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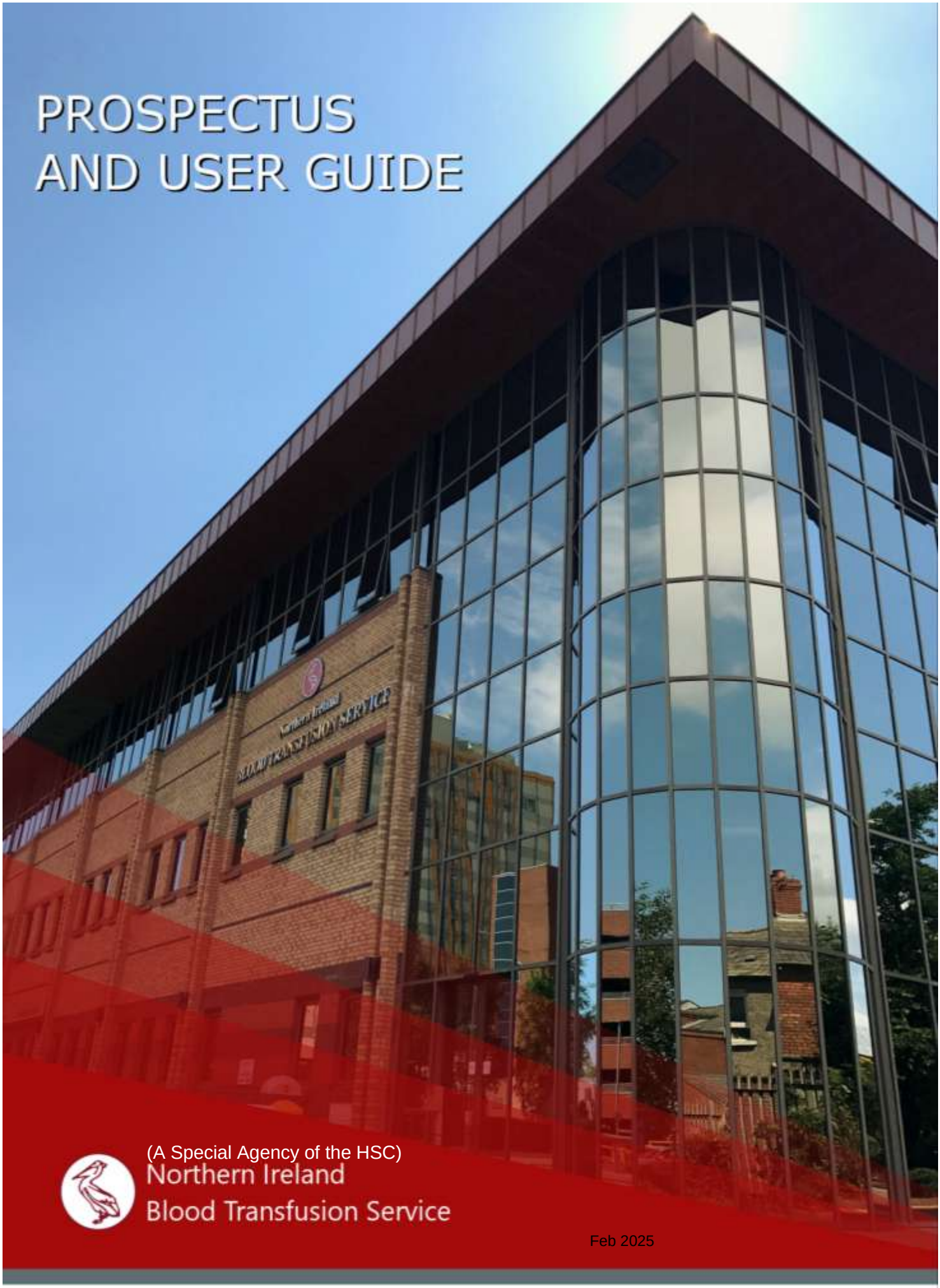

Northern Ireland Blood Transfusion Service
Belfast City Hospital Complex
Lisburn Road
Belfast
BT9 7TS

Telephone No. (028) 90321414
Fax No. (028) 90439017

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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.

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has recommended that it is appropriate to withdraw specific variant Creutzfeldt-Jakob (vCJD) control measures on plasma. The SaBTO recommendations mean that it is no longer necessary to complete pathogen inactivation of UK plasma for individuals born after 1st January 1996. All plasma is now manufactured from donations in NI.

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).

Hospital Blood Banks can request a list of NIBTS extension numbers (FORM:DD:2206) by calling (028) 90321414.

Outside of normal office hours the Biomedical Scientist on-call for NIBTS can be contacted on (07774619337). If unable to make contact using this number please use alternative number (07535724570). If still unable to make contact please ring Belfast City Hospital switchboard on (028) 90329241. If both mobile numbers and BHSCT switch board are unsuccessful please use the NIBTS landline number 02890 534623.

The initial point of contact will be the Biomedical Scientist on-call who can seek medical advice as appropriate or otherwise direct the caller (see also 'Ordering Procedure', page 10).

3 SENIOR PERSONNEL

Designation	Name	Telephone Number
Chief Executive	Mrs K Jackson	*(028) 90534645*
Medical Director	Dr A Allameddine	*(028) 90534644*
Consultant in Transfusion Medicine	Dr K Maguire	*(028) 90534644*
Consultant in Transfusion Medicine	Vacant	
Consultant in Transfusion Medicine	Dr L Kirkpatrick	*(028) 90534644*
Head of Testing Laboratories	Mr M Gillespie	*(028) 90534714*
Quality & Regulatory Compliance Manager	Ms A Macauley	*(028) 90321414*
Deputy Quality & Regulatory Compliance Manager (Acting)	Mr S Jamison	*(028) 90534695*
Head of HR/Corporate Services	Mrs Verity Cochrane	*(028) 90534686*
Finance Manager	Mr E McCann	*(028) 90534683*
Nursing and Donor Services	Mrs S Hart	*(028) 90534669*
Head of Blood and Component Supply Chain Services (Acting)	Mrs B Mullin	*(028) 9053 4705*
Hospital Services (Acting)	Mrs A Donnelly-Davidson	*(028) 90534627*
Reference Laboratory	Mr A Rainey	*(028) 90534605*
Automated Serology	Mr P Madden	*(028) 90534632*
Microbiology Laboratory (Acting)	Mrs S Rainey	*(028) 90534638*

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

4.1 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.

4.2 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.

5. 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 the Blood Safety and Quality Regulations – 2005 (as amended) (BSQR), environmental legislation, UKAS Accreditation to ISO 15189 standards and EU Blood Directives 2002/98/EC.

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.
- We will set quality objectives to maintain and improve quality through a planned system of quality management, which will cover every part of our activity. An essential part of this system is audit and review procedures.
- This policy will be communicated to all staff and will be reviewed annually for suitability and effectiveness.
- 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 2005 (as amended) (BSQR) and a Wholesale Distributors' Licence, by the Medicines and Healthcare products Regulatory Agency (MHRA). The NIBTS Diagnostic Laboratory Service is in receipt of accreditation from the United Kingdom Accreditation Service (UKAS) which is accreditation to ISO 15189:2022, Medical Laboratories –

requirements for quality and competence. The schedule of patient testing activities for which NIBTS hold accreditation can be accessed on the UKAS website or by request to NIBTS Document Control (028) 534673.

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 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 at the meeting Hospital Services/Immunohaematology/ Antenatal Patient Testing Users' Meeting.

6. SUPPLY OF BLOOD PRODUCTS

6.1 DEFINITIONS

Blood components	Therapeutic derivatives of whole blood prepared by NIBTS.
Plasma derivatives	Therapeutic derivatives from the plasma component of blood which have been manufactured by appropriately licensed commercial fractionators.
Blood products	General term encompassing both blood components and plasma derivatives

6.2 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, and found negative for HIV 1 and 2 antibody/antigen, hepatitis B surface antigen, hepatitis B core antibody, hepatitis C antibody, syphilis antibody and HTLV 1&2 antibody. All donations are tested for HIV RNA, HCV RNA, HBV DNA and HEV RNA.

All blood components are leucodepleted in accordance with the Guidelines for UKBTS with a specification for leucocytes of <5x 10^6/l per unit (99%), <1x10^6/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.

6.3 CUSTOMER RESPONSIBILITY

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.

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 confirm to NIBTS that the consignment details are correct.

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.

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 Quality Department – see section 9.

6.4 BLOOD COMPONENTS / 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:

Neonatal Transfusion
Red Cells for Exchange Transfusion.

- Plasma reduced (semi-concentrated) cells which are X-ray irradiated, CMV antibody negative, HbS 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 (≥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.

Red Cells for 'Top-Up' Transfusion

- Red cells suspended in optimal additive solution (OAS) are available as 'paedipacks' (4-6 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. The following ABO groups are provided: 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, CMV antibody negative and HbS 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.

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 however, now include antenatal transfusion to protect foetus and for neonates for 28 days following estimated delivery date.

HbS Negative Blood

- NIBTS provides HbS negative blood for:
  - Manufacture of whole blood and red cell components for intrauterine transfusion, neonatal exchange transfusion.
  - Transfusion of children and adults with haemoglobinopathy.

Irradiated Blood Components

- X-ray 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.

Phenotyped Red Cells

- NIBTS maintains an inventory of R1R1 Kell negative red cells, R1r / R2r Kell negative red cells and Kell negative red cells. These are available as a stock item and may be requested from NIBTS Hospital Services Department by e-mailing **bloodrequests@nibts.hscni.net**
- R2R2 Kell negative red cells and red cells with extended phenotypes will be issued on request. The hospital blood bank should make these requests to the Reference Laboratory on (028) 90 534605 accompanied by an e-mail to Hospital Services at **bloodrequests@nibts.hscni.net**.

'Emergency Use' Blood

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

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.

HLA Selected Red Cells

- HLA matched red cells: Indicated for patients who meet the following two criteria (1) On transplant list (2) not receiving chronic immunosuppressive therapy. All requests should be discussed with the medical team.

6.5 ORDERING PROCEDURE

Laboratory Testing: Blood components / products are only issued after all laboratory tests have been completed and this has been validated by computer for each product.

6.6 HOW TO CONTACT US

The NIBTS Hospital Services Department is open 9 am to 5 pm Monday to Friday (except Bank/Public holidays).

At other times an On-call service is provided.

All orders **MUST** be submitted by e-mail to **bloodrequests@nibts.hscni.net**.

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

For On-call, outside these times, however, the Biomedical Scientist should be telephoned prior to sending the email.

Outside of normal office hours the Biomedical Scientist on-call for NIBTS can be contacted on (07774619337). If unable to make contact using this number please use alternative number (07535724570). If still unable to make contact please ring Belfast City Hospital switchboard on (028) 90329241. If both mobile numbers and BHSCT switch board are unsuccessful please use the landline number 02890 534623.

Orders to be e-mailed using the relevant Order Forms: DD:807, DD:808, DD:1741 and DD:1855 issued to hospital blood banks. All NIBTS forms are document controlled and may be obtained by telephoning the Document Control Officer on (028) 90534673.

6.7 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 email at any time during the day or night will initiate immediate action. These should be accompanied by a phone call.

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

The Blood Safety and Quality Regulations, 2005 (as amended) 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.

HLA Selected Platelets and Red Cells: These may be requested by contacting either Dr A Sadiq, Dr K Maguire or Dr L Kirkpatrick on (028) 90534644. (028) 90534678 or (028) 90534687.

6.8 CONSIGNMENT NOTES

Each consignment of blood, blood components and / or products is accompanied by a computer printed consignment note detailing the contents (two copies) which is signed by the issuing Biomedical Scientist. Hospital blood bank staff must first check the contents of each consignment; then sign and return one copy to NIBTS to confirm receipt of the consignment, as soon as possible.

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 (as amended) requires full traceability donor to patient and hospital blood bank staff are reminded of the absolute requirement to check consignment note details.

6.9 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 gel packs / freezer packs / PCMs, as quickly as possible to NIBTS Hospital Services. These boxes should not be used for onward delivery of blood to satellite or remote locations.

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

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.

In-date blood / blood components will only be accepted back by NIBTS Hospital Services Department under specific circumstances, normally this being a compelling medical need has been established e.g. HLA selected components. The return must be requested by or agreed with NIBTS. To allow acceptance of the return of blood / blood components all conditions listed on form DD:062, must be satisfied. Form DD:062, is issued to Hospital Blood Banks and is document controlled. New versions will be notified / issued to hospital blood banks by the NIBTS Document Control Officer (028)90534673. The form must be completed and accompany in-date blood / blood components being returned.

DAT 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.

6.10 CONCESSIONARY RELEASE

In exceptional circumstances blood components / 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 mandatory test results.
Concessionary release can only take place with approval of the Quality and Regulatory Compliance Manager and NIBTS medical consultant, in close consultation with clinical colleagues.

7. BLOOD GROUP REFERENCE SERVICE

The Blood Group Reference Laboratory (BGRL) is located on the ground floor in the NIBTS building, in the grounds of the Belfast City Hospital and can be contacted by telephoning: (028) 90534605

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.

7.1 RANGE OF SERVICES PROVIDED

- Identification/confirmation of red cell antibodies
- Investigation of blood group anomalies

- Extended red cell phenotyping
- Provision of phenotyped blood
- Compatibility testing for patients with atypical red cell antibodies and provision of crossmatched blood
- Resolving the serological complexities associated with patients receiving monoclonal antibody therapies
- Investigation of autoimmune haemolytic anaemias
- Cold and warm autoantibody investigation including serial auto-adsorptions and selective alloadsorptions
- Investigation of haemolytic disease of the new-born
- Investigation of blood transfusion reactions
- Anti-A, anti-B titration studies for solid organ renal transplant recipients
- Investigation of platelet antibodies and platelet crossmatching
- Human Platelet Antigen (HPA) genotyping
- Red cell genotyping
- Estimation of suspected Foetal Maternal Haemorrhage, >2mls, by Flow Cytometry
- Provision of HbS negative blood for the manufacture of whole blood and red cell components for intrauterine transfusion, neonatal exchange transfusion and for the transfusion of children and adults with haemoglobinopathy

7.2 SAMPLE REFERRAL BY NIBTS:

On occasion, samples may need to be referred onwards from the 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, NHS Blood & Transplant, North Bristol Park, Filton, Bristol, BT34 7QH, UK) A copy of the subsequent report will be forwarded to the requesting hospital as quickly as possible after receipt.

7.3 REQUESTING ARRANGEMENTS

It is important that the information given on request forms and blood samples should conform to specifications described in the current BSH 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 (028)90534673.

Requests for investigations and crossmatching must be made on the Blood Group Serology Request Form, FORM:DD:545 (issued to hospital blood

banks), and completed as per NIBTS Policy document POL:LP:009 ‘Sample Referral to the Reference Laboratory’. Blood samples should be provided as follows:

7.4 PATIENT CONSENT FOR SAMPLE TESTING AND STORAGE

All tests carried out on a patient need the informed consent of the patient. The responsibility for obtaining informed consent for the test(s) resides with the individual ordering the test(s). Informed consent must cover all the tests being carried out, implications of their results and disclosure of clinical and personal details to personnel, in the requesting organisation and any other healthcare organisations involved in providing the testing. Consent for the testing of patient samples is obtained from the patient when the sample is being taken. For most samples this involves consent being obtained by staff in the hospital trust who are referring the sample. Where a sample is taken by a member of staff in NIBTS consent will be obtained by NIBTS. Taking a sample for transfusion in NI requires the taker to be "right patient, right blood" trained.

Where standard investigations are not conclusive, and/or genetic tests are available, these will be undertaken if considered in the patient’s best interest. The laboratory will assume that a valid consent has been obtained by the referring clinician, including where appropriate, consent provided for extracted DNA to be stored for possible future, consented, testing and for quality purposes. Please note that genetic tests undertaken would only be in relation to blood transfusion.

NIBTS will accept samples for testing on the basis that the clinician responsible for the care of the patient has obtained the appropriate and valid consent for the test, storage and sharing of the patient's information with the relevant Health Care Professionals to generate the result. The name of the requestor, who should normally be medical, must be provided to satisfy requirements for consent to test.

7.5 SAMPLES

All samples should be transported in a sealed bag. This transport bag should be clearly labelled from NIBTS and should protect the confidentiality of patient details on the samples and request form. All samples and accompanying documentation should conform to the current version of NIBTS document SOP:HS:009, ‘Transport of Samples to NIBTS’, issued to Hospital Blood Banks. Please see also the current version of NIBTS document SOP: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 (028) 90534673.

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, X-ray irradiated etc.)
- Transfusion history

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 Biomedical Scientist 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 at 2-8^{o}C 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.

Investigation	Minimum Samples Required
Red Cell Antibody Investigation	2 x 6ml sample (EDTA)
Extended Red Cell Phenotyping	1 x 6ml sample (EDTA)
Crossmatching Blood for Patient	2 x 6ml sample (EDTA)
Investigation of Crossmatching Problem	2 x 6 ml sample (EDTA) from patient and labelled sample from donor line of appropriate blood pack
Routine platelet antibody testing	1 x 6ml clotted sample from patient (samples that cannot be transported immediately should be stored at 2-8^{o}C and arrive at NIBTS within 48 hours)
Investigation of Fetomaternal Alloimmune Thrombocytopenia (FMAIT)	1x 6 ml EDTA and 1 x 6 ml clotted sample from mother 1 x 6ml EDTA sample from father 1 ml EDTA sample from infant
Transfusion Reactions	Pre-transfusion sample, if available Two post-transfusion 6 ml EDTA samples (and 1x 6ml clotted sample, if possible) Return of the relevant donor pack(s)
Investigation of Autoimmune Haemolytic Anaemia	2 x 6 ml EDTA samples (clotted samples may be requested)
Investigation of Haemolytic Disease of the Newborn	2 x 6ml sample from mother (EDTA) Sample from baby (or cord blood sample)
Red Cell Genotyping	1 x 6ml sample (EDTA)
Estimation of Foetal Maternal Haemorrhage (by flow cytometry)	1 x 6ml sample (EDTA)

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

7.7 PROVISION OF PHENOTYPED BLOOD

During the hours of 9am – 5pm (Monday to Friday), requests for R_1R_1 or

Kell negative phenotyped red cells should be made by e-mail to the Hospital Services Department, **bloodrequests@nibts.hscni.net**.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 (028) 90534673.

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 an e-mail to the NIBTS Hospital Services Department **bloodrequests@nibts.hscni.net**.

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.

7.8 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 lb staff to have suitable antigen negative blood available on standby for the delivery.

7.9 REPORTING

The basic principle for reporting is to send the report to the requesting transfusion laboratory. Please contact the Reference Laboratory if you require different reporting arrangements.

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 Win Path Enterprise 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.

7.10 PLATELET ANTIBODY TESTING

Investigations for platelet autoantibodies are indicated in immune thrombocytopenic purpura (ITP). Investigations for platelet alloantibodies are indicated in drug induced immune thrombocytopenic purpura (DIITP),

foetomaternal alloimmune thrombocytopenia (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.

Any urgent sample that requires processing out of hours (for example, FMAIT investigations) must be authorised by NIBTS medical consultants.

The solid phase red cell adherence assay, Capture-P is used for the detection of platelet antibodies and for platelet crossmatching. The Immucor PakPlus ELISA technique is used for platelet antibody screening and the Immucor Luminex Pak Lx Assay (a multiplex bead-based assay) is used for platelet antibody identification. The ELISA & Luminex tests will also detect antibodies to Human Leucocyte Antigen (HLA) Class I in human serum. Genotyping for platelet antigens (HPA typing) is undertaken by molecular techniques.

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

Platelet antibody identification tests are routinely performed on fresh clotted samples (1 x 6ml). Samples referred for antibody identification must be received at NIBTS within 48 hours of sampling.
Molecular HPA typing requires EDTA samples (1 x 6ml (adults) and 1 x 1 ml (infants)).

Advice regarding appropriate samples, or any related queries can be obtained by contacting the Reference Laboratory (028) 90534605. Specific request form (FORM:DD:770) may be obtained by contacting the Laboratory (as above) or by contacting the NIBTS Document Control Officer (028) 90534673.

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

7.11 FOETAL MATERNAL HAEMORRHAGE TESTING (BY FLOW CYTOMETRY)

All requests for FMH testing must be accompanied with a completed DD:2320 form and the Reference Lab must be notified prior to sample referral (the Reference Lab will only test samples when the estimated bleed from the Kleihauer test is > 2ml).

Samples received by 12 noon on Friday will be tested on the same day whereas samples received on Friday afternoon will be tested on Monday am the following week (if results are deemed as potentially clinically urgent over weekend or holiday periods the request must be discussed with NIBTS medical team prior to referral).

Testing will be performed using the same sample used to perform the Kleihauer test by the referring hospital blood bank (1 x 6mls EDTA).

On completion of FMH tests the results will be communicated by phone to the referring hospital blood bank and followed up by a report.

7.12 TEST TURNAROUND TIMES (TAT)

Performance for serological and genotyping tests are monitored on a monthly basis

Test Name	Turn-around time (TAT)	Confirmation that method has been validated / verified	Reference Range, including MU if relevant	Name of EQA scheme
Blood grouping, antibody identification, crossmatching and phenotyping	95% reported within 5 working days	Accredited to ISO15189 as per schedule 8198	>95% results within +/- 1 reaction grade of target	NEQAS BTLP, NEQAS Extended Phenotyping
Investigation of autoantibodies / transfusion reactions and serologically complex investigations	95% reported within 5 working days	Accredited to ISO15189 as per schedule 8198	>95% results within +/- 1 reaction grade of target	NEQAS BTLP, NEQAS Extended Phenotyping, NEQAS Direct Antiglobulin Test (DAT)
Anti-A and anti-B titres	95% reported within 5 working days	Accredited to ISO15189 as per schedule 8198	>95% results within +/- 1 reaction grade of target	NEQAS ABO titration
FMH quantitation (by flow cytometry)	95% reported within 5 working days	Currently not accredited	<10%	NEQAS FMH quantitation
Red Cell Genotyping	85% reported within 10	Accredited to ISO15189	Robustness testing demonstrated	NEQAS Red Cell Genotyping

	working days	as per schedule 8198	accuracy within 50% of recommended DNA concentration.	
Human Platelet Antigen (HPA) Genotyping	85% reported within 10 working days	Accredited to ISO15189 as per schedule 8198	Robustness testing demonstrated accuracy within 20% of recommended DNA concentration.	NEQAS (H&I) (scheme 10 HPA genotyping)
Platelet antibody identification	95% reported within 5 working days	Currently not accredited	Robustness testing demonstrated accuracy within 10% of recommended pipetting volumes.	NEQAS (H&I) (scheme 11 HPA Antibody detection / specification)
Sickle cell screening	95% reported within 5 working days	Currently not accredited	LOD established at 15% HbS with ability to identify donors with sickle cell trait	NEQAS (Haematology) Abnormal Haemoglobins

7.13 SAMPLE REFERRAL

On occasion, samples may be referred onwards from the Blood Group Reference Laboratory for further testing, confirmation of antibody specificities or for molecular genotyoing by DNA techniques. These samples will be sent, with the permission of the requesting hospital, to the NHS Blood & Transplant, North Bristol Park, Filton, Bristol, BT34 7QH, UK. A copy of the subsequent report will be forwarded to the requesting hospital as quickly as possible after reception.

7.14 CODE OF CONFIDENTIALITY

All patient test results are treated in strictest confidence and NIBTS medical and biomedical scientist staff comply with a professional code of confidentiality.

8. AUTOMATED SEROLOGY DEPARTMENT

8.1 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 new-born otherwise at risk of haemolytic disease of the foetus and new-born (HDFN). 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 HDFN.

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.

8.2 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

8.3 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 Reference Laboratory. The correct requests forms from these departments must be used to avoid inclusion in the routine NIBTS workload.

Contact details:

Automated Serology Department Manager	Mr P Madden	(028) 90534632
Deputy Automated Serology Department Manager	Ms J Carr	(028) 90534632
Microbiology Laboratory Manager (Acting)	Mrs S Rainey	(028) 90534638
Deputy Microbiology Laboratory Manager	Vacant	
Antenatal Office Manager	Mrs R Collins	(028) 90534609

8.4 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) 90534632.

8.5 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 Standards in Haematology (BSH) Guidelines.

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

8.6 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.

8.7 TRANSPORTATION OF ANTENATAL SAMPLES:

Please refer to:

1. Current Guidelines on Hospital Blood Bank Documentation and Procedures BSH (Sample Collection).
2. Post Office Guidelines. Inland Postal Services Publications (Despatch of Samples).
3. See also current versions of NIBTS Procedures SOP:HS:009 'Transport of Samples to NIBTS' and SOP: 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 (028) 90534673.

Upon taking the sample, it should be kept at 2-6^{o}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.

8.6 ANTENATAL ROUTINE TESTING

Patient Consent, sample testing and storage

All tests carried out on a patient need the informed consent of the patient. The responsibility for obtaining informed consent for the test(s) resides with the individual ordering the test(s). Informed consent must cover all the tests being carried out, implications of their results and disclosure of clinical and personal details to personnel, in the requesting organisation and any other healthcare organisations involved in providing the testing. Consent for the testing of patient samples is obtained from the patient when the sample is being taken. For most samples this involves consent being obtained by staff in the hospital trust who are referring the sample. Where a sample is taken by a member of staff in NIBTS consent will be obtained by NIBTS. Taking a sample for transfusion in NI requires the taker to be "right patient, right blood" trained.

Where standard investigations are not conclusive, and/or genetic tests are available, these will be undertaken if considered in the patient's best interest. The laboratory will assume that a valid consent has been obtained by the referring clinician, including where appropriate, consent provided for extracted DNA to be stored for possible future, consented, testing and for quality purposes. Please note that genetic tests undertaken would only be in relation to blood transfusion.

NIBTS will accept samples for testing on the basis that the clinician responsible for the care of the patient has obtained the appropriate and valid consent for the test, storage and sharing of the patient's information with the relevant Health Care Professionals to generate the result. The name of the requestor, who should normally be medical, must be provided to satisfy requirements for consent to test.

ABO and Rh Group

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

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 BSH Guidelines for Blood Grouping and Red Cell Antibody testing during pregnancy.

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	HDFN unlikely
4-10 IU/mL	Moderate risk of HDFN
>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 feto-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 HDFN, affected offspring must be referred to such a unit. It should also be noted that HDFN has been reported at levels less than 4 IU/mL (Bowell et al, 1982). Once the referral to the feto-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 HDFN, refer to specialist unit
>15 IU/mL	Risk of severe HDFN, refer to specialist unit

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

8.7 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.

8.8 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.

8.9 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. Antibody results, needing investigation require manual input into the LIMS system. These reports 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.

Additionally, on completion of testing, results are automatically transferred to Northern Ireland Maternity System (NIMATS).

Copy Report : Copy reports may be obtained upon request from NIBTS Antenatal Office, telephone number (028) 90 534642.

8.10 FREQUENCY OF RED CELL SEROLOGY TESTING IN ANTENATAL PATIENTS

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

8.11 ROUTINE MICROBIOLOGY TESTING

All pregnant women should be tested at least once in each pregnancy (usually at booking) for immunity to rubella, syphilis antibodies, hepatitis B surface antigen and for HIV 1&2 antibody/antigen irrespective of the result in previous pregnancies.

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

Samples for these tests must be taken into a 5ml EDTA plasma preparation tube (PPT- white top with gel separator) 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 by and are available from NIBTS. **NOTE:** Samples will only be accepted for testing if the label is handwritten.

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 at 2-8ºC and transported at ambient temperature.
- Specimen Conditions- Do not use specimens with the following conditions:
  - Heat-inactivated
  - Pooled
  - Grossly haemolysed
  - Obvious microbial contamination
- 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 (028) 90534632.

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.

Reporting

Rubella Immunity

Results are classified into 2 categories and reported as:

- Rubella antibody detected >10 IU/ml. Regard as immune
- Rubella anti-body detected <= 10 IU/ml. Regard as Non-Immune

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, Kelvin Building, Royal Victoria Hospital, Grosvenor Road, Belfast BT12 6BA.

Syphilis Antibodies
Results are reported for syphilis antibody negatives.

Reactive samples are referred for confirmation to Regional Virus Reference Laboratory, which is located at Belfast Health & Social Care Trust, Kelvin Building, Royal Victoria Hospital, 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.

Hepatitis B
Results are reported for HBsAg negatives. Reactive samples are referred to the 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) 90534638 or Dr K Maguire (028) 90534644.

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. On completion of testing results are automatically transferred to Northern Ireland Maternity System (NIMATS).

Any results, which require manual input into the LIMS system, are authorised by Biomedical Scientists. Confirmed results returned from Virus Reference Laboratory are authorised by a medical officer.

The Consultant in Transfusion Medicine will provide clinical advice and interpretation, where appropriate.

8.12 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:

- For serology results (blood group, antibodies, titre, quantitation results etc.): Biomedical Scientist, (028) 90534632.

- For Rubella, syphilis, Hepatitis B and HIV results: Biomedical Scientist, (028) 90534638.

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

8.13 CODE OF CONFIDENTIALITY

All patient test results are treated in strictest confidence and NIBTS medical and biomedical scientist staff comply with a professional code of confidentiality.

9. MEDICAL TEAM

The medical team in NIBTS offer clinical support and advice for donors and an advisory service to requesting clinicians, for the interpretation of results provided by NIBTS and for the appropriate selection of blood and blood components. Advice from the medical team can be requested during normal working hours by telephoning (028) 90534644 or outside normal working hours by contacting the Biomedical Scientist on call. Alternatively, non-urgent queries can be addressed to medicalsupport@nibts.hscni.net.

10. 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; including specialist training for Clinical Scientists.

(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 out of hour's duties. Training for support staff to further career opportunities, for example, support for the IBMS Certificates of Achievement.

(c) One year placements for students undertaking an IBMS accredited BSc in Biomedical Sciences; incorporating completion of the IBMS Registration Portfolio.

(d) Laboratory tours for medical students, Biomedical Science students, graduate recruitment programme, nurses and other health care workers.

(e) Participation in work experience schemes/visits for schools and colleges.

11. QUALITY INCIDENTS AND COMPLAINTS

Quality incidents, including adverse events / reactions and defective products or services.

In order to continue to provide quality products and services it is necessary for customers to notify the NIBTS of any defect in products e.g. leaking packs, or if a delay in receipt of blood is identified. These must be reported to the NIBTS Quality Department, telephone (028) 90534695 or e-mail: qualityincident@nibts.hscni.net

The procedure for reporting such defects is described in detail in NIBTS SOP: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.

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 (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 (028) 90534673.
- Notification should be sent to NIBTS Quality Department. Clinical advice will be provided by Dr K Maguire, or Dr A Sadiq on (028) 90534644.

Users who are unhappy with any aspect of the service provided by NIBTS are encouraged to forward and suggestions, questions or complaints to the NIBTS Quality Department.

12 APPENDIX 1. BLOOD COMPONENTS AVAILABLE FROM NIBTS

Note: 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	280ml ± 60ml	CPD red cells in SAG-M additive solution Haematocrit: 0.50 – 0.70 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	280ml ± 60ml	CPD red cells in SAG-M additive solution Haematocrit: 0.50 – 0.70 Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit Haemoglobin: ≥40g/unit	+4°C ±2°C	35 days	Prepared on request	Approval by NIBTS Medical Consultant
3	Leucodepleted Red cells in Additive Solution for Neonatal Use (5 / 6 split packs per primary red cell donation)	Groups O R_1R_1, A R_1R_1, O rr, A rr Kell negative CMV antibody negative HbS Negative	42-52ml	CPD red cells in SAG-M additive solution Haematocrit: 0.50 – 0.70 Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit	+ 4°C ±2°C	35 days	Stock item Other groups prepared on request. (Phenotyped blood may not always be available, but can be prepared on request).	

NOTE: 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 5.4

APPENDIX 1 cont.

No	Components	Group	Approx. Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
4	Leucodepleted Red Cells. Semi-concentrated for exchange transfusion	O R1R1 A R1R1 O rr Kell negative CMV antibody negative HbS Negative	320ml ± 100ml	Fresh CPD red cells (within 5 days of collection) re-suspended in plasma (plasma volume calculated based on red cell weight). Haemoglobin: ≥40g/unit Haematocrit: 0.50 - 0.60 Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit	+ 4°C ±2°C	23 hours from time of preparation	Prepared on request	Approval by NIBTS Medical Consultant
5	Leucodepleted Red Cells(CPD) Re-suspended in group AB Plasma	O R1R1 A R1R1 O rr Kell negative CMV antibody negative HbS Negative	320ml ± 100ml	Fresh CPD red cells (within 5 days of collection) re-suspended in 135 ml plasma. Haemoglobin: ≥40g/unit Haematocrit: 0.50 – 0.60 Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit	+ 4°C ±2°C	23 hours from time of preparation	Prepared on request (Phenotyped blood available on request)	Approval by NIBTS Medical Consultant
6	Plasma removed Leucodepleted Red Cells Resuspended in Sag-M Additive Solution	All ABO & Rh groups	280ml ± 60ml	100ml SAG-M Haematocrit: 0.50 – 0.70 Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit Haemoglobin: ≥40g/unit Total Protein: ≤0.5g/unit	+4°C ±2°C	10 days 48 hrs if irradiated	24 hrs notice required 48 hrs notice required for phenotyped	Approval by NIBTS Medical Consultant
7	Leucodepleted Pooled Platelets Buffy Coat Derived in PAS / Plasma mix All platelets are X-ray irradiated	O Positive O Negative A Positive A Negative Group B prepared as required	310ml ± 50ml	4 x CPD red cell derived Buffy coats re-suspended in platelet additive solution (PAS) / Plasma mix 70% / 30%. Platelets: ≥240 x 10^9/unit Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit pH ≥6.4	+22°C ±2°C Agitated	7 days	Stock item	

No	Components	Group	Approx. Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
8	Leucodepleted Pooled Platelets Buffy Coat Derived in 100% plasma All platelets are X-ray irradiated	O Positive O Negative A Positive A Negative Group B prepared as required	310ml ± 50ml	4 x CPD red cell derived Buffy coats re-suspended in 100% plasma Platelets: ≥240 x 10^9/unit Leucocytes: 99% <5x10^6/unit 90% <1x10^6/unit pH ≥6.4	+22°C ±2°C Agitated	7 days	Contingency for pooled Buffycoat platelets resuspended in PAS/plasma mix	Hospital blood banks and Clinicians to be informed if contingency implemented
9	Leucodepleted Platelets, Apheresis All platelets are X-ray irradiated	All ABO groups	>160ml	ACD/CPD plasma Platelets: ≥240 x 10^9/unit Leucocytes: 99% <5x10^6/unit 90% <1x10^6/unit pH ≥6.4	+22°C ±2°C Agitated	7 days	Stock item	Antigen typed (HLA or HPA) platelets available by arrangement with NIBTS Medical Consultant

NOTE: 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 5.4

APPENDIX 1 contd.

No	Components	Group	Approx. Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
10	Leucodepleted Platelets Apheresis for Neonatal Use.	All ABO & Rh Groups	40-80ml	Prepared as an aliquot from whole leucodepleted apheresis unit (see No 7) Platelets: ≥40 x 10^9/unit Leucocytes: 99% <5x10^6/unit 90% <1x10^6/unit pH ≥6.4	+22°C ±2°C Agitated	5 days	Prepared on request	
11	Leucodepleted Apheresis Platelets re-suspended in Platelet Additive Solution All platelets are X-ray irradiated	All ABO & Rh Groups	180-220ml	Apheresis platelets plasma removed and re-suspended in platelet additive solution. Platelets: ≥200 x 10^9/unit Residual leucocytes: 99% of product <5x10^6/unit 95% of product <1x 10^6/unit pH ≥6.4	+22°C ±2°C Agitated	24 hours from start of preparation	Prepared on request Must be pre-ordered a minimum of one day in advance	Approval by NIBTS Medical Consultant for new patients
12	Leucodepleted Fresh Frozen Plasma	All ABO groups	>240ml	CPD frozen plasma Contains all clotting factors. Leucocytes: 99% <5x10^6/unit 90% <1x10^6/unit FVIII: Mean ≥0.70 IU/ml 90% ≥0.50 IU/mL Total Protein: ≥50g/L Platelets: <30 x 10^9/litre	≤-25°C	3 years	Stock item	

NOTE: 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 5.4

APPENDIX 1 contd.

No	Components	Group	Approx. Unit Volume	Constituents	Storage Temp	Shelf Life	Availability	Remarks
13	Leucodepleted Fresh Frozen Plasma Paediatric / Neonatal use	All ABO groups	50-75 ml	Frozen Plasma Contains all clotting factors Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit FVIII: Mean ≥0.70 IU/ml 90% ≥0.50 IU/mL Total Protein: ≥50g/L Platelets: <30 x 10^9/litre	≤-25°C	3 years	From stock	Produced from plasma collected from NIBTS donors (MB treated no longer required)
14	Leucodepleted Pooled Cryoprecipitate	All ABO Groups Rh+ve	100ml - 250ml	Cryoprecipitate pooled from 5 single units of CPD plasma. Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit >Fibrinogen: ≥700 mg/unit >Factor VIII: ≥350 IU/unit Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit	≤-25°C	3 years	From stock	
15	Leucodepleted Cryoprecipitate Paediatric / Neonatal use	All ABO Groups	37-53 ml	Cryoprecipitate pooled from single units of CPD plasma. Leucocytes: 99% <$5x10^6$/unit 90% <$1x10^6$/unit >Fibrinogen: ≥140 mg/unit >Factor VIII: ≥70 IU/unit	≤-25°C	3 years	From stock	Produced from plasma collected from NIBTS donors (MB treated no longer required)
16	Octaplas (Solvent/deter-gent treatment [S/D])	All ABO Groups	200 ml	As per Data Insert: Human plasma proteins 45-70mg/ml Contains all clotting factors	≤-18°C	4 years at ≤ -18°C	From stock (where possible 2 days' notice)	Recommended for TTP patients

NOTE: 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 5.4

13. APPENDIX 2. PLASMA DERIVATIVES AVAILABLE FROM NIBTS

Pulse Product No.	Product Name	Size	Dose	Supplier
V912	Anti-D IM	500IU	50µg/ml	Bio products laboratory
V935	Hepatitis B Ig	500IU	100IU/ml	Bio products laboratory
V921	Tetanus Ig	250IU	100IU/ml	Bio products laboratory
0939	Human Rabies Immunoglobulin	500IU	150IU/ml	Bio Products Laboratory
D001	Rhophylac 1500iu	1500IU	300µg/2ml	CSL Behring
D002	Alburex 20%	100ml	200g/l	CSL Behring
PL76	Alburex 5%	500ml	50g/l	CSL Behring
HALB	Human Albumin 20%	50ml	200g/l	Grifols
AL02	Albutein 20%	100ml	200g/l	Grifols
AL04	Albutein 5%	500 ml	50g/l	Grifols
OCTA	Grp A Octaplas	200ml	as required	Octapharma Ltd
OCAB	Grp AB Octaplas	200ml	as required	Octapharma Ltd
OCTB	Grp B Octaplas	200ml	as required	Octapharma Ltd
OCTO	Grp O Octaplas	200ml	as required	Octapharma Ltd
PL47	Octaplex	20ml	500IU	Octapharma Ltd

14. APPENDIX 3. Clinical Indications for Irradiation of Cellular Blood Components

(In accordance with ‘ Guidelines on the use of irradiated blood components prepared by the British Committee for Standards in Haematology blood transfusion task force’. *British Journal of Haematology*, 2010, 152, 35-51. It should be noted that all platelets are X-ray irradiated

HLA selected platelets

Transfusions from relatives

Intrauterine transfusion (IUD)

Exchange transfusion

Transfusion until 6 months after the expected delivery date (40 weeks gestation) of newborns who have previously had IUT

Congenital T-cell immunodeficiency

Bone marrow allografting and autografting

Hodgkin’s disease

Patients on treatment with purine analogies i.e. fludarabine, cladribine, deoxycoformycin, and other purine antagonists with a similar mode of action such as bendamustine and clofarabine.

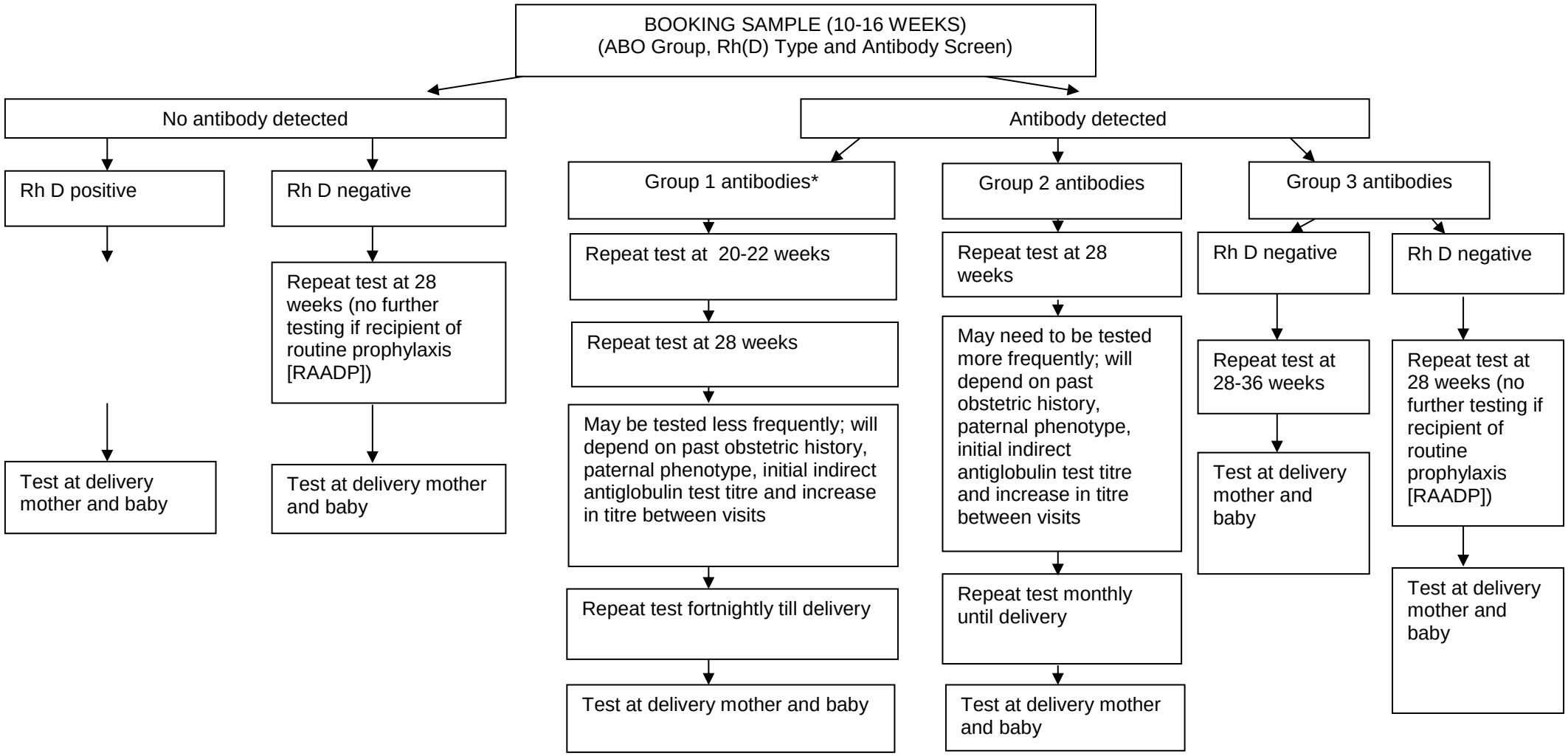
Treatment with anti-thymocyte globulin (ATG)

Treatment with alemtuzumab (anti-CD52)

All granulocyte components should be irradiated.

Indications not listed here should be discussed with NIBTS Medical Consultant.

15 APPENDIX 4. Antenatal Screening for Red Cell Antibodies



* 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