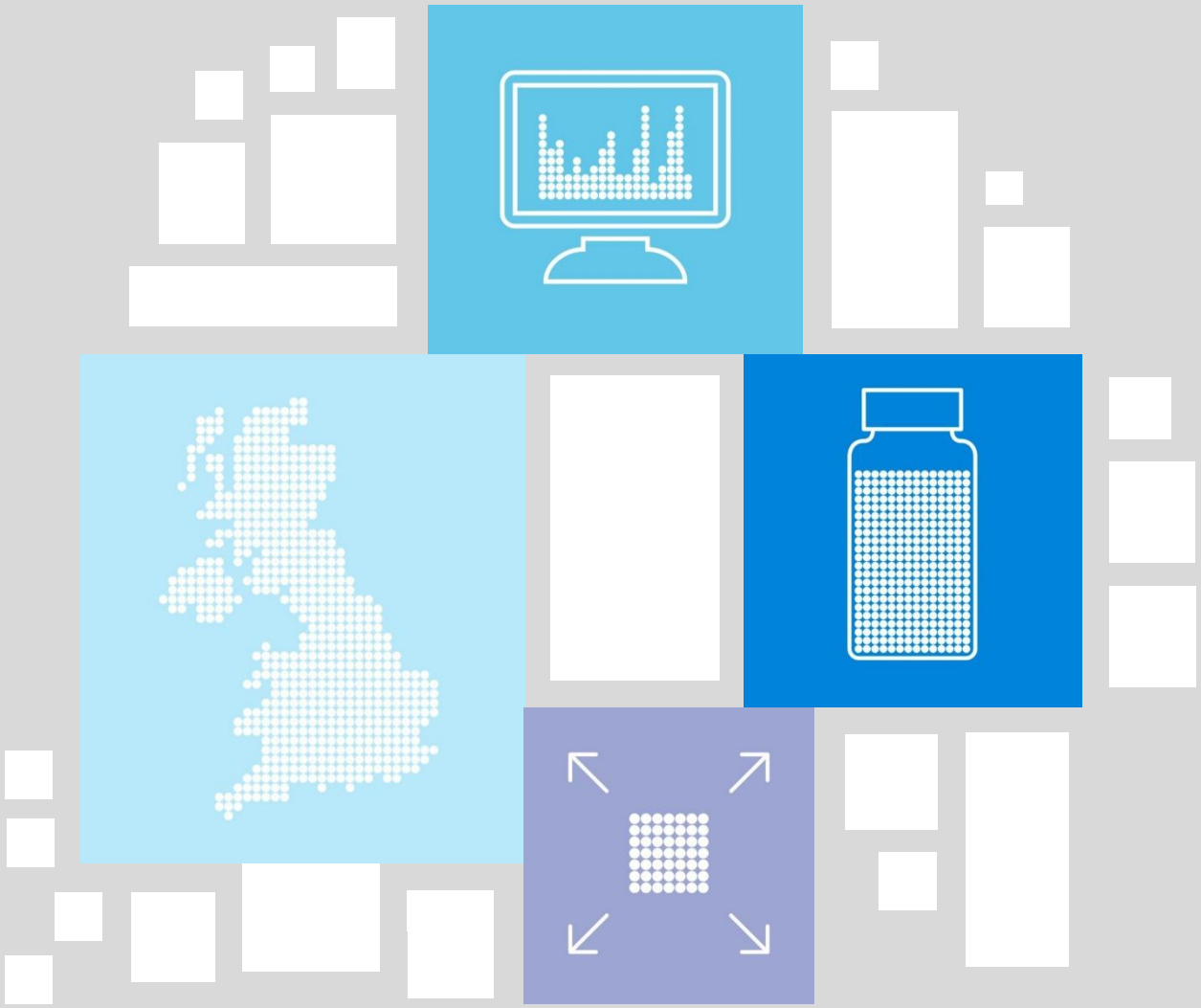
# UK NEQAS

## Immunology, Immunochemistry & Allergy



# Participation Handbook

## 2026-2027

# Programmes for Immunology, Immunochemistry and Allergy 2026-2027

**UK NEQAS for IMMUNOLOGY, IMMUNOCHEMISTRY and ALLERGY**
**Northern General Hospital**
**Herries Road**
**SHEFFIELD**
**S5 7AU**
**UNITED KINGDOM**

**Telephone:** **+44 (0) 114 271 5715**
**E-mail:** **ukneqas@immqas.org.uk**
**Internet:** **www.immqas.org.uk**

# 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 Standard.

# GENERAL INFORMATION

## Location

UK NEQAS for Immunology, Immunochemistry and Allergy operates from the Northern General Hospital in Sheffield.

