UK NEQAS
Haematology and Transfusion

UK NEQAS Blood Transfusion Laboratory Practice (BTLP) Schemes

Point of Care RhD typing

PARTICIPANTS' MANUAL

Version 6, Issued December 2021

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GENERAL ORGANISATION AND OVERSIGHT OF UK NEQAS BTLP

Location

UK NEQAS BTLP is hosted by the West Hertfordshire Hospitals NHS Trust and is based at Croxley Business Park in Watford, in a Unit shared with UK NEQAS Haematology

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Key scheme personnel

Director: Richard Haggas
Operational Manager: Katy Veale
EQA Scientists: Arnold Mavurayi, Claire Whitham, Dipika Shah
Office Manager: May Wadhia
Executive Assistant: Isabella De-Rosa
IT Manager: Vasilis Rapanakis
Deputy Office Manager and Logistics Coordinator: Lisa Watkins-Price

Other clerical and logistics support staff are employed jointly with UK NEQAS Haematology. This maximises the cost effective use of staff in common areas such as administration, packing and dispatch.

The Quality Manager for the UK NEQAS Unit is Claire Whitham.

UK NEQAS Charity

All UK NEQAS designated schemes are members of the UK NEQAS Consortium – a not-for-profit company limited by guarantee and a UK Registered Charity. This organisation, served by its elected Executive Committee and the UK NEQAS Office, fulfils central co-ordinating and administrative functions.

Each Scheme maintains its designation as a UK NEQAS Scheme through its compliance with the UK NEQAS Codes of Practice. These are available from the UK NEQAS main website: www.ukneqas.org.uk.

Steering committee

The Schemes are advised by the BTLP Steering Committee. The Committee comprises scientific and clinical members and the membership is ratified by the UK NEQAS Board of Trustees. The Chair is independent of UK NEQAS operational issues, and is currently Dr Peter Baker, Blood Transfusion Laboratory Manager, Royal Liverpool University Hospital, L7 8XP.

Quality Assurance in Pathology Committee and National Quality Assurance Advisory Panels (NQAAP)

Oversight of performance in EQA within the UK is the professional responsibility of The Quality Assurance in Pathology Committee (formerly the Joint Working Group in Quality Assurance), a committee of the Royal College of Pathologists (RCPath). The committee has established National Quality Assurance Advisory Panels (NQAAPs) for specific disciplines to monitor the performance of UK laboratories providing a direct or indirect clinical service and to offer advice to any laboratory with unresolved persistent unsatisfactory performance (PUP). Membership consists of the Chairs of the NQAAPs, and representatives from the Institute of Biomedical Sciences, the National Screening Committee and the UK Accreditation Service (UKAS). The QAPC works with laboratories with unresolved persistent unsatisfactory performance but is also bound to report this to the Care Quality Commission. The QAPC has defined Conditions of EQA Scheme Participation, which can be found on the RCPath website https://www.ukneqasbtlp.org/external_links. The chair of the QAPC is Dr Berenice Lopez.

UK NEQAS BTLP makes an annual report on scheme activities and performance of UK laboratories to the NQAAP for Haematology, and makes quarterly reports of persistent unsatisfactory performance (PUP) to the Chair of the Panel, using defined criteria which have been approved by the Panel. The Chair of the Haematology NQAAP is Dr Keith Gomez.

Confidentiality

Details of performance in the Scheme are confidential between the participating organisation and the Scheme Director (and designated senior UK NEQAS staff). However, persistent unsatisfactory performance is reported to the NQAAP.

As a part of our host NHS Trust, UK NEQAS BTLP is subject to Freedom of Information Act regulations.

Accreditation

West Hertfordshire Hospitals NHS Trust, operating UK NEQAS Haematology and Transfusion, is a UKAS accredited proficiency testing provider, (No 7805) (BS EN ISO/IEC 17043 2010). A copy of the UKAS Accreditation Schedule is available to download here.

Data security

The purpose of the Data Protection Act 2018 (the Act) is to prevent the misuse of personal data held electronically and to ensure that organisations holding such data conform to a required standard. West Hertfordshire Hospitals NHS Trust, the host organisation for UK NEQAS BTLP, is registered as a Data Controller under the Act. The contact details provided by participants at registration are held securely in a database in order to identify those participants registered for a given activity and to generate address labels for the dispatch of material or reports. In addition, the survey results are held securely (as non-personal data) in the database for analysis, performance assessment and report production. At the time of publication, all participant contact details are retained for the lifetime of the EQA database; however, email and postal addresses will not be used for contacts that are no longer 'active'.

The Scheme will keep performance analysis data for a minimum of eight years; however, responsibility for maintaining historical records of individual performance lies with the participating laboratory. RCPath guidance suggest that participating laboratories retain EQA

records for a minimum of eight years, to ensure continuity of data available for laboratory accreditation purposes over two inspection cycles and equivalence with performance records for the equipment used. All participants are entitled to view their personal computer records on request.

E-mail addresses supplied by participants are used for contacting participants to inform them of survey distribution and report availability. In addition, these details are used to provide information on meetings and other activities, and to invite participation in on-line surveys specifically relevant to the scheme. Email addresses may also be used for contacting participants on national pathology or blood transfusion related matters if consent is given at registration or re-registration.

Helpline

- Advice on any aspect of the scheme or other related matters on performance may be sought from the Scheme Director or Operational Manager by telephone or in writing.
- Problems or enquiries relating to a specific exercise or exercise material may be directed to one of the senior scheme staff.
- Invoicing or registration enquiries may be directed to the Office Manager.

Names and contact numbers can be found on page 1.

Complaints

We encourage participants to contact senior staff to discuss queries and to offer suggestions for improvement. However, if you are unhappy with the service and wish to make a complaint, this should be directed, preferably in writing (by letter or email), to the Scheme Director or the Operational Manager as appropriate to the nature of the complaint. Complaints relating to samples or packing issues should be accompanied by photographic evidence where possible, as this will help with investigation. All written complaints will receive an acknowledgement within one week of receipt and a full written response within four weeks of receipt. Any unresolved complaints can be directed to the Chair of the Steering Committee, the UK NEQAS President, the Chair of the NQAAP for (Haematology) or the Chair of the Quality Assurance in Pathology Committee (links to appropriate page of the UK NEQAS and RCPath websites are available on the ' external links' section of the Scheme website – http://www.ukneqasbtlp.org).

- Chair of steering Committee: https://www.ukneqasbtlp.org/btlpsteeringcommittee
- UK NEQAS President: https://www.ukneqasbtlp.org/external_links
- Chair of NQAAP: https://www.ukneqasbtlp.org/external_links
- Chair of QAPC: https://www.ukneqasbtlp.org/external_links

Appeals

Appeals relating to performance issues should be made in the first instance to the Scheme Director or Operational Manager, and will be dealt with in the same way as complaints. In the event that the appeal is unresolved, it should be escalated to the Chair of the Steering Committee or the Chair of the National Quality Assurance Advisory Panel. The International Blood Group Reference Laboratory acts as an independent arbiter for any additional blood group serology investigations required on EQA material.

AIMS OF AND PARTICIPATION IN THE SCHEME

The aims of UK NEQAS are primarily educational. Provision of identical samples to all participating centres allows inter-centre comparison and also identifies the overall level of performance within the UK. Corrective action taken as a result of unsatisfactory performance can lead to an improvement in proficiency within an individual centre. Learning from others through reports of exercises, leads to an improvement within the UK as a whole. By linking results with techniques and procedures, specific strengths and weaknesses can be identified, driving change. National guidelines are reinforced and the need for new guidelines identified.

RhD typing results assessed in this Scheme are qualitative and target results are not assigned as the result of statistical analysis. These results are analysed on the basis of whether they agree with the 'true' result based on testing in-house and by the supplier of the material.

