NHS Blood and Transplant

Red Cell Immunohaematology

User Guide 2015

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Red Cell Immunohaematology User Guide

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This Guide

This guide outlines the Red Cell Immunohaematology (RCI) services provided by NHS Blood and Transplant (NHSBT). The guide is of use to medical and scientific staff in hospital transfusion laboratories and others involved in, for example, antenatal care. The guide contains information about the organisation of the services and contact details for key staff.

Details of the products available from NHSBT Reagents are included.

NHS Blood and Transplant (NHSBT)

The National Blood Transfusion Service was founded in 1946 and was, until 1994, providing services on a regionally. In 1993 a Special Health Authority was created and in 2006 this Special Health Authority merged with UK Transplant, forming NHS Blood and Transplant (NHSBT). NHSBT is a national service and employs around 6,000 staff. The accountability for supplying blood services lies with NHSBT and the strategy for the service is formulated nationally, with local delivery. The core purpose is:

To save and improve patients' lives

Management of Red Cell Immunohaematology

RCI is managed nationally by the Head of Function, supported by National Operations and Process Improvement managers. Clinical support is provided by Consultant Haematologists. The service is supported by the Quality function.

There are 8 laboratories providing RCI services at Colindale, Tooting, Filton, Birmingham, Liverpool, Sheffield, Leeds and Newcastle.
Each of the RCI laboratories is managed by a Head of Laboratory (HoL), and each laboratory is supported by a medical consultant. See Appendix 1 for contact details.

The RCI function includes a Reagents Department based in Liverpool, managed by Reagents Operations Manager and the National Reagents Strategy Manager.

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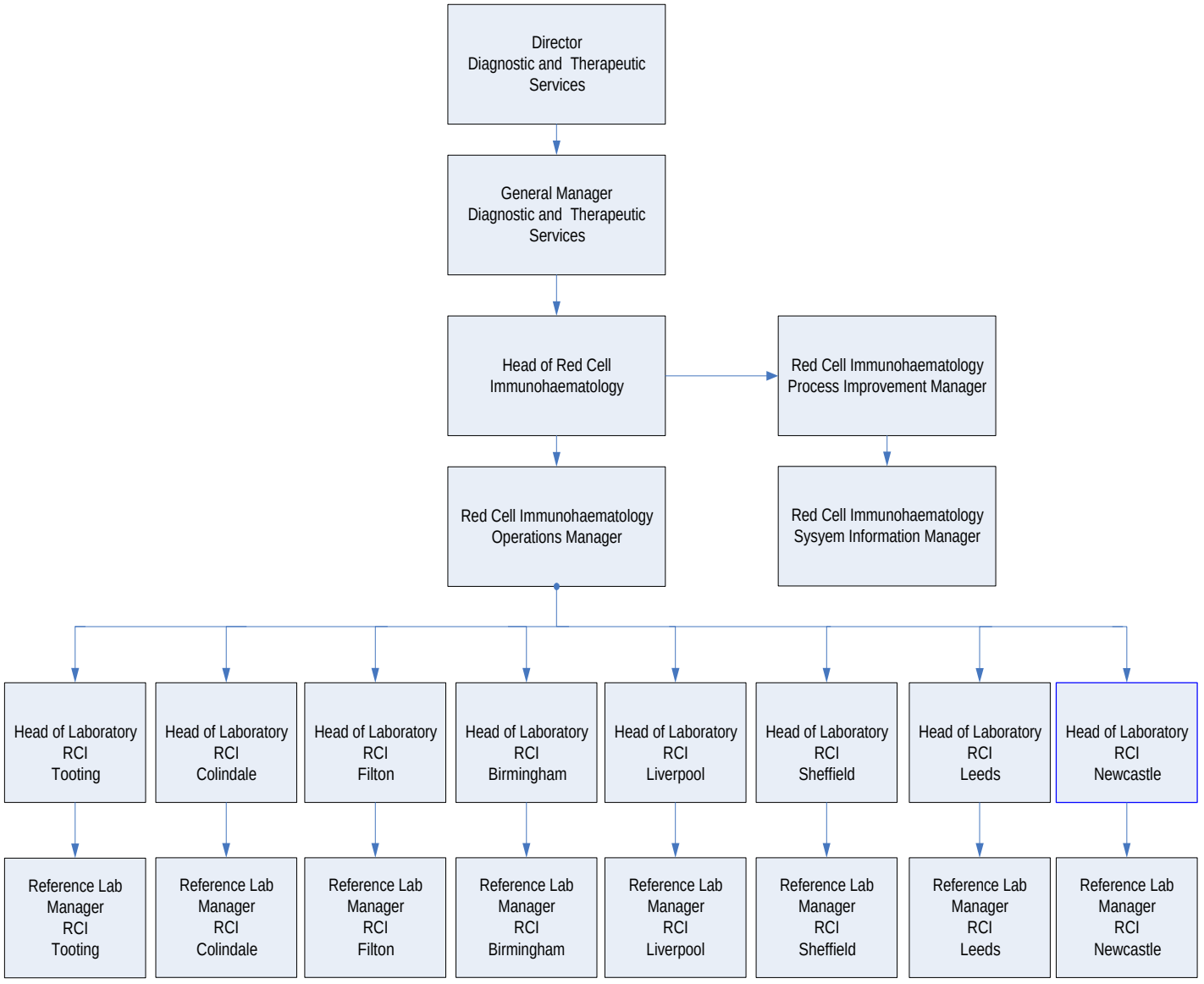
Management diagram – RCI



Quality statement

RCI services, in common with other NHSBT services, are committed to a total quality philosophy. All work is carried out within the framework of a documented quality system, according to Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) and in compliance with the Blood Safety and Quality regulations and Data Protection and Freedom of Information Acts. Techniques and procedures are validated, described in standard operating procedures (SOP) and conducted by staff whose proficiency is regularly monitored.

