UK NEQAS Blood Transfusion Laboratory Practice (BTLP) Schemes

Pre-Transfusion Testing (PTT)
Fetomaternal Haemorrhage (FMH)
ABO Titration (ABOT)
Direct Antiglobulin Test (DAT)
Red Cell Genotyping (RCG)
Pilot schemes
TACT

PARTICIPANTS' MANUAL

Version 18, Issued December 2021

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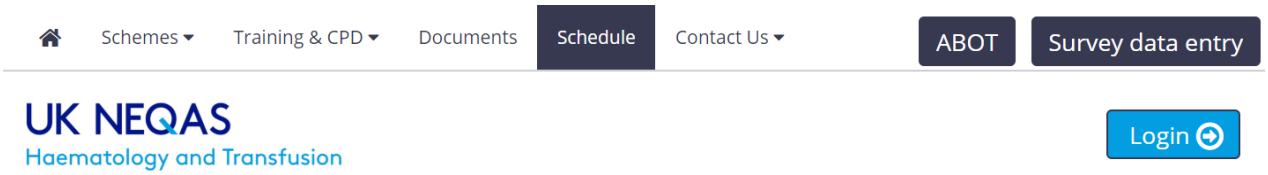
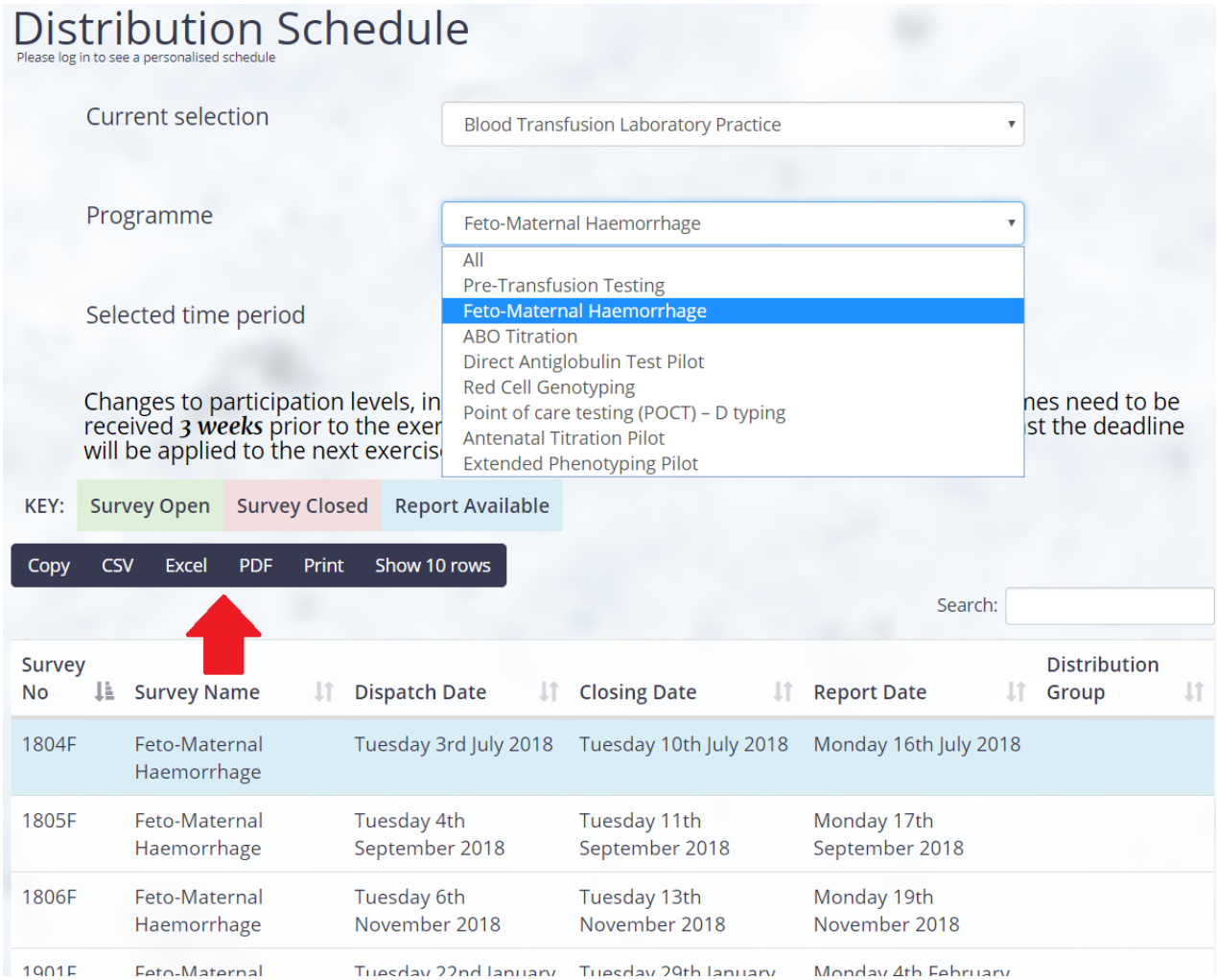
FREQUENTLY ASKED QUESTIONS

Q: How do I know when to expect the exercise material?
A: You should have received an annual schedule at registration or re-registration. A schedule can also be found on the UK NEQAS Haematology and Transfusion website.

1. Go to https://www.ukneqasbtlp.org
2. Click on the 'Schedule' tab



3. Select Blood Transfusion Laboratory Practice, the programme required, e.g. FMH, and the time period required (annual schedule or 'latest distributions'), and the schedule will be displayed as below



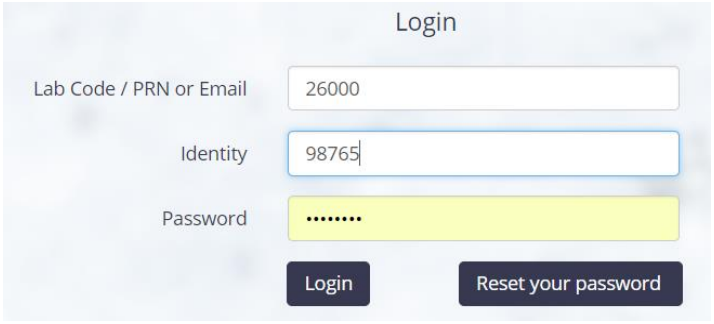
Q: What do I do if my specimens don't arrive when expected?
A: If they haven't arrived by three days after the published distribution date (4 days for non-UK participants), you should phone the Scheme for advice.

Q: What do I do if I miss the closing date?
A: Results for the Pre-Transfusion Testing and FMH Schemes are not routinely accepted after the closing date. Please contact the scheme if you would like to discuss non-submission of results.

Q: What do I do if the sample quality is unsatisfactory or if I break the samples?
A: Phone the Scheme on 01923 587 111 to request a repeat sample. You will be asked for your PRN and the reason for your request. Samples that are found to be unsuitable for analysis should be kept pending contact with the scheme, as we may request photographs or return of the samples to assist our investigation into the cause.

Q: What do I do if I've forgotten my password?
A: You can request a password re-set on-line

1. Go to www.ukneqasbtlp.org
2. Click on 'login'
3. Enter your Lab Code / PRN or email and your Identity in the text boxes provided then click on the "Reset your password" button.



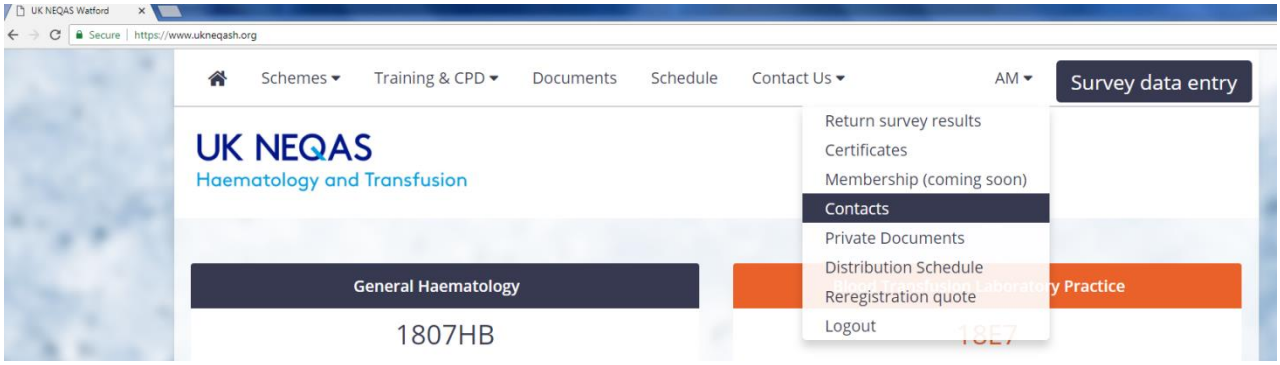
You should now be presented with message stating your password reset link has been sent successfully.

You should receive an email within a few minutes. If you have not received the password reset email please check your junk mail folder.

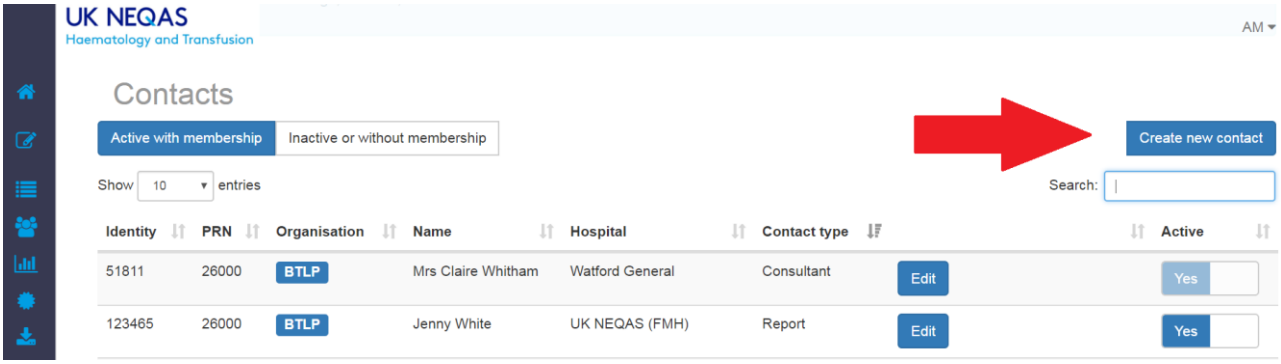
Q: Why has the login that the laboratory has been using stopped working?
A: To give increased security to users, each identity and password belongs to a named contact and not to an institution. It may be that the login that the laboratory is using belongs to an individual that is no longer listed as a UK NEQAS contact. When a contact is no longer registered with us, their login is inactivated.

Q: Can I create and edit contact details for my laboratory?
A: All contacts can edit their own information and change their own passwords on-line, and main contacts can also create, remove and edit contact details:

1. Login to www.ukneqasbtlp.org
2. Located on the top on the website should be your initials. With your mouse hover over this to reveal a drop down menu, then select "contacts"



3. You should now see a list of contacts with their names and contact types.



Q: My laboratory has two blood group analysers – can I register both for EQA?
A: Given that there is only one correct result for each test, we recommend that laboratories do not have two separate registrations. We recommend that you subject one analyser to EQA and use daily IQC to assure that both are giving the same results. Alternatively, where the two analysers employ different processes, the EQA exercises can be alternated between the two, or half the samples tested on the first analyser and the other half on the second. The same approach can be used to incorporate manual testing into your EQA schedule.

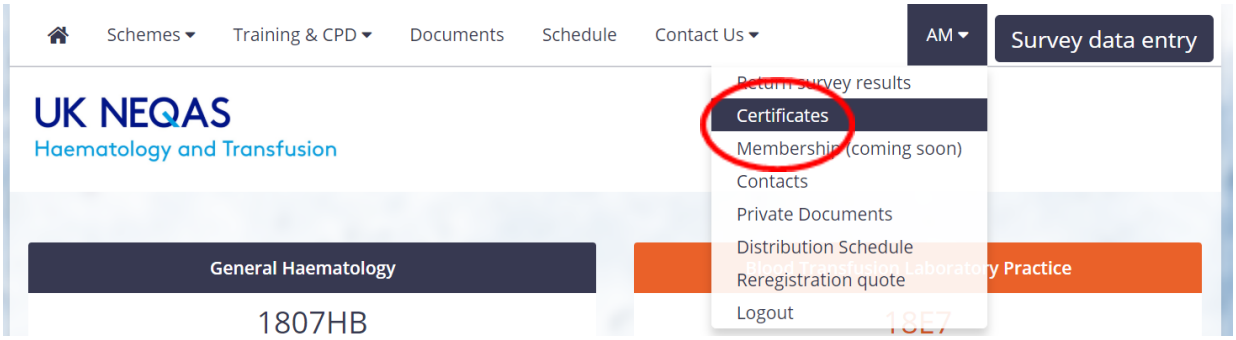
Q: When I make a UI submission, why is there no box for anti-Kp^a, anti-Lu^a or anti-C^w or in the '*specificities that cannot be excluded*' section that appears for antibody identification?
A: Once antibodies have been positively identified and all reactions accounted for, there is no requirement to go through a process of exclusion for antibodies to antigens of low frequency and/or of low clinical significance, with either EQA or clinical samples, so they are not listed as specificities in the *'specificities that cannot be excluded'* section. E.g. if the Jk^b antigen masks Lu^a on the panel, additional cells and techniques do not need to be used to exclude anti-Lu^a in the presence of anti-Jk^b, and so long as the antibody identification is otherwise complete a UI submission is not required in this situation.

Q: Why do I not have a web data entry field for red cell phenotyping?
A: Your laboratory is not registered for phenotyping and you should contact the Scheme by email to request a change in registration.

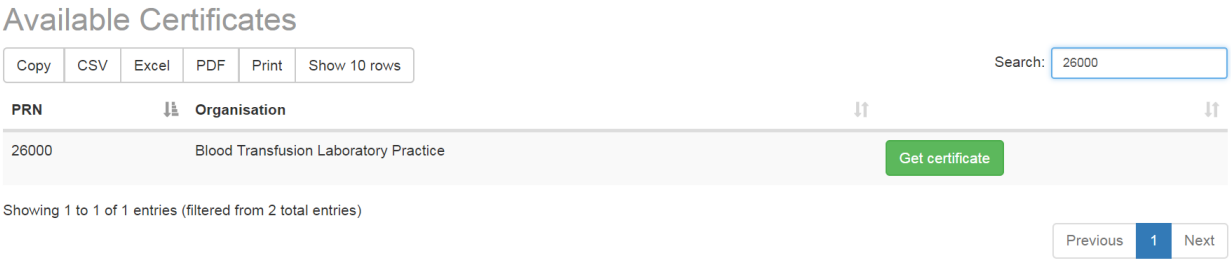
Q: Why does the graph show a penalty score when I did not make any errors in the PTT exercise?
A: Error scores cumulate over three consecutive exercises and the graphs display penalty scores for both the current exercise (shown by the open circle) and cumulative performance (closed circle).

Q: Can I produce a certificate of registration in the BTLP Schemes?
A: Yes, registration certificates are available on-line for the main BTLP Pre-transfusion Testing and FMH Schemes. These currently demonstrate registration but not participation or performance:

1. Login to www.ukneqasbtlp.org
2. On the top hand right corner find the drop down menu with your initials next to it



3. Click on the initials and choose certificates.
4. On the next screen you will see a number of certificates available to you depending on which PRNs and organisations you are a registered contact for.
5. Click the Get certificate button on the relevant PRN and organisation. A PDF file will be downloaded to your computer. You can use the Search box find a particular certificate.



Q: Do I need to let UK NEQAS BTLP know if I change technology, kits or reagents?
A: No, as we collect the information required at data entry for each BTLP exercise.

THE UK NEQAS CHARITY

UK NEQAS facilitates optimal patient care by providing a comprehensive external quality assessment service in laboratory medicine. Through education and the promotion of best practice, it helps ensure that the results of investigations are reliable and comparable wherever they are produced.

The UK NEQAS charity is led by an elected President and an Executive Board of Trustees, with representation from UK NEQAS Schemes in the main disciplines of laboratory medicine. The Board of Trustees is served by the UK NEQAS charity office, located at the Northern General Hospital in Sheffield, which administers central UK NEQAS affairs.

UK NEQAS Charity Central Office

President: Mr Liam Whitby

Company Secretary: Mrs Julie Gelder

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UK NEQAS Blood Transfusion Laboratory Practice (BTLP) is a member of the UK NEQAS charity and operates in accordance with the UK NEQAS Codes of Practice (available from the UK NEQAS charity website, www.ukneqas.org.uk).

Further details of all other UK NEQAS services can be obtained from the UK NEQAS charity office.

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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Telephone: +44 (0) 1923 587 111
Fax: +44 (0) 1923 397397
Email: btlp@ukneqas.org.uk
Website: www.ukneqasbtlp.org

Scheme Personnel

Director: Richard Haggas
Operational Manager: Katy Veale
Senior EQA Scientist and TACT lead: Claire Whitham
Senior EQA Scientist: Dipika Shah
EQA Scientist: Arnold Mavurayi
Business Manager: Nazia Hussain
Office Manager: May Wadhia
Executive Assistant: Isabella De-Rosa
IT Manager: Vasilis Rapanakis
Logistics Coordinator and Deputy Office Manager: Lisa Watkins-Price

Other administration 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.

Steering Committee

The Schemes are advised by the UK NEQAS BTLP Steering Committee. The Committee comprises scientific and clinical members and the Chair 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. Current membership of the BTLP Steering Committee and Scientific Advisory Groups (SAGs) is available at https://www.ukneqasbtlp.org/btlpsteeringcommittee.

Quality Assurance in Pathology Committee (QAPC) 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 (QAPC), a committee of the Royal College of Pathologists (RCPath). The QAPC 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 Quality Assurance in Pathology Committee 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

Registration information, raw data and performance details are confidential between the individual participant, the Scheme Director and designated UK NEQAS staff. The identity, performance details (and some relevant raw data) of any UK participant may be shared with the NQAAP as part of the reporting of persistent unsatisfactory performance. Performance data may be shared with local management, regional QA officers, regulatory and accrediting bodies and suppliers of equipment and reagents, where appropriate and necessary, but only with written permission from the participant. The identity of a UK laboratory providing direct or indirect clinical services will be disclosed to the chair of the Haematology NQAAP and, at the Chair's discretion, to the Quality Assurance in Pathology and the UK Accreditation Service, in the event of the laboratory being reported to the NQAAP for unresolved persistent unsatisfactory performance.

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

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.

Intellectual Property

Reports are subject to copyright and may not be distributed, published or used for publicity in any form without the written consent of the Scheme Director or Operational Manager on each and every occasion, though the participant may share their performance data with individual clients (e.g. clinicians) without consultation.

Accreditation

The UK NEQAS BTLP schemes for PTT and FMH held unconditional accreditation with CPA (EQA) from 1999 until February 2016, and have been accredited to ISO Standards: 17043:2010, Conformity assessment – General requirements for proficiency testing, by UKAS, since February 2016. The DAT Scheme was accredited to ISO17043 during 2020 as an extension to scope. Pilot schemes are not accredited.

UK NEQAS Haematology and Transfusion operated by West Herts Hospitals NHS Trust is a UKAS accredited proficiency testing provider No. 7805.

Helpline

- Advice on any aspect of the BTLP Schemes or pilots may be sought from the Scheme Director or Operational Manager by telephone or in writing (by letter or email).
- Problems or enquiries relating to a specific exercise or exercise material may be directed to one of the senior scientific staff.
- Invoicing or registration enquiries may be directed to the Office Manager.

The Unit is officially open from 09.00 and 17.00, Monday to Friday. Telephone calls made outside of these times may be answered but cannot be guaranteed. Names and contact numbers can be found on page 6.

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 QAPC (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

Complaints are reviewed at regular staff meetings and an annual audit is presented to the Senior Management Group as part of the Annual Management Review, and to the Steering Committee.

Appeals

Appeals relating to performance issues should be made in the first instance to the Operational Manager or Director, 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, or any disagreements relating to UI submissions for antibody identification.

AIMS OF UK NEQAS EQA SCHEMES

The aims of all UK NEQAS Schemes are primarily educational. Provision of identical samples to all participating laboratories allows inter-laboratory 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 laboratory. 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.

EQA forms an essential part of quality assurance within a laboratory and provides evidence of individual laboratory performance. However, it gives only a snapshot of a laboratory'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.

Whilst ABO titration and FMH results are quantitative, the blood group serology results assessed in the PTT 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 although the technical and interpretative skills of the person performing the test inevitably influence the results submitted (at least where testing is manual or only partially automated), EQA does not replace the need for continued operator competency assessment.

Participation in an appropriate, accredited EQA Scheme is a requirement of accreditation to ISO15189.

SERVICES PROVIDED

UK NEQAS BTLP currently provides the services outlined below. Samples are provided as part of the services and are not available for purchase individually.

ISO17043 accredited EQA schemes

- Pre-transfusion testing (PTT) – formerly known as BTLP
- Feto-Maternal Haemorrhage (FMH)
- ABO titration (ABOT)
- Direct Antiglobulin Testing (DAT)

Full details of these schemes can be found on pages 15-41.

Pilot schemes

Before a scheme is recognised as a full UK NEQAS scheme, it is operated on a pilot basis, whilst feasibility, stability of material, and systems for performance monitoring are assessed and developed. There may or may not be a charge for pilot exercises (including delivery charges), depending on the costs involved and the maturity of the pilot. Participation in pilot schemes may be restricted due to limited resources in terms of staff, IT or material.

Current pilot EQA schemes:

- Antenatal Antibody Titration (ANT)
- Extended Red Cell Phenotyping (ERP)

Details available at https://www.ukneqasbtlp.org/btlp.php

N.B. Following transition of DAT to full UK NEQAS Schemes in 2020, an extension to the scope of ISO17043 accreditation will be sought to include these schemes. The RCG scheme will transition to a full scheme when all aspects related to scoring have been validated.

Information on the current status of pilot schemes is provided to all BTLP participants each year at re-registration, and to participants in specific pilot schemes when significant developments occur. Please contact us via btlp@ukneqas.org.uk for an update at any other time.

Training Assessment and Competency Tool (TACT)

Although this service has been developed by UK NEQAS BTLP it is not external quality assessment. TACT is an online, fully interactive knowledge and competency assessment tool available for use on a 24/7 basis. The aim of this system is to provide laboratory staff and managers with a training and competency assessment tool, not solely focussed on the practical applications of training, but on the theoretical knowledge of Biomedical Scientists working in blood transfusion laboratories. There are two user guides for how to subscribe and how to use the system on the UK NEQAS BTLP website: https://www.ukneqash.org/tact.php.

TACT itself is accessed by visiting the website: https://tact.ukneqasbtlp.org.uk.

Please direct any enquiries to tactsupport@ukneqasbtlp.org.uk.

REGISTRATION

Eligibility for participation

Participation is open to all clinical laboratories and manufacturers of relevant kits and analysers, in the UK and overseas, although there may be restrictions on overseas participation in some schemes due to availability or stability of material.

Cost of participation

A fee sheet is sent to prospective participants on enquiry, and to existing participants at re-registration time. Early in the calendar year, participants receive details of how to re-register on-line. Re-registration requires an official purchase order to cover membership for the following fiscal year (April to March) against which an invoice will be raised and issued during the first quarter of the year.

Different arrangements may be in place for participants from outside the UK, and are detailed in the registration or re-registration documentation. Payment may be made directly or through an agent (see section on Distribution Agents, page 14).

EQA services are subject to VAT at the standard rate. In accordance with regulations, VAT is not applicable to NHS establishments within England.

Details of how payment may be made are included on the invoice. Non-payment within the period stated on the invoice may result in disruption of services and ultimately in suspension from the relevant scheme. Re-instatement will incur an additional administrative fee of £50.00.

Participant reference number (PRN)

At registration, each participant 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 a participating organisation; however, the same number may be assigned to several departments or sub-departments within the same organisation. Laboratories which participate in UK NEQAS Haematology and BTLP schemes are assigned the same PRN, whilst performance data remains confidential within each scheme. Where there is more than one registration in the same institution, each will be uniquely identified by the addition of a suffix to the main PRN, e.g. PRNs 12345 and 12345A.

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

Completing the registration form

Master address details
New participants are required to provide addresses and contact numbers for the following on the registration form:-

- The consultant clinically responsible for the relevant clinical service (mandatory for UK participants);
- The main contact, i.e. the scientist/manager to whom the exercise material and exercise correspondence will be directly addressed.

Return of results is via web-entry and accurate e-mail addresses are essential. Additional contacts can be registered for notification that the survey is open on the web, or that the reports are ready to be downloaded from the web.

Letters concerning unsatisfactory performance are addressed to the consultant and copied to the main contact.

Participation details
This section requires participants to register for all tests covering the work routinely undertaken in their laboratory.

Finance details
Participants are requested to provide details of the invoice address along with a purchase order number. Within the UK, invoices cannot be raised without an order number. It is important to indicate the type of laboratory, since this may impact on VAT or postal requirements.

Terms and conditions
By signing the registration form, new participants agree to abide by the UK NEQAS Terms and Conditions, which in the case of UK laboratories, includes the QAPC Conditions of EQA Scheme Participation available from the RCPath website, which can be reached via a link on the UK NEQAS website*. Existing participants indicate their continued acceptance of the Terms and Conditions at re-registration.

* https://www.ukneqasbtlp.org/external_links

Changes to registered information

Alterations to the tests and schemes for which you are registered should be sent to us in writing, either by letter or email, signed or sent by one of the named contacts, the head of the laboratory or laboratory manager. We request that 3 weeks' notice is given for participation changes to be effective for the next exercise.

Contact details should be updated whenever there is a change to laboratory personnel registered with UK NEQAS BTLP, and this can be done through the UK NEQAS Haematology and Transfusion website https://www.ukneqasbtlp.org.

It is the participating laboratory's responsibility to ensure that the registered information held by the Scheme is complete and up-to-date. It is also the participating laboratory's responsibility to deactivate individual registered contacts if the member of staff retires, resigns or moves to another role that does not require them to have access to UK NEQAS data. Registered contacts that have been deactivated will be removed from the UK NEQAS database after one year.

Participants with nhs.net domain addresses should take particular care to deactivate registered contacts when they move to another NHS Trust as their email address will otherwise remain active on our database and they could receive information about their previous registration.

Cancellation or suspension of participation

Please notify the Scheme office directly (by letter, fax or email) if you wish to cancel your participation for any test or exercise, giving at minimum of three weeks' notice before the next distribution date for the relevant exercise. The Scheme may apply an administration charge, equivalent to one quarter's registration fee, for deregistration in the second half of the participation year.

UK laboratories are asked to supply a reason for deregistration from any part of the Scheme's services. Deregistration by a UK participant with unresolved performance problems is notified to the NQAAP immediately.

You may suspend your participation temporarily if your laboratory is not offering the test as a clinical service for any reason, providing that you notify us in writing (by letter or email).

The Scheme will cancel the registration of any participating laboratory that fails to pay the appropriate charges. Any UK laboratory under the remit of the Quality Assurance in Pathology committee will be notified to the NQAAP for Haematology in the event that services are cancelled due to non-payment of subscription fees.

Certificate of registration

Certificates of registration are available via the UK NEQAS Haematology and Transfusion website. (see FAQ for details).

Distribution agents

UK NEQAS BTLP uses the services of a number of recognised distribution agents for the distribution of EQA services outside the UK. There are many advantages to this for the participant; in particular, the agent acts as a point of contact in the region, may offer translation services or assistance with interpretation of documents and the agent may act as a central delivery point, reducing the impact of courier costs.

A participant who registers through a distribution agent is the customer of that agent and is responsible for payment of their subscription fees directly to the agent, in their local currency. The agent has the right to refuse registration to a participant who does not pay their fees and will advise UK NEQAS BTLP to cease provision of EQA services.

The fees charged by a distribution agent for UK NEQAS BTLP services will be inclusive of charges for any additional services provided by the agent and therefore cannot be compared directly to the UK price list.

Distribution agents are expected to abide by the UK NEQAS Haematology and Transfusion terms and conditions for agents, which are available from the scheme office.

SOURCE OF EXERCISE MATERIAL

All red cells are obtained from NHS Blood and Transplant (NHSBT) from standard adult donations or from placental donations for cord cells.

The vast majority of plasma is also provided by NHSBT from either standard donations or from donors with red cell antibodies who donate specifically for EQA purposes. A small amount of plasma is sourced commercially. Human IgG monoclonal antibodies are used to supplement the polyclonal specificities available.

All blood donations 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 Control of Substances Hazardous to Health (COSHH) information sheet is included with each exercise. The containers and contents must be handled and discarded in line with laboratory policy for potentially infectious material.

DESPATCH OF EXERCISE MATERIAL AND TIME FOR COMPLETION

Distribution schedules

Annual schedules of the exercise despatch dates are distributed to participants at registration or annual re-registration. These can be displayed via the website (see FAQ), and are also available to download (as pdfs) from via https://www.ukneqasbtlp.org/documents.php.

Any significant changes to the schedule are highlighted on the UK NEQAS website www.ukneqasbtlp.org and participants are informed by email. UK laboratories should contact the scheme for advice if the exercise material has not been received within three days after the published distribution date. Laboratories outside of the UK should contact the scheme if the exercise material has not been received within four days after the published distribution date, or within the delivery limits quoted by the courier.

Exercise materials are despatched within the UK by first class mail, addressed to the main contact as defined in the registration form. Different arrangements are in place for participants outside of the UK, and vary from country to country; couriers may be required to ensure that material is received in a timely way. Dispatch of samples to non-UK countries is subcontracted to QED Haematology.

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.

Closing dates

The time available for submission of results varies by exercise type, and details are included in the distribution schedules. The time period does occasionally vary, e.g. to incorporate a bank holiday, and the closing date is always included in the instructions provided with each exercise, and is also available on the UK NEQAS website. Results are not routinely accepted after the closing date for any of the BTLP schemes.

UNDERTAKING EXERCISES AND SUBMITTING RESULTS

General Considerations

In keeping with the QAPC conditions of participation, 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 laboratory performance, as highlighted in the following examples:

- There should be no collusion with other institutions. Any suspicion of collusion, if confirmed, will be reported to the NQAAP for Haematology.
- The most expert member of staff should not always perform the exercise, unless no other staff members 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.
- The same specimen should not be tested multiple times unless the results indicate that this would be the case with a similar clinical specimen, e.g.
    - PTT samples should only be put through one analyser, unless more than one would be used for testing a similar clinical sample.
    - PTT samples should be tested by a single grouping or antiglobulin technique only, unless more than one would be used for testing a similar clinical sample.
    - Acid elution films for assessment of FMH should only be reviewed by the same number of staff that would review a similar clinical film.
    - If more than one flow cytometer is used for estimation of FMH, it is appropriate for the samples to be run on each analyser as the result obtained is numerical and there is no absolute correct result. In this instance a separate registration for each flow cytometer is required.
- 'Patient' samples should be assigned accession numbers and booked into the Laboratory Information System (LIMS) wherever possible, and any manual transcription steps checked before results are submitted.
- Where initial testing gives anomalous results, e.g. an apparent ABO/D typing anomaly or unresolved antibody identification, this may involve more than one technique, and/or additional checking by a more experienced member of staff, as appropriate for the results obtained.
- Spare material may be used to test additional techniques or staff members, but only **after** the results have been submitted. Some material should also be reserved until the report has been received in case repeat testing is necessary. The Scheme has a limited supply of spare material, which can be requested if further material is required before results can be submitted, e.g. in the case of a difficult antibody mixture. FMH slides should be kept until after the report has been received, in case review is required.
- Late results are not routinely accepted after the closing date for any of the BTLP schemes.

QUESTIONNAIRES

Questionnaires regarding particular techniques, reagents or procedures are issued using SurveyMonkey, an on-line survey tool. It is important that these are completed and submitted by the closing date as the data may be analysed in direct comparison to performance in the practical exercise to inform the report, although the results submitted will not influence scoring.

A biennial practice questionnaire is also issued; the information provided is used for observing trends in practice and for monitoring overall compliance with BSH guidelines, and is often used to support guideline revisions. All information obtained by questionnaire is confidential; however, detailed summaries of the overall data are reported back to all participants. We recognise that national guidelines in other countries may vary with respect to some of the recommendations, and do not comment on compliance outside of the UK.

Overview

The aim of the PTT Scheme is to assess performance in undertaking standard pre-transfusion serological testing, and decision making with respect to selection of red cells for crossmatching or issue. Additional educational elements are sometimes included with PTT exercises, but not scored, e.g. testing in an emergency situation, or selection of components for a range of patient types.

Tests assessed

- ABO grouping
- D typing
- Antibody detection
- Antibody identification
- Crossmatching
- Red cell phenotyping (C,c,E,e and K)

Scheme Design

Schedules and sample type R exercises

Major 'R' coded exercises (four per annum), are distributed on a Monday and close Monday, 14 days later, unless specified otherwise in the instructions. These exercises comprise:

- Three 'patient' whole blood samples for ABO and D typing, phenotyping for C,c,E,e and K, and DAT if relevant.
- Three patient' plasma samples for antibody screening, antibody identification and crossmatching.
- Three 'donor' red cell samples for crossmatching.

'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 FFP and modified Alsever's solution have been added. They are unsuitable for antibody screening, identification, auto control, crossmatching or phenotyping (other than for C,c,E,e and K), unless indicated otherwise in the instructions. For this reason, theoretical 'patient' phenotypes are provided on the instruction sheet, unless the exercise format states otherwise.

Plasma samples are pooled from several donations and are filtered to exclude bacteria. These functions are subcontracted to the NHS Blood and Transplant (NHSBT) Reagents Unit, but may also be undertaken in-house by UK NEQAS. Plasma samples are assumed, for the purposes of the exercise, to be from the same 'patient' as the corresponding whole blood sample. However, these may not always match in every respect including ABO, and it is important that they are only used for the tests indicated in the instructions and on the sample labels. It also makes them unsuitable to use as part of an auto control.

'Donor' red cell samples are usually derived from single donations and are suspended in modified Alsever's solution, containing antibiotics, to a concentration of approximately 10%, although donations with matched phenotypes may be pooled.

Schedules and sample type E exercises
Antibody screen/identification 'E' coded exercises (six per annum) are distributed on a Monday and close on Thursday of the following week (i.e. 10 days later) unless specified otherwise in the instructions. These exercises comprise:

- Four 'patient' plasma samples for antibody screening and antibody identification.

Exercise and sample identifiers
Exercises are numbered sequentially from 1 to 10, prefixed with the last two digits of the year and E or R as appropriate, e.g. 20E1, 20R2, refer to the first two exercises in 2020.

Samples are labelled with the exercise code, the date, the sample type (whole blood, plasma etc.) the sample identifier (Patient 1, Patient 2, Donor W, Donor Y etc.), the tests required and the storage temperature.

Details included
Limited demographic details may be included with the exercise, such as age and gender, in which case these should be taken into account for interpretation of blood grouping results, and for issue of red cells.

Details of samples provided and specific instructions for completion are included.

Level of participation
UK participants are expected to participate in all ten exercises if they routinely undertake antibody screening and/or antibody identification. There are a few specialist departments that only undertake ABO/D typing, and these participate in only the four 'R' coded exercises. Non-UK participants may elect to participate in the 'R' coded exercises only.

Stability and homogeneity

All patient and donor pools are subject to manual pre-acceptance testing by the techniques in most common use in UK laboratories, i.e. Bio-Rad ID-system, Ortho BioVue, Immucor Capture R and Grifols DG Gel; testing is also undertaken using a tube technique which acts as a non-commercial 'standard'. Three sets of exercise material are subjected to the postal system. One set of posted samples is tested in-house on receipt and another on the closing date. Any significant deterioration in reaction grades by any technique may result in withdrawal from scoring for the relevant tests. The third set of samples is left at room temperature and tested if there is any indication that there have been delays in the transport system or if there are more incorrect results than would be expected.

Homogeneity of the plasma pools has been demonstrated by historical participant data in terms of 100% detection rate of several weak antibodies and consistency of strength of reaction within technique, reported for the UK NEQAS 'standard' anti-D.

A selection of plasma pools containing a range of IgG antibodies previously included in UK NEQAS exercises has been tested in-house and shown to remain stable for the duration of the exercise when stored at 37^{O}C for 8 hours, followed by 30^{O}C for up to 96 hours, with the remainder of the 14 days at 2-8^{O}C. The red cells in modified Alsever's solution used for the donor samples have demonstrated similar stability. The whole blood samples demonstrate varying levels of haemolysis on storage at different temperatures, however the A, B and D antigens remain stable. The whole blood samples are particularly prone to haemolysis when coated with IgG antibody to

mimic a positive DAT, and manual testing may be required to determine the ABO/D group in these circumstances.

Testing

ABO/D Grouping

Full ABO/D grouping should be undertaken on the whole blood samples.

Antibody screening and Identification (ID)

Antibody screening should be undertaken on the separate plasma samples unless specified otherwise. Antibody identification should be undertaken if the antibody screen is positive and the laboratory is registered for antibody ID. If the laboratory has reached the limit of its resources and antibody identification is incomplete, panel sheets may be submitted for review by the Scheme as an Unable to Identify (UI) submission (see next section on completion of results for further details).

Direct Antiglobulin Test

A direct antiglobulin test (DAT) need only be performed if this procedure is normally performed on patients' samples, or if this test is indicated by positive results obtained with reagent (diluent) controls, or if requested to in the exercise instructions. Separate samples are provided for assessment of the DAT as part of the DAT pilot scheme.

Crossmatching

Crossmatching can be undertaken on the basis of theoretical compatibility / deselection or on the basis of a serological crossmatch.

Donor samples provided for assessment of crossmatching may be different ABO and D groups from the Patient samples provided. Donors should not be deselected on the basis of ABO and D type unless there is either an ABO incompatibility, or the Patient is D negative with atypical antibodies identified and the Donor is D positive. This is required so that assessment of crossmatching can be undertaken. Participants have the opportunity to record their laboratory policy by stating that although compatible, the unit would not be selected for transfusion in clinical practice..

Red Cell Phenotyping (Rh and K)

Rh and K phenotyping should be undertaken on the patient ‘whole blood’ samples. The patient whole blood samples are not suitable for testing for other blood group antigens as they are prepared from a pool of four or more donations, not matched for all antigens, and the resulting mixed field reactions make them unsuitable for additional phenotyping.

Recording and submitting results

Technologies

For every exercise, participants are asked to record the technologies used to test each ‘patient’ sample. This allows participants who have more than one technology in routine use to select a different technology for each sample or from one exercise to the next. An individual sample should only be tested by one technology unless use of more than one reflects clinical practice; in this case all technologies used should be recorded.

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 serological reactions as negative, weak, 1+, 2+, 3+ or 4+.

Where only one reaction grade can be recorded to represent testing vs. more than one red cell, e.g. for the antibody screen, the strongest reaction observed should be recorded.

Interpretation

All penalty scoring is based on the **interpretation** of the results as entered in each section, and completion of these sections is mandatory. The exception to this is for C, c, e, E and K cell phenotyping, where the recorded reactions are used for scoring. UK participants are telephoned for missing data, which must be supplied in writing (by email). Verbal results are not accepted since the Scheme requires a clear audit trail of any edits to results.

Antibody Identification

a) UI submissions

'Unable to Interpret' (UI) is an acceptable result, provided that panel profiles are submitted and the conditions set out in **Appendix I** (based on BSH guidance) are met. This allows all laboratories undertaking antibody identification on clinical samples to register for EQA, without attracting penalties for being unable to interpret results simply due to a lack of resources.

This option should be used where there is a mixture of antibodies that cannot be fully elucidated or where one antibody is positively identified, but another of potential clinical significance cannot be excluded. Before reporting UI, a full investigation, to the limit of in-house resources, should be undertaken, and any specificity that can be positively identified should be recorded in addition to UI. Specificities that might be present but cannot be confirmed should be recorded as *'specificities that cannot be excluded'*. As UK NEQAS samples currently include a maximum of two specificities, if two are *positively* identified, a UI submission need not be made. This may change in the future, in which case adequate notice will be given.

Where the UI box is ticked on the data entry page, the 'antibodies not excluded' section will appear for completion. All identification and screening panel profiles used must be submitted for assessment (uploaded via the web data entry page), and the sections indicated on the data entry page completed with an explanation of the reason for the incomplete identification. If the Scheme agrees with the interpretation of UI, no penalty is given. If the Scheme disagrees, penalty points are allocated, with a letter detailing the reasons. The International Blood Group Reference Laboratory acts as an external arbiter in the case of appeals. If no UI submission is made, scoring is based on the antibodies that have been positively identified alone.

b) Antibodies to low frequency antigens and/or of low clinical significance

The EQA plasma may contain antibodies to low frequency antigens (LFAs), with a frequency of <1%, in addition to the current maximum of two specificities. On the rare occasion that your panel contains a cell positive for an LFA, which results in you being unable to conclusively identify the antibodies present, we will accept a UI submission. There is no need to exclude the presence of antibodies to LFAs, as long as all positive reactions have been accounted for.

Antibodies of low clinical significance may be distributed for positive identification, in which case their presence should be recorded by ticking the appropriate box provided. Since there is no requirement to exclude antibodies to antigens of low frequency and/or of low clinical significance that may be masked, in either EQA or clinical samples, they are not listed in the *'specificities that cannot be excluded'* section which appears when 'UI' is ticked. E.g. If the Jk^b antigen masks Lu^a on the panel, additional cells and techniques do not need to be used to exclude anti-Lu^a in the

presence of anti-Jk^{b}. There is no need to make a UI submission in this situation so long as the antibody identification is otherwise complete.

c) Rh antibody mixtures

Since there is no requirement to exclude anti-E in the presence of anti-c (or anti-C in the presence of anti-e) in routine pre-transfusion testing, options are provided for anti-c±E and anti-e±C, and these are counted as a single specificity for the purposes of EQA. It is not uncommon for anti-G to be present in a mixture of anti-C+D, but the Scheme does not test for the presence of anti-G (as it has no clinical relevance outside of the antenatal setting); the antibody mixture should therefore be reported by the Scheme as anti-C+D.

Crossmatching

The interpretation recorded may be reached either as a result of:

- Serological crossmatching.
- Theoretical de-selection of the 'donor' unit(s) for major ABO incompatibility, or for 'patients' with atypical antibodies following phenotyping of the donations.
- Theoretical selection based on the blood group +/- other phenotypes of the 'donor' and the blood group and antibody status of the 'patient'.

To indicate that a serological crossmatch has been performed, both the reaction grades and interpretations should be recorded. Where the unit has been selected/deselected on the grounds of theoretical compatibility/incompatibility, only the interpretation need be recorded. On the website, a positive reaction by IAT will default to 'incompatible' as will theoretical deselection, whereas a negative reaction by IAT (or theoretical selection) will default to 'compatible'; these defaults can be overridden by the participant if required.
Units may be 'deselected' in the following circumstances only:

- Major ABO incompatibility.
- Donation is antigen positive for an antibody positively identified in the plasma.
- Donations are D positive, and the 'Patient' D negative with a positive antibody screen.

There is an option on the result page to indicate that although the donation is serologically compatible, it would not be issued under laboratory policy. For example, you may wish to indicate that you would not transfuse a donation that is not typed for K, or would not transfuse a group O donation to a group AB patient. This element is not assessed or taken into account for scoring, which is based solely on the interpretation of compatible / incompatible, but the overall data may be analysed and reported where relevant to the exercise.

Assigned 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. Extensive testing is also completed in-house, at intervals up to the closing date, on exercise material that has been subjected to the postal system. The IBGRL acts as a reference laboratory if required.

Reports

Each participant receives an individual, confidential report detailing any errors made by their laboratory in the current exercise, any cumulative errors, and their overall cumulative performance, within six working days of closing for 'E' exercises and nine working days for 'R' exercises. It also includes a summary of overall results for the UK or other relevant peer group outside of the UK. An example of an 'R' exercise report type is shown in Appendix 2.

Where there is a difference in detection rate by technique or IAT technology, the data may be represented by additional bar charts or text.

A pdf of a PowerPoint presentation is available on the web results page to download for presentation by participants to members of staff or at regional meetings. This summarises errors and learning points based on UK data, and may also include additional associated educational discussion and references.

An anonymised version of the UK report is provided as information for non-UK participants.

Supplementary reports or information may also be distributed at a later date, with further analysis and discussion.

Assessment and penalty scoring

There are seven areas of assessment: ABO grouping, D typing, antibody screening, antibody identification, crossmatching, red cell phenotyping, and return of results. Scores are weighted for clinical significance and are reviewed by the Steering Committee. Any changes are approved by the NQAAP for Haematology.

Participants are scored in each of the areas for which they are registered, 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 laboratories record the 'correct' result (i.e. halved where 50-80% obtain the expected result).

Penalty Scores are applied for each instance of:

a) ***Incorrect ABO group:*** **SCORE = 100**
ABO typing exceptions: a result of UI (unable to interpret) will not incur a penalty where the sample is direct antiglobulin test positive, a weak ABO subgroup, or contains a dual population of red cells.

b) ***Incorrect D type*****: SCORE = 100**
D typing exceptions: a result of UI (unable to interpret) will not incur a penalty where the sample is direct antiglobulin test positive, weak or partial D, or contains a dual population of red cells, otherwise a result of UI will incur 50 penalty points.

c) ***False-negative antibody screen*****: SCORE = 100**

d) ***False-positive antibody screen*****: SCORE = 40**

e) ***Incorrect antibody identification:*** **SCORE = 80**
(one or more antibody present not identified):
e.g. anti-E reported (correct result anti-D), *or* anti-E reported (correct result anti-E+Fy^a)

f) ***Partially correct identification:*** **SCORE = 40**
(antibodies present are identified, but additional specificities not present are recorded as positively identified) where no UI submission is made or where the Scheme does not agree with the interpretation (see appendix 1)
e.g. anti-E+K or anti-E+UI (correct result anti-E) *or* anti-E+UI (correct result anti-E+Fy^a)

g) ***Unable to identify any specificity where no UI submission is made or where the Scheme does not agree with the interpretation*** *(see appendix 1):* **SCORE = 50**

h) ***Missed ABO incompatibility:*** **SCORE = 100**

i) ***Missed non-ABO incompatibility in routine exercises:*** **SCORE = 60**

j) ***Missed non-ABO incompatibility in urgent exercises:*** **SCORE = 80**

k) ***Missed compatibility:*** **SCORE = 30**

l) ***Incorrect red cell phenotype (where one or more reaction recorded for a single sample is incorrect):*** **SCORE = 40**

m) ***Non-return of results for an exercise:*** **SCORE = 50**

A sample or section of the exercise is sometimes excluded from penalty scoring. This may be pre-planned, where a particular sample is selected to demonstrate a specific educational point, but where more than one observation or interpretation may be considered to be correct. This may also be instigated as the result of significant deterioration of a sample during the life of an exercise, e.g. where an antibody is no longer detectable by all IAT technologies in the UK NEQAS laboratory on the closing date. Any such decisions relating to scoring are detailed in the exercise report.

The score for each area is summed over three exercises into a Cumulative Score for that area of assessment. The ABO grouping, D typing and crossmatching areas are summed over the current and previous two 'R' coded exercises, where results have been submitted. The antibody screening and identification areas are summed over the current and previous two exercises, where results have been submitted, whether 'R' or 'E' coded.

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.

Performance monitoring (UK laboratories only)

Definition of unsatisfactory performance (UP)
A cumulative score of ≥100 in any category, including non-return.

Definition of persistent unsatisfactory performance (PUP)
More than one episode of UP in any category during a rolling 12 month period. This excludes an UP score in more than one category in a single exercise.

Actions taken by UK NEQAS for UK participants
Senior Scheme personnel aim to contact all laboratories with unsatisfactory performance within the UK clinical sector by telephone, within five working days of the closing date. The problems are discussed with the laboratory contact, or in their absence a deputy, with a view to gaining an understanding of the source of the error. Repeat samples and evidence-based advice are offered where appropriate, and details of all calls are kept in a confidential log and/or electronically in the database. Outcomes that may be of benefit to the UK overall, may be detailed and commented upon anonymously in the report. Laboratories with borderline performance, and occasionally satisfactory performance, but with errors in the exercise, are also contacted by phone where time allows, and where constructive help can be offered, or where useful information may be obtained for the report. Details of these calls are also logged.

Action to be taken by participants
Any errors in EQA should be investigated and the outcome documented on the 'Corrective and Preventive Action' (CAPA) sheet, available to download from the information website, and a copy returned to the Scheme by email or post.

FETO-MATERNAL HAEMORRHAGE (FMH) SCHEME

Overview

The aim of the FMH Scheme is to assess performance of clinical laboratories in screening and/or quantifying the volume of FMH in post-delivery D negative women, for the purpose of administering sufficient anti-D Ig to prevent sensitisation to the D antigen.

Tests/procedures assessed

- Screening for FMH by acid elution (AE) or flow cytometry (FC) to determine whether fetal cells are present and whether quantification would be triggered
- Quantification of FMH in mL packed cells
  - by acid elution (AE)
  - by flow cytometry (FC)
- Dose of anti-D Ig suggested in combination with follow-up procedures (referral for quantification by flow cytometry and request for a repeat sample) to determine whether the participant would place a woman at risk of sensitisation to the D antigen in a similar clinical situation.

Scheme Design

Schedule and sample types:
Two samples are distributed six times a year, with each representing a sample from a post-delivery D negative woman requiring routine anti-D Ig prophylaxis. Bleed sizes vary and include 0mL bleeds. Exercises are distributed on a Tuesday, and close the following Tuesday (i.e. 7 days later) unless specified otherwise in the instructions.

D positive cord cells are mixed with one or more donations from group AB D negative (or ABO matched) adult donors (tested for abnormal haemoglobins) in calculated proportions for each sample. Broad spectrum antibiotics are added to ensure sterility.

Exercise and sample identifiers
Exercises are numbered sequentially from 01 to 06, prefixed with the last two digits of the year and suffixed with the Scheme identifying letter, e.g. 2101F, 2102F, refer to the first two exercises in 2021.

'Patient' samples are labelled with the exercise code, the sample type (whole blood), the sample identifier (Patient 1 and Patient 2) and the storage temperature.

Level of participation
Laboratories can register for acid elution and/or flow cytometry screening and/or quantification, to reflect the testing undertaken in-house on clinical samples.

Laboratories registering for quantification by acid elution will automatically be registered for acid elution screening unless otherwise indicated, and will be required to answer to questions relating to follow-up.

Where quantification is undertaken by acid elution and flow cytometry, two separate registrations will be required.

Homogeneity and Stability

The material is dispensed using a validated technique to ensure homogeneity throughout the process. Acid elution (AE) testing (also known as the Kleihauer) is used to establish that the adult cells remain intact, elute appropriately and that the ghost cells are countable, and that the cord cells have stained pink and are countable. This is undertaken on the day of despatch (post bottling) and again on closing day on samples that have been subjected to the postal system. In addition, the acid elution median results are plotted by date tested as an additional assessment of stability.

Flow cytometry (FC) is used to establish stability and homogeneity. Post bottling, at least three samples are selected to include the beginning, middle and end of the bottling process, and are tested in duplicate.

FC tests are repeated on the closing date on samples which have been subjected to the postal system. The FC results are used to evidence stability over the course of the exercise. Stability testing at different temperatures showed that samples are stable for one week after distribution.

Samples which have not met the stability criteria are withdrawn from scoring for AE and/or FC as necessary.

Testing

Blood films for acid elution should be made and reviewed in the same way as clinical samples. However, it should be noted that the whole blood used is collected into Citrate Phosphate Dextrose (CPD) and hence there is already some dilution of the red blood cells. This should be taken into account if diluting these samples prior to testing.

The blood films should be screened for fetal cells, and if any are seen, the laboratory will need to decide whether or not the number of fetal cells observed triggers quantification. Those registered for quantification should proceed to estimate the bleed volume, using the same checking procedures that are in place for clinical samples.

Flow cytometry screening and quantification should be undertaken in the same way as for a similar clinical sample.

Recording and submitting results

- The stated *method details* should be entered and checked to ensure that they are correct.
- *Actual Bleed Volume* results should be recorded as mL packed fetal cells to one decimal place, and the *Reported FMH Result* as it would be reported in clinical practice.
- *Percentage fetal cells* should be recorded for flow cytometry, where possible. If the percentage is unknown, please record 999.
- The *calculated* and *prescribed* anti-D Ig doses should be given in international units (IU). This field should be completed for all acid elution registrations and for flow cytometry registrations, where this is part of clinical practice. Please record these doses in whole numbers.

- Questions regarding follow-up procedures should be completed as if the EQA sample were from a D negative woman having delivered a D positive baby.

Assigned values

Target bleed volume ranges are planned for the year and samples are made by adding the calculated volume of cord cells to adult cells, taking the PCV of each into account. However, there are other variables in both the adult and cord cells, and there is no means of validating the absolute value of the simulated FMH. The participants' consensus result, using the method median is therefore used to calculate the penalty scores as described in the next section.

Flow cytometry is the accepted reference method, and the flow cytometry median is used as the assigned value for calculating the amount of anti-D Ig required when identifying acid elution users making 'potential for sensitisation' errors.

Reports

Each participant receives an individual, confidential report showing their results and the overall results for the current exercise within their method group. Individual current and cumulative scores are displayed to demonstrate trends in performance. These reports are posted to the web within six working days of the closing date.

An anonymised copy of the acid elution and flow cytometry quantification reports are also made available on the web server.

An example of each type of report is shown in Appendices 3, 4 and 5.

Supplementary reports or information may also be distributed at a later date, with further analysis and discussion.

Assessment and penalty scoring

There are four areas of assessment:

1. The numerical score for accuracy of quantification, described below.
2. Grossly outlying acid elution results. Each outlying result is shown as a single unit on a bar chart on the report.
3. The clinical significance of decision-making by participants registered for all acid elution testing (and flow cytometry screening), relating to anti-D immunoglobulin dosing, and follow-up. This is designed to identify episodes where women would be put at risk of sensitization in a similar clinical situation. Each 'potential for sensitisation' error is shown as a single unit on a second bar chart on the report.
4. Return of results.

Statistical processing

The median for each method, and the standard deviation (SD) derived from the method inter-quartile range, are used to produce a deviation index (DI). The DI from the results of the six most recent, scored, specimens for which results have been returned is used to calculate the analytical performance score.

Scoring is not applicable to acid elution results where the bleed is <4mL (based on the flow cytometry median), and is not applicable for either method where the bleed is 0mL.

Samples are withdrawn from scoring if they do not meet stability criteria, and maybe withdrawn where it transpires that the nature of the material has influenced the results for a specific group of participants, e.g. where a D variant cord sample is inadvertently used.

There are three steps involved in the calculation of the analytical score:

1. The method DI is calculated using the formula

$$DI = \frac{x_i - x_{pt}}{SD_{pt}}$$

Where x_i is the laboratory result
x_{pt} is the median value
SD_{pt} is the estimated SD*

*The Estimated SD (Est SD) is calculated using the equation:

$$Estimated\ SD = \frac{IQR}{1.349}$$

Where: IQR=Interquartile range
1.349 = the spread for the standard Gaussian distribution at the IQR

Example DI calculation: where FMH = 16.2mL, median = 17.3, IQR = 15.2 - 19.7

$$DI = \frac{17.3-16.2}{(19.7-15.2) / 1.349} = 0.33$$

1. The absolute value of the Method DI is taken (ignoring the sign) and any DI values greater than 3.5 are rounded down to 3.5, to avoid very high values having an excessive effect on the calculation.

2. The resulting DI values for the six most recent specimens for which results have been returned are added together and then multiplied by a constant to give the Analytical Performance Score. Where this requires the inclusion of one of the two samples from a previous exercise, i.e. in the event of a non-scoring sample or a missing result, sample 2 will be used. The constant is currently set at 8 for acid elution and 7 for flow cytometry.

Examples are given in tables 1 and 2 below for two laboratories at the end of 1903F:

Table 1: The following DIs were obtained for a participant using acid elution (AE)

Survey	Patient 1	Patient 2
1806F	0.37	-2.04
1901F	4.69	Not scored
1902F	Not scored for AE	3.20
1903F	2.59	-1.33

Score = (1.33+2.59+3.20+3.50+2.04+0.37) x8 = 104.2

Table 2: The following DIs were obtained for a participant using Flow Cytometry (FC)

Survey	Patient 1	Patient 2
1806F	Not part of most recent 6	-0.39
1901F	0.45	Not scored
1902F	-0.60	0.09
1903F	0.54	0.21

Score = (0.21+0.54+0.09+0.60+0.45+0.39) x7 = 16.0

Uncertainty of the assigned (target) value

Uncertainty of measurement provides a quantitative estimate of the quality of a test result, and therefore is a core element of a quality system for laboratories. The same principle applies to EQA where the uncertainty of the assigned or target value is a measure of the quality of the EQA material. ISO 13528:2015 states, "*If the standard uncertainty of the assigned value is large in comparison with the performance evaluation criterion, then there is a risk that some participants will receive action and warning signals because of inaccuracy in the determination of the assigned value, not because of any cause of the participant."*

The standard uncertainty of the assigned value in EQA depends upon the method used to derive the assigned value, the number of laboratories (consensus values) and other factors including homogeneity, transport and instability. Where the assigned value and standard deviation are determined from a consensus of participants' results, as for FMH, the uncertainty of the assigned value is assumed to include the effects of inhomogeneity, transport and instability.

The standard uncertainty of the assigned value is calculated using the formula:

$$u(x_{pt}) = 1.25 \times \frac{S^*}{\sqrt{p}}$$

Where $u(x_{pt})$ = standard uncertainty of the assigned value x_{pt}

S^* = robust standard deviation (RSD) of the data

p = number of results

According to ISO 13528:2015, the uncertainty of the assigned value may be considered to be negligible and need not be included in the interpretation of EQA performance if it is less than 0.3 times the standard deviation of the results (SD_{pt}). The SD_{pt} is the standard deviation used to calculate the deviation index.

The uncertainty of each assigned or target value is stated on the survey report.

Performance monitoring (UK laboratories only)

Definition of unsatisfactory performance (UP)

- Non-return of results in two of three consecutive surveys.
- An initial analytical score of ≥100 or an existing score of >100 but falling (see Table 3).
- A single grossly outlying acid elution result, where the DI is <-2 or >3.5. These values are subject to periodic review.
- An insufficient dose of anti-D Ig (to cover the FC median, where this is ≥4mL) combined with no recommendation for follow-up (i.e. repeat sample or referral/ testing by flow cytometry), by laboratories registered for AE.
- An insufficient dose of anti-D (to cover the FC median) where the AE or FC screen does not trigger quantification (in-house or referral).

Definition of persistent unsatisfactory performance (PUP)

- An analytical score of ≥100 where this is rising (see Table 3).
- Two or more episodes of unsatisfactory performance within a 12 month period.
- Two episodes of UP due to non-return of results within a 12 month period.
- A combination of UP as defined in a, b, c or d, with UP due to non-return.

Table 3 describes the performance status in relation to the analytical performance score.

Table 3 - Definition of Borderline, UP and PUP for analytical penalty scoring

Performance	Performance status
Score of 80-99	Borderline
Score of 100+	UP
Score of 100+ and falling	UP
Score of 100+ and rising or not falling (inc non-return)	PUP
Score of 100+ on two occasions in one 12 month period	PUP

ABO TITRATION (ABOT) SCHEME

Overview

Following an exploratory pilot exercise in 2009 which demonstrated wide variation in practice and results, the ABO titration pilot scheme was launched in 2010 and became a full UK NEQAS Scheme for the 2017/18 cycle of exercises. The main aim is to assess practice and improve standardisation in centres undertaking ABO titration to support ABO incompatible (ABOi) solid organ transplant, where titration results influence decisions regarding acceptance of patients to the ABOi transplant programme and suitability for transplant.

A 'Standard' technique (using Bio-Rad (DiaMed) gel technology) has been developed as a tool to investigate variation in results and to achieve standardisation across centres. Participants are asked to submit results for the 'Standard' technique alongside their in-house technique where possible.

Tests assessed

- Titration of ABO antibodies by IAT and direct room temperature (DRT)
    - Using in-house techniques, and if possible the equivalent 'standard' techniques that are provided with each exercise. Only techniques with ≥20 participants are scored.
- A_1 typing is included with each exercise; this test is optional and not currently scored.

Scheme Design

Schedules and sample type

ABO titration exercises are distributed on a Monday and close Monday, 14 days later, unless specified otherwise in the instructions. These exercises comprise:

- Three plasma samples for titration of anti-A or anti-B, prepared from filtered fresh frozen plasma.
- Red cells (approximately 30% in modified Alsever's solution) for titration and for A_1 typing.

Plasma samples are pooled from several donations and are passed through a 0.2µm filter to exclude bacteria. These functions are subcontracted to NHS Blood and Transplant (NHSBT) Reagents Unit, but may also be undertaken in-house by UK NEQAS.

Red cell samples are derived from a single donation and are suspended in modified Alsever's solution, containing antibiotics, to a concentration of approximately 30%.

Exercise and sample identifiers

Exercises are numbered sequentially from 1 to 4, prefixed with the year in which they distributed, e.g. 20ABOT1 being the first exercise in the calendar year 2020. Samples are labelled with the exercise code, the date, the sample type (red cells or plasma) the sample identifier (Patient 1, Patient 2 etc.), the tests required and the storage temperature.

Details included

Details of samples provided and specific instructions for completion are included. Those who undertake renal (or other solid organ) transplant, are requested to treat the plasma samples as being from patients awaiting ABO incompatible transplant from a living donor.

Level of participation

Laboratories are expected to participate in all four exercises.

Homogeneity and stability

All patient plasma samples are subject to manual pre-acceptance testing using the 'standard' Bio-Rad (DiaMed) techniques for IAT and DRT. A set of exercise material is subjected to the postal system, and these samples are tested on receipt and on the closing date. Any significant deterioration in titre will trigger withdrawal from scoring for the relevant tests.

Homogeneity of the plasma pools has been demonstrated by historical participant data from the main BTLP scheme (where pools are prepared in the same way), in terms of 100% detection rate of several weak antibodies and consistency of strength of reaction within technique, reported for the UK NEQAS 'standard' anti-D.

Plasma pools containing ABO antibodies have been tested in-house and shown to remain stable for the duration of the exercise when stored at 37^{O}C for 8 hours, followed by 30^{O}C for up to 96 hours, with the remainder of the 14 days at 2-8^{O}C. The red cells in modified Alsever's solution used for the titration samples have demonstrated similar stability.

Testing

Participants are requested to undertake titration, using the red cells provided, of anti-A and / or anti-B on the three plasma samples using in-house techniques and, if possible, the equivalent standard techniques provided with each exercise, using Bio-Rad (DiaMed) technology.

Recording and submitting results

Data entry and reporting is via the UK NEQAS Haematology and Transfusion website. Exercise reports include the participant's own results and summary data for the exercise (medians and range by method and technology).

Assigned values

Target titration values are planned for the year and samples made by pooling plasma donations containing anti-A and / or anti-B. The titration result varies by technology used, and no definitive value can be obtained. Therefore the participant' consensus result by technology is used as the 'target' value for scoring purposes.

Reports

Each participant receives an individual, confidential report showing their results and the overall results for the current exercise within their method group. Individual current and cumulative scores are displayed to demonstrate trends in performance. These reports are posted to the web within six working days of the closing date. An example of an ABO titration report is shown in Appendix 6.

Assessment and penalty scoring

Areas of assessment

- Titration value

Categories of testing scored

Difference from median result for results obtained by:

- Standard IAT
- Standard DRT
- Any other in-house technology with >20 laboratories testing by IAT or DRT

Definition of satisfactory results

The titration value is within 1 doubling dilution of 'target', i.e. method median.

Penalty scores for 'outlying' results

- One point for each doubling dilution >1 away from 'target', e.g. if the target were 32, then one point would be incurred for results of 8 or 128, two points for 4 or 256, three points for 2 or 512 etc.
- If a median result lies between two titres, the median result will be stated as half way between the two titres (e.g. if 25 submitted results are 32 and below, and 25 submitted results are 64 and above, the median titre will be 48). If this occurs, scores will be include 0.5 points as part of the scoring system (e.g. a result of 16 or 128 will incur 0.5 points, a result of 8 or 256 will incur 1.5 points etc.).
- Within each exercise, points for each sample are accumulated by category
- Points are also accumulated across exercises by category

Performance monitoring (UK laboratories only)

Definition of unsatisfactory performance (UP)

1. A total of three points within a category of testing in a single survey.
2. A total of three points within a category of testing in the last 9 scored samples for which results were returned.
3. Non-return of results in two of the three most recent surveys.

Definition of persistent unsatisfactory performance (PUP)

1. More than one episode of unsatisfactory performance in any category of testing, within

   12 months.
2. Two episodes of UP due to non-return of results in a 12 month period.
3. One episode of UP from each of the above within a 12 month period.

DIRECT ANTIGLOBULIN TEST (DAT) SCHEME

Overview

The UK NEQAS DAT pilot scheme was launched in 2015/16 with limited participation and the initial aim of establishing stability of the samples. The DAT pilot was opened to all participants in 2017/18 and progressed to a full UK NEQAS Scheme in April 2020. The aim is to assess direct antiglobulin testing performed for clinical indications such as, investigation of transfusion reactions, HDFN and AIHA.

Tests assessed

- DAT polyspecific
- DAT monospecific (anti-IgG and anti-C3d)

Scheme Design

Schedules and sample type

Each exercise comprises two samples of red cells suspended in Alsever's solution for preparation as appropriate for the DAT technology in use. In order to facilitate an increasing demand for participation two exercises are prepared at the same time, one for UK participants only and the other for non-UK participants (the exercises are suffixed with a U and N respectively; e.g. 21DAT2U and 21DAT2N). Each sample is usually derived from a single donation and is suspended in modified Alsever's solution, containing antibiotics, to a concentration of approximately 10%.

There are four sets of exercises per year. Exercise packages are dispatched by first class post within the UK and by courier (DHL) to non-UK participants unless otherwise requested. The DAT exercises coincide with PTT 'R' coded exercises and, where laboratories are registered for both, these form part of the same delivery. DAT exercises close are open for one week, rather than two weeks for the PTT 'R' exercise; the shorter duration for the DAT exercise is based on stability studies for DAT samples.

Exercise and sample identifiers

Exercises are numbered sequentially from 1 to 4, prefixed with the last two digits of the year and 'DAT', e.g. 21DAT1U (and 21DAT1N), 21DAT2U (and 21DAT2N) refer to the first two exercises in 2021.

Samples are labelled with the exercise code, the issue and closing dates, the sample identifier and the storage temperature.

Details included

Details of samples provided and specific instructions for completion are included.

There is no clinical context associated with the DAT exercises, unless otherwise indicated in the instructions for a specific exercise.

Level of participation

UK participants are expected to participate in all four exercises.

Stability and Homogeneity

Pilot studies 2014-17 demonstrated that the DAT samples remained stable for at least one week post distribution. All DAT pools are subject to manual pre-acceptance testing. A set of exercise material is subjected to the postal system. Posted samples are tested in-house on receipt and again on the closing date. Any significant deterioration in reaction grades results in withdrawal from scoring for the relevant tests.

Testing

Participants are requested to investigate the samples in the same way as clinical samples where a DAT is requested, i.e. initial and any follow-up DAT testing.

Return of results

There is the facility to report results of testing with polyspecific AHG, anti-IgG and anti-C3d. Data entry of results is via the UK NEQAS Haematology and Transfusion website https://www.ukneqasbtlp.org.

Assigned values

Assessment is by comparison of each participant's result vs. the expected result determined by the supplier of the material and UK NEQAS BTLP in-house testing.

Reports

Each participant receives an individual, confidential report showing the overall results for the current exercise, plus their own current and cumulative results to demonstrate the trends in performance. Reports are posted to the web within fifteen working days of the closing date. An example of each type of report is shown in Appendix 7.

Assessment and penalty scoring

Interpretations are scored in line with other BTLP schemes. Penalty scores allocated as per tables 4 and 5, using principles of weighting for clinical significance, partially correct but not unsafe answers, and allowing the reporting of 'Unable to Interpret' (UI) where there are anomalous results with a reagent control.

Table 4 – DAT scoring for samples - reagent control not included or recorded as negative

Expected Result	Interpretation where reagent control, if included, is Negative					
	Negative	Positive	Positive IgG only	Positive C3d only	Positive IgG + C3d	Unable to interpret
Negative	0	30	30	30	30	30
IgG only	60	0	0	60	30	30
C3d only	60	0	60	0	30	30
IgG & C3d	60	0	30	30	0	30

Table 5 – DAT scoring for samples - reagent control recorded as positive

Expected Result	Interpretation where reagent control, if included, is Positive					
	Negative	Positive	Positive IgG only	Positive C3d only	Positive IgG + C3d	Uninterpretable
Negative	0	30	30	30	30	0
IgG only	60	0	0	60	30	0
C3d only	60	0	60	0	30	0
IgG & C3d	60	0	30	30	0	0

There is cumulative scoring with points accumulating over a rolling window of the six most recent samples, where results have been returned and samples have been scored.

Performance monitoring (UK laboratories only)

Definition of unsatisfactory performance (UP)
A cumulative score of ≥100 in any category, including non-return.

Definition of persistent unsatisfactory performance (PUP)
More than one episode of UP in any category during a rolling 12 month period.

RED CELL GENOTYPING (RCG) SCHEME

Overview

The UK NEQAS red cell genotyping pilot scheme was launched in 2016, following a pre-pilot project in collaboration with ISBT in 2014/15, where one of the outcomes was recognition that EQA for 'routine' red cell genotyping would be useful. A UK NEQAS pilot scheme was launched in 2016/17 and became a full UK NEQAS EQA Scheme in 2019/20. Four exercises are distributed per year. Each exercise comprises two whole blood samples representing samples from haemoglobinopathy patients referred for genotyping to facilitate transfusion support. Exercise packages are dispatched by first class post within the UK and by courier (DHL) to non-UK participants unless otherwise requested. On each distribution day, an email is sent confirming that the exercise has been dispatched.

Tests assessed

- Genotype
- Predicted phenotype

Scheme Design

Schedules and sample type

Each exercise comprises two samples of whole blood (non-leucodepleted). These samples are derived from single blood donations.

There are four exercises per year. Exercise packages are dispatched by first class post within the UK and by courier (DHL) to non-UK participants unless otherwise requested.

Exercise and sample identifiers

From April 2020, exercises were numbered sequentially from 1 to 4, prefixed with the last two digits of the year and 'RCG', e.g. 20RCG2, 20RCG3.

Samples are labelled with the exercise code, the issue date, the sample identifier and the storage temperature.

Details included

Details of samples provided and specific instructions for completion are included.
There is no clinical context associated with the DAT exercises, unless otherwise indicated in the instructions for a specific exercise.

Level of participation

UK participants are expected to participate in all four exercises.

Stability and Homogeneity

Review of results submitted throughout the pilot scheme demonstrated that the material is stable for the duration of the exercise, i.e. a minimum of 2 weeks post distribution.

Testing

Participants are requested to test the samples to the same degree as a similar clinical sample in the given clinical scenario, and to report the genotype and predicted phenotype in ISBT terminology for D, Cc, Ee, MN, Ss, Kk, Fy^a, Fy^b, Fy, Jk^a, Jk^b, Do^a and Do^b.

Recording and submitting of results

Data entry of results is via the UK NEQAS Haematology and Transfusion website www.ukneqasbtlp.org, the options for reporting genotype and predicted phenotype on the data entry page are presented in ISBT terminology. An option to report 'other' is provided for use only if is not be possible to select an option in ISBT terminology that represents the result obtained. If the result would be reported to clinicians in different terminology, this can be specified in a supplementary question in each section.

A link to a table with ISBT terminology for common alleles is provided in the instructions which will available online. Assessment is by comparison of each participant's result vs. the consensus result for each allele. In the event of there not being clear consensus on a result, this will be investigated before reporting, and participants' results reviewed in light of any further information. Once the scheme transitions form a pilot scheme to a full scheme (planned for June 2020), scoring and performance monitoring will be applied. Reports include assessment of individual results, an indication of overall results for the exercise and a discussion.

Assigned values

The participants' consensus result is used as the 'expected' result for scoring purposes. Where variant results are reported, the expected result is reviewed and the sample may be withdrawn from scoring after further investigation and on the advice of the RCG SAG.

Reports

Each participant receives an individual, confidential report showing their laboratory's results and the overall results for the current exercise. Individual current and cumulative scores are displayed to demonstrate trends in performance. These reports are posted to the web within 40 working days of the closing date.

An example of report is shown in Appendix 8.

Supplementary reports or information may also be distributed at a later date, with further analysis and discussion.

Assessment and penalty scoring

Scores will be allocated as shown in Table 6.

Table 6 – Scoring for RCG exercises

Error	Possible causes (apart from data entry)	Score
Genotype and predicted phenotype incorrect but matching each other	Testing	60
Genotype incorrect only (including GATA zygosity)	Testing	60
Phenotype incorrect only	Interpretation	60
D zygosity error	Testing or interpretation (minor impact)	30
Genotype and predicted phenotype incorrect but not matching each other	Testing and interpretation	120

Dropdown responses provided in ISBT terminology. Selection of the 'Other' option is considered incorrect unless there is no consensus, or the laboratory has undertaken additional testing and reported something deemed appropriate by the RCG Scheme Advisor / SAG.

There is cumulative scoring with points accumulating over a rolling window of the most recent six samples (three exercises), where results have been returned and samples have been scored.

Performance monitoring (UK laboratories only)

Definition of unsatisfactory performance (UP)
A cumulative score of ≥100 in any category, including non-return.

Definition of persistent unsatisfactory performance (PUP)
More than one episode of UP in any category during a rolling 12 month period.

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, often leading to transfusion of inappropriate blood components or products, and are considered to be equally important as serological or interpretation errors. However, more detailed analysis in any technical report supplements usually excludes these errors, so as not to mask any trends in performance of techniques or reagents.

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 individual performance, e.g. contamination of specimen by the participant, analysis of incorrect specimen, or results incorrectly communicated to UK NEQAS BTLP.

Follow-up of Unsatisfactory Performance (UP) and Persistent Unsatisfactory Performance (PUP) – UK only

Unsatisfactory performers in the UK may be contacted in writing by the Scheme Director, in which case the consultant or equivalent is the point of contact, with the laboratory contact receiving a copy of any such correspondence. Persistent unsatisfactory performance, defined as more than one episode of unsatisfactory performance in a 12 month period, for any test or combination of tests, is reported to the NQAAP for Haematology on a quarterly basis.

UK laboratories identified as PUPs are contacted by the Scheme in writing. Participants are usually requested to complete a 'Corrective and Preventive Action' (CAPA) form, giving details of their investigation, implications for clinical practice and corrective actions. These should be returned to the Scheme to aid effective performance monitoring. PUPs are also reported to the National Quality Assurance Advisory Panel for Haematology on an annual basis using a 'traffic light' system as required by the QAPC. Where a laboratory's performance gives particular cause for concern, PUP may be notified to NQAAP in an additional ad-hoc report at the discretion of the Scheme Director.

UK laboratories identified as UPs are contacted in writing at the discretion of the Scheme Director.

Appendix 1 – UI 'Rules'

Acceptance of a result of UI for antibody identification

This process should only be used where antibodies of likely clinical significance cannot be fully elucidated or excluded. N.B. UK NEQAS BTLP Pre-transfusion testing (PTT) samples do not contain more than two specificities, so if you have positively identified two specificities please do not make an UI submission. ***The following rules will apply:***

a. the following will incur penalties

- Misinterpretations contributed to by false negative or false positive reactions.
- If a specificity (actually present) is not entered as positively identified and we feel that it can be identified based on two positive and two negative reactions (as stated in BSH guidelines) by whatever method is appropriate (e.g. IAT, OR enzymes in the case of Rh). This will be based on a maximum of 2 antibodies being present. (N.B: Serological reactions obtained with the antibody screening cells should be included in the interpretation).
- If a specificity not actually present is entered as positively identified.
- If a specificity is entered as 'cannot be excluded', but we feel that it can be excluded, either because of one or more negative reactions with an appropriate antigen positive cell, or because of one or more negative reactions by a particular method. For example, stating that an Rh antibody cannot be excluded from an antibody mixture in the presence of a negative result with an enzyme treated cell carrying the corresponding antigen would incur a penalty.
- If a specificity is entered as 'cannot be excluded', but the patient phenotype provided shows that the patient is positive for the corresponding antigen.
- If a clinically significant antibody is not identified in the presence of an enzyme non-specific antibody.

b. the following will not incur penalties

- Being unable to exclude a specificity in line with BSH guidelines, e.g. having no apparent homozygous cell available to exclude anti-Jk^{a}.
- Including a specificity (if actually present) even if the inclusion does not comply with BSH guidelines (e.g. only one r'r cell).
- If an antibody (actually present) is reacting with homozygous but not with heterozygous cells, and is recorded as 'cannot be excluded' rather than as 'positively identified'. However, this would only apply if our in-house testing also found non-reactivity with heterozygous cells by the same technique; otherwise, this would be classed as a false negative result.

c. the following documentation is required for a UI submission to be considered

- UI should be selected in addition to any antibody that can be positively identified, following interactive instructions on the web data entry page.
- Details of any clinically significant antibodies that cannot be positively identified, but cannot be excluded must be provided, together with a full explanation of why identification cannot be confirmed.
- Scanned copies of all antibody ID and screening panel sheets showing the reactions recorded should be uploaded via the website. If it is not possible to upload documents, page 2 of the UI submission form on the website can be used, but only by prior arrangement with the Scheme.

If supporting paperwork is not submitted, only the antibodies recorded as positively identified will be considered for performance monitoring purposes.

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Summary of exercise material & your performance

SUMMARY OF EXERCISE MATERIAL

Patient 1 - O D positive, C+c+E+e+ (R1R2) K+, inert
Patient 2 - A D negative, C-c+E-e+ (rr) K-, anti-E titre 2 vs. r''r cells
Patient 3 - B D positive, C+c+E-e+ (R1r) K-, inert
Titres obtained by tube LISS suspension in the UK NEQAS laboratory on the closing date

Donor W - O D negative, E- e+
Donor Y - O D negative, E+ e+
Donor Z - O D negative, E+ e+

Definition of Penalty Scores

0 to 79	Satisfactory
80 to 99	Borderline
100 to 150	Unsatisfactory

Your Performance Summary :		**Penalty Score this exercise**	**Cumulative Penalty Score**	**Cumulative Performance**
Non-Return penalty		0	0	
Late-Return penalty		0	0	
Return cumulative score			0	Satisfactory
ABO	No Errors	0	0	Satisfactory
RhD	No Errors	0	0	Satisfactory
Antibody Screen	No Errors	0	0	Satisfactory
Antibody Identification	No Errors	0	0	Satisfactory
Phenotyping	No Errors	0	0	Satisfactory
Crossmatch	No Errors	0	0	Satisfactory

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For information on data analysis and performance assessment see the UK NEQAS (BTLP) Participants' Manual (www.ukneqasbtlp.org)

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UK NEQAS
Haematology and Transfusion

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ABO and RhD Grouping	

SUMMARY OF EXERCISE MATERIAL

Patient 1 - O D positive
Patient 2 - A D negative
Patient 3 - B D positive

Your results in bold
Expected results are shaded

Patient 1

Your Result :	**O D Positive**		**Your Score = 0**
Overall Results :	O D Positive	100.00% n=(380)	

Patient 2

Your Result :	**A D Negative**		**Your Score = 0**
Overall Results :	A D Negative	100.00% n=(380)	

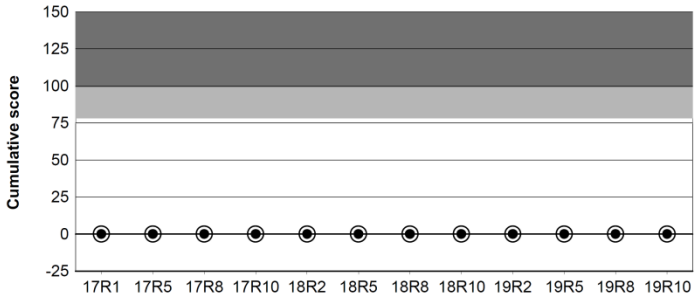
Patient 3

Your Result :	**B D Positive**		**Your Score = 0**
Overall Results :	B D Positive	99.74% n=(379)	
	A D Positive	0.26% n=(1)	

Your overall score for this exercise :	**ABO**	**0**
	RhD	**0**

Your last 3 returns contribute to the cumulative scores ● Cumulative Score ○ Distribution Penalty X Non Return

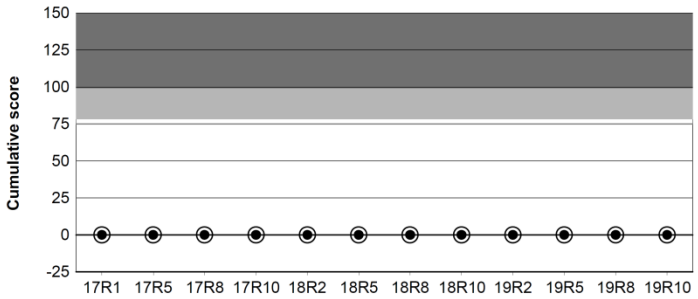
ABO Derived penalty score



Current Performance : Satisfactory
Cumulative Score : 0

Unsatisfactory
Borderline
Satisfactory

RhD Derived penalty score



Current Performance : Satisfactory
Cumulative Score : 0

Unsatisfactory
Borderline
Satisfactory

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Antibody Screening and Identification

SUMMARY OF EXERCISE MATERIAL

Patient 1 - Inert
Patient 2 - Anti-E
Patient 3 - Inert

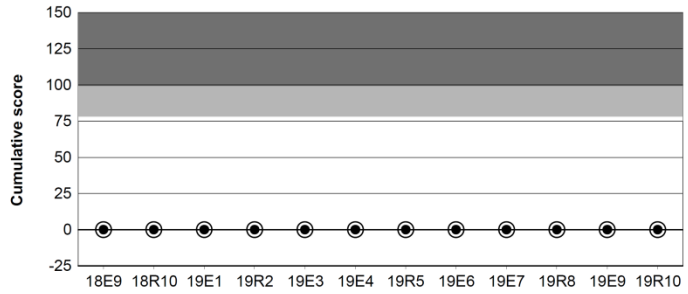
Your results in bold
Expected results are shaded

	Antibody Screen		Antibody Identification	
Patient 1				
Your Result :	**No specific antibody detected** Your Score = 0			
Overall Results :	No specific antibody detected	100.00% n=(375)		
Patient 2				
Your Result :	**Antibody present** Your Score = 0		**E** Your Score = 0	
Overall Results :	Antibody present	99.73% n=(374)	E	99.72% n=(350)
	No specific antibody detected	0.27% n=(1)	E, K	0.28% n=(1)
Patient 3				
Your Result :	**No specific antibody detected** Your Score = 0			
Overall Results :	No specific antibody detected	100.00% n=(375)		

Your overall score for this exercise :	**Antibody Screening**	**0**
	Antibody Identification	**0**

Your last 3 returns contribute to the cumulative scores ● Cumulative Score O Distribution Penalty X Non Return

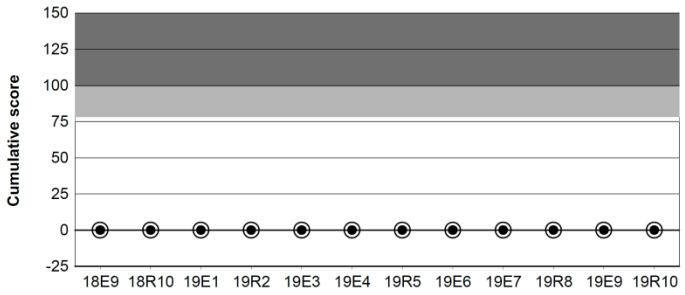
Antibody screen derived penalty score



Current Performance : Satisfactory
Cumulative Score : 0

Unsatisfactory
Borderline
Satisfactory

Antibody identification derived penalty score



Current Performance : Satisfactory
Cumulative Score : 0

Unsatisfactory
Borderline
Satisfactory

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UK NEQAS
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Crossmatching summary	

SUMMARY OF EXERCISE MATERIAL

Patient 1 - O D positive, inert
Patient 2 - A D negative, anti-E
Patient 3 - B D positive, inert
Donor W - O D negative, E- e+
Donor Y - O D negative, E+ e+
Donor Z - O D negative, E+ e+

Your results in bold

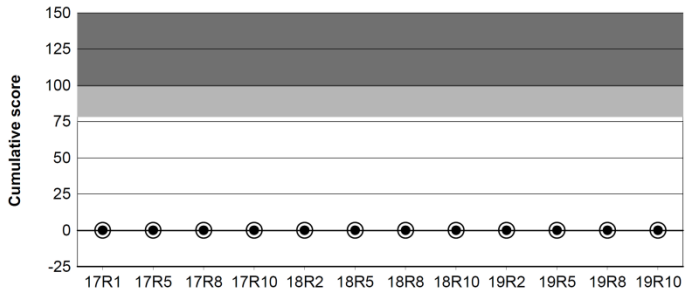
Expected results are shaded

	Donor W	Donor Y	Donor Z
Patient 1			
Your Result :	**C**	**C**	**C** **Your Score = 0**
Overall Results :	C 100.0% n=(371)	C 100.0% n=(371)	C 100.0% n=(371)
Patient 2			
Your Result :	**C**	**I**	**I** **Your Score = 0**
Overall Results :	C 98.9% n=(367)	I 99.5% n=(369)	I 99.5% n=(368)
	I 1.1% n=(4)	C 0.5% n=(2)	C 0.5% n=(2)
Patient 3			
Your Result :	**C**	**C**	**C** **Your Score = 0**
Overall Results :	C 99.7% n=(370)	C 99.7% n=(370)	C 99.5% n=(369)
	I 0.3% n=(1)	I 0.3% n=(1)	I 0.5% n=(2)

Your overall score for this exercise : **X-match total score** **0**

Your last 3 returns contribute to the cumulative scores ● Cumulative Score ○ Distribution Penalty **X** Non Return

X-match total score



Current Performance : Satisfactory
Cumulative Score : 0

Unsatisfactory
Borderline
Satisfactory

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Laboratory: xxxxx

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Phenotyping summary

SUMMARY OF EXERCISE MATERIAL
Patient 1 - C+c+E+e+ (R1R2) K+
Patient 2 - C-c+E-e+ (rr) K-
Patient 3 - C+c+E-e+ (R1r) K-

Your results in bold
Expected results are shaded

Patient 1

Your Result :	C+	c+	E+	e+	K+	Rh Interpretation :	R1R2		Your Score = 0
Overall Results :	C+	c+	E+	e+	K+		R1R2	92.06%	n=(255)
	C+	c+	E+	e+	K+			6.14%	n=(17)
	C+	c+	E+	e+	K-			1.08%	n=(3)
	C+	c+	E+	e+	K+		Other	0.36%	n=(1)
	C+	c+	E+	e+	K+		R1R1	0.36%	n=(1)

Patient 2

Your Result :	C-	c+	E-	e+	K-	Rh Interpretation :	rr		Your Score = 0
Overall Results :	C-	c+	E-	e+	K-		rr	91.73%	n=(255)
	C-	c+	E-	e+	K-			6.83%	n=(19)
	C-	c+	E+	e-	K-			0.36%	n=(1)
	C-	c+	E+	e-	K-		rr	0.36%	n=(1)
	C-	c+	E-	e+	K-		Other	0.36%	n=(1)
	C-	c+	E-	e+	K-		R0	0.36%	n=(1)

Patient 3

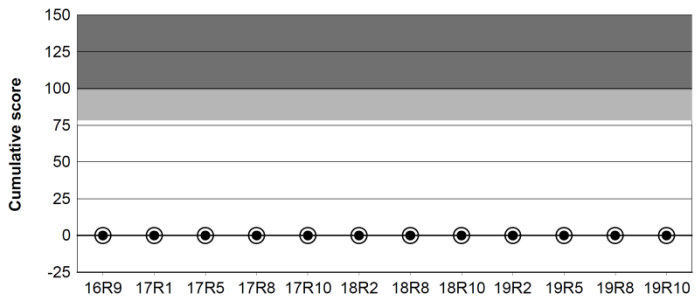
Your Result :	C+	c+	E-	e+	K-	Rh Interpretation :	R1r		Your Score = 0
Overall Results :	C+	c+	E-	e+	K-		R1r	90.61%	n=(251)
	C+	c+	E-	e+	K-			7.22%	n=(20)
	C+	c+	E-	e+	K+		R1r	0.72%	n=(2)
	C+	c+	E-	e+	K-		r'r	0.36%	n=(1)
	C+	c+	E-	e+	K-		R1R1	0.36%	n=(1)
	C+	c+	E-	e-	K-		R1r	0.36%	n=(1)
	C+	c-	E+	e+	K-		Other	0.36%	n=(1)

Your overall score for this exercise : Serological Phenotyping 0

Your last 3 returns contribute to the cumulative scores

● Cumulative Score ○ Distribution Penalty

Phenotyping derived penalty score



Current Performance : Satisfactory
Cumulative Score : 0

Unsatisfactory
Borderline
Satisfactory

Printed at 14:35 on Thursday, 12 December, 2019 (Final Report)

For information on data analysis and performance assessment see the UK NEQAS (BTLP) Participants' Manual (www.ukneqasbtlp.org)
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UK NEQAS Haematology and Transfusion	BTLP (For UK and ROI)	Page 1 of 1
	Distribution: 19R10 Date: 18 November 2019	
Supplementary report		

MAIN AIMS OF THE EXERCISE

1. Detection of incompatibility due to an Rh antibody
2. Detection and identification of a weak antibody
3. Introduction of Rh and K phenotyping on patient samples

RETURN RATE - 380/383 (99.2%) laboratories returned results by the closing date.

SAMPLE QUALITY

Satisfactory sample quality was reported by all participants for all patient plasma samples, and by >99% of participants for patient whole blood and donor samples.

EXERCISE FORMAT

This was the first exercise to include Rh (C, c, E, e) and K phenotyping on the patient whole blood samples. This has been introduced to allow effective assessment of the most common phenotyping undertaken in the majority of UK laboratories. For those laboratories wishing to be assessed for phenotyping of other antigens, the Extended Red Cell Phenotyping (ERP) Pilot Scheme is available and covers C, c, E, e, K, k, M, N, S, s, Fy^a, Fy^b, Jk^a, and Jk^b typing.

ABO/D TYPING

One laboratory reported Patient 3 (B positive) as A positive due to a data entry error.

ANTIBODY SCREENING

One laboratory did not detect the anti-E in Patient 2 as a result of testing the patient whole blood samples intended for ABO/D typing and Rh and K phenotyping only, in place of the patient plasma samples.

ANTIBODY IDENTIFICATION

All laboratories undertaking antibody identification identified the anti-E in Patient 2. One laboratory reported a second specificity, anti-K, which was not present.

COMPATIBILITY TESTING

Six laboratories made a total of 12 errors in compatibility testing. Two laboratories appear to have made transposition errors during testing or reporting; one transposing Donors W and Y, and the other transposing Patients 2 and 3 vs. Donor Z. One laboratory obtained the correct serological test results but deselected four compatible donors based on a misunderstanding of the exercise instructions. One laboratory, with two errors, recorded all donors as compatible with all patients, possibly as a result of using the patient whole blood samples for crossmatching. The final two laboratories recorded Donor W (E-) as incompatible vs. Patient 2 (anti-E).

PHENOTYPING

Eight laboratories recorded a total of seven false negative reactions and five false positive reactions, leading to a total of nine incorrect sets of reactions. Of these, five laboratories record an incorrect K type, and four recorded one or more incorrect Rh reactions. Two sets of incorrect Rh phenotype results were assigned the expected Rh interpretation (i.e. rr for Patient 2 and R_1r for Patient 3), so it is possible that incorrect reactions were recorded due to data entry error. 258/278 (92.8%) laboratories recorded an Rh interpretation for one or all of the patients and four made an incorrect interpretation based on their result pattern; two of these did not take into account the D type of the patient when making the interpretation. An Rh interpretation of 'other' was reported by one laboratory for each patient. Rh interpretation is not a scored element of the exercise.

DISCUSSION

To reduce the potential for procedural errors, checks are required at critical points in the pre-transfusion process, e.g. sample labelling, performing and interpreting manual tests and transcribing information. When performing crossmatching, testing only one patient at a time will reduce the chances of transposition / transcription errors both in EQA and in clinical practice.

In a UK NEQAS survey of UK and ROI laboratories in 2017, 74% of laboratories responding indicated that they used Rh shorthand notation in one or more of three different circumstances, i.e. in conversation with blood transfusion staff, for blood ordering, or recording on the laboratory information management system. It is essential that the D type is taken into account when making this interpretation.

Report for exercise 19R8 emergency testing enclosed.

Appendix 3 – FMH acid elution screen and quantification report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 1 of 3
	Performance Summary	

Your registration: Screening and Quantification by Acid Elution

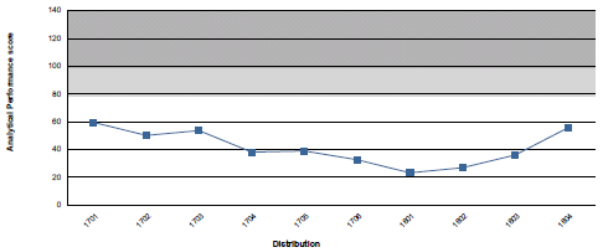
Performance Summary:	Score this exercise	Cumulative Score	Cumulative Performance
Non-return penalty	0	0	
Late return penalty	0	0	
Participation score	0	0	Satisfactory
Accuracy of quantification	19.9	55.7	Satisfactory
Outlying quantification result	0	0	Satisfactory
Potential for sensitisation	0	0	Satisfactory

Accuracy of quantification

Definition of performance scores

Satisfactory: 0 - 79
Borderline: 80 - 99
Unsatisfactory Performance:
≥100 for the first time in 12 months
≥100 where this is falling

For definitions of Persistent Unsatisfactory Performance (PUP), refer to the Participants' Manual.



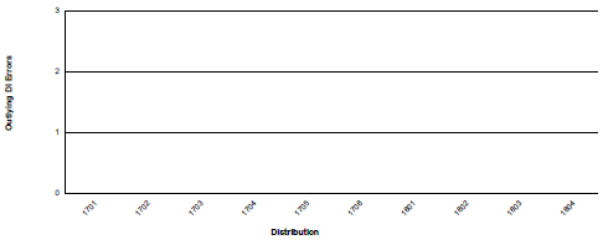
Cumulative analytical performance score: 55.7

Outlying quantification results (DI outside the range -2 to +3.5)

Patient 1: Not scored
Patient 2: Within range

Outlying results this exercise: 0
Cumulative outlying results: 0

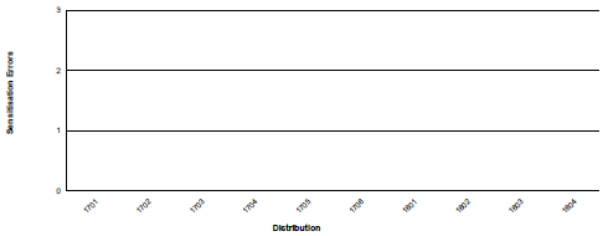
For definitions of Unsatisfactory Performance (UP), and Persistent Unsatisfactory Performance (PUP), refer to the Participants' Manual.



Clinical Significance: Potential for sensitisation

'Potential for sensitisation' errors this exercise
Screening: 0
Quantification: 0

For definitions of Unsatisfactory Performance (UP), and Persistent Unsatisfactory Performance (PUP), refer to the Participants' Manual.



Comments

Aims: To assess practice when FMH results are close to critical points with respect to doses of anti-D Ig commonly used in the UK (1500IU) and close to the trigger point for referral for quantification by flow cytometry according to UK (BSH) guidelines.
Removal from scoring: The specimen for Patient 1 was prepared to simulate an FMH of <4mL and has been excluded from performance monitoring for testing by acid elution. It was discovered that the cord donation used in the preparation of Patient 1 is a probable D variant; this may have affected the results for flow cytometry users and a supplementary report relating to this will follow.
Results: Although Patient 1 was non-scoring, it is interesting to note that three laboratories (all UK) stated that quantification would not have been triggered in line with BSH recommendations for an FMH ≥2mL.
Four non-UK laboratories made a 'potential for sensitisation' error for Patient 2.
Discussion: This was the second exercise after the redesign of the scheme. If you have any comments on any aspect of the scheme, please let us know by emailing BTLP@UKNEQAS.ORG.UK.

Printed at 15:35 on Monday, 16 July, 2018 (Final Report)

For information on data analysis and performance assessment see the UK NEQAS (BTLP) Participants' Manual (www.ukneqasbtlp.org)
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Authorised by: Ms J White (Scheme Manager)

Appendix 3 – FMH acid elution screen and quantification report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 2 of 3
	Results: 1804F Patient 1	

Summary of material

A mixture of D negative adult whole blood and D positive cord cells to simulate a post-delivery FMH specimen.

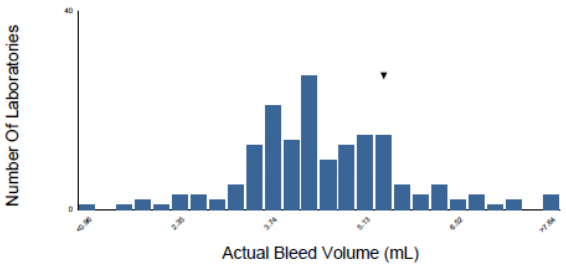
Sample Quality

You Reported: Satisfactory sample quality

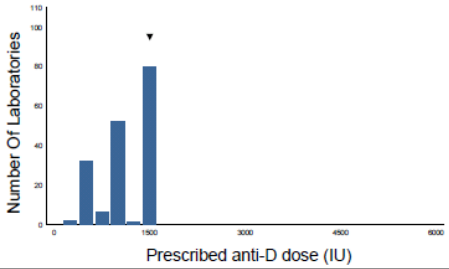
Overall: 97.7% Satisfactory

Overall quantification results by acid elution

Number registered	180
Number of results analysed	170
Return Rate	94.4%
Method median (mL)	4.3
Uncertainty of method median (mL)	0.11
I.Q.Range (mL)	3.6 - 5.1
Estimated SD	1.1
Minimum reported (mL)	0.0
Maximum reported (mL)	29.4



Overall D dosing results



Median dose	1000
Reported Range	
Minimum	0
Maximum	1500
Number	170

* Based on BSH guidance
** Where no quantification is triggered, performance is based on whether or not the initial anti-D dose covers the flow cytometry method median.

Your Results

Screening (Method: Acid Elution - ClinTech)

Result		Expected result
Fetal cells seen	Yes	Yes
Quantification triggered	Yes	Yes *

Quantification (Method: Acid Elution - ClinTech)

Result		Your accuracy performance	
FMH Quantification (mL)	5.3	% Difference from method median	23.3
Reported FMH	5.3	Deviation Index (DI)	Not applicable

Clinical Significance - based on flow cytometry method median of 2.6mL

Result		Expected result
Prescribed anti-D dose (IU)	1500	Not scored *
Referral for flow cytometry	Yes	Not scored
Repeat sample requested	Yes	Not scored

Your Performance**: Not scored

Comments

Performance monitoring:
This sample was not scored as the bleed volume was <4mL.

Further information to follow in a supplementary report.

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Appendix 3 – FMH acid elution screen and quantification report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 3 of 3
	Results: 1804F Patient 2	

Summary of material

A mixture of D negative adult whole blood and D positive cord cells to simulate a post-delivery FMH specimen.

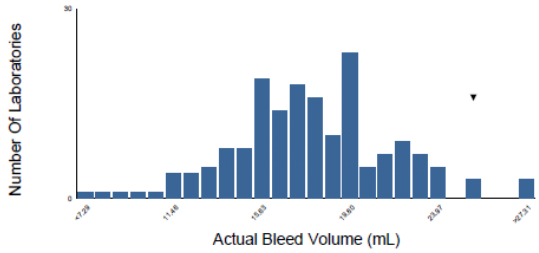
Sample Quality

You Reported: Satisfactory sample quality

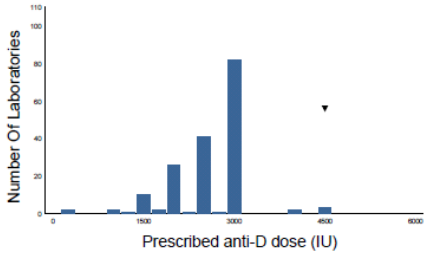
Overall: 99.0% Satisfactory

Overall quantification results by acid elution

Number registered	180
Number of results analysed	173
Return Rate	96.1%
Method median (mL)	17.3
Uncertainty of method median (mL)	0.32
I.Q.Range (mL)	15.2 - 19.7
Estimated SD	3.3
Minimum reported (mL)	0.0
Maximum reported (mL)	202.0



Overall D dosing results



Median dose	3000
Reported Range	
Minimum	0
Maximum	4500
Number	173

* Based on BSH guidance
** Where no quantification is triggered, performance is based on whether or not the initial anti-D dose covers the flow cytometry method median.

Your Results

Screening (Method: Acid Elution - ClinTech)

Result		Expected result
Fetal cells seen	Yes	Yes
Quantification triggered	Yes	Yes *

Quantification (Method: Acid Elution - ClinTech)

Result		Your accuracy performance	
FMH Quantification (mL)	25.6	% Difference from method median	48.0
Reported FMH	25.6	Deviation Index (DI)	2.49

Clinical Significance - based on flow cytometry method median of 14.9mL

Result		Expected result
Prescribed anti-D dose (IU)	4500	>=1863 IU *
Referral for flow cytometry	Yes	Not applicable
Repeat sample requested	Yes	Not applicable

Your Performance**: Patient not at risk of sensitisation if followed up according to BSH guidelines

Comments

Performance monitoring:
Eight outlying results were returned; five were due to underestimation and three to overestimation.

Results:
Excluding results from two non-UK laboratories, one reporting 0mL for both samples, and one with an overestimation of 200mL, the range for this sample was 7.5 - 32.4mL.

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Authorised by: Ms J White (Scheme Manager)

Appendix 4 – FMH acid elution screen report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 1 of 2
	Performance Summary	

Your registration: Screening by Acid Elution

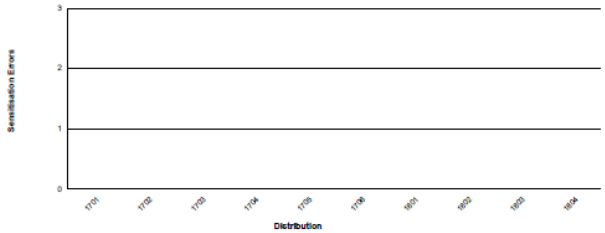
Performance Summary:	Score this exercise	Cumulative Score	Cumulative Performance
Non-return penalty	0	0	
Late return penalty	0	0	
Participation score	0	0	Satisfactory
Potential for sensitisation	0	0	Satisfactory

Clinical Significance: Potential for sensitisation

'Potential for sensitisation' errors this exercise

Screening: 0

For definitions of Unsatisfactory Performance (UP), and Persistent Unsatisfactory Performance (PUP), refer to the Participants' Manual.



Comments

Aims:
To assess practice when FMH results are close to critical points with respect to doses of anti-D Ig commonly used in the UK (1500IU) and close to the trigger point for referral for quantification by flow cytometry according to UK (BSH) guidelines.

Summary of Material:
Specimens for Patients 1 and 2 each comprised a mixture of D negative adult whole blood and D positive cord cells to simulate post-delivery FMH specimens.

Removal from scoring:
The specimen for Patient 1 was prepared to simulate an FMH of <4mL and has been excluded from performance monitoring for testing by acid elution. It was discovered that the cord donation used in the preparation of Patient 1 is a probable D variant; this may have affected the results for flow cytometry users and a supplementary report relating to this will follow.

Return Rate:
Results were returned by 52/54 (96.3%) participants.

Results:
Although Patient 1 was non-scoring, it is interesting to note that all laboratories stated that fetal cells were seen, and 51/53 (96.2%) would have triggered quantification in line with BSH recommendations for an FMH ≥2mL.

All participants observed fetal cells in Patient 2 and would have referred the sample for quantification.

Discussion:
This was the second exercise after the redesign of the scheme. If you have any comments on any aspect of the scheme, please let us know by emailing BTLP@UKNEQAS.ORG.UK.

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Appendix 4 – FMH acid elution screen report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 2 of 2
	Results: 1804F	

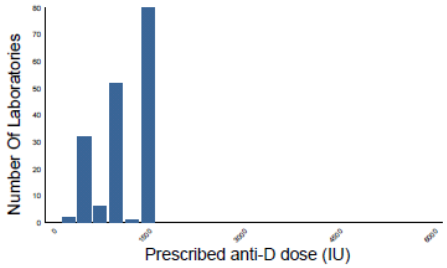
Your Method: Acid Elution - ClinTech

Sample Quality (SQ)

Sample	Your reported SQ	% Satisfactory SQ overall
Patient 1:	Satisfactory	97.7%
Patient 2:	Satisfactory	99.0%

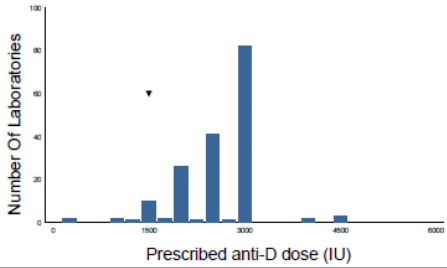
Patient 1 - Flow cytometry median = 2.6mL (minimum anti-D dose required = 325iu)

	Your result	Expected result
Fetal cells seen:	Yes	Yes
Quantification triggered:	Yes	Yes *
Your Initial anti-D dose:	1500	
Your Performance:	**Not scored ****	



Patient 2 - Flow cytometry median = 14.9mL (minimum anti-D dose required = 1863iu)

	Your result	Expected result
Fetal cells seen:	Yes	Yes
Quantification triggered:	Yes	Yes *
Your Initial anti-D dose:	1500	
Your Performance:	**Satisfactory ****	



* Based on BSH guidance

** Where no quantification is triggered, performance is based on whether or not the initial anti-D dose covers the flow cytometry method median.

Comments

None for this exercise.

Printed at 15:34 on Monday, 16 July, 2018 (Final Report)

For information on data analysis and performance assessment see the UK NEQAS (BTLP) Participants' Manual (www.ukneqasbtlp.org)
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Authorised by: Ms J White (Scheme Manager)

Appendix 5 – FMH flow cytometry report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 1 of 3
	Performance Summary	

Your registration: Screening and Quantification by Flow Cytometry

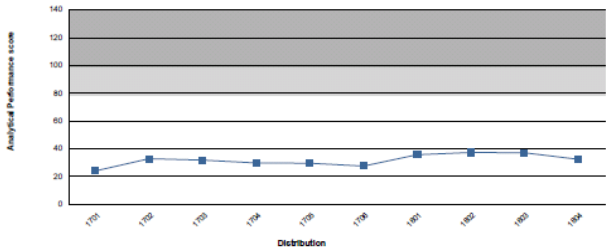
Performance Summary:	Score this exercise	Cumulative Score	Cumulative Performance
Non-return penalty	0	0	
Late return penalty	0	0	
Participation score	0	0	Satisfactory
Accuracy of quantification	2.1	32.4	Satisfactory
Potential for sensitisation	0	0	Satisfactory

Accuracy of quantification

Definition of performance scores

Satisfactory: *0 - 79*
Borderline: *80 - 99*
Unsatisfactory Performance:
≥100 for the first time in 12 months
≥100 where this is falling

For definitions of Persistent Unsatisfactory Performance (PUP), refer to the Participants' Manual.

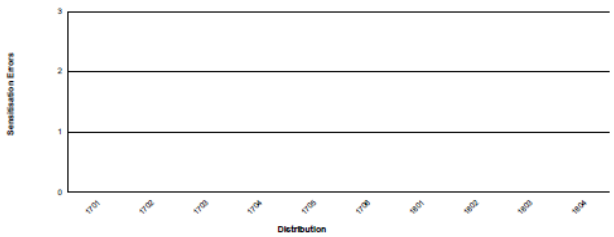


Cumulative analytical performance score: 32.4

Clinical Significance: Potential for sensitisation

'Potential for sensitisation' errors this exercise
Screening: 0

For definitions of Unsatisfactory Performance (UP), and Persistent Unsatisfactory Performance (PUP), refer to the Participants' Manual.



Comments

Aims:
To assess practice when FMH results are close to critical points with respect to doses of anti-D Ig commonly used in the UK (1500IU) and close to the trigger point for referral for quantification by flow cytometry according to UK (BSH) guidelines.

Removal from scoring:
The specimen for Patient 1 was prepared to simulate an FMH of <4mL. After preparing the material, further testing (at IBGRL) revealed that the cord donation used for Patient 1 is a probable D variant. This may have affected the results for those using an anti-D marker by flow cytometry, and for this reason Patient 1 has been withdrawn from scoring for all participants.

A supplementary report will follow detailing the investigation and findings together with potential clinical implications.

Users of anti-D markers will be sent a short additional questionnaire to investigate testing algorithms for Patient 1.

Discussion:
This was the second exercise after the redesign of the scheme. If you have any comments on any aspect of the scheme, please let us know by emailing BTLP@UKNEQAS.ORG.UK.

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For information on data analysis and performance assessment see the UK NEQAS (BTLP) Participants' Manual (www.ukneqasbtlp.org)
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FAX: 0192 321 7934 Phone: 0192 321 7933
Authorised by: Ms J White (Scheme Manager)

Appendix 5 – FMH flow cytometry report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 2 of 3
	Results: 1804F Patient 1	

Summary of material

A mixture of D negative adult whole blood and D positive cord cells to simulate a post-delivery FMH specimen.

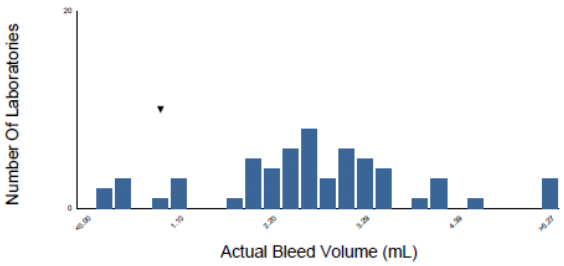
Sample Quality

You Reported: Satisfactory sample quality

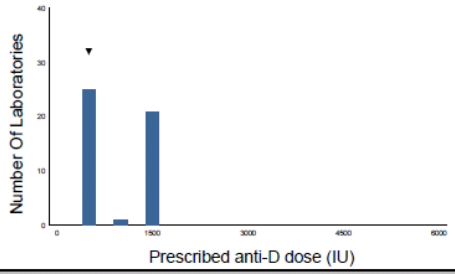
Overall: 97.7% Satisfactory

Overall quantification results by flow cytometry

Number registered	64
Number of results analysed	59
Return Rate	92.2%
Method median (mL)	2.6
Uncertainty of method median (mL)	0.14
I.Q.Range (mL)	1.9 - 3.1
Estimated SD	0.9
Minimum reported (mL)	0.0
Maximum reported (mL)	17.6



Overall D dosing results



Median dose	500
Reported Range	
Minimum	500
Maximum	1500
Number	47

* Based on BSH guidance
** Where no quantification is triggered, performance is based on whether or not the initial anti-D dose covers the flow cytometry method median.

Your Results

Screening (Method: Flow Cytometry - Becton Dickinson/FACS Canto II/BRAD 3 FITC Anti-D)

Result		Expected result
Quantification triggered	Yes	Yes *

Quantification (Method: Flow Cytometry - Becton Dickinson/FACS Canto II/BRAD 3 FITC Anti-D)

Result		Your accuracy performance	
FMH Quantification (mL)	0.7	% Difference from method median	-73.1
Reported FMH	0.7	Deviation Index (DI)	Not applicable
% Fetal Cells	0.03		

Clinical Significance - based on flow cytometry method median of 2.6mL

Result		Expected result
Prescribed anti-D dose (IU)	500	Not scored *
Repeat sample requested	Yes	Not scored

Your Performance**: Not scored

Comments

The method median was 2.5mL, (range 0 - 5.3 mL) for users of an anti-D marker, and 2.85mL (range 1.8 - 17.6mL) for users of non-anti-D markers.

The cord used to prepare this sample is a probable D variant and we would suggest that participants using an anti-D marker review their original results in light of this information. Further information will follow in a supplementary report.

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For information on data analysis and performance assessment see the UK NEQAS (BTLP) Participants' Manual (www.ukneqasbtlp.org)
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Appendix 5 – FMH flow cytometry report

UK NEQAS Haematology and Transfusion	Feto-Maternal Haemorrhage	Laboratory:
	Distribution: 1804F Date: 03 Jul 2018	Page 3 of 3
	Results: 1804F Patient 2	

Summary of material

A mixture of D negative adult whole blood and D positive cord cells to simulate a post-delivery FMH specimen.

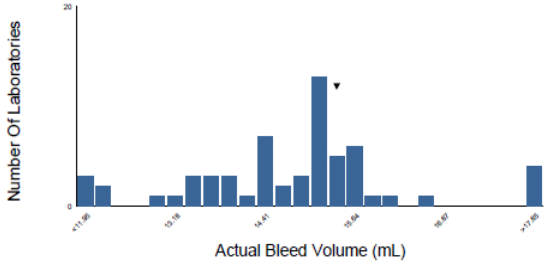
Sample Quality

You Reported: Satisfactory sample quality

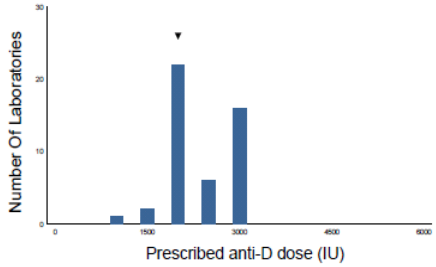
Overall: 99.0% Satisfactory

Overall quantification results by flow cytometry

Number registered	64
Number of results analysed	60
Return Rate	93.8%
Method median (mL)	14.9
Uncertainty of method median (mL)	0.16
I.Q.Range (mL)	13.9 - 15.2
Estimated SD	1.0
Minimum reported (mL)	7.3
Maximum reported (mL)	34.3



Overall D dosing results



Median dose	2000
Reported Range	
Minimum	1000
Maximum	3000
Number	47

* Based on BSH guidance
** Where no quantification is triggered, performance is based on whether or not the initial anti-D dose covers the flow cytometry method median.

