



Birmingham Quality Participants' Manual

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1. General Information

1.1. Background

Birmingham Quality is the main UK NEQAS centre for the Clinical Chemistry division of Laboratory Medicine in the UK. The UK NEQAS service began at Birmingham in 1969; a brief description of its history may be found in Whitehead & Woodford (1981).¹ Birmingham Quality also provides some non-UK NEQAS services which are delivered to the same standard of operation as for its UK NEQAS services. Full details of all the EQA services offered can be found on the Birmingham Quality website at <https://birminghamquality.org.uk>.

1.2. Aims

- To provide professionally-led and scientifically-based EQA services with a primarily educational objective, to help laboratories appraise their performance and monitor improvements.
- To achieve this through operation, frequent distributions of multiple specimens and rapid performance feedback.
- To distribute EQA material which as closely as possible represents clinical specimens.
- To distribute educational or exploratory specimens to assess problem areas found in clinical practice.
- To distribute educational or exploratory specimens to assess problem areas found in clinical practice.
- To perform continuous assessment within rolling time windows of usually 6 to 12 distributions, providing information on total error, bias and consistency of bias ('A', 'B' & 'C' scores) through the use, wherever possible, of validated target values.
- To produce reports which are clear, informative, intelligible and structured to assist interpretation and enable use by different levels of laboratory staff.
- To give information on method performance as well as for the individual laboratory. This, is important for comparing and evaluating methods.
- To help to ensure clinical laboratory test results are accurate, reliable and comparable wherever they are produced.
- To improve patient care through the expert design and delivery of EQA programmes and the skilful interpretation and communication of the data they generate to all relevant stakeholders.

1.3. UK NEQAS Code of Practice

Please go to the Birmingham Quality website for full details, see [this link](#)

1.4. Location

Birmingham Quality (UK NEQAS) is situated at the

**Institute of Research and Development
Birmingham Research Park
Vincent Drive
Edgbaston
Birmingham B15 2SQ, United Kingdom**

The PO Box address is: **Birmingham Quality (UK NEQAS), PO Box 3909, Birmingham, B15 2UE, UK**, but courier services should always be given the full address and post code above.

For a map, please enter B15 2SQ into a suitable online mapping service.

Birmingham Quality is adjacent to the **Queen Elizabeth Hospital**, part of the **University Hospitals Birmingham NHS Foundation Trust (UHBFT)**, and **Birmingham University**.

See <https://birminghamquality.org.uk/contact-us>

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1.5. Administration

Birmingham Quality is administered as a separate self-financing unit within Clinical Delivery Group 11 (CDG 11) of UHBFT, which provides employment and financial services. It is independent from the pathology services provided by UHBFT.

Some aspects of our services may be subcontracted; where this occurs, competent subcontractors are used, and Birmingham Quality remains responsible for their activities. Scheme design, performance evaluation and report authorisation are never subcontracted.

Additionally, Birmingham Quality uses products and services provided by external service providers to support our schemes, for example procurement of serum, however Birmingham Quality maintain responsibility to our participants for these products/services.

1.6. Staffing & Management

Birmingham Quality is directed by a Consultant Clinical Scientist with many years' experience of EQA work with designated UK NEQAS Scheme Organiser status. The Director is supported by the Deputy Director (a Consultant Clinical Scientist) and a second Consultant EQA Scientist.

The above senior scientists all have UK NEQAS Scheme Organiser status and possess professional registration with the Health and Care Professions Council (HCPC). Designation as a UK NEQAS Organiser is by the Board of Trustees of the UK NEQAS Charity, based on experience and expertise.

The range of EQA services offered and the programme Director/ Organiser of the service can be viewed using the link: <https://birminghamquality.org.uk/eqa-programmes>

Day to day management of Birmingham Quality is the responsibility of the Director. Day to day management of the individual EQA services is the responsibility of the Scheme Organisers.

All staff are employees of UHBFT and are solely employed in the provision of EQA services. They follow specific training and competency programmes.

The Quality Team is responsible for the development, implementation and maintenance of the Quality Management System and maintaining compliance with ISO/IEC 17043 — Conformity Assessment — General requirements for the competence of proficiency testing providers.

1.7. Communications

The telephone number is: 0121 414 7300 [non-UK +44 121 414 7300] which is continuously manned from 0830 to 1700h Monday to Friday, with voice mail recording at other times, on official holidays or in case of high call volumes. Callers will be asked the nature of their request or enquiry, and will then be transferred to an appropriate member of the team (see below).

It is particularly important that participants co-operate with our Quality System requirements for telephone communications which is in place to better serve their needs. All callers will be asked for their name, laboratory identifier code (where relevant) and department and for an indication of the nature of the call, before it is passed to the most relevant member of staff for attention.

Most communications can be dealt with speedily and effectively by our highly experienced and knowledgeable administrative and scientific support staff without referral to senior staff. Callers can therefore be confident

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that they do not have to speak to the Organiser on each and every occasion. All contact information is logged and the outcome of calls and actions audited.

Birmingham Quality participants wishing to make general enquiries, should contact us via any of the routes described at <https://birminghamquality.org.uk/contact-us>

For non-participants, the departmental **email** address is birminghamquality@uhb.nhs.uk

All your Reports and Request Cards / Results Documents use your UK NEQAS ID as the index to all of your data. This is fundamental to the way we operate. You must quote your UK NEQAS ID in all correspondence. This is essentially your Account Number. Without this we cannot handle your enquiry. Many physical laboratories have more than one UK NEQAS ID. This could be another analyser or another site. In the same way that Patients are often identified by two-out-of-three of Name, Date-of-Birth or Hospital or NHS number, we need to be sure who we are dealing with. We may ask you supplementary questions if you are phoning. If you email us, please don't assume that we know who you are just by virtue of your footer. You may have an NHS.net account which gives us no indication where you are calling from. You must quote the UK NEQAS ID to which your enquiry refers.

If it is a general enquiry you can just quote you 'main' UK NEQAS ID. If you are changing things for a particular analyser or site you must be clear as to which UK NEQAS ID these changes refer. Unfortunately, saying 'all of them' isn't sufficient for us to act on your request.

All participants use their UK NEQAS laboratory identifier as username, and a password which is notified to them when they join. Most Participants have been with us for years and will have some local internal SOP / Document that contains this information. Because a Laboratory Account is accessed by multiple individuals, it is better to ask your colleagues for your local approach if you lose / forget passwords because if we change your log-in password for you personally, it will be up to you to share this with rest of your Department. Your password can be changed to something more memorable and can be changed by you, the participant.

Please contact Birmingham Quality by email if you require further information or re-notification of your password.

Senior scientific staff have personal email addresses. These should only be used for messages of a specific nature which only the individual concerned can answer. They should NOT be used for EQA results, method changes or general enquiries as they are individual, private addresses, and as such may not be scanned each day or during holiday periods when the staff members are absent.

Director: finlay.mackenzie@uhb.nhs.uk
Deputy Director: rachel.marrington@uhb.nhs.uk
Consultant EQA Scientist: martin.roch@uhb.nhs.uk

1.8. Websites

Information about Birmingham Quality and the EQA services it provides can be found at the following address: birminghamquality.org.uk

The main UK NEQAS Website is at uknegas.org.uk. This provides general information about the UK NEQAS organisation as a whole, as well as specific information for each UK NEQAS centre.

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1.9. Marketing

In addition to information being provided on the Birmingham Quality website, Birmingham Quality may contact participants directly specifically with information relating to Clinical Chemistry EQA Schemes only.

1.10. External Regulation of Our Services

- **Accreditation:** Birmingham Quality is accredited by UKAS against the requirements of ISO/IEC 17043:2010 – Conformity Assessment – General requirements for proficiency testing. The scope of accreditation can also be viewed on the UKAS website:

[Scope of Accreditation](#)

Pilot analytes and Pilot Schemes are not immediately accredited to ISO/IEC 17043:2010; however, at Birmingham Quality they are operated and managed using exactly the same quality management system procedures as accredited Schemes.

- **UK NEQAS Consortium:** Birmingham Quality has close ties with other UK NEQAS operations through the UK NEQAS Consortium. All UK NEQAS-designated services comply fully with the UK NEQAS Code of Practice
- **Steering Committees & Specialist Advisory Groups:** Birmingham Quality has in-house expertise relevant to Clinical Chemistry, but does seek advice from relevant Specialist Advisory Groups, Steering Committees, Scientific Advisors, Specialist Committees, Task and Finish Working Groups etc where appropriate. Birmingham Quality provides updates on Schemes to Specialist Advisory Groups and Steering Committees.
- **National Quality Assurance Advisory Panels:** All full UK NEQAS schemes (i.e. not surveys or non-UK NEQAS schemes) report to the National Quality Assurance Advisory Panel (NQAAP) for Chemical Pathology, Microbiology (UK NEQAS for Antibiotic Assays and UK NEQAS for Antifungal Assays) and Haematology (UK NEQAS for Vitamin K).

1.11. Education

Birmingham Quality is committed to providing a high quality EQA service and part of this includes providing supporting training and educational material about EQA. A number of educational videos are available, once you have logged in, behind the green button on the Result & Reports webpage. These will assist you with understanding what EQA is, how Birmingham Quality delivers an EQA service and also Report Interpretation.

Birmingham Quality also provide monthly EQA surgery webinars. These are free to attend for all participants enrolled in current Schemes and cover a range of topics. Participants are encouraged to submit questions beforehand and some of these are covered in the webinar. Feedback is sought from participants at the end of each webinar.

1.12. Other Links

Birmingham Quality has close links (formal & informal) with UK professional groups, EQA providers in other sectors, European groups such as CEN, EURACHEM and EQALM, and international organisations such as IFCC. We work with the British In Vitro Diagnostics Association (BIVDA), Medicines and Healthcare Products Regulatory Authority (MHRA), Association for Laboratory Medicine (LabMed), Institute for Biomedical Science (IBMS) and European Federation for Laboratory Medicine (EFLM).

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2. Terms and Conditions of Participation

2.1. Eligibility

Birmingham Quality services are designed principally for UK public and private sector clinical laboratories serving clinicians and patients. Non-UK clinical laboratories, those with purely research or industrial roles, manufacturers of diagnostic instruments and reagents, and other laboratories are also welcome to participate. Manufacturers may do so 'anonymously', whilst a product is not yet available on the market, or on an 'information only' basis, i.e. without receiving samples and returning results.

We have a standard class of participation where participants deal directly with Birmingham Quality for all aspects of participation including performance surveillance and financial matters.

We have two further classes

[1] *Network Coordinators* who may receive, with suitable authority, collated data from its Network of Laboratories. This is particularly useful for large, multi-centred Trusts.

[2] *Hub and Spoke* participation where only the Hub is considered to be a full participant and our dealings are only with the Hub (which, for example, may be a Point of Care Coordinator).

Note: It is the Hub that is responsible for all financial matters and is responsible for the following up of out-of-consensus performance. Our Hub reports make this easy to administer, but because the payment structure for Hub and Spoke situations are heavily discounted, Birmingham Quality does not deal with Spokes directly unless other arrangements have been agreed. We may, for example, send a single package to the hub coordinator for onward distribution to the wards and the responsibility of onward distribution lies with the Hub.

2.2. Terms and Conditions

The act of requesting registration or re-registering (whether by email, letter, web form, quotation or purchase order) confirms a participant's willingness to be bound by the Birmingham Quality Terms and Conditions of EQA participation (M-COR-002). Refer to the Birmingham Quality website for the current Terms and Conditions.

For UK clinical service laboratories, the act of enrolling in a scheme confirms their willingness to be bound additionally by the Quality Assurance Pathology Committee (QAPC) Conditions of Participation (the terms and conditions and other information about the Quality Assurance in Pathology Committee can be accessed via <https://www.rcpath.org/profession/committees/qapc.html>)

Any manufacturer whose assay is represented in the EQA programmes also agrees to be bound by the QAPC Conditions of Participation and may be brought to the attention of the Medicines and Healthcare products Regulatory Agency (MHRA) in the event of poor assay performance.

2.3. Period

Participation in all Birmingham Quality Schemes is deemed to be continuous with automatic annual renewal and invoicing for subscription fees for each NHS financial year (1st April to 31st March), unless Birmingham Quality are advised to the contrary, in writing, a minimum of one month in advance of annual renewal. Participation may begin at any time during the year; part-year charges are higher than pro rata.

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The UK NEQAS for Vitamin K Scheme operates from 1st January to 31st December.

2.4. Enrolment Procedure

Participation begins at the first distribution following receipt of fully completed enrolment questionnaires sent in response to a formal request to participate. Questionnaires gather full details of the participating laboratory and the methods it uses for the analyte(s) concerned.

As indicated above, enrolment may take place at any time. Visit <https://birminghamquality.org.uk/contact-us> for information about how to contact us with enrolment requests.

On enrolment, each participant is given a unique UK NEQAS laboratory code (now shared across all UK NEQAS centres), which remains associated with that participant indefinitely. Laboratories with more than one analytical area (e.g. routine & emergency laboratories) may make multiple enrolments, where Birmingham Quality will create 'daughter' codes (e.g. 10123A, 10123B). Laboratories at multiple sites but administered by a single department may receive separate codes. Reattribution of codes and data can be accomplished where laboratories close, merge or de-merge. Participant codes must not be disclosed to third parties.

2.5. Charges

Annual subscription charges are based on the full actual costs of providing EQA services according to the not-for-profit terms of the UK NEQAS Code of Practice. As such they are subject to continuous review and may be reduced as participation increases or if surpluses are generated. Equally they may be increased if costs rise or if participation decreases. Current charges are available as a Price List on the 'Centre' button found on the Results and Reports website. You will need your user name and password to access this information.

In the event of a participant failing to pay the membership fee by the due date, the Scheme Organiser reserves the right to terminate, without notice, the membership of that participant without prejudice to any claim for payment for services already provided.

2.6. Refunds

Refunds are not available; however, transfer of subscription charges to other EQA programmes may be possible under exceptional circumstances at the discretion of the Director.

2.7. Confidentiality

Each laboratory will be registered under a unique code number, which is common across UK NEQAS centres, in the case of UK NEQAS services to ensure confidentiality and impartiality. The fact of participation, identifiable raw data and identifiable performance scores are confidential to the participant and will not be released by the Scheme Organiser to third parties other than under any agreed and defined mechanism for providing follow-up and counselling to Laboratories outside our Limits of Acceptable Performance. All participants offering a direct or indirect clinical service in the UK are subject to the Quality Assurance Pathology Committee (QAPC), and its Quality Assurance in Pathology Committee Terms of Reference. Participants will be informed of any referral to NQAAP/QAPC which impacts them and the content of such referral. These data may also be shared with local management, regional Quality Assurance officers, accrediting bodies and suppliers of equipment and reagents where appropriate and necessary, but only with the participant's explicit permission.

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Birmingham Quality is committed to maintaining confidentiality throughout the course of performing an EQA service. Participants have the right to waive confidentiality for the purposes of discussion and mutual assistance e.g. to improve performance or for regulatory or recognition purposes.

All reports, and all the data they contain, issued by the Schemes are Copyright and may not be distributed, published or used for promotion in any form without explicit permission of the Scheme Organiser on each and every occasion.

Participants are free to share information concerning their own individual participation or performance with individual clients (clinicians, GPs etc.) without consultation, but must not include Scheme data in their advertising. The Scheme may use anonymised specimen and rolling time-window data to produce summary or method-specific or state-of-the-art data in Commentaries, Webinars and Publications etc.

For more information on our Privacy Notice as to how Birmingham Quality uses your data, please see the [Privacy Notice Statement](#) on the Birmingham Quality Website.

2.8. Impartiality

Birmingham Quality is committed to impartiality in all activities that are undertaken by personnel working at Birmingham Quality including scientific advisors, specialist advisory group members and steering group members. This is risk assessed and regularly monitored.

2.9. Use of Material

The materials distributed are provided as specimens for the sole purpose of enabling external quality assessment at the recipient's laboratory during the current distribution.

Birmingham Quality specimens do not meet the definition of a reference material and do not intend to be reference material.

There is no intrinsic value to the specimens but they are an essential component to the service that is provided by Birmingham Quality. They do not constitute in vitro medical diagnostic devices (IVDs) and EQA specimens are explicitly excluded from the scope of the IVD Directive and its successor Regulation.

No claim is made that they may be suitable for any other purpose or at any other point in time. Resale or distribution to third parties is strictly prohibited. It is accepted, however, that residual material may be retained by the participant and used as part of method evaluation. Only very limited supplies of fresh samples are available for this purpose.

If materials are to be used in research which is expected to be published, or if participation forms part of contractual agreements with third parties (e.g. in drug trials), written consent must be obtained from the relevant Scheme Organiser on each and every occasion.

2.10. Repeat Samples

Limited numbers of single samples or sets from a particular distribution are usually available to full participants primarily to those who are unable to return results within the distribution window, but are also considered for those participants who may wish to check aberrant results or evaluate new methods. Birmingham Quality reserves the right to ask why repeat samples are needed and limit their supply if this would compromise the service to other participants. Participants are advised to retain any surplus EQA material for initial investigation of erroneous results.

