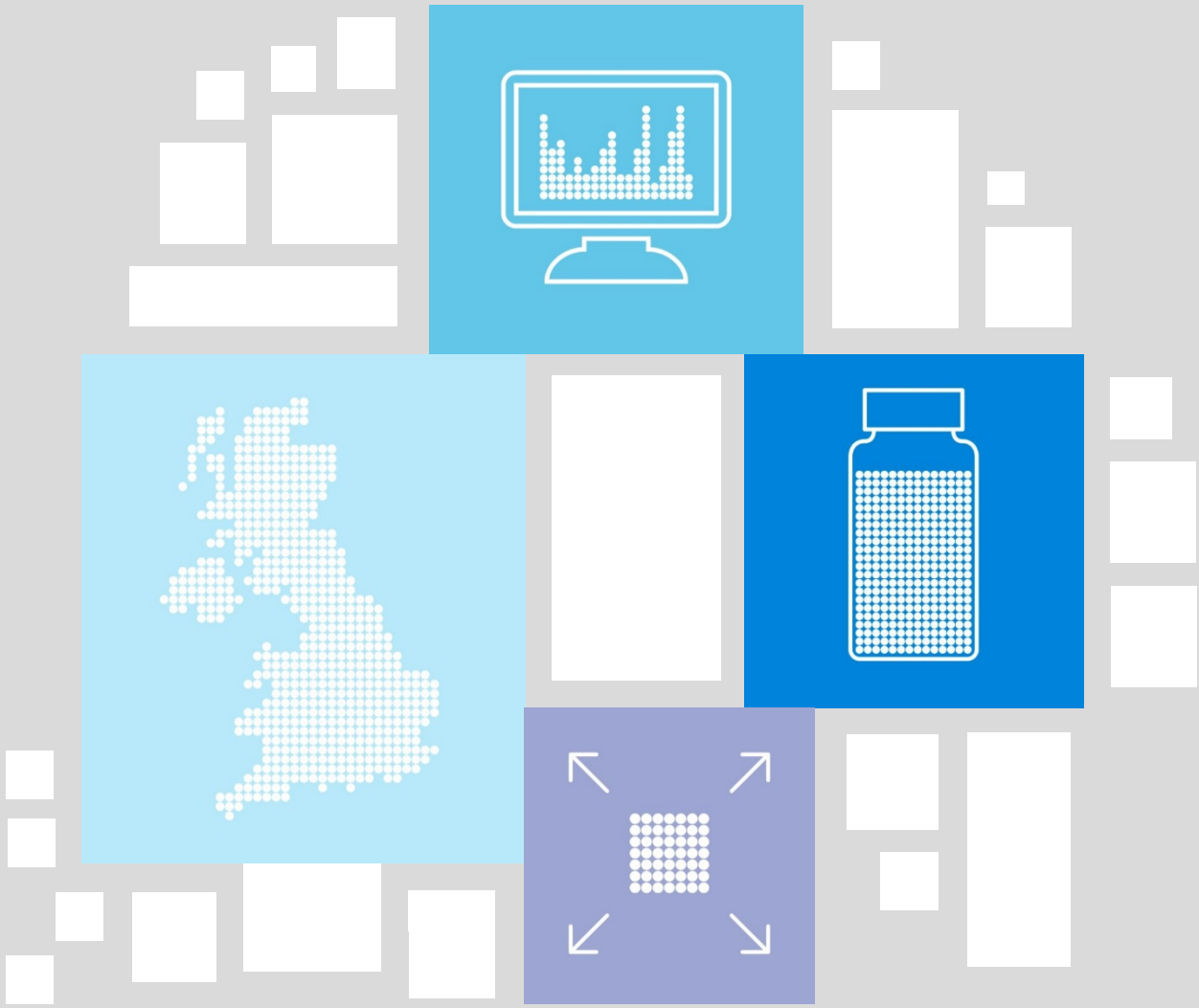
UK NEQAS

Immunology, Immunochemistry & Allergy



Participation Handbook

2021 - 2022

Programmes for

Immunology, Immunochemistry and Allergy

2021 - 2022

UK NEQAS for IMMUNOLOGY, IMMUNOCHEMISTRY and ALLERGY
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Contents

Preface

This Participation Handbook provides the information necessary for you to participate effectively in the UK National External Quality Assessment Schemes for Immunology, Immunochemistry and Allergy. Samples and reports are sent to named individuals in each participating laboratory. The reports should be made available to all appropriate laboratory staff.

INTRODUCTION

The overall aim of UK NEQAS for Immunology, Immunochemistry and Allergy is to promote optimal patient care by facilitating the availability of reliable immunological laboratory investigations, through the provision of objective information on laboratory performance and professional advice and assistance where appropriate.

UK NEQAS for Immunology, Immunochemistry and Allergy is recognised by the UK NEQAS Consortium and operates in accordance with the UK NEQAS Codes of Practice. Accreditation is undertaken by United Kingdom Accreditation Services (UKAS) using ISO 17043:2010 Standard.

GENERAL INFORMATION

Location

UK NEQAS for Immunology, Immunochemistry and Allergy operates from the Northern General Hospital in Sheffield. It shares its premises with the UK NEQAS Central Office.

Facilities

UK NEQAS for Immunology, Immunochemistry and Allergy has dedicated office facilities and laboratory space. All samples are prepared, bottled and packaged on site. Envelopes are franked on site and collected directly by Royal Mail or courier to minimise delays.

Scheme Staff

Director:	Dina Patel Ravishankar Sargur
Operations Manager:	David Gill Carol Stanley Hazel Wilkinson
Senior Biomedical Scientist:	Corinna Barber Samantha Bex Samantha Lewis
Biomedical Scientist:	Gazala Rehman
Laboratory Assistant:	Penny Adams Paul Bartley Andrew Jamieson Alexandra Kay Kristina Parkin Conner Ramsay Lorna Roberts
Registrations / Finance:	Jake Allerton Peter Farley Emma Kay Jo Wild

Contact Details

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PO Box 894
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UNITED KINGDOM

Telephone: (+44) 114 271 5715

Email: ukneqas@immqas.org.uk

Website: www.immqas.org.uk

The telephone is staffed between the hours of 08:30 and 16:00 Monday to Friday with an answering machine to pick up all messages outside these times. Callers will be asked the nature of their request or enquiry and transferred to the appropriate member of staff. Participants are requested to give their Laboratory Code Number when contacting the Centre. All calls and the actions taken are logged.

Laboratory Code Number

In common with all other UK NEQAS Centres, these programmes operate on a confidential basis with participant laboratories identified by a unique code number. The sequence of code numbers is common to all UK NEQAS Centres.

A participant may be assigned additional code numbers with alphabetic suffixes – 12345, 12345A, and 12345B etc – if more than one method is in use for a single analyte. This will occur, for example, when a method under evaluation or development is used in addition to the usual or established method.

All communications between the participant laboratory and the organising centre should quote the laboratory code number.

Computer Systems

UK NEQAS for Immunology, Immunochemistry and Allergy currently uses the Wolfson EQA Core Computer System (developed by the Wolfson Computer Laboratory in Birmingham) and the KPMD EQA Computer System (an SQL-based system developed by KPMD in association with ourselves). Both systems enable the handling of EQA data with scoring systems and report output. Web entry of results is mandatory for the majority of schemes.

Non-Analytical Errors

Laboratories are encouraged to report non-analytical errors which may have occurred in the transcription and relaying of their results. The occurrence will be recorded in a '*blunder*' register but the analytical result can be corrected to give a more accurate indication of the individual laboratory's performance. **Non-analytical errors** can be reported via our website. Fill in all fields of the email, and attach a copy of your lab's results (lab worksheet or computer printout).

Incident Reporting

For each distribution of each scheme, the Centre may contact participants returning out of consensus results, and requests they complete and return an incident form within a stated timeframe. This is a mutually-beneficial exercise as the laboratory's root-cause analysis provides it (and UK NEQAS for Immunology, Immunochemistry & Allergy) with evidence as to why the error(s) happened and any further action(s) which are required, and provides evidence of compliance with ISO 17043:2010 and ISO 15189:2012.

Blunders

Participants who have submitted an incorrect result due to a non-analytical error (ie: an error in transcription when entering results into the UK NEQAS IIA web entry system, or a unitage error in converting their usual reporting units to the units reported on the EQA scheme) may contact the Centre to have their score removed and their report amended. They must state the Scheme, Distribution number and reason(s) for the error, and copies of results obtained (lab worksheet or computer printout) must be appended.

Participant Appeals

Participants wishing to appeal against a score that is not the result of a potential "blunder" must contact the Director or Operations Managers, stating the Scheme, Distribution number and reason(s) why they are appealing. Copies of results obtained (lab worksheet or computer printout) must be appended.

Late Returns

Late returns are defined as results received after the distribution has closed, but before the report is published. Participants should return late results along with an explanation of why results were returned late. Late returns are monitored by the Centre.

Very Late Returns

Very late returns are defined as results received after the distribution has closed, and after the report is published. Very Late Returns will only be accepted if they are accompanied by evidence of results (e.g. a lab worksheet or computer printout) and an explanation of why results were returned very late. Very late returns are monitored by the Centre.

Help and Advice

Help and advice in aspects relating to analytes covered by the programmes is available from the Centre, either by telephone, email or by pre-arranged visits. Technical assistance and training can be arranged on request. There is also a help and FAQ section on our website for frequently asked questions.

