Allergen Component Testing

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2016
Clinical Application:	Diagnosis and management of allergic disease
Purpose of the programme:	Allergy and Immunodeficiency EQA scheme
Analytes:	The programme consists of two elements, Recombinant Allergens and Phadia ImmunoCAP ISAC 112, and includes the assessment of common or clinically important individual recombinant IgE specificities from the following allergen groups: Venom, Egg, Nuts, Latex, Birch, and Milk. Other allergen specificities may be included, subject to the availability of clinically validated donor serum units. The ISAC element of the scheme covers all allergens currently available for this method. Please contact UK NEQAS IIA for a concise list of allergens if required. *The sample analytes included will depend on their prevalence in the general population, therefore not all analytes may be covered during the year*
Units for Reporting:	Recombinant Allergens: Grade and kU/L (arbitrary) Phadia ISAC 112: ISU-E (ISAC standardized units)
Samples Distributed:	Liquid format. Normal and pathological human serum
Number of Distributions per Year:	6
Number of Samples per Distribution:	2 (only 1 to be tested on ISAC)
Frequency of Distributions:	Every two months as outlined in the **Distribution Schedule**. A maximum of nine recombinant allergen specific IgE tests will be analysed on each specimen for the Recombinant Allergen element of the scheme. All 112 allergens currently available for the ISAC method are to be analysed for the ISAC element (only relevant to the first specimen).
Schedule of Analysis:	**Data entry** is via the web for the submission of results. ISAC results are submitted via the web in csv file format. Data analysis is commenced 21 days after sample dispatch. Late returns are only accepted for the Recombinant Allergen element of the scheme and will contribute to the laboratory's cumulative performance statistics. No late results for the ISAC element will be accepted.
Data Analysis:	**Recombinant Allergens:** Analysis by grade shows the overall response and the method specific responses. **ISAC:** Analysis by units shows the overall response and the method specific responses. Analysis of the quantitative responses for both elements in Units shows the All Laboratory Trimmed Mean (ALTM) with truncation at 2SD, SD and CV%. Reports show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS and MRVIS, the DV for calculation of VI being taken from the ALTM. Chosen Coefficient of Variation for Recombinant Allergen Specific Components (IgE) is 15%

Performance Scoring:	Cumulative performance scores are based on the quantitative response with MRVIS scoring over a running window of twelve samples or twelve months
Criteria of Performance:	Performance assessment is allergen specific. Quantitative performance is assessed for each allergen, and is over a running period of 6 distributions containing that allergen (12 months) The overall quantitative performance is expressed as the OMRVIS, the mean of all the individual allergen specific MRVIS The semiquantitative Grades are assessed by MI scoring in relation to the Consensus Designated Response (CONDR). (For this purpose, Grades 2 – 6 are considered as CLEAR POSITIVE) Overall MIS (OMIS) greater than 3 will also be considered as poor performance
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive distributions