**IFCC Working Group on Harmonization of Autoimmune Tests: report of the ongoing initiatives.**

J. Sheldon, I. Zegers, SS Pierangeli, PL Meroni on behalf of the IFCC Working Group

*Background*: Accuracy of any diagnostic test for autoimmune diseases (AID) is critical for making a correct/early diagnosis and for starting a prompt treatment. Efforts in standardisation of diagnostic tests for autoimmune diseases are a necessary task, whose goals include the validation of new tests in comparison with the historical ones, the evaluation of their diagnostic/prognostic value, the identification/interpretation of useful algorithms, and the identification or preparation of reference materials. Robust and traceable reference materials are critical and while they are available for many analytes, they are yet available for autoimmune serology tests.

*Aim*: the IFCC WG on harmonization of autoimmune tests is an international task force devoted to the preparation and validation of reference materials for autoantibody tests.

*Methods & Results*: the WG has identified potential areas of autoantibody standardization. These are IgG antibodies to myeloperoxidase (MPO), proteinase 3 (PR3) and glomerular basement membrane (GBM), and IgG and IgM antibodies to beta2 glycoprotein I (2GPI). Plasmapheresis material has been used for the preparation of candidate reference materials for of MPO, PR3 and GBM. Anti-2GPI IgG antibodies have been isolated from a pooled of two sera from patients with Antiphospholipid Syndrome (APS) by protein G Sepharose and affinity chromatography. Two cell clones of human B cells have also been collected as potential source for IgG and IgM antibodies to 2GPI.

Data from analysis of the candidate preparations for IgG anti-MPO suggests that processing (including various additives and free-drying) does not influence the behavior of the material. Preliminary commutability studies using 18 candidate materials, 30 patients and 9 different ELISA based methods show clear potential for harmonization of results using a common reference material. Formal commutability studies of candidate materials analysed with patients samples will start in spring 2012. Preparation and analysis of candidate materials for IgG anti PR3 and IgG anti GBM using a similar protocol to the preparation of will IgG anti-MPO is also planned for 2012.

A panel of affinity purified IgG fractions against 2GPI is currently under evaluation. A human monoclonal IgG (HCAL clone) specifically reacting with 2GPI has been obtained and this will be analysed alongside the polyclonal preparations.

*Comments*: the preliminary results strongly support the possibility of preparing harmonisation reference materials for autoantibody testing in line with the aims of the IFCC WG.