

UK NEQAS

**Better Tests,
Better Outcomes.**

Compendium II

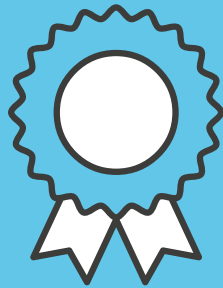
UK National External Quality Assessment Service

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01.

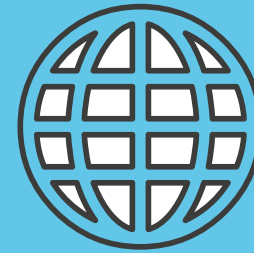
Who are UK NEQAS?



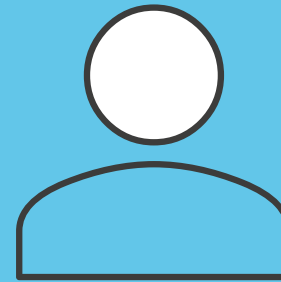
Premier consortium
of not-for-profit EQA
providers.

50

Half a century
of international
expertise.



Worldwide
interlaboratory
comparisons.



Designed to help
participants.



Committed to
quality & education.

Promoting quality improvement and harmonisation worldwide.

UK NEQAS: World Wide Quality Assessment

UK NEQAS is international

We promote harmonisation by providing worldwide comparative data.

We work closely with manufacturers and regulatory agencies to provide early warning and corrective action for assays, analysers and training.

We disseminate global and regional best practice guidance.

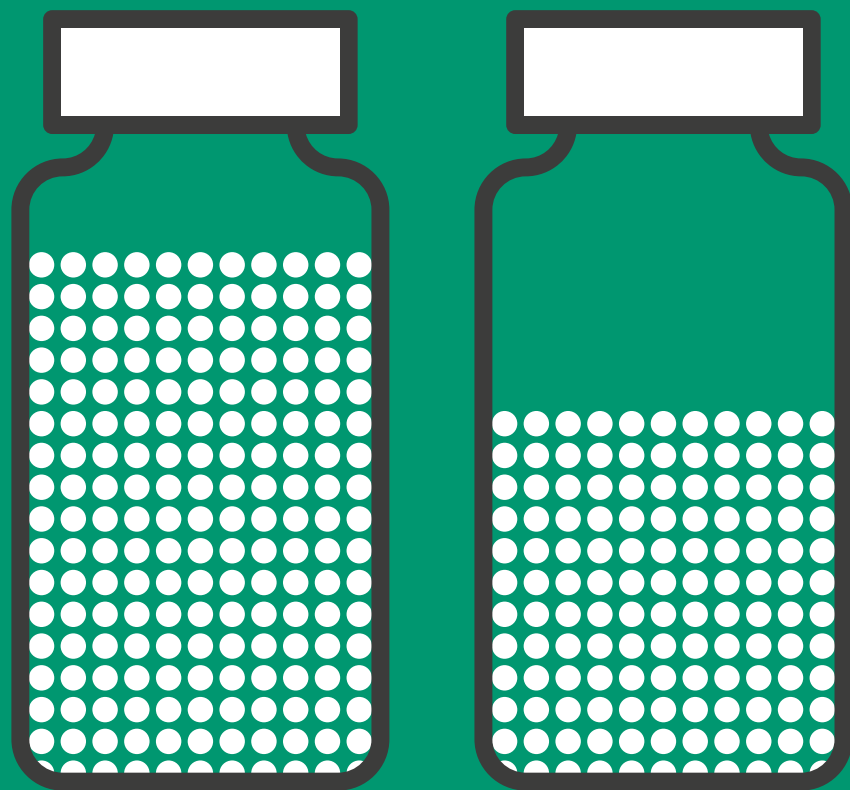
Key

■ Countries in which UK NEQAS operates

www.ukneqas.org.uk

02.

UK NEQAS: Why are we here?



UK NEQAS: Right result, right action

International Quality Expertise

We help ensure optimal quality in testing for the benefit of patients worldwide

We believe that the result of tests should be

- › Comparable and translatable
- › Safe and result in the correct outcome
- › Clinically useful to the patient

UK NEQAS has experience and expertise

50 years experience in External Quality Assessment (EQA) and its clinical relevance across all the disciplines (Immunology and Allergy, Cellular Pathology, Clinical Biochemistry, Haematology, Transfusion and Transplantation, Genetic and Molecular Diagnostics, Virology and Microbiology Leucocyte Immunophenotyping, Reproductive Science, Bacteriology, Parasitology).

UK NEQAS supports clinical governance and quality assurance structures and provides leadership

- › UK NEQAS educates its members, the public and participants. UK NEQAS identifies and supports best practice internationally
- › Innovative UK NEQAS schemes use EQA data to continually improve
- › UK NEQAS provides leadership and harmonises the quality of diagnostic and/or clinical services internationally
- › UK NEQAS supports and trains our participants' laboratories to inform and embed best practice
- › UK NEQAS integrated EQA and whole process through PREPQ (Pre & Post-Analytical Quality Monitoring Service)

- › UK NEQAS promotes critical thinking about internal and external quality assurance through:
 - › Masterclasses
 - › Educational events
 - › Electronic learning
 - › Interpretative EQA schemes and
 - › One-to-one support and advice

UK NEQAS focusses on clinically important quality

- › Our schemes are designed and run by organisers and managers who are wholly committed to leadership in better healthcare worldwide, are experts in current clinical practice in laboratory and clinical diagnostics
- › Our organisers are appointed for their expertise and commitment to public service ethos

UK NEQAS is independent and impartial

Our independence and commitment to best patient care is assured through our Trustees.

UK NEQAS shares and promotes best practice through education and leadership

- › Highlighting best practice, common errors or poor practice, up-to-date guidance and clinically relevant performance issues
- › Supporting continuous quality improvement within UK NEQAS and our participants
- › We contribute to and publicise current international professional guidance and share good practice

03.

UK NEQAS:
One service, one standard.
Best practice in EQA.



UK NEQAS: one service, one standard

Excellence guaranteed

UK NEQAS is relevant and useful

- › Our outputs are suitable for use in governance, incident and corrective action reporting, accreditation and training
- › Our schemes address clinically relevant issues rather than simple methodological performance
- › We add value by encouraging root cause analysis/corrective and preventative action, assisting RCA/CAPA analysis
- › We provide external verification of the quality of services and build public confidence in them
- › We provide near-patient testing (NPT)/point-of-care testing (POCT) tailored to non scientific staff and networks

UK NEQAS is unique in its breadth and depth of coverage

- › EQA has multiple specialities in a one-stop-shop to harmonise best practice standards
- › Whole process quality services
- › Education and support for users
- › Root cause analysis support
- › Best practice guidance

UK NEQAS harmonises practice and promotes best practice

- › UK NEQAS has harmonised policies and procedures
- › All schemes provide the same level of service and operate to current best practice standards
- › UK NEQAS supports and encourages innovation, scheme development and shared best practice across the organisation

UK NEQAS is trusted by participants and regulators

- › We actively encourage engagement with our participants in developing and maintaining best practice
- › We are active in offering support at an early stage
- › We assist in the root cause analysis and corrective actions to avoid persistent poor performance or clinical harm

04.

UK NEQAS: What UK NEQAS does for patients.



UK NEQAS promotes harmonisation and accuracy

Better care for patients everywhere

UK NEQAS focuses on tests which make a difference to care across all the disease spectrum; from cancer to autoimmunity, from blood transfusion to transplantation, from genetic diseases to allergy.

UK NEQAS helps services give a safe and effective clinical outcome for patients.

UK NEQAS educates laboratories, medical and scientific staff on clinically relevant issues.

UK NEQAS shares best practice.

UK NEQAS helps labs achieve International Standards Organisation (ISO) accreditation and harmonised quality.

UK NEQAS provides impartial quality assessment independently of accreditation bodies and regulators.

UK NEQAS promotes harmonisation of results internationally.

UK NEQAS is responsive - it listens to the feedback of participants and regulators.

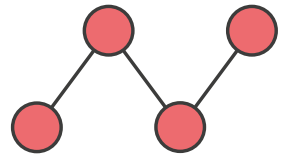
The Right Tests

We focus on tests that make a difference to care. We cover all diagnostic specialities.



Monitoring Performance

UK NEQAS keeps watch over ongoing quality in laboratories.



Encouraging Excellence

We encourage continuous quality for laboratory improvement through support for laboratories.



Educating Participants

We provide ongoing education in quality for our participant laboratories and staff.



Helping Accreditation

Good EQA performance is an important part of ISO accreditation for laboratories.



05.

UK NEQAS: Why people value UK NEQAS.

“UK NEQAS EQA schemes are well known worldwide, providing participating laboratories with better Quality Assurance to clinicians”

“Help provided is always excellent”

“Excellent for Continuing Professional Development (CPD)”

“Very helpful to see what policies other labs follow for same scenario”

“An invaluable resource, to meet other participants and to hear the steering committee’s opinion during the ‘lively’ debates”

“Good tips for United Kingdom Assessment Service (UKAS) preparations”

“Interactive sessions”

“Hands-on experience – software was very good”

“Good to see the customer’s point of view on how they handle samples and use the kits we make”

“Opened up my mind to new ways of investigating problems”

“Made you think about ‘thinking outside the box’”

“The case studies are a first class way to learn, wish I’d done it before now”

“Contributed greatly to my understanding of UK NEQAS reports and root cause analysis”

06.

UK NEQAS: Increasing the effectiveness of Quality Assessment.



6.1

Supporting end-to-end EQA

PREPQ: Pre- and Post-Analytical Quality Monitoring Service

The aim

We must quality assure throughout the testing and reporting process to meet the recommendations of:

- > The UK Pathology Quality Assurance Review report in 2015
- > The transition of clinical laboratory accreditation to ISO15189
- > The increased recognition by professional bodies that laboratories should take responsibility for quality outside the analytical phase

The UK NEQAS Pre- and Post-Analytical Quality Monitoring Service (PREPQ) pilot was developed to allow clinical laboratories to monitor untoward events in the pre- and post-analytical phases. The service will eventually cover all laboratory disciplines.

What UK NEQAS delivers

The PREPQ monitoring service extends the scope of quality surveillance beyond the analytical phase. Adverse incidents in the pre- and post-analytical phases are expressed as defects per million opportunities (dpmo) and sigma metrics. Eleven quality indicators (8 pre-analytical and 3 post-analytical) are monitored; all chosen for clinical relevance and practicality, including indicators published by the International Federation of Clinical Chemistry and laboratory medicine. The scheme is entirely web-based, using the UK NEQAS Results Service operated by the Wolfson Computer Laboratory based at Birmingham Quality.

By 2016 we had more than 250 participants enrolled for the pilot exercises. As anticipated, participants found data extraction challenging, indicating the need for harmonisation and standardisation of practice which we are facilitating through feedback on best practice.

The benefits

The service will make a significant contribution to quality improvement in laboratory medicine, offering:

- > End-to-end quality management of the total testing process
- > Support for ISO15189 accreditation
- > Support for the UK Pathology Quality Assurance or other quality dashboard metrics
- > Use of the UK NEQAS network to share best practice with a wide participating laboratory base
- > Flexible registration, reporting and data submission by discipline, department, hospital, service or network according to the participant's needs
- > Sigma metrics reporting
- > Secure, on-line submission
- > PREPQ will drive harmonisation of terminology and data collection practices
- > PREPQ has pan-disciplinary application and is relevant to all disciplines

Quality Assurance masterclasses: practical learning, real time proficiency

The aim

UK NEQAS observed that increased pressure on resources for training in troubleshooting EQA issues often appeared to lead to delays in rectification of performance issues.

A practical and time-efficient solution to improve and maintain these skills was needed.

What UK NEQAS delivers

One day masterclasses with the following key learning topics:

- › Effective and efficient investigation of non-conformity and root cause analysis
- › Effective internal quality control (IQC) and monitoring - how to detect problems and make the best of your processes
- › Effective use of EQA to improve your laboratory practice
- › Troubleshooting IQC and EQA from a laboratory perspective
- › Technical validation of diagnostic tests and evaluating new methodologies
- › How to interpret EQA reports and identify performance issues

The benefits

Key features of masterclasses include:

- › Active participation in real time proficiency testing, focussing on practical skills
- › Providing new staff with laboratory troubleshooting skills
- › Reinforcing knowledge of existing staff
- › Pre and post-course assessment to monitor progress and development
- › Utilising computer-based workshops, discussions and presentations
- › Tutorial-based structured learning in a 'virtual' hospital environment
- › Led by senior laboratory, clinical and scientific experts

Proficiency and efficiency testing: combined technical assessment and clinical interpretation in histocompatibility and immunogenetics

The aim

Transplantation is the perfect example of the importance of integrated assessment of technical and interpretive aspects of the patient pathway. UK NEQAS H&I offers participants a technical assessment of individual techniques, and our interpretive educational scheme offers participants clinical scenarios to compare their clinical decision making.

Results and assay repertoires vary greatly from centre to centre and may be unique, particularly in the field of solid organ transplantation.

UK NEQAS H&I needed to design a scheme able to cope with this complexity to derive comparative performance indices.

What UK NEQAS delivers

We introduced an educational scheme wherein participants perform multiple assays using a single set of samples and then provide a clinical interpretation of their own results.

We distribute blood and serum samples for laboratories to perform their own combination of assays which may include:

- › HLA typing (polymerase chain reaction with sequence specific primers - PCR-SSP and/or sequence specific oligonucleotide probes - PCR-SSO, sequence based typing - SBT etc.)

- › Cross matching by serological methods (complement dependant cytotoxicity - CDCXM and/or flow cytometry - FCXM)
- › Antibody detection and/or specificity (Luminex, CDC and enzyme-linked immunosorbent assay - ELISA)

Participants provide a clinical interpretation of the results as if they were obtained in a clinical setting, including transplant risk stratification. All results are fed back to participants and we also provide a summary with key data, common/notable responses and trends.

The benefits

This gives participants the ability to:

- › Monitor performance of multiple techniques within a single scheme
- › Make clinical interpretations based on their own results and compare with others
- › Compare local policies for clinical assessment and 'equity of access'

The scheme reflects current clinical practice, and informs future integrated technical and interpretive scheme design. This would eliminate the requirement for participation in multiple schemes for individual assays, reducing the scheme costs and time needed for participants.

6.2

International collaborative leadership in quality improvement

Professional organisations, Royal Colleges, accreditation providers and international partners

The aim

UK NEQAS shares many of our quality and patient care objectives with professional, patient and regulatory bodies.

