UK NEQAS
Immunology, Immunochemistry & Allergy

Schemes Available

Programmes in 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 Assay (Mycobacterium Tuberculosis)
- 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 Associated Glycoproteins (MAG)
- UK NEQAS for SARS-CoV-2 / COVID-19 Antibodies
- Pilot UK NEQAS for NMDAR

Programmes in 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 Allergen Component Testing
- UK NEQAS for Tryptase

Programmes in Immunochemistry

- UK NEQAS for Alkaline Phosphatase Isoenzymes
- UK NEQAS for β2Microglobulin
- UK NEQAS for C1 Esterase Inhibitor and Functional Complement Assays
- UK NEQAS for C-Reactive Protein & Procalcitonin
- 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 Haem Pigments
- UK NEQAS for CSF Proteins and Biochemistry
- UK NEQAS for Alpha 1 Antitrypsin and Phenotype Identification
- UK NEQAS for CSF β2 Transferrin and β Trace Protein
- UK NEQAS for Interleukin-6 (IL6)

Programmes in Oncology

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

Digital Programmes (Image Based)

- Digital ANA (dANA) – Image Based

New Pilot Programmes – Immunoglobulin D and Scleroderma

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: Good — Total MIS: Zero Adequate — Total MIS: 1-2 Poor — Total MIS: >2 A OMIS of >2 (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 identification of antibody to nuclear antigens (ANA), dsDNA and to the saline-extractable nuclear antigens (ENAs) SSA(Ro), SSB(La), Sm, RNP, Sm/RNP, Scl70, Jo-1, ENA screen, and the pattern of antinuclear staining on immunofluorescence in the HEp-2 cell system including the identification of centromere antibody. The ICAP classification is followed.
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:

	Total MIS
Good	zero
Adequate	1-3
Poor	>3

An OMIS of 3 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:

	Total MIS
Good	zero
Adequate	1-3
Poor	>3

An OMIS of 3 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:

	Total MIS
Good	Zero
Adequate	1-2
Poor	>2

An OMIS of 3 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

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 Poor — Total MIS: >1
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, anti-DSG-1 antibodies, anti-DSG-3 antibodies, anti-BP-180 antibodies and anti-BP-230 antibodies

Units for Reporting: Positive or Negative, U/mL, Ratio, 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:

	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

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
Poor		>1

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:	Paraneoplastic Antibodies – present or absent Antibody identification – Analytes from list, ANNA-1 etc
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: 1-2 Poor — Total MIS: >2
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 - 3
Poor	>3

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:	Results may be reported as Ratio, Titre, Other or N/A
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 also show the number of Positive or Negative responses for each method
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 — 1 Poor — >1
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 — 1 Poor — >1
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:

	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.

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:	6
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

Pilot UK NEQAS for N-methyl-D-aspartate receptor (NMDAR) antibodies

Accreditation Status:	*currently not accredited to ISO 17043*
Date Scheme started:	2023
Clinical Applicability:	Autoimmune encephalitis with no known common infectious cause
Analytes:	NMDAR
Units for Reporting:	Qualitative: Positive / 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 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 — 1 - 2 Poor — >2
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:

	Total MIS
Good	zero
Adequate	1 - 2
Poor	>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	6%
IgG2	6%
IgG3	6%
IgG4	6%

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* and Pneumococcal Serotype Specific antibodies. ***Each analyte is available separately***

Units for Reporting:

Tetanus	IU/mL HiB mg/L
Pneumococcal Serotypes	mg/L µg/mL

Samples Distributed: Liquid format. Normal and pathological human serum

Number of Distributions per year: 6

Number of Samples per Distribution: 6 (2 x Tetanus, 2 x HiB, 2 x Pneumococcal)

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 and *H. influenza* 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	20%

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 12%

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 - 3
Poor		>4

Overall MIS (OMIS) greater than 4 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:

	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.