Complaints

Any complaints regarding the service provided by UK NEQAS for Immunology, Immunochemistry and Allergy should be directed to either the Director or Operations Manager. Complaints should be in the form of an email or letter. A formal complaints procedure is in place and wherever possible will be actioned internally. Where a problem cannot be resolved it will be referred to the Chairman of the Joint Working Group on Quality Assurance.

Changes to Schemes

UK NEQAS for Immunology, Immunochemistry and Allergy shall promptly advise participants of any changes to EQA Scheme design or operation. Various aspects of EQA schemes can, from time to time, be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and the EQA Scheme provider is responsible for this work.

Packaging

The packaging of samples for UK NEQAS for Immunology, Immunochemistry and Allergy complies with the International Air Transport Association (IATA) packaging instruction 650.

Participant Meetings

Meetings will be scheduled to fulfil the educational role of UK NEQAS for Immunology, Immunochemistry & Allergy and to allow participant laboratories to discuss matters of current interest relating to the programmes. Whilst every effort will be made to arrange these in association with a relevant national meeting, this may not always prove possible.

Internet

Data entry and report retrieval via the internet is now mandatory for all programmes. Please contact the Centre if you experience any difficulties.

The UK NEQAS IIA website – **www.immqas.org.uk** – uses the HTTP Secure (HTTPS) transfer protocol which provides encrypted communication for **data entry**

Accreditation

Sheffield Teaching Hospitals NHS Foundation Trust is a **UKAS accredited proficiency testing provider (No. 7795)** operating UK NEQAS for Immunology, Immunochemistry & Allergy.

Any schemes not currently accredited to ISO 17043:2010 are indicated as "pilot" schemes.

Aims

1. To provide participants with an objective assessment of their performance both within their laboratory and in relation to that of other laboratories
2. To provide information on the relative performance of the available kits and methods
3. To identify factors associated with good and poor performance
4. To monitor and improve the between-laboratory agreement

Schedule of Distributions

Distributions are made at four, eight or twelve weekly intervals according to the schedule included in each programme data-sheet. These schedules are intended as guides and should not be taken as absolute timetables.

Due to inherent difficulties with postal transmissions during the month of December, no distributions are scheduled between week 50 and week 02 of the calendar year. The **distribution schedule** is available on our website.

Precautions

All serum-based materials distributed by UK NEQAS for Immunology, Immunochemistry & Allergy are of human origin. They are tested at the single donor stage and shown to be negative for Hepatitis B surface antigen and for antibody to HIV1, HIV2 and Hepatitis C in accordance with DH, IRMM and FDA requirements. For most of the programmes the materials also contain ProClin 150™ as an antimicrobial agent.

Sample Receipt

All samples for participants outside the UK are dispatched via courier; however, if any samples are not received in accordance with the distribution schedule, please inform us as soon as possible. This enables us to send a repeat sample (if available) and to investigate the reason for delayed delivery.

Where 3mL bottles are used, there is a rubber insert in the cap and therefore there will not be a separate rubber stopper inserted into the neck of the bottle under the cap.

Due to the nature of the bottle it is possible that some of the sample material will collect in the cap, so please ensure that prior to removing the cap the sample bottle is placed in an upright position and the material within has been allowed to settle back inside the bottle.

The next section contains advice for participants on how samples should be stored upon receipt.

Sample Stability

Samples are freshly prepared prior to dispatch and are transported in a liquid format, with anti-microbial agents as appropriate unless specified to the contrary.

All samples will remain stable at ambient temperatures during normal transit times. They may be stored as unopened vials for up to seven days refrigerated (we would recommend refrigerated samples are stored at 4 ± 3 °C where possible). If longer periods of storage are anticipated prior to analysis, the samples should be stored frozen. (We would recommend frozen samples are stored at -20 ± 6 °C where possible.)

In view of the time course for sample preparation and dispatch, and the liquid specimen format, formal thermal degradation studies are not performed.

Once tested, participants should dispose of samples according to local policies and procedures.

Repeat Samples

A limited supply of **back samples** are retained by the Centre, which are available to participants upon request via our website. Alternatively you can call or email your request.

CONFIDENTIALITY

Registration information, raw result data and performance details are confidential between the individual participant, the Director and designated UK NEQAS for Immunology, Immunochemistry & Allergy staff. The performance details (and some relevant raw result data) of any UK participant may be shared with the relevant regulatory authority (including National Quality Assurance Advisory Panel, NQAAP) under defined circumstances as part of the reporting of persistent poor performers. In such circumstances, affected participants are notified in writing of this action.

Other interested parties requesting information are provided with INFO reports, which give an overview of results but do not reveal the raw or performance data of any particular laboratory.

General Data Protection Regulations (GDPR, 2018)

The Sheffield Teaching Hospitals NHS Foundation Trust, which is the host organisation for UK NEQAS for Immunology, Immunochemistry and Allergy, is compliant with the terms of the GDPR. Information provided by participants on the registration forms is held on computer in order to identify those participants registered for each scheme and to generate address labels for dispatch of material and reports.

UK NEQAS IIA Privacy Policy
UK NEQAS IIA Terms & Conditions

QUALITY MANAGEMENT SYSTEM

UK NEQAS for Immunology, Immunochemistry and Allergy operates a quality management system which complies with ISO 17043:2010 Quality Management System requirements. The aims of the quality management system are to improve participant satisfaction and scheme quality. The UK NEQAS for Immunology, Immunochemistry and Allergy Quality Policy (see page 15) provides the basis for running the schemes in a manner that will fulfil the needs of its participants.

Feedback and suggestions from participants are always welcome. Participant Satisfaction Surveys are distributed on an annual basis. Other questionnaires may also be sent which are more scheme specific. Feedback is analysed and changes are made wherever possible to improve the service.

QUALITY POLICY

UK NEQAS
Immunology, Immunochemistry & Allergy

QUALITY POLICY

Document QDOC-001 **Version 16**

- UK NEQAS for Immunology, Immunochemistry & Allergy (UK NEQAS IIA) operates a quality management system to ensure all goods and services supplied to participants are fit for purpose and of adequate quality as measured by objective standards. This shall be achieved through implementation of the system, formulation of specific quality objectives, quality improvements and monitored through regular audits
- All staff shall be familiar with the quality policy and quality manual and shall implement all procedures and policies relevant to their work
- All staff shall be committed to good professional practice
- Quality assessment samples shall be uniform in character within each batch and of sufficient stability to ensure that all participants receive equivalent material. Where possible specimens shall be representative of equivalent clinical material likely to be encountered in routine Clinical Immunology, Immunochemistry & Allergy
- Within limits of production capacity, repeat specimens shall be made available to participants on request
- Documentation supplied to participants shall be timely, accurate, error free and well presented
- Responses to communications from participants shall be timely, courteous and helpful
- The confidentiality of participants' Proficiency Testing (PT) results shall be maintained
- UK NEQAS IIA will not engage in any activity that may compromise its independence and integrity in providing a PT service. These criteria shall be met by:
  - A commitment to quality by senior management
  - The motivation of all staff including quality awareness training
  - Adequately maintained premises, facilities and equipment
  - Adequate resources
  - Defined, documented specifications and procedures under suitable control
  - Effective quality assurance procedures
  - The incorporation of quality features into new product design
  - Rapid resolution of problems and an ability to learn from them
  - Change control mechanisms
  - Compliance with current national and international standards or guidance for PT **(specifically *ISO 17043:2010 Conformity assessment - General requirements for proficiency testing)***
- In the provision of its services, UK NEQAS IIA will comply with all relevant legislation including health and safety, transportation and environmental

Signed on behalf of UK NEQAS IIA:
Dina Patel, Scientific Director:

Effective Date:
01th April 2021

Review Date: 01/04/2021

Controlled Copy
Printed on April 01, 2021

Do Not Duplicate
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REGISTRATION

Prospective Participants

For prospective new participants **a registration enquiry form** is available from our website.

Following the receipt of the completed registration form, you will be issued with a Laboratory number and registered for the schemes you requested. Every effort is made to include the participant in the next available distribution but this cannot be guaranteed. The invoice will be sent to the finance address provided.

Annual Re-registration

Between January and March of each year, participants are sent a registration form and are asked to confirm or change their registration details for the following financial year. **A purchase order number must be provided.**

Changes in Registration Details

Please inform us of any **changes to your registration details** (contact name, sample address, finance address, telephone number, e-mail address etc) immediately using our website. Alternatively, any changes can be sent to us via email or letter.

Cancellation or Suspension of Participation

Please notify us in writing if you wish to cancel your participation in any scheme. Please be advised that cancellation will mean the loss of all previous data received from you and your scoring history. You may suspend your participation in any scheme temporarily if your laboratory is not offering the test as a clinical service for any reason. However, payment will still apply. Any laboratory which fails to make payment for the scheme will result in the cancellation of registration and referral to the relevant NQAAP.

Subscription Fees

The fees are in respect of all distributions and the associated reports within a twelve-month period commencing April 1st.

Postage costs, First Class Mail within the UK and Airmail overseas, are included within the subscription fee.

Failure to pay subscription fees on presentation of an invoice will result in discontinuation of participation and automatic referral to the relevant NQAAP.

CONDITIONS OF PARTICIPATION

Eligibility for Participation

Participation is open to all diagnostic and research laboratories. Diagnostic kit manufacturers and their agents are encouraged to subscribe to all relevant programmes on either a full participation or an information only basis.

Conditions:

1. EQA samples must be treated in an identical manner to a laboratory's routine clinical samples
2. Participants must inform the Centre of any problems with their testing facilities
3. Participants must inform the Centre of any method changes
4. Failure to pay subscription fees on presentation of an invoice will result in discontinuation of participation and automatic referral to the relevant NQAAP
5. All reports and the data they contain are copyright and may not be published in any form without the permission of the Director
6. Collusion between laboratories is not allowed. If a laboratory was suspected of collusion, the Centre would review the laboratories' participation in its schemes

Failure to return results

The number and frequency of specimen distributions for each scheme are deemed to be appropriate by the relevant Steering Committee under the Terms of Reference. When a participant fails to return results for 3 or more distributions within the scoring window they will be contacted by the Director and may be referred to the appropriate NQAAP as a Persistent Poor Performer.

STEERING COMMITTEES & NATIONAL QUALITY ASSURANCE ADVISORY PANELS

The advisory and steering committee structures for UK NEQAS for IMMUNOLOGY, IMMUNOCHEMISTRY and ALLERGY (UK NEQAS IIA) have been organised into separate Steering Committees and Specialist Advisory Groups to provide specialist advice in the clinical areas covered by the various programmes. This will allow greater freedom to seek advice and support in respect of different analytes and to reschedule responsibility for the programmes as required. The responsibility for monitoring performance is divided between the National Quality Assurance Advisory Panels for Immunology and for Chemical Pathology, and broadly follows the division of analytes between the Steering Committees and Specialist Advisory Groups.

Immunology Steering Committee

Chair	Mr P VIRGO	Bristol
Secretary	Mrs D PATEL	UK NEQAS IIA
Members	Dr M BUCKLAND	London
	Mr R CARTWRIGHT	Scunthorpe, NQAAP - Immunology
	Prof W EGNER	UK NEQAS IIA
	Dr J HARVEY	London
	Dr S HOLDING	Hull
	Dr A KARIM	Birmingham
	Dr R SARGUR	UK NEQAS IIA
	Mr C SCOTT	London
	Dr R WHEELER	London

Programmes for Autoimmunity

UK NEQAS for General Autoimmune Serology
UK NEQAS for Antibodies to Nuclear and Related Antigens
UK NEQAS for Phospholipid Antibodies
UK NEQAS for Neutrophil Cytoplasmic and Glomerular Basement Membrane Antibodies
UK NEQAS for Acetylcholine Receptor Antibodies
UK NEQAS for Bullous Dermatosis
UK NEQAS for Coeliac Disease Antibodies
UK NEQAS for Interferon Gamma Release Assays (Mycobacterium Tuberculosis) IGRA TB
UK NEQAS for Paraneoplastic Antibodies
UK NEQAS for Diabetic Markers
UK NEQAS for Ganglioside Antibodies
UK NEQAS for Myositis Associated Antibodies
UK NEQAS for Phospholipase A2 Receptor Antibodies
UK NEQAS for Myelin Associated Glycoprotein IgM Antibodies (MAG)
UK NEQAS for SARS-CoV-2 / COVID-19 Antibodies

Programmes for Allergy and Immunodeficiency

UK NEQAS for Antibody to Fungal and Avian Antigens
UK NEQAS for IgG Subclasses
UK NEQAS for Specific Microbial Antibodies
UK NEQAS for Total IgE
UK NEQAS for Allergen Specific IgE

UK NEQAS for C1 esterase inhibitor and functional complement assays
UK NEQAS for Allergen Component Testing
UK NEQAS for Tryptase

National Quality Assurance Advisory Panel for Immunology

Chair	Dr Mark Gompels	Bristol Royal College of Pathologists

Members are nominated by the Association of Clinical Pathologists, the British Society for Histocompatibility and Immunogenetics, the British Society for Immunology and the Institute of Biomedical Sciences.

Immunochemistry Steering Committee

Chair	Dr P W MASTERS	Sheffield
Secretary	Mrs D PATEL	UK NEQAS IIA
Members	Dr L BUSWELL	Lincolnshire
	Dr S HOLDING	Hull
	Dr P MONAGHAN	Manchester
	Dr M PETCHEY	Coventry
	Dr A ROWBOTTOM	Preston
	Dr R SARGUR	UK NEQAS IIA
	Ms C STANLEY	UK NEQAS IIA
	Dr C E STURGEON	UK NEQAS Peptide Hormone
	Dr D TURNOCK	York

Programmes for Immunochemistry

UK NEQAS for β2 Microglobulin
UK NEQAS for C-Reactive Protein
Pilot UK NEQAS for Point of Care CRP Testing
UK NEQAS for Ultrasensitive C-Reactive Protein
UK NEQAS for CSF IgG Oligoclonal bands
UK NEQAS for CSF Proteins and Biochemistry
UK NEQAS for Alpha 1 Antitrypsin and Phenotype Identification
UK NEQAS for CSF Haem Pigments
UK NEQAS for β2 Transferrin and β Trace Protein
UK NEQAS for Alkaline Phosphatase Isoenzymes
Pilot UK NEQAS for Interleukin-6 (IL6)

Programmes for Oncology

UK NEQAS for Monoclonal Protein Identification
Pilot UK NEQAS for Cryoprotein (image based)
UK NEQAS for Prostate Specific Antigen
UK NEQAS for Tumour Markers (CA Series)
UK NEQAS for Ultrasensitive PSA (UPSA)

National Quality Assurance Advisory Panel for Chemical Pathology

Chair	Dr P TWOMEY	Norwich Royal College of Pathologists

Members are nominated by the Association of Clinical Biochemists, the Association of Clinical Pathologists and the Institute of Biomedical Sciences.

Specialist Advisory Group for EQA of CSF Analysis

Chair	Dr E LEWIS	Chester
Secretary	Mrs D PATEL	UK NEQAS IIA
Members	Ms K BIRCH	Liverpool
	Dr M CHAPMAN	London
	Dr J GOODFELLOW	Glasgow
	Dr A KARIM	Birmingham
	Dr G MCKEEMAN	Belfast
	Dr R SARGUR	UK NEQAS IIA

Other UK NEQAS centres which survey performance in analytes of similar clinical relevance or application include:

UK NEQAS for Clinical Chemistry

Dr F MacKenzie
Wolfson EQA Laboratory
PO Box 3909
BIRMINGHAM
B15 2UE

Immunoglobulins and Complement proteins, Urine albumin

UK NEQAS for Lymphocyte Subpopulations

Mr L Whitby
UK NEQAS for Leucocyte Immunophenotyping
Pegasus House
4th Floor Suite
463A Glossop Road
SHEFFIELD
S10 2QD

CD4 and CD8 enumeration, CD34 enumeration

UK NEQAS for Peptide Hormones and Related Substances

Dr C E STURGEON
UK NEQAS (Edinburgh)
Department of Laboratory Medicine
The Royal Infirmary of Edinburgh
EDINBURGH
EH16 4SA

CEA, AFP, hCG, NTD and Down's Syndrome screening.

Advisory Panel - Terms of Reference

The National Quality Assurance Advisory Panels (NQAAPs) are responsible to the pathology professions for monitoring the maintenance of satisfactory standards of diagnostic work in clinical laboratories in the United Kingdom, whether in the public or private sector.

They are accountable to the professions through the Joint Working Group on Quality Assurance (JWGQA) and their relationship with participants is strictly professional and confidential. Members of the NQAAPs are nominated by the appropriate professional bodies and approved by the JWGQA.

The NQAAPs provide help, support and education to participants in UK NEQAS and other EQA programmes in a confidential setting. Members of the Immunology Panel represent the British Society for Immunology, the Association of Clinical Pathologists, the British Society for Histocompatibility and Immunogenetics, the Institute of Biomedical Sciences and the Royal College of Pathologists.

The Chemical Pathology Panel is similarly constituted with representation from the Association of Clinical Biochemists, the Association of Clinical Pathologists, the Institute of Biomedical Scientists and the Royal College of Pathologists.

Steering Committee - Terms of Reference

To advise the Organiser on the overall design and operation of the programme, including:

- the appropriateness of the investigations surveyed
- nature of the specimens distributed
- number and frequency of specimen distributions
- source of target values
- data analysis and performance assessment
- data presentation
- communication with participants
- communication with the diagnostic industry
- research and development for the programme

In consultation with the Director / Organiser, to liaise with the relevant NQAAP in the setting of performance criteria.

To consider, and advise the Director / Organiser on, the need for initiation or termination of EQA services for analytes within the discipline covered.

To receive any representation, to the Chair, members, or Director / Organiser, from participants concerning the programme.

REPORTS AND THEIR INTERPRETATION

The formats of the individual distribution reports vary in some details but broadly include a summary page, followed by further pages which give method related statistics for each sample and analyte, and a cumulative performance table. Developments in the presentation of the reports and the associated computer programs are under continual review and refinement.

The **Variance Index Scoring System** is used for data analysis in those programmes with a quantitative element and a numeric result. In those programmes or sections within programmes which call for an interpretative element or qualitative response the **Misclassification Index Scoring** system is used.

Principle Variance Index Scoring System

The variance index scoring system gives a simple but reliable indication of laboratory performance in a similar format for all analytes. It has proved robust over many years of use and has been applied successfully in a number of EQA programmes.

The basic concept is the **coefficient of variation**. This recognises that the variation in a technique as measured by the **standard deviation** often depends on the size of the measurement. The coefficient of variation divides the standard deviation by the average size of the measurement in an attempt to allow for this. It is usually expressed as a percentage. For practical purposes it is assumed that this ratio holds good for both small and large measurements.

In essence, the **variance index** is an expression of the relationship between the laboratory's coefficient of variation and the coefficient of variation of the technique for the analyte. The technique CV is not the actual value taken from the distribution or a measure of the clinically acceptable error but an arbitrary scaling factor, the **chosen coefficient of variation**, selected to represent the current state of the art and to produce VIs of a similar magnitude for all analytes.

The variance index records the degree of deviation from the designated value without regard for sign. Inclusion of the sign, deviations below the target being **negative** and deviations above the target being **positive**, results in the **bias index**. Consistency of error is best judged by looking at performance over a period of time, smoothing out erratic results by averaging the indices over, say, the last 10 EQA results. The smoothed bias index, the **mean running bias index score**, gives an indication of any consistent tendency to over-(positive) or under-(negative) estimates.

The smoothed variance index, the **mean running variance index score**, gives an indication of the degree of imprecision in that it averages the deviations without regard to sign. This will be influenced by large biases in either direction from the target values, and imprecision is best judged by the variability of the bias index, the **standard deviation of the bias index score**.

Cumulative performance scores will, on occasions, show a negative value for the MRVIS. Whilst not being mathematically correct, this is a flag which indicates that the laboratory concerned failed to return data on that distribution.

Definitions

The various indices used in the variance index scoring system may be defined as:

All Laboratory Mean (ALM): The mean of all results returned for a sample.

All Laboratory Trimmed Mean (ALTM): The recalculated mean value after exclusion of all results outside 2 (or 3) SD from the All Laboratory Mean. In some programmes the trimming is performed at the 10th and 90th centiles.

Method Laboratory Trimmed Mean (MLTM): The recalculated mean value of results returned by all laboratories using the same method. Widely discrepant results are trimmed as for the ALTM.

Group Laboratory Trimmed Mean (GLTM): As for MLTM but using all results from laboratories with related methods which have been predefined into a method group.

Designated Value (DV): For most programmes and analytes this is the All Laboratory Trimmed Mean (ALTM), but may, in certain situations, be a Method Mean (MLTM), a Grouped Method Mean (GLTM), or a preset value determined by prior definition or distribution. MLTM or GLTM are used in preference to the ALTM for those analytes where there are marked differences in numeric values obtained by different methods or with different commercial calibrants.

Chosen Coefficient of Variation (CCV): An arbitrary scaling factor selected for each analyte to correct for the current state of the art so as to produce VISs in a 'common currency'. The CCV does not represent a 'clinically acceptable error'.

Variance Index (VI): The difference, irrespective of sign, between the result returned and the designated value, expressed as a percentage of the designated value. This is divided by the CCV for the analyte expressed as a percentage.

$$VI = \frac{(\text{result} - DV).\ 10000}{DV \qquad CCV}$$

Variance Index Score (VIS): For values of VI less than 400, VIS=VI. The maximum VIS is 400.

Bias Index Score (BIS): Identical to the VIS but retaining the sign; a result higher than the designated value will give a positive BIS, whilst a lower result will give a negative BIS.

Standard Deviation of the BIS (SDBIS): The SD of the BISs in the current analytical time window, usually 10 or 12 valid results.

Mean Running VIS (MRVIS): The mean of the VISs in the current analytical time window.

Mean Running BIS (MRBIS): The arithmetic mean of the BISs in the current analytical time window.

Overall Mean Running VIS (OMRVIS): The mean of the MRVISs in the current analytical time window for all analytes in the programme.

Interpretation of variance index scores and indices

MRBIS gives an indication of the bias of the assay over a period of time, the degree of imprecision, and variability of the bias, being demonstrated by the SDBIS.

MRVIS is a compound index, and contains elements of both bias and imprecision. It is this index which is used in the classification of overall laboratory performance.

Interpretation of the Estimated Standard Uncertainty of the Consensus Mean

An estimate of the Standard Uncertainty of the Consensus Mean (the assigned 'Target' value) is calculated and displayed on the participant reports for all samples where participant performance scores are based on quantitative results. This enables the scoring system to be checked to ensure that it is fit for purpose and so minimise the risk that some laboratories will receive action/warning signals that are due to the inaccuracy in the determination of the assigned 'Target' value rather than any cause within the laboratory.

The Standard Uncertainty (U) is calculated using the standard deviation (SD) of the results and the number of data points (NTRIM), after trimming has been applied.

$U = 1.25 \times (SD / \sqrt{NTRIM})$

It is expected that the Standard Uncertainty will be less than 0.3 x CCV for the analyte. If this is not met, then participants will be informed that the uncertainty is not negligible by the addition of an appropriate comment to the report.

Please note that when MLTM is the assigned 'Target' value, U is Method related; when GLTM is the assigned 'Target' value, U is Grouped Method related; when ALTM is the assigned 'Target' value, U is All Laboratory related.

Reference:

Bullock DG, Wilde CE. *Annals of Clinical Biochemistry* 1985; 22:273-282

Misclassification Index Scoring System

The Misclassification Index Scoring System gives an indication of the number of instances where a laboratory has returned a qualitative response which is at variance with that defined for the specimen. The defined response may be preset by the Organiser in the light of the clinical information available or it may represent the majority view of the laboratories participating in the programme. In some circumstances the defined response may be set by prior distribution of the specimen to a panel of 'expert' laboratories.

The various indices and parameters used in the system may be defined as:

Designated Response (DR): The defined response for a specimen.

Consensus Designated Response (CONDR): The response as defined by consensus amongst the participants in the programme. The threshold for the definition of consensus is defined within each programme but is usually 80%.

Overall Misclassification Index Score (OMIS): The number of misclassifications by a particular laboratory during a defined period of time for an individual analyte. The time window usually includes the most recent 10 or 12 valid results. Atypical or equivocal results are excluded from scoring and will not influence the OMIS.

Total Misclassification Index Score (Total MIS): This index is designed to give an overall assessment of a laboratory's performance in a programme calling for qualitative responses to a number of analytes. Total MIS is the cumulated OMISs for all of the analytes in the programme assessed by a laboratory during the defined time window.

Interpretation of misclassification index scores

MIS counts the number of times a laboratory gives a wrong result. It follows, therefore, that the ideal MIS is zero. A MIS of 5, in a programme where the defined time window was 10 valid samples, would mean that the laboratory had made 5 correct responses and 5 incorrect responses; or, that they were as likely to get the answer on any individual sample right as they were to get it wrong.

MIS is analyte specific and gives an indication of qualitative performance for that particular analyte. OMIS cumulates the MIS values for all analytes within a programme, and gives an indication of overall performance for the analytes surveyed in the programme. As with the MIS, the ideal OMIS will also be zero, no incorrect results for any analyte during the current time window.

Performance Monitoring

For each EQA programme there are criteria of unsatisfactory performance that have been agreed with the relevant NQAAP. When a participating laboratory shows unsatisfactory performance or fails to return results for an analyte for which they have registered, the Director will make contact with the laboratory. Laboratories which fall within the Persistent Poor Performance category as defined in the individual programme data-sheets will be referred to the Chair of the appropriate NQAAP. The remit of the individual Panels extends to encompass all laboratories offering a clinical diagnostic service within the United Kingdom.

iEQA – Interpretative External Quality Assessment

What is it?

This is a web-based educational scheme that allows individuals to practise their clinical or scientific interpretative skills on a virtual patient's results. **ALL** scientific laboratory and medical staff in participant laboratories can navigate through a series of test results and medical information to investigate a case in the same manner as they would in a real laboratory or clinical setting. All the information that would normally be available will be accessible in various formats from numerical results through to scans, images, sample information and clinical history. You may draw conclusions and make comments and compare them with the 'correct' answer as well as that produced by your peer group. This will include the nominal cost of investigation and the efficiency with which you completed the case. You may repeat any case as many times as you wish to demonstrate improvement or to assist learning.

The scheme is registered for CPD with the IBMS

Who can register?

This scheme is available to ALL grades of scientific staff in participant laboratories.
See our website for further details **www.immqas.org.uk**

How to register

To register, or to send us your comments, please contact the Centre by emailing us at:
eqacases@immqas.org.uk

PROGRAMMES FOR AUTOIMMUNITY

General Autoimmune Serology

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 1982, reconfigured 2002

Clinical Applicability: Diagnosis of autoimmune disease

Analytes: Citrullinated Proteins (CP), Rheumatoid Factor IgM (RF), Thyroid Peroxidase Antibody (TPO), Anaemia Related Antibodies (GPC), Liver Disease Antibodies (LKM including AMA and SMA) and TSH Receptor Antibodies (TRAb). ***Each analyte is available separately***
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: U/mL in relation to the appropriate International Reference Preparations, or titre. Qualitative responses or interpretation of quantitative results are recorded as POSitive or NEGative

Samples Distributed: Liquid format. Normal and pathological human serum

Number of Distributions per year: 6

Number of Samples per Distribution: 6 (1 x RF, 1 x TPO, 1 x CP, 1 x Liver, 1 x GPC and 1 x TRAb)

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 are recorded for each analyte and assessed in relation to the designated response. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported

Performance Scoring: MI scoring

Criteria of Performance: Laboratory performance is classified in terms of OMIS derived from the qualitative responses for all analytes for which the laboratory is registered over a running analytical window of 6 Distributions (12 months)

The categories of performance are:

	Total MIS
Good	Zero
Adequate	1
Poor	>1

A OMIS of >1 (out of a possible six in the defined time window) for any one analyte will also be classified as poor performance.

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

Antibodies to Nuclear and Related Antigens

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1987, reconfigured 2002
Clinical Applicability:	Diagnosis of autoimmune disease
Analytes:	Qualitative and quantitative identification of antibody to nuclear antigens (ANA), dsDNA and to the saline-extractable nuclear antigens (ENAs) SSA(Ro), SSB(La), Sm, RNP, Scl70, Jo-1, and the pattern of antinuclear staining on immunofluorescence in the HEp-2 cell system including the identification of centromere antibody *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:	Qualitative and quantitative responses for the ANA, DNA, Centromere and ENA antibodies in relation to relevant reference preparations
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 are assessed in terms of MI scoring for each antibody specificity in relation to the Designated Response. Laboratories also submit the immunofluorescent staining pattern of antinuclear antibody. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance for each antibody specificity is classified in terms of MI scoring over a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1-2 Poor — Total MIS: >2 An OMIS of 2 or more for any one analyte will be classed as poor performance.
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Phospholipid Antibodies

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1987
Clinical Applicability:	Diagnosis of autoimmune disease
Analytes:	Identification and quantitation of Cardiolipin antibody (IgG and IgM), and will survey performance in the assays for antibodies to β2–Glycoprotein1 (both IgG and IgM) and Phosphatidylserine (IgG only). Other new generation phospholipid antibody assays will be considered for inclusion if clinical need dictates
Units for Reporting:	Qualitative responses phospholipid antibodies; Quantitative responses in GPLU/mL and MPLU/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:	Laboratories are requested to give a qualitative interpretation of the cardiolipin, β2GP1 and phosphatidylserine antibody results. This element of the programme is assessed by MI scoring. Reports show the quantitative responses returned for each analyte in relation to both All Laboratory and Method / Manufacturer specific data
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS derived from the qualitative responses for all analytes for which the laboratory is registered during a time window encompassing 6 Distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1-2 Poor — Total MIS: >2 An OMIS of 2 or more for any one analyte will be classed as poor performance.
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

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:

ANCA

	Total MIS
Good	Zero
Adequate	1-2
Poor	>2

An OMIS of 2 or more for any one analyte will also be classified as poor performance.

GBM

	Total MIS
Good	Zero
Adequate	1
Poor	>1

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

Acetylcholine Receptor Antibody

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1991
Clinical Applicability:	Diagnosis and monitoring of Myasthenia Gravis
Analytes:	ACR
Units for Reporting:	nmol/L
Samples Distributed:	Liquid format. Normal and pathological human serum Additional materials may be produced for specific recovery experiments by the addition of a reference serum to an analyte-free serum matrix
Number of Distributions per year:	4
Number of Samples per Distribution:	3
Frequency of Distributions:	Every three 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 are recorded for each analyte and assessed in relation to the designated response. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) The categories of performance are: Good — Total MIS: Zero Adequate — Total MIS: 1-2 Poor — Total MIS: >2
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Bullous Dermatosis Antibodies

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1995
Clinical Applicability:	Diagnosis of Bullous Dermatosis
Analytes:	Dermatosis Basement Membrane and Desmosome Antibodies
Units for Reporting:	Positive or Negative, U/mL, or titre as appropriate
Samples Distributed:	Liquid format. Normal and pathological human serum
Number of Distributions per year:	6
Number of Samples per Distribution:	1
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 are assessed by MI scoring in relation to the designated response
Performance Scoring:	MI scoring and OMIS for all analytes for which the laboratory is registered
Criteria of Performance:	Laboratory performance is assessed over a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: Zero Adequate — Total MIS: 1 Poor — Total MIS: >1
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Coeliac Disease Antibodies

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1995
Clinical Applicability:	Diagnosis of Coeliac Disease
Analytes:	Gliadin, deamidated gliadin peptide (DGP), endomysial and tissue transglutaminase antibodies (TTG)
Units for Reporting:	Positive or Negative, U/mL, or titre as appropriate
Samples Distributed:	Liquid format. Normal and pathological human serum
Number of Distributions per year:	6
Number of Samples per Distribution:	1
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 are recorded for each analyte and assessed in relation to the designated response. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported
Performance Scoring:	MI scoring for all analytes for which the laboratory is registered
Criteria of Performance:	Laboratory performance is assessed over a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: Zero Adequate — Total MIS: 1-2 Poor — Total MIS: >2 An OMIS of 2 or more for any one analyte will also be classified as poor performance
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Interferon Gamma Release Assays (Mycobacterium tuberculosis) IGRA TB

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 2009

Clinical Applicability: Test for latent tuberculosis infection and a useful aid for diagnosing M. tuberculosis complex infection

Analytes: IGRA TB

Units for Reporting: Qualitative responses (Positive, Negative and Indeterminate), Quantitative responses (IU/mL), number of T-spots, Clinical and Technical Interpretations

Samples Distributed: Normal and pathological human serum
Distributions are linked to cases on the UK NEQAS for Immunology, Immunochemistry & Allergy Interpretative EQA Scheme (iEQA) website

Number of Distributions per year: 6

Number of Samples per Distribution: 2 sets of 4 (Nil, TB1 antigen, TB2 antigen and Mitogen), or one pre-incubated microtiter strip consisting of two samples

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 show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS and MRVIS
Chosen Coefficient of Variation for Interferon gamma is 20%
Qualitative responses are assessed in relation to the designated response

Performance Scoring: MRVIS / MI scoring

Criteria of Performance: OMIS for qualitative results over a running analytical window of 6 Distributions (12 months)

Good	OMIS	Zero
Adequate		1-2
Poor		>2

Individual laboratory performance over a running analytical window of 6 Distributions (12 months) for Interferon Gamma Release Assay quantitation is expressed in terms of MRBIS, SDBIS and MRVIS

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

Paraneoplastic Antibodies

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2009
Clinical Applicability:	Paraneoplastic autoantibodies are seen with a variety of neurological manifestations and can be associated with an underlying malignancy
Analytes:	ANNA-1 (Hu), ANNA-2 (Ri), PCA-1 (Yo), CRMP5 (CV2), Amphiphysin, Ma-2 (Ta) and neurological GAD *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:	Qualitative responses or interpretation of qualitative results are recorded as Positive or Negative
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 are assessed in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS derived from the qualitative responses for all analytes for which the laboratory is registered over a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: Zero Adequate — Total MIS: 1 Poor — Total MIS: >1
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Diabetic Markers

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 2011

Clinical Applicability: Aiding the clinical diagnosis of type I diabetes

Analytes: Islet cell (ICA), Glutamic Acid Decarboxylase (GAD) and Protein Tyrosine Phosphatase (IA2), Insulin antibody (IA), Zinc Transporter 8 Antibody (ZnT8), Diabetic Marker Autoantibody Screen

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:
Islet cell: qualitative (titre) or U/mL
GAD: U/mL
IA2: U/mL
IA: U/mL % Binding
ZnT8: U/mL
Diabetic Marker Autoantibody Screen: U/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 28 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics

Data Analysis: Qualitative responses are recorded for each analyte and assessed in relation to the designated response. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported

Performance Scoring: MI scoring

Criteria of Performance: Laboratory performance is classified in terms of OMIS over a running analytical window of 6 Distributions (12 months). Cumulative performance scores are based on qualitative response

The categories of performance are:

	Total MIS
Good	zero
Adequate	1 - 2
Poor	>2

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

Ganglioside Antibody Markers

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2014
Clinical Applicability:	Diagnosis of neuropathy syndromes
Analytes:	IgG, IgM, IgG/IgM: GM1, GM2, GD1a, GD1b and GQ1b *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:	Titre
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 are recorded for each analyte and assessed in relation to the designated response. Reports show method or kit related statistics in terms of Method Laboratory Trimmed Mean (MLTM) and range of results reported
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS derived from the qualitative responses for all analytes for which the laboratory is registered over a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1 - 3 Poor — Total MIS: >3
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Myositis Associated Antibodies

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2017
Clinical Applicability:	Diagnosis of autoimmune disease
Analytes:	Jo-1, PL7, PL12, PM-SCL100, Mi-2, SRP and ANA *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:	Qualitative and quantitative responses for Jo-1, PL7, PL12, PM-SCL100, Mi-2, SRP, and the pattern of antinuclear staining on immunofluorescence in the HEp-2 cell system
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 are recorded for each analyte and assessed in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS over a running analytical window of 6 distributions (12 months). The categories of performance are: Good — Total MIS zero Adequate — Total MIS 1 - 3 Poor — Total MIS >3
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions.

Phospholipase A2 Receptor Antibodies (PLA2R)

Accreditation Status:	**UKAS Schedule of Accreditation**
Date scheme started:	2018
Clinical Application:	Primary (idiopathic) membranous nephropathy
Analytes:	PLA2R
Units for Reporting:	mg/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 2 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 are assessed by MI scoring in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS over a running analytical window of 6 distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1 - 2 Poor — Total MIS: >2
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions.

Myelin Associated Glycoprotein IgM Antibodies (MAG)

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2019
Clinical Applicability:	IgM anti – MAG found in sensory motor neuropathies and IgM paraprotein associated neuropathies
Analytes:	MAG
Units for Reporting:	Qualitative and quantitative responses for MAG
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 are assessed in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS over a running analytical window of 6 distributions (12 months) Categories of performance are: Good – Total MIS zero Adequate – Total MIS 1 - 2 Poor – Total MIS >2
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions.