## 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<br>Ravishankar Sargur |
| **Centre Manager:** | Carol Stanley |
| **Operations Manager:** | Amina Bhayat-Cammack<br>David Gill<br>Matt Fletcher |
| **Senior Biomedical Scientist:** | Corinna Barber<br>Samantha Bex<br>Samantha Lewis |
| **Biomedical Scientist:** | Gazala Rehman<br>Joy Obi |
| **Biomedical Science Associate Practitioner:** | Leah Higton<br>Sophia Braithwaite |
| **Laboratory Team Leader:** | Andrew Jamieson |
| **Laboratory Assistant:** | Hope Tudor<br>Kristina Parkin<br>Paul Bartley |
| **Registrations / Finance:** | Emma Kay<br>Faruq Audu<br>Hasan Ramzan<br>Scott Warrender |

## Contact Details

**Contact Address:** UK NEQAS for Immunology, Immunochemistry and Allergy
Northern General Hospital
SHEFFIELD S5 7AU
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 us). Both systems enable the handling of EQA data with scoring systems and report output. Web entry of results is mandatory for most 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 and ISO 15189.

## 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. *Click here to contact us directly*

## Participant Appeals

Participants wishing to appeal against a score that is not the result of a potential "blunder" must contact the Director, Centre Manager 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. *Click here to contact us directly*

## 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. *Click here to contact us directly*

## 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. *Click here to contact us directly*

## 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 searchable FAQ section on our website for frequently asked questions. *Click here to contact us directly*

## Complaints

Any complaints regarding the service provided by UK NEQAS for Immunology, Immunochemistry and Allergy should be directed to either the Director, Centre Manager 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 Quality Assurance in Pathology Committee (QAPC).

*Click here to contact us directly*

## Complaints and Appeals Policy

UK NEQAS IIA has a documented procedure for handling complaints and appeals, summarized below:

- Receipt of complaints/appeals will be acknowledged
- The matter will be investigated at the earliest possible opportunity
- We aim to provide a response within 10 working days, which will be either (i) a final decision or (ii) a progress report indicating the likely time until the final decision will be available
- The Centre actively takes steps to ensure that complaints/appeals do not result in discriminatory actions.

## Changes to Programmes

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 17043:2023 are indicated as "pilot" schemes. Any element of a scheme where the minimum number of returned results required to make scoring statistically meaningful is not met will not be accredited to ISO 17043:2023.*

## 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 datasheet. 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. The Safety Data Sheet for UK NEQAS IIA samples is here: UK NEQAS IIA Safety Data Sheet

## Repeat Samples

A limited supply of back samples are retained by the Centre, which are available to participants upon request via our website **Contact us** page.

# 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 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 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 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 21**

- 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 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 2026**

**Review Date: 01/04/2027**

**Controlled Copy** **Do Not Duplicate** *Printed on April 01, 2026* *Page 1 of 1*

# 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 courier 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.

## Certificate of Participation

A Certificate of Participation is available upon request. However, if the certificate is for the current registration year, then a laboratory must have already participated in at least 50% of the distributions for their subscribed schemes within the year.

# 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** | Dr Sarah **Linstead** | LONDON |
| **Secretary** | Mrs Dina **Patel** | UK NEQAS IIA |
| | Dr Matthew **Buckland** | LONDON |
| | Dr Ravishankar **Sargur** | UK NEQAS IIA |
| | Dr Alison **Whitelegg** | SOUTHAMPTON |
| | Ms Sophie **Lloyd Davies** | LONDON |
| | Ms Carol **Stanley** | UK NEQAS IIA |
| | Dr Elizabeth **Walker** | LONDON |
| | Dr Daniel **Payne** | NQAAP |

