

Early Diagnosis of CCP Auto-antibodies in a 5-PLEX Novel Planar Microarray RA Assay

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Early detection and monitoring of anti-CCP-IgA autoantibody is beneficial in pre-symptomatic prognosis and early management of rheumatoid arthritis. A sensitive anti-CCP antibody assay (IgA, IgG) has been tested for simultaneous measurement of rheumatoid factors (RF) -RF-IgA, IgG and IgM using SQI's IgX- PLEX assay. Testing 10 microliter serum samples, the multiplex planar microarray fluorescent immunoassay offers quantitative/semi-quantitative and positive/negative results for anti-CCP antibody (IgA, IgG), RF- IgA, IgG and IgM in each sample well of a 96-well, RA assay microarray plate. Sensitive fluorescent tagged markers captured on microarray spots are read in a microarray scanner. Each microarray is processed with reference to quality control and calibration incorporated into every sample well. Early cohort human Rheumatoid Arthritis (clinical diagnosis by ACR criteria) serum samples (n=50) and normal controls (n=100) were tested and results compared with conventional immunoassays. The study demonstrated that the new test achieved 81.5% sensitivity and 95.0% specificity. At the fixed specificity of 97.5%, this anti-CCP assay was 4.2% more sensitive than single analyte anti-CCP tests e.g.(Clin. Chem. 2007; 53(8):1527-33 , Bizzaro et al.). Similar methodology has confirmed factor concordance for each of the RF multiplexed array assays e.g. (Clin Rev Allergy Immunol. 2009 Dec 9.Epub.Lea et al). This novel 5-PLEX assay system will permit the simultaneous detection of early anti-CCP autoantibody and rheumatoid factor immuno-globulins of rheumatoid arthritis with high sensitivity and specificity.