

**Detection of antiphospholipid antibodies: efficient evaluation of hypercoagulable states.** Dier, K., Whittier, A., Fink, C.A., Lopez, L.R. *Corgenix, Inc. Westminster, CO.*

Due to the heterogeneity of antiphospholipid (aPL) antibodies and the increasing number of tests available for their detection, many laboratories are questioning which test(s) are most specific and/or sensitive, and how to efficiently contain the cost involved. To determine which assay(s) best fulfill these needs, we measured simultaneously three aPL antibodies (IgG aCL, aPS, and anti-B2GPI) on serum samples from diseased patient groups and correlated the results with their clinically history of thrombosis (antiphospholipid syndrome [APS]). Patient samples were tested on commercially available ELISA kits (REAADS) following the manufacturer's recommended procedure. Results were calculated in GPL, GPS, and G units for aCL, aPS, and anti-B2GPI antibodies respectively. Cutoffs and reportable ranges of each assay were 23 GPL (0 - 80 GPL) for aCL, 16 GPS (0 - 100 GPS) for aPS, and 20 G units (0 - 200 G units) for anti-B2GPI. A large control population of healthy blood donors demonstrated specificity of 97% for aCL, 96% for aPS, and 100% for anti-B2GPI. A group of 28 samples from unselected SLE patients resulted in 25% positive for aCL (mean=18.2 GPL), 36% positive for aPS (mean=23.2 GPS), and 21% positive for anti-B2GPI (mean=26.2 G units). A second group of 12 SLE patients selected for history of thrombosis resulted in 58% positive for aCL (mean=32.5 GPL), 75% positive for aPS (mean=41.8 GPS), and 58% positive for anti-B2GPI (mean=69.1 G units). A third group of 9 patients with primary APS resulted in 67% positive for aCL (mean=47.4 GPL), 100% positive for aPS (53.0 GPS), and 89% positive for anti-B2GPI (mean=111 G units). The highest prevalence was observed in all groups for aPS. The best correlation was observed between aPS and anti-B2GPI ( $r=0.916$ ), followed by aCL and aPS ( $r=0.910$ ), and aCL and anti-B2GPI ( $r=0.826$ ). When the number of positive tests on individual samples was analyzed, the unselected SLE samples showed that 14% had 3, 14% had 2, and 11% had 1 positive assay. The selected SLE samples showed that 58% had 3, none had 2, and 17% had 1 positive assay. The primary APS samples showed that 56% had 3, 44% had 2, and none had 1 positive assay. In both the healthy blood donor and SLE control group (no history of thrombosis), none of the samples had positive results in all three assay. The percent of patients with 3 positive assays was higher in the selected SLE and primary APS groups. Patients with a positive aPS and anti-B2GPI was also higher in these groups (58% and 88%). These results indicate that an individual may present any combination of these aPL antibodies, but the presence of three positive assays correlated best with APS. However, aPS appears to be the most useful method to screen for positive samples, and the best combination of two assays was aPS with anti-B2GPI. Using only one assay may result in missing positive samples.

*Clinical Chemistry* Vol. 45, No. 6, Supplement, 1999, #265. Presented at AACC 51<sup>st</sup> Annual Meeting in New Orleans, July 1999.