Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

Type: RCI IBTS CM
Document No.: IBTS/RCI/CM/0001[5]
Title: **CUSTOMER MANUAL FOR THE RED CELL IMMUNOHAEMATOLOGY LABORATORY**
Owner: QA DOC CON QA DOC CONTROL
Status CURRENT
Effective Date: 27-Jan-2026
Expiration Date: 27-Jan-2028

Review

Review: IBTS DOC REVIEW AND APPROVAL

Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	BECKY WHITE	BECKY WHITE
2	RCI WRITER IBTS	MEGAN GALLAGHER	MEGAN GALLAGHER
3	RCI REVIEWER IBTS	CIARA BAUER	CIARA BAUER
4	LABS HEAD OF TESTING IBTS	PADRAIG WILLIAMS	PADRAIG WILLIAMS
4	X EXPIRE MEDICAL HEAD OF DEPT NBC	KIERAN MORRIS	KIERAN MORRIS
4	RCI HEAD OF DEPT NBC	CONOR GALVIN	CONOR GALVIN
5	Labs Patient Testing Quality & Regulatory Reviewer IB	MARIA KANE	MARIA KANE

Change Orders

Changes as described on Change Order: **Change Order No.**

Change Orders - Incorporated

Changes as described on Change Order: **Change Order No.**
IBTS/CO/0445/25

Valid on Day of Printing, Verify Current Version
Printed By: **Date:**

TITLE: CUSTOMER MANUAL FOR THE RED CELL IMMUNOHAEMATOLOGY LABORATORY

Change Description:

1 Addition of section 1.18 impartiality and confidentiality.
2 Addition of section 1.15 on release confidential information, 1.16 Freedom of information & 1.17 samples and records in the event of the closure of the laboratory.
3 Removed reference to Laboratory Manual.
4 Updated Att 13.1 updated Hospital names.
5 Updated 3.6.1 and 7.1 re TAT monitoring in line with NF 45.
6 Updated section 6.2 to detail procedure if sample leaked in transit & line to say sample transport system is the responsibility of the referring hospital.
7 Updated section 4.1 to say request form is considered an agreement
8 Updated section 3.9 Included ref to clinical indications, limitations and frequency of testing.
9 Section 7.9 ref ranges for antenatal testing, 7.10 Sample quality, limitations and interpretation.
10 Added to table 1.8 and numbered all tables in the text.
11 Removed BSH working limits table, added detail to 5.3.8 re sample storage and validity of red cells.
12 RCI label address
13 IVDR
14 Changed ES to CG
15 Correct weblinks
16 Section 7-RCI do not claim accreditation for 'referral test services'
17 Sharefile reports

Reason for Change:

1 IR 141/25
2 IR 197/25
3 CC 283/25
4 CC 099/25
5 CO 279/25
6 Audit Rec RCI-ISO-VA21102024
7 Audit Rec RCI-ISO-HA01112024
8 IBTS/QA/GA/0009
9 Requirement for ISO 15189:2022 standard CC 308/24
10 Requirement for ISO 15189:2022 standard CC 308/24
11 Requirement for ISO 15189:2022 standard CC 308/24
12 IBTS/CO/0326/25
13 IVDR
14 CC 201/25
15 IR 219/25
16 Requirement for ISO 15189:2022 standard CC 308/24
17 CC 350/24

Referenced Documents

IBTS/MED/SOP/0050	IBTS/EXT/DOC/0017	BT - 0345
IBTS/QA/QM/0001	IBTS/EXT/DOC/0034	BT - 0396
IBTS/EXT/DOC/0012	IBTS/RCI/FORM/0001	BT - 0597
IBTS/EXT/DOC/0025	IBTS/RCI/SOP/0013	BT - 0685
IBTS/EXT/DOC/0033	BT - 0007	

SmartSolve Roles

MED CON BMR HLA NBC	MED SMO NBC	RCI SMS NBC
MED CON IH NBC	RCI LA NBC	RCI THOD NBC
MED CON MSD IBTS	RCI MS NBC	RCI TMS NBC

Training Type

Staff trained in previous versions	**New staff & staff returning from long term leave**
Read only	Read only

SmartSolve Document Category

Category	**Mobile**	**Cryobiology**	**Website**	**GDP**
Yes / No	No	No	Yes	No

TABLE OF CONTENTS

1 INTRODUCTION 6

2 QUALITY POLICY 8

3 GENERAL INFORMATION 10
- 3.1 RCI Laboratory 10
- 3.2 Laboratory Director 11
- 3.3 Service Operating Times 11
- 3.4 Key Personnel and Contact Details 12
- 3.5 Sample Testing Schedule 12
- 3.6 Turnaround Times 15
- 3.7 Service Fees and Charges 16
- 3.8 Data Protection 16

4 REQUEST FORMS 18
- 4.1 General Information: 18

Samples and Forms 18
- 4.2 RCI Laboratory Request Forms 19
- 4.3 Ordering IBTS Request Forms 20
- 4.4 Completion of Request Forms 20

5 SAMPLE INFORMATION 22
- 5.1 Sample Collection 22
- 5.2 Service Requestor Responsibilities 23
- 5.3 Sample Labelling 23

6 SAMPLE DELIVERY, PACKAGING AND TRANSPORT 28
- 6.1 Sample Delivery 28
- 6.2 Sample Packaging and Transport 28

7 TESTING PROVIDED 29
- 7.1 Services Provided 31
- 7.2 Referral Test Services 41
- 7.3 Provision of Rare Donor Red Cell Components from International Rare Blood Programmes 45
- 7.4 Concessionary Release of Blood Components 45
- 7.5 Medical and Scientific Consultancy Service 46
- 7.6 Haemovigilance Advisory Service 46
- 7.7 Repeat Examination 46
- 7.8 Further Examination of the Primary Sample 46

8 EXTERNAL AND INTERNAL QUALITY ASSURANCE SCHEMES 47
- 8.1 External Quality Assessment Programmes (EQA) 47
- 8.2 Inter-Laboratory Comparison Scheme 48
- 8.3 Internal Quality Assessment Programme 48
- 8.4 Authorisation 48
- 8.5 Non-Conformance / Failure in an EQA Scheme 48

9 REPORTING OF RESULTS 48
- 9.1 Approval of Test Results and Issuing Reports 48
- 9.2 Issuing Reports on Critical Samples where Results are Delayed. 50
- 9.3 Reporting of Results by Fax / Encrypted Email/ Sharefile 50
- 9.4 Telephoned Results 50
- 9.5 Archiving of Patients Records 51

10 CUSTOMER SERVICE / SATISFACTION AND REVIEW 51
- 10.1 Service Level Agreements 51
- 10.2 Customer Complaints / Compliments 51

10.3 Quality Management Review 51
10.4 Customer Liaison 51
10.5 Hospital Transfusion Committees 52
10.6 Continuous Improvement 53
10.7 Traceability 53
10.8 Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs) 55
11 REFERENCES 57
12 ATTACHMENTS 58

TITLE: CUSTOMER MANUAL FOR THE RED CELL IMMUNOHAEMATOLOGY LABORATORY

1 INTRODUCTION

1.1 This manual is designed to provide an overview of the services available from the Red Cell Immunohaematology (RCI) Laboratory at the National Blood Centre. It is intended for the customers of both the routine compatibility services, routine antenatal services and of the referral Immunohaematology service.

1.2 The services described are provided to hospitals, hospital blood transfusion laboratories and medical practitioners in the public and private health care sectors in the Republic of Ireland.

1.3 This manual specifies the minimum requirements for the labelling of samples and for the completion of request forms to ensure sufficient information is received for the requested service to be optimally delivered. The RCI laboratory will accept correctly completed request forms from designated facilities requesting its service provided the pertinent details are completed and the samples accompanying the forms meet the current specified criteria. Authorised personnel will review test request documentation to determine suitability of tests requested.

1.4 The RCI Laboratory is subject to regular scheduled inspection by the Health Products Regulatory Authority (HPRA) for compliance as a Blood Establishment to the relevant EU Directives and Irish Statutory Instruments (SI 360 of 2005, SI 547 of 2006, SI 562 of 2006).

1.5 The laboratory complies with S1 547 of 2006 incorporating Articles 14 and 15 of Directive 98/ 2002/EC (Traceability Requirements, Notification of SAR/E).

1.6 All work is carried out within the framework of a documented quality system, according to Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP). The laboratory operates to internal policies and procedures for all activities as defined by the IBTS Quality Management System. This manual is a controlled document as part of that System. All red cell referral & compatibility services undergo continuous review through quality assurance and audit activities.

1.7 Samples are disposed of by the laboratory in accordance with IBTS Health and Safety procedures and, in compliance with waste management regulations.

1.8 This manual should be read in conjunction with the IBTS product master files which are available for view on giveblood.ie website.

1.9 IBTS laboratory management is committed to the provision of a full and effective service. To this end it ensures:

- Optimum staff recruitment, training, development and retention at all levels.
- Procurement, validation and maintenance of appropriate equipment /resources.
- Maintaining sample integrity and thereby the correct performance of laboratory examinations.
- Use of examination procedures that are fit for purpose and ensure the highest achievable quality.
- Timely, confidential, accurate and clinically useful reporting of examination results.
- Assessment of customer satisfaction, in addition to internal audit and external quality assessment.
- Notification to users of significant changes to RCI laboratory processes/procedures where the results or their interpretation could be significantly different, prior to implementation.

1.10 A copy of this manual is available on the internet at: https://healthprofessionals.giveblood.ie/clinical-services/transfusion-transplantation/red-cell-immunohaematology-diagnostics/
Hard copies of the customer guide will not be supplied.

1.11 When key changes are made to either the tests or the services identified in this manual, the customer will be notified in writing or by email. The electronic copy of the manual will be modified and made available to the customer on the website above.

1.12 The term 'BSH Guidelines 2012' shall refer to 'Guidelines for pre-transfusion compatibility procedures in Blood Transfusion Laboratories' British Committee for Standards in Haematology, 2012, throughout the document.

1.13 The term 'Hospital Blood Transfusion Laboratory' is used to describe the Blood Transfusion Laboratories, in hospitals to which the RCI laboratory provides a referral service.

1.14 The term 'Hospital Blood Bank' is used to describe the situation where the RCI laboratory acts as the institution's Hospital Blood Bank.

1.15 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released, unless prohibited by law.

1.16 The laboratory does not make any patient information public however requests can be made via Freedom of information. The requester is requested to follow the Freedom of Information requests as per the giveblood.ie website.

1.17 The laboratory shall ensure the on-going availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory. In the event that the legal entity (i.e. The IBTS) was to close all records and samples would be the property of the State.

1.18 All staff All staff directly involved in activities that impact patient testing, are required to demonstrate their agreement to comply with the Impartiality & confidentiality requirements of ISO 15189 annually. This is done through the Impartiality & Confidentiality Statement. Third party contractