

Scleroderma Associated Antibodies (Pilot)

Accreditation Status:	<i>currently not accredited to ISO 17043</i>								
Date Scheme started:	Started 2024								
Clinical Applicability:	Diagnosis and monitoring of autoimmune scleroderma								
Analytes:	Scl-70, CENP A, CENP B, RP11, RP155, Fibrillarin, NOR90, Th/To, PM-Scl 100, PM-Scl 75, Ku, PDGFR, Ro-52 (SER/064)								
Units for Reporting:	Qualitative responses or interpretation of quantitative results 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:	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 commences 21 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics.								
Data Analysis:	Reports show method or kit related statistics. Qualitative responses are recorded and assessed in relation to the designated response.								
Performance Scoring:	MI scoring based on Consensus Designated Response								
Criteria of Performance:	Laboratory performance is classified in terms of OMIS for qualitative responses for analytes for which the laboratory is registered 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>1-3</td></tr><tr><td>Poor</td><td>>3</td></tr></tbody></table> A OMIS of >3 (out of a possible six in the defined time window) for any one analyte will also be classified as poor performance.		<u>Total MIS</u>	Good	Zero	Adequate	1-3	Poor	>3
	<u>Total MIS</u>								
Good	Zero								
Adequate	1-3								
Poor	>3								
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions								