

Publication of the Month

February 02/12: Recommendations on APS testing

Key messages:

- *At the 13th International Congress on Antiphospholipid Antibodies in April 2010 in Galveston, Texas, a task force of scientists and pioneers in the field discussed that a broad international consensus for the measurement of aCL and anti- β 2GPI is still lacking.*
 - *Therefore, this task force developed international consensus guidelines on the recommended best practices for immunoassays for end users (clinical laboratories) and kit developers.*
-

Lakos G, Favaloro EJ, Harris EN, Meroni PL, Tincani A, Wong RC, Pierangeli SS
International consensus guidelines on anticardiolipin and anti-(beta)2-glycoprotein testing: Report from the 13th International Congress on Antiphospholipid Antibodies
Arthritis Rheum 2012;64:1-10

Background:

Although several publications broached the issue of the lack in standardization for the diagnosis of the antiphospholipid syndrome (APS) according to the international classification criteria discordance remains in the development and usage of ELISAs for the determination of anticardiolipin (aCL) and anti- β 2-glycoprotein I (anti- β 2GPI) antibodies.

The authors as members of a task force therefore developed state-of-the-art recommendations and expectations for end users and manufacturers regarding aCL and anti- β 2GPI testing.

Summary:

The most important recommendations directed towards the users (clinical laboratories) are:

Testing for isotypes of aCL and anti- β 2GPI:

The IgG and IgM isotypes are recommended for both aCL and anti- β 2GPI. If these tests are negative but APS still suspected the IgA isotype should be tested for both aCL and anti- β 2GPI.

Positive/negative controls:

A positive and a negative control should be used in each run. If one of the controls falls out of its range the run should be rejected.

Reporting of results:

Results should be reported in units and in semiquantitative ranges. For aCL GPL/MPL/APL units are recommended. Interpretations should be negative, medium-positive, and high-positive.

Interpretative comments:

The comments are strongly recommended to assist clinicians in the interpretation of test results.

Conclusions:

The adoption of the task force's evidence-based recommendations for aCL and anti- β 2GPI testing will help users, developers, and manufacturers in the standardization and harmonization of assays for APS diagnosis.

Comment:

The standardization of assays for aCL and anti- β 2GPI testing to reach a comparability of results and therefore a consistent basis for interpretation is a long demanded issue in APS diagnosis. These recommendations are a huge step into this direction, especially because they are dedicated towards all involved parties.

