Standardization of autoantibody testing: a paradigm for serology in rheumatic diseases

Abstract:
Autoantibody measurement is an excellent tool to confirm the diagnosis of rheumatic autoimmune diseases. Hence, reliability and harmonization of autoantibody testing are essential, but these issues are still a matter of debate. Intrinsic variability in analytes and reagents as well as heterogeneity of the techniques are the main reasons for discrepancies in inter-laboratory variations and reporting of test results. This lack of reliability might be responsible for wrong or missed diagnoses, as well as additional costs due to assay repetition, unnecessary use of confirmatory tests and/or consequent diagnostic investigations. To overcome such issues, the standardization of autoantibody testing requires efforts on all aspects of the assays, including the definition of the analyte, the pre-analytical stages, the calibration method and the reporting of results. As part of such efforts, the availability of suitable reference materials for calibration and quality control would enable the development of a reliable reference system. Strong-positive sera from patients have been used as reference materials in most of the autoantibody assays for rheumatic diseases; however, antigen-affinity-purified immunoglobulin fractions or in some cases reliable monoclonal antibody preparations offer more adequate tools for standardization. Systematic assessments of reference materials are currently underway, and preliminary results appear to be encouraging.

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