

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												
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:	<p>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.</p> <p>The Designated Value (DV) for the calculation of VI is the Group Laboratory Trimmed Mean (GLTM)</p> <p>Chosen Coefficient of Variation is specific for each subclass; current values are</p> <table> <tbody> <tr> <td>IgG1</td> <td>6%</td> </tr> <tr> <td>IgG2</td> <td>6%</td> </tr> <tr> <td>IgG3</td> <td>6%</td> </tr> <tr> <td>IgG4</td> <td>6%</td> </tr> </tbody> </table>	IgG1	6%	IgG2	6%	IgG3	6%	IgG4	6%				
IgG1	6%												
IgG2	6%												
IgG3	6%												
IgG4	6%												
Performance Scoring:	MRVIS												
Criteria of Performance:	<p>Laboratory performance is assessed in relation to each subclass over a running analytical window of 6 Distributions (12 months)</p> <table> <tbody> <tr> <td>Ideal</td> <td>MRVIS</td> <td><50</td> </tr> <tr> <td>Good</td> <td></td> <td>50 - 100</td> </tr> <tr> <td>Adequate</td> <td></td> <td>101 - 200</td> </tr> <tr> <td>Poor</td> <td></td> <td>>200 or SDBIS >200</td> </tr> </tbody> </table> <p>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</p>	Ideal	MRVIS	<50	Good		50 - 100	Adequate		101 - 200	Poor		>200 or SDBIS >200
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 Distribution												