

IgG Subclasses

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|--|--|--------------------|-------|------|------|------|----------|----------|----|-----------|------|--|--------------------|
| 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: | <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. 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><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></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><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></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 Distributions | | | | | | | | | | | | |