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2.11. Verification Samples

This is an add on service. For some Schemes Birmingham Quality is able to provide additional specimens for assay verification purposes only. Each Scheme will have its fixed, designated content; it is not an *a la carte* service. There is a charge associated with this service. The cost covers the preparation/processing/handling and associated data only. The material has no intrinsic value and we do not charge for the material itself. Please contact Birmingham Quality for more information if you require this service.

2.12. Reporting of Results

All full participants are expected to return results promptly within the specified reporting period. Those under the remit of the NQAAP (UK clinical services only) are expected to return 100% of results within the relevant cumulative performance scoring period. Where a laboratory is unable to return a set of results, an explanation must be provided using the comments box on the online result entry page.

2.13. Demographic information

Participants are responsible for ensuring that the contact (including invoicing contacts), method and reporting units information held by Birmingham Quality is current and up-to-date. Method and unit information can be communicated using the online method update facility (available via the 'Edit' button on the online Results & Reports page). Participants will need their user name and password to use this facility.

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3. Materials

Material supplied by NHSBT (Section 3.1) and Remnant Material (Section 3.3) is not 'sold' to UK NEQAS. The charges that we pay for these materials are for the preparation/processing and handling only. EQA material has no intrinsic value; you are paying for a service.

3.1. Sources of Blood and Serum

The majority of serum used is obtained from NHS Blood & Transplant (NHSBT), whom Birmingham Quality have a contract with. Commercial material may support requirements. Some schemes/analytes require serum from patients either collected specially by collaborating physicians or NHSBT (e.g. glycosylated haemoglobins), or pooled from residual patients' serum supplied by participants.

3.2. Sources of Other Bodily Fluids

These are obtained either from healthy volunteers or from patients through special arrangements with collaborating physicians or participant laboratories. Some material is purchased through commercial suppliers.

3.3. Remnant Material

Remnant Material is highly valuable to many Schemes as this material is truly representative of that that the laboratory receives from patients.

Use of laboratory remnant material for Quality Assurance purposes is covered by the Human Tissue Act 2004 and Birmingham Quality welcomes any donations from laboratories.

Please contact Birmingham Quality if you have any remnant material that may be suitable for distribution through the schemes.

3.4. Informed Consent

Where additional material is obtained from healthy volunteers or patients, informed consent is sought prior to collection of the material.

Providers of materials to EQA schemes must ensure that donors are given sufficient information to enable them to give informed consent for this use. Birmingham Quality can supply generic patient information and a consent form for this purpose. General non-specific consent may not always be appropriate for some applications. Wherever possible and appropriate, samples should be anonymised so that they are not traceable back to the individual patient. Providers should ensure they have a paper trail and 'cradle to grave tracking' of these materials.

3.5. Commutability

We aim to distribute specimens that are as close as possible to human clinical material. This means that our specimens should behave with the same characteristics and behave the same way as your patient specimens. Simplistically, if it does behave in the same way you can be reassured that if you get the correct result on the EQA material you are likely to get the correct result with clinical specimens. Please remember is there are specificity issues with your assay then that that you see (and may not be aware of on patients) will also be seen on our EQA material.

If you get the 'wrong' result you need to be sure that this is because of an issue with your measurement procedure and not the EQA material. There are many quite complicated and sophisticated approaches that EQA Providers can use, all of which rely on statistics and probabilities rather than giving a simple yes/no answer. As a rule of thumb, the more heavily manipulated an EQA material is, the less commutable it is likely to be. An aqueous standard might not behave in the same way as a serum sample. Similarly, a de-lipidated,

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de-fibrinated plasma will not be as good as a serum from a single blood donation. Spiking samples with pure compound doesn't in itself make the material non-commutable.

The contrast between an IQC material and an EQA material is reflected in what is the crucial USP that each aspires to. An IQC needs to be stable and have a long shelf but needn't have a true value associated with it; laboratories can calculate their own set point. Our EQA materials on the other hand are often much more like clinical specimens and are designed to give a measure of relative bias as a minimum and absolute bias as a best case scenario.

3.6. Target Values and Reference Method Analysis

Target Values should be validated. We use the best estimate of the truth (see Section 6.3). This can be validated by having Reference Method Values carried out on the material. Most measurands do not have Reference Procedures or Reference Materials. For simple measurands Recovery experiments, dilutions and test of parallelism are usually sufficient to give confidence. It should be noted that a value from a Reference Method on a non-commutable material isn't worth the expense as it has no validity. As a rule of thumb, a selection of materials rather than all materials undergoing validation work-ups is usually sufficient. Having frequent distributions across a range of concentrations with different base materials and occasional reference method values is, in the opinion of Birmingham Quality, better than having a Reference Method Value on the only two samples that you send out in a year.

Reference Methods are often very different from the routine methods a laboratory would use. Even when the routine method principle is specific, for example using a mass spectrometer, the Reference Method Mass Spectrometer will be often many times more precise and many times more accurate than the Field Method MS. It is not unusual for a Reference Method value to be generated by having multi replicates over multiple runs which is why the cost is in the high hundreds of pounds. It is not only the expense which makes using Reference Method Procedures prohibitive, the relative lack of availability and the waiting times, often months, makes contemporaneous use difficult.

3.7. Safety

Blood collected by NHSBT is subject to the same UK safety testing procedures as blood used for transfusion. Other materials are either specially tested (where tests are available) after obtaining informed consent from patients, or not tested and participants informed of this fact. The latter circumstances apply where the risk is minimal. Please read the safety notice below.

IMPORTANT SAFETY NOTICE

As for clinical specimens, Birmingham Quality samples should be handled as if capable of transmitting infection. Appropriate procedures should be used to minimise contact with samples and for their disposal

3.8. Initial Analysis & Storage

Primary materials are stored appropriately according to matrix (so as not to affect the critical analytes) after removal of samples for safety testing or analysis to establish analyte levels.

3.9. Pool Processing

The principal features of routine pool processing are available on request, but the emphasis is placed on minimum number of donations per pool and minimal disturbance to the matrix. Non-pooled material (i.e. a single donation of bodily fluid provided by an individual) will be used in preference to pooled material wherever possible and where volume constraints allow. From time to time, special pools are prepared to address

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specific problems or scientific/clinical issues (e.g. additions of known interferents). Participants are regularly informed in scheme reports of the nature and constitution of materials distributed.

3.10. Participant Handling and Storage of EQA Materials

It is recommended that EQA samples should be analysed immediately upon receipt. Where this is not possible, the samples should always be handled and stored by participant laboratories as closely as possible to the way they handle and store patients' samples. The length of time in storage should be kept to an absolute minimum and where the samples have been refrigerated or frozen, they should be brought to room temperature and mixed gently prior to analysis.

3.11. Transport

Where EQA samples require onward transportation i.e. from one participant to another, it is recommended that they are treated as patient samples and are transported according to local transport procedures. Birmingham Quality have tested the integrity of specimens during transportation and can assert that the quality of EQA specimens is not adversely affected for a maximum of 48 hours when transported via Royal Mail at UK ambient temperatures.

Birmingham Quality advise that all overseas participants receive specimens via courier.

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4. Online Services

Birmingham Quality recognises the importance of the Internet for communication with and provision of services to participants, as well as interaction with oversight committees, professional bodies and the diagnostic industry.

Birmingham Quality is committed to the development of unified, easy to use web interfaces which enhance the utility of existing services to participants and enable new services to be developed. Wherever possible, this will be done in collaboration with other UK NEQAS centres and schemes, so as to maintain a pan-UK NEQAS unified approach. At present the Peptide Hormones Edinburgh follows a different statistical design approach and therefore is not included on the Dashboard.

The UK NEQASs for Microbiology (Colindale), Peptide Hormones (Edinburgh and Guildford), Cardiac Markers (Glasgow) and Andrology (Manchester) also use our online Results and Reports service.

These services have been enabled, but accessibility differs between centres:

- 1) **Results and Reports** (detailed further in Section 7),
- 2) **Interpretative Comments**,
- 3) **NPex** (detailed further in Section 13),
- 4) **Dashboards** (detailed further in Section 7)

If you have any comments on, or requests for Internet-based services, please contact us using any of the routes described at <https://birminghamquality.org.uk/contact-us>

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5. Operations

5.1. Distribution Cycle

All schemes operate according to a regular cycle of activity, based nominally on 4, 6, 11 or 22 distributions per year. A distribution has a unique identifier (usually numeric) with fixed sample despatch and results return dates. When the distribution is generated, a 'snapshot' of participation (labs, analytes & methods) is taken for the duration of that distribution cycle. Changes in participation that occur during the current distribution cycle are incorporated before data processing.

5.2. Pool Distribution Policy

It is intended that within any given performance assessment period, a number of different materials will be distributed that assess the range of analyte concentrations agreed by our expert groups and advisors to be clinically important. How successfully this policy is delivered in practice also depends on scheme size and analytes, whether materials are multi- or single analyte and the availability of suitable clinical material. Our Schemes are designed to be clinically challenging and reflect real patient specimens; therefore on occasion we will distribute specimens with known interferences. We may ask audit style questions to obtain information about current clinical practice on specific areas. This information is then reported back to registered participants.

5.3. Distribution Dates

The schedule for the current calendar year (and the next year when known) is available at <https://birminghamquality.org.uk/schedules>, but dates may be subject to minor changes dependent upon operational circumstances.

Participants shall be advised promptly of any changes to scheme design or operation in writing normally via the 'feedback' page on reports at the first distribution post change.

Late and amended results are not routinely available for the POCT Suite; occasionally at the Schemes Organiser's discretion changes can be made.

5.4. Method Classification

A crucial element of participation for all schemes is the correct assignment of method codes, since performance scoring may be method-based the provision of accurate method-related information is an important element of the service.

Methods are given unique codes in the computer system at Birmingham Quality, with parallel coding or sub-codes for alternative reagents/calibrators etc. Considerable effort is expended by Birmingham Quality staff to ensure the accuracy of method coding and updating records when these change. Participants are required to co-operate with this process by completing fully and returning method questionnaires at the point of enrolment, and informing us of errors, omissions or changes at the earliest opportunity. Method and reporting unit information can be updated using the online method change facility.

It is essential that Birmingham Quality are informed of any departure from the manufacturer's stated protocol, together with supporting information on the validation of this approach. Once a participant's enrolment in a scheme has been finalised, it is the participant's responsibility to notify us of any changes to their methods or reporting units. Our method update service is web-based and is accessed online via the 'Methods' button on the 'Results and Reports page'. You can select from a dropdown of methods or select the default option from the major manufacturer's products. If you are not using the system according to the manufacturer's

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instructions, please select the in-house category within your system's method principle. Method codes have been harmonised for UK NEQAS hormone schemes, Edinburgh (peptide hormones & tumour markers) and Guildford (peptide hormones) schemes.

5.5. Packaging & Mailing

Single samples or sets (depending on the scheme) for each distribution are mailed to the registered scheme contact(s) using the fastest and most appropriate route possible. First class mail is used for the UK (courier service also available at additional cost), with courier (Express) deliveries strongly recommended for European and overseas participants. The packages are clearly marked 'open on receipt'. Packaging complies with current UK legislation for the mailing of pathological material.

Where there are separate samples for each analyte (e.g. steroids) tubes have colour-coded caps. All tubes are labelled with the scheme, distribution identifier, analyte (where appropriate) and sample number. The naming convention for the latter has been standardised across all schemes and comprises a sequential numeric distribution identifier plus a letter where there are multiple specimens in a distribution (e.g. 256A, 256B, 256C).

The Distribution Schedule for all schemes is available on the Birmingham Quality website. Once the specimens have been despatched, the registered scheme contacts are sent an e-mail notification of sample despatch. If for any reason specimens are not received, not received when expected, or are damaged upon receipt, notify Birmingham Quality via one of the methods listed under 1.7 Communications.

Participants in the UK NEQAS for Vitamin K Scheme receive all specimens as a single shipment for the start of the year. Four batches are sent out each year with a schedule for analysis. Vitamin K₁ is known to be stable at room temperature and so is not couriered on ice. Specimens should be stored frozen by the recipient participant until the month of analysis. Specimens should be protected from light and will be transported to allow this.

5.6. Results Documents

All schemes have distribution-specific request cards / results documents which are individual to each participant. These carry the laboratory code, a full list of the analytes available in the scheme (a box appears next to the analytes for which the laboratory is registered along with confirmation of their reporting units), as well as messages about sample handling and return of results. In some cases method confirmation is also included. They are under constant review to make them easy to understand and use, and may change from time to time to reflect improvements. The functionality of the Results document mirrors the Results return section of the online service.

5.7. Sample Handling

The general rule is that participants should treat EQA samples identically to those from patients. It is recognised that sample tubes and requests are different and multiple samples may be received for certain analytes. In principle; however, accession numbering and assay should be the same as for patients.

In order that there should be uniformity of handling amongst participants, it is recommended that if an assay is not to be performed on the day of receipt and specific storage conditions have not been specified on the results document, serum, urine, fluid or plasma-based EQA samples should be frozen at -20 °C or below, and thawed completely and carefully with thorough mixing on the day of assay. For other specimens (whole blood, human faeces, artificial faeces and artificial sweat) where specific storage conditions have not been specified on the results document, these should be stored at +4 °C until the day of assay.

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The length of time for which the specimens are stored should be kept to an absolute minimum. Unless instructed otherwise, participants should ensure that ALL samples in a given distribution are analysed on the same day, with the same batch of reagents, and in the same analytical 'run', batch or calibration cycle, to ensure that unknown additional variability is not introduced.

Once analysis is complete, please retain any residual EQA material for troubleshooting purposes. Laboratories should store as they normally would do, but in the absence of a local protocol it is recommended that the storage conditions on the results document are followed.

5.8. Results Reporting Procedure

Unless specified otherwise, all results must be returned using our online service. This provides the most rapid means of reporting results, with real-time validation against plausibility limits and confirmation of submission.

Results should be entered in the units shown on the online service form, taking care to match sample numbers and avoid transcription or transposition errors. If the units displayed on your results document are different to your usual reporting units, please notify us using the online methods update facility.

Figures and decimal points should be unambiguous. Please do not enter leading zeroes. 'Less than' or 'greater than' results can be entered online using the '<' and '>' symbols as appropriate. Please do not leave a space between the '<' or '>' symbol and the numerical result.

Laboratories should report EQA results to the same number of decimal places as they would report results for clinical specimens.

In the unlikely event that the online results entry system is not available, results transcribed onto the original document may be sent as an e-mail attachment to Birmingham Quality, **by prior arrangement with Birmingham Quality**. Results received by any route other than the online results entry service, not previously agreed with Birmingham Quality, will not be included in the data-processing for that distribution.

Please avoid obscuring results documents with sample or bar code labels and ensure that all figures and decimal points are clear and unambiguous.

Registered online service users may enter/update/amend their results for online service enabled schemes at any time while the distribution is open.

Late results may be entered online after the closing date and at any time up until the close of the next distribution. These will be incorporated into cumulative analysis at the next distribution. All late results are flagged as such in our database. Late results are not routinely accepted for POCT Suite.

Null returns where there are no results available e.g. if there are no patients' samples to assay, if the assay is out of service, or if one or more results from a panel of analytes is missing, then enter XPL into the results entry boxes for the affected analytes/specimens and provide a brief explanation in the comments box at the bottom of the results entry screen. Where it is not possible to return any results for a particular distribution, please check the box at the top of the results entry screen marked 'Tick this box if you have no results at all for this distribution; you must provide a brief explanation in the comments box below'.

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When entering results online, Participants should always **check the methods** for which they are registered, and make a correction if a change has occurred, using the online method update facility. Method changes can be applied retrospectively but only as far back as the distribution prior to the one currently open (2 distributions for the UK NEQAS for Clinical Chemistry).

5.9. Amendments Prior to Data Processing

Participants who discover an error in their reported results before the reporting deadline can amend their results via the online service at any time whilst the distribution is open.

5.10. Amendments After Data Processing

If errors are identified after the return-by date, requests to amend non-analytical errors should be made online under the usual Results button, ensuring the correct Distribution number has been selected. Requests for amendments can only be made for the distribution prior to the one currently open (2 distributions prior to the one currently open for the UK NEQAS for Clinical Chemistry). Simply edit the affected results and re-submit. The requestor should include their name and a valid reason.

Amending results is at the discretion of the scheme Organiser and is not an automatic entitlement. The Organiser reserves the right to request additional evidence in the form of the original output from the analyser.

All amended results are flagged as such in our database. Procedures for amendment and scoring of non-analytical errors ('blunders') are described in the 'Performance Problems' (10) section of this manual. Problems associated with any errors made by Birmingham Quality will be amended as soon as practicable and a new report generated. There is internal audit of such occurrences, which are rare.

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6. Data Processing

6.1. Data Handling

All Scheme data are held on secure network servers which are backed up daily. Data processing is performed using bespoke EQA software modules which have been developed in association with the Wolfson Computer Laboratory since 1969. These allow all schemes to be optimally configured according to Birmingham Quality house style.

6.2. Calculation of Target Values

Target values are crucial to scheme design and usefulness and are the basis for accurate performance scores. In all cases, a robust estimator of the central tendency of the data set and its dispersion are calculated. Clearly the larger the number of data points the better the estimate, which becomes important when method-related target values are employed rather than those from all laboratories or groups of methods.

To eliminate the distorting effect of grossly atypical results, outliers are trimmed from both tails of the ranked data set, with a corrected estimate of dispersion (SD or CV) usually by the method of Healy (1979)² to allow for the removal of extreme values which are not 'true' outliers. The data processing for individual schemes is conducted using individually configured modules within the computer system.

For all our Schemes we have a minimum data set size that we use to calculate a target value. We are aware that for analytes that have a low number of users, those participants do want to see some level of assessment even though both they and Birmingham Quality are well aware of the limitations of this approach. Statistically speaking, this carries a huge uncertainty overhead but the alternative is not to provide Laboratories with any indication of their performance.

For those analytes with an ALTM target that regularly comprises fewer than 8 results, there is often no formal Performance Assessment.

6.3. Validity of Target Values

For target values to provide an accuracy base for method evaluation and comparison, they should be validated. For those analytes (e.g. drugs) which are exogenous to normal body fluids, weighed-in values which are independent from scheme data can be used to validate targets. For analytes which are endogenous and where reference methods exist (e.g. IDMS for steroid hormones), target values can be compared with reference values. Where there is no accuracy base, but internationally-recognised reference preparations exist (e.g. TSH), target values may be validated using recovery/linearity (dilution) exercises. These are performed at regular intervals throughout the year. Birmingham Quality is committed to continually assess the ongoing validity of its consensus and/or target values.

Where the ALTM is known to be 'incorrect' and the scheme contains sufficient users of mass spec field methods, the latter is used as the target value. This itself is validated by comparison with reference or candidate reference method values.

In the Glycated Haemoglobins scheme, secondary reference method values obtained from reference laboratory network members are reported to participants; however, these are not used as the target value.

Birmingham Quality does not perform in house or use any external service provider for the measurement or testing to calculate target values.

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6.4. Consensus - coping with non-numerical results - a Scheme wide approach

For everything that we do, whether it is for numeric or non-numeric results, we always try to compare your results to the 'best estimate of the truth'.

Participants should be aware that there are subtle differences and nuances of meaning between 'mode or consensus' and 'target' and 'being the right answer'. A consensus is just a 'mode'. It is the most abundant answer, but may not always be the right answer. We can calculate an overall mode, a method principle mode or method mode. Each Scheme/Analyte will have, for sound scientific reasons, its own default target. Though reviewed periodically, this does not get changed from month to month or from specimen to specimen.

The target response is the simply the response against which you are compared.

There can be occasional situations where the mode is clearly not the best estimate of the truth or there is no single mode. Under these circumstances, based on the evidence available (e.g. weighed-in value), the Organiser may assert a 'target' response. This does allow, for example, a specimen with a very high spike to tip the balance to be "Positive" if there was a tie between "Positive" and "Negative". This can be particularly useful when the data sets are small. Likewise if the weighed-in value was exactly that of a cut-off value, we may decide to call it 'a tie' and no one would be penalised.

6.5. Calculation of Performance Scores

As well as providing data on closeness to the target value in a given distribution, schemes employ scoring systems which yield a performance score averaged over a number of distributions and individual samples within a rolling time window to give a robust estimate of overall bias and its variability.

The scoring method used for all Birmingham Quality schemes is the 'ABC of EQA' system. Worked examples of how these are calculated and used are available under the 'Centre' button on the online Results and Reports page. You will need your user name and password to access this information.

Unlike many other schemes which conduct a series of discrete cycles after which an 'end-of-cycle report is prepared, UK NEQASs operate on the basis of continuous analysis for a rolling time window. Organisers have the option to exclude certain methods from the calculation of target values and/or certain pools from scoring if these may perturb performance unduly or are atypical in any way. Such actions may be undertaken in consultation with the appropriate Specialist Advisory Group (SAG).

6.6. Acceptable Performance Criteria

Limits for acceptable performance scores are recommended by the Scheme Organiser and endorsed by the NQAAP after due deliberation and consultation with Organiser and SAG, to reflect the state of the art of analysis and encourage improvement. Procedures are used to identify those laboratories which have breached these limits on a set number of occasions within the cumulative reporting period. Schemes are required to provide information on persistent poor performers to the relevant NQAAP. See Section 10.

6.7. Processing Surveillance

As each distribution is processed, Organisers carefully check the resulting data for integrity and consistency of results, and any unexpected shifts in method-related values which might signal a clinically-important shift in diagnostic products. If any are identified, the manufacturer is contacted so that the findings can be discussed and a preliminary brief report can be made. Target values for pools that have been distributed previously are given special attention. Sample reports are then prepared and parameters for graphic and tabular data checked and adjusted where necessary. Anomalies are corrected before reports are published.

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7. Reports and Report Interpretation

7.1. Target Turn-Around Times for Reporting

All monthly, fully accredited Birmingham Quality EQA services have the following associated performance target: *"Reports are to be published to the web server before the next Distribution is open to UK participants."* For the fortnightly UK NEQAS for Clinical Chemistry, the target is 5 working days.

In reality, for the vast majority of Schemes, the time between distribution closure and publication of reports will be less than 5 working days. The exact time is recorded and is regularly audited.

The situation for Pilot schemes is inherently more variable owing to their fluid nature, but Birmingham Quality always aim to have reports published and available before the next Distribution is despatched. Once again, these dates are recorded and subject to audit and review.

7.2. Report Versions

The current definitive report is that on the secure Results and Reports website. When reports for a scheme distribution are published the name and date of authorisation are stated, and the time and date of publication are printed on each page. Unless specified in the report (e.g. an initial report awaiting republishing with a commentary) this may be considered as a 'final' report.

Revised reports including a participant's late or amended results are identified by the words "LATE Results" or "AMENDED" below the laboratory code at the top right of the report. Changes in target values resulting from inclusion of late or amended results are normally trivial (and will always improve target validity), and will be reflected in reports for subsequent distributions. On the rare occasions when revised reports are published for a distribution, the revised report is clearly identified as such, with reference to the date when the report which is replaced was published.

7.3. Distribution of Reports

The default status for report distribution is 'paper-free'. Participants may download their reports as electronic .pdf files from the secure Results and Reports website.

7.4. Report Formats

Schemes' reports are the main interface with participants, and a great deal of effort has gone into making these informative and easy to interpret.

All scheme reports are generated as A4 format PDF files, which display the data in a number of discrete tabular and graphic formats shared across related schemes.

Most scheme reports now have 'traffic light' colour coding, where symbols and their colour (green, yellow or red) indicate how close individual percentage biases are to the target value, and whether performance scores lie within or outside acceptable limits. Examples are available on request, but all reports share most of the following features:

- Distribution summary (tabular)
- Participation summary
- Method summary
- Overall performance summary (graphical)(Performance Summary Icons / Cumulative Summary)
- Current performance scores and limits of acceptable performance
- Individual results obtained, target values, deviation from the target value (tabular)

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- Histogram of all results (method group and individual results marked)
- Table of method-related results (means, SDs, CVs)
- Table of results, target values and deviations for all distributions in the cumulative assessment period
- Graphical indication of performance scores
- Graphical indication of method-related performance scores
- Table of method-related performance scores
- 'Snapshot page' (ABC of EQA) showing a selection of useful graphs and useful for troubleshooting performance problems
- Some schemes (e.g. neonatal screening) also have information on the interpretative elements of participation. Where appropriate, Birmingham Quality provide plots which combine information about the relationship between numerical results and their interpretation broken down by method
- Where relevant and appropriate for the scheme and its target value(s), Birmingham Quality may provide a standard uncertainty of the target value(s) calculated according to the principles outlined in ISO 13528 *“Statistical methods for use in proficiency testing by interlaboratory comparison”*

A guide for interpreting your Birmingham Quality EQA report (A-WKS-031K) and other guidance documents are available under the 'Centre' button on the online Results and Reports page. You will need your user name and password to access this information. These should be studied carefully, and our staff consulted if clarification is needed. All are under continuous review with the intention to extend harmonisation of both aspects of scheme design throughout our schemes and in collaboration with other UK NEQAS centres.

7.5. Result Validation

Birmingham Quality will send an email notification to the registered scheme contacts when pdf reports for a scheme have been published to the website. Each report is specific for the laboratory identifier and password entered.

The results for that distribution should be **checked to ensure that they are the ones returned by your laboratory**. Mistakes can occur if the submit button has not been clicked after results have been updated or if figures have been misinterpreted whilst being transcribed. Requests to amend non-analytical errors should be made on the web under the usual Results button ensuring the correct Distribution number has been selected. It is very important to check your report as soon as possible after publication as requests for amendments can only be made for the distribution prior to the one currently open. Simply edit the affected results and re-submit. The requestor should include their name and a valid reason. Amending results is at the discretion of the Programme Organiser and is not an automatic entitlement. The Organiser reserves the right to request additional evidence in the form of the original output from the analyser. All amended results are flagged as such in our database.

Also, it is crucially important that **participants' methods (and sub-methods, instruments, reagents, calibrants and reporting units where appropriate) are accurately identified**, especially where performance is assessed against the method mean. Any apparent discrepancies should be corrected using the online methods update facility. If the method or unit information you wish to specify is not available via the dropdown list on the method update facility please supply as much information as possible (manufacturer and model number of the analyser, manufacturer, description and product code of the reagent & calibrator, and reporting units in the 'Your comments' section.

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7.6. Current distribution

Use the **distribution summary pages** to examine the deviation of your results from the designated target value and (if not the target) the mean (or median) of your method group for each analyte. If deviations are consistent with usual overall or method-related bias and cumulative (A, B and C) scores remain stable and within acceptable limits, then it may not be necessary to examine analyte-specific pages in detail. If, however, there are unusual deviations for certain analytes, types of material or analyte concentration which appear not to be shared by other users of the method, then detailed examination of the problem area will be required. (If these are very large, then non-analytical errors should be suspected.) Where appropriate, use the 'traffic light' colour coding to identify aberrant results.

In the case of schemes which use a single sample for more than one analyte and results appear to be divergent across many analytes all in one direction, the occurrence of a systematic technical error (eg faulty sampling or dilution, inappropriate delay in assaying) should be suspected.

In examining **analyte-specific pages**, participants should relate their results to the overall and method-related distribution of results for each sample as indicated by the histogram and table of method means and CVs. Apparently discrepant results which lie in the tails of the distribution might signify a non-analytical error, others which lie just within the distribution may simply reflect atypical, but not abnormal, variation. Where reports include a table of results for previous distributions (e.g. hormone schemes) it will be helpful to look at results for the same pool distributed on a previous occasion to check for pool and/or concentration-related effects.

7.7. Rolling Time Window Performance (A, B and C) Scores

One of the main purposes of a performance score derived from a number of distributions and many samples is to 'smooth out' the natural variation in deviations from target values over a number of distributions, by trimming extreme values and deriving a robust estimate of the central tendency for overall bias together with an index of its consistency. Thus when interpreting the performance score elements of reports, it is important to note that (a) a small number of atypical results is unlikely to affect overall scores, and (b) aberrant results which are numerous enough to affect performance scores will take some time to work their way out of the scoring 'window'.

The principal concern of EQA is the overall bias of participants' results and the consistency (variability) of this bias over time with different materials and different analyte concentrations. It is important to note that when the score that relates to 'consistency of the bias' ('C' score) is high, then the confidence which can be placed in the overall bias score (B score) is reduced (and vice versa). Also, the C score may relate to assay imprecision (and/or reproducibility), but only if there are insignificant pool- or analyte concentration-dependent variations in deviations from the target value or changes over time. Only internal quality control (IQC) can give a clear assessment of analytical imprecision.

When interpreting performance scores, participants should look for atypical results in a single isolated distribution (as above) and relate these to IQC data on the day of analysis, and then for shifts or trends over a number of distributions which might indicate a method- or instrument-related problem. Note that the C score always increases when the B score changes in either direction, so that this will occur when bias shifts and again if a correction is made. Only after a full period of stable performance (with or without a change in bias) will the C score decrease to low levels. The graphical elements of cumulative reports show this clearly in relation to acceptable limits of performance (not all schemes) and the overall behaviour of different method groups. Attempts should be made to correlate trends and/or shifts in bias with IQC data, which in turn should indicate whether changes in personnel, data reduction, procedures, calibration, reagent batches or instruments are implicated.

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The Performance Summary Icons (PSI) page provides the Participant with at-a-glance information about their performance. This page displays a 'penalty box plot' for each analyte in the scheme for which the participant is registered. A 'traffic light' banner representing the worst case performance achieved by the participant for either the B or C score associated with that analyte is incorporated into each penalty box plot. As each point on the graph represents a user of the same method as the participant, and the limits of acceptable performance are clearly marked, it is possible for the participant to ascertain very quickly if they are breaching the acceptable limits of performance and whether all users of the method agree. Clicking on the analyte-specific icon will take the user directly to the analyte-specific pages of that report to allow for detailed analysis of the distribution data.

7.8. Method Comparisons

Reports may include tables of performance scores for all methods with >3 users. Included will be an estimate of the central tendency of the method group (eg median) and its dispersion (eg interquartile range = 25th–75th percentile). It should be noted that method-related scores are less reliable when there are <10 users of the method. Nevertheless, it is often useful for participants to compare the performance of their method in relation to others, especially where target value validation experiments reveal possible problems with calibration, linearity or baseline security.

7.9. Network Reports

Network Reports are a summary of B and C score data from a number of individual laboratory codes for a specific Scheme. A separate Network login and password is provided to participants. Please contact Birmingham Quality if you would like to set up a Network for individual laboratory codes. We will need to ensure that you have the right to have access to data for all requested laboratory codes before a Network is set up. Not all Schemes have Network Reports available.

7.10. Method Reports

Facilities exist for reports to be based on a particular method rather than an individual laboratory. This has the same functionality in terms of data analysis and presentation, but individual results are replaced by the trimmed method mean. These reports are of value to participating manufacturers for monitoring their products, and to laboratories evaluating methods or undertaking a tendering exercise. Method reports may be requested on an ad hoc basis or received routinely by certain types of participant. Those interested should contact the relevant Scheme Organiser to discuss their requirements in detail.

7.11. Special Reports

The computer system allows Scheme Organisers to extract data in a non-routine way from the EQA database to investigate problems with methods or illustrate features of participation and performance. These are not normally distributed to participants, but requests can often be met if the content and purpose of the report are carefully specified. Transmission of such data in electronic form is preferred. Those interested in this enhancement to routine reporting should contact the relevant scheme Organiser. Also available are special reports for point of care testing co-ordinators and laboratory network co-ordinators. Please contact us for further information.

7.12. Dashboards

Dashboards are available for either an individual laboratory code or a network. The dashboard is a front interface that links to the Results & Reporting website so that you can see from a high level overview how a single laboratory code or single network is performing down to individual analyte level at a single distribution. The dashboard allows results reporting as well as viewing reports. The dashboard is password controlled, on the Participants Results & Reports webpage.

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The Dashboard is pan Chemistry and covers all ABC style schemes from Birmingham Quality, Glasgow and Guildford. Edinburgh Schemes are not currently available on the Dashboard as a different reporting system is used.

7.13. Use of Birmingham Quality Data in Publications

All reports, and all the data they contain, issued by the Schemes are Copyright and may not be distributed, published or used for promotion in any form without explicit permission of the Scheme Organiser on each and every occasion.

Participants are free to share information concerning their own individual participation or performance with individual clients (clinicians, GPs etc.) without consultation, but must not include Scheme data in their advertising. The Scheme may use anonymised specimen and rolling time-window data to produce summary or method-specific or state-of-the-art data in Commentaries, Webinars and Publications etc.

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8. UK NEQAS for Urine Dipsticks

8.1. Scoring, Statistics and Report format

The approach we have taken for scoring in this scheme is subtly different to the 'routine laboratory' EQA in that it reflects the setting in which the tests are carried out and the reduced sampling frequency we are working with. The approach taken to reporting has been tailored to suit non laboratory-trained healthcare professionals.

There are **2 Specimens** per distribution and there is a distribution **every month**.

"Your result" is displayed as coloured tabs and as the numerical/+based result.

The "Consensus response", which is the Manufacturer 'mode' average is displayed as coloured pads and also as the numerical/+based value associated with that pad. If there is a 'tie' there is no consensus.

Data is calculated for each 'analyte' for each specimen and this is displayed as a coloured triangle or diamond under the by-line "On this specimen you were...".

The options being Very Low aka **VLo** (Red), Low aka **Lo** (Yellow), **Spot on** (Green), High aka **Hi** (Yellow) and Very High aka **VHi** (Red), referring to the number of pads away from the target that any given result was.

The "Recent Performance" is split into 3 parts:

- "This time",
- "Recent trend" and
- the rolling time-window performance (expressed as Good, OK and Poor coloured circle 'traffic lights')

The rolling time-window covers **3 distributions**, being equivalent to the last **6 specimens** in most cases. It is possible to have a rolling time-window score as long as the Participant has 4 specimens' worth of data in the rolling time-window.

"This time" is the results for each of the two specimens, expressed in words.

"Recent trend" is in two parts. The first part is the current rolling time-window score expressed in words, e.g "Currently Good". The second part is a comparison of the Participant's performance in this current distribution's 2 specimens compared with what their rolling time-window score was at the previous distribution. This allows them to see if their current 2 results are better, worse or the same as they were getting previously.

The rolling time-window score is the best 'estimate' of their recent performance. It is expressed as coloured circle 'traffic lights'. Green for "Good", Yellow for "OK" and Red for "Poor".

Participants can therefore see how they performed for

- each of two specimens, individually
- the current rolling time-window 'average' performance over the last 3 months
- the two current specimens compared to the previous rolling time window, giving them an indication of directional 'trend'.

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If Participants have any difficulty in interpreting their report in terms of their performance on the current two specimens, or in terms of their performance over the recent past, they can contact us for advice. If Participants are part of a Hub-and-Spoke set up, advice should be sought from the 'Hub Lead' in the first instance.

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9. Scoring for POCT

9.1. Looking at the same data in a number of different ways

This can be done by symbols, tables or statistics. With symbols, we use the ubiquitous 'RAG' rating. Red is considered to be out-of-consensus. A Red time-window score should initiate a more detailed look at what the Participant is doing. Yellow is borderline. Green is acceptable, but everyone can get better!

Essentially we look at data for each analyte for each specimen in the distribution and also looking at the previous 3 months' worth of data to look for trends.

We keep separate tallies of nil returns, partial returns and late or amended results so that this is dealt with independently of the analytical performance. Both are important, but it is easier to deal with them separately.

9.2. Specimen/Analyte data

We ascribe a tick or a cross for every result that is submitted. We keep both a count of the number of errors and also the average size of the error as it is useful to have both. The 'stick graph' has an extra sub-category of a 'yellow' result. This is still considered to be an acceptable result.

9.3. Time-window summation of 'errors' for an Analyte

For both the end user and the POCT Coordinator we use a simple summation of the number of crosses that have been accrued. There is a minimum number of results (opportunities) that has to be met before a rolling score is calculated. The collated information across all the Participants is information of great interest to both Commissioners and to Coordinators. Coordinators can benchmark the performance of their Participants against the performance of all Participants or of other 'Networks'. This data is colour-coded into a standard Red, Yellow or Green traffic light score.

9.4. Nil returns

This is when a participant does not return any results at all. We expect a 100% return rate but if the Participant tells us why they have been unable to return results, we log this as 'Explanation provided – or XPL rather than as a nil return. This doesn't count against them if this is an infrequent happening.

9.5. Partial returns

This is where the Participant returns some results but not a full set. This could be a missing analyte/analytes or a whole specimen missing.

9.6. Late and Amended results

This is where after the event, and when the Participant may have seen the EQA report, they can still submit results. To ensure this is not abused, we do log late or amended results and have criteria established. A failure of each type is allowed for 1 distribution, once a year.

Late and amended results are not routinely available for the POCT Suite, occasionally at the Schemes Organiser's discretion changes can be made.

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10. Performance Criteria - Limits of Acceptable Performance and Performance Problems

10.1. Performance Criteria

The current limit of acceptable performance for each scheme and analyte may be found at the top right-hand area of the 'Histogram' page of the scheme report.

10.2. Non-analytical errors

These are defined as 'blunders' made by participants, which appear as anomalous results (which may or may not be classified as outliers), and may fall into the following categories:

- Assaying the wrong samples
- Assaying the right samples in the wrong order
- Incorrectly transcribing laboratory results from computer systems or worksheets to results documents
- Use of incorrect units and/or conversion factors
- Technical errors, eg incomplete mixing after thawing, faulty sampling/pipetting, double addition etc.

It is important to note that atypical results that derive from assay failures which are recognised as such only after receipt of the Scheme report are not 'blunder's — they are **analytical errors** that have **not** been detected by internal quality control (IQC) procedures.

If blunders remain uncorrected, they contaminate the database and may affect target values (especially if these are based on method means) and individual performance scores. Requests for blunders to be corrected may be submitted as an amendment request using the online results return facility as described in the 'Operations' section of this manual. These are not routinely acknowledged, and are acted on at the next distribution, with publication of an amended report to our web service. A computer 'flag' is attached to each amended blunder and a cumulative record maintained for each participant.

10.3. Participation and Return Rate

According to NQAAP requirements for acceptable performance, UK participants are expected to return 100% of results within the relevant cumulative performance scoring period. Where a laboratory is unable to return a set of results, an explanation must be provided (see 'Null returns' in 'Operations' section of this manual).

Birmingham Quality will assess a laboratory's performance as satisfactory if they have in total up to 2 late and/or amended distributions from the last 12.

10.4. Performance Surveillance and Advisory Panel Liaison

The Scheme Organiser highlights out-of-consensus performance in the routine report by the use of scores, symbols, graphs, banners and 'traffic lights'. The fact of Birmingham Quality providing participants with a red banner or red traffic light constitutes a formal communication from Birmingham Quality of out of consensus performance, and separate communication about this performance problem may not be sent.

It is the responsibility of the Participant to act on, investigate and resolve all out-of-consensus performance. If there is a red banner for any analyte on the Performance Summary Icon (PSI) page, then this should be logged in their Quality Management System. For any red B or C score traffic light, participants are expected to both acknowledge and fix the problems as part of their routine Quality Management System.

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Birmingham Quality is here to help. If participants are unsure as to why they have out-of-consensus problems or if they are having difficulties with their Root Cause Analysis, then they should contact us.

Birmingham Quality in addition to some other EQA providers has agreed to participate in an oversight structure from its inception where Birmingham Quality is required to report to the NQAAP for Chemical Pathology, Microbiology and Haematology. It is important to note that this process is not mandatory for EQA providers, but Birmingham Quality feel that this is an important part of our governance structure. Laboratories who are persistently having unacceptable performance (UK clinical services only) are reported to the NQAAPs. Initially Birmingham Quality will make contact with the participant inviting them to discuss action to correct the poor performance. If a satisfactory response is made and improvement in performance ensues, no further action is taken. If poor performance persists or no response is made, then a Panel letter (direct from Panel Chairman to Head of Department with lab identity and UK NEQAS lab code disclosed) is written requesting that decisive action is taken to re-establish satisfactory performance; this may include a site visit by Panel members. If this fails, the Quality Assurance in Pathology Committee may take further action.

Where poor performance is purely method-related (e.g. all users have a large positive or negative bias), Organisers will normally work directly with manufacturers to assist with correction of any problem; analogous procedures are in place for apparently IVD-related problems (see QAPC guidelines).

If the respective NQAAP cannot resolve either laboratory or manufacturer issues then there is an escalation process to the QAPC.

Birmingham Quality is also able to escalate manufacturer issues to the MHRA via the yellow card route.

Birmingham Quality has taken the decision to keep all participants informed of assays that are included within an escalation plan. This information can be found under the Centre Button on the Results & Reports webpage.

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11. Exploratory Exercises

11.1. Recovery Experiments

These are undertaken either as a continuous part of the scheme design or as regular 'one-off' exercises (eg steroid hormones). Generally, a low endogenous analyte (or stripped) basal pool is prepared, which is then divided into the same number of portions as there are samples in a distribution. To these (except the basal portion), linearly related amounts of pure analyte in a suitable solvent are added and the resultant solution stirred to ensure complete mixing. Aliquots of these pools are then included in a single distribution.

Data processing is conducted in two different ways according to the scheme involved. Some (eg Thyroid hormones) analyse the individual recoveries for each addition, whilst others (eg Steroid hormones) use linear regression (analyte concentration observed vs amount of analyte added) to derive an overall indication of fractional recovery across the concentration range (= regression slope). The resultant data and Organiser's comments are made available to participants as a separate report (examples available on request).

11.2. Reference Method Exercises

Isotope-Dilution Gas Chromatography Mass Spectrometry (IDMS) is the reference method for a number of analytes in Clinical Chemistry (Stöckl et al 1996)³. It can be used to provide a highly accurate target value, independent of 'EQAS effects' caused by the proportions of different methods contributing to the ALTM or method mean. Such target values enable scheme data (especially method-related results) to be directly linked to an accuracy base of reference methods and materials, which enable routine methods to be probed for calibration errors and specificity problems.

In the past, exercises have been limited to cortisol, progesterone, oestradiol and testosterone in the steroid schemes, but have been extended to other analytes and schemes including total thyroxine in the thyroid scheme and creatinine in the eGFR scheme. Two approaches are taken, either to target a small range of pools, or to target all pools in a performance scoring period, and re-process the scheme scoring data using the GCMS target value instead of the ALTM. Copies of reports will be made available to participants shortly after the exercise has been completed.

11.3. Linearity Exercises

These are performed from time to time and usually involve mixing of high and low concentration pools in different proportions so as to obtain pools with linearly related concentrations in the same matrix. Sometimes materials may be physically manipulated to achieve concentrations outside normal ranges.

11.4. Interpretative Exercises

From time to time, Birmingham Quality will invite participants to complete questionnaires about their service, and include distributions of matched samples with a clinical question, which is used to assess how participants interpret results in clinical practice. An example of this is an exercise for alpha-1-antitrypsin (A₁AT). Participants were first surveyed to establish whether they offered the assay for adults and/or children, and to obtain details of reference ranges and analytical imprecision. A distribution was then made of a normal A₁AT sample and one designed to mimic a homozygous deficiency state. Participants were asked to give an interpretation of the results and recommendations for further investigations. The results were collated and a report published through the schemes.

The web-based **UK NEQAS for Interpretative Comments** is a primarily educational service which assesses the appropriateness of comments added to results by individuals.

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12. Feedback from Service Users

12.1. Feedback

Birmingham Quality welcomes feedback both positive and negative. We are also open to suggestions for improvement and all feedback is recorded within our Quality Management System. You can contact us by any method detailed in the Communications Section (Section 1.7)

12.2. Complaints – Definition

Birmingham Quality has a Feedback from Service Users policy and procedure which details how Complaints are managed. This is available upon request.

A complaint is considered to be any communication, written or verbal, from internal or external sources indicating deficiencies relating to the identity, quality, durability, reliability, safety, effectiveness or performance of the EQA service. Formal complaints and other communications which point out deficiencies, difficulties or problems (which are classified by Birmingham Quality as errors) are recorded together with any response or action taken by us. These are audited by the Quality Manager.

12.3. Types of Complaint and How to make a Complaint

Most problems experienced by participants consist of minor misunderstandings or problems with specimens and reports, which can usually be resolved over the telephone by any member of staff. If difficulties persist, then participants with continued justified cause for complaint about any aspect of the service should communicate their concerns immediately to the relevant member of senior staff, preferably in writing (email or letter) though a preliminary telephone call may assist in clarifying the issue and establishing the requisite action.

- Where the complaint is about **scheme logistics**, then the **Quality Manager** is the appropriate point of first contact.
- Where the matter is related to **performance assessment** and **scheme design**, the relevant **Scheme Organiser** is more appropriate.
- If the complaint concerns the **conduct of a member of UK NEQAS staff**, or a **satisfactory response has not been received** from the individual first contacted, then the **Director** should be contacted.
- Birmingham Quality will acknowledge receipt of your complaint (within two working days), perform preliminary investigation to determine if it relates to Birmingham Quality activities and if substantiated will be fully investigated through to resolution. The outcome of your complaint and notice for the end of the complaint handling process will be communicated to you. Birmingham Quality will use Q-Pulse to ensure that your complaint is appropriately recorded, managed through to completion with appropriate action(s) taken for resolution.
- Timescale for resolution is variable based on the nature of the complaint received and scale of the investigation required.
- If matters remain unresolved, or the action taken by us is not satisfactory to the complainant, the next step is to refer the complaint to the Chairman of the appropriate **Specialist Advisory Group** where it relates to scheme design, or the main **UK NEQAS Steering Committee for Clinical Chemistry** where it is a more general policy matter.
- If the issue concerns **performance assessment**, the **Chairman of the Advisory Panel** may also be contacted.
- Where lack of compliance with **ISO/IEC 17043 Standards** is suspected by the complainant, then in the first instance contact the Quality Team at Birmingham Quality using one of the contact options

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<https://birminghamquality.org.uk/contact-us>. If the complaint is not resolved to the satisfaction of the complainant then UKAS may be contacted via customerfeedback@ukas.com, quoting the Birmingham Quality UKAS Customer Number, 7860.

- Similarly, where the **UK NEQAS Code of Practice** itself is the issue of concern, the **President of UK NEQAS** may be appropriate.
- In all cases, Birmingham Quality staff will provide the names and contact details of the appropriate individuals.

12.4. Appeals Against the Evaluation of Your Performance

Birmingham Quality has a Feedback from Service Users policy which details how Appeals are managed. This is available upon request.

If you wish to appeal against the evaluation of your performance, please contact us via any of the routes described at <https://birminghamquality.org.uk/contact-us>

Your appeal will be handled according to our Feedback from Service Users procedure.

- Birmingham Quality will acknowledge receipt of your appeal (within two working days), an investigation will take place to ascertain your appeal is valid, with Q-Pulse used to ensure your appeal is recorded, tracked and managed with action taken for resolution.
- The outcome of your appeal (upheld/not upheld) will be communicated to you.
- Timescale for resolution is variable based on the nature of the appeal received and scale of the investigation required.

With regards to appeals against the evaluation of your performance, the Directors decision is final.

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13. NPEx

13.1. Overview

Birmingham Quality now routinely makes requests and receives results for their UK NEQAS Services using X-Lab's lab-to-lab communications vehicle, the National Pathology Exchange (NPEx).

This new, innovative approach simplifies the booking-in and reporting elements of the EQA process.

The process itself is simple and intuitive but relies on sophisticated message handling and encryption by Birmingham Quality which feeds into the established NPEx model.

By semi-automating critical stages within the process, significant savings in staff time can be made and the potential for manual transcription errors is removed.

Electronic results via NPEx will automatically populate the existing UK NEQAS Online Results service that participants are familiar with.

Currently, electronic reporting is restricted to quantitative results.

The majority of Birmingham Quality schemes are now active for NPEx participation.

13.2. Registering Interest

In the first instance please contact enquiries@x-labsystems.co.uk and request an information pack regarding the Birmingham Quality UK NEQAS collaborative project.

Birmingham Quality will then guide you through a testing phase until you are ready to proceed to live electronic resulting.

13.3. Results Documents — how they are different

NPEx users will receive modified result documents where the result boxes have been replaced by unique sample barcodes which will match the NPEx requests made by Birmingham Quality.

In addition, there is a reserved space on the result document to apply a local laboratory barcode sticker for each specimen to cross reference NPEx and LIMS.



13.4. Sample Handling — what is different

Participants will already be familiar with the NPEx process of booking in samples from referring laboratories.

Birmingham Quality mimic a referring laboratory but provide custom barcode manifests (our result documents) for booking in EQA samples instead of the usual NPEx generated one.

Since all the specimens are pre-requested on NPEx the overhead of manually booking-in EQA specimens is greatly reduced.

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13.5. Results Reporting Procedure — what is different

The primary difference, and one of the biggest benefits, is that results are automatically transmitted via NPEx back to the participants UK NEQAS Online Results account.

Participants still retain any local control over whether results are checked before release.

13.6. Amendments Prior to Data Processing

Amended results can still be sent via NPEx up to the closing date of the distribution.

The full functionality of the UK NEQAS Online Results and Reports service remains available to participants to view and edit results as before, including manual entry of late and amended results.

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14. Footnotes

14.1. Feedback

This Manual has been made as comprehensive as possible, but it is appreciated that revision may be required to reflect progress. Participants are invited to make comments and suggestions, not only on the Manual but any aspect of our schemes or procedures, so that amendments may be made for the next edition. Please contact Birmingham Quality with your comments and suggestions here: <https://birminghamquality.org.uk/contact-us>

14.2. Acknowledgements

The continued loyalty of all participants, which has enabled Birmingham Quality to develop and expand to meet the challenges of the new EQA environment, is acknowledged.

The careful work of Birmingham Quality staff, the support of colleagues at other UK NEQAS centres and advice from members of expert committees and professional bodies are acknowledged.

Birmingham Quality is grateful to our host the University Hospitals Birmingham NHS Foundation Trust and the support that they provide.

14.3. Further Copies of This Manual

This document is the current definitive version of the Participants Manual and may be downloaded or printed by Birmingham Quality Scheme participants for their personal use.

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