Monoclonal Proteins

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 1993

Clinical Applicability: Diagnosis of monoclonal gammopathy in serum and urine

Analytes: Total serum protein, Albumin, IgG, IgA, IgM, free light chains (Kappa, Lambda and ratio), urine total protein & Monoclonal Component identification and Quantitation **(SER/019)**

Units for Reporting: Isotype of heavy and light chain together with the concentration of monoclonal protein in g/L. Serum free light chains in mg/L

Samples Distributed: Liquid format. Normal and pathological human serum and urine

Each distribution will contain a serum sample and a urine sample, they should be considered as separate requests for investigation.
It should NOT BE ASSUMED that they emanate from the same patient

Number of Distributions per year: 6

Number of Samples per Distribution: 2 (1 urine and 1 serum)

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: Whilst the programme will analyse participant's isotype identification and monoclone quantitation, the returns will require data on total serum protein, albumin, IgG, IgA, IgM (and urine total protein). This latter information will not be formally analysed as it is covered in other EQA programmes but will be of value in the recognition of analytical or isotype identification problems

Chosen Coefficient of Variation: 14% for Serum Monoclonal Component Quantitation
Chosen Coefficient of Variation: 20% for Bence Jones Protein Quantitation

Performance Scoring: MI Scoring - The qualitative elements of electrophoresis, isotype and free light chains identification
MRVIS - Assessment of the monoclone quantitation and free light chains

Criteria of Performance: The qualitative elements of electrophoresis and isotype identification are assessed by MI scoring over a running analytical window of 6 Distributions (12 months)

Good	OMIS	Zero
Adequate		1 - 2
Poor		>2

Poor Performance

For the monoclonal component and serum Free Light Chain quantitation, laboratory performance is assessed in relation to the MRVIS over a running analytical window of 6 Distributions.

Ideal	MRVIS	<50
Good		50 - 100
Adequate		101 - 200
Poor		>200 or SDBIS >200

Persistent Poor Performance:

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