SARS-CoV-2 / COVID-19 Antibodies

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2020
Clinical Applicability:	Detection of antibodies to SARS-CoV-2 / COVID-19 confirming previous infection
Analytes:	Antibodies to SARS-CoV-2 as IgG, IgM, IgA, Total Ig
Units for Reporting:	Qualitative and quantitative responses, method dependent
Samples Distributed:	Liquid format. Normal and pathological human serum
Number of Distributions per year:	12
Number of Samples per Distribution:	2
Frequency of Distributions:	Every month as outlined in the **Distribution Schedule**
Schedule of Analysis:	**Data entry** is via the web for the submission of results. Data analysis is commenced 14 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics
Data Analysis:	Group Laboratory Trimmed Mean (GLTM) with truncation at 2SD, SD, and CV%. Reports also show method and manufacturer specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, and MRVIS. The Designated Value (DV) for calculation of VI is the Method Laboratory Trimmed Mean (MLTM) Chosen Coefficient of Variation for quantitative results is 20%
Performance Scoring:	MI scoring and MRVIS
Criteria of Performance:	Laboratory performance for the qualitative element of the Scheme is assessed over a running analytical window of 12 Distributions (12 months)

Good	OMIS = 0
Adequate	OMIS = 1 -2
Poor	OMIS = >2

Individual laboratory performance over a running analytical window of 12 Distributions (12 months) quantitation is expressed in terms of MRBIS, SDBIS and MRVIS

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

PROGRAMMES FOR ALLERGY AND IMMUNODEFICIENCY

Antibody to Fungal & Related Antigens

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1991
Clinical Applicability:	Diagnosis and monitoring of Extrinsic Allergic Alveolitis and Type III hypersensitivity diseases including Aspergillus and Candida infections, Bird Fancier's and Farmer's Lung
Analytes:	Aspergillus fumigatus, Candida albicans, Pigeon Serum, Pigeon Feathers, Pigeon Droppings, Pigeon Mix, Budgerigar Serum, Budgerigar Feathers, Budgerigar Droppings, Budgerigar Mix and Micropolyspora faeni *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:	Qualitative and quantitative responses
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 results are assessed by Misclassification Index Scoring in relation to a Designated Response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS derived from the qualitative responses for all analytes for which the laboratory is registered during a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1 - 2 Poor — Total MIS: >2 An OMIS of 2 or more for any one analyte will be classed as poor performance
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

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:	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 10% IgG2 15% IgG3 17.5% IgG4 15%
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 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

Specific Microbial Antibodies

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 1998

Clinical Applicability: Diagnosis and management of antibody deficiency syndromes

Analytes: *Haemophilus Influenzae (HiB)*, *Pneumococcus, Tetanus, Salmonella ser. Typhi (S.Typhi)* and Pneumococcal Serotype Specific antibodies. ***Each analyte is available separately***

Units for Reporting:

Tetanus	IU/mL
HiB	mg/L
Pneumococcal Serotypes	mg/mL
	µg/mL
S.Typhi (pilot)	U/mL

Samples Distributed: Liquid format. Normal and pathological human serum

Number of Distributions per year: 6

Number of Samples per Distribution: 8 (2 x HiB, 2 x Tetanus, 2 x Pneumococcal and 2 x S.Typhi)

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 28 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) for Tetanus, Pneumococcal, *H. influenza* and S. Typhi antibodies with truncation at 2SD, SD and CV%. Reports show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS and MRVIS

Chosen Coefficient of Variation is specific for each analyte:

Tetanus antibody	20%
H. influenzae type B antibody	20%
Pneumococcal antibody	15%

Performance Scoring: MRVIS

Criteria of Performance: Laboratory performance is assessed in relation to each antibody over a running analytical window of 6 Distributions (12 months)

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

Total IgE

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1979
Clinical Applicability:	Diagnosis and management of allergic disease
Analytes:	Total IgE
Units for Reporting:	kU/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 show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS and MRVIS Chosen Coefficient of Variation for Total IgE is 8%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance is assessed over a running analytical window of 6 Distributions (12 months)

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

Allergen Specific IgE

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 1988

Clinical Applicability: Diagnosis and management of allergic disease

Analytes: The programme includes the assessment of common or clinically important, individual IgE specificities, for example:

D1	Dermatophagoides pteronyssinus
E1	Cat epithelium
E5	Dog dander
F1	Egg white
F2	Cow's milk
F13	Peanut
F17	Hazel nut
G6	Timothy grass
I1	Bee venom
I3	Wasp venom
K82	Latex
M3	Aspergillus fumigatus
M6	Alternaria alternata
T3	Birch
W6	Mugwort

Other allergen specificities may be included, subject to the availability of clinically validated donor serum units

Units for Reporting: Grade and kU/L (arbitrary)

Samples Distributed: Liquid format. Normal and pathological human

Number of Distributions per year: 6

Number of Samples per Distribution: 2

Frequency of Distributions: Every two months as outlined in the **Distribution Schedule.** Four allergen specific IgE tests will be analysed on each specimen

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: Analysis by grade shows the overall response and the method specific responses. Analysis of the quantitative responses 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 MLTM

Chosen Coefficient of Variation for Allergen Specific 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)

Ideal	MRVIS	<50
Good		50 - 100
Adequate		101 - 200
Poor		>200 or SDBIS >200

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)

Good	OMIS	Zero
Adequate		1 - 2
Poor		>2

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

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

Tryptase

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2010
Clinical Applicability:	The serum tryptase concentration reflects both the clinical severity of the allergic reaction and the reaction mechanisms. Serum tryptase can also be utilised for determining suspected mastocytosis and suspected acute allergic reactions
Analytes:	Tryptase
Units for Reporting:	Quantitative responses (µg/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 show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS and MRVIS Chosen Coefficient of Variation for Tryptase is 8%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance is classified in terms of the MRVIS over a running analytical window of 6 Distributions (12 months)

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

PROGRAMMES

FOR

IMMUNOCHEMISTRY

Alkaline Phosphatase (ALP) Isoenzymes

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2019
Clinical Applicability:	Identification of the alkaline phosphatase (ALP) isoenzyme type, to determine the tissue source of the elevated ALP in serum.
Analytes:	ALP Isoenzymes including liver, bone, intestinal and placental isoenzymes.
Units for Reporting:	Qualitative and quantitative responses for the predominant and secondary ALP isoenzyme, together with interpretation of results using coded comments.
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 28 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics
Data Analysis:	Qualitative responses are recorded for each analyte and assessed in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is classified in terms of OMIS over a running analytical window of 6 distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1 - 3 Poor — Total MIS: >3
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions.

β2 Microglobulin

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1987
Clinical Applicability:	Diagnosis and monitoring of B-cell malignancies
Analytes:	β2 Microglobulin
Units for Reporting:	mg/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** for β2 Microglobulin is 7%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance is classified in terms of the MRVIS over a running analytical window of 6 Distributions (12 months)

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

C1 Esterase Inhibitor and Functional Complement Assays

Accreditation Status:	UKAS Schedule of Accreditation
Date Scheme started:	2002
Clinical Applicability:	Diagnosis of Hereditary Angioedema and monitoring of complement activation
Analytes:	Performance will be monitored in the antigenic and functional assays for C1 Esterase Inhibitor. Laboratories are required to return data on Complement C3 and C4 to permit the interpretation of the C1 Esterase Inhibitor levels
Units for Reporting:	g/L in relation to relevant international standards, functional activity (%)
Samples Distributed:	Liquid format. Normal and pathological human serum Additional materials may be produced by the addition of purified C1 Esterase Inhibitor, C3 or C4 to an analyte free serum matrix
Number of Distributions per year:	4
Number of Samples per Distribution:	2
Frequency of Distributions:	Every three 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 28 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 and manufacturer specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, and MRVIS. The Designated Value (DV) for calculation of VI is the Method Laboratory Trimmed Mean (MLTM) Chosen Coefficient of Variation is 10%
Performance Scoring:	MI scoring and MRVIS
Criteria of Performance:	Laboratory performance for the qualitative element of the Scheme is assessed over a running analytical window of 4 Distributions (12 months)

Good	OMIS = 0
Adequate	OMIS = 1 -2
Poor	OMIS = >2

Individual laboratory performance over a running analytical window of 4 Distributions (12 months) quantitation is expressed in terms of MRBIS, SDBIS and MRVIS

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

C-Reactive Protein (CRP) & Procalcitonin (PCT)

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1982
Clinical Applicability:	Monitoring of the acute phase response
Analytes:	C-Reactive Protein Procalcitonin
Units for Reporting:	mg/L CRP, ng/mL PCT
Samples Distributed:	Liquid format. Normal and pathological human serum Additional materials may be produced for specific recovery experiments by the addition of purified CRP to an analyte-free serum matrix
Number of Distributions per year:	12
Number of Samples per Distribution:	2
Frequency of Distributions:	Every month as outlined in the **Distribution Schedule**
Schedule of Analysis:	**Data entry** is via the web for the submission of results. Data analysis is commenced 14 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 Chosen Coefficient of Variation for C-Reactive protein is 8% Chosen Coefficient of Variation for Procalcitonin is 20%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance is classified in terms of the MRVIS over a running analytical window of 12 Distributions (12 months)

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

Pilot Point of Care C-Reactive Protein (CRP) Testing

Accreditation Status: *currently not accredited to ISO 17043:2010*

Date Scheme started: 2017

Clinical Applicability: Monitoring of the acute phase response

Analytes: C-Reactive Protein

Units for Reporting: mg/L

Samples Distributed: Liquid format. Normal and pathological human serum

Additional materials may be produced for specific recovery experiments by the addition of purified CRP to an analyte-free serum matrix

Number of Distributions per year: 4

Number of Samples per Distribution: 2

Frequency of Distributions: Currently seasonal as outlined in the **Distribution Schedule**

Schedule of Analysis: **Data entry** is via the web for the submission of results. Data analysis is commenced 14 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, 3SD, and CV%.
Reports also show method specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, and MRVIS