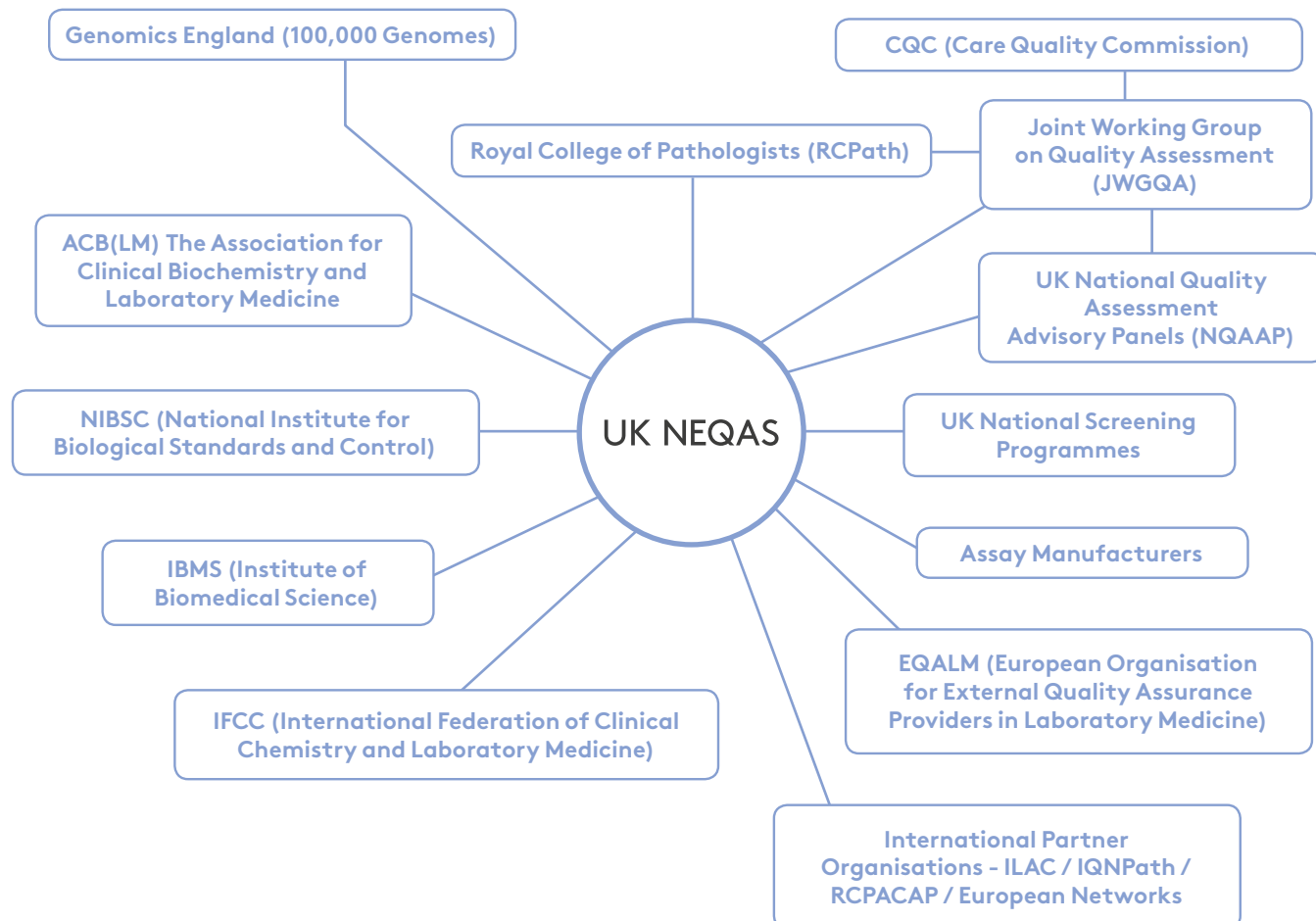
We work extensively to influence and contribute to this work for the benefit of all.

What UK NEQAS delivers

We bring independent expertise in Quality Assurance, grounded in clinical practice and international experience.

The benefits

Improved Quality Assessment and Assurance for all to underpin accreditation and governance.



Harmonising performance across methods: detection of antibiotic resistance

The aim

Increasing carbapenem resistant Gram negative bacteria constitute an important growing public health issue worldwide. Acquisition of the carbapenamase enzymes that destroy antibiotics restricts treatment options. Transmissible carbapenamases are of a great concern because they can be unpredictably passed to other bugs, including Enterobacteriaceae and Pseudomonas aeruginosa in the gut and nose.

Clinical diagnostic laboratories must be able to detect resistant bugs. We cover all methods for laboratory antimicrobial susceptibility testing:

- > Manual quantitative methods such as gradient strips
- > Qualitative methods determining S/I/R in disk diffusion
- > Semi automated systems determining break point MIC susceptibilities

What UK NEQAS delivers

We cover a wide range of fully genotypically and phenotypically characterised organisms.

We re-designed our web-based reporting to capture ESBL and carbapenamase results.

Each published report provides expert commentary describing the genotypic resistant mechanisms (whole genome sequencing) in comparison with phenotypic susceptibilities to improve understanding and interpretation.

The benefits

UK NEQAS gives participants the ability to:

- > Monitor, evaluate and improve their own performance in detecting carbapenamase resistance
- > Provide laboratory management with an insight into their performance on the detection of multi drug resistant organisms
- > Help participants correct any failure to correctly determine the susceptibilities through root cause analysis and direct educational support
- > Allow participants to demonstrate that laboratories worldwide comply with international guidelines on susceptibility testing for the benefit of their patients

UK NEQAS & international collaborative projects

The aim

The European Network for Rare and Congenital Anaemias (ENERCA) was a project funded by the European Commission through the Executive Agency for Health and Consumers (EAHC). It aimed to improve the care of patients with haemoglobinopathies and thalassaemias, red cell enzymopathies, red cell membrane disorders, congenital dyserythropoietic anaemias, primary disorders of iron metabolism and other very rare anaemias. Phase 3 of the project was established to deliver a 'White Book' of recommendations for clinical and laboratory practice to improve the welfare and long-term quality of life of patients affected by these rare and chronic conditions.

What UK NEQAS delivers

As a leading provider of haemoglobinopathy and red cell enzyme external quality assessment services in Europe, UK NEQAS Haematology contributed significantly to the 'Quality of Patient Care' work package in the ENERCA project phase 3, highlighting the essential role of EQA as part of good quality management in the clinical laboratory.

Extensive links with participants throughout Europe and expertise in the preparation and distribution of EQA materials allowed UK NEQAS Haematology to support this work through questionnaires and practical exercises.

The benefits

The ENERCA White Book aims to improve and harmonise clinical and laboratory services for patients with rare anaemias and illustrates the contribution of UK NEQAS and EQA to quality improvement in laboratory services.

A core list of laboratory tests for the diagnosis of rare anaemias was developed, including 'routine' and more specialised investigations tailored to the diagnosis of specific conditions.

Recommendations were made for networked provision of these tests, i.e. which tests should be restricted to specialist centres and which should be more widely offered by local testing sites.

UK NEQAS Haematology surveyed EQA providers to establish the availability, frequency and cross-border provision of EQA services and identify gaps in specialist testing. EQA providers were asked to identify a 'wish list' of tests that they would like to be able to provide EQA for and promote collaborative working between EQA organisations. This highlighted where expertise might be shared and where new service provision is necessary.

A practical EQA exercise for performance assessment of Hb A2 measurement was undertaken, free of charge to the end user, which provided information on performance of this test across a range of testing laboratories.

Quality improvement through guideline development: CSF haem pigments guidelines

The aim

To harmonise practice and produce guidelines for CSF haem pigments analysis.

Spectrophotometric examination of cerebrospinal fluid (CSF) for bilirubin is an important investigation when subarachnoid haemorrhage (SAH) is suspected, but a computerized tomographic scan of the head shows no bleeding.

The UK NEQAS Immunology, Immunochemistry & Allergy (IIA) Specialist Advisory Group for CSF Analysis published national guidelines for analysis of CSF bilirubin in suspected SAH patients which covers preanalytical, analytical and interpretative stages of spectrophotometric analysis of CSF.

We produced reproducible and stable solutions containing both oxyhaemoglobin and bilirubin at low concentrations.

What UK NEQAS delivers:

- › Provision of an interpretive EQA scheme for CSF haem pigments analysis
- › Production of an innovative artificial matrix to mimic real CSF to enable a feasible and effective EQA scheme
- › Real time iterative feedback from the scheme to evaluate, improve and validate practical and translatable guidelines that work in real life diagnostic practice
- › Dissemination of results to users

The benefits

UK NEQAS IIA has developed and refined a scheme designed to monitor analytical and interpretative performance targeted at clinically relevant decisions, based on real life-practice.

Production of CSF haem pigments guidelines has enabled harmonisation of practice globally.

Reduction of inappropriate testing has resulted.

Use of spectrophotometry in preference to visual inspection for the detection of CSF bilirubin was a key recommendation from the guidelines. Analysis of CSF for bilirubin by visual inspection has ceased after the UK NEQAS scheme highlighted deficiencies of this method.

6.3

Supporting continuous quality improvement in networks and laboratories

UK NEQAS: supporting national and international initiatives on kidney function

The aim

Improved Creatinine measurement to support national UK screening diagnostic programmes.

Several recent initiatives to monitor kidney function rely on accurate and precise blood tests. Acute Kidney Injury (AKI) is concerned with a recent onset of a problem whilst the estimation of Glomerular Function Rate [eGFR] is a useful tool in the diagnosing and monitoring of long term, chronic kidney disease (CKD). Both of these conditions rely on the measurement of creatinine which is a waste product of protein breakdown that must be removed from the body in urine via the kidneys. There are a series of complex algorithms used to categorise patients to make sure they go on the correct treatment pathway.

100,000 deaths each year in UK hospitals are associated with acute kidney injury. Up to 30% could be prevented with the right care and early treatment to prevent patients requiring dialysis treatment for chronic kidney failure.

The challenge is for all laboratories to correctly identify patients at risk by measuring their creatinine levels in blood and all produce the same numbers and outcomes for patients.

What UK NEQAS delivers

Since 2005, UK NEQAS has been involved in the design of these algorithms for both CKD and AKI, and has circulated challenging specimens to laboratories to ensure they have optimised their systems:

- > To report the correct result
- > To detect relatively small changes in concentrations
- > To undertake continued monitoring of long term performance with patient materials

The algorithms continue to evolve and UK NEQAS will continue to provide national oversight of their uptake and performance.

The benefits

UK NEQAS uses its schemes to raise awareness of these clinically driven initiatives. UK NEQAS also works with manufacturers of testing equipment and reagents to ensure that they continue to meet continually improving measurement standards.

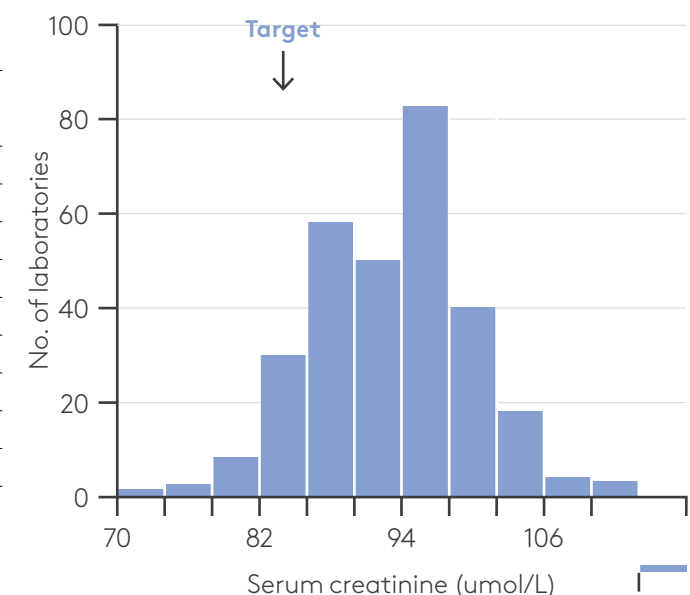
The ability of UK NEQAS to repeat distributions over long periods of time enables monitoring of progress in these aims.

UK NEQAS distributed the same specimen ten years apart as part of the CKD project. In 2006 the majority of laboratories over-estimated the true creatinine concentration, implying more disease than actually present. By 2016, almost all laboratories reported close to the true creatinine concentration and would have correctly classified the patient (See Figure 1).

Most labs over-estimate. Only one Enzymatic user, mostly Traditional Jaffe users

Specimen :11A	n	Mean	SD	CV(%)
All methods [ALTM]	294	93.6	6.6	7.0
Dry slide [1]	31	88.9	2.7	3.0
OCD (J&J) original [1JJ]	31	88.9	2.7	3.0
Traditional Kinetic Jaffe [11]	223	93.3	6.3	6.7
Abbott reagents [11AB]	28	95.8	2.6	2.7
Beckman (Olympus) [11OL]	63	97.3	2.9	3.0
Beckman reagents [11BK]	35	93.3	4.2	4.5
Roche Integra reagents [11RO]	13	86.1	6.5	7.6
Roche Modular reagents [11BO]	65	88.8	4.0	4.7
Oxidation (inc O'Leary) [14]	26	99.7	3.9	3.9
Enzymatic [9]	1	84.0		
Roche Cobas/Modular [9BO]	1	84.0		

2006: True Creatinine value ~ 81 umol/L



Most labs very close to target, 139 Enzymatic users with a majority of Compensated Jaffe users

Specimen :119B	n	Mean	SD	CV(%)
All methods [ALTM]	367	80.4	4.7	5.9
Dry slide	17	78.5	3.0	3.8
Compensated Kinetic Jaffe	193	79.8	5.0	6.2
Abbott reagents [10AB]	48	75.2	1.6	2.2
Beckman reagents [10BK]	13	81.5	5.0	6.1
Beckman (Olympus) [10OL]	23	79.3	3.6	4.5
Roche Modular reagents [10BO]	91	82.2	4.3	5.3
Siemens ADVIA [10TE]	17	80.7	2.7	3.3
Enzymatic	139	80.5	3.6	4.4
Abbott reagents [9AB]	34	80.1	1.8	2.2
Roche Cobas/Modular [9BO]	75	82.5	2.8	3.4
Siemens ADVIA [9TE]	18	74.5	1.9	2.6

2016: True Creatinine value ~ 81 umol/L

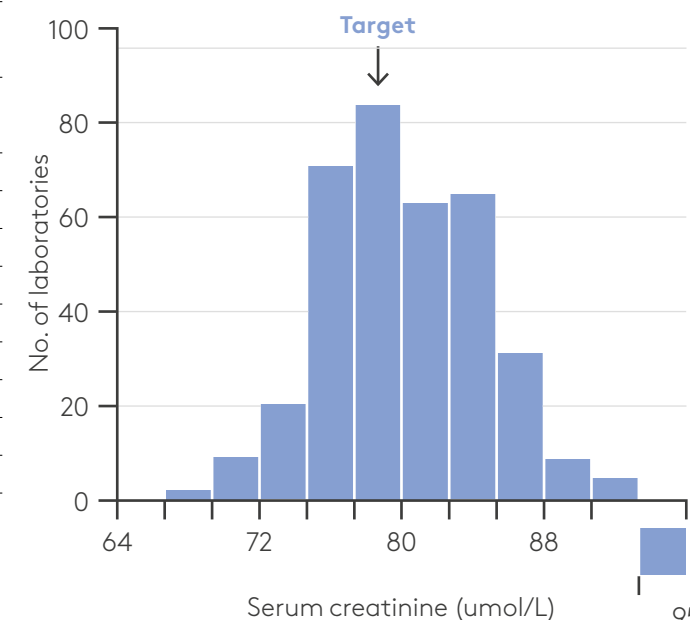


Figure 1: Improvement in Creatinine measurements over a ten year period. Taken from UK NEQAS for eGFR. Reference: <https://www.thinkkidneys.nhs.uk/aki/> (accessed 30 Sept 2016) N:\U\Exec2016\Creatinine.docx

UK NEQAS sample exchange register: Finding your perfect sample exchange partner

The aim

EQA schemes cannot always be easily provided for specialist testing of rare analytes because there are not enough users to make a full scheme viable.

In the absence of an EQA scheme, laboratories are required to consider sample exchange or other mechanisms to enable accreditation to ISO standards.

What UK NEQAS delivers

UK NEQAS aim to help its participants ensure best quality by facilitating contacts with other specialists to allow them to put in place effective sample exchange mechanisms. We provide a sample exchange register with contact details to enable location of laboratories in need of a sample exchange mechanism to meet accreditation requirements.

The benefits

- > Laboratories can easily advertise their available repertoire and establish exchange agreements through UK NEQAS membership
- > Where an EQA scheme is not currently available, laboratories are assisted to find alternative arrangements to meet ISO accreditation requirements, demonstrate good practice and improve patient care

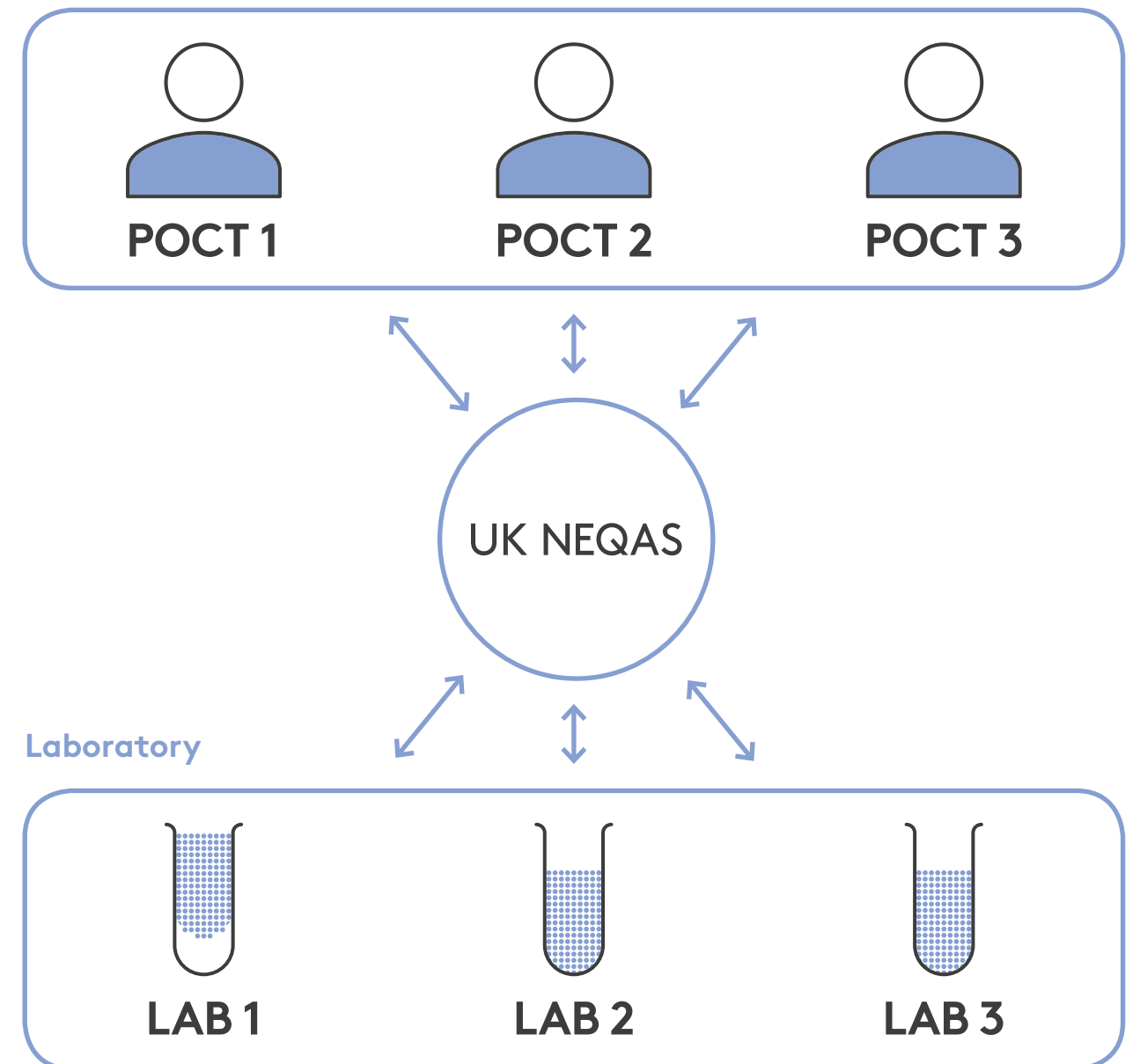
UK NEQAS IIA does not monitor the performance of the analytes covered by a sample exchange scheme but provides suggested methods to enable participants to perform their own analysis.

The sample exchange register allows laboratories to fulfil ISO 15189:2012 clause 5.6.5.

UK NEQAS links networks and POCT providers

Network reports aid effective monitoring

Point of care tester



Promoting use of root cause analysis in continuous quality improvement

The aim

Many non-conformances in EQA schemes are due to non-analytical errors, for example transcription of results or sample handling problems. It often transpires that these errors may not have been noticed because simple quality processes are not in place. In some instances feedback from labs following 'EQA incidents' are incomplete and/or ambiguous making it unclear if issues had been resolved satisfactorily.

Developing skills in Root Cause Analysis (RCA), Critical Control Point Analysis and implementing corrective actions helps reduce all types of error.

