EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

E-learning EFLM

חשיבות סטנדרטיזציה והרמוניזציה של הבדיקות האוטואימוניות

The importance of standardisation is only just being realised and addressed in autoantibody measurements. Immunoglobulins have a high degree of molecular heterogeneity, there are subclasses of IgG and IgA, and the affinity and avidity of antigen-antibody binding can vary both between and within individuals. An immune stimulus may generate a monoclonal, oligoclonal or polyclonal response and this pattern of response will vary between individuals and even within an individual over the disease course. There are multiple methods available for autoantibody detection which will vary in their abilities to detect different types of immunoglobulins. Finally, the antigen to which we are trying to measure antibodies is usually a protein with its own molecular heterogeneity which may also be influenced by the source of the antigens and the preparation process. Considering these complexities, it is unsurprising that there is marked variation in autoantibody concentrations measured with different methods. However, the increasing reliance on automated quantitative autoantibody results has made standardisation or harmonisation of these tests vital. The IFCC through a working group and more recently a committee have been integral to investigating and producing certified materials for IgG anti myeloperoxidase (ERM-DA476/IFCC) and IgG anti proteinase 3 (ERM-DA483/IFCC) with values assigned in mg/L, traceable to ERM Da 470k/IFCC (the certified reference materials for IgG). Evaluation of patient samples showed that use of these materials will give a significant reduction in the spread of the numerical results over different methods. However, there was only 30% concordance between positivity and negativity of results when interpreted with respect to each methods reference ranges. The introduction of certified reference material (CRM) will be the essential first step in standardisation of autoantibody testing and although it does not solve every issue, it should give us a point of reference to identify the other components of the methods that need to be harmonised before we can have comparability in autoantibody results.

and a short biography…
Dr. Joanna Sheldon is a Consultant Clinical Scienitst in Immunology and Director of the Supraregional Protein Reference Unit at St. George's Hospital in London, part of South West London Pathology. The PRU is a NHS laboratory service receiving samples sent from all round the U.K. and the test repertoire covers allergy, autoimmune serology, CSF analysis, cytokines and monoclonal protein identification. Dr Sheldon has is particularly interested in training and education and in delivering high quality results. Dr. Sheldon was part of the IFCC committee that oversaw the production of the international reference preparation for plasma proteins. Dr Sheldon now chairs the IFCC Committee on the Harmonisation of Autoantibody Testing that is currently working on preparation and validation of International Reference Materials for autoantibodies.