NHSBT Quality Managers carry out regular audits to establish and improve the level of GMP and ISO15189 compliance. These complement external licensing and accreditation inspections by the Medicines and Healthcare products Regulatory Agency (MHRA) and Clinical Pathology Accreditation UK (CPA). RCI is committed to maintaining accreditation (CPA/UKAS) as a managed network covering all its laboratories.

RCI is committed to standardising practice and strive for a consistent and high quality service for all RCI laboratories. Working together with the NHSBT medical directorate, clinical policies and procedures are being implemented and developed in accordance with the principles of clinical governance.

All RCI laboratories participate in UK NEQAS (or EQAS) exercises for all relevant disciplines.

NHSBT quality experts are always pleased to share their expertise with colleagues in the wider NHS where time and resources allow. If you need help, contact the Quality Department to discuss your requirements (Appendix 1).

Complaints / compliments

NHSBT is committed to continuously improving the quality and range of services provided and welcomes any comments or suggestions from users. For compliance with clinical governance it is essential that failures of service and near misses which could have affected patient care are reported, and forms have been made available to hospital transfusion laboratories for this purpose. Please do not hesitate to discuss complaints with either Customer Services or the relevant medical consultant or Head of Laboratory. We always strive to provide a satisfactory response to any complainant. However, if you are unhappy with the handling of your complaint, please contact the Head of Hospital Customer Service (Appendix 1) Full details of the NHSBT complaints procedure can be found at: http://hospital.blood.co.uk/communications/Hospital_complaints/index.asp

Complaints must be clearly separated from communication about adverse reactions to transfusion, near misses or Patient Adverse Events which have or could have affected the quality of patient care. Such incidents and near misses often require immediate action and you are advised to discuss these with a NHSBT medical consultant or a senior laboratory scientist at your local blood centre. Serious events must be reported to SABRE (see below).

Services provided by RCI laboratories

RCI provides the following services in support of hospital transfusion laboratories:

- Investigation of antibody problems, including crossmatching
- Investigation of haemolytic transfusion reactions
- ABO/D typing, including typing problems
- Investigation of positive direct antiglobulin tests, including autoimmune haemolytic anaemia (AIHA), including crossmatching
- Determination of blood group by molecular methods when conventional serology is not applicable
- Investigation of IgA deficiency
- Investigation of haemolytic disease of the fetus and newborn (HDFN)
- Antenatal reference services including quantification and titration of antibodies
- Determination of feto-maternal haemorrhage FMH (testing is centralised and may be provided by another RCI laboratory)
- Provision of phenotyped blood
- Provision of suitable blood for IUT and at delivery
- Medical and scientific advice

Type of investigations

Atypical antibodies, serological and crossmatching problems

Samples referred for the investigation of atypical antibodies will be tested both to confirm the specificity of the antibodies and to exclude the presence of additional alloantibodies. RCI reference laboratories have access to a large number of phenotyped red cells in addition to routine antibody identification panels to enable a full investigation to be completed. The patient's Rh and K phenotype will be performed on the first sample received from that patient, plus testing for any other implicated antigens. Clinical advice on further transfusion support is given as appropriate. Results are entered on the NHSBT national patient database and an antibody card will be issued for patients with irregular antibodies.

Serological and crossmatching problems can be discussed with the scientific staff and samples referred for investigation. Advice can be given as to the type of blood that is suitable for transfusion and the availability of such blood. Where appropriate, crossmatching may be undertaken by RCI following discussion with the referring hospital transfusion laboratory.

Haemolytic Transfusion Reactions

See appendix 2 for guidance on reporting adverse reactions to transfusions.

ABO typing, Rh phenotyping, DAT and antibody screen / identification will be performed on both pre- and post-transfusion samples if available. If no antibodies are detected by standard methods a more sensitive method may be applied. Eluates will be prepared as necessary and tested against a panel of cells, including A_1 and B cells, by an IAT method.

An ABO, Rh phenotype and DAT will be performed on any implicated red cell units and re-crossmatching will be carried out against the pre- and post-transfusion samples.

If possible please include a clotted sample to allow testing of serum The tests above will be performed using plasma if this is the only patient sample(s) available. However, if all tests for antibodies are negative and there is strong evidence of haemolysis, a serum sample may be requested in order to repeat the tests. It is possible that some weak, complement-dependent antibodies will be more readily detected in serum.

If all reactions are negative, further investigations will be considered for non-haemolytic transfusion reactions e.g. HLA antibodies, anti-IgA.

Transfusion advice: If further blood is required urgently the NHSBT will provide ABO, Rh phenotype matched, K negative units. Pre-transfusion tests will be performed using the post- transfusion sample.

ABO/D grouping and antibody screening

Routine ABO/D groups can be performed with or without an antibody screen and a blood group card can be issued. A charge is usually made for this service.

Problems with ABO/D grouping

Samples can be referred for investigation if anomalous results are obtained with routine ABO or D grouping, e.g. to distinguish between partial and weak D antigens. With ABO grouping problems saliva may be requested. It is important to include relevant clinical data on the request form. A blood group card may be issued if required.

Direct antiglobulin test (DAT)

In a high proportion of DAT positive cases with free autoantibodies referred to the RCI laboratories, alloantibodies are also present. Therefore it is recommended that samples from patients requiring a transfusion and with a positive DAT are referred so that clinically significant alloantibodies, which might be masked, can be detected and identified. In these cases absorptions may be performed and adequate volumes of samples are required.

In recently transfused patients who develop a positive DAT, this may be caused by alloantibodies bound to donor red cells (indicating a possible delayed haemolytic reaction); in such cases an eluate needs to be prepared for which at least 3mL of packed red cells are needed.

In patients with a positive DAT and a negative antibody screen who need transfusions, samples should not routinely be referred prior to each transfusion episode. An eluate is indicated only if there is evidence of a delayed haemolytic transfusion reaction, a change in serology or if a higher frequency of transfusion than normal is required to maintain an adequate level of haemoglobin. The DAT may be positive in patients or in healthy individuals without overt haemolysis.

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Autoimmune haemolytic anaemia

An ABO, Rh and K phenotype are performed on all referrals.
A DAT is performed with isotype and complement specific reagents (anti-IgG, -IgA, -IgM, -C3c, -C3d).

Alloantibodies in addition to autoantibodies: samples are tested to ensure clinically significant alloantibodies that may be masked by autoantibodies are detected and identified.

Eluates are prepared and tested only if the patient has been recently transfused or has received a haemopoietic stem cell or bone marrow transplant. If other tests have proved inconclusive an eluate might be of value.

Transfusion advice: If you require blood cross-matched for a patient with a positive DAT and free autoantibody, please make this clear on the request form or speak to a RCI scientist.

Red Cell genotyping

Red cell blood group determination is undertaken in RCI laboratories to support and enhance timely decision-making to improve the safety of transfusion and improve patient outcomes.

In particular, the ability to determine blood type in previously transfused patients, and those with immunoglobulin coated cells will be of significant benefit. The service is available for referrals from all users but is provided from Tooting, Colindale, Birmingham, Sheffield, Filton, and Newcastle sites.

Blood groups currently determined by this method are: Rh C, c, E, e, Cw, M, N, S, s, K, k, Jka, Jkb, Fya, Fyb, Doa, Dob

The use of this test will be determined by RCI and clinical staff as part of the investigation. There is no facility to request this test from RCI, and there is no charge applied when it is undertaken.

Blood grouping results will be reported as phenotype or genotype depending on the method employed.

Drug associated autoimmune haemolytic anaemia

Haemolysis suspected to be associated with the use of a certain drug can be investigated, but advice should be sought from an RCI medical consultant before sending samples.

Cold agglutinins / haemolysins and cold haemagglutinin disease

A DAT is performed and the plasma is investigated for the presence of clinically significant red cell alloantibodies strictly at 37°C. It is not necessary to warm separate samples unless titration studies are required or specifically requested to do so by the NHSBT laboratory. Cold agglutinin titrations can be performed on request in Cold Haemagglutinin Disease patients.

Transfusion advice: SAGM-suspended cells that are ABO compatible, K negative and of a Rh phenotype matched with that of the patient are selected for transfusion. If the patient has clinically significant red cell antibodies units must also be negative for the relevant antigen(s). The blood is crossmatched by a standard antiglobulin technique strictly at 37°C. It is advised that units are transfused through a blood warmer.

Biphasic haemolysins and paroxysmal cold haemoglobinuria

Biphasic haemolysins as a cause of AIHA are extremely rare and mainly seen as a post-viral event in children. Routine investigations for AIHA do not include the test for biphasic haemolysins but where indicated, or on request, the Donath-Landsteiner test can be performed if paroxysmal cold haemoglobinuria (PCH) is suspected. If positive, the specificity of the antibody can be determined to confirm the diagnosis.

Transfusion advice: The haemolysis in PCH is generally self-limiting. Transfusion requirements can be discussed with a NHSBT medical consultant.

Paroxysmal nocturnal haemoglobinuria

If you require investigation of a suspected case of PNH the NHBTS laboratories will refer you to as specialist centre such as

Haematology Malignancy Diagnosis Service at Leeds Teaching Hospitals. Tel 0113 392 6285. Hospitals may refer samples there directly for testing.

Birmingham Heartlands: 0121 424 0706

Haematology dept King's College Hospital, London 0203 299 3520

Transfusion advice: Previously washed red cells were recommended for PNH patients. However, there is no evidence that the survival of washed red cells is better than that of those suspended in SAG-M.

Provision of crossmatched units in difficult cases

Where the provision of crossmatched units is problematic, , the RCI laboratory can undertake the crossmatch. Please make the request for crossmatched units clear on the request form and / or discuss with your local laboratory.

Investigation of IgA deficiency

In cases of anaphylactic transfusion reaction or other indications, samples can be referred to test for IgA deficiency and the presence of antibodies to IgA. A card is issued to the requesting clinician together with the RCI report for IgA deficient patients in whom IgA deficiency is diagnosed as part of a transfusion reaction, with or without anti-IgA. who have experienced transfusion reactions.

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Antenatal Red Cell Serology Screening

RCI offers an antenatal serology screening service which comprises

ABO and RhD type and antibody screen using fully automated systems, with interface to RCI's LIMS. NHSBT reverse group and screening cells are used, and all systems are subject to internal and external audit to BSQR and CPA/UKAS standards.

Non-routine samples can immediately be referred to RCI for investigation of anomalous groups and irregular antibodies. Antibody quantification and/or titration are available in-house.

Results are available on Sp-ICE immediately they are authorised by RCI

Expert clinical advice is available within NHSBT.

Haemolytic disease of the fetus and newborn (HDFN)

Suspected cases of HDFN can be investigated by RCI reference laboratories to detect and identify the causative red cell antibody, including immune ABO antibodies. Samples are required from mother and newborn, carefully labelled to distinguish between them.

Antenatal reference service

RCI offers an antenatal reference service for women whose plasma contains irregular antibodies. The specificity of the antibody is determined or confirmed and the concentration is measured. All investigations related to the prevention of HDFN are in accordance with the Guideline for Blood Grouping and Antibody Testing in Pregnancy (2006).
www.bcshguidelines.com

Pregnant women with a positive red cell antibody screen

If the antibody is confirmed and is of clinical significance to the fetus, the antibody will be quantified or titrated and follow-up tests performed as recommended by BCSH guidelines above. Antibody cards and explanatory leaflets are issued to all women who have clinically significant antibodies.

The follow-up investigations are:

- Monitoring maternal red cell alloantibody levels
- Identification of possible additional antibodies

In addition the following may be recommended:

- Red cell phenotyping of the father
- Fetal genotyping (at IBGRL) using peripheral maternal blood samples

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Measurement of maternal antibody levels during pregnancy (quantification and titration)

Measurement of antibody concentration depends on the antibody specificity:

- anti-D and anti-c are quantified in comparison to a national standard (see below)
- other antibodies, including anti-K, are titrated by testing a series of doubling dilutions of the antibody. The result is expressed as a titre, i.e. the greatest dilution of plasma which gives a serological reaction. A titre of 32 or above is generally considered to have the potential to cause HDFN.
- antibodies such as anti-P_1, anti-Le^a and Le^b, which do not cause HDFN, do not require measurement.

Anti-D and anti-c are the antibodies most likely to cause significant fetal disease. Therefore, pregnant women with these antibodies should be followed-up at monthly intervals until 28 weeks gestation and at two-weekly intervals thereafter to term. Anti-D and anti-c are quantified against a national standard and the strength of the antibody is reported in international units (IU/mL).

The measurement of antibody in international units is one of the tools available for assessing the likelihood of HDFN. An increase by 50% or greater over the previous level indicates a significant rate of increase, irrespective of the period of gestation.

Generally the significance of anti-D and anti-c levels during pregnancy is as follows:

Anti-D less than 4 IU/mL	HDFN unlikely
Anti-D 4-15 IU/mL	Moderate risk of HDFN, requiring referral to a specialist obstetric unit
Anti-D greater than 15 IU/ mL	High risk of HDFN, requirement as above

NB. It should be noted that HDFN has been reported at levels less than 4 IU/mL.

Anti-c less than 7.5 IU/ mL	HDFN unlikely, continue to monitor
Anti-c 7.5 – 20 IU/mL	Moderate risk of HDFN, requiring referral to a specialist obstetric unit
Anti-c greater than 20 IU/mL	High risk of HDFN, requirement as above

The NHSBT antenatal reports provide clinical advice regarding risk of HDFN and follow-up required.

It is essential that pregnant women with levels of anti-D of ≥ 4 IU/mL or anti-c at ≥ 7.5 IU/mL are referred to an obstetric unit with experience in non-invasive monitoring for fetal anaemia at the earliest opportunity. NHSBT provides this advice in the antenatal test reports.

Measurement of uncertainty data for quantification, titration and FMH estimation is available on request.

Quantification of post-prophylaxis anti-D

The adoption of the NICE guidance recommending routine antenatal anti-D prophylaxis for D negative women, there is a marked increase in the incidence of low level anti-D in antenatal samples taken after anti-D injection. The policy of RCI is **not** to quantify anti-D if:

- The woman has a documented record of having received prophylactic anti-D within the past 8 weeks (after administration of 500 IU) or 12 weeks (after 1500 IU) and did not have detectable anti-D prior to the prophylaxis.

AND

- The serological reaction against D positive reagent red cells is weak. The yardstick used by RCI laboratories is that no reaction is stronger than a score of 2 in a column IAT technique

We advise that it is not necessary to quantify antibodies such as those described above unless there is some extenuating circumstance. However, if hospital transfusion laboratories choose to refer such antibodies for quantification we will do so. It must be made clear on the request form that antibody quantification is specifically requested.

Anti-K(ell) is a significant cause of HDFN but in >80% of cases the partner is K negative. Guidelines recommend a sample from the father of the pregnancy should be K typed. NHSBT will not routinely request partner samples, but will recommend on the maternal report that they are tested. If the partner is typed as K negative either by NHSBT, or the hospital transfusion laboratory provides written confirmation that they have typed the partner as K negative , samples from the mother will be requested for re-testing at 28 weeks gestation. The report will state the current partner's details and it will be the responsibility of the healthcare professional monitoring the pregnancy to confirm this. If the father is K positive or if there is any doubt, samples will be requested at monthly intervals to 28 weeks and fortnightly thereafter to term.

The concentration of **anti-K and other clinically significant antibodies** is assessed by testing dilutions of the patient's plasma and the results are reported as a titre.

Pregnant women with clinically significant antibodies other than anti-D, anti-c and anti-K should normally be re-tested at 28 weeks gestation. The results at this time will determine the frequency of follow-up testing. These antibodies are titrated as for anti-K.

Many red cell antibodies have the potential to cause HDFN. Therefore, it is essential for ALL pregnant women found to have clinically significant red cell antibodies to be referred to a hospital obstetric unit for management of their pregnancy. For women with clinically significant antibodies, including anti-K, with a titre of ≥ 32 it is also recommended that referral to a specialist obstetric unit be considered (as for women with significant levels of anti-D or anti-c - see above).

Clinical advice is given on reports of all pregnant women with antibodies that could cause fetal disease.

Exclusion of further antibodies

All samples referred for antibody monitoring are tested to exclude further clinically significant red cell antibodies that might have developed.

Paternal phenotype

When an antibody with a high chance of causing HDFN is detected (i.e. anti-D, anti-c, anti-K or other significant antibody with a high titre) the maternal report will recommend that a sample from the father of the fetus is phenotyped, because paternal testing can be a useful to guide clinical management.

Fetal genotype

If there is a high risk of severe HDFN, caused by anti-D, anti-c or anti-K, then prediction of the relevant genotype of the fetus should be considered on the advice of a Consultant in fetal medicine. Fetal D, C, c, E and K genotyping can be performed on a sample of maternal blood. The molecular typing service is provided by IBGRL. www.blood.co.uk/ibgrl

Determination of feto-maternal haemorrhage

In any case where the Kleihauer test indicates a FMH > 2mL of fetal red cells, or where the test result is equivocal, a sample (the same as used for the Kleihauer test) can be referred to NHSBT for confirmation by flow cytometry. Advice on how much additional anti-D is recommended for large bleeds will be provided by an RCI Consultant Haematologist.

To ensure timely testing, please phone your local blood centre if you intend to send samples for flow cytometry.

Please note that for large bleeds >40mL an intravenous (IV) anti-D preparation is recommended in preference to intramuscular injection

See 'Phenotyped Blood' section for information about ordering units for intra-uterine and exchange transfusion

Medical and scientific advice

Advice on all aspects of RCI investigations can be obtained from Consultant Haematologists and senior scientists. Contact details are given in Appendix 1. This advice is available 24 hours per day and details of how to contact us outside our normal working hours are given in 'On Call' below.

Reports include advice on selection of units for transfusion and, in the case of antenatal samples, advice on the significance of antibodies in pregnancy and the requirements for re-testing.

On Call

All blood centres can be contacted 24 hours per day, every day of the year (Appendix 1).

Urgent cases:

RCI aim to report 95% of results within five working days. Any referral which requires a report before this time, or any crossmatch request should be treated as an urgent request.

During normal working hours contact the local RCI laboratory or Consultant Haematologist. Out of normal RCI laboratory working hours, for clinical and scientific advice and discussion about urgent cases and requests for urgent investigations, phone the Hospital Services department. They can put you in contact with a RCI laboratory scientist or a medical consultant.

Both during and outside RCI laboratory working hours your NHSBT contact will ask you for information about urgent referrals in order to understand the urgency and to assist in the appropriate investigation. In addition to the patient demographics you will be asked for: the patient's condition, current haemoglobin level, transfusion and/or obstetric history, drug history, if relevant, and transfusion requirement (special requirements etc). We will also ask for a summary of your serological findings.

Collection of data on the outcome of pregnancies with clinically significant antibodies.

In order to collect and collate data on the effect of red cell antibodies on the fetus and newborn, NHSBT will issue a questionnaire for selected women who have red cell antibodies. The questionnaire requests information about the outcome of the pregnancy and condition of the baby. The aim is to build up a body of evidence about the effect of antibodies of known specificity and strength which will be valuable in determining future policies and practices for the testing and treatment of pregnant women with antibodies. Expectant mothers are informed via the antenatal information leaflet "Blood Groups and Red Cell Antibodies in Pregnancy" and on the information sheet issued with cards sent to women with significant red cell antibodies. Data Protection requirements are satisfied by the statements on the questionnaires together with the Service Level Agreement between the NHSBT and your Trust. The help and co-operation of users in completing these questionnaires is an essential contribution to this initiative.

Information cards

For patients with clinically relevant irregular red blood cell antibodies or IgA deficiency, a card will be sent.

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Request forms, samples, labelling requirements

Request forms

Request forms can be ordered free of charge from any NHSBT RCI or Customer Services department There is one request form for all RCI reference work (1A).

Sample requirements

Full details of minimum sample requirements are listed on the reverse of the request forms.

In summary:

Alloantibody investigation	2 x 6ML EDTA
ABO/Rh grouping problems	1 x 6mL EDTA
Extended RBC phenotype	1 x 6mL EDTA
Auto-immune haemolytic anaemia + positive DAT	2 x 6mL EDTA
Haemolytic transfusion reaction	2 x 6mL EDTA post transfusion 1 x 6mL EDTA pre transfusion + lines/remnants from units
Compatibility testing	2 x 6mL EDTA
IgA deficiency/antibodies	2 x 6mL EDTA
Haemolytic disease of the newborn	2 x 6mL EDTA + 1mL cord blood
Anti-D/-c quantification	2 x 6mL EDTA
Paternal phenotyping	1 x 6mL EDTA
Assessment of FMH or other minor RBC population	1 x 6mL EDTA
Routine antenatal screening	2 x 6mL EDTA
All other investigations,	Please contact your local RCI laboratory

Haemolysed and Lipaemic samples

Sending haemolysed and/or lipaemic samples should be avoided where possible as free haemoglobin and/or fatty plasma can produce test result errors especially when using automated equipment. Such samples may have to be rejected. However it is recognised that there are situations when haemolysis, in particular, is a result of the patient's condition. Please ensure that relevant details are included on the request form to help determine suitability of samples for investigation.

Labelling of samples / completion of request forms

An NHSBT request form must accompany every sample. Request forms are the basis of the correct identification of the patient. The SHOT scheme has shown that serious hazards of transfusion are often caused by clerical errors. The points of identification provided on the request form must match the information provided on the sample. The NHSBT will not accept referrals with an inadequate request form or sample labelling (see Guidelines for Compatibility Testing in Blood Transfusion Laboratories 2012).
www.bcshguidelines.com

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In case of a clinical emergency NHSBT may agree with the requesting Consultant Haematologist or laboratory scientist to proceed with the requested investigations. However, in such cases reports or issues of blood products will carry an explicit warning that the three points of identification were not used for the samples and / or request form.

The requester is advised to check the identifiers and to obtain reassurance about the identifiers used for the linking between patient and sample.

Samples with *Addressograph,* i.e. pre-printed labels, are not accepted by RCI. Labels which have been generated and attached at the bedside at the time of phlebotomy from scanning bar-coded wristbands on an automated system are acceptable for samples. Since it is not possible to distinguish reliably between these and *Addressograph* labels they can be accepted only from referring organisations which have informed NHSBT, in writing, that their sample labels are generated in an audited system and are demand printed at the time of phlebotomy. Please contact your local Customer Services Manager if you wish to discuss notifying NHSBT.

The NHSBT will not normally test samples unless three or more identical points of identification are used on both forms and tubes.

Minimum patient identification. Surname and first name are one identifier:

- Surname / family name
- First name(s) in full (correctly spelt)
- NHS number or hospital number
- Date of birth

Also required:

- Date of venepuncture
- Signature of venepuncturist

While RCI will accept hospital number as a third identifier, we would remind users that the hospital number does not specifically identify your patient. Since some hospitals use the same numbering systems and NHSBT stores patient data on a national database, the use of hospital number without other points of identification may lead to errors. Please use the NHS number where available. RCI are working towards a zero tolerance policy for inadequately labelled samples.

The sample tube should be signed by the person taking the sample and must be dated to ensure that it is fresh enough to give accurate results within the parameters of the test(s) requested. For pre transfusion samples, the time the sample was taken must also be on the sample tube. If this is not provided RCI will use a default time of 00:00 (midnight)

All samples must be accompanied by a request form specifying the tests or investigations required (where appropriate) and should have the signature and name of the person making the request.

Please note these are the minimum standards acceptable for labelling and request form completion

The following additional information is required on the request form:

- Requesting hospital (Please use your NHS code)
- Name of consultant or clinician
- Ethnic origin of patient
- Type of investigations requested, including requests for crossmatched units
- Clinical condition
- Current haemoglobin level (for cross match requests)
- Recent transfusion history (for hospital reference cases)
- Dates and doses of recent anti-D prophylaxis

We should be informed if samples are from private patients. The terms and conditions of service provision for the NHS by the NHSBT are agreed with the National Commissioning Group. Service provision for private patients may be charged differently.

Clinical information is essential for providing the most appropriate laboratory tests. The quality of clinical advice will also depend on provision of adequate clinical information. Absence of clinical information may lead to a delay in processing of the sample if the requester needs to be contacted to agree on the type of investigations.

The sample must be dated as the outcome of several tests may be influenced by the age of the sample. It also allows NHSBT to monitor turnaround times.

The type of investigation requested and reason for the request must be clearly identified on the request form.

Tubes

Glass tubes are not acceptable.
It is the responsibility of the referrer to ensure samples tubes are in date. NHSBT may reject blood samples that are taken in to expired sample tubes.

Packaging of samples

It is the responsibility of the sender to ensure that all samples are packaged in accordance with the current recommendations on the Transport of Dangerous Goods: United Nations Model Regulations to prevent breakage or spillage in transit. The outside of the box or package containing the samples must be clearly addressed to the appropriate Red Cell Immunohaematology Department with storage instructions for labile material. NHSBT reserves the right to refuse to handle any samples which are inappropriately packaged or labelled.

For advice on posting samples see www.royalmail.com

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Transport of samples

Routine samples

Samples for non-urgent testing by RCI can be given to the NHSBT blood delivery driver.

Urgent samples

For urgent samples during or after normal working hours, please phone the RCI laboratory and discuss the arrangements for sending the samples. Urgent samples should be transported directly from the hospital transfusion laboratory or requesting clinician to the blood centre. **NHSBT transport is not suitable for samples requiring urgent investigation.**

Packages must be clearly labelled to ensure samples do not go astray. Blood centre location maps can be provided on request or from NHSBT website for couriers carrying urgent samples.

Reports

A medical consultant or a senior scientist sees all non-routine reports before they are issued and relevant clinical comments are made. The basic principle for reporting is to send the report to the requester. RCI reports on referrals received through hospital transfusion laboratories will be addressed to the requesting laboratory, however the final responsibility lies with the hospital Consultant Haematologist who may or may not delegate that responsibility to the laboratory manager.

Copy Reports:

Copy report arrangements with service users are documented. If additional copies are required these need to be identified on the request form. Printed reports will be reconciled against documented requirements and the request form. If the request form and documented arrangement conflict the requirement for additional copies will be confirmed with the requestor.
When requested, urgent reports can be faxed to a requester.

SP-ICE

Users may access RCI results on the NHSBT web browser at any time. Results are placed on the web browser as soon as the reports are printed and are therefore available before the hard copy report has reached the requester. For further details about access to the web browser contact the NHSBT Information Governance Manager (Tel. 0191 202 4581).

Computer records

The RCI laboratories are supported by a national computer system, Hematos, on which patient data are stored. NHSBT computer systems are registered under the Data Protection Act. Staff access to the patient database is on a need-to-know basis for clinical care purpose only and patient confidentiality is respected at all times.

NHSBT REAGENTS

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Red Cell Immunohaematology Reagents

NHSBT reagents are produced at the Liverpool Centre.

Quality Statement

Where applicable, products are CE marked (98/79/EC) and all products comply with the standards laid down in the Guidelines for the Blood Transfusion Services in the UK (current edition) and are prepared to best standards of practice.

Ordering of reagents

Ideally reagents should be ordered on a standing order basis which is renewed each year. Alternatively they can also be ordered or on an ad-hoc basis by telephone, in writing or by e-mail (reagentscs.nhsbt.nhs.uk) to Reagents Customer Services

Prices

A price list is available on request from the contacts listed below and on-line.

Red Cell Reagents

All cells have a 52 day expiry date and are CE marked.

ABO reverse grouping and Rh control cells

10mL volumes of 3% A_1, A_2, Brr, BR_1r and OR_1r cells in Alsevers
10mL volumes of 0.8% A_1rr, Brr and OR_1r cells in DiaMed CellStab
10mL volumes of 0.8% A_1rr, Brr and OR_1r cells in Grifols CellMedia

Antibody detection and identification

2-cell screen - consisting of OR_1R_1 and OR_2R_2 with homozygous expression of the S, s, Fy^a, Fy^b, Jk^a and Jk^b antigens and positive for K, P_1, N, Le^a and Le^b.

3-cell screen - consisting of OR_1R_1, OR_2R_2, and Orr with homozygous expression of the antigens as per the 2-cell screen.

Screening cells are supplied in Alsevers, BioRad CellStab or Grifols CellMedia

A range of antibody identification panels is available and are supplied as native or enzyme treated in Alsevers, CellStab and CellMedia. Panel cells in LISP are also available (non-enzyme treated only).
Two panel sets in Alsevers, CellStab and CellMedia (native and enzyme treated) are available at all times with each panel derived from a different set of donors to allow better identification of antibody mixtures.

rr screening cells are available in CellStab and CellMedia for use in determining the presence of red cell antibodies in patients who have received prophylactic anti-D. A further pair of r'r and r"r cells are available for use in conjunction with the rr set in order to assist in the detection of anti-C and/or anti-E antibodies.

Titration cell sets consisting of R_1R_Z and R_1R_2 cells in CellStab are available for use in antibody titration tests.

Antiglobulin test

IgG coated cells
For addition to apparent negative antiglobulin reactions to ensure that there has been no inhibition of the anti-IgG. Sensitised with anti-D to give a grade 2-3 positive reaction to help ensure that even partial inhibition is detected.
Supplied as 1 x 10mL of 4% suspension

Weak IgG anti-D control
0.08 to 0.1 IU/mL for use as a positive control in antibody screening. Supplied as 1x10mL volume.

Weak anti-c, anti-K and anti-Fy^a controls.
Supplied as 1 x 10mL volume

Inert serum from group AB donors for use as a negative control
Supplied as 1 x 10mL volume

Serological controls and other products

Whole blood controls
A and B cells (one of which is RhD positive and the other RhD negative). One containing anti-D and the other anti-K.
Supplied as a set of 2 x 5mL volumes.

IPEx
Supplied 6 times a year this can be used for internal proficiency testing, staff training etc. Most exercises are accompanied by some CPD questions.

See Appendix 1 for NHBTS Reagents contact details

NHSBT Reagents documents including order forms, price lists, product inserts, material safety data sheets, product profiles and certificates can be found at:
www.blood.co.uk/reagents

Red Cell Immunohaematology User Guide

Appendix 1

CONTACT DETAILS

		Office	Mobile
Head of RCI	Dr. Mark Williams	0113 820 8675	0776 428 0733
National Operations Manager - RCI	Sarah Thompson	0151 268 7144	0782 335 1741
Process Improvement Manager - RCI	Tess Winfield	0113 828 8659	0759 035 2173
Clinical Director - Diagnostics	Dr. Nay Win	020 3123 8309	0771 144 7104
Lead Quality Specialist - SpS	Keith Smith		0771 144 7199
Head of Hospital Customer Service	Chris Philips	01912026612	07889304517

REAGENTS:

		Telephone	Mobile
National Reagents Strategy Manager	Malcolm James Vincent Drive, Edgbaston, Birmingham B15 2SG	0121 278 4061	0776 428 0818

New or amended orders and General Enquiries	Estuary Banks, Speke, Liverpool L24 8RB	0151 268 7157	Fax: 0151 268 7156

RCI:

BIRMINGHAM
Address: Vincent Drive, Edgbaston, Birmingham, B15 2SG

		Office	Mobile
Centre switchboard		0121 278 4000	
Hospital Services Department		0121 278 4037	
RCI Consultant Haematologist	Dr Rekha Anand	0121 278 4013	0776 428 0630
Customer Services Manager	Craig Wilkes	0121 278 4132	0752 529 9020
Head of Laboratory	Ian Skidmore	0121 278 4125	0780 890 6443

FILTON
Address: North Bristol Park, Northway, Filton, Bristol, BS34 7QH

		Office	Mobile
Centre switchboard		0117 921 7200	
Hospital Services Department		0117 921 5724	
RCI Consultant Haematologist	Dr Tom Latham	0117 921 7474	0751 576 1072
Customer Services Manager	Elaine Macrate	0117 921 7449	0771 1447589
Head of Laboratory	Wendy Etheridge	0117 921 7511	0776 428 0719

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COLINDALE
Address: Colindale Avenue, London, NW9 5BG

		Office	Mobile
Centre switchboard		0208 957 2700	
Hospital Services Department		0208 957 2800	
RCI Consultant Haematologist	Dr. Fiona Regan	0208 957 2834	0771 144 7235
Customer Services Manager	Antonia Hyde	0208 957 2730	0776 428 0268
Head of Laboratory	Tracey Tomlinson	0208 957 2743	0771 144 7196

LEEDS
Address: Bridle Path, Leeds, LS15 7TW

		Office	Mobile
Centre switchboard		0113 820 8600	
Hospital Services Department		0113 820 8607	
RCI Consultant Haematologist	Dr Robert Webster	0114 358 4813	0771 144 7308
Customer Services Manager	Robin Coupe	0113 820 8695	0771 144 7558
Head of Laboratory	Dianne Armstrong	0113 820 86	

LIVERPOOL
Address: 14 Estuary Banks, Speke, Liverpool, L24 8RB

		Office	Mobile
Centre switchboard		0151 268 7000	
Hospital Services Department		0151 268 7170	
RCI Consultant Haematologist	Dr Therese Callaghan	0151 268 7012	0771 1447383
Customer Services Manager	Christine Gallagher	0151 268 7123	0772 027 5376
Head of Laboratory	Daniel Palmer	0151 268 7144	0752 529 9023

NEWCASTLE
Address: Holland Drive, Newcastle upon Tyne, NE2 4NQ

		Office	Mobile
Centre switchboard		0191 202 4400	
Hospital Services Department		0191 202 4500	
RCI Consultant Haematologist	Dr Hazel Tinegate	0191 202 4548	0776 428 0306
Customer Services Manager	Robin Coupe	0191 202 4553	0771 144 7558
Head of Laboratory	Martin Maley	0191 202 4416	

SHEFFIELD
Address: Longley Lane, Sheffield, S5 7JN

		Office	Mobile
Centre switchboard		0114 358 4800	
Hospital Services Department		0114 358 4832	
RCI Consultant Haematologist	Dr Robert Webster	0114 358 4813	0771 144 7308
Customer Services Manager	Delia Smith	0114 358 4988	0776 428 0854
Head of Laboratory	David Ward	0114 358 4855	0787 263 6762

TOOTING
Address: 75 Cranmer Terrace, Tooting, London, SW17 0RB

		Office	Mobile
Centre switchboard		0203 123 8300	
Hospital Services Department		0203 123 8352	
RCI Consultant Haematologist	Dr Nay Win	0203 123 8309	0771 144 7104
Customer Services Manager	Richard Whitmore	0203 123 8408	0776 428 0831
Head of Laboratory	Doris Lam	0203 123 8346	0772 027 5322

Appendix 2

Reporting adverse reactions to transfusions

There is a regulatory requirement in the UK under the terms of the Blood Safety and Quality Regulations 2005 to report adverse reactions related to transfusion. The Medicines and Healthcare products Regulatory Agency (MHRA) has been appointed the Competent Authority on behalf of the Secretary of State to administer the regulations, and has developed a web-based haemovigilance reporting system called SABRE (Serious Adverse Blood Reactions and Events) to facilitate reporting.

All Trusts in the UK should be registered with the MHRA and must submit a 'notification' report to them as soon as possible following a reaction. At the time of reporting, there is the opportunity to tick a box allowing SHOT (the Serious Hazards of Transfusion confidential enquiry) access to the report details. Failure to tick this box will result in a call from the MHRA Adverse Incident Centre to advise the reporter of the need to report also to SHOT.

The SHOT Office will review the incident details and, if appropriate, will assign a questionnaire for the reporter to complete on-line. An automated e-mail is generated informing the reporter which questionnaire has been allocated and containing a link to access it. This SHOT questionnaire should be completed and returned via SABRE as soon as possible. Automated reminders will be sent at regular intervals until the questionnaire is completed.

Following investigation of the incident by the reporting hospital, and where appropriate by the blood services, the reporter is required to submit a 'confirmation' report to MHRA via SABRE which effectively closes the case, provides an assessment of the likelihood of the reaction being due to the blood component and details, where appropriate, any corrective and preventative actions put in place to reduce the likelihood of the event recurring.

Current SHOT reporting categories may be found at;
http://www.shotuk.org/wp-content/uploads/2010/04/SHOT-Categories-2009.pdf

Cases in which the wrong blood component was transfused (IBCT), cases of acute transfusion reactions (ATR) including anaphylaxis and delayed haemolytic transfusion reactions (HTR) may be referred to RCI for investigation.