What UK NEQAS delivers

- › Any participant submitting results that are out of consensus receives an EQA incident form electronically
- › Participants are encouraged to quickly perform an RCA and identify any correctable cause and risk-assess the problem
- › The RCA return is recorded as evidence of good practice
- › If the RCA appears to have missed a relevant issue, feedback and assistance is offered to the participant
- › The process can also be used as a training tool; labs can encourage trainees to complete the initial draft and review outcomes

The benefits

- › The process is educational
- › The process is a training tool
- › The process is evidence of a proficient quality system highlighting:
 - ›› Efficient RCA skills
 - ›› Risk assessment which meets both internal and external governance needs
 - ›› Identification of appropriate corrective or monitoring actions
 - ›› Reflective learning on internal processes and policies
 - ›› Ability to review and interpret EQA and IQC data to guide trouble-shooting
- › Participation provides individual CPD in RCA, EQA and IQC

6.4

Providing practical education and expertise in clinical diagnostics

National Academy for Clinical Flow Cytometry

The aim

UK NEQAS Leucocyte Immunophenotyping (LI) EQA programmes have identified international variation in flow cytometric quality, and lack of adherence to standardised best practice clinical flow cytometry techniques including:

- › CD4+ T-Lymphocytes for HIV monitoring
- › CD34+ Stem Cell Enumeration
- › Paroxysmal Nocturnal Haemoglobinuria (PNH) testing
- › Leukaemia immunophenotyping

There are no agreed national training syllabuses. Clinical flow cytometry variation impacts directly upon patient treatment particularly in PNH detection and leukaemia, with serious and potentially fatal consequences.

What UK NEQAS delivers

A new National Academy

UK NEQAS for Leucocyte Immunophenotyping established a National Academy for Clinical Flow Cytometry (NACFC), in partnership with the University of Sheffield, and an unrestricted educational grant from Alexion Pharmaceuticals Inc. Academy courses aim to:

- › Teach best practice clinical flow cytometric techniques to UK and international clinical laboratories
- › Promote harmonisation and best practice
- › Deliver interactive proficiency based, practical training

The initial courses focused upon the detection and monitoring of PNH, a condition where patients are at the highest risk of adverse effects from incorrect analysis.

Courses feature wet and dry workshops using patient samples and teach best practice in data acquisition, analysis and interpretation. The courses were supported by input from international PNH experts from the UK and North America with specific emphasis on one-to-one teaching.

The benefits

This is the first initiative to promote harmonised best practice in flow cytometric PNH testing and interpretation, including use of standardised nomenclature, data acquisition and analysis.

Participant scientists benefited from having "face-to-face" interaction with renowned international experts in high quality PNH testing.

A whole-process approach to instrument specific pre-analytical, analytical and post-analytical variables in order to minimise laboratory errors is central. Feedback has been excellent with many participants re-visiting and amending their own practice as a result of attendance thus improving patient care.

Genetic counselling – a sequential educational EQA reflecting clinical practice

The aim

Better EQA for Genetic Counselling. Families with suspected genetic conditions are generally assessed by a genetic counsellor or a Clinical Genetics physician. Results are discussed at consultations. The counsellor must be proficient in recognising the condition, selecting tests and guiding the patient through the diagnostic process and extended family counselling. Inappropriate testing or misinterpretation of results could result in:

- › Incorrect diagnosis or prognosis
- › Incorrect clinical advice and management

While UK NEQAS provides external quality assessment programmes for the accuracy of analysis and/or interpretation, there was no EQA for genetic counselling centres. An online pilot scheme was developed at the behest of the European Genetic Counselling community and in co-operation with the European Society for Human Genetics Quality Committee, to provide sequential reflective learning in counselling practice.

What UK NEQAS delivers

CEQAS, the UK NEQAS Cytogenomics service, developed the EQA for Genetic Counselling (GC). This pilot consists of four multi-stage case scenarios for different genetic diagnostic pathways. Centres can enrol for any or all of the cases covering:

- › Cardiovascular genetics
- › Dysmorphology
- › Monogenic disorders
- › Oncogenetics

Cases are either pre- or post-test scenarios, compiled by clinical geneticists, based on real clinical cases. Participants can see referral information, clinical details, test-results and/or images. These are provided sequentially online. Each stage requires questionnaire based assessment before the next stage is accessible. Centres can review the previous stage but cannot adjust the answers. Each case scenario is validated by a panel of expert assessors, patient organisations and a Specialist Advisory Group for Genetic Counselling.

The benefits

The feasibility of a multi-stage serial educational scheme was validated. All centres receive feedback to encourage reflective learning and obtain an overview of proficiency when counselling patients. Each EQA case scenario has multiple structured learning points addressing clinically relevant issues. The EQA has highlighted the need for a three generational family history, psychosocial support and reproductive options to improve future patient care.

UK NEQAS cellular pathology technique: proficiency testing for non-gynaecological diagnostic cytology

The aim

Non-gynaecological (gynae) diagnostic cytology is increasingly used within cellular pathology, but the patient outcome is mainly dependent upon the quality of the sample. High quality diagnostic preparation requires staff with the appropriate skills and knowledge.

The centralisation of gynaecological cytology services results in staff with these specialised skills transferring to central hub gynaecological cytology services, while histopathology departments inherit diagnostic cytology services.

There is very limited external national guidance or standardisation for these services. UK NEQAS saw a need for a national EQA/PT scheme to support quality in diagnostic cytology covering the varied specimen types and preparation techniques.

What UK NEQAS delivers

Standardised proficiency testing, information and support on all aspects of non-gynae diagnostic cytology technique is delivered through 6 assessments per year allowing participants to submit a variety of non-gynae diagnostic cytology preparations from their in-house repertoire.

Comprehensive feedback is provided on proficiency tested submissions, together with detailed information, proficiency testing criteria and definitions, which form a participant's handbook.

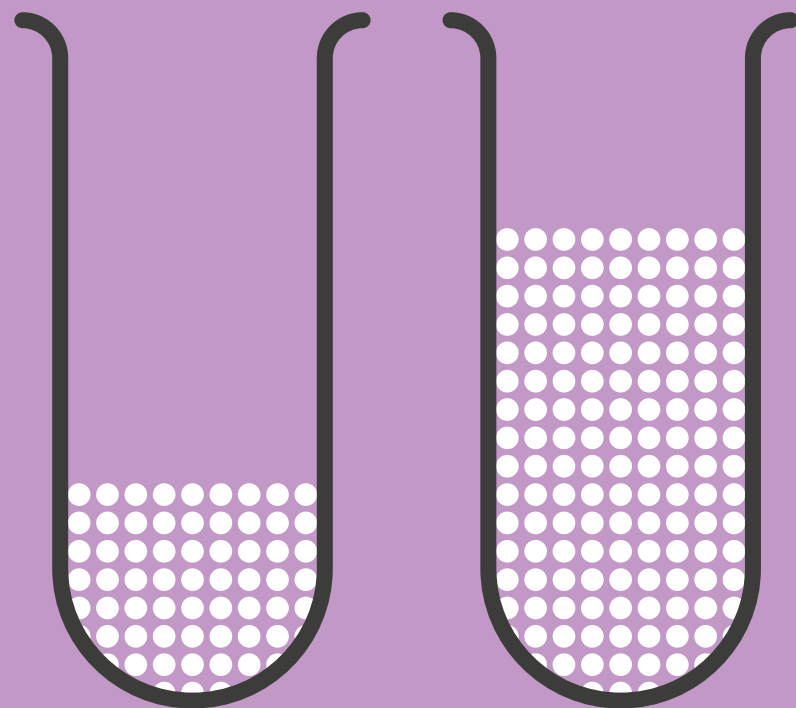
Troubleshooting and technical advice are also offered on an individual basis via e-mail. A UK NEQAS CPT newsletter is made available to all participants, sharing best practice and methodology.

The benefits

- › Raising awareness of relevant quality issues in non-gynae diagnostic cytology which are critical to patient outcomes
- › Detailed feedback to participants to improve quality
- › Support and advice for outliers, to improve the standards and service
- › Sharing of good performance and best practice, ensuring high quality and consistency across laboratories
- › On line participant surveys to continually improve the scheme to ensure it meets the demanding needs of the participants and service users

07.

UK NEQAS: Innovation – the science and development of EQA.



7.1

Maintaining relevance – matching schemes to current pathogens

UK NEQAS for molecular detection of viruses

The aim

The three main viruses that cause contagious diarrhoea and vomiting worldwide are noroviruses, rotaviruses and adenoviruses. They circulate throughout the year but the infections peak at different times.

- > Norovirus is called the "winter vomiting bug" because it's more common in winter
- > Rotavirus diarrhoea used to affect almost every child by the age of 5 until a vaccine was developed
- > Rotavirus is still a major killer in the developing world through dehydration. World Health Organization estimated that rotavirus infections caused between 475,000 and 580,000 deaths worldwide in 2004
- > Adenovirus type 40 (Ad40) and 41 (Ad41) subgenus F cause infantile gastroenteritis worldwide causing up to 17% of sporadic diarrhoea in children less than 2 years of age

What UK NEQAS delivers

We modify our molecular/serological schemes to include the most common circulating strains of adenovirus and rotavirus in the community - using the clinical knowledge and expertise of our clinical advisory groups and world-wide public health surveillance reports. Sometimes, uncommon genotypes are included for educational purposes to maintain skills throughout the repertoire. We send 4 freeze dried faecal samples twice a year to detect norovirus, adenovirus and rotavirus nucleic acid and/or antigen in stool.

The benefits

- > UK NEQAS helps educate laboratories with detection of common and rare viruses and their current circulation patterns, to support their clinicians
- > UK NEQAS laboratories monitor performance to:
 - » Evaluate their methods in comparison to peers
 - » Determine the sensitivity and specificity of their assays
 - » Allow laboratories to determine whether their assays are fit for purpose for particular strains/ genotypes that are circulating at the time
 - » Help hospitals benchmark their compliance with guidelines for nosocomial infections
 - » Identify non-conformance due to methods lacking sensitivity or specificity
 - » Assist in resolution of problems through support to participants and educational activities

7.2

UK NEQAS online competency assessment in blood transfusion in a virtual laboratory environment

Innovative interpretative EQA

The aim

Accreditation and regulatory bodies in the UK require evidence to demonstrate on-going competency for blood transfusion staff. This is supported by professional committee recommendations to ensure safe and effective delivery of blood transfusions to patients.

Some hospitals manage this successfully, but others struggle to maintain a satisfactory system for competency assessment. Limited resources, increasing multi-disciplinary working, with rotating staff from other departments and out-of-hours working all cause difficulty.

Many participants use UK NEQAS samples to help demonstrate staff competence to undertake and interpret serological tests. If more than one member of staff undertakes the testing prior to submission of results, personal performance assessment is lost.

We developed an easy-to-use, resource-light electronic system to help laboratory managers manage staff competency using assessment of knowledge to clearly demarcate the line between lab EQA performance and individual competency.

What UK NEQAS delivers

UK NEQAS developed an online, fully interactive system, representing a virtual laboratory environment. This includes a performance dashboard area for managers to quickly and easily assess the knowledge and competency of their individual staff members.

The benefits

A participant can:

- > Log in and complete scenarios on an electronic platform that represents a 'real-life' laboratory
- > Carry out tests as performed in a blood transfusion laboratory
- > Receive real-time feedback on performance using a marking logic based upon UK guidelines
- > Build up an easily accessible and auditable CPD record of competency over time
- > Allow managers to monitor staff competency easily and objectively
- > Highlight individual training requirements and development opportunities for staff

Participants make decisions based on their training and knowledge. On completion of the scenario, a green or red mark is awarded for each activity.

This system is specifically designed to address targeted areas of perceived poor knowledge in blood transfusion laboratory staff.

The educational basis of the system has since been adopted by other UK NEQAS schemes, and others are in development. In future iterations more complex and extended scenarios will be introduced, to fully encompass all tasks performed in the blood transfusion setting. We will also include staff groups involved in the transfusion process outside of the laboratory.



Virtual Hospital

To test proficiency in real time

Choose iEQA Cases

Investigation, Interpretation and Troubleshooting

Compare Performance with:

Previous attempts, Peers and Experts

Decisions Costs Outcomes

08.

UK NEQAS: EQA for genomic and personalised medicine.



8.1

Ensuring the quality of whole genome sequencing as part of the UK '100,000 Genomes' project

Supporting Personalised Medicine

The aim

The UK pledged £300 million to deliver 100,000 whole genome sequences for rare diseases and cancer, to transform the UK health service and patient care. However, the implementation of whole genome sequencing in UK health services is challenging and requires quality DNA samples extracted from a range of sample types to ensure high quality, reportable sequencing results.

UK NEQAS was requested to:

- › Assess the ability of laboratories to provide DNA samples meeting the required standards for sequencing
- › Continually assess the extraction methods performed

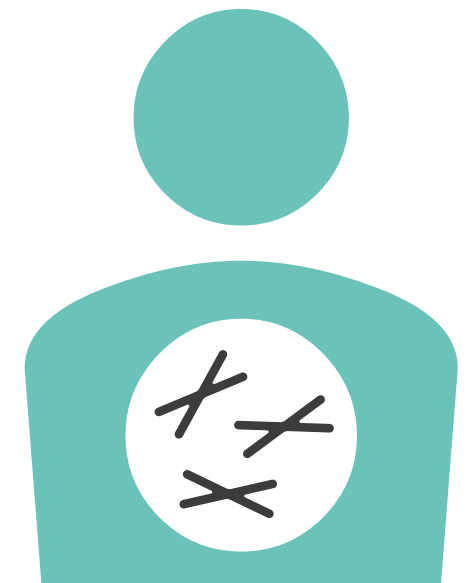
The benefits

- › The results improved the DNA extraction protocols used for genetic, cancer and genomic testing across the country
- › We enabled development of minimum national standards for NHS Genomic Medicine Centres providing 100,000 Genomes Project analyses
- › Resulting improvement in routine testing practice for other molecular diagnostics encourages ongoing development of additional genomics UK NEQAS schemes

What UK NEQAS delivers

We developed and delivered EQA using a panel of metrics to determine the quality of DNA samples for whole genome sequencing (WGS).

