



THE 10TH INTERNATIONAL CONGRESS ON ANTIPHOSPHOLIPID ANTIBODIES

The 10th International Congress on Antiphospholipid Antibodies was held in Giardini Naxos, Sicily, Italy on September 29 - October 3, 2002. Professor Y. Shoenfeld from Israel and a local organizing committee hosted this scientific event that attracted over 400 researchers interested in the most recent developments on antiphospholipid antibodies, from all over the world. The Mediterranean resort of Giardini Naxos provided a perfect environment for scientific discussions. Located on the east coast of Sicily in the foothills of Mount Etna (north of Catania), Giardini Naxos, with its ancient Roman and Grecian ruins, is one of the most beautiful areas of Italy. A brief summary of the most relevant topics discussed is presented below. Scientific abstracts submitted for presentation at the congress have been published in a special issue of the journal *Lupus* 11(9), 2002.

In a pre-congress session organized by the European Forum on Antiphospholipid Syndrome (APS), Dr. Cervera (Spain) reviewed the clinical and serologic findings of a European registry of 1,000 APS patients. These findings have been recently published (*Arthritis and Rheumatism* 46:1019;2002), and represent the most updated and comprehensive study on APS patients. In addition, Dr. Reber (Switzerland) presented the initial results from the European anti-B2GPI Standardization Program. Some of these findings have already been discussed in the October 2002 issue of THE READER. With the increasing importance of anti-B2GPI antibodies in APS, the lack of standardization of anti-B2GPI assays will be a significant topic of discussion (and perhaps of controversy) in the years to come. This part of the congress also included a comprehensive review of the therapy for APS.

Several sessions of the congress are worth mentioning. One session was dedicated to anti-Prothrombin (aPT) antibodies in APS. The prevalence, heterogeneity and clinical association of aPT antibodies with thrombosis was thoroughly discussed. In one study using a murine APS animal model, the injection of purified aPT antibodies induced thrombosis. The consensus was that aPT antibodies have a role in APS.

On the pathogenesis of APS, the role of infections in the etiology of APS continues to be an intriguing proposal. Data was presented to support this hypothesis. In relation to pregnancy morbidity seen in female patients with APS, several reports showed data indicating that high serum levels of antibodies to Laminin-1 were significantly associated with reproductive failure. Future clinical studies on anti-Laminin-1 antibodies will help to establish the clinical utility of this serologic marker.

One session that attracted a great deal of attention and probably represented one of the most exciting developments in APS, was dedicated to the possible association of atherosclerosis and antiphospholipid antibodies. It has been recently recognized that patients with Systemic Lupus Erythematosus (SLE), an autoimmune disease, and patients with APS develop atherosclerosis prematurely. Two research groups showed that anti-phospholipid antibodies correlate with premature atherosclerosis and recurrent coronary graft failure. In addition, other groups detected antibodies to oxidized LDL-cholesterol (oxiLDL) in patients with SLE and APS. OxiLDL as well as B2GPI have been found in atherosclerotic plaques by immuno-histochemical staining. Dr. Matsuura (Japan) recently described an interaction between B2GPI and oxiLDL, while no interaction was observed with native LDL. The presence of B2GPI/oxiLDL complexes in circulation was confirmed by Corgenix using Dr. Matsuura's technology. The Corgenix group also reported autoantibodies to the B2GPI/oxiLDL complex in patients with SLE or APS. All of this suggests that oxidative stress may be an early event in atherosclerosis and plays an important role in modifying native LDL.

Dr. Ames and Alves (UK) reported that the enzyme Paraonase which protects the LDL molecule from oxidation, was decreased in mouse models and in patients with SLE and APS. We will definitely hear more about these new findings in the near future. The next International Congress on Antiphospholipid Antibodies will be held in Sydney, Australia in 2004.

NEW AUTOIMMUNE PRODUCTS

Corgenix now offers the following **RhiGene MESACUP ELISA** products for your autoimmune testing needs. All of these kits are FDA Cleared for diagnostic use in the US:

- Catalog: #10739 **MESACUP ANA Test**
#10740 **MESACUP-2 Test SS-A**
#10741 **MESACUP-2 Test SS-B**
#10742 **MESACUP-2 Test Sm**
#10743 **MESACUP-2 Test RNP**
#10744 **MESACUP-2 Test Scl-70**
#10745 **DSG-1 & DSG-3 ELISA Test**

Please contact Corgenix Customer Support or your Corgenix Sales Representative for more information or to place an order.

READER ANNOUNCEMENTS

- **NEW Specific CPT Code for anti-Prothrombin testing:** the new CPT code established by the AMA for aPT antibodies is:

CPT Code 0030T Antiprothrombin (phospholipid cofactor) antibody, each Ig class

The new code is described in the recently published **cpt** 2003 Professional Edition. Most laboratories have been submitting aPT testing for reimbursement under an unlisted code (e.g. 83520). Now that a specific code has been assigned, the **0030T** code should be used for both aPT IgG and aPT IgM isotypes.

- For the latest information on the **Corgenix** diagnostic products and instrumentation, for technical or customer support, or to place an order, we invite you to visit our new website www.corgenixonline.com. Product literature and previous issues of **THE READER** are also available online. Thank you to all of our customers who have ordered product online since the website was launched in October.

- **Corgenix** is pleased to announce that our **Hyaluronic Acid (HA) Test Kit** will be CE marked before the end of 2002. While the HA Kit will be our first CE marked product, we are well on our way to compliance for our entire product line. Under the leadership of Nanci Dexter, Director of Quality and Regulatory Affairs at Corgenix, CE marking will be completed well in advance of the European IVD Directive deadline of December 7, 2003. With fewer than five business quarters now remaining until the deadline, many companies need to take urgent action to begin the compliance process. Nanci shares her experience and advice on CE marking in an interview published in the September 2002 issue of *IVD Technology*.

READER PRODUCT FEATURE

REAADS Anti-Prothrombin (aPT) IgG and IgM ELISA Test Kits

For *In Vitro* Diagnostic Use

| | |
|-------------------------|---|
| Assay format - | 96-well microtiter plate (8 x 12 strips) with breakaway wells |
| Sample matrix - | Human serum or 3.2% sodium citrate plasma |
| Sample dilution - | 1:51 |
| Antigen substrate - | Human prothrombin |
| Conjugate - | Horseradish peroxidase (HRP) conjugated anti-human IgG or IgM |
| Chromogenic substrate - | TMB (single component) |
| Stopping solution - | 0.36 N Sulfuric acid |
| Assay incubations | |
| Sample - | 15 min @ room temperature |
| Conjugate - | 15min @ room temperature |
| Substrate - | 10 min @ room temperature |
| Wavelength - | 450 nm |
| Clinical specificity - | IgG aPT 95%; IgM aPT 97% |
| Clinical sensitivity - | Unselected SLE: IgG 15%, IgM 12%; Primary APS: IgG 18%, IgM 27% |
| Product numbers - | 10238 IgG aPT Test Kit 10240 IgM aPT Test Kit |

Happy Holidays!

Best wishes to you and your families from all of us at Corgenix. May the peace and joy of the season be yours through the New Year. We appreciate your business and look forward to your continued support in the coming year.

During the holidays, Corgenix will be operating on a limited schedule, beginning Monday, December 23 until Thursday, January 2, 2003. Please check your inventory and plan ahead to assure an adequate supply of kits during the holidays. All standing orders due by the end of the month will be shipped on Thursday, December 26. For technical assistance or an emergency shipment, please contact us by email at www.corgenixonline.com, or call and leave a phone message at (800) 729-5661 or (303) 457-4345, and a Customer Service Representative will return your call.

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