EQA is primarily intended to identify problems with systems, techniques, processes and procedures, and forms an essential part of quality assurance, providing objective evidence of individual centre performance. However, it gives only a snapshot of a centre's performance at any given time and the information reported back is inevitably a retrospective view. It should be undertaken in addition to, not in place of, other quality assurance measures, including use of internal controls, training and assessment of competence.

Scope and frequency of tests offered

There are four exercises per year for RhD typing. Exercises are given a 5-digit code derived from the last two digits of the year, followed by R, a number, and a B; e.g. 21R8B. The samples sent do not have the B suffix.

The participating organisation receives a schedule of the exercise despatch dates at registration or annual re-registration. The schedule is also published on the UK NEQAS website. Any significant changes to the schedule are highlighted on the website and participants informed by email. UK NEQAS aims to dispatch all exercises on schedule; if the exercise material has not been received within three days after the published distribution date, please phone the Scheme for advice. https://www.ukneqash.org/schedule

Participant Reference Number (PRN)

At registration, each participating centre is assigned a PRN that is used on performance reports and for internal data handling, in order to preserve confidentiality. This number is unique to each participating centre.

It is essential that the PRN be correctly quoted with all communications, including telephone enquiries.

New registrations and amendments to existing registrations

Once authorised by the POCT organisation, details of new registrations or amendments to the details of existing participants are forwarded to UK NEQAS using the standard form provided.

The form is returned to the organisation by UK NEQAS confirming that the request has been authorised and implemented, and in the case of new registrations the completed form includes the PRN and other login details required for result submission.

Forms for new registrations and registration amendments are available from the UK NEQAS (BTLP) Office Manager.

Source of exercise material

'Patient' whole blood samples are derived from a pool of four or more donations which may be whole blood or red cells to which ABO compatible fresh frozen plasma and Alsever's has been added. The reported quality rate for each sample is expected to be >95% satisfactory.

All materials are tested at source for HBsAg, HIV 1, HIV 2, HCV and for HTLV antibodies, and found to be negative. However, such testing does not ensure that exercise materials are free from infectious agents and a COSHH (Control of Substances Hazardous to Health) information sheet is included with each exercise. The containers and contents must be handled and discarded in line with routine policy for potentially infectious material.

Dispatch of exercise material

Exercise materials are despatched within the UK by first class mail, addressed to the main contact.

All packaging complies with current IATA regulations. The nature of the contents of the package ('Exempt human specimens'), the temperature of storage on receipt, and the address of the sender are indicated on the package.

Exercise format

There are currently four exercises per year, each comprising three 'patient' whole blood samples for RhD typing. The samples are identified with the exercise code (excluding the final 'B') and the patient identifier: *20R8 Patient 1, 20R8 Patient 2* or *20R8 Patient 3.*

Undertaking the exercise

The EQA samples should be handled, as far as possible, in the same way as routine clinical samples, so that the exercise is representative of routine performance, as highlighted in the following examples:

- There should be no collusion with other centres.
- The most expert member of staff should not always perform the exercise, unless no other staff are available.
- There should be no collaboration between different staff members unless the results indicate that this would be the case with a similar clinical sample.
- All testing undertaken on the EQA samples should be performed using the same processes used for clinical samples, and all the same checks made before reporting results.

Spare material may be used to test the competency of additional staff members, but only **after** the results have been submitted. Some spare material should also be kept until the report is received in case repeat testing is necessary. If further material is required before results can be submitted, e.g. in the case of a broken sample, this is available on request from UK NEQAS.

COMPLETION AND SUBMISSION OF RESULTS

Web-entry

On registration for web-entry, an ID code and password are supplied by e-mail. Instructions for completion of the web-forms and accessing report on the web can be found online here, or on the Documents/Surveys page of the website. https://www.ukneqash.org/documents/2. Results can be partially entered and saved at any time before the closing date.

Faxed, emailed or posted copies of results are only acceptable in exceptional circumstances, and must be discussed first with a member of the Scheme staff. All web results are collected automatically as part of the closing of data entry on the web, including those 'saved' but not 'submitted'. The latter will be analysed and reported as if they had been submitted by the participant.

Reaction grades

These are not used for penalty scoring, but can provide useful statistical information, and they form the basis of the result interpretation. Participants are asked to grade positive serological reactions as weak or strong positive.

Interpretation

All penalty scoring is based on the **interpretation** of the results as entered on the data entry screen, and completion of this section is mandatory. Participants are telephoned for missing data, which must be supplied in writing (usually by email). Verbal results are not accepted since the Scheme requires a clear audit trail of any edits to results.

Late results

Results are not accepted after the closing date, except in exceptional circumstances. If there are extenuating circumstances leading to non-submission of results, these will be considered by the scheme on a case by case basis.

DEFINITION OF ERRORS AND PENALTY SCORING

Target values

Blood group serology results are categorical data and the target value is the 'true' value as determined by the Supplier (NHSBT Reagents Unit) and the UK NEQAS laboratory. Material is only distributed following pre-acceptance testing within the UK NEQAS laboratory. Testing is also completed in-house, at intervals up to the closing date, on exercise material that has been subjected to the postal system.

Assessment

Participants are scored on their interpretations and for return of results. Penalty scores are based on comparison of individual results to the correct results; however, there is an element of consensus, in that penalties are reduced where <80% of participants record the correct result.

Penalty scores

1.) For each incorrect RhD typing:

- where at least 80% of participants obtain the expected result - **SCORE = 100**
- where 50% - 79% of participants obtain the expected result - **SCORE = 50**

NB: a result of UI (unable to interpret) will incur a penalty (50 points) unless this is an expected result for that sample.

2.) For each non-return of results for an exercise - **SCORE = 50**

The score in each area (i.e. RhD typing and non-return) is summed over 3 exercises into a Cumulative Score.

The Cumulative Score for each area of assessment ranges from 0 to 150. For each component of the exercise, any total of greater than 150, is set to 150.

Non-technical errors

Discrepant results due to obvious transposition or transcription errors are analysed as received and are included in the initial overall analysis of performance. These frequently reflect errors that occur in clinical practice, leading to incorrect clinical decisions, and are therefore considered to be equally important as serological or interpretation errors.

If a participant incurs an error through a fault in the operation of the scheme, for example through the provision of an incorrect specimen, this will be corrected. Erroneous results arising from participants' actions remain as received for the assessment of performance, e.g. contamination of specimen by the participant, analysis of incorrect specimen, or results incorrectly communicated to UK NEQAS BTLP.

REPORTS

Each participant receives an individual, confidential report detailing any errors in the current exercise, cumulative errors, and overall cumulative performance. It also includes a summary of overall results for the appropriate peer group. Reports will be released within 9 working days of the closing date. An example report can be found here.

A summary of results is provided by email to the regional managers after each exercise, including non return of results and details of any errors incurred.

PERFORMANCE MONITORING

Definitions of performance:

A cumulative score of:

< 100 - indicates satisfactory performance

100 - 150 - indicates unsatisfactory performance

Actions to be taken by participants

Any errors should be investigated in line with local policy, and appropriate action taken to prevent recurrence.

Actions taken by UK NEQAS for UK participants

Senior Scheme personnel may contact participants with errors. The problems are discussed with the participating centre, with a view to gaining an understanding of the source of the error. Repeat samples and advice are offered, and details of all calls are kept in a confidential log and/or electronically in the database. Outcomes may be detailed and commented upon anonymously in the report.

Unsatisfactory performers may be contacted in writing by the UK NEQAS Scheme Director, with letters copied to the Organisation's Medical Director or relevant regional manager, they will be sent prior to the next exercise closing.