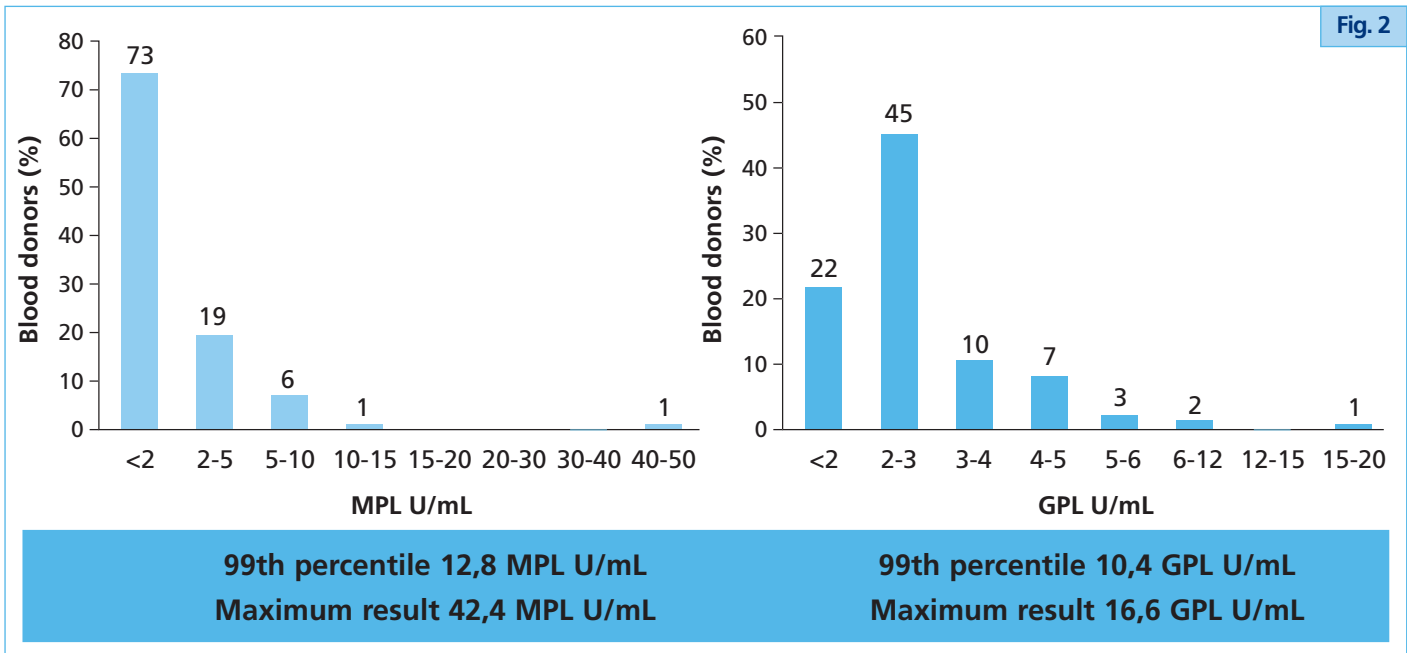


Fig. 2