<table>
<thead>
<tr>
<th>CONTENTS</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequently Asked Questions</td>
<td>1 - 2</td>
</tr>
<tr>
<td>UK NEQAS Charity</td>
<td>3</td>
</tr>
<tr>
<td>General Organisation and oversight of the Scheme</td>
<td>4 - 6</td>
</tr>
<tr>
<td>Location</td>
<td>4</td>
</tr>
<tr>
<td>Scheme Personnel</td>
<td>4</td>
</tr>
<tr>
<td>Steering Committee</td>
<td>4</td>
</tr>
<tr>
<td>NQAAP &amp; JWG</td>
<td>4 - 5</td>
</tr>
<tr>
<td>Confidentiality</td>
<td>5</td>
</tr>
<tr>
<td>Accreditation</td>
<td>5</td>
</tr>
<tr>
<td>Data Security</td>
<td>5</td>
</tr>
<tr>
<td>Helpline</td>
<td>6</td>
</tr>
<tr>
<td>Complaints</td>
<td>6</td>
</tr>
<tr>
<td>Appeals</td>
<td>6</td>
</tr>
<tr>
<td>Aims of and Participation in the Scheme</td>
<td>7</td>
</tr>
<tr>
<td>Services provided</td>
<td>8</td>
</tr>
<tr>
<td>Registration</td>
<td>8 - 11</td>
</tr>
<tr>
<td>Eligibility for Participation</td>
<td>8</td>
</tr>
<tr>
<td>Cost of Participation</td>
<td>8 - 9</td>
</tr>
<tr>
<td>Participant Reference Number (PRN)</td>
<td>9</td>
</tr>
<tr>
<td>Completing the Registration Form</td>
<td>9 - 10</td>
</tr>
<tr>
<td>Changes to registration</td>
<td>10</td>
</tr>
<tr>
<td>Cancellation or suspension if participation</td>
<td>10</td>
</tr>
<tr>
<td>Certificates of registration</td>
<td>10</td>
</tr>
<tr>
<td>Distribution Agents</td>
<td>11</td>
</tr>
<tr>
<td>Source of Exercise Material</td>
<td>12</td>
</tr>
<tr>
<td>Despatch of Exercise Material and Time for Completion</td>
<td>12</td>
</tr>
</tbody>
</table>
Scope and Design of Exercises

BTLP (main scheme for pre-transfusion testing) 13 - 14
FMH 14 - 15
TACT 15

Stability and Homogeneity 16

Undertaking the Exercises and Submitting Results 17 – 21

General considerations 17
BTLP (main scheme for pre-transfusion testing) 17 – 20
FMH 21

Questionnaires 21

Late Results 22

Assigned Values 22

Penalty Scoring System 23 – 27

Non-technical errors 23
BTLP (main scheme for pre-transfusion testing) 23 – 25
FMH 25 - 27

Reports 28

Performance Monitoring 29 - 30

Appendices 31 - 45

1 - Conditions for Acceptance of UI for Antibody identification 31
2 - Example of BTLP report 32 - 37
3 - Example of FMH acid elution quantification report 38 - 40
4 - Example of FMH acid elution screen report 41 - 42
5 - Example of FMH flow cytometry report 43 - 45
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 website: http:\www.ukneqasbtlp.org

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 can still be analysed until the reports have been published on the web. However, a non-return report will be sent in the first instance and will be replaced by a late-return report a week later. Late results do attract 50 penalty points and the testing must have been performed on or before the closing date, as we cannot guarantee the integrity of the samples after the closing date. If in doubt, contact the Scheme.

Q: What do I do if the sample quality is unsatisfactory or if I break the samples?
A: Phone the Scheme on 01923 217933 to request a repeat sample. You will be asked for your PRN and the reason for your request.

Q: What do I do if I cannot find or have forgotten my ID or password?
A: Email the Scheme at btlp@ukneqas.org.uk. If you are not the main contact, your email request will need to be copied to the main contact, in order for us to release an ID or password.

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 for manual testing.

Q: Why does the graph show a penalty score when I did not make any errors in the BTLP 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: On the web result page, why is there no box for anti-Kp\(a\), anti-Lu\(a\) or anti-Cw\(a\) or in the ‘specificities that cannot be excluded’ section for antibody identification?
A: 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\(b\); you should not say that an antibody has been ‘positively identified’ if it is totally masked by another, as in this example. Again, using the example of anti-Jk\(b\), if one Jk(b-) cell gives a positive reaction, and the specificity cannot not be assigned using additional cells or techniques, a UI submission should be made (there is a separate form for this), which can include specifying that an antibody to a low frequency antigen cannot be excluded.

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

Q: Can I register both acid elution and flow cytometry techniques for FMH?
A: Yes you can. You will be given a second registration number (usually the same as your original number but with a letter as a suffix, e.g. 12345A) for the second method. If you screen by acid elution and quantify by flow cytometry, you will also need two registrations, which will need to be managed separately by the laboratory to avoid the flow cytometry results inadvertently influencing the screening results.
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: Dr Bill Egner
Company Secretary: Mrs Julie Gelder

UK NEQAS Office
PO Box 401
Sheffield
S5 7YZ, UK
Telephone: +44 (0)114 261 1689
FAX: +44 (0)114 261 1049
Email: office@ukneqas.org.uk
Web: www.ukneqas.org.uk

UK NEQAS Blood Transfusion Laboratory Practice 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.
GENERAL ORGANISATION AND OVERSIGHT OF THE SCHEMES

Location
UK NEQAS (BTLP) is hosted by the West Hertfordshire Hospitals NHS Trust and is based at Watford General Hospital, in a Unit shared with UK NEQAS (H)

Postal address: PO Box 133, Watford, WD18 0WP
Telephone: +44 (0) 1923 217933
Fax: +44 (0) 1923 217934
Email: btlp@ukneqas.org.uk
Web-site: www.ukneqasbtlp.org

Scheme Personnel
Director: Dr Megan Rowley
Manager/ Deputy Director: Mrs Clare Milkins
Deputy Manager: Ms Jenny White
Senior EQA scientist: Ms Claire Whitham
EQA Scientist: Mr Arnold Mavurayi
Business Manager: Mrs Pinky Bambhra
Office Manager: Ms May Wadhia
Executive Assistant: Ms Isabella De-Rosa
IT Manager: Mr Vasilis Rapanakis
Logistics Coordinator: Mr Stephen Herbert

Other administration and logistics support staff are employed jointly with UK NEQAS (H). 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 Clare Milkins.

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

Joint Working Group (JWG) and National Quality Assurance Advisory Panels (NQAAP)
Oversight of performance in EQA within the UK is the professional responsibility of the Joint Working Group on Quality Assessment (JWG), a committee of the Royal College of Pathologists (RCPath). The JWG 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 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 Joint Working Group works with laboratories with unresolved persistent unsatisfactory performance but is also bound to report this to the Care Quality Commission. The JWG has defined Conditions of EQA Scheme Participation, which can be found on the RCPPath website*.
UK NEQAS (BTLP) makes an annual report on scheme activities and performance of UK laboratories to the Panel 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.

* [https://www.ukneqasbtlp.org/external_links](https://www.ukneqasbtlp.org/external_links)

**Confidentiality**
Details of performance in the Scheme are confidential between the participating laboratory and the Scheme Director (and designated senior UK NEQAS staff). However, persistent unsatisfactory performance is reported to the NQAAP. If participating laboratories wish their results to be shared with, for example, a regional QA officer, this can be arranged, but only with written consent from the person designated as responsible for the laboratory’s performance. The fact and level of participation may be disclosed on request or published on the UK NEQAS website.

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

**Accreditation**
The main BTLP and FMH Schemes 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. Pilot schemes are not accredited. The legal entity is West Hertfordshire Hospitals NHS Trust.

**Data Security**
The Data Protection Act (1988) prevents the misuse of personal data held electronically and ensures that organisations holding such data conform to certain standards.

The West Hertfordshire Hospitals NHS trust is registered as a ‘data user’ under the terms of the Act. Information provided in the registration forms by participants is held in a database in order to identify those participants registered for each test and to generate address labels for the despatch of material, reports or letters. In addition, the results from an exercise are held (as non-personal data) in a database for analysis.

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

- Advice on any aspect of the Schemes may be sought from the Scheme Manager or Deputy Scheme Manager by telephone or in writing.
- Problems or enquiries relating to a specific exercise or exercise material may be directed to one of the senior 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 3.

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 Scheme Manager as appropriate to the nature of the complaint. 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 National Quality Assessment Advisory Panel (Haematology) or the Chair of the Joint Working Group (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 JWG: 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 Scheme 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 AND PARTICIPATION IN THE 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 FMH results are quantitative, blood group serology results 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 CPA (UK) Ltd and ISO15189 standards.
SERVICES PROVIDED

Until April 2016, the Scheme for Feto-Maternal Haemorrhage (FMH) was jointly managed by UK NEQAS (BTLP) and UK NEQAS (H). Following a strategic review of services, FMH has been fully incorporated into the BTLP services. Services currently provided by BTLP are:

- Blood Transfusion Laboratory Practice (main scheme for pre-transfusion testing)
- Feto-Maternal Haemorrhage
- Training Assessment and Competency Tool (TACT)

Pilot schemes
Before a scheme is recognised as a full 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 schemes offered:
- ABO Titration
- Direct Antiglobulin Test
- Red Cell Genotyping (from June 2016)

Please contact the Scheme Manager for more information on the current status of these pilots.

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 online. 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 of 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 8).
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 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 Transfusion schemes are assigned the same PRN, whilst performance data remains confidential within each scheme. Where more than one method is registered (e.g. FMH by acid elution and flow cytometry), the second method 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 JWG 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](https://www.ukneqasbtlp.org/external_links)

Changes to registered information
Alterations to your registered details, should be sent to us in writing, either by letter, fax or email, signed or sent by one of the named contacts, the head of the laboratory or laboratory manager. The facility will soon be available to make changes to some of your registered details yourself via the website.

We request that 3 weeks’ notice is given for changes to be effective for the next exercise.

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 of 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 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, including by email or fax.

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 Joint Working Group on Quality Assessment 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
A certificate of registration is available via our website or from the Scheme office, once payment has been received (this service will be available in the autumn 2016).
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. Web entry access details may be made available to a distribution agent responsible for the registration of a participant, with the participant’s permission. This is solely for the purpose of assisting the participant with access to the data entry and report web pages. The distribution agent is required to keep any known participants’ details and performance information confidential.
SOURCE OF EXERCISE MATERIAL

All red cells are obtained from NHS Blood and Transplant (NHSBT) from normal 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.

All materials are tested at source for HBsAg, HIV 1, HIV 2, HCV and 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
Participants receive schedules of the exercise despatch dates at registration or annual re-registration. These are also available to download from the website: https://www.ukneqasbtlp.org/documents.php

Any significant changes to the schedule are highlighted on the website and participants 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.

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 published with the instructions.
SCOPE AND DESIGN OF EXERCISES

BTLP (main scheme for pre-transfusion testing)

Purpose

To assess performance in undertaking standard pre-transfusion serological testing, and decision making with respect to selection of red cells for crossmatch or issue. More educational aspects are also sometimes included (though not scored), e.g. testing in an emergency situation, or selection of components for a range of patient types.

Tests assessed

- ABO grouping
- D grouping
- Antibody detection
- Antibody identification
- Crossmatching
- Red cell phenotyping

Scheme Design

- **Schedules and sample type**
  
a) 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, and DAT if relevant.
  - Three patient’ plasma samples for antibody screening, antibody identification and crossmatching.
  - Three ‘donor’ red cell samples for crossmatching and red cell phenotyping.

‘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, 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 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. 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.

b) 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). 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. 16R1, 16E2, refer to the first two exercises in 2016.

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.

---

**Feto-Maternal Haemorrhage**

**Purpose**

To assess the performance of clinical laboratories in screening and/or quantifying the size of a feto-maternal haemorrhage 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 (fetal cells seen and quantification triggered)
- Quantification of FMH in mL packed cells
  - by acid elution
  - by flow cytometry
- Dose of anti-D Ig suggested in combination with follow-up procedures (referral for 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. This is only applicable to those registered for acid elution.
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 prophylaxis. Bleed sizes vary and include 0mL bleeds. Exercises are distributed on a Tuesday, and close the following Tuesday (i.e. 7 days later).

  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. 1601F, 1602F, refer to the first two exercises in 2016.

  ‘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 both acid elution and/or flow cytometry, to reflect the testing undertaken in-house on clinical samples. Participants who register for quantification by acid elution, will automatically be registered for screening as well, and will be required to answer to questions relating to follow-up.

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 send any enquiries to tactsupport@ukneqasbtlp.org.uk.
STABILITY AND HOMOGENEITY

BTLP (main scheme for pre-transfusion testing)

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 subject to the postal system. The posted samples are tested in-house on receipt and on the closing date. Any significant deterioration in reaction grades by any technique results 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°C for 8 hours, followed by 30°C for up to 96 hours, with the remainder of the 14 days at 2-8°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.

Feto-Maternal Haemorrhage

The material is dispensed using a validated technique to ensure homogeneity throughout the process. Acid elution testing (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. In addition, the acid elution median results are plotted by date tested as an additional assessment of stability.

Flow cytometry 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.

Flow cytometry tests are repeated on the closing date on samples which have been subjected to the postal system. The flow cytometry results are used to evidence stability over the course of the exercise. Stability testing at different temperatures is in progress.

Samples which have not met the stability criteria are withdrawn from scoring for acid elution and/or flow cytometry as necessary.
UNDERTAKING EXERCISES AND SUBMITTING RESULTS

General Considerations

In keeping with the JWG 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 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.
  - BTLP samples should only be put through one analyser, unless more than one would be used for testing a similar clinical sample.
  - BTLP 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.
- ‘Patient’ samples should be assigned accession numbers and booked into the computer, and 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 spare material should also be kept until the report has been received in case repeat testing is necessary. If further material is required before results can be submitted, e.g. in the case of a difficult antibody mixture, this is available on request from UK NEQAS. FMH slides should be kept until after the report has been received, in case review is required.

