



PARTICIPANTS'
MANUAL
Point of Care RhD typing

UK NEQAS for Blood Transfusion Laboratory Practice

UK NEQAS (BTLP)
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Watford
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GENERAL ORGANISATION OF THE SCHEME

Location

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

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Key Scheme Personnel

Director: Dr Megan Rowley

Manager/ Deputy Director: Mrs Clare Milkins

Deputy Manager: Ms Jenny White

EQA Scientists: Mr Arnold Mavurayi, Ms Claire Whitham

Office Manager: Ms Pinky Bambhra

Executive Assistant: Ms Isabella De-Rosa

IT Manager: Mr Vasilis Rapanakis

Logistics Coordinator: Mr Stephen Herbert

Other clerical and logistics support staff are employed jointly with UK NEQAS (H) and (FMH). 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; this is a joint post shared with the other Schemes based at Watford General Hospital.

UK NEQAS Charity

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

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

www.ukneqas.org.uk.

Steering Committee

The Scheme is advised by a Steering Committee. The Committee comprises scientific and clinical members and the membership is ratified by the UK NEQAS Executive Committee. The Chairman is independent of UK NEQAS operational issues, and is currently Dr Peter Baker, Blood Transfusion Laboratory Manager, Royal Liverpool University Hospital, L7 8XP.

National Quality Assessment Advisory Panel (NQAAP) and Joint Working Group (JWG)

NQAAPs are professional groups which are responsible to the pathology professions and the Health Departments for monitoring the maintenance of satisfactory standards of laboratory performance in the United Kingdom, whether in the private or public sector. Their members are nominated by the Royal College of Pathologists, the Association of Clinical Pathologists and the Institute of Biomedical Science, as well as by specialist professional bodies. The Panels are discipline specific and the Chair of each Panel reports to the Joint Working Group (JWG) on Quality Assessment in Pathology.

UK NEQAS (BTLT) 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.

The Joint Working Group for Quality Assessment in Pathology (JWG) is a multidisciplinary group accountable to the Royal College of Pathologists for the oversight of performance in external quality assessment schemes (EQA) in the UK. Membership consists of the Chairmen of the National Quality Assessment Advisory Panels (NQAAPs), and representatives from the Institute of Biomedical Sciences, the Independent Healthcare Sector, the Department of Health and the UK Accreditation Service (UKAS). The JWG has defined Conditions of EQA Scheme Participation, which can be found on the RCPATH website*.

*http://www.rcpath.org/Resources/RCPATH/Migrated%20Resources/Documents/J/Joint_Working_Group_Conditions_of_Participation_August10.pdf.

Confidentiality

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

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

Accreditation

The Scheme has held unconditional accreditation with CPA (EQA) since 1999 with a two yearly inspection cycle, the most recent inspection being in July 2012. The Scheme is currently in the transition process from CPA standard to ISO Standards:17043:2010, Conformity assessment – General requirements for proficiency testing, and is awaiting inspection by UKAS.

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 a given activity 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 about matters relating to the operations of UK NEQAS, UK NEQAS related questionnaires and annual meetings or training courses.

Helpline

- Advice on any aspect of the scheme or other related matters on performance 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 scheme staff.
- Invoicing or registration enquiries may be directed to the Office Manager.

Names and contact numbers can be found on page 2.

Complaints

We encourage participants to contact the scheme 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.

Complaints are reviewed at regular staff meetings and an annual audit is presented to the Management Executive Committee 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 of an unsatisfactory response, the appeal should be escalated to the Chair of the Steering Committee or the Chair of the National Quality Assessment Advisory Panel. The International Blood Group Reference Laboratory acts as an independent arbiter for any additional blood group serology investigations required on EQA material.

AIMS OF AND PARTICIPATION IN THE SCHEME

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

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

SCOPE AND FREQUENCY OF TESTS OFFERED

There are four exercises per year for D typing. Exercises are given a 5-digit code derived from the last two digits of the year, followed by R, a single-digit number, and a B; e.g. 14R4B.

The participating organisation receives a schedule of the survey despatch dates at registration or annual re-registration. The schedule is also published on the UK NEQAS website. Any significant changes to the schedule are highlighted on the website and participants informed by email. If the exercise material has not been received within three days after the published distribution date, please phone the Scheme for advice.

<http://www.ukneqasbtlp.org/content/Pageserver.asp>

PARTICIPANT REFERENCE NUMBER (PRN)

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

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

NEW REGISTRATIONS AND AMENDMENTS TO EXISTING REGISTRATIONS

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

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

SOURCE OF EXERCISE MATERIAL

'Patient' whole blood samples are derived from a pool of four or more donations which may be whole blood or red cells to which ABO compatible fresh frozen plasma and Alsever's has been added.

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

DESPATCH OF EXERCISE MATERIAL

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

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

EXERCISE FORMAT

There are currently four exercises per year, each comprising three 'patient' whole blood samples for RhD typing. The samples are identified with the exercise code (excluding the final 'B') and the patient identifier: *14R4 Patient 1*, *14R4 Patient 2* or *14R4 Patient 3*.

UNDERTAKING THE EXERCISE

General Considerations

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

- There should be no collusion with other institutions.

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

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

COMPLETION AND SUBMISSION OF RESULTS

Web-entry

On registration for web-entry, an ID code and password are supplied by e-mail. Instructions for completion of the web-forms and accessing report on the web are given in Appendix 1. Results can be partially entered and saved at any time before the closing date.

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

Reaction Grades

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

Interpretation

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

LATE RESULTS

The scheme tests the exercise material 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.

Acceptable results received after the closing date, but before the reports have been posted to the web (this may be 3-8 working days after the closing date), are assessed, but incur a late penalty (see next section). 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 a replacement report, which includes the individual participant's data and any related penalty scores, but with amended report text in place of the educational script on the original.

DEFINITION OF ERRORS AND PENALTY SCORING

Target Values

Blood group serology results are categorical data and the target value is the 'true' value as determined by the Supplier (NHSBT Reagents Unit) and the UK NEQAS laboratory. Material is only distributed following pre-acceptance testing within the UK NEQAS laboratory. 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.

Assessment

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

Penalty Scores

1.) For each incorrect RhD typing:

- where at least 80% of participants obtain the expected result - **SCORE = 100**
- where 50% - 79% of participants obtain the expected result - **SCORE = 50**
- where 20% - 49% of participants obtain the expected result - **SCORE = 25**

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

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

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

Non-technical errors

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

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

REPORTS

Each participant receives an individual, confidential report detailing any errors in the current exercise, cumulative errors, and overall cumulative performance. It also includes a summary of overall results for the appropriate peer group.

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

PERFORMANCE MONITORING

Definitions of performance:

A cumulative score of:

- 0 - 80** - indicates satisfactory performance
- 80 - 99** - indicates borderline performance
- 100 - 150** - indicates unsatisfactory performance

Actions to be taken by participants

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

Actions taken by UK NEQAS for UK participants

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

Unsatisfactory performers may be contacted in writing by the UK NEQAS Scheme Director, with letters copied to the Organisation's Medical Director or relevant regional manager.

Appendix 1

Web return of results

1. Go to www.ukneqasbtlp.org and click on the circled area (this area will display the closing date for any BTLT exercise that is open at the time) to reach the web data entry login screen (2.).



2. Enter your PRN (Lab Code), Identity and Password and click on the 'Log in' button

The screenshot shows the login form for UK NEQAS Haematology Schemes. It features a blue header with the UK NEQAS logo and the text 'Haematology Schemes'. Below the header, there are three input fields labeled 'Lab Code', 'Identity', and 'Password'. A 'Log in' button is positioned at the bottom of the form.

3. Pick 'Blood Transfusion Laboratory Practice' from the drop-down list of Schemes, and then click on the distribution required from the list displayed.

The screenshot shows the UK NEQAS National External Quality Assessment Site interface. At the top, there is a blue header with the UK NEQAS logo and the text 'UK NEQAS National External Quality Assessment Site'. Below the header, there is a section for 'Select Distributions for' with a drop-down menu set to 'Blood Transfusion Laboratory Practice'. There are links for 'Click here for HELP', 'Registration Details', and a 'Logout' button. Below this, there is a table with columns for 'Dist. No', 'Date Issued', 'Closing Date', 'Completed', 'Data Collected', 'Dist. Closed', 'Report', and 'Questionnaire'. The table contains several rows of data, each representing a distribution with its respective dates and completion status.

Dist. No	Date Issued	Closing Date	Completed	Data Collected	Dist. Closed	Report	Questionnaire
15R1B	19/01/2015	02/02/2015	✓	✓	✓	✓	✓
14R9B	13/10/2014	27/10/2014	✓	✓	✓	✓	✓
14R7B	14/07/2014	28/07/2014	✓	✓	✓	✓	✓
14R4B	22/04/2014	06/05/2014	✓	✓	✓	✓	✓
14R1B	20/01/2014	03/02/2014	✓	✓	✓	✓	✓
13R9B	14/10/2013	28/10/2013	✓	✓	✓	✓	✓
13R7B	15/07/2013	29/07/2013	✓	✓	✓	✓	✓
13R4B	15/04/2013	29/04/2013	✓	✓	✓	✓	✓

4. The screen below will be displayed for the sample quality to be recorded.

- Select satisfactory or unsatisfactory from the dropdown next to whole blood / red cell for each of the three samples.
- If any of the samples are unsatisfactory, please select the reason in the column headed 'reason'.

5. Enter your RhD testing results for the three 'patient' samples, moving between pages by clicking on the tabs labelled 'Patient 1', 'Patient 2' etc.

- Enter the date the samples were received and the date that they were tested (in the form DD/MM/YYYY).
- Enter your result (reaction) with Rapid Rh reagent in the column headed anti-D1
- Enter your result (reaction) with the reagent negative control in the column headed Ctrl
- Select 'Unable to test' in the column headed ABO interpretation

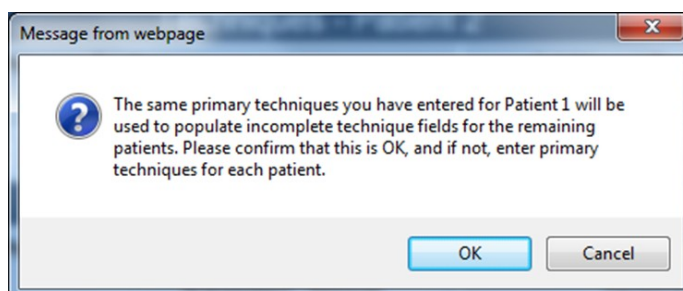
- Enter the Rh D test result that you would record in the register and patient's notes in the column headed 'D interpretation'
 - For RhD positive select 'Pos'
 - For RhD negative select 'Neg'
 - For equivocal results where a venous sample would be drawn for confirmation, select 'UI' (Unable to interpret).

There is no need to enter anything in the columns headed anti-A, anti-B, A cells, B cells and anti-D2, or in the techniques and direct antiglobulin test sections.

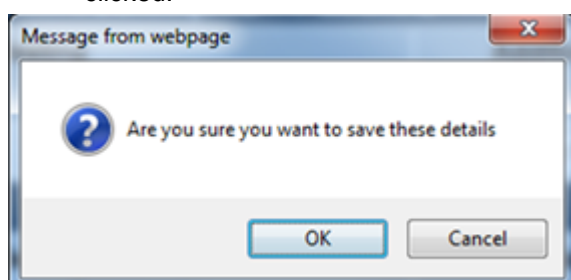
6. Click on the techniques tab, and for Patient 1 Test 'ABO/D', select BPAS from the technology dropdown list and 'manual' from the automated / manual dropdown list.

Test	Primary Testing		Additional Testing (if required to make an interpretation)	
	Technology	Automated / Manual	Technology	Automated / Manual
ABO/D	BPAS	Manual	-- Select Technique --	-- Select --

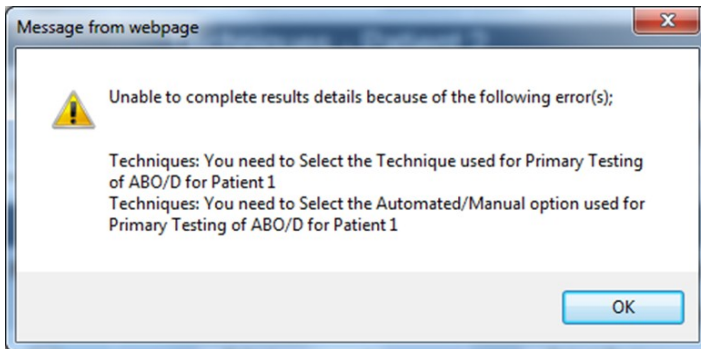
When the following pop-up message will appear, click on OK to populate the techniques for the other two patients.



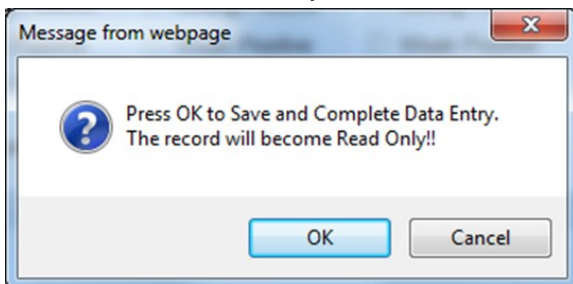
7. When you have finished a session of entering results, click on the save button. At this stage you can edit your results as often as you like. The following message will appear when the 'save' button is clicked:



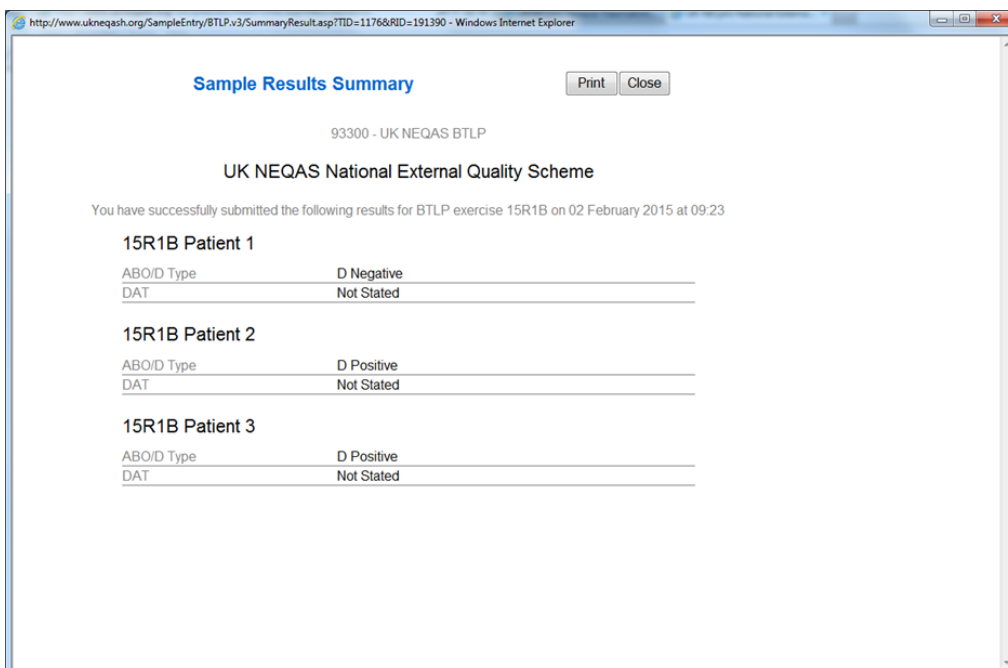
8. Once all the results have been entered, the 'submit' button should be clicked. If results have not been entered into the mandatory fields an error message will appear, similar to the one below:



9. Once the mandatory fields have been completed, the following message will appear:



10. Clicking on 'OK', a pop-up screen similar the one below will be displayed showing a summary of your results, after which time the results cannot be edited by the participant. It is advisable to check that the intended results have been submitted at this stage, and if you realise a data entry mistake has been made (before the closing date), contact the Scheme to request us to re-open your data entry page so that you can re-enter and re-submit your results:



11. If you wish to send us an e-mail regarding the current exercise, click on the link 'e-mail scheme' button at the top of the data entry screen (beside 'save' and 'submit'). This will open your e-mail client with the Scheme's e-mail address and your PRN completed ready to send.
12. To Log off the web server, click on the 'Back to List' button and then click on the 'Logout' button or exit from your browser in the usual way

Accessing Reports on the Web

1. Follow steps 1 to 3 of instructions for web return of results to access the data entry pages. Exercises for which the report is ready will have a tick in the 'Report' column.

Dist. No	Date Issued	Closing Date	Completed	Data Collected	Dist. Closed	Report	Questionnaire
15R1B	19/01/2015	02/02/2015	✓	✓	✓	✓	
14R9B	13/10/2014	27/10/2014	✓	✓	✓	✓	
14R7B	14/07/2014	28/07/2014	✓	✓	✓	✓	
14R4B	22/04/2014	06/05/2014	✓	✓	✓	✓	
14R1B	20/01/2014	03/02/2014	✓	✓	✓	✓	
13R9B	14/10/2013	28/10/2013	✓	✓	✓	✓	
13R7B	15/07/2013	29/07/2013	✓	✓	✓	✓	
13R4B	15/04/2013	29/04/2013	✓	✓	✓	✓	

2. Highlight the distribution that you want the report for and click on it. This will open the Sample entry details window. Click on the 'Reports' button (circled below), and a new window will open listing the reports available for this exercise.

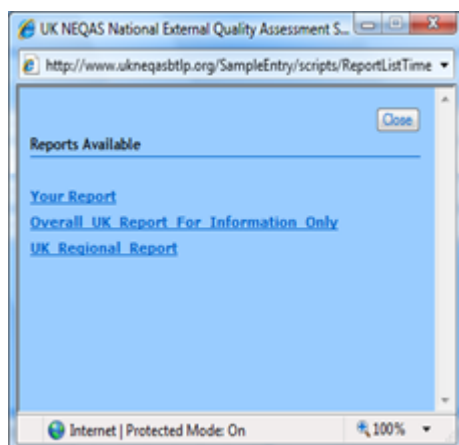
UK NEQAS National External Quality Assessment Site

Sample Entry Details

BLOOD TRANSFUSION LABORATORY PRACTICE

Distribution Number: 15R1B Participant: 93300 Issued: 19/01/2015 Closing: 02/02/2015 Received Date (dd/mm/yyyy): 19/01/2015 Analysed Date (dd/mm/yyyy): 19/01/2015

Sample Quality	Patient 1	Patient 2	Patient 3	Techniques
Sample Quality				
Sample	Quality	Reason	Other Reason	
Patient 1 - Plasma/Serum	Satisfactory	-- Select --		
Patient 1 - Whole Blood / Red Cells	Satisfactory	-- Select --		
Patient 2 - Plasma/Serum	Satisfactory	-- Select --		
Patient 2 - Whole Blood / Red Cells	Satisfactory	-- Select --		
Patient 3 - Plasma/Serum	Satisfactory	-- Select --		
Patient 3 - Whole Blood / Red Cells	Satisfactory	-- Select --		
Donor W	Satisfactory	-- Select --		
Donor Y	Satisfactory	-- Select --		
Donor Z	Satisfactory	-- Select --		



3. Click on the 'Your Report' folder to open a pdf of your individual report. Other reports of general interest (e.g. report supplements, meeting flyers etc.) may also be available and can be accessed by clicking on the appropriate line.
4. Once the report is displayed, you can save a copy or print it using the appropriate buttons on the Adobe Reader menu bar. If you wish to view reports from another Survey you should go back to the list of distributions. You need to wait for around one minute between opening different PDF Reports on the Web Results Service. This is because the system caches the details of the report and another report cannot be opened until the cache is cleared. The cache is cleared after one minute (the minimum value that can be set).
5. To Log off the web server, click on the 'Back to List' button and then click on the 'Logout' button or exit from your browser in the usual way.

Note: PDF copies of reports will remain on the website for at least six months, after which time they may be archived to off-line storage.