Your Results

Screening (Method: Flow Cytometry - Becton Dickinson/FACS Canto II/BRAD 3 FITC Anti-D)

Result		Expected result
Quantification triggered	Yes	Yes *

Quantification (Method: Flow Cytometry - Becton Dickinson/FACS Canto II/BRAD 3 FITC Anti-D)

Result		Your accuracy performance	
FMH Quantification (mL)	15.2	% Difference from method median	2.0
Reported FMH	15.2	Deviation Index (DI)	0.31
% Fetal Cells	0.69		

Clinical Significance - based on flow cytometry method median of 14.9mL

Result		Expected result
Prescribed anti-D dose (IU)	2000	>=1863 IU *
Repeat sample requested	Yes	Not applicable

Your Performance**: Patient not at risk of sensitisation if followed up according to BSH guidelines

Comments

The method median was 14.9mL, (range 11.7 - 16.5mL) for users of an anti-D marker, and 14.3mL (range 7.3 - 34.3mL) for users of non-anti-D markers.

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Appendix 6 – ABO Titration Report

UK NEQAS Haematology and Transfusion	ABO Titration Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920ABOT1 Date: 29-04-2019	

Introduction

This was the first exercise in the 2019-20 cycle of the ABOT scheme. Participants were requested to titrate anti-A in three plasma samples against the A_1 red cells provided. The titrations were to be undertaken with routine methods and techniques (using those for assessing patient suitability for ABO incompatible living organ transplantation where appropriate to clinical practice), and also using a standard DiaMed technique provided, where the required resources were available.

Scores are presented on page 5 of this report along with the basis for scoring.

Material

The following material was provided:

• Samples for Patients 1, 2 and 3, prepared from filtered fresh frozen plasma (Patient 1 and Patient 3 group O, and Patient 2 group B).

• One group A_1 red cell sample for titration.

Standard DiaMed techniques for DRT and IAT were provided with the exercise instructions (see Appendix 1), and these are referred to as 'standard' techniques in this report.

Return rate / data analysis

The exercise was distributed to 99 laboratories, 38 in the UK and Republic of Ireland (ROI) and 61 outside of the UK. Results were returned by 94/99 (94.9%) laboratories by the closing date.

ABO titration is undertaken to support ABO incompatible transplant programmes in 73/93 (78.5%) laboratories answering the question; of these 46 support ABO incompatible renal transplant programmes.

Results obtained using the 'standard' technique(s) for DRT and/or IAT were returned by 73/94 (77.7%) laboratories. Thirty nine of these also returned results for an in-house DRT and/or IAT method. Twenty one laboratories returned results for in-house methods only.

Not all laboratories tested by both IAT and DRT – the numbers of results analysed for each method are shown in Table 1.

All participants recorded satisfactory sample quality for all plasma samples.

Graphical representations of the distribution of results for DRT standard and IAT standard are shown on pages 2 and 3.

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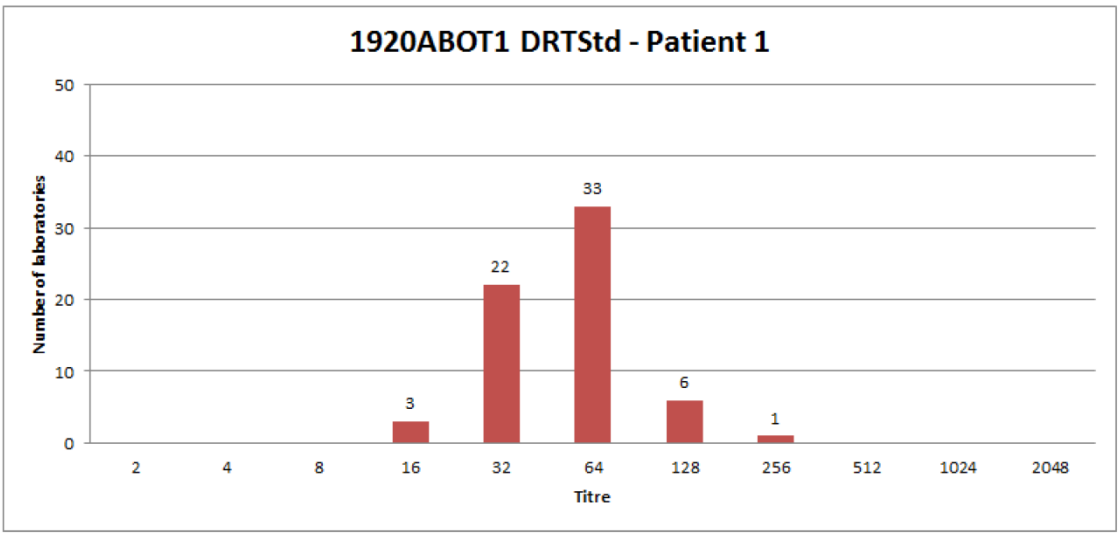
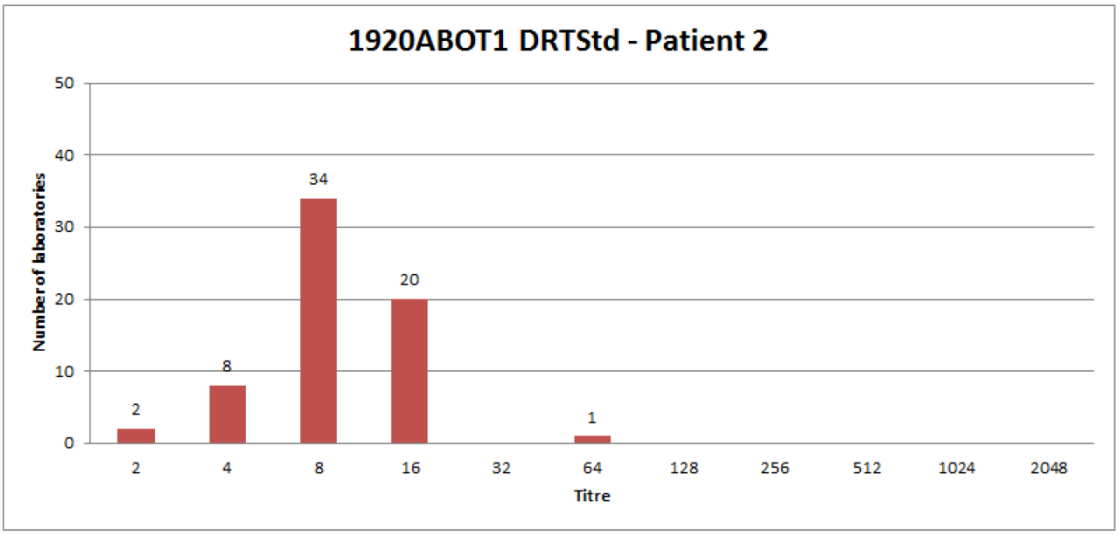
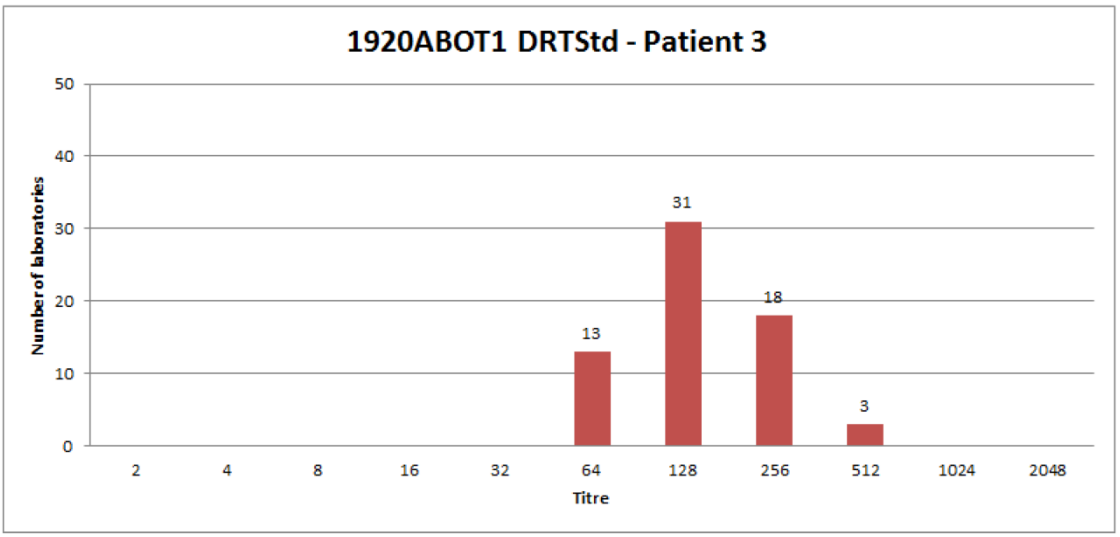
Appendix 6 – ABO Titration Report

UK NEQAS Haematology and Transfusion	ABO Titration Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920ABOT1 Date: 29-04-2019	







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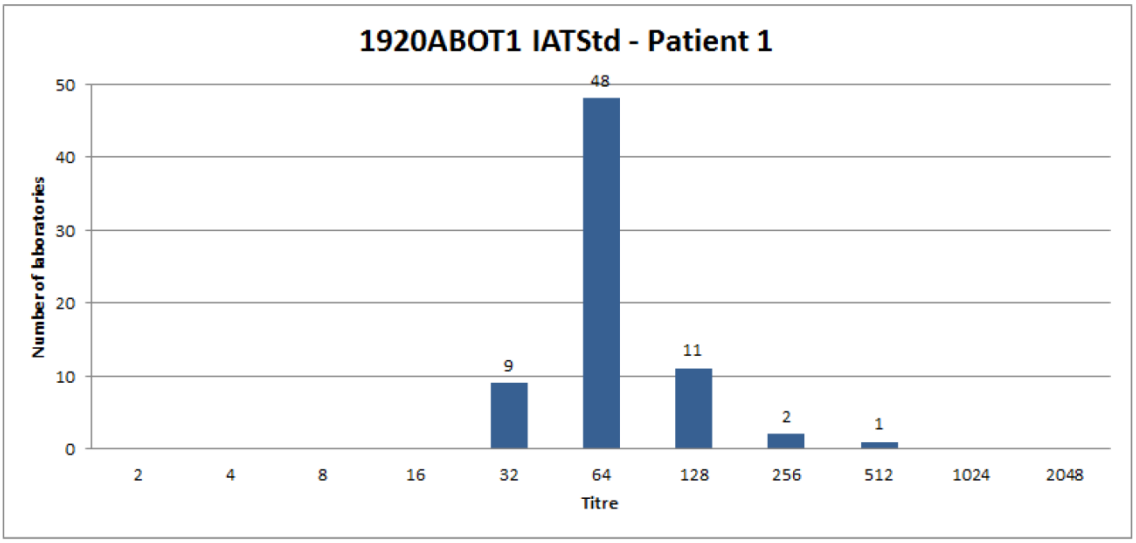
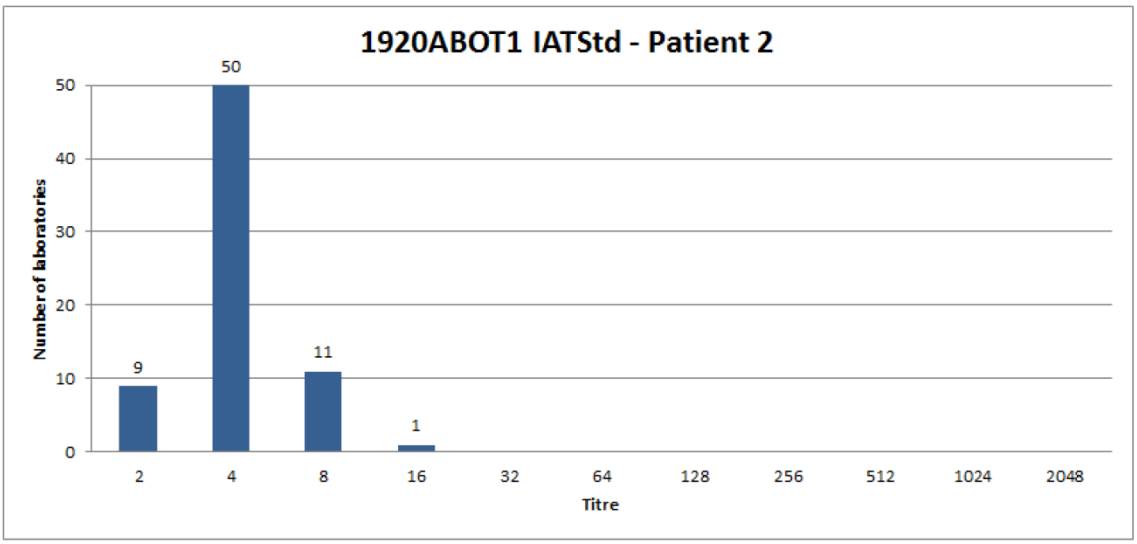
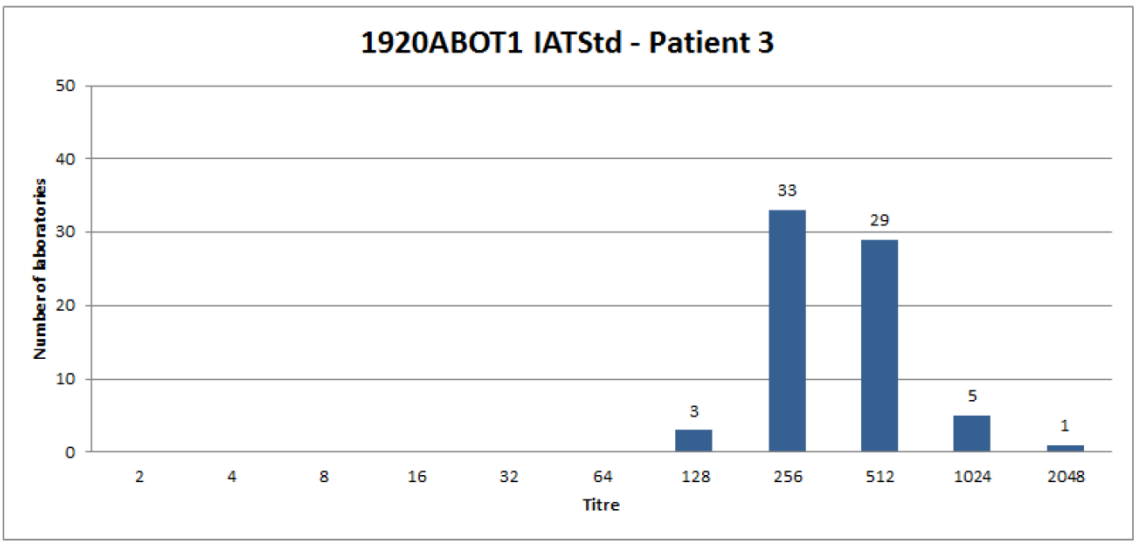
Appendix 6 – ABO Titration Report

UK NEQAS Haematology and Transfusion	ABO Titration Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920ABOT1 Date: 29-04-2019	







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Appendix 6 – ABO Titration Report

UK NEQAS Haematology and Transfusion	ABO Titration Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920ABOT1 Date: 29-04-2019	

Titration results

Table 1 shows the method median titration results by DRT, IAT using untreated plasma and IAT using pre-treated plasma, and Table 2 shows your results.

Table 1 - Titration median result and range, by method and technology

Technique	Titration result (range)					
	Patient1 number of results	Patient1 median (range)	Patient2 number of results	Patient2 median (range)	Patient3 number of results	Patient3 median (range)
DRT Standard	65	64 (16-256)	65	8 (2-64)	65	128 (64-512)
DRT In-house DiaMed	11	32 (16-64)	11	4 (2-16)	11	64 (32-256)
DRT In-house BioVue	9	32 (16-64)	9	4 (2-8)	9	128 (32-256)
DRT In-house Grifols	4	32 (32-64)	4	8 (4-8)	4	128 (64-256)
DRT In-house Tube	19	32 (8-128)	19	8 (2-32)	19	64 (4-128)
DRT In-house Immucor	6	8 (8-16)	6	4 (4-8)	6	16 (16-32)
IAT Standard	71	64 (32-512)	71	4 (2-16)	71	256 (128-2048)
IAT In-house (untreated) DiaMed	4	160 (64-512)	4	4 (4-8)	4	384 (128-1024)
IAT In-house (untreated) BioVue	8	128 (64-256)	8	6 (4-32)	8	512 (256-2048)
IAT In-house (untreated) Grifols	4	64 (32-128)	4	4 (4-4)	4	256 (128-512)
IAT In-house (untreated) Tube	10	64 (8-256)	10	8 (2-16)	10	512 (64-1024)
IAT In-house (untreated) Immucor	6	32 (16-64)	6	2 (1-2)	6	256 (64-256)
IAT In-house DTT Treated (or equivalent) DiaMed	11	32 (16-64)	11	2 (0-2)	11	256 (128-512)
IAT In-house DTT Treated (or equivalent) BioVue	1	128 (128-128)	1	4 (4-4)	1	512 (512-512)
IAT In-house DTT Treated (or equivalent) Grifols	1	16 (-)	0	0 (-)	1	128 (-)
IAT In-house DTT Treated (or equivalent) Tube	4	24 (0-64)	4	0 (0-4)	4	160 (32-256)

Table 2 - Your results (PRN xxxxx)

Technique	Titration Result		
	Patient1 (Anti-A)	Patient2 (Anti-A)	Patient3 (Anti-A)
DRT Standard	32	8	64
IAT Standard	32	4	256

UK NEQAS Haematology and Transfusion	ABO Titration Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920ABOT1 Date: 29-04-2019	

Scoring for ABO titration

Categories of testing scored

Difference from median result for results obtained by:

1. Standard IAT
2. Standard DRT
3. Any other in-house technology with >20 laboratories testing by IAT or DRT

Definition of satisfactory results

Titration value within 1 doubling dilution of 'target', i.e. method median.

'Scores' for 'outlying' results

- One point for each doubling dilution >1 away from 'target', e.g. if the target were 32, then one point would be incurred for results of 8 or 128, two points for 4 or 256, three points for 2 or 512 etc.
- Points will be accumulated within each category, within each exercise
- Points will be accumulated between exercises, also by category

Table 3 - Your scores (PRN xxxxx)

Technique	Score for this exercise[1]	Performance this exercise	Cumulative score[2]	Cumulative performance
DRT Standard	0	Satisfactory	0	Satisfactory
IAT Standard	0	Satisfactory	0	Satisfactory

[1]includes all three current samples
[2]includes nine most recent samples where results were returned (including the current samples)

Table 4 - Non-return scores (PRN xxxxx)

Non-return score for this exercise	Cumulative non-return score[1]	Your performace
0	0	Satisfactory

[1]includes three most recent exercises

Performance Monitoring (UK Laboratories only)

Definition of unsatisfactory performance (UP)

- A total of three points within a category of testing in a single survey.
- A total of three points within a category of testing over three surveys (current and two previous for which results were returned).
- Non-return of results in two of the three most recent surveys.

