Scleroderma Associated Antibodies (Pilot)

Accreditation Status: *currently not accredited to ISO 17043*

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:

	Total MIS
Good	Zero
Adequate	1-3
Poor	>3

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.

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