Anti Phospholipid Antibodies

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 1987

Clinical Applicability: Diagnosis of autoimmune disease

Analytes: Identification and quantitation of Cardiolipin antibody (IgG and IgM), and will survey performance in the assays for antibodies to β2–Glycoprotein1 (both IgG and IgM) and Phosphatidylserine (IgG only). Other new generation phospholipid antibody assays will be considered for inclusion if clinical need dictates **(SER/006)**

Units for Reporting: Qualitative responses phospholipid antibodies; Quantitative responses in GPLU/mL and MPLU/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: Laboratories are requested to give a qualitative interpretation of the cardiolipin, β2GP1 and phosphatidylserine antibody results. This element of the programme is assessed by MI scoring. Reports show the quantitative responses returned for each analyte in relation to both All Laboratory and Method / Manufacturer specific data

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 during a time window encompassing 6 Distributions (12 months)

The categories of performance are:

	Total MIS
Good	zero
Adequate	1-3
Poor	>3

An OMIS of 3 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