- › Participants were assessed for DNA extraction from a range of patient materials
- › Key performance indicators (Red/Amber/Green rating) were successfully implemented to:
 - › Measure and monitor the sample quality
 - › Enable NHS England to monitor UK NEQAS scheme performance of laboratories as part of the NHS laboratory contractual agreements



8.2

UK NEQAS: Up-to-date EQA for novel identification systems for bacteria

Supporting personalised medicine

The aim

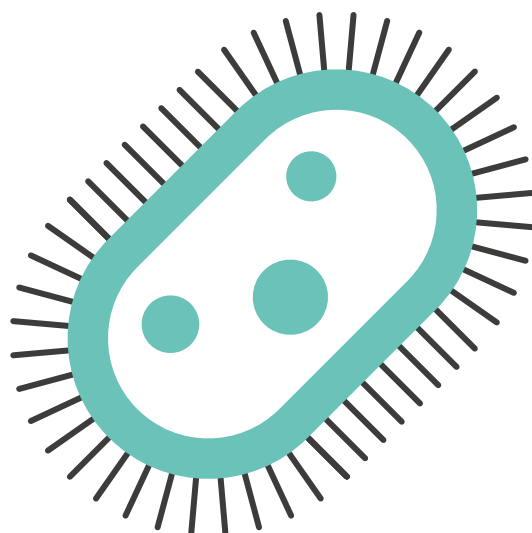
The advent of new technologies in proteomics and genomics is rapidly changing traditional techniques for bacterial classification, identification, and characterization in the 21st century. Semi-automated systems based on biochemical characterisation such as the VITEK and Phoenix platforms are gradually being replaced by MS-MALDI-TOF and molecular based techniques.

What UK NEQAS delivers

- › We design general bacteriology scheme panels to cover the current range of pathogens currently circulating and clinically important nosocomial infections
- › Our scientific knowledge and expertise combined with our expert clinical advisory groups ensure that we continually focus on issues of clinical importance
- › We designed our web-based reporting to meet laboratory and clinical needs
- › We improved our data collection to include method capture and are now able to present method-based results analysis
- › UK NEQAS results analysis highlights any observed trends in the methods. These are communicated to participants in the published reports

The benefits

- › UK NEQAS enables performance monitoring of commercial systems and in-house methods
- › UK NEQAS examines clinically relevant limits of detection
- › UK NEQAS data supports peer assessment and bench marking (UK and internationally) of current test algorithms
- › UK NEQAS help with early detection of inadequate performance in detection systems and comparative performance, informing clinical manufacturer and laboratory actions
- › UK NEQAS works with manufacturers to continually optimise their systems and kits



8.3

UK NEQAS for molecular detection of respiratory viruses

Supporting personalised medicine

The aim

Respiratory infections are the leading cause of mortality worldwide causing at least 6% of worldwide morbidity and mortality. Influenza is an important vaccine-preventable cause. Many viruses are responsible, including influenza viruses, adenovirus, respiratory syncytial viruses, human enteroviruses, rhinoviruses, human metapneumovirus, bocavirus, human coronaviruses and human parainfluenza viruses.

Only virological detection can identify the causative agent.

Detection of viruses by cell culture or serology are too slow to be useful for patient care. Molecular testing is now the main diagnostic tool. However, there is a current lack of standardisation between assays.

What UK NEQAS delivers

UK NEQAS needed to develop a sample stability and performance assessment mechanism suitable for a wide range of assay methodologies (Single Target Traditional/Real-Time PCR, Multiplex Traditional/Real-Time PCR, RT-PCR, Real-time RT-PCR, Isothermal and others).

The benefits

A one-stop-shop approach is provided which:

- › Covers all relevant respiratory viruses
- › Will include bacterial pathogens planned in near future
- › Covers both common and uncommon pathogens
- › Allows comparison of performance of different assays
- › Enables performance monitoring of commercial and in-house methods
- › Provides updates and education on current circulating strains
- › Enables validation of assays with the most recent circulating pathogens
- › Can be used to inform health authorities about the pathogens
- › Enables benchmarking
- › Provides support for participants

8.4

UK NEQAS provision for specialist centres: international specialist molecular testing in haemoglobinopathies

Supporting personalised medicine

The aim

The haemoglobinopathies and thalassaemia syndromes are major clinical problems worldwide. Although carriers are rarely affected, accurate detection of clinically significant conditions is essential both for genetic counselling and diagnostic purposes. Screening relies mainly on protein chemistry with molecular techniques offered in a small number of specialist referral laboratories. In the UK, haemoglobinopathy and thalassaemia screening standards are overseen by a National Screening Programme, which has supported the development of EQA for all levels of testing.

What UK NEQAS delivers

UK NEQAS Haematology enables integrated interpretation of haematological data and clinical information to examine both DNA test selection and use of DNA investigations to achieve the correct outcome. In addition to alpha and beta globin gene mutational analysis, participants are performance-assessed on interpretation of results using the case details provided, recommendations for further action and the correct use of the HGVS nomenclature against a model answer.

The benefits

- › UK NEQAS responded to professional and clinical requirements

- › Provision of combined technical and interpretive EQA for DNA diagnostics for haemoglobinopathies is a complex and specialist field with too few centres to support a national EQA service in the UK, but;
 - ›› There is no other EQA provider of these services in Europe
 - ›› The programme was wanted by high level, expert laboratories throughout Europe and the Middle East
 - ›› International EQA provision could support a scheme for specialist, haemoglobinopathy DNA diagnostic laboratories
 - ›› There is mutual benefit to UK laboratories and patients in peer assessment against leading, international diagnostic laboratories

UK NEQAS therefore developed an international scheme which:

- › Adapts to international needs: - we avoid a UK-centric approach and ensure the scheme addresses the needs of all participants
- › Recognises the specific geographical distribution of haemoglobinopathy mutations
- › Performance assesses against national recommendations
- › Is assessed by an internationally experienced expert advisory panel which provides helpful context-specific feedback and reports

8.5

Testing breast cancer for selection of HER2-targeted therapy

Supporting personalised medicine

The aim

Breast cancer is the most common form of cancer in the UK with 53,000 new cases every year, increasing by 0.6% yearly. Surgical removal is the first treatment, but this does not always remove all cancer at the primary site, and some may have already spread before surgery.

In order to ensure the best chance of cure, further therapies are given to the patient following surgery. One of these is Herceptin, which targets tumours that have the HER2-receptor.

Herceptin improves survival rates by 40% in HER2-positive breast cancer patients.

Finding the right patients by 'HER2 testing' to receive the drug is vital because:

- › Herceptin only works in 15% of primary breast cancers that have large amounts of the HER2 protein
- › Herceptin can cause serious cardiac complications in a small percentage of patients
- › Herceptin is expensive
- › The tests require highly specialised knowledge and skill to ensure correct results

What UK NEQAS delivers

- › UK NEQAS ICC & ISH monitors the quality of HER2 testing done in UK and overseas
- › This helps ensure the right patients get Herceptin
- › We provide education and support. The results are then assessed by a panel of experts who provide feedback on the quality of test method and interpretation

The benefits

- › Selecting the right treatment for the right patient
- › Using the right test:
 - ›› Examining tumour cells for over-expression of HER2 protein using immunocytochemistry (ICC)
 - ›› Directly looking at the HER2 mutation using in-situ hybridisation (ISH) (HER2-positive cases have more copies of the gene than normal)

The UK NEQAS ICC & ISH scheme ensures that tests are:

- › Carried out using standardised and reproducible methodologies
- › Reported appropriately in line with published UK guidelines

Compendium II

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