BTLP (main scheme for pre-transfusion testing)

Testing

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

- **Antibody screening/Identification**
  Antibody screening should be undertaken on the separate plasma samples unless specified otherwise. 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 a 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**
  Even where no serological incompatibility exists, the ‘donors’ (labelled with the ABO and D type) will not be ABO/D identical to all three of the ‘patients’, as the latter are deliberately a mixture of ABO and D types, to allow assessment of ABO/D typing for a range of blood groups, and also to assess sample transposition errors. Participants are required to undertake crossmatching in these circumstances, e.g. D positive blood to a D negative recipient or group O to an AB recipient, so that serological crossmatching can be assessed, even though it may not be routine practice to choose to transfuse such units. Participants have the opportunity to record their laboratory policy by stating that although serologically compatible, the unit would not be selected for transfusion in clinical practice, although this element is not scored.

• **Red Cell Phenotyping**
  Red cell phenotyping should be undertaken on the ‘donor’ samples. It is recognised that in practice, hospital laboratories may phenotype patients’ cells but not necessarily donations, since the latter may have already been typed and labelled by the Blood Centre. However, the EQA whole blood samples are made from a pool of four or more donations, not matched for all antigens, and the resulting mixed field reactions make them unsuitable for phenotyping.

**Recording and submitting results**

• **Techniques**
  For every exercise, participants are asked to record the techniques used for each ‘patient’ sample. This allows participants who have more than one technique in routine use to select a different technique for each sample or from one exercise to the next. An individual sample should only be tested by one technique unless use of more than one reflects clinical practice; in this case all techniques 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 positive serological reactions as weak or strong positive, defined as follows:

  **Strong Positive:**
  Grade 3 or 4 for column agglutination technology and solid phase, as defined by the manufacturer.
  Grade 3 – 5 by tube technique, i.e. entire cell button dislodges in small or large clumps.
  A suitable equivalent for other techniques.

  **Weak Positive:**
  Any positive result not defined as strong.
• **Interpretation**
  All penalty scoring is based on the *interpretation* of the results as entered on the result form in each section, and completion of these sections is mandatory. The exception to this is for red cell phenotyping, where the recorded reactions are used for scoring. UK participants are telephoned for missing data, which must be supplied in writing (by fax or 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 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’. Bearing in mind that 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 a result of UI is returned, all identification and screening panel profiles must be submitted for assessment, with an explanation of the reason for the incomplete identification on a form that can be downloaded via a link on the web data entry page. 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 only on the antibodies that have been positively identified.

  b) **Rh 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 anti-G as it has no clinical relevance outside of the antenatal setting; the antibody mixture would therefore be reported by the Scheme as anti-C+D.
c) **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 go through a process of exclusion for antibodies to antigens of low frequency and/or of low clinical significance (when they are masked), with either EQA or clinical samples, 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\(^b\).

• **Crossmatching**

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

- a) Serological crossmatching.
- b) Theoretical *de-selection* of the ‘donor’ unit(s) for major ABO incompatibility, or for ‘patients’ with atypical antibodies following phenotyping of the donations.
- c) Theoretical *selection* as in electronic issue.

To indicate that a serological crossmatch has been performed, both the reaction grades and interpretations should be recorded. Where the unit has been selected/de-selected 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 electronic issue) will default to ‘compatible’; these defaults can be overridden by the participant if required.

Units may be ‘deselected’ in the following circumstances only:

- a) Major ABO *incompatibility*.
- b) Donation is antigen positive for an antibody positively identified in the plasma.
- c) 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, you would not issue it under laboratory policy. For example, you may wish to indicate that you would not transfuse a donation not typed for K, or transfuse a group O donation to a group AB patient. This does not affect the scoring, but may be analysed and reported where relevant to the exercise.
Feto-Maternal Haemorrhage

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 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 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.

Recording and submitting results
- The stated method details should be checked to ensure that they are correct, and these should be updated if necessary.
- 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 and for acid elution if calculated routinely.
- 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.
- Follow-up procedures (relevant to acid elution results only) should be completed as if the EQA sample were from a D negative woman having delivered a D positive baby.

QUESTIONNAIRES

Questionnaires regarding particular techniques, reagents or procedures are frequently issued using an on-line survey tool, namely SurveyMonkey. It is extremely 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.

The information obtained is essential for observing trends in practice and for monitoring overall compliance with BCSH 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.
LATE RESULTS

The exercise material is tested in-house on the closing date to provide evidence that it has remained stable throughout the course of the distribution. Therefore, results received after the closing date will only be analysed if the samples have been tested by the closing date – the ‘date tested’ field must have been completed for late results to be accepted. Participants should contact the Scheme before submitting late results.

Acceptable results received after the closing date, but before the reports have been posted to the web (this may be 2-8 working days after the closing date), are assessed, but incur a late penalty (see section on penalty scoring). Late results are analysed as part of a single process, shortly after reports have been posted to the web. Participants first receive a ‘non-return’ report, which includes the overall data, and any additional attachments, e.g. supplementary reports or meeting flyers. This is followed by an updated report displaying their data, with the amended date indicated in the footer on the front page. Both original and amended reports are available on the web. Participants are notified by email when an amended report is available.

ASSIGNED VALUES

BTLP (main scheme for pre-transfusion testing)

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.

Feto-Maternal Haemorrhage

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.
PENALTY SCORING SYSTEMS

Non-technical errors – all schemes

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).

BTLP (main scheme for pre-transfusion testing)

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.

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.
Penalty Scores

a) For each incorrect ABO grouping
   where at least 20% of participants obtain the expected result - SCORE - 100

   NB: a result of UI (unable to interpret) incurs a penalty (50 points) unless the sample is
direct antiglobulin test positive, a weak ABO subgroup, or gives a mixed field picture.

b) For each incorrect D typing:
   where at least 20% of participants obtain the expected result - SCORE - 100

   NB: a result of UI (unable to interpret) incurs a penalty (50 points) unless the
sample is
direct antiglobulin test positive, a weak or partial D, or gives a mixed field picture.

c) For each false-negative antibody screen:
   where 80% - 100% of participants obtain the expected result - SCORE - 100
   where 50% - 79% of participants obtain the expected result - SCORE - 50
   where 20% - 49% of participants obtain the expected result - SCORE - 25

d) For each false-positive antibody screen:
   where 80% - 100% of participants obtain the expected result - SCORE - 40
   where 50% - 79% of participants obtain the expected result - SCORE - 20
   where 20% - 49% of participants obtain the expected result - SCORE - 10

e) For each incorrect antibody identification:
   e.g. 1 anti-E reported (correct result anti-D)
   e.g. 2 anti-E reported (correct result anti-E+Fy^a)

   where 80% - 100% of participants obtain the expected result - SCORE - 80
   where 50% - 79% of participants obtain the expected result - SCORE - 40
   where 20% - 49% of participants obtain the expected result - SCORE - 20

f) For each partially correct identification where no UI submission is made or where the
   Scheme does not agree with the interpretation (see appendix 1):

   e.g. 1 anti-E+K or anti-E+UI (correct result anti-E)
   e.g. 2 anti-E+UI (correct result anti-E+Fy^a)

   where 80% - 100% of participants obtain the expected result - SCORE - 40
   where 50% - 79% of participants obtain the expected result - SCORE - 20
   where 20% - 49% of participants obtain the expected result - SCORE - 10

g) For being unable to identify any specificity where no UI submission is made or where the
   Scheme does not agree with the interpretation (appendix 1): - SCORE - 50

h) For each missed ABO incompatibility:
   where 80% - 100% of participants obtain the expected result - SCORE - 100
   where 50% - 79% of participants obtain the expected result - SCORE - 50
   where 20% - 49% of participants obtain the expected result - SCORE - 25

i) For each missed non-ABO incompatibility in routine exercises:
   where 80% - 100% of participants obtain the expected result - SCORE - 60
   where 50% - 79% of participants obtain the expected result - SCORE - 30
   where 20% - 49% of participants obtain the expected result - SCORE - 15
For each missed non-ABO incompatibility in urgent exercises:
- where 80% - 100% of participants obtain the expected result - **SCORE - 80**
- where 50% - 79% of participants obtain the expected result - **SCORE - 40**
- where 20% - 49% of participants obtain the expected result - **SCORE - 20**

For each missed compatibility:
- where 80% - 100% of participants obtain the expected result - **SCORE - 30**
- where 50% - 79% of participants obtain the expected result - **SCORE - 15**
- where 20% - 49% of participants obtain the expected result - **SCORE - 10**

For each non-return or late return of results for an exercise - **SCORE - 50**

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. Non-return and late return penalties are combined.

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.

Feto-Maternal Haemorrhage

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. An example is shown in the report in Appendix 3.
3. The clinical significance of decision-making by participants registered for acid elution, 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.
4. Return of results.
**Statistical processing**

The median for each method, and the standard deviation (SD) derived from the method interquartile range, are used to produce a deviation index (DI). The DI from the results of the six most recent 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.

There are three steps involved in the calculation of the 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 consensus trimmed mean value or 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

2. 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.

3. 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. 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 1603F:

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

<table>
<thead>
<tr>
<th>Survey</th>
<th>Patient 1</th>
<th>Patient 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1506F</td>
<td>0.37</td>
<td>Not scored</td>
</tr>
<tr>
<td>1601F</td>
<td>4.69</td>
<td>-2.04</td>
</tr>
<tr>
<td>1602F</td>
<td>Not scored for AE</td>
<td>3.20</td>
</tr>
<tr>
<td>1603F</td>
<td>2.59</td>
<td>-1.33</td>
</tr>
</tbody>
</table>

Score = (0.37+2.04+3.50+3.20+1.33+2.59) x8 = 104.2
Table 2: The following DIs were obtained for a participant using Flow Cytometry (FC)

<table>
<thead>
<tr>
<th>Survey</th>
<th>Patient 1</th>
<th>Patient 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1506F</td>
<td>Not part of most recent 6</td>
<td>Not scored</td>
</tr>
<tr>
<td>1601F</td>
<td>0.45</td>
<td>-0.39</td>
</tr>
<tr>
<td>1602F</td>
<td>-0.60</td>
<td>0.09</td>
</tr>
<tr>
<td>1603F</td>
<td>0.54</td>
<td>0.21</td>
</tr>
</tbody>
</table>

Score = (0.45+0.39+0.60+0.09+0.54+0.21) 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 inhomogeneity, 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.
REPORTS

BTLP (main scheme for pre-transfusion testing)

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 eight 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.

Feto-Maternal Haemorrhage

Each participant receives an individual, confidential report showing the overall results for the current survey within their method group, plus their own current and cumulative results to demonstrate the trends in performance. These are posted to the web within four working days of the closing date. An example of each type of report is shown in Appendices 3, 4 and 5.

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

All schemes

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

A scheme report is distributed at least every two years, summarising data from all exercises and questionnaires. This also includes learning points, trend analysis, error rates and scheme developments.

Use of reports

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 on each and every occasion, though the participant may share their performance data with individual clients (e.g. clinicians) without consultation.
PERFORMANCE MONITORING

BTLP (main scheme for pre-transfusion testing)

- **Definition of unsatisfactory performance (UP)**
  A cumulative score of $\geq 100$ 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.

- **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, fax or post.

- **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 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 as a whole, 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.

Feto-Maternal Haemorrhage

- **Definition of unsatisfactory performance (UP)**
  a. An initial analytical score of $\geq 100$ or an existing score of $>100$ but falling (see Table 3)
  b. A single grossly outlying acid elution result, where the DI is $<-2$ or $>3.5$. These values are subject to periodic review.
  c. An insufficient dose of anti-D Ig (to cover the flow cytometry method median, where this is $\geq 4$mL) combined with no recommendation for follow-up, by laboratories registered for acid elution.
  d. An insufficient dose of anti-D (to cover the flow cytometry method median) where the acid elution screen does not trigger quantification (in-house or referral).
  e. Late or non-return of results in two of three consecutive surveys.
- **Definition of persistent unsatisfactory performance (PUP)**
  a. An analytical score of $\geq 100$ where this is rising (see Table 3).
  b. One episode or more of unsatisfactory performance in 2 of 3 consecutive surveys.
  c. Two episodes of UP due to late or non-return of results in a 12 month period.
  d. 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**

<table>
<thead>
<tr>
<th>Performance</th>
<th>Performance status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score of 80-99</td>
<td>Borderline</td>
</tr>
<tr>
<td>Score of 100+</td>
<td>UP</td>
</tr>
<tr>
<td>Score of 100+ and falling</td>
<td>UP</td>
</tr>
<tr>
<td>Score of 100+ and rising or not falling (inc non-return)</td>
<td>PUP</td>
</tr>
<tr>
<td>Score of 100+ on two occasions in one 12 month period</td>
<td>PUP</td>
</tr>
</tbody>
</table>

**All schemes**

Unsatisfactory performers 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 a quarterly basis using a ‘traffic light’ system as required by the JWG. UK laboratories identified as UPs are contacted in writing at the discretion of the Scheme Director.
Appendix 1

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) 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 BCSH 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 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 BCSH guidelines, e.g. having no homozygous cell available to exclude anti-Jkα.
- Including a specificity (if actually present) even if the inclusion does not comply with BCSH 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
- The UI box should be marked in addition to any boxes for antibodies that you can confidently identify.
- The UI submission must include details of antibodies that cannot be positively identified, but cannot be excluded, and your explanation of why identification cannot be confirmed.
- Copies of all panel sheets showing the reactions recorded, (including those used for antibody screening) must be returned with your exercise result sheet and marked with your PRN.

If supporting paperwork is not submitted, antibodies recorded as positively identified will be considered as your result for performance monitoring purposes.
### Summary of Exercise Material

- **Patient 1** - Group AB D positive, inert
- **Patient 2** - Group A D positive, inert
- **Patient 3** - Group O D positive, anti-K, Fya: anti-K titre 4 vs. K+k+, Fy(a+b+) cells and anti-Fya titre 2 vs. K+k+, Fy(a+b-) cells
- **Donor W** - Group O D positive Ro (cDe), Fy(a+b-), K-
- **Donor Y** - Group O D positive R1r (CDe/dDe), Fy(a+b+), K-
- **Donor Z** - Group O D positive R2R2 (cDe/cDe), Fy(a+b-), K-

### Definition of Penalty Scores

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

### Your Performance Summary:

<table>
<thead>
<tr>
<th>Penalty Score</th>
<th>Cumulative Penalty Score</th>
<th>Cumulative Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Return penalty</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Late-Return penalty</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Return cumulative score</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>ABO</td>
<td>No Errors</td>
<td>0</td>
</tr>
<tr>
<td>RhD</td>
<td>No Errors</td>
<td>0</td>
</tr>
<tr>
<td>Antibody Screen</td>
<td>No Errors</td>
<td>0</td>
</tr>
<tr>
<td>Antibody Identification</td>
<td>No Errors</td>
<td>0</td>
</tr>
<tr>
<td>Phenotyping</td>
<td>No Errors</td>
<td>0</td>
</tr>
<tr>
<td>Crossmatch</td>
<td>1 Error(s)</td>
<td>90</td>
</tr>
</tbody>
</table>

**Printed at 16:26 on Tuesday, 9 February, 2016 (Final Report)**

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

UK NEQAS (BTLp), PO Box 133, WATFORD WD18 0WP

FAX: 0192 321 7934 Phone: 0192 321 7933

© Copyright Notice: UK NEQAS reports are confidential, and no data may be published without the Organiser's permission
### Appendix 2 – BTLP report

#### SUMMARY OF EXERCISE MATERIAL
- **Patient 1**: Group AB D positive
- **Patient 2**: Group A D positive
- **Patient 3**: Group O D positive

<table>
<thead>
<tr>
<th>Patient</th>
<th>Your Result</th>
<th>Your Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient 1</strong></td>
<td>AB D Positive</td>
<td>0</td>
</tr>
<tr>
<td>Overall Results</td>
<td>AB D Positive</td>
<td>99.48% n=(381)</td>
</tr>
<tr>
<td></td>
<td>O D Positive</td>
<td>0.26% n=(1)</td>
</tr>
<tr>
<td></td>
<td>AB D Not stated</td>
<td>0.26% n=(1)</td>
</tr>
<tr>
<td><strong>Patient 2</strong></td>
<td>A D Positive</td>
<td>0</td>
</tr>
<tr>
<td>Overall Results</td>
<td>A D Positive</td>
<td>99.74% n=(382)</td>
</tr>
<tr>
<td></td>
<td>A D not stated</td>
<td>0.26% n=(1)</td>
</tr>
<tr>
<td><strong>Patient 3</strong></td>
<td>O D Positive</td>
<td>0</td>
</tr>
<tr>
<td>Overall Results</td>
<td>O D Positive</td>
<td>99.48% n=(381)</td>
</tr>
<tr>
<td></td>
<td>AB D Positive</td>
<td>0.26% n=(1)</td>
</tr>
<tr>
<td></td>
<td>O D not stated</td>
<td>0.26% n=(1)</td>
</tr>
</tbody>
</table>

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

### Your last 3 returns contribute to the cumulative scores

**ABO Derived penalty score**

- **Current Performance**: Satisfactory
- **Cumulative Score**: 0

**RhD Derived penalty score**

- **Current Performance**: Satisfactory
- **Cumulative Score**: 0
Appendix 2 – BTLP report

**SUMMARY OF EXERCISE MATERIAL**

Patient 1 - Inert
Patient 2 - Inert
Patient 3 - Anti-K+Kya

**Antibody Screen**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Your Result</th>
<th>Overall Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
<td>None Detected</td>
<td>None Detected 99.73% n=374</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Antibody Present 0.27% n=1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient 2</th>
<th>Your Result</th>
<th>Overall Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None Detected</td>
<td>None Detected 99.73% n=374</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Antibody Present 0.27% n=1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient 3</th>
<th>Your Result</th>
<th>Your Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antibody Present</td>
<td>99.47% n=373</td>
</tr>
<tr>
<td></td>
<td>None Detected</td>
<td>0.53% n=2</td>
</tr>
</tbody>
</table>

**Antibody Identification**

<table>
<thead>
<tr>
<th></th>
<th>K, Kya</th>
<th>Your Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 3</td>
<td></td>
<td>100.00% n=350</td>
</tr>
</tbody>
</table>

**Your overall score for this exercise:**

- Antibody Screening: 0
- Antibody Identification: 0

**Your last 3 returns contribute to the cumulative scores**

- Antibody screen derived penalty score:
  - Current Performance: Satisfactory
  - Cumulative Score: 0

- Antibody identification derived penalty score:
  - Current Performance: Satisfactory
  - Cumulative Score: 0

Printed at 16:25 on Tuesday, 9 February, 2016 (Final Report)

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

Scheme Director: Dr M Rowley
Authorised by: Mrs C Milkins (Scheme Manager)

© Copyright Notice: UK NEQAS reports are confidential, and no data may be published without the Organiser’s permission
Appendix 2 – BTLP report

### SUMMARY OF EXERCISE MATERIAL
Patient 1 - Group AB D positive, inert
Patient 2 - Group A D positive, inert
Patient 3 - Group O D positive, anti-K+Kya
Donor W - Group O D positive Ro (cDE), Fy(a+b+), K-
Donor Y - Group O D positive R1r (CDe/cDe), Fy(a+b+), K-
Donor Z - Group O D positive R2R2 (cDE/cDE), Fy(a-b+), K-

<table>
<thead>
<tr>
<th>Patient</th>
<th>Donor W</th>
<th>Donor Y</th>
<th>Donor Z</th>
<th>Overall Results</th>
<th>Your Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>0</td>
</tr>
<tr>
<td>Your Result</td>
<td>C 99.7% n=347</td>
<td>C 99.7% n=347</td>
<td>C 100.0% n=375</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>I 0.3% n=1</td>
<td>I 0.3% n=1</td>
<td>I 0.3% n=1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient</th>
<th>Overall Results</th>
<th>Your Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C 100.0% n=347</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>C 100.0% n=347</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>C 99.7% n=347</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>I 0.3% n=1</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient</th>
<th>Overall Results</th>
<th>Your Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I 99.9% n=371</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>I 98.4% n=369</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C 1.1% n=4</td>
<td></td>
</tr>
</tbody>
</table>

Your overall score for this exercise: X-match total score 90

Your last 3 returns contribute to the cumulative scores

<table>
<thead>
<tr>
<th>Cumulative Score</th>
<th>Distribution Penalty</th>
<th>Non Return</th>
</tr>
</thead>
<tbody>
<tr>
<td>150</td>
<td></td>
<td></td>
</tr>
<tr>
<td>130</td>
<td></td>
<td></td>
</tr>
<tr>
<td>110</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Current Performance: Unsatisfactory
Cumulative Score: 150

Unsatisfactory
Borderline
Satisfactory

Printed at 16:25 on Tuesday, 9 February, 2016 (Final Report)
### Appendix 2 – BTLP report

#### SUMMARY OF EXERCISE MATERIAL

- **Donor W** - Group O, D positive, R O (cDe)
- **Donor Y** - Group O, D positive, R 1r (CDelode)
- **Donor Z** - Group O, D positive, R 2R2 (cDEEdOe)

#### Donor W

<table>
<thead>
<tr>
<th>Your Result</th>
<th>C-</th>
<th>c+</th>
<th>E-</th>
<th>e+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>C-</td>
<td>c+</td>
<td>E-</td>
<td>e+</td>
</tr>
</tbody>
</table>

**Interpretation:**

- **R0**
  - Your Score = 0
  - R0: 84.50% $n^\text{m}(218)$
  - rr: 6.98% $n^\text{m}(18)$
  - Other: 6.59% $n^\text{m}(17)$
  - R2r: 0.39% $n^\text{m}(1)$

#### Donor Y

<table>
<thead>
<tr>
<th>Your Result</th>
<th>C+</th>
<th>c+</th>
<th>E-</th>
<th>e+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>C+</td>
<td>c+</td>
<td>E-</td>
<td>e+</td>
</tr>
</tbody>
</table>

**Interpretation:**

- **R1r**
  - Your Score = 0
  - R1r: 93.41% $n^\text{m}(241)$
  - r'r: 1.94% $n^\text{m}(5)$
  - Other: 1.55% $n^\text{m}(4)$
  - R1r: 1.16% $n^\text{m}(3)$
  - R1r: 0.78% $n^\text{m}(2)$
  - R0: 0.39% $n^\text{m}(1)$
  - R1r: 0.39% $n^\text{m}(1)$

#### Donor Z

<table>
<thead>
<tr>
<th>Your Result</th>
<th>C-</th>
<th>c+</th>
<th>E+</th>
<th>e-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>C-</td>
<td>c+</td>
<td>E+</td>
<td>e-</td>
</tr>
</tbody>
</table>

**Interpretation:**

- **R2R2**
  - Your Score = 0
  - R2R2: 90.27% $n^\text{m}(232)$
  - R2R2: 2.33% $n^\text{m}(6)$
  - R1R2: 1.95% $n^\text{m}(5)$
  - R1R2: 1.56% $n^\text{m}(4)$
  - r'r: 0.78% $n^\text{m}(2)$
  - R1R2: 0.78% $n^\text{m}(2)$
  - R2R2: 0.39% $n^\text{m}(1)$
  - R2R2: 0.39% $n^\text{m}(1)$
  - R2R2: 0.39% $n^\text{m}(1)$

#### Your overall score for this exercise:

**Serological Phenotyping:** 0

- **Cumulative Score**
- **Distribution Penalty**

#### Phenotyping derived penalty score

- **Current Performance:** Satisfactory
- **Cumulative Score:** 0

<table>
<thead>
<tr>
<th>Unsatisfactory</th>
<th>Borderline</th>
<th>Satisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>-25</td>
<td>0</td>
<td>25</td>
</tr>
</tbody>
</table>

Printed at 16:26 on Tuesday, 9 February, 2016 (Final Report)
Appendix 2 – BTLP report

MAIN AIMS OF THE EXERCISE

1. Detection of incompatibility due to anti-Fy*
2. Identification of an antibody mixture
3. Rh phenotyping

RETURN RATE - 383/390 (98.2%) returned results by the closing date.

SAMPLE QUALITY

Satisfactory sample quality was reported by >99% participants for all patient plasma and donor samples. Ten laboratories (2.6%) reported unsatisfactory sample quality for one or more of the whole blood samples, due to haemolysis.

PROCEDURAL ERRORS

One laboratory booked in the request for Patient 2 on the barcoded accession number allocated to Patient 3 and vice versa. Subsequent checks on the sample and request demographics that are routinely in place for clinical samples were omitted for the EGA samples, leading to the reporting of one false positive and one false negative antibody screen. Another transposed all results for Patients 1 and 3 at the data entry stage, resulting in two ASO errors, two antibody screening errors, two missed incompatibilities and two missed compatibilities. In this case, samples for Patients 1, 2 and 3 were allocated descending rather than ascending laboratory accession numbers, and although all results were associated with the correct sample on the LIMS, when this data was transcribed to the website the lowest accession number was taken to denote Patient 1 and the highest Patient 3. A further two laboratories made data entry errors and another appears to have transposed Donors W and Z at some stage during testing or reporting, in all, accounting for four missed incompatibilities for Patient 3 (two vs. Donor W and two vs. Donor Y) and two missed compatibilities (Patient 3 vs. Donor Z).

COMPATIBILITY TESTING (Excluding procedural errors noted above)

Three laboratories, using DiaMed manual techniques, each missed one incompatibility for Patient 3: one vs. Donor W (Fy(a+b-)) and two vs. Donor Y (Fy(a-b+)). The two laboratories that repeated the crossmatch after the closing date both obtained a clear positive reaction using the same technique, but have been unable to establish the cause of the original missed incompatibility. One laboratory, using a DiaMed automated technique, missed the incompatibility between Patient 3 and Donor Y. Examination of the original machine printout showed a very weak cell suspension in the crossmatching column, and a positive reaction was found on repeat after the closing date. Nine laboratories reported an incompatibility between Patient 3 and Donor Z (Fy(a-b+)), with three basing this on theoretical de-selection, and six on a positive reaction in the IAT crossmatch (five using DiaMed and one BioVue).

PHENOTYPING

Overall, ten laboratories recorded a total of seven false negative reactions and seven false positive reactions, leading to a total of 11 incorrect sets of reactions. Of these, eight were assigned the expected interpretation, i.e. Rh for Donor Y and Rh for Donor Z, so it is possible that the incorrect reactions were recorded due to data entry error. Conversely, 38 sets of correct reactions were assigned an incorrect interpretation, with 24 of these due to not taking the D type into account. Four laboratories reporting correct reactions, did not record the shorthand Rh interpretation for any of the three donors, and two reported ‘other’ for all interpretations. An additional 15 laboratories selected ‘other’ for Donor W only, presumably as they were unwilling to select the option R. This single option was provided rather than Rh and Rh, as it is not possible to distinguish between these without molecular testing, or to decide which is most probable without knowing the ethnicity of the ‘donor’. Penalty scoring for Rh phenotyping is based on the reactions recorded rather than the shorthand interpretation.

DISCUSSION

EQA samples should follow, as far as is possible, the same process as clinical samples, so that performance in EQA is relevant to clinical practice. Labelling samples is a critical point in the pre-transfusion process and patient demographics on the sample should always be re-checked prior to validation of results. Checks should be in place to reduce the potential for procedural error when identifying samples for testing during manual procedures such as crossmatching, and when transcribing any critical test results.
Appendix 3 – FMH Acid elution quantification report

Your registration: Screening and Quantification by Acid Elution

Participation Performance Summary:

- Non-return penalty: 0
- Late return penalty: 0
- Cumulative participation score: 0
- Satisfactory

Accuracy of quantification

Definition of performance scores

- 0 - 79: Satisfactory
- 80 - 99: Borderline
- >=100: Persistent unsatisfactory performance

Cumulative analytical performance score: 84.7

Screening: Potential for sensitisation

- Patient 1: Quantification triggered
- Patient 2: Quantification triggered

Clinical Significance

‘Potential for sensitisation’ errors this exercise
- Screening: 0
- Quantification: 0

Persistent unsatisfactory performance (PUP) is classified as one or more errors in 2 out of 3 consecutive exercises

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

- Patient 1: Within range
- Patient 2: Within range
- Outlying results this exercise: 0
- Cumulative outlying results: 1

Comments

Results: Three laboratories (one UK and two non-UK) each made one potential for sensitisation error in this exercise. Eleven outlying results were reported by ten laboratories, nine due to underestimation and three to overestimation.

FMH questionnaire: A SurveyMonkey link to a questionnaire on FMH techniques and practice is included in the email that you will have received to notify you that this report is ready to download. Alternatively, the link can be copied and pasted from here https://www.surveymonkey.co.uk/r/FMH2016. We would be grateful if you could complete this questionnaire by Friday 10th June. The data will be used to inform a review of BCSH guidance on FMH, and to help us to provide EQA that is relevant to clinical practice.

Printed at 15:11 on Thursday, 19 May, 2016 (Final Report)
Appendix 3 – FMH Acid elution quantification report

Your Method: Acid Elution - ClinTech

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

Sample Quality
You Report: Satisfactory sample quality
Overall: 98.6% Satisfactory

Overall quantification results by acid elution

<table>
<thead>
<tr>
<th>Number registered</th>
<th>174</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of results analysed</td>
<td>168</td>
</tr>
<tr>
<td>Return Rate</td>
<td>96.6%</td>
</tr>
<tr>
<td>Method median (mL)</td>
<td>15.00</td>
</tr>
<tr>
<td>Uncertainty of method median (mL)</td>
<td>0.32</td>
</tr>
<tr>
<td>I.Q.Range (mL)</td>
<td>13.1 - 17.5</td>
</tr>
<tr>
<td>Estimated SD</td>
<td>3.3</td>
</tr>
<tr>
<td>Minimum reported (mL)</td>
<td>3.9</td>
</tr>
<tr>
<td>Maximum reported (mL)</td>
<td>30.2</td>
</tr>
</tbody>
</table>

Overall D dosing results

Median dose: 2500
Reported Range:
Minimum: 500
Maximum: 30000
Number: 168

Your Results

Accuracy

<table>
<thead>
<tr>
<th>Result</th>
<th>Your performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMH Quantification (mL)</td>
<td>20 % Difference from method median 33.3</td>
</tr>
<tr>
<td>Reported FMH</td>
<td>19.95 Deviation Index (Di) 1.52</td>
</tr>
<tr>
<td>% Fetal Cells</td>
<td>No result</td>
</tr>
</tbody>
</table>

Clinical Significance - based on flow cytometry method median of 13.40mL

<table>
<thead>
<tr>
<th>Result</th>
<th>Expected result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fetal cells seen</td>
<td>Yes</td>
</tr>
<tr>
<td>Quantification triggered</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Result

<table>
<thead>
<tr>
<th>Prescribed anti-D dose (IU)</th>
<th>2500 Sufficient to cover flow cytometry median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat sample requested</td>
<td>Yes Patient not at risk of sensitisation if followed up according to BCSH guidelines **</td>
</tr>
<tr>
<td>Referral for flow cytometry</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Comments

Results: One laboratory appears to have transposed Patients 1 and 2; excluding the result from this laboratory, the revised range of bleed volume results reported is 6.8 - 30.2mL. Four outlying results were returned (excluding one apparently due to transposition), with three due to underestimation and one to overestimation. Two 'clinical significance' errors were made by non-UK laboratories, where had this been a clinical sample, insufficient anti-D would have been issued to cover the flow cytometry method median.

* Based on BCSH guidance ** Where no quantification is triggered, performance is based on whether or not the initial anti-D dose covers the flow cytometry method median.
Appendix 3 – FMH Acid elution quantification report

Your Method: Acid Elution - ClinTech

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

Sample Quality
You Reported: Satisfactory sample quality
Overall: 96.6% Satisfactory

Overall quantification results by acid elution

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number registered</td>
<td>174</td>
</tr>
<tr>
<td>Number of results analysed</td>
<td>168</td>
</tr>
<tr>
<td>Return Rate</td>
<td>96.6%</td>
</tr>
<tr>
<td>Method median (mL)</td>
<td>6.30</td>
</tr>
<tr>
<td>Uncertainty of method median (mL)</td>
<td>0.13</td>
</tr>
<tr>
<td>I.Q.Range (mL)</td>
<td>5.5 - 7.3</td>
</tr>
<tr>
<td>Estimated SD</td>
<td>1.4</td>
</tr>
<tr>
<td>Minimum reported (mL)</td>
<td>2.1</td>
</tr>
<tr>
<td>Maximum reported (mL)</td>
<td>12.7</td>
</tr>
</tbody>
</table>

Overall D dosing results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median dose</td>
<td>1000</td>
</tr>
<tr>
<td>Reported Range</td>
<td>500</td>
</tr>
<tr>
<td>Maximum</td>
<td>2000</td>
</tr>
<tr>
<td>Number</td>
<td>168</td>
</tr>
</tbody>
</table>

Your Results

Accuracy

<table>
<thead>
<tr>
<th>Result</th>
<th>Your performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMH Quantification (mL)</td>
<td>9.5</td>
</tr>
<tr>
<td>% Difference from method median</td>
<td>50.8</td>
</tr>
<tr>
<td>Reported FMH</td>
<td>9.52</td>
</tr>
<tr>
<td>Deviation Index (DI)</td>
<td>2.37</td>
</tr>
<tr>
<td>% Fetal Cells</td>
<td>No result</td>
</tr>
</tbody>
</table>

Clinical Significance - based on flow cytometry method median of 5.00mL

<table>
<thead>
<tr>
<th>Result</th>
<th>Expected result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fetal cells seen</td>
<td>Yes</td>
</tr>
<tr>
<td>Quantification triggered</td>
<td>Yes *</td>
</tr>
</tbody>
</table>

Comments

Results: One laboratory appears to have transposed Patients 1 and 2, but this has not affected the range of bleed volume results or led to an outlying result being reported. Seven outlying results were returned, five due to underestimation and two to overestimation. One 'clinical significance' error was made by a UK laboratory reporting a result between 2 and 4mL; 500U anti-D was issued with no follow-up (i.e. repeat sample or referral for flow cytometry). Another laboratory issuing 500IU anti-D would have requested a repeat sample, but would not have referred for flow cytometry.

* Based on BCSH guidance ** Where no quantification is triggered, performance is based on whether or not the initial anti-D dose covers the flow cytometry method median.
Appendix 4 – Acid elution screen report

**UK NEQAS**
Hoematology and Transfusion

<table>
<thead>
<tr>
<th>Laboratory:</th>
<th>Feto-Maternal Haemorrhage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution:</td>
<td>1603F</td>
</tr>
<tr>
<td>Date:</td>
<td>10 May 2016</td>
</tr>
</tbody>
</table>

**Performance Summary**

**Participation Performance Summary:**

<table>
<thead>
<tr>
<th>Penalty Score</th>
<th>Cumulative Penalty Score</th>
<th>Cumulative Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>this exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-return penalty</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Late return penalty</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Cumulative participation score</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

**Screening: Potential for sensitisation**

Patient 1: Quantification triggered
Patient 2: Quantification triggered

**Clinical Significance**

*Potential for sensitisation* errors this exercise
Screening: 0

*Persistent unsatisfactory performance (PUP) is classified as one or more errors in 2 out of 3 consecutive exercises*

**Summary of Material**

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

**Return Rate**

Results were returned by 49/53 (92.5%) participants.

**Results**

There were no ‘potential for sensitisation’ errors made in this survey.

**FMH questionnaire**

A SurvveMonkey link to a questionnaire on FMH techniques and practice is included in the email that you will have received to notify you that this report is ready to download; alternatively, the link can be copied and pasted from here https://www.surveymonkey.co.uk/f/FMH2016.

We would be grateful if you could complete this questionnaire by Friday 10th June. The data will be used to inform a review of BCSH guidance on FMH, and to help us to provide EQA that is relevant to clinical practice.
Appendix 4 – Acid elution screen report

<table>
<thead>
<tr>
<th>Sample</th>
<th>Your reported SQ</th>
<th>% Satisfactory SQ overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1:</td>
<td>Satisfactory</td>
<td>98.6%</td>
</tr>
<tr>
<td>Patient 2:</td>
<td>Satisfactory</td>
<td>98.6%</td>
</tr>
</tbody>
</table>

**Patient 1 - Flow cytometry median = 13.40mL (minimum anti-D dose required = 1675iu)**

<table>
<thead>
<tr>
<th>Fetal cells seen:</th>
<th>Your result</th>
<th>Expected result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quantification triggered:</th>
<th>Yes</th>
<th>Yes *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Initial anti-D dose:</td>
<td>1500</td>
<td></td>
</tr>
<tr>
<td>Your Performance:</td>
<td>Satisfactory **</td>
<td></td>
</tr>
</tbody>
</table>

**Patient 2 - Flow cytometry median = 5.00mL (minimum anti-D dose required = 625iu)**

<table>
<thead>
<tr>
<th>Fetal cells seen:</th>
<th>Your result</th>
<th>Expected result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quantification triggered:</th>
<th>Yes</th>
<th>Yes *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Initial anti-D dose:</td>
<td>1500</td>
<td></td>
</tr>
<tr>
<td>Your Performance:</td>
<td>Satisfactory **</td>
<td></td>
</tr>
</tbody>
</table>

* Based on BCSH 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
Appendix 5 – Flow cytometry report

Your registration: Quantification by Flow Cytometry

<table>
<thead>
<tr>
<th>Participation Performance Summary:</th>
<th>Penalty Score</th>
<th>Cumulative Penalty Score</th>
<th>Cumulative Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-return penalty</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Late return penalty</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>Cumulative participation score</td>
<td>0</td>
<td>0</td>
<td>Satisfactory</td>
</tr>
</tbody>
</table>

Definition of performance scores

0 - 79: Satisfactory
80 - 99: Borderline
>=100: Persistent unsatisfactory performance

Cumulative analytical performance score: 92.7

Comments

FMH questionnaire

A SurveyMonkey link to a questionnaire on FMH techniques and practice is included in the email that you will have received to notify you that this report is ready to download; alternatively, the link can be copied and pasted from here https://www.surveymonkey.co.uk/r/FMH2016.

We would be grateful if you could complete this questionnaire by Friday 10th June. The data will be used to inform a review of BSH guidance on FMH, and to help us to provide EQA that is relevant to clinical practice.
### Appendix 5 – Flow cytometry report

#### Summary of material

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

#### Sample Quality

You Reported: Satisfactory sample quality

Overall: 98.6% Satisfactory

#### Overall quantification results by flow cytometry

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number registered</td>
<td>62</td>
</tr>
<tr>
<td>Number of results analysed</td>
<td>55</td>
</tr>
<tr>
<td>Return Rate</td>
<td>88.7%</td>
</tr>
<tr>
<td>Method median (mL)</td>
<td>13.40</td>
</tr>
<tr>
<td>Uncertainty of method median (mL)</td>
<td>0.12</td>
</tr>
<tr>
<td>I.Q. Range (mL)</td>
<td>12.8 - 13.8</td>
</tr>
<tr>
<td>Estimated SD</td>
<td>0.7</td>
</tr>
<tr>
<td>Minimum reported (mL)</td>
<td>8.7</td>
</tr>
<tr>
<td>Maximum reported (mL)</td>
<td>15.4</td>
</tr>
</tbody>
</table>

#### Your Results

#### Accuracy

<table>
<thead>
<tr>
<th>Result</th>
<th>Value</th>
<th>% Difference from method median</th>
<th>Deviation Index (DI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMH Quantification (mL)</td>
<td>14.8</td>
<td>10.4</td>
<td>1.89</td>
</tr>
<tr>
<td>Reported FMH</td>
<td>14.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Fetal Cells</td>
<td>0.68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed anti-D dose (IU)</td>
<td>3000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Comments

None for this specimen.
### Appendix 5 – Flow cytometry report

**Your Method:** Flow Cytometry - Becton Dickinson/FACS Canto II/BRAD 3 FITC Anti-D

**Summary of material**
- A mixture of D negative adult whole blood and D positive cord red cells to simulate a post-delivery FMH sample.

**Sample Quality**
- You Reported: Satisfactory sample quality
- Overall: 98.6% Satisfactory

#### Overall quantification results by flow cytometry

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number registered</td>
<td>62</td>
</tr>
<tr>
<td>Number of results analysed</td>
<td>55</td>
</tr>
<tr>
<td>Return Rate</td>
<td>88.7%</td>
</tr>
<tr>
<td>Method median (mL)</td>
<td>5.00</td>
</tr>
<tr>
<td>Uncertainty of method median (mL)</td>
<td>0.08</td>
</tr>
<tr>
<td>I.Q.Range (mL)</td>
<td>4.5 - 5.1</td>
</tr>
<tr>
<td>Estimated SD</td>
<td>0.5</td>
</tr>
<tr>
<td>Minimum reported (mL)</td>
<td>2.3</td>
</tr>
<tr>
<td>Maximum reported (mL)</td>
<td>6.6</td>
</tr>
</tbody>
</table>

#### Your Results

**Accuracy**

<table>
<thead>
<tr>
<th>Result</th>
<th>Your performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMH Quantification (mL)</td>
<td>5.8</td>
</tr>
<tr>
<td>% Difference from method median</td>
<td>16.0</td>
</tr>
<tr>
<td>Reported FMH</td>
<td>5.8</td>
</tr>
<tr>
<td>Deviation Index (DI)</td>
<td>1.66</td>
</tr>
<tr>
<td>% Fetal Cells</td>
<td>0.27</td>
</tr>
<tr>
<td>Prescribed anti-D dose (IU)</td>
<td>1500</td>
</tr>
</tbody>
</table>

**Comments**

**Results**

Six (non-UK) laboratories reported FMH values of <4mL. Four of these recorded an anti-D Ig dose, with two suggesting <=500IU, and two >1000IU.
UK NEQAS Blood Transfusion Laboratory Practice
PO Box 133
Watford
WD18 0WP
UK
T: +44 (0)1923 217933
E: btlp@ukneqas.org.uk
W: www.ukneqasbtlp.org