

ANCA and GBM Antibodies

| Accreditation Status: | UKAS Schedule of Accreditation | | | | | | | | |
|--|---|--|------------------|------|------|----------|-----|------|----|
| Date Scheme started: | 1987 | | | | | | | | |
| Clinical Applicability: | Diagnosis of autoimmune disease | | | | | | | | |
| Analytes: | Identification of the Neutrophil Cytoplasmic Antibodies, C-ANCA, P-ANCA, and Glomerular Basement Membrane (GBM). Quantitative assessment is currently restricted to the Proteinase 3 (PR3) and Myeloperoxidase (MPO) antibodies and to GBM antibodies, but will be extended to include other ANCA specificities as required | | | | | | | | |
| Units for Reporting: | Qualitative responses for the ANCA specificities; quantitative assessment of the specific antibodies in U/mL and IU/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: | Qualitative responses for ANCA (C-ANCA and P-ANCA), MPO, PR3 and GBM are assessed in relation to the Designated Response | | | | | | | | |
| Performance Scoring: | MI scoring | | | | | | | | |
| Criteria of Performance: | Laboratory performance for ANCA is assessed over a running analytical window of 6 Distributions (12 months). The categories of performance are: <table> <thead> <tr> <th></th> <th><u>Total MIS</u></th> </tr> </thead> <tbody> <tr> <td>Good</td> <td>Zero</td> </tr> <tr> <td>Adequate</td> <td>1-2</td> </tr> <tr> <td>Poor</td> <td>>2</td> </tr> </tbody> </table> <p>An OMIS of 3 or more for any one analyte will also be classified as poor performance.</p> | | <u>Total MIS</u> | Good | Zero | Adequate | 1-2 | Poor | >2 |
| | <u>Total MIS</u> | | | | | | | | |
| Good | Zero | | | | | | | | |
| Adequate | 1-2 | | | | | | | | |
| Poor | >2 | | | | | | | | |
| Persistent Poor Performance: | Defined as being in the Poor Performance category for two or more successive Distributions | | | | | | | | |