## Programmes for Immunology

UK NEQAS for Anaemia Related antibodies
UK NEQAS for Anti Neutrophil Cytoplasmic antibody
UK NEQAS for Antibodies in Bullous Dermatosis
UK NEQAS for Antibodies in Coeliac Disease
UK NEQAS for Antibody to Fungal and Related antibodies
UK NEQAS for Cryoglobulins (image based)
UK NEQAS for Diabetic Markers
UK NEQAS for Digital ANA (dANA)
UK NEQAS for IgG Subclasses
UK NEQAS for Interferon Gamma Release Assays
UK NEQAS for Liver Disease antibodies
UK NEQAS for Myositis antibodies
UK NEQAS for Nuclear antibodies
UK NEQAS for Phospholipase A2 Receptor antibodies (PLA2R)
UK NEQAS for Phospholipid antibodies
UK NEQAS for Rheumatoid antibodies
UK NEQAS for SARS COV-2 antibodies
UK NEQAS for Specific Microbial antibodies
Pilot UK NEQAS for anti TNF drug antibodies
Pilot UK NEQAS for Digital Electrophoretic Patterns
Pilot UK NEQAS for Scleroderma associated antibodies
Pilot UK NEQAS for UK NEQAS for IgD

## Immunochemistry Steering Committee

| | | |
|---|---|---|
| **Chair** | Dr Lesley **Buswell** | LINCOLNSHIRE |
| **Secretary** | Mrs Dina **Patel** | UK NEQAS IIA |
| | Dr Phillip **Monaghan** | MANCHESTER |
| | Dr Mike **Petchey** | COVENTRY |
| | Prof. Anthony **Rowbottom** | PRESTON |
| | Dr Ravishankar **Sargur** | UK NEQAS IIA |
| | Ms Carol **Stanley** | UK NEQAS IIA |
| | Dr Catherine **Sturgeon** | EDINBURGH |
| | Dr Daniel **Turnock** | YORK |
| | Dr Adrian **Heaps** | BRISTOL |
| | Dr Simon **Salter** | LONDON |
| | Dr Anna **McHugh** | HULL |
| | Dr Funmi **Akinlade** | NQAAP |

## Programmes for Immunochemistry

UK NEQAS for Alkaline Phosphatase Isoenzymes
UK NEQAS for Allergen Component Testing
UK NEQAS for Allergen Specific IgE
UK NEQAS for Alpha 1 Antitrypsin and Phenotype Identification
UK NEQAS for B2 Microglobulin
UK NEQAS for C1 INH and Functional Complement Assays
UK NEQAS for C-Reactive Protein
UK NEQAS for Interleukin-6 (IL6)
UK NEQAS for Monoclonal Protein Identification
UK NEQAS for Procalcitonin
Uk NEQAS for Prostate Specific Antigen
UK NEQAS for Total Serum IgE
UK NEQAS for Tryptase
UK NEQAS for Tumour Markers
UK NEQAS for Ultrasensitive C-Reactive Protein
UK NEQAS for Ultrasensitive PSA (UPSA)
Interpretative EQA Programme (iEQA)

## Neuroimmunology Steering Committee

| | | |
|---|---|---|
| **Chair** | Mrs Katherine **Birch** | LIVERPOOL |
| **Secretary** | Mrs Dina **Patel** | UK NEQAS IIA |
| | Dr Miles **Chapman** | LONDON |
| | Dr John **Goodfellow** | GLASGOW |
| | Dr Ravishankar **Sargur** | UK NEQAS IIA |
| | Dr Maria **Squires** | EDINBURGH |
| | Dr Carrie **Chadwick** | LIVERPOOL |
| | Ms Carol **Stanley** | UK NEQAS IIA |
| | Ms Bushra Afreen **Zaidi** | BROMPTON |
| | Mr James **Hoy** | OXFORD |
| | Dr Melanie **Hart** | LONDON |
| | Prof. Michael **Lunn** | LONDON |

## Programmes for Neuroimmunology

UK NEQAS for Acetylcholine Receptor Antibodies
UK NEQAS for CSF Beta 2 Transferrin
UK NEQAS for CSF Haem Pigments
UK NEQAS for CSF IgG Oligoclonal bands
UK NEQAS for CSF Proteins and Biochemistry
UK NEQAS for Ganglioside Antibodies
UK NEQAS for Myelin Associated Glycoprotein IgM Antibodies (MAG)
UK NEQAS for Paraneoplastic Antibodies
Pilot UK NEQAS for Autoimmune Encephalitis Associated Antibodies

## Alkaline Phosphatase Isoenzyme (ALPI) Analysis Special Advisory Group

| | | |
|---|---|---|
| **Chair** | Dr Daniel **Turnock** | YORK |
| **Secretary** | Mrs Dina **Patel** | UK NEQAS IIA |
| | Dr Sarah **Glover** | HARROGATE |
| | Dr Rebecca **Batchelor** | EDINBURGH |
| | Ms Carol **Stanley** | UK NEQAS IIA |
| | Dr Simon **Salter** | LONDON |
| | Dr Eleanor **Oakes** | SHEFFIELD |

## 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.

## 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 Quality Assurance in Pathology Committee (QAPC) 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 QAPC.

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.

## National Quality Assurance Advisory Panel for Immunology

| | | |
|---|---|---|
| Dr Daniel **Payne** | 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.

## National Quality Assurance Advisory Panel for Chemical Pathology

| | | |
|---|---|---|
| Dr Funmi **Akinlade** | 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.

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 Immunophenotyping

Mr S Scott
UK NEQAS for Leucocyte Immunophenotyping
4th Floor Suite Pegasus House
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

# 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 programmes are under continual review and refinement.

Scheme staff with the authority to authorise the release of reports for publication are shown in the footer of each report. Details of scheme staff who authorised the release of an individual report are available upon request.

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 several 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 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, 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 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, 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.

### Statistical Robustness and Low Numbers of Results

For both qualitative and quantitative EQA schemes, UK NEQAS IIA has a policy of requiring a minimum number of 30 active participants for each ISO 17043 accredited scheme.

To ensure that assigned values and performance assessments are statistically reliable and fair, UK NEQAS IIA normally requires a minimum of 30 returned results within a method group to calculate a robust consensus mean. This minimum number is widely accepted in statistical practice as supporting reliable estimation of group performance.

Where fewer than 30 returned results are available within a method group, the calculated mean may be less statistically robust and participant results should therefore be interpreted with additional care. In these circumstances, UK NEQAS IIA will take appropriate action to ensure performance assessment remains fair, which may include using an alternative reference value (e.g. GLTM/ALTM or another suitable wider consensus value), withholding formal performance scoring for that method group until sufficient returned results are available, and/or applying expert review where necessary.

In addition, where GLTM/ALTM is considered inappropriate for a particular method (for example, due to known method-related bias, poor comparability between platforms, or non-consensus behaviour), UK NEQAS may apply an alternative assigned value approach to avoid any unintended advantage or disadvantage to any method group.

UK NEQAS IIA may continue to report results for method groups with fewer than 30 returned results to ensure the EQA service remains inclusive and does not unfairly favour established, high-volume methods. This supports the participation and evaluation of newer or less commonly used methods, while ensuring that interpretation and performance assessment remain proportionate and aligned with the principles of impartiality and independence set out in ISO/IEC 17043.

### 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.*

## References:

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

Kuselman, I. and Fajgelj, A. (2010) 'IUPAC/CITAC Guide: Selection and use of proficiency testing schemes for a limited number of participants—chemical analytical laboratories (IUPAC Technical Report),' *Pure and Applied Chemistry*, 82(5), pp. 1099–1135

ISO 13528:2022

# 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. Where there are significant differences between methodologies the threshold for the definition of consensus may vary, but the lowest limit for consensus will be 70% for all ISO 17043 accredited schemes.

**Overall Misclassification Index Score (OMIS):** The number of misclassifications by a particular laboratory during a defined period 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 several analytes. Total MIS is the cumulated OMISs for all 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 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 contact the laboratory. Laboratories which fall within the Persistent Poor Performance category as defined in the individual programme datasheets 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 accredited to ISO 17043 available from UK NEQAS IIA

***Click on the programme name for further details***

***Please see Pilot Programmes section for programmes not accredited to ISO 17043***

**AUTOIMMUNITY PROGRAMMES**

General Autoimmune Serology - this scheme has been reconfigured into 4 new programmes:

- Rheumatoid Antibodies
- Thyroid Antibodies
- Anaemia Related Antibodies
- Liver Disease Antibodies

Rheumatoid Antibodies

- Rheumatoid Factor (SER/001)
- Citrullinated Proteins (SER/036)

Thyroid Antibodies

- Thyroid Microsome Antibody/TPO (SER/002)
- Thyroid Stimulating Hormone Receptor Antibody/TRAb (SER/048)

Anaemia Related Antibodies

- Gastric Parietal Cell Antibodies (SER/034)