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. 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 All Laboratory Trimmed Mean (ALTM) 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:

	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

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. The Designated Value (DV) for NOA and NBA for calculation of VI is the All Laboratory Trimmed Mean (ALTM)

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 are available in the hyperlinks below:

National Guidelines for CSF analysis in suspected SAH

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	8%
	Albumin	9%
	IgG	6.5%
	Lactate	6%
	Glucose	4%

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: Phenotype Identification 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, tumour, 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:

	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

Interleukin-6 (IL6)

Accreditation Status:	**UKAS Schedule of Accreditation**
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 22%
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: 29% for FLC Chosen Coefficient of Variation: 14% 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 is classified in terms of OMIS derived from the qualitative responses for:

- Further analysis of sample required
- Immunofixation Gel
- Presence of a Cryoprotein
- Cryoprotein type

over a running analytical window of 4 Distributions (12 months)

The categories of performance are:

	Total MIS
Good	zero
Adequate	1 - 2
Poor	>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

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.
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 6%
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	7%
CA15-3 and Breast markers	10%
CA19-9 and GI markers	10%
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 12.5%
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

DIGITAL PROGRAMMES

(Image Based)

Digital ANA (dANA) - image based

Accreditation Status: *accreditation to ISO 17043 pending*

Date Scheme started: 2021

Clinical Applicability: Recognition of HEp-2 patterns seen in autoimmune disease in accordance with International Consensus on Antinuclear Antibody (ANA) Patterns (ICAP).

Analytes: A digital based image programme. Includes identifying the presence and identification of staining patterns in HEp-2 cell lines usings the ICAP system. Multiple digital users can be registered.

Units for Reporting: N/A

Samples Distributed: A set of 3 digital images (magnification 1x100, 1x200, 1x400) from healthy donors or patients with autoimmune connective tissue disease.

Number of Distributions per Year: 4

Number of Samples per Distribution: 2 digital samples per distribution

Frequency of Distributions: Every 12 weeks as outlined in the **Distribution Schedule**

Schedule of Analysis: Access to the digital images 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 is classified in terms of OMIS derived from the qualitative responses for:

- HEp-2 Cell Staining
- Cell location of staining
- Description of Nuclear staining pattern (Level 1)
- Description of Nuclear staining pattern (Level 2)

over a running analytical window of 4 Distributions (12 months)

The categories of performance are:

Total MIS	
Good	zero
Adequate	1 - 2
Poor	>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

NEW PILOT PROGRAMMES

UK NEQAS
Immunology, Immunochemistry & Allergy

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Pilot EQA Scheme for

Immunoglobulin D (IgD)

Registration now open

An EQA programme that provides you with the confidence that the right result from the right test is produced at the right time

Why Choose UK NEQAS?

- **Helpful** & polite staff on hand to help with **troubleshooting & training**
- **Frequent distributions** of EQA samples to identify performance issues promptly
- **Continuous education** and support linked to clinical best practice
- **Value for money** — Not for profit organisation

Clinical Applicability

Assist with the diagnosis of Hyper IgD Syndrome (HIDS)

Accreditation Status

This scheme is in Pilot phase and is therefore not currently accredited

Distribution Information

4 distributions per year,
2 samples per distribution

Reporting of Results

Web based data entry submission of quantitative results

UK NEQAS for Immunology, Immunochemistry & Allergy
Northern General Hospital, Sheffield, S5 7AU, UK
T: 0114 2715715; E: ukneqas@immqas.org.uk

www.immqas.org.uk

UK NEQAS
Immunology, Immunochemistry & Allergy

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Pilot EQA Scheme for

Scleroderma associated Antibodies

(comprising Scl-70, CENP A, CENP B, RP 11, RP 155, Fibrillarin, NOR 90, Th/To, PM Scl 100, PM Scl 75, Ku, PDGFR, Ro 52 antibodies)

An EQA programme that provides you with the confidence that the right result from the right test is produced at the right time

Why Choose UK NEQAS?

- **Helpful** & polite staff on hand to help with **troubleshooting & training**
- **Frequent distributions** of EQA samples to identify performance issues promptly
- **Continuous education** and support linked to clinical best practice
- **Value for money** — Not for profit organisation

Clinical Applicability

Assist with the diagnosis of Systemic Sclerosis

Accreditation Status

This scheme is in Pilot phase and is therefore not currently accredited

Distribution Information

6 distributions per year,
2 samples per distribution

Reporting of Results

Web based data entry submission of quantitative & qualitative results

UK NEQAS for Immunology, Immunochemistry & Allergy
Northern General Hospital, Sheffield, S5 7AU, UK
T: 0114 2715715; E: ukneqas@immqas.org.uk

www.immqas.org.uk