

General Autoimmune Serology

Accreditation Status:	UKAS Schedule of Accreditation								
Date Scheme started:	1982, reconfigured 2002								
Clinical Applicability:	Diagnosis of autoimmune disease								
Analytes:	Citrullinated Proteins (CP), Rheumatoid Factor IgM (RF), Thyroid Peroxidase Antibody (TPO), Anaemia Related Antibodies (GPC), Liver Disease Antibodies (LKM including AMA and SMA) and TSH Receptor Antibodies (TRAb). Each analyte is available separately <i>The sample analytes included will depend on their prevalence in the general population, therefore not all analytes may be covered during the year</i>								
Units for Reporting:	U/mL in relation to the appropriate International Reference Preparations, or titre. Qualitative responses or interpretation of quantitative results are recorded as POSitive or NEGative								
Samples Distributed:	Liquid format. Normal and pathological human serum								
Number of Distributions per year:	6								
Number of Samples per Distribution:	6 (1 x RF, 1 x TPO, 1 x CP, 1 x Liver, 1 x GPC and 1 x TRAb)								
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 recorded for each analyte and assessed in relation to the designated response. 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 is classified in terms of OMIS derived from the qualitative responses for all analytes for which the laboratory is registered over a running analytical window of 6 Distributions (12 months) The categories of performance are: <table border="0" style="margin-left: 40px;"> <tr> <td></td> <td style="text-align: center;"><u>Total MIS</u></td> </tr> <tr> <td style="padding-left: 20px;">Good</td> <td style="text-align: center;">Zero</td> </tr> <tr> <td style="padding-left: 20px;">Adequate</td> <td style="text-align: center;">1-2</td> </tr> <tr> <td style="padding-left: 20px;">Poor</td> <td style="text-align: center;">>2</td> </tr> </table>		<u>Total MIS</u>	Good	Zero	Adequate	1-2	Poor	>2
	<u>Total MIS</u>								
Good	Zero								
Adequate	1-2								
Poor	>2								
	A OMIS of >2 (out of a possible six in the defined time window) for any one analyte will also be classified as poor performance.								
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions								