Antibodies to Nuclear and Related Antigens

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1987, reconfigured 2002
Clinical Applicability:	Diagnosis of autoimmune disease
Analytes:	Qualitative identification of antibody to nuclear antigens (ANA), dsDNA and to the saline-extractable nuclear antigens (ENAs) SSA(Ro), SSB(La), Sm, RNP, Sm/RNP, Scl70, Jo-1, ENA screen, and the pattern of antinuclear staining on immunofluorescence in the HEp-2 cell system including the identification of centromere antibody. The ICAP classification is followed. *The sample analytes included will depend on their prevalence in the general population, therefore not all analytes may be covered during the year*
Units for Reporting:	Qualitative and quantitative responses for the ANA, DNA, Centromere and ENA antibodies in relation to relevant reference preparations
Samples Distributed:	Liquid format. Normal and pathological human serum
Number of Distributions per year:	6
Number of Samples per Distribution:	2
Frequency of Distributions:	Every two months as outlined in the **Distribution Schedule**
Schedule of Analysis:	**Data entry** is via the web for the submission of results. Data analysis is commenced 21 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics
Data Analysis:	Qualitative responses are assessed in terms of MI scoring for each antibody specificity in relation to the Designated Response. Laboratories also submit the immunofluorescent staining pattern of antinuclear antibody. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance for each antibody specificity is classified in terms of MI scoring over a running analytical window of 6 Distributions (12 months)

The categories of performance are:

	Total MIS
Good	zero
Adequate	1-2
Poor	>3

An OMIS of 2 or more for any one analyte will be classed as poor performance.

Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions