

Autoimmune Serology ANCA and GBM

Accreditation Status:	UKAS Schedule of Accreditation								
Date Scheme started:	1987								
Clinical Applicability:	Diagnosis of autoimmune disease								
Analytes:	Identification of the Neutrophil Cytoplasmic Antibodies, C-ANCA, P-ANCA, and Glomerular Basement Membrane (GBM). Quantitative assessment is currently restricted to the Proteinase 3 (PR3) and Myeloperoxidase (MPO) antibodies and to GBM antibodies, but will be extended to include other ANCA specificities as required (SER/017)								
Units for Reporting:	Qualitative responses for the ANCA specificities; quantitative assessment of the specific antibodies in U/mL and IU/mL								
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 for ANCA (C-ANCA and P-ANCA), MPO, PR3 and GBM are assessed in relation to the Designated Response								
Performance Scoring:	MI scoring								
Criteria of Performance:	Laboratory performance for ANCA is assessed over a running analytical window of 6 Distributions (12 months). The categories of performance are: <table><thead><tr><th></th><th><u>Total MIS</u></th></tr></thead><tbody><tr><td>Good</td><td>Zero</td></tr><tr><td>Adequate</td><td>1-2</td></tr><tr><td>Poor</td><td>>2</td></tr></tbody></table> <p>An OMIS of 3 or more for any one analyte will also be classified as poor performance.</p>		<u>Total MIS</u>	Good	Zero	Adequate	1-2	Poor	>2
	<u>Total MIS</u>								
Good	Zero								
Adequate	1-2								
Poor	>2								
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions								