

**Northern Ireland
Blood Transfusion Service
(A Special Agency of the HSC)**



PROSPECTUS AND USER GUIDE

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Quality Assurance Manager	Mr G Geddis	4671
Regulatory Affairs & Compliance Manager	Ms A Macauley	4633
Donor Services General Manager	Mr C Kinney	4667
Head of HR/Corporate Services	Mr I Ritchie	4686
Finance Manager	Mr G Bell	4683
Apheresis Unit	Dr B Bradley	4669
Hospital Services	Mrs P Gowdy Mrs B Mullin	4615/4610 4634
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1 INTRODUCTION

This prospectus and user guide aims to provide a description of the products and services available from the Northern Ireland Blood Transfusion Service (NIBTS). It also describes the procedures for requesting these products and services.

All blood components prepared from donations in NI are provided by our voluntary, non-remunerated donors. As a freely donated gift there is no charge for the blood itself and charges and costs referred to in this document relate to the operational costs of collection, testing, processing, storage, supply and distribution.

All plasma derivatives are obtained from imported plasma, as required by the UK Government. This is a precautionary measure against the possible risk from variant CJD (vCJD) in the UK population. Since June 1998 UK Transfusion Services have been required to use imported plasma for the manufacture of plasma products.

The NIBTS provides a 24-hour service including immunohaematological reference service and medical consultant advice on all aspects of blood transfusion practice.

2 CONTACTING NIBTS

NIBTS may be contacted during office hours (9am to 5pm, Monday to Friday) at telephone number (028) 90321414, fax number (028) 90439017 (Secretaries Office) or (028) 90534611 (Hospital Services).

Outside of normal office hours NIBTS may be contacted through the Belfast City Hospital switchboard, telephone number (028) 90329241. The initial point of contact will be the Biomedical Scientist (BMS) on-call who can seek medical advice as appropriate or otherwise direct the caller (see also 'Ordering Procedure', page 14).

3 SERVICE AND BUDGET AGREEMENTS (SBAs) WITH TRUSTS AND THE HSC BOARD

3.1 Background

The present funding arrangements for the supply of products and services by NIBTS have been in operation since 1 April 1994.

Hospital Trusts have SLAs with NIBTS for the supply of such products (with the exception of products used in the management of haemophilia which are funded directly by the HSC Board). The NIBTS also have SLAs with the HSC Board for the provision of patient testing services (including antenatal testing) and other related services.

3.2 Blood and Blood Products (Excluding Haemophilia Products)

NIBTS has SLAs with each Trust for the supply of these products. Such contracts include agreed volumes (approximate) and charges.

4 QUALITY STATEMENT

Quality is regarded as of paramount importance at the Northern Ireland Blood Transfusion Service. This Quality Policy applies to all services provided by NIBTS:

- Collection, processing, testing, storage and issue of blood components
- Procurement and provision of plasma products
- Provision of patient testing services – blood group serology and virology screening(HIV, HbsAg, Syphilis and Rubella Immunity),for antenatal patients, and reference services to hospital blood banks in N Ireland for blood group serology and platelet serology.

This commitment is demonstrated by the development of a quality management system, which will ensure the provision of safe, efficacious and timely blood products and services for both patients and donors. This system will comply with

all relevant legislation including Blood Safety and Quality Regulations, Environmental legislation, and UKAS/ CPA Accreditation standards.

The policy rests on the following principles:

- Our definition of quality is 'conformance with requirements'. We will carefully specify the requirements for our suppliers and our processes and will comply with the requirements of our users. Performance against these specifications will be monitored
- The training and education of staff shall be of a level to ensure that all staff recognise their responsibility to maintain and improve quality through awareness of the Quality Manual and compliance with relevant procedures. Staff are committed to good professional practice.
- The health and welfare of staff and visitors.

While aiming for the lowest possible failure rates on all aspects of NIBTS operations, systems and procedures have been developed to permit rapid and satisfactory handling of all complaints and defects. In this way the interface between NIBTS and its supply and user base is continually monitored and where necessary reviewed and revised.

NIBTS is licensed as a blood establishment. NIBTS has been granted a Blood Establishment Authorisation under the Blood Safety and Quality Regulations (BSQR), 2005 and a Wholesale Distributors' Licence, by the Medicines and Healthcare products Regulatory Agency (MHRA). The NIBTS Diagnostic Laboratory Service is also in receipt of accreditation from the Clinical Pathology Accreditation Ltd (CPA), now a wholly owned subsidiary of UKAS. UKAS is currently managing the transition of all CPA accredited laboratories to UKAS accreditation to ISO 15189:2012, Medical Laboratories – requirements for quality and competence .

NIBTS is committed to the promotion of best transfusion practice in N Ireland. NIBTS convenes the NI Transfusion Committee and NIBTS is represented on the Committee. NIBTS Medical Consultants are members of 5 individual Hospital Transfusion Committees and are closely involved in the development of guidance for clinical practice and audits for compliance with agreed standards of best transfusion practice. NIBTS is also represented on the UK & Ireland Better Blood Transfusion Network.

This Medical Consultant resource is available at NIBTS and where at all possible, requests for assistance from clinical units will be facilitated.

In order to measure the level of satisfaction with services provided by NIBTS and identify service improvements questionnaires will be issued. The questionnaires will be specific in the terms of target users. The results will be provided back to users at two annual user meetings. To ensure adequate representation, a quorum for these meetings has been determined to be a minimum of five people, including representation from three Trusts and two NIBTS representatives, covering Quality and Laboratories.

- 1 Hospital Services/Immunohaematology Users' Meeting
- 2 Antenatal Patient Testing Users' Meeting

5 **SUPPLY OF BLOOD PRODUCTS**

5.1 Definitions

Blood components. Therapeutic derivatives of whole blood prepared (apart from methylene blue treated plasma components) by NIBTS.

Plasma derivatives. Therapeutic derivatives from the plasma component of blood which have been manufactured by appropriately licensed commercial fractionators.

Plasma for fractionation is currently sourced outwith the UK because of the possible risk of transmission of variant CJD from UK donor plasma.

Blood products. A general term encompassing both blood components and plasma derivatives.

5.2 Standards

All blood products will conform to or exceed specifications set out in the BSQR and take account of the current version of the Guidelines for Blood Transfusion Services in the United Kingdom (Red Book), and any nationally agreed revisions to these guidelines.

All blood products are prepared from donations which have been screened, labelled negative for HIV 1 and 2 antibody/antigen, hepatitis B surface antigen, hepatitis C antibody, syphilis antibody and HTLV 1&2 antibody. All donations are also tested for HIV RNA; HCV RNA and HBV DNA.

All blood components are leucodepleted in accordance with the Guidelines for UKBTS with a specification for leucocytes of $<5 \times 10^6/l$ per unit (99%), $<1 \times 10^6/l$ per unit (90%).

The issue of blood products is supported by a 24-hour service for investigation of urgent serological problems and by 24-hour consultant medical advice.

5.3 Customer Responsibility

5.3.1 Trusts must note that under the Consumer Protection Act of 1987 blood is defined as a product. Hospital blood banks can be seen in the role of 'supplier', 'keeper' and in some cases 'producer' in the chain of product supply to the patient.

Trusts must comply with requirements of BSQR. Trusts must therefore ensure that correct procedures are in place for the handling and storage of blood products from the time of receipt to transfusion which ensure the maintenance of quality. Trusts must have systems in place for full traceability of products. The NIBTS reserve the right to inspect, by mutual agreement, hospital blood banks regarding such procedures and systems.

5.3.2 Products issued from NIBTS to Trusts are accompanied by consignment notes that detail the contents of that consignment. In order to assure compliance with the UK Regulations SI 2005/50 hospital blood bank staff must check and sign that the consignment details are correct and return the signed consignment note to Northern Ireland Blood Transfusion Service.

5.3.3 Hospitals receiving blood products produced by the NIBTS will be responsible for ensuring that 'giving sets', used to administer such products are compatible with the 'ports' on blood packs received.

5.3.4 Where any adverse event associated with a blood component/product, any defect in the quality of products or services are identified these must be reported to NIBTS Regulatory Affairs and Compliance Department – see page 37

5.4 Blood Products Available from NIBTS

The range of blood components prepared and supplied by NIBTS is described in Appendix 1.

The range of plasma derivatives available is listed in Appendix 2.

Our policies for the supply of certain specially prepared blood components are described below:

5.4.1 Neonatal Transfusion

(a) Red Cells for Exchange Transfusion

Plasma reduced (semi-concentrated) cells which are gamma irradiated, CMV antibody negative are available for exchange transfusion. The following ABO groups are provided: O (Rh) D positive; O (Rh) D negative (rr); A (Rh) D negative (rr). These units are prepared and issued within 5 days of collection and are screened for high titre ($\geq 1:100$) anti-A and anti-B. Resuspension of red cells in donor plasma for exchange transfusion will also be prepared by NIBTS on demand.

(b) Red Cells for 'Top-Up' Transfusion

Red cells suspended in optimal additive solution (OAS) are available as 'paedipacks' (6-8 aliquots from single blood donation). This unit can be dedicated for a particular baby receiving several, small-volume (<10 ml/kg) transfusions, thus significantly reducing donor exposure. ABO groups O R₁R₁ (CDe/CDe); A R₁R₁ (CDe/CDe); O Rh(D) negative (rr) and A (Rh)D negative (rr). All donations are labelled Kell negative and CMV antibody negative. These units are prepared within 5 days of collection and have a 35 day expiry. Other ABO groups and Rh(D) types can be supplied with notice.

5.4.2 CMV Antibody Negative Blood

NIBTS maintains an inventory of CMV antibody negative cellular blood components and these can be supplied on request for appropriate patient groups.

The patient groups for which CMV antibody negative components are required have been greatly reduced and now include antenatal transfusion to protect foetus and for neonates for 28 days following estimated delivery date.

5.4.3 Irradiated Blood Components

Gamma irradiated cellular blood components can be supplied on request. Indications for use are as listed in Appendix 3 and medical and hospital services staff will be happy to discuss other possible indications for use.

5.4.4 Phenotyped Red Cells

NIBTS maintains an inventory of R₁R₁ and R₂R₂ Kell negative red cells. These are available as a stock item and may be requested from NIBTS Hospital Services Department by faxing (028) 90534611.

Red cells with extended phenotypes will be issued on request. The hospital blood bank should make these requests to the Blood Group Reference Laboratory on (028) 90534605.

5.4.5 'Emergency Use' Blood

'Emergency use' or 'flying squad' red cell components Group O (Rh) D negative (cde/cde) and Kell negative are available on request

5.4.6 HLA Selected Platelets

HLA selected platelets may be provided on request for patients who are refractory to random platelets and who have anti-HLA antibodies.

Cross-matched compatible platelets (using solid phase red cell adherence Capture P assay) may also be provided for patients who are refractory and in whom we have demonstrated platelet antibodies.

5.5 **ORDERING PROCEDURE**

5.5.1 Laboratory Testing

Blood products are only issued after all laboratory tests have been completed and this has been validated by computer for each product. See also 1.5.7.

5.5.2 How to Contact Us

The NIBTS Hospital Services Department is open 9 am to 5 pm (Monday to Friday)

At other times an on-call service is provided.

All orders **MUST** be submitted by fax:

Fax - (028) 90534611

During 9am to 5 pm (Monday to Friday) NIBTS do not accept telephone requests unless there is a technical reason why faxes cannot be submitted.

For on-call, outside these times, however, the BMS should be telephoned prior to sending the fax.

First contact number of the Belfast City Hospital switchboard is (028) 90329241. They will pass the call to the NIBTS BMS on-call. Internal NIBTS extensions should not be used. A confirmation fax must be submitted.

Orders to be faxed using the relevant Order Form DD:807, DD:808 or DD:809, issued to hospital blood banks. All NIBTS forms are document controlled and may be obtained by telephoning the Document Control Officer on ext. 4673.

5.5.3 Requesting and Delivering Arrangements

Requests for delivery should be placed from 9 am to 5 pm, Monday to Friday. Requests for hospital blood bank routine orders should be received at NIBTS one working day prior to collection. (Monday orders may be received for dispatch that same day and urgent orders will be ready for collection within 2 hours.)

Emergency requests received by fax at any time during the day or night will initiate immediate action.

Consignments of blood and blood components are collected from Hospital Services reception at the rear of the building.

The Blood Safety and Quality Regulations, 2005 requires full traceability of blood components from donor to recipient. It is the legal responsibility of hospital staff to comply with this requirement i.e. the fate of all blood components received by the blood bank must be traceable (whether transfused or not). It is therefore paramount that hospital blood bank staff check consignment note details.

5.5.4 HLA Selected Platelets and Red Cells

These may be requested by contacting either Dr K Maguire, extension 4687 or Dr K Morris, extension 4644.

5.5.5 Consignment Notes

Each consignment of blood, blood components and/or products is accompanied by a computer printed consignment note detailing the contents (two copies) and signed by issuing BMS. Hospital blood bank staff must first check the contents of each consignment and then sign to acknowledge receipt of the order and return one copy of the consignment note to NIBTS, Belfast City Hospital Complex, Lisburn Road and the other copy retained for the blood bank records.

Where there is a discrepancy in the content of the delivery the hospital blood bank should notify the NIBTS Hospital Services immediately.

NIBTS will occasionally perform lookbacks on recent issues of consignments of blood in an effort to reconcile discrepancies on PULSE (NIBTS computer system).

The Blood Safety and Quality Regulations, 2005 requires full traceability donor to patient and hospital blood bank staff are reminded of the absolute requirement to check consignment note details.

5.5.6 Packaging

Blood and blood components are packaged for transport to hospital blood banks in order to protect contents and maintain the recommended temperature during delivery. The hospitals **MUST** return containers, including polystyrene insulation and cooler, as quickly as possible to NIBTS Hospital Services. These boxes should not be used for onward delivery of blood to satellite or remote locations.

5.5.7 Return of Unused Blood/Blood Components to NIBTS Hospital Services from Hospital Blood Banks

i Outdated blood/blood components must not be returned to the NIBTS Hospital Services.

Hospitals are required to retain details of outdated blood/blood components as required by BSQR and for audit purposes.

ii In-date blood/blood components will only be accepted back by NIBTS Hospital Services Department if there is a compelling medical need and they are requested by NIBTS e.g. HLA selected components and all conditions listed on form DD:062, are satisfied. Form DD:062, issued to Hospital Blood Banks is document controlled and new versions will be notified/issued by NIBTS Document Control Officer (ext. 4673). The form must be completed and accompany in-date blood/blood components being returned.

iii DC Positive Units as defined in section 12.12 of current guidelines for the Blood Transfusion Service in the United Kingdom must not be returned to NIBTS.

5.5.8 Concessionary Release

In exceptional circumstances blood products may be made available which do not meet all mandatory requirements e.g. where the clinical situation justifies this. An example would be delayed release of PCR test results. Concessionary release can only take place with approval of Regulatory Affairs and Compliance Manager/Quality Manager and NIBTS medical consultant in close consultation with clinical colleagues.

6 **BLOOD GROUP REFERENCE SERVICE**

The laboratory is situated on the ground floor in the NI Blood Transfusion Service building in the grounds of the Belfast City Hospital.

The Blood Group Reference Laboratory (BGRL) can be contacted by telephoning the NIBTS (028) 90321414, Ext 4605 or directly (028) 90534605, or by fax 90534611.

The Reference Laboratory is open from 9 am until 5 pm, Monday to Friday (excluding Bank and Public holidays). An emergency on-call service is available at all times outside the quoted hours. The BMS on-call for the NIBTS can be contacted via the Belfast City Hospital switchboard (028) 90329241.

6.1 **Range of Services Provided**

- Identification/confirmation of red cell antibodies
- Investigation of blood transfusion reactions
- Provision of phenotyped blood
- Compatibility testing for patients with atypical red cell antibodies and Provision of crossmatched blood
- Investigation of autoimmune haemolytic anaemias
- Investigation of platelet antibodies and platelet crossmatching
- Cold and warm autoantibody investigation including serial auto-adsorptions and selective alloadsorptions.
- Investigation of haemolytic disease of the newborn
- Investigation of ABO anomalies
- Anti-A, anti-B titration studies for solid organ renal transplant recipients

Sample Referral by NIBTS:

On occasion, samples may need to be referred onwards from the Blood Group Reference Laboratory for further elucidation or for confirmation of antibody specificities. These samples will be sent, with the permission of the requesting

hospital, to the IBGRL (International Blood Group Reference Laboratory, SW Regional Transfusion Centre, 500 North Bristol Park, North Way, Filton, Bristol, BS34 7QH). A copy of the subsequent report will be forwarded to the requesting hospital as quickly as possible after receipt.

6.2 Requesting Arrangements

It is important that the information given on request forms and blood samples should conform to specifications described in the current BCSH Guidelines for the administration of blood components. Failure to do so will result in the samples being rejected for testing and a request for further samples. Forms should be completed in full, including the patient's previous transfusion and obstetric history, if possible.

If you wish to discuss a serological problem or make a technical enquiry we are pleased to offer advice on the telephone.

All NIBTS forms/procedures are document controlled and new versions will be notified/issued by NIBTS Document Control Officer (ext. 4673) Requests for investigations and crossmatching must be made on the Blood Group Serology Request Form, DD:545 (issued to Hospital Blood Banks) and blood samples provided as follows:

6.3 Samples

All samples and accompanying documentation should conform to the current version of NIBTS document SOP:06:HS:009, 'Transport of Samples to NIBTS', issued to Hospital Blood Banks. Please see also the current version of NIBTS document SOP:97:HS:005, 'Procedure for dealing with Spillage', also issued to Hospital Blood Banks. All NIBTS forms/procedures are document controlled and new versions will be notified/issued by NIBTS Document Control Officer (ext. 4673).

It is the responsibility of the sender to ensure that all samples are packaged in accordance with the current European Agreement concerning Carriage of Dangerous Goods by Road Regulations. The outside of the box or package containing the samples must be clearly addressed to the Laboratory. The NIBTS reserves the right to refuse to handle any samples which are inappropriately packaged or labelled. Please ensure packaging of specimens / documentation ensures patient data protection.

A request form must accompany every sample. Request forms are the basis to establish the correct identification of the patient. The points of identification on the request form must match the information provided on the sample. The laboratory may reject samples with inadequately completed request forms or incomplete sample labelling. The Reference Laboratory may agree, in emergency circumstances, to complete testing of such samples, but the issue of blood products or laboratory reports will carry an explicit warning that the four points of identification were not used for the sample or request form. The following information is mandatory on samples:

- Surname
- Forename in full
- Date of birth (not age)
- Hospital number or Health & Care number
- Date of venepuncture

The following additional information is required on the request form:

- Requesting hospital
- Known risk sample
- Type of investigation required
- Crossmatch requests (how much, when etc.)
- Any special blood requirements (CMV antibody negative, gamma irradiated etc.)

Samples and request forms must be signed.

Further clinical and laboratory information may assist in the selection of appropriate testing and expedite reporting and crossmatched blood issue.

For all urgent samples please phone the Laboratory or the BMS on call respectively and discuss the arrangements for sending the samples.

Samples should either be sent immediately to the Hospital Services Department in the NIBTS building or to the NIBTS reception desk. Hospital or taxi drivers should be given clear instructions in regard to the destination of the samples. Any container containing samples destined for the Reference Laboratory must be clearly marked with that information. Failure to do so may result in delayed testing.

Samples which are deemed to be inadequate for testing, adulterated, contaminated or haemolysed (unless the haemolysis is immune-mediated) and samples over 7 days will not be accepted for testing.

Key factors that may affect testing

- Sample storage time: in general samples should be sent to the laboratory with minimum delay and arrive within 24 hours of collection.
- Samples storage and transportation temperature: in general, samples should be stored and transported at ambient temperature.
- Sample type and volume: please ensure that the correct anticoagulant (EDTA) or no anticoagulant (clotted) is used. It is also important to supply adequate volumes of blood to allow completion of testing (see section 2.3)

Red Cell Antibody Investigation

2 x 6ml EDTA sample from patient

Crossmatching Blood for Patient

2 x 6ml sample (EDTA) from patient

Investigation of Crossmatching Problem

2 x 6ml sample (EDTA) from patient and sample from donor line of appropriate blood pack

Transfusion Reactions

Pre-transfusion sample, if available

Two post-transfusion 6 ml EDTA samples (and 2x 6ml clotted sample, if possible)

Return of the relevant donor pack(s)

Investigation of Autoimmune Haemolytic Anaemia

Two 6 ml EDTA samples + one 6ml clotted sample from patient

Investigation of Haemolytic Disease of the Newborn

2 x 6ml sample from mother (EDTA)

Sample from baby (or cord blood sample)

Out of Hours Arrangements

When possible, antibody investigations and crossmatching should be referred to the laboratory during the working day, when laboratory staffing optimally supports the frequently lengthy investigations that may have to be performed. However,

the BMS on-call is available for urgent crossmatching, investigations and the provision of phenotyped blood.

6.4 Provision of Phenotyped Blood

During the hours of 9am – 5pm (Monday to Friday), requests for R₁R₁ or Kell negative phenotyped red cells should be made by fax to the Hospital Services Department, fax number: (028) 90534611 using FORM:DD:807 (issued to hospital blood banks). All forms are document controlled and may be obtained by telephoning the Document Control Officer on ext. 4673.

Requests for other phenotypes should be made directly to the Reference Laboratory. In many cases, this phenotyping will be undertaken in response to specific orders so time should be allowed for the screening and verification processes. To prevent the possibility of misunderstandings all requests for phenotyped blood should be accompanied by a fax to the NIBTS Hospital Services Department (028) 90534611.

On occasion, requests for blood of rare phenotypes cannot be met from our current stocks. In these circumstances, specific local blood donors may have to be identified, bled and tested; or we may have to request blood units from NHS Blood and Transplant (NHSBT) or, in very rare cases, the National Frozen Blood Bank. Each of these options will delay the provision of blood, but NIBTS will endeavour to minimise the delay and provide appropriate advice in the interim

6.5 Provision of Blood for Use at Time of Childbirth

The Reference Laboratory should be informed as soon as any woman with red cell alloantibodies other than anti-D is admitted for delivery. This will enable us to have suitable antigen negative blood available on standby for the delivery.

6.6 Donations with Positive Direct Antiglobulin Test (DAT)

Blood donations are not routinely tested by the direct antiglobulin test (DAT); therefore, on crossmatching, you may find a unit with a positive DAT. If you have such a donation please return it to the Reference Laboratory marked 'positive DAT', accompanied by an Incident Report Form, FORM:DD:949 (issued to Hospital Blood Banks). All NIBTS forms/procedures are document controlled and new versions will be notified/issued by NIBTS Document Control Officer (ext. 4673).

6.7 Reporting

The basic principle for reporting is to send the report to the requesting transfusion laboratory. Please contact the BGRL if you require different reporting arrangements. Reports are authorised by BMS Band 6 and above and is facilitated by double blind entry into the NIBTS LIMS system.

75% of results are normally available within one working day of sample reception. Hospital staff are, after appropriate training, able to directly access test results on the Diagnostic Services System. A printed serological report stating the patient's details, BTS reference number and the serological findings of the investigation will normally be issued to the hospital laboratory within 3 working days (target 95%). Crossmatched blood issued to hospital blood banks will be accompanied either by a full report, detailing patient identification details and the results of laboratory testing, or by an interim report containing similar information.

Blood group cards are supplied for issue to all patients demonstrated to have clinically significant antibodies.

6.8 Platelet Antibody Testing

Investigations for platelet autoantibodies are indicated in immune thrombocytopenic purpura (ITP). Investigations for platelet alloantibodies are

indicated in drug induced immune thrombocytopaenic purpura (DIITP), foetomaternal alloimmune thrombocytopaenia (FMAIT), platelet refractoriness, platelet transfusion reactions and post-transfusion purpura (PTP).

These are specialised tests and so are only undertaken during the normal working day (9 am to 5 pm, Monday to Friday). As testing takes a minimum of four hours, samples requiring a result on a particular day must be received before 1 pm on the day in question.

The solid phase red cell adherence assay, Capture-P is used for the detection of platelet antibodies and for platelet crossmatching. The GTI-Pak 12□G ELISA technique is used for platelet antibody identification. Phenotyping for the platelet antigen HPA-1a is undertaken by an ELISA technique.

Platelet auto antibody may be detected by using GTI-AutoPak which may confirm a laboratory diagnosis of ITP in the absence of free platelet auto antibodies.

The samples required will depend on the test being undertaken, the clinical circumstances, the patient's platelet count and recent platelet transfusion history.

Tests are routinely performed on EDTA samples. EDTA samples facilitate the procurement of a sample of the patient's own platelets, especially where investigations for platelet autoantibodies are indicated. 4 x 6 ml EDTA samples are necessary, but if the patient's platelet count is very low, or if the patient has been recently transfused with platelet concentrates, a smaller sample may be acceptable.

Advice regarding appropriate samples, or any related queries can be obtained by contacting the Blood Group Reference Laboratory {direct line – (028) 90534605}. Specific request form (DD:770) may be obtained by contacting the Laboratory (as above) or by contacting the NIBTS Document Control Officer (ext. 4673).

The name of the requesting medical officer should be recorded on the request form, to facilitate further consultation.

Sample Referral:

On occasion, samples may be referred onwards from the Blood Group Reference Laboratory for further testing, confirmation of antibody specificities or for platelet phenotyping by DNA techniques. These samples will be sent, with the permission of the requesting hospital, to the Platelet Immunology Laboratory, SW Regional Transfusion Centre, 500 North Bristol Park, North Way, Filton, Bristol, BS34 7QH. A copy of the subsequent report will be forwarded to the requesting hospital as quickly as possible after reception.

7 ANTENATAL TESTING SERVICES PROVIDED BY NIBTS

Background

The two main purposes of antenatal red cell serology testing are to identify Rh(D) negative women who may require anti-D immunoglobulin prophylaxis and to identify newborns otherwise at risk of haemolytic disease of the newborn (HDN). There is another secondary purpose, which is to facilitate the selection of appropriate blood in the event of mother or baby requiring a transfusion.

For these reasons it is accepted that all women should have their ABO group and Rh(D) type checked and plasma screened for red cell antibodies during pregnancy. Only 1-2% of pregnant women will form antibodies and up to a third of these are not clinically significant. Of the clinically significant antibodies, anti-D remains the most important though anti-Kell and anti-c antibodies may also cause severe HDN.

All pregnant women should be tested (once in each pregnancy) for immunity to rubella, syphilis antibodies, hepatitis B surface antigen and for HIV antibody irrespective of the result in previous pregnancies.

Laboratory and sample reception locations: NIBTS Antenatal Laboratory, Microbiology Laboratory and sample reception are all located on the first floor in the NIBTS building in the grounds of the Belfast City Hospital. Routine antenatal samples will be received at NIBTS main reception and at the NIBTS back delivery/dispatch hatch.

The laboratories are open from 9 am until 5 pm, Monday to Friday (excluding Bank and Public holidays). Samples will be received between the hours of 9 am and 5 pm during working days. Samples not expected to arrive during this time should be refrigerated and sent to NIBTS on the next working day.

ALL SAMPLES DESTINED FOR NIBTS, SHOULD ONLY BE DELIVERED TO NIBTS AND NOT BELFAST CITY HOSPITAL

Service provided: The services include routine red cell serology and screening of all antenatal patients for the presence of HIV1&2 antibody/antigen, the presence of hepatitis B surface antigen (HBsAg), syphilis antibodies and immunity to rubella. Testing is carried out on routine samples only and will normally have three working day turnaround from receipt of sample. For patients with exceptional results, turnaround times may be exceeded due to extra testing required. Samples deemed as urgent should be labelled as such and processed through the relevant department e.g. Virus Reference Laboratory or NIBTS Blood Group Reference Laboratory. The correct requests forms from these departments must be used to avoid inclusion in the routine NIBTS workload.

Contact details:

Automated Serology Laboratory Manager: Mr P Madden,

(028) 90321414 ext, 4607

Deputy Automated Serology Laboratory Manager: Ms J Carr,

(028) 90321414 ext, 4635

Microbiology Laboratory Manager: Mr M Clarke,

(028) 90321414, ext 4639

Deputy Microbiology Laboratory Manager: Mrs S Rainey

(028) 90321414, ext 4639

Antenatal Office Manager: Ms J Calvert, (028) 90321414, ext 4677

7.1 Supply of Request Forms and Sample Tubes

Sample tubes and request forms are provided by NIBTS during normal working hours and are available from sample reception, telephone number: (028) 90321414 ext 4647.

Blood Group Serology Samples

Samples for antenatal testing must be taken into a 6 ml EDTA sample tube containing EDTA anticoagulant labelled 'K2E (EDTA) Crossmatch' with an expiry date of tube exceeding the sampling date by at least one week. A 6 ml sample is required.

Samples will only be accepted for testing if the labels are handwritten and conform to the current British Committee for Standards in Haematology (BCSH) Guidelines.

Each sample must be accompanied by a completed antenatal request form. For supply of forms and tubes, see information above.

Request Form

Request forms must have all sections completed with no data entry recorded as not applicable. It is also important that if a patient has received anti-D prophylaxis that this should be recorded with date(s) and dose(s) administered.

Transportation of Antenatal Samples:

NOTE: Please refer to:

(1) Current Guidelines on Hospital Blood Bank Documentation and Procedures BCSH (Sample Collection).

(2) Post Office Guidelines. Inland Postal Services Publications (Despatch of Samples).

(3) See also current versions of NIBTS Procedures SOP:06:HS:009 'Transport of Samples to NIBTS' and SOP:97:HS:005, 'Procedure for Dealing with spillage', issued to Hospital Blood Banks. All NIBTS forms/procedures are document controlled and new versions will be notified/issued by NIBTS Document Control Officer (ext. 4673).

Upon taking the sample, it should be kept at 2-6°C prior to dispatch, every attempt should be made to avoid dispatch where the sample would arrive over the weekend/Bank holidays.

All Biohazard samples must be clearly labelled as such on BOTH request form and sample, not just on the Microbiology sample but on all samples from that particular patient.

Test Performance

Samples insufficient in volume, grossly haemolysed, collected into the wrong sample tube/time expired sample tube, inadequately or incorrectly labelled sample/request form or samples over seven days old may **NOT** be tested.

7.2 Antenatal Routine Testing

7.2.1 ABO and Rh Group

All samples have their ABO group and Rh(D) type tested.

7.2.2 Red Cell Antibody Screening

All samples are screened for red cell antibodies in accordance with current UK Guidelines for the Blood Transfusion Services and the current BCSH Guidelines for Blood Grouping and Red Cell Antibody testing during pregnancy.

7.2.3 Red Cell Antibody Monitoring

All samples containing anti-D and or anti-c are titrated and quantitated for antibody concentration. Quantitation results are expressed in international units per ml (iu/ml). NIBTS will forward samples for quantitation to the Scottish National Blood Transfusion Service (SNBTS) at the following address:

Antibody Quantification Laboratory
Clinical Services
SNBTS
NHS National Services Scotland
West of Scotland Blood Transfusion Service
25 Shelley Road
Glasgow G12 0XB

All other clinically significant antibodies will be titrated using the anti-human globulin (AHG) technique and the result reported as AHG titre. While awaiting

quantitation results for anti-D/anti-c, an interim report may be produced without the quantitation result. When quantitation result(s) are received from SNBTS, they are added to the NIBTS report. This report can follow at a later period and is then deemed the final report.

Reference Values

Anti-D level:

<4 iu/mL	HDN unlikely
4-10 iu/mL	Moderate risk of HDN
>10 iu/mL	High risk of hydrops fetalis

As a consequence of developments in the assessment of foetal anaemia and in the technique of intrauterine anaemia (IUT) the significant anti-D level is that which triggers referral to a specialist foeto-maternal unit. Non-invasive assessment can then be used to monitor foetal anaemia (Scheier et al, 2004). A woman whose anti-D level is 4 iu/mL or greater and/or has a rising anti-D level and/or has a history of HDN, affected offspring must be referred to such a unit. It should also be noted that HDN has been reported at levels less than 4 iu/mL (Bowell et al, 1982). Once the referral to the foeto-maternal unit has been made the value of subsequent samples for anti-D quantification is doubtful. A sample at 28 weeks should be tested for the presence of further red cell antibodies.

Anti-c level:

<7.5 iu/mL	Continue to monitor
7.5 to 15 iu/mL	Risk of moderate HDN, refer to specialist unit
>15 iu/mL	Risk of severe HDN, refer to specialist unit

It is important to note that anti-c may cause delayed anaemia in the neonate.

7.3 Testing of Partner

Phenotyping and blood group will be carried out on those paternal samples where the mother is shown to have a clinically significant antibody; in such cases NIBTS will request a sample from the father when the report on the antibody is issued.

By request Rh(D) typing will be carried out on partners of Rh(D) negative mothers who are considering opting out of routine antenatal anti-D prophylaxis. Where partner is Rh(D) negative the mother may decide to withdraw from the programme.

7.4 Tests for which Fees are Payable

A blood group and red cell antibody screen may be carried out on individuals who are neither an antenatal patient nor a blood donor. A fee of £20 will be charged. Cheques should be made payable to:

“Northern Ireland Blood Transfusion Service’. Upon receipt of payment a report and a blood group card will be issued.

Please note that NIBTS does not provide private blood grouping for paediatrics/minors.

7.5 Reporting

A report giving details of ABO group, Rh(D) type and current antibody status will be issued in respect of all antenatal samples submitted for testing. The report will comment on the clinical significance of any antibodies detected and suggest a date for retesting. Reports for patients with negative antibody screens are automatically authorised on transfer to the NIBTS LIMS system. Any results, which do not have clinically significant antibodies but require manual input into the LIMS system, are authorised by BMS staff Band 6 and above. Reports with clinically

significant antibodies will be authorised by the Consultant in Transfusion Medicine, who will provide clinical advice and interpretation, where appropriate. Results warranting more urgent attention will be telephoned.

Blood group cards will be provided for all patients who have clinically significant antibodies and warning cards provided for all Rh(D) negative antenatal patients with no immune anti-D, alerting that anti-D immunoglobulin prophylaxis is indicated. 90% of reports will normally be issued within 3 working days of receipt of sample. For patients with exceptional results, reporting times may be exceeded due to extra testing required.

Copy Report

Copy reports may be obtained upon request from NIBTS antenatal office, telephone number (028) 90321414 ext 4679 or ext 4680.

7.6 User Access to Diagnostic Services System

Approved users trained on remote access to the Diagnostic Services System can access results and print copy reports locally. Contact Medical Secretary on 02890 534644 to request access.

7.7 Frequency of Red Cell Serology Testing in Antenatal Patients

The NIBTS recommended frequency of testing is outlined in Appendix 4.

7.8 Rubella, Syphilis, Hepatitis B, Anti-HIV 1&2 Antibody Testing

All pregnant women should be tested (once in each pregnancy) for immunity to rubella, syphilis antibodies, hepatitis B surface antigen and for HIV antibody/antigen irrespective of the result in previous pregnancies.

7.8.1 Samples for HIV 1&2, Hepatitis B, Syphilis and Rubella Testing

Samples for these tests must be taken into a 6ml EDTA sample tube and labelled. The sample tube must NOT be used beyond the expiry date stated on the tube. The sample must be forwarded to NIBTS to ensure that testing can be completed within 7 days from the bled date. Sample tubes and request forms are supplied and are available from NIBTS.

NB: Samples will only be accepted for testing if the label is handwritten.

Each sample must be accompanied by the appropriate Antenatal Microbiology Request form. Request forms and sample tubes are available on request from NIBTS Antenatal Reception (ext. 4647).

Request Form

It is recommended that request form details be handwritten.

Request form must be signed by the health care professional taking the sample.

Request forms must be completed in full with no data entry recorded as 'not applicable'. It is also important that if a patient has rubella contact or rash that this is recorded with a date, if available.

7.8.2 Reporting

a) Rubella Immunity

Results are classified into 2 categories and reported as:

Rubella antibody >10 iu/ml, regard as immune

Rubella antibody <10 iu/ml, regard as non-immune

The reference range for immunity is printed on the report.

Note: It is important to state that NIBTS does not provide a diagnostic service for primary rubella infection. Where this is considered clinically significant or where there is concern about a rash contact in pregnancy, samples must be referred to Virus Reference Laboratory, Royal Group of Hospitals, Grosvenor Road, Belfast BT12 6BA.

b) Syphilis Antibodies

Results are reported for syphilis antibody negatives.

Reactive samples are referred for confirmation to RVH Regional Virus Reference Laboratory, which is located at Belfast Health & Social Care Trust, Kelvin Building, Grosvenor Road, Belfast, BT12 6BA.

Confirmed positive results are reported by the Regional Virus Reference Laboratory directly to the clinical user. Confirmed negative samples are reported as syphilis antibody negative by NIBTS.

c) Hepatitis B

Results are reported for HBsAg negatives. Reactive samples are referred to RVH Regional Virus Reference Laboratory for confirmation. Any confirmed positive results will be communicated under separate cover with appropriate advice to the patient's GP or obstetrician/midwife. If you have any queries please contact Microbiology Laboratory, telephone number (028) 90321414, extension 4637/4638 or Dr K Maguire, extension 4687.

d) HIV Antibodies

Results are reported for HIV antibody/antigen negatives. Reactive samples are referred to the Virus Reference Laboratory for confirmation. Confirmed positive results are reported by the Virus Reference Laboratory directly to the clinical user.

95% of microbiology reports will be issued within 3 working days of receipt of sample.

Reports for patients with negative screens or patients, who are Rubella Immune are automatically authorised on transfer to the NIBTS LIMS system. Any results, which require manual input into the LIMS system, are authorised by BMS staff Band 6 and above. Confirmed results returned from VRL are authorised by a medical officer. The Consultant in Transfusion Medicine, will provide clinical advice and interpretation, where appropriate.

Additional examinations

Any outstanding test should be forwarded to the laboratory within 10 working days of receipt of report requesting a further sample.

Request for results during normal working hours:

Antenatal users and blood bank users have been trained on the Diagnostic Services System which provides remote access for users and allows printing of copy reports. If unable to obtain results via remote access please contact the laboratories between 9 am and 5 pm.

If unable to access results on the DSS system, contact details are given below.

For serology results (blood group, antibodies, titre, quantitation results etc):

Biomedical Scientist, (028) 90321414, ext 4632

For rubella, syphilis, Hepatitis B and HIV results:

Biomedical Scientist, (028) 90321414 ext 4637/4638

Request for urgent results outside normal working hours may be telephoned to the Biomedical Scientist on call by contacting BCH switchboard on (028)S 90329241 for contact details.

8 **TRAINING PROGRAMMES**

Training programmes of varying duration may be provided (pending workload). These include:

- (a) Practical and theoretical instruction for SpRs preparing for FRCPATH examination.
- (b) Training for Biomedical Scientists pre and post HCPC registration, continuing professional development and also training in serological procedures for Biomedical Scientists from hospital laboratories prior to undertaking emergency 'on-call' duties.
- (c) One year placements for students undertaking BSc in Biomedical Sciences.
- (d) Visits to the Centre for medical students, nurses and other health care workers.
- (e) Participation in work experience schemes/visits for schools and colleges.

9 **QUALITY INCIDENTS INCLUDING ADVERSE EVENTS/REACTIONS AND DEFECTIVE PRODUCTS OR SERVICE**

9.1 In order to continue to provide quality products and services it is necessary for customers to notify the NIBTS of any defect in products eg leaking packs, or delay in receipt of blood are identified these must be reported to the NIBTS Regulatory Affairs and Compliance Department, telephone (028) 90534633 or e-mail: qualityincident@nibts.hscni.net

The procedure for reporting such defects is described in detail in NIBTS SOP:07:QA:070, 'Procedure for Reporting and Management of Quality Incidents'

issued to hospital blood banks. As indicated in this procedure all possible information relating to the incident should be provided and where products are involved these should be returned if it is safe to do so.

9.2 Adverse Events Due to the Transfusion of Products Supplied by NIBTS

The BSQR require mandatory reporting online to SABRE (serious adverse blood reactions and adverse events). NIBTS still requires to be notified of suspected TRALI, post transfusion infection and bacterial contamination incidents. Complaints may also be received in relation to other aspects of service provided by NIBTS. NIBTS incident report form (DD:949), issued to all Hospital Blood Banks, should be used for this purpose. All NIBTS forms/procedures are document controlled and new versions will be notified/issued by NIBTS Document Control Officer (ext. 4673).

Notification should be sent to NIBTS Regulatory Affairs and Compliance Department. Clinical advice will be provided by Dr K Maguire, extension 4687 or Dr K Morris, extension 4644.

APPENDIX 1
BLOOD COMPONENTS AVAILABLE FROM NIBTS

NB Red Cells can be irradiated on Request. All platelet components are irradiated.

No	Components	Group	Approx Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
1	Leucodepleted Red Cells in Additive Solution	All ABO & Rh groups	280 ml ± 60 ml	CPD red cells in 100ml, SAG-M Haematocrit 50%-70% Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit Haemoglobin >40g/unit	+4°C ±2°C	35 days	Stock item	
2	Leucodepleted Autologous Donation Red Cells in SAG-M	All ABO & Rh groups	280 ml ± 60 ml	CPD red cells approx 200ml, SAG-M additive solution 100 ml Haematocrit 55%-75% Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit Haemoglobin >40g/unit	+4°C ±2°C	35 days	On request	Approved by NIBTS Medical Consultant
3	Leucodepleted Red cells in Additive Solution for Neonatal Use	Groups O R ₁ R ₁ , A R ₁ R ₁ , O rr, A rr Kell negative	30 ml ± 5 ml	CPD red cells in SAG-M additive solution CMV antibody negative Haematocrit 50%-70% Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit Haemoglobin >5 g/unit	+ 4°C ±2°C	35 days	Stock item/group AB prepared on request. (Phenotyped blood may not always be available, but can be prepared on request).	NIBTS Medical Consultant for new patients

NB Components 'prepared on request' may take up to 4 hours to prepare. Components 'from stock' will routinely be available at the time of request
See also item 1.4.3

APPENDIX 1 contd

No	Components	Group	Approx Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
4	Leucodepleted Red Cells. Resuspended in same donor plasma	All ABO groups CMV antibody -ve	400 ml ± 40 ml	Fresh CPD red cells (within 5 days of collection) resuspended in 120 ml plasma. Haemoglobin 40g/unit Haematocrit 45%-65% Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit	+ 4°C ±2°C	12 hours from time of preparation	Prepared on request	
5	Leucodepleted Red Cells (CPD) Resuspended in Group Specific Plasma	All ABO groups CMV antibody -ve	400 ml ± 40 ml	Fresh CPD red cells (within 5 days of collection) resuspended in 120 ml plasma. Haemoglobin 40g/unit Haematocrit 45%-65% Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit	+ 4°C ±2°C	12 hours from time of preparation	Prepared on request	
6	Leucodepleted Platelets Pooled Buffy Coat Derived All platelets are gamma irradiated	All ABO groups and Rh groups excluding AB	310 ml ± 50 ml	CPD plasma with platelets >240 x 10 ⁹ /pool Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit	+22°C ±2°C Agitated	5 days	Stock item	
7	Leucodepleted Platelets, Apheresis All platelets are gamma irradiated	All ABO groups excluding AB	>160 ml	ACD/CPD plasma with platelets >240 x 10 ⁹ /unit Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit	+22°C ±2°C Agitated	5 days	Stock item	Antigen typed platelets available by arrangement with NIBTS consultant

NB Components 'prepared on request' may take up to 4 hours to prepare.
See also item 1.4.3

Components 'from stock' will routinely be available at the time of request

APPENDIX 1 contd

No	Components	Group	Approx Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
8	Leucodepleted Platelets Apheresis for Paediatric Use. All platelets are gamma irradiated	All ABO & Rh Groups except AB	100 ml ± 10 ml	As platelets, apheresis, leucodepleted, prepared as an aliquot from whole apheresis unit (see No 7) Platelets > 150 x 10 ⁹ /unit	+22°C ±2°C Agitated	Up to 5 days	Stock item	
9	Leucocyte Pool (Buffycoat derived)	All ABO & Rh Groups	300ml ± 20ml	4 x Buffycoat residue packs and selected male plasma for resuspension	+22°C±2°C	8 hours	Prepared on request	Only with approval by NIBTS Consultant.
10	Leucocytes (Buffy Coat) [Concessionary release]	All ABO & Rh Groups	50 ml ± 5 ml	Leucocytes >1.0x10 ⁶ /unit, in CPD plasma with red cells and platelets	+ 22°C ±2°C	6 hours	Prepared on request	Only with approval by NIBTS Medical Consultant using concessionary release procedure.

NB Components 'prepared on request' may take up to 4 hours to prepare.
See also item 1.4.3

Components 'from stock' will routinely be available at the time of request

APPENDIX 1 contd

No	Components	Group	Approx Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
11	Leucodepleted Gamma Irradiated Plasma Removed Apheresis Platelets	All ABO & Rh Groups	>160*ml	Apheresis platelets filtered, plasma removed and resuspended in saline. Residual leucocytes: - 99% of product <5 - 95% of product <1	+22°C ±2°C Agitated	12 hours from time of commencement of preparation	Prepared on request	Authorisation by NIBTS medical consultant for new patients
12	Leucodepleted Fresh Frozen Plasma	All ABO groups	>240 ml	CPD plasma separated and frozen within 8 hours of collection. Contains all clotting factors. Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit FVIIIc > 0.7 iu/ml Platelets < 30 x 10 ⁹ /litre	-25°C or below	1 year	Stock item	
13	Leucodepleted Methylene Blue Treated and Removed Fresh Frozen Plasma	Most ABO groups	200 ml ± 10 ml	Plasma separated and frozen within 8 hours of collection Contains all clotting factors Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit FVIIIc > 50 iu/ml	-25°C or below	3years	From stock	Recommended for transfusion recipients born after 01.01.96. Produced from plasma collected outwith UK

NB Components 'prepared on request' may take up to 4 hours to prepare. Components 'from stock' will routinely be available at the time of request
See also item 1.4.3

APPENDIX 1 contd

No	Components	Group	Approx Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
14	Leucodepleted Methylene Blue Treated and Removed Fresh Frozen Plasma for Neonatal Use	Most ABO Groups	75 ml ± 10 ml	Plasma separated and frozen within 8 hours of collection Contains all clotting factors Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit FVIIIc > 50 iu/ml	-25°C or below	3years	From stock	Recommended for transfusion recipients born after 01.01.96. Produced from plasma collected outwith UK
15	Leucodepleted Pooled Cryoprecipitate (a pool of 5 donor cryoprecipitates)	All ABO Groups Rh+ve	200 ml ± 20 ml	Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit Cryoprecipitate from single units of CPD plasma. >Fibrinogen 700 mg/unit >Factor VIIIc 350 iu/unit	-25°C or below	2 years	From stock	
16	Leucodepleted Methylene Blue Treated and Removed Cryoprecipitate for Neonatal Use	Most ABO & Rh Groups	60 ml ± 5 ml	Leucocytes - 99% <5x10 ⁶ /unit - 90% <1x10 ⁶ /unit Cryoprecipitate from single units of plasma. >Fibrinogen 140 mg/unit >Factor VIIIc 70 iu/unit	-25°C or below	3 years	From stock	Recommended for transfusion recipients born after 01.01.96. Produced from plasma collected outwith UK

NB Components 'prepared on request' may take up to 4 hours to prepare.
See also item 1.4.3

Components 'from stock' will routinely be available at the time of request

APPENDIX 1 contd

No	Components	Group	Approx Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
17	Octaplas (Solvent/detergent treatment [S/D])	All ABO Groups	200 ml	See insert	-18°C or below	4 years at ≤ -18°C	From stock (where possible 2 days notice)	TTP
18	Leucodepleted Saline Washed Red Cells	All ABO & Rh Groups	280ml ± 10ml (270ml-290ml)	Red cells supplemented. Filtered and saline washed (3 times). Leucocytes - 99% <math> < 5 \times 10^6 / \text{unit}</math> - 90% <math> < 1 \times 10^6 / \text{unit}</math> Residual protein <math> < 0.5 \text{g} / \text{unit}</math>. Haemoglobin >math> > 40 \text{g} / \text{unit}</math>	+4°C ±2°C	12 hours from time of commencement of preparation	On request	For new patient by arrangement with NIBTS Medical Consultant

NB Components 'prepared on request' may take up to 4 hours to prepare. Components 'stock item' will routinely be available at the time of request
See also item 1.4.3

Saline Washed Components must be Pre-ordered Minimum One Day in Advance

APPENDIX 2**PLASMA DERIVATIVES AVAILABLE FROM NIBTS**

Pulse Product No.	Product Name	Size	Dose	Supplier
PL45	Kiovig	10g	100mg/ml	Baxter Healthcare
PL48	Kiovig	20g	100mg/ml	Baxter Healthcare
PL53	Kiovig	5g	100mg/ml	Baxter Healthcare
PL65	Kiovig	30g	100mg/ml	Baxter Healthcare
L29	Subcuvia	10ml	160g/l	Baxter Healthcare
PL38	Subcuvia	5ml	160g/l	Baxter Healthcare
V911	Anti-D Ig	250IU	250IU	Bio Products Laboratory
V912	Anti-D Ig	500IU	500IU	Bio Products Laboratory
V935	Hepatitis B Ig	500IU	100IU/ml	Bio Products Laboratory
V941	Hepatitis B Ig	200IU	100IU/ml	Bio Products Laboratory
PL31	Subgam Ig	750mg	160mg/ml	Bio Products Laboratory
PL37	Subgam Ig	1500mg	160mg/ml	Bio Products Laboratory
V921	Tetanus Ig	250IU	100IU/ml	Bio Products Laboratory
V936	Varicella Zoster Ig	250mg	100µg/ml	Bio Products Laboratory
PL05	Vigam Liquid	5g	5g/100ml	Bio Products Laboratory
PL21	Vigam Liquid	10g	5g/100ml	Bio Products Laboratory
PL41	20% Albumin	100ml	20g/100ml	Bio Products Laboratory
PL46	20% Albumin	50ml	20g/100ml	Bio Products Laboratory
0811	4.5% Albumin	500ml	4.5g/100ml	Bio Products Laboratory
0812	4.5% Albumin	100ml	4.5g/100ml	Bio Products Laboratory
PL57	Privigen 10%	10g	100mg/ml	CSL Behring
PL58	Privigen 10%	20g	100mg/ml	CSL Behring
PL56	Privigen 10%	5g	100mg/ml	CSL Behring
D001	Rhophylac	2ml	150IU/ml	CSL Behring
FL02	Flebogammadif 5%	10g	10g/200ml	Grifols
FL03	Flebogammadif 5%	5g	5g/100ml	Grifols
FL06	Flebogammadif 10%	10g	100mg/ml	Grifols
FL05	Flebogammadif 10%	20g	100mg/ml	Grifols
FL07	Flebogammadif 10%	5g	100mg/ml	Grifols
PL63	Gammanorm	10ml	165mg/ml	Octapharma Ltd
OCTA	Group A Octaplas	200ml	as required	Octapharma Ltd

OCAB	Group AB Octaplas	200ml	as required	Octapharma Ltd
OCTB	Group B Octaplas	200ml	as required	Octapharma Ltd
OCTO	Group O Octaplas	200ml	as required	Octapharma Ltd
PL54	Octagam 10%	10g	100mg/ml	Octapharma Ltd
PL55	Octagam 10%	5g	100mg/ml	Octapharma Ltd
PL62	Octagam 10%	20g	100mg/ml	Octapharma Ltd
PL66	Hizentra 20%	1g	2g/10ml	CSL Behring
PL67	Hizentra 20%	2g	2g/10ml	CSL Behring
PL68	Hizentra 20%	4g	4g/20ml	CSL Behring
PL47	Octaplex	20ml	500µg/20ml	Octapharma Ltd

APPENDIX 3

Clinical Indications for Gamma Irradiation of Cellular Blood Components

(In accordance with BCSH Guidelines 'Guidelines on gamma irradiation of blood components for the prevention of transfusion-associated graft-versus-host disease

Transfusion Medicine, 1996, 6, 261-271)

It should be noted that all platelets are gamma irradiated

HLA selected platelets

Transfusions from relatives

Intrauterine transfusion (IUT)

Exchange transfusion

Transfusion within first 24 months post EDD for newborns who have previously had IUT

Congenital T-cell immunodeficiency

Bone marrow allografting and autografting

Hodgkin's disease

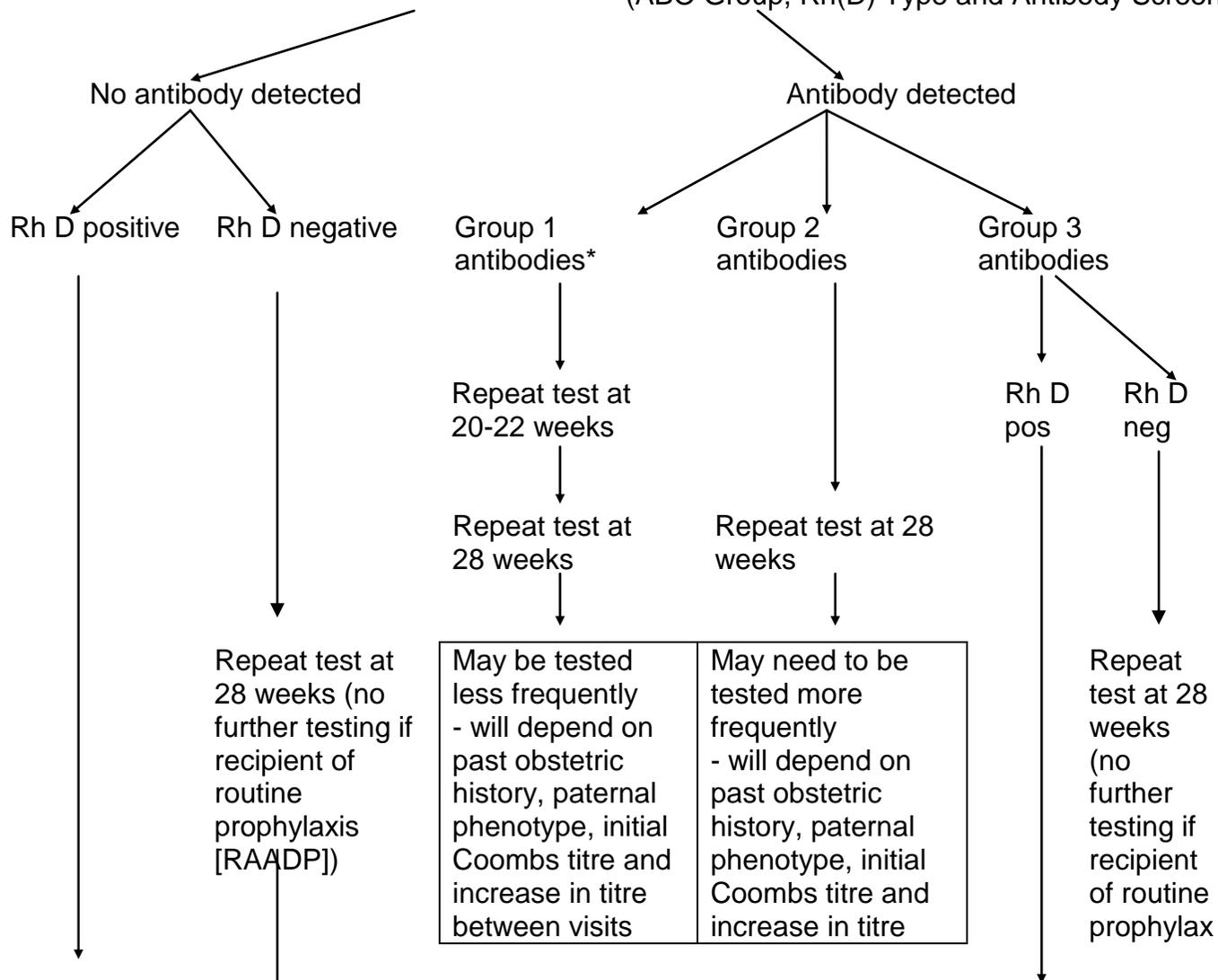
Patients on treatment with purine analogues ie fludarabine, cladribine, deoxycoformycin

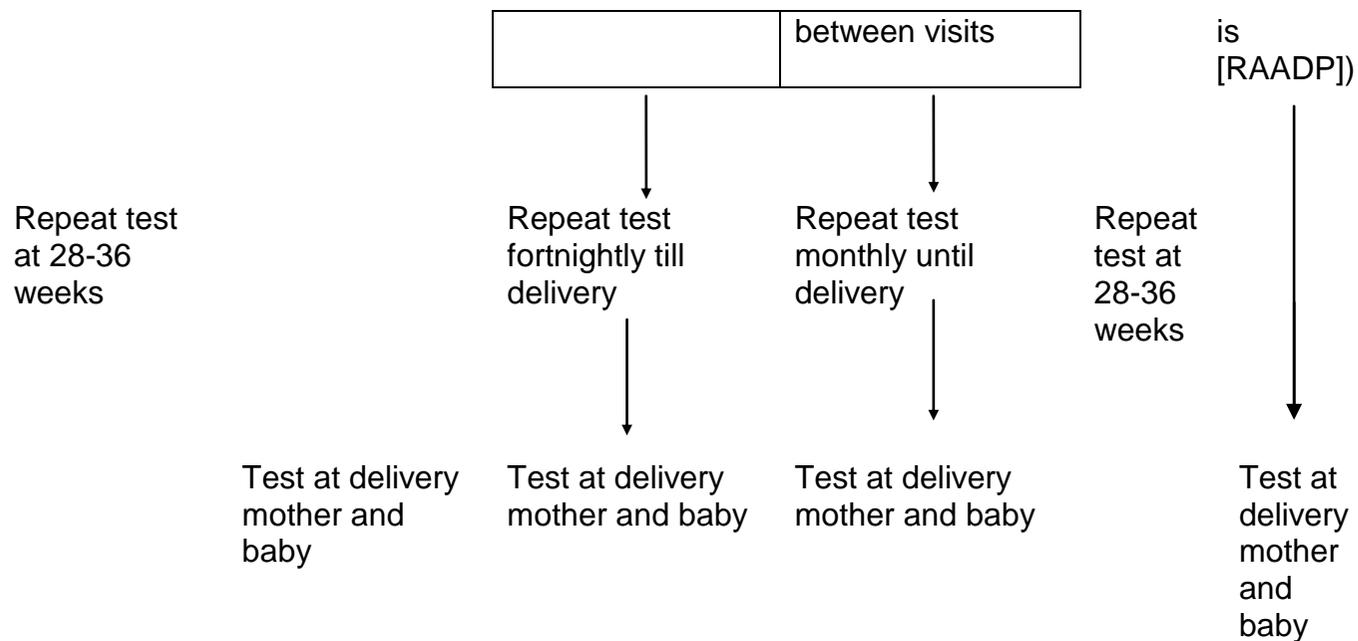
Treatment with anti-thymocyte globulin (ATG)

Treatment with alemtuzumab (anti-CD52)

Indications not listed here should be discussed with NIBTS Medical Consultant

Appendix 4
Antenatal Screening for Red Cell Antibodies
BOOKING SAMPLE (10-16 WEEKS)
(ABO Group, Rh(D) Type and Antibody Screen)





* All samples containing anti-D/anti-c will be quantitated and results expressed in iu/ml.
At delivery test mother for ABO group, Rh D type, antibody screen and if Rh D negative for Kleihauer screen.
At delivery test baby for ABO group, Rh D type, Direct antiglobulin test, Hb, and serum bilirubin.

APPENDIX 4 contd

Group 1 Antibodies (Clinically significant accounting approximately 100%, morbidity, 95% mortality from HDN)	Anti-D, anti-Kell, anti-c
Group 2 Antibodies (Clinically significant, do not usually cause severe HDN)	Anti-Fy ^a , anti-Fy ^b , anti-Jk ^a , anti-Jk ^b , anti-M, anti-N, anti-S, anti-s, anti-E anti-e, anti-C, anti-C ^w , anti-Ce, anti-Lu ^a
Group 3 Antibodies (Not clinically significant)	Anti-Le ^a , anti-Le ^b , anti-P ₁ , anti-I, anti-HI, cold autoagglutinin, non-specific enzyme