IgG Subclasses

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 1991

Clinical Applicability: Diagnosis of antibody deficiency states and IgG4 Related Disease

Analytes: Total IgG, IgG1, IgG2, IgG3 and IgG4 (SER/018)

Units for Reporting: g/L

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: All Laboratory Trimmed Mean (ALTM) with truncation at 2SD, SD and

CV%. Reports also show method specific statistics. Individual laboratory

performance is expressed in terms of MRBIS, SDBIS, and MRVIS.

The Designated Value (DV) for the calculation of VI is the Group Laboratory Trimmed

Mean (GLTM)

Chosen Coefficient of Variation is specific for each subclass; current values are

 IgG1
 6%

 IgG2
 6%

 IgG3
 6%

 IgG4
 6%

Performance Scoring: MRVIS

Criteria of Performance: Laboratory performance is assessed in relation to each subclass over

a running analytical window of 6 Distributions (12 months)

 Ideal
 MRVIS
 <50</th>

 Good
 50 - 100

 Adequate
 101 - 200

Poor >200 or SDBIS >200

In addition, the summation of the four subclasses should equate to within 10%, ideally within 5%, of the total IgG as estimated by an independent method

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

successive Distribution