Liver Disease Antibodies

- Identification of antibodies associated with autoimmune liver disease (SER/004)
- To include Mitochondrial antibodies, Liver Kidney Microsomal (LKM) antibodies, Smooth Muscle Antibodies (SMA) and other liver antibodies (PML, Ro-52)

Antibodies to Nuclear and Related Antigens

- Nuclear Antibodies (ANA/DNA/ENA) (SER/005)
- Nuclear Antibodies (ANA/DNA) (SER/003)

Acetylcholine Receptor Antibody (ACR) (SER/008)

Anti Phospholipid Antibodies (SER/006)

Autoimmune Serology ANCA and GBM (SER/007)

Bullous Dermatosis Antibodies (SER/009)

Coeliac Disease Antibodies (SER/010)

COVID-19/SARS CoV-2 Antibodies (SER/059)

Diabetic Markers (SER/047)

Ganglioside Antibody (SER/050)

Interferon Gamma Release Assays (SER/039)

Myositis Associated Antibodies (SER/054)

Myelin Associated Glycoprotein IgM Antibodies (SER/057)

Paraneoplastic Antibodies (SER/038)

Phospholipase Receptor 2 Antibodies (SER/055)

**ALLERGY & IMMUNODEFICIENCY PROGRAMMES**

Allergen Specific IgE (SER/032)

Allergen Component Testing (SER/051)

Fungal & Related Antigens

- Fungal Antibodies (SER/016)
- Avian Antibodies (SER/017)

IgG Subclasses (SER/018)

Specific Microbial Antibodies

- Tetanus Antibodies (SER/043)
- H.Influenzae Antibodies (SER/044)
- Pneumococcal Antibodies (SER/045)

Total Serum IgE (SER/031)

Tryptase (SER/040)

**IMMUNOCHEMISTRY PROGRAMMES**

Alkaline Phosphatase Isoenzymes (SER/056)

Alpha 1 Antitrypsin Phenotype Identification (SER/037)

Beta 2 Microglobulin (SER/013)

C1 Inhibitor and Functional Complement (SER/033)

C-Reactive Protein (SER/014)

Procalcitonin (SER/061)

CRP Ultrasensitive Assays (SER/028)

CSF Oligoclonal Bands (SER/015)

CSF Haem Pigments (SER/042)

CSF Proteins & Biochemistry (SER/041)

CSF Beta 2 Transferrin / Beta Trace Protein (SER/046)

Interleukin-6 (SER/060)

**ONCOLOGY PROGRAMMES**

Monoclonal Proteins (SER/019)

Total PSA (SER/020) & Free PSA (SER/030)

Tumour Markers

- Ovarian Markers (CA125) (SER/021)
- Gut Markers (CA199) (SER/022)
- Breast Markers (CA153) (SER/023)
- Lung Markers (NSE) (SER/024)
- Chromogranin A (SER/049)

Ultrasensitive PSA (SER/058)

**DIGITAL PROGRAMMES**

Digital ANA (image based) (DA/601)

Digital Cryoprotein (image based) (SER/052)

## Pilot Programmes – currently not accredited to ISO 17043

**NEW** Digital Electrophoretic Patterns (pilot) (dEP) DA/602

Anti-TNF Drugs and Antibodies (pilot) (TNFA(SER/065) / TNFI(SER/066))

Autoimmune Encephalitis Associated Antibodies (pilot) (SER/062)

Immunoglobulin D (pilot) (IgD) SER/063

Point of Care CRP Testing (pilot) (POC/555)

Scleroderma (pilot) (SCL) SER/064

# 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 $\alpha$1antitrypsin, $\alpha$1acid 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<br>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<br>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.org
Internet: https://nibsc.org/

[2] Sanquin Diagnostics Services
International Laboratory for Biological Standards
Plesmanlaan 125
1066 CX
AMSTERDAM
THE NETHERLANDS

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Fax: +31 20 512 36 60

[3] AF-CDC ANA Reference Laboratory, 1-1202 A25
Centers for Disease Control & Prevention
Immunology Branch, DHR, CID
1600 Clifton Road, NE
ATLANTA, GA 30333
USA

Tel: (404) 639 33 11

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PO Box 894
SHEFFIELD, S5 7YT
UNITED KINGDOM

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E-mail: uknegas@immqas.org.uk
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