Chosen Coefficient of Variation for C-Reactive protein is 8%

Performance Scoring: MRVIS

Criteria of Performance: Laboratory performance is classified in terms of the MRVIS over a running analytical window of 4 Distributions (12 months)

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

Ultrasensitive C-Reactive Protein (uCRP)

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1999
Clinical Applicability:	Monitoring of the acute phase response in neonates. Prognostic indicator of cardiovascular disease and risk assessment for coronary artery disease
Analytes:	Ultrasensitive C-Reactive Protein
Units for Reporting:	mg/L
Samples Distributed:	Liquid format. Normal and pathological human serum Additional materials may be produced for specific recovery experiments by the addition of purified CRP to an analyte-free serum matrix
Number of Distributions per year:	12
Number of Samples per Distribution:	2
Frequency of Distributions:	Every month as outlined in the **Distribution Schedule**
Schedule of Analysis:	**Data entry** is via the web for the submission of results. Data analysis is commenced 14 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 Chosen Coefficient of Variation for Ultrasensitive C-Reactive Protein is 8%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance is classified in terms of the MRVIS over a running analytical window of 12 Distributions (12 months)

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

CSF IgG Oligoclonal Bands

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1996
Clinical Applicability:	Diagnosis of multiple sclerosis
Analytes:	CSF IgG Oligoclonal Bands
Units for Reporting:	Presence or absence of IgG oligoclonal banding in the CSF sample and the pattern type
Samples Distributed:	Liquid format. Normal and pathological human cerebrospinal fluid, with a paired serum sample The concentration of IgG in the CSF and serum sample will be predetermined and this information will be included with the distribution to allow the appropriate dilution of the samples
Number of Distributions per year:	6
Number of Samples per Distribution:	2 (1 x CSF and 1 x serum pair)
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 and pattern type are assessed by MI scoring in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is assessed over a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1-2 Poor — Total MIS: >2
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Cerebrospinal Fluid Haem Pigments

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 2000

Clinical Applicability: Diagnosis of subarachnoid haemorrhage

Analytes: The programme surveys performance in assays for the identification of haem pigments and the quantitation of bilirubin and oxyhaemoglobin

Units for Reporting: Presence or absence of haem pigments and their identification. Quantitation of CSF bilirubin and oxyhaemoglobin absorbance. Interpretation of results using coded comments

Samples Distributed: Liquid format. Normal or pathological CSF will be distributed whenever sufficient volumes can be obtained. The majority of samples will, however, be of an artificial matrix developed for use in the programme

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 are assessed by MI scoring in relation to the designated response

Performance Scoring: MI scoring

Criteria of Performance: Laboratory performance is assessed over a running analytical window of 6 Distributions (12 months)

	OMIS Net Oxyhaemoglobin Absorbance	OMIS Net Bilirubin Absorbance	Interpretation
Good	Zero	Zero	Zero
Adequate	1-2	1-2	1-4
Poor	> 2	> 2	> 4

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

Samples should be tested as soon as possible upon receipt

National Guidelines for CSF analysis in suspected subarachnoid haemorrhage can be found under "Posters, Papers and Presentations" on the UK NEQAS IIA website:

National Guidelines for CSF analysis in suspected subarachnoid hemorrhage

Revision of National Guidelines for CSF analysis in suspected SAH

Cerebrospinal Fluid Proteins and Biochemistry

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 2000

Clinical Applicability: Assessment of neurological disease

Analytes: CSF Total protein, albumin, IgG, glucose and lactate

Units for Reporting: Total protein g/L, Albumin and IgG mg/L, Glucose and Lactate mmol/L in relation to the relevant International Standards

Samples Distributed: Liquid format. Normal or pathological CSF will be distributed whenever sufficient volumes can be obtained. The majority of samples will, however, be of an artificial matrix developed for use in the programme

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 and manufacturer specific statistics

Chosen Coefficient of Variation:

Total protein	15%
Albumin	10%
IgG	10%
Lactate	10%
Glucose	5%

Performance Scoring: MRVIS

Criteria of Performance: Laboratory performance for the quantitative biochemistry element is classified in terms of the MRVIS over a running analytical window of 6 Distributions (12 months)

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

Alpha 1 Antitrypsin Phenotype Identification

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2007
Clinical Applicability:	The quantitation of AAT is indicated in the evaluation of chronic obstructive airway disease (COPD), emphysema and in neonatal and adult liver disease where low concentrations may have diagnostic importance AAT genetic status (PI phenotyping) should be performed in all cases of deficiency when the quantitative assay gives results below the age related median concentration. The PI phenotyping should be determined in all children with liver disease irrespective of AAT concentration
Analytes:	Alpha 1 Antitrypsin, PI Phenotyping *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:	g/L
Samples Distributed:	Liquid format. Normal and pathological human serum
Number of Distributions per year:	4
Number of Samples per Distribution:	2
Frequency of Distributions:	Every three 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 28 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics
Data Analysis:	Qualitative and phenotype responses are assessed by MI scoring in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is assessed over a running analytical window of 4 Distributions (12 months) The categories of performance for Phenotype Identification are:

	Total MIS
Good	Zero
Adequate	1-3
Poor	>3

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

CSF β2 Transferrin and β Trace Protein

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	2011
Clinical Applicability:	The diagnosis of cerebrospinal fluid (CSF) rhinorrhea or otorrhea (leakage of CSF into the nose or ear canal, usually as a result of head trauma, tumor, congenital malformation, or surgery) is often difficult to confirm. CSF B2 Transferrin testing is used to determine the presence or absence of CSF (in serum) in such cases. Beta 2 Transferrin is only found in CSF, ocular fluids and perilymph, therefore it can be used as a marker to determine the presence of CSF in various secretions (typically from the nose and ear)
Analytes:	CSF β2 Transferrin, β Trace Protein
Units for Reporting:	Qualitative: Positive /Negative Quantitative: mg/L
Samples Distributed:	Normal and pathological human serum. Serum based or CSF samples
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 28 days after sample dispatch. Late returns are accepted and will contribute to the laboratory's cumulative performance statistics
Data Analysis:	Qualitative responses are assessed by MI scoring in relation to the designated response
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance is assessed over a running analytical window of 6 Distributions (12 months) The categories of performance are: Good — Total MIS: zero Adequate — Total MIS: 1 Poor — Total MIS: >1
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Pilot Interleukin-6 (IL6)

Accreditation Status:	*currently not accredited to ISO 17043*
Date Scheme started:	2020
Clinical Applicability:	Monitoring of inflammatory responses
Analytes:	Interleukin-6
Units for Reporting:	pg/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:	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 Chosen Coefficient of Variation is 20%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance is classified in terms of the MRVIS over a running analytical window of 6 Distributions (12 months)

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

PROGRAMMES

FOR

ONCOLOGY

Monoclonal Protein Identification

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1993
Clinical Applicability:	Diagnosis of monoclonal gammopathy in serum and urine
Analytes:	Total serum protein, Albumin, IgG, IgA, IgM, free light chains (Kappa, Lambda and ratio), urine total protein & Monoclonal Component identification and Quantitation
Units for Reporting:	Isotype of heavy and light chain together with the concentration of monoclonal protein in g/L. Serum free light chains in mg/L
Samples Distributed:	Liquid format. Normal and pathological human serum and urine Each distribution will contain a serum sample and a urine sample, they should be considered as separate requests for investigation. **It should NOT BE ASSUMED that they emanate from the same patient**
Number of Distributions per year:	6
Number of Samples per Distribution:	2 (1 urine and 1 serum)
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:	Whilst the programme will analyse participant's isotype identification and monoclone quantitation, the returns will require data on total serum protein, albumin, IgG, IgA, IgM (and urine total protein). This latter information will not be formally analysed as it is covered in other EQA programmes but will be of value in the recognition of analytical or isotype identification problems Chosen Coefficient of Variation: 30% for FLC Chosen Coefficient of Variation: 15% for Monoclonal Component Quantitation
Performance Scoring:	MI Scoring - The qualitative elements of electrophoresis and isotype identification MRVIS - Assessment of the monoclone quantitation and free light chains
Criteria of Performance:	The qualitative elements of electrophoresis and isotype identification are assessed by MI scoring over a running analytical window of 6 Distributions (12 months)

Good	OMIS	Zero
Adequate		1 - 2
Poor		>2

Poor Performance

For the monoclonal component and serum Free Light Chain quantitation, laboratory performance is assessed in relation to the MRVIS over a running analytical window of 6 Distributions.

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

Pilot Cryoprotein (image based)

Accreditation Status:	*currently not accredited to ISO 17043*
Date Scheme started:	2017
Clinical Applicability:	Diagnosis of cryoglobulinaemia
Analytes:	A virtual case study containing sample images, clinical scenario, laboratory results and testing protocols. With the information and images provided each participant decides their own pathway according to their laboratory protocols. Includes identifying the presence and typing of a cryoprotein
Units for Reporting:	N/A
Samples Distributed:	1 virtual case study
Number of Distributions per Year:	4
Number of Samples per Distribution:	1 case study per distribution
Frequency of Distributions:	Every 12 weeks as outlined in the Distribution Schedule
Schedule of Analysis:	Access to the virtual case study is via the web and includes the submission of interpretations. Data analysis is commenced 21 days after release of case. Late returns cannot be accepted.
Data Analysis:	Qualitative responses are assessed in terms of MI scoring for each scoring element in relation to the Designated Response.
Performance Scoring:	MI scoring
Criteria of Performance:	Laboratory performance for each scoring element is classified in terms of MI scoring over a running analytical window of 4 Distributions (12 months)
Persistent Poor Performance:	Defined as being in the Poor Performance category for two or more successive Distributions

Prostate Specific Antigen (PSA)

Accreditation Status:	**UKAS Schedule of Accreditation**
Date Scheme started:	1990
Clinical Applicability:	Diagnosis and management of prostate carcinoma
Analytes:	Total PSA, Free PSA **Each analyte is available separately**
Units for Reporting:	µg/L (total and free PSA) in relation to the WHO International Standard
Samples Distributed:	Liquid format. Normal and pathological human serum. Additional materials may be produced for specific recovery experiments by the addition of purified Free PSA analyte-free human serum pools
Number of Distributions per year:	12
Number of Samples per Distribution:	2
Frequency of Distributions:	Every month as outlined in the **Distribution Schedule**
Schedule of Analysis:	**Data entry** is via the web for the submission of results. Data analysis is commenced 14 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 Chosen Coefficient of Variation for Prostate Specific Antigen is 6% Chosen Coefficient of Variation for Free Prostate Specific Antigen is 10%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance for Total PSA and Free PSA is classified in terms of the MRVIS over a running analytical window of 12 Distributions (12 months)

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

Tumour Markers (CA Series)

Accreditation Status: UKAS Schedule of Accreditation

Date Scheme started: 1988

Clinical Applicability: Diagnosis and management of malignant disease

Analytes: CA125, CA15-3, CA19-9 and their notional equivalents, Neuron Specific Enolase (NSE) and Chromogranin A (pilot analyte). **All analytes are available separately**

Units for Reporting: kU/L (CA series markers), µg/L (NSE), ng/mL and nmol/L (Chromogranin A)

Samples Distributed: Liquid format. Normal and pathological human serum

Number of Distributions per year: 6

Number of Samples per Distribution: 10 (2 x CA125, 2 x CA15-3, 2 x CA19-9, 2 x NSE, 2 x Chromogranin A)

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 and manufacturer specific statistics. Individual laboratory performance is expressed in terms of MRBIS, SDBIS, and MRVIS. Because of marked differences in antigenic potency of some commercial kits, the Designated Value (DV) for calculation of VI is the Method Laboratory Trimmed Mean (MLTM).

Chosen Coefficient of Variation:

CA125 and Ovarian markers	10%
CA15-3 and Breast markers	12.5%
CA19-9 and GI markers	12.5%
NSE and Lung markers	12.5%
Chromogranin A (pilot analyte)	30.0%

Performance Scoring: MRVIS

Criteria of Performance: Laboratory performance is classified in terms of the MRVIS over a running analytical window of 6 Distributions (12 months)

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

Cancer Treatment Trials: Participation in these EQA programmes is often a requirement for laboratories providing analytical services to clinicians wishing to enter patients. Such laboratories will be required to agree to the organiser releasing their performance data to the relevant Trials Office

Ultrasensitive PSA (UPSA)

Accreditation Status	**UKAS Schedule of Accreditation**
Date Scheme started:	2019
Clinical Applicability:	A marker of recurrence for post radical prostatectomy patients
Analytes:	UPSA
Units for Reporting:	µg/L in relation to the WHO International Standard
Samples Distributed:	Liquid format. Normal and pathological human serum
Number of Distributions per year:	12
Number of Samples per Distribution:	2
Frequency of Distributions:	Every month as outlined in the **Distribution Schedule**
Schedule of Analysis:	**Data entry** is via the web for the submission of results. Data analysis is commenced 14 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 Chosen Coefficient of Variation for ultrasensitive Prostate Specific Antigen is 10%
Performance Scoring:	MRVIS
Criteria of Performance:	Laboratory performance for ultrasensitive PSA is classified in terms of the MRVIS over a running analytical window of 12 Distributions (12 months)

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

REFERENCE PREPARATIONS AND CALIBRANTS

Reference Preparations or 'standards' exist in a hierarchy that includes Primary Reference Materials produced on behalf of the International Agencies, National Reference Preparations, commercial calibrants or 'standards', and working calibrants or controls.

Primary Reference Materials: These are produced on behalf of the International Agencies and are designed to provide a long-term point of reference. Usually referred to as International Reference Preparations or IRPs, they are lyophilised materials that should be stored below -18°C. Where a unitage is ascribed, this may be in terms of units per ampoule or units per mL after reconstitution. Users should beware of this distinction and remember that reconstitution of the lyophilisate with distilled water will result in an increase in volume of approximately 6%. Reference Preparations defined as units per ampoule will yield concentrations in the reconstituted volume that are, on average, 6% lower than that assigned to the ampoule.

Secondary Reference Materials: These are assigned values in relation to the IRP and are intended to be readily available for the calibration of commercial or working calibrants. Some of these materials are produced for the specific purpose, whilst others originated as candidate preparations in the process of establishment of the IRP. They are usually designated as National Reference Preparations and are produced to the same standard as the IRPs. In some instances National Reference Preparations are established in response to local needs and in the absence of an accepted IRP.

The IFCC / BCR / CAP Certified Reference Material for Plasma Protein Analysis, ERM 470, whilst being, technically in part at least, a secondary reference material, is the *de facto* standard for the fourteen plasma proteins for which it has assigned values. All commercial calibrants are assigned values in relation to ERM 470. This material gives essentially new values for α1antitrypsin, α1acid glycoprotein, transferrin, and transthyretin that are reflected in changes in the rating of most of the currently available commercial calibrators.

The IRPs and ERM 470 are intended for use by national or reference laboratories to calibrate secondary materials, and by commercial companies to assign values to their calibrants or kit controls. They are not intended for use in the day-to-day assay.

To ensure the longevity of these materials, the custodians will only normally release one ampoule of each preparation to a requesting laboratory or organisation each year.

IRPs exist for some, but not all, of the analytes covered by UK NEQAS for Immunology, Immunochemistry & Allergy. The IRPs and National Reference Preparations are listed for Information together with the addresses of their respective custodians. Where relevant, quantitative data in UK NEQAS for Immunology, Immunochemistry & Allergy is expressed in terms of the IRP.

For those analytes where an appropriate reference material or IRP does not exist, UK NEQAS for Immunology, Immunochemistry & Allergy will endeavour to collaborate with the relevant International Agency in the production of such a material. As a short term expedient UK NEQAS for Immunology, Immunochemistry & Allergy will develop reference materials for use within the programmes where these are shown necessary to permit inter-laboratory assessment of quantitative data.

International or National Reference Preparations:

ERM 470	Human serum proteins	[5]

ERM 470 is available to commercial companies and to laboratories involved in calibrant production or validation through IRMM in Europe and the United States. It will not be generally available to diagnostic laboratories.

IgE	WHO 2nd International Reference Preparation 75/502	[1]
PSA	WHO 1st International Standard for total PSA (90:10)	[1]
	WHO 1st International Standard for free PSA	[1]
	CRM 613 1 µg/ampoule	[5]

Reference sera for Anti-Nuclear and related antibodies:

66/233	WHO 1st Reference Preparation for Anti-nuclear antibody (W1064) - homogeneous pattern. (1970)	[1]
66/233	Antinuclear factor serum, human	[1]
	WHO International Reference Human Serum for Anti-nuclear Ribonuclear Protein (nRNP) autoantibody	[2]
68/340	Anti-nucleolar factor plasma, human	[1]
	IUIS Reference Preparation for IgM class Anti-nuclear antibody H.L	[2]
AF-CDC-ANA#1	ANA homogeneous/rim pattern - dsDNA	[3]
AF-CDC-ANA#2	ANA speckled pattern - SSB/La	[3]
AF-CDC-ANA#3	ANA speckled pattern	[3]
AF-CDC-ANA#6	ANA nucleolar pattern	[3]
AF-CDC-ANA#8	ANA anti-centromere	[3]
AF-CDC-ANA#5	anti-Sm	[3]
AF-CDC-ANA#4	anti-RNP	[3]
AF-CDC-ANA#7	anti-SSA / Ro	[3]
AF-CDC-ANA#9	anti-Scl70	[3]
AF-CDC-ANA#10	anti-Jo-1	[3]

Reference sera for other Autoantibodies:

W1066	Rheumatoid Arthritis Serum, Human	[1]
65/093	Anti-Thyroglobulin serum, human 1st International Reference Preparation 1978	[1]
66/387	Anti-Thyroid microsome serum, human	[1]
08/204	2nd International Standard for Thyroid Stimulating Antibody	[1]
69/065	Autoimmune antibody to human spermatozoa	[1]
67/183	Primary Biliary Cirrhosis serum, human	[1]
W1062	WHO International Reference Human Serum for anti-Smooth Muscle (anti-Actin) antibody 1st International Standard, 1973	[1]
76/525	Anti-birch pollen serum, human	[1]
78/545	Anti-Aspergillus fumigatus serum, human	[1]

Addresses of Custodians of Reference Materials:

[1] National Institute for Biological Standards and Control
Blanche Lane
South Mimms, Potters Bar
HERTS, EN6 3QG
UNITED KINGDOM

Tel: +01707 64 10 00
E-mail: enquiries@nibsc.hpa.org.uk
Internet: http://www.nibsc.ac.uk

[2] Sanquin Diagnostics Services
International Laboratory for Biological Standards
Plesmanlaan 125
1066 CX
AMSTERDAM
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Fax: +31 20 512 36 60

[3] AF-CDC ANA Reference Laboratory, 1-1202 A25
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Immunology Branch, DHR, CID
1600 Clifton Road, NE
ATLANTA, GA 30333
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