Definition of persistent unsatisfactory performance (PUP)

- More than one episode of unsatisfactory performance in any category of testing, within 12 months.
- Two episodes of UP due to non-return of results in a 12 month period.
- One episode of UP from each of the above within a 12 month period.

UK NEQAS Haematology and Transfusion	ABO Titration Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920ABOT1 Date: 29-04-2019	

Appendix 1

'Standard' techniques 1920ABOT1

- Prepare dilutions of plasma in saline (PBS or NaCl) using a doubling dilution method. Make the dilutions with a minimum volume of 200µl, using an automatic pipette. Use a new tip to dispense each dilution.
- Prepare a 0.8 - 1% red cell suspension in CellStab (use ID-diluent 2 if CellStab is not available).
- Read the endpoint of the titration as the last weak reaction.

LISS indirect antiglobulin test (**IAT**) using IgG or polyspecific cards

a. Add 50ul of cells suspended in CellStab or ID-diluent 2 to each microtube
b. Add 25ul of each plasma dilution to the corresponding microtube
c. Incubate at 37oC for 15'
d. Centrifuge 10' in DiaMed centrifuge

Direct agglugtination at room temperature (**DRT**) using NaCl cards

a. Add 50ul of cells suspended in CellStab or ID-diluent 2 to each microtube
b. Add 50ul of each plasma dilution to the corresponding microtube
c. Incubate at RT for 15'
d. Centrifuge 10' in DiaMed centrifuge

UK NEQAS
Haematology and Transfusion

Direct Antiglobulin Test (DAT) Pilot
Blood Transfusion Laboratory Practice

Laboratory: xxxxx

Distribution: 20DAT4 **Date: 16-11-2020**

Introduction

Two red cell samples (in Alsever's solution) were provided for testing.

- Patient 1 was coated with IgG (3+ reaction obtained in-house by BioRad technology at closing day testing)
- Patient 2 was coated with complement (2+ reaction obtained in-house by BioRad technology at closing day testing)

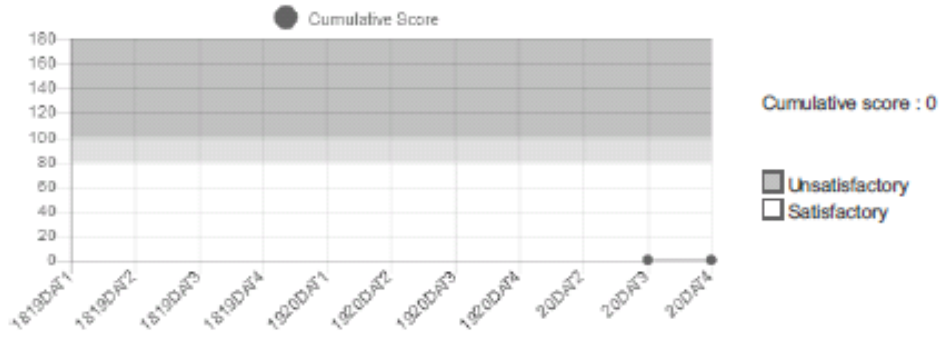
This exercise is the first one to include performance scores for the DAT scheme. The cumulative scores includes a score for any errors made in the last exercise (20DAT3) as well as the current exercise. Non-return scores do not include those for 20DAT3.

Definition of Penalty Scores

0-99	Satisfactory
100-150	Unsatisfactory

Your Performance Summary :	Penalty Score this exercise	Cumulative Penalty Score	Cumulative Performance
Non-Return Penalty	0	0	Satisfactory
DAT	0	0	Satisfactory

Your last 3 returns contribute to the cumulative scores



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UK NEQAS Haematology and Transfusion	Direct Antiglobulin Test (DAT) Pilot Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 20DAT4 Date: 16-11-2020	

Return rate / data analysis

The exercise was distributed to 385 laboratories, 297 in the UK and Republic of Ireland (ROI) and 88 outside of the UK. Results were returned by 340/385 (88.3%) laboratories by the closing date.

Sample quality

335/340 (98.5%) participating laboratories reported satisfactory sample quality for both samples. Five (1.5%) recorded unsatisfactory sample quality for one or both samples, with four citing haemolysis and one citing an insufficient cell concentration. Four of these laboratories were able to return results for at least one sample.

Results of testing

Patient 1 (DAT 3+ positive vs. anti-IgG)

309/339 (91.2%) laboratories reported Patient 1 as either 'Positive' (33) or 'Positive - IgG only' (276). Nine of these laboratories recorded a positive reaction vs. the manufacturer's internal control well, with four also recording a weak false positive reaction vs. anti-C3d. Six of the laboratories reporting Patient 1 as 'Positive', recorded a positive reaction vs. anti-IgG and a negative reaction in the manufacturer's internal control, but did not specify the coating molecule.

Thirteen laboratories reported Patient 1 as 'Positive - IgG & C3d'; all of these recorded a false positive reaction vs. anti-C3d, with one laboratory also recording a positive reaction in the manufacturer's internal control well, and one not recording a reaction vs. a control

Seventeen laboratories reported Patient 1 as 'uninterpretable', with ten of these citing a positive reaction in the manufacturer's internal control, and seven citing a 'mixed-field' reaction vs. one or more reagents used.

Patient 2 (DAT 2+ positive vs. anti-C3d)

302/339 (89.1%) laboratories reported Patient 2 as either 'Positive' (28) or 'Positive - C3d only' (274); five laboratories reporting an interpretation of 'Positive' recorded false positive reactions vs. anti-IgG and did not record a result vs. anti-C3d.

Two laboratories reported Patient 2 as 'Positive - IgG only'; one of these recorded a false positive reaction vs. anti-IgG and did not return a reaction grade vs. anti-C3d, and the other, presumably making a data entry error, recorded the expected reactions vs. anti-IgG and anti-C3d reagents.

Three laboratories reported Patient 2 as 'Positive - IgG & C3d', with all of these recording false positive reactions vs. anti-IgG and one laboratory also recording a weak positive reaction in the manufacturer's internal control.

Four laboratories reported Patient 2 as 'Negative', with three of these only testing vs. an anti-IgG reagent, and the remaining laboratory presumably making a data entry error, recording expected reactions vs. anti-IgG and anti-C3d reagents.

Twenty-seven laboratories reported the result as 'uninterpretable', with all of these citing a positive reaction in the manufacturer's internal control.

Appendix 7 – DAT Report

Discussion

Data analysis for this exercise has not been linked to the technology used to perform the testing. This is due to an internal incident in which the questionnaire used to gather testing information was not included on the data entry website.

To reduce the potential for procedural errors, checks are required at critical points in the pre-transfusion process, e.g. sample labelling, performing and interpreting manual tests and transcribing information.

When 'mixed-field' reactions are observed in antigen typing, an interpretation of blood group cannot be made without obtaining further clinical information (e.g. transfusion history). In the case of direct antiglobulin testing (DAT), a 'mixed-field' result can indicate a dual cell population with some cells coated with antibody (and / or complement) while some are not; in these cases the result may still be interpreted as DAT positive as some of the circulating red cells are coated with a molecule of interest. Genuine mixed-field DAT results may be seen in cases of antibody mediated transfusion reactions or during the formation of a new red cell antibody following a recent transfusion; clinical and transfusion history will be needed to ascertain the cause. Occasionally weaker reactions in column agglutination technology may appear as 'mixed-field' where cells located diffusely throughout the column may not be clearly seen; regardless of the pattern of positivity observed, an interpretation of "DAT positive" is appropriate.

Appendix 7 – DAT Report

UK NEQAS Haematology and Transfusion	Direct Antiglobulin Test (DAT) Pilot Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 20DAT4 Date: 16-11-2020	

Your results for Patient 1

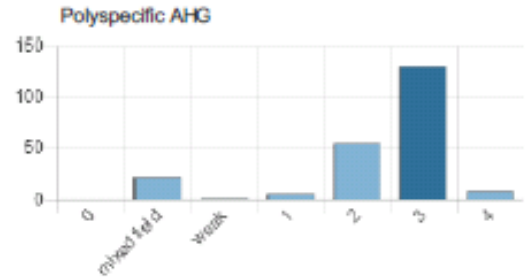
Reaction grade vs.	Your Result
Polyspecific AHG	3+
Anti-IgG	3+
Anti-C3d	Negative
Reagent control	Negative

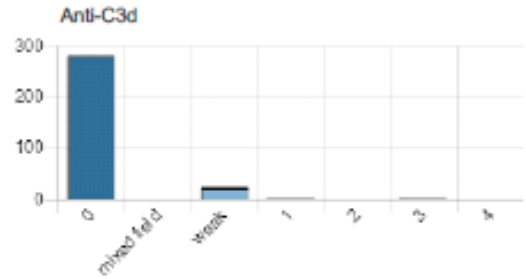
Interpretation

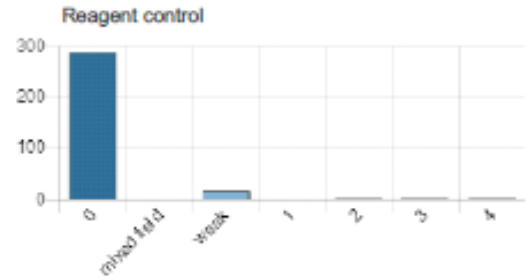
Reported reaction	Positive IgG only

Overall data - interpretation for Patient 1

Interpretation	Count	Percentage
Positive IgG + C3d	13	3.83%
Positive IgG only	276	81.42%
Positive C3d only	0	0%
Positive	33	9.73%
Negative	0	0%
Uninterpretable	17	5.01%







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Appendix 7 – DAT Report

UK NEQAS Haematology and Transfusion	Direct Antiglobulin Test (DAT) Pilot Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 20DAT4 Date: 16-11-2020	

Your results for Patient 2

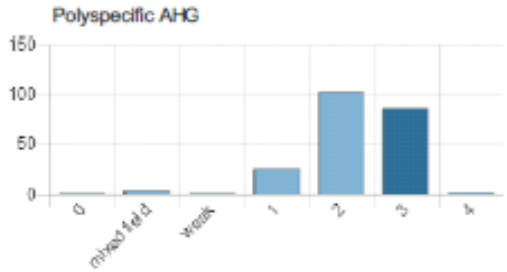
Reaction grade vs.	Your Result
Polyspecific AHG	3+
Anti-IgG	Negative
Anti-C3d	2+
Reagent control	Negative

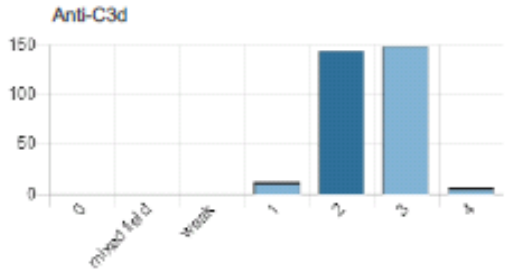
Interpretation

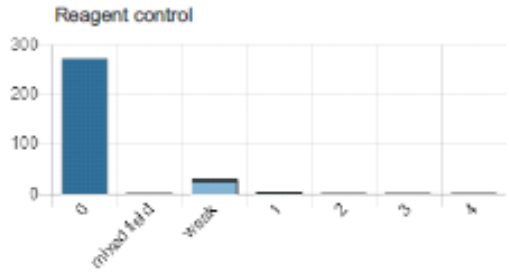
Reported reaction	Positive C3d only

Overall data - interpretation for Patient 2

Interpretation	Count	Percentage
Positive IgG + C3d	3	0.89%
Positive IgG only	2	0.59%
Positive C3d only	274	81.07%
Positive	28	8.28%
Negative	4	1.18%
Uninterpretable	27	7.99%







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UK NEQAS Haematology and Transfusion	Red Cell Genotyping Pilot Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920G2 Date: 09-09-2019	

Introduction

Two whole blood samples were provided, representing samples from haemoglobinopathy patients referred for genotyping to facilitate transfusion support. Laboratories were requested to undertake red cell genotyping in the same way as for a similar clinical sample, and report the method used, and the genotype and predicted phenotype for D, Cc, Ee, MN, Ss, Kk, Fy^a, Fy^b, Fy, Jk^a, Jk^b, Do^a and Do^b.

Return rate / data analysis

The exercise was distributed to 45 laboratories, 9 in the UK and Republic of Ireland (ROI) and 36 outside of the UK. Results were returned by 43/45 (95.6%) laboratories by the closing date.

42/43 (97.7%) laboratories reported satisfactory sample quality for both samples. One laboratory reported unsatisfactory sample quality for both Patients 1 and 2 citing poor DNA quality and low yield.

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Results of testing

Five laboratories returned results that were outwith consensus and these are highlighted in Table 1.

Table 1: Results outwith consensus

Laboratory	Patient sample	Reported genotype	Consensus genotype	Reported predicted phenotype	Consensus predicted phenotype
Lab A	1	Homozygous for GATA mutation (*FY*02N.01*)	GATA mutation not present	Fy(a-b+)	Fy(a-b+)
Lab B	2	*DO*01/02*	*DO*02/02*	Do(a+b+)	Do(a-b+)
Lab C	1	*RHD*01/01N.01*	*RHD*01/01*[1]	D positive	D positive
Lab D	2	*FY*02/02*	*FY*01/02*	Fy(a-b+)	Fy(a+b+)
Lab E	2	*FY*02/02*	*FY*01/02*	Fy(a-b+)	Fy(a+b+)

[1] Consensus of the 11 laboratories reporting *RHD* zygosity.

Questionnaire data from the 43 participating laboratories

1. How do your results routinely get transferred for reporting?

- 28 (67%) manual step (7 transcribe to a paper report and 21 to an IT system)
- 14 (33%) automatic transmission of results to IT
- 1 laboratory did not answer this question

2. How are genotyping results routinely translated to predicted phenotypes?

- 3 never report a predicted phenotype
- 16/40 (40%) by the testing platform software
- 7/40 (18%) using another IT programme
- 17/40 (42%) manually

31/43 (72%) include a manual step in either transfer of results or translation of genotype to predicted phenotype.

3. Which platforms were used to test this exercise?

A single platform was used to test this exercise by 36/43 (84%) laboratories whilst seven used two or more platforms to report results on this occasion.

Table 2 shows the numbers using each platform, both as a single test and in combination with another platform.

Table 2: Platforms used to test exercise 1920G2

Platforms used	Single	In combo	Total
BA Gene	3	1	4
HEA Beadchip +/- *RHD* Beadchip	3	2	5
Inno-Train Fluogene	10	2	12
Inno-Train ReadyGene	8	3	11
Progenika IDCORE XT	8	2	10
In-house	4	4	8

Results outwith consensus (highlighted in Table 1)

Discussion

Laboratory A reported a homozygous GATA mutation *(FY*02N.01)* for Patient 1, most probably due to data entry error since the consensus predicted phenotype (Fy(a-b+)) was reported. Three laboratories (B, D and E) reported results where both the genotype and predicted phenotype were incorrect but consistent with each other; each made errors in a single blood group system for Patient 2.

Laboratory C made a *RHD* zygosity error, reporting *RHD*01/01N.01* where the consensus was of those reporting zygosity was *RHD*01/01*. Whilst the consensus predicted phenotype (D positive) was reported and there would be no clinical consequences in the scenario given in this exercise, errors in *RHD* zygosity testing are potentially significant in an antenatal setting.

Routine data handling in participating laboratories

Responses to the additional questions on the reporting of clinical results demonstrated that 67% of laboratories manually transcribe results either to an IT system or to paper reports and this is unchanged since last reported in 2017. 40% of those translating genotype to predicted phenotype do so without the use of IT (*cf.* 46% in 2017). Overall, 72% laboratories include a manual step in either transfer of results for reporting or translation of genotype to predicted phenotype. Whilst it is recognised that some of the errors seen in EQA might be due to procedural errors at some point up to and including data entry, there is potential for similar errors to occur in clinical practice where results are interpreted and transcribed manually.

Testing platforms used for EQA

Results for this exercise (in which no variants were identified) were obtained using a single platform in 84% of laboratories. It may be that more than one platform is required to test for all blood group systems in some laboratories, but EQA samples should be subject to the same degree of testing as would be applied to comparable clinical samples so that performance in EQA can reflect issues in clinical practice.

UK NEQAS Haematology and Transfusion	Red Cell Genotyping Pilot Blood Transfusion Laboratory Practice	Laboratory: xxxxx
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Your results for Patient 1

Result(s) outwith consensus? : No

Your results for Patient 1, compared to consensus results

Consensus results		Antigens	Your results				
Genotype	Predicted phenotype[1]		Genotype	Specify 'other' genotype	Predicted phenotype	Specify 'other' phenotype	Other terminology reported to clinicians
*RHD*01* (zygosity not determined)	D positive	D	*RHD*01/01*		D positive		
*RHCE*C/C*	C+ c-	CcEe	*RHCE*C/C*		C+ c-		
*RHCE*e/e*	E- e+	CcEe	*RHCE*e/e*		E- e+		
*GYPA*02/02*	M- N+	MN	*GYPA*02/02*		M- N+		
*GYPB*04/04*	S- s+	Ss	*GYPB*04/04*		S- s+		
*KEL*02/02*	K- k+	Kk	*KEL*02/02*		K- k+		
*FY*02/02* GATA mutation not present	Fy(a-b+)	Fy^a Fy^b Fy	*FY*02/02* GATA mutation not present		Fy(a-b+)		
*JK*01/02*	Jk(a+b+)	Jk^a Jk^b	*JK*01/02*		Jk(a+b+)		
*DO*01/02*	Do(a+b+)	Do^a Do^b	*DO*01/02*		Do(a+b+)		

[1]The consensus of those testing for zygosity (n=11) was *RHD*01/01*

UK NEQAS Haematology and Transfusion	Red Cell Genotyping Pilot Blood Transfusion Laboratory Practice	Laboratory: xxxxx
	Distribution: 1920G2 Date: 09-09-2019	

Your results for Patient 2

Result(s) outwith consensus? : Yes - shaded results correspond to results outwith the consensus result

Your results for Patient 2, compared to consensus results

Consensus results		Antigens	Your results				
Genotype	Predicted phenotype[1]		Genotype	Specify 'other' genotype	Predicted phenotype	Specify 'other' phenotype	Other terminology reported to clinicians
*RHD*01N.01/01N.01*	D negative	D	*RHD*01N.01/01N.01*		D negative		
*RHCE*C/c*	C+ c+	CcEe	*RHCE*C/c*		C+ c+		
*RHCE*e/e*	E- e+	CcEe	*RHCE*e/e*		E- e+		
*GYPA*01/01*	M+ N-	MN	*GYPA*01/01*		M+ N-		
*GYPB*03/04*	S+ s+	Ss	*GYPB*03/04*		S+ s+		
*KEL*02/02*	K- k+	Kk	*KEL*02/02*		K- k+		
*FY*01/02* GATA mutation not present	Fy(a+b+)	Fy^a Fy^b Fy	*FY*02/02* GATA mutation not present		Fy(a-b+)		
*JK*02/02*	Jk(a-b+)	Jk^a Jk^b	*JK*02/02*		Jk(a-b+)		
*DO*02/02*	Do(a-b+)	Do^a Do^b	*DO*02/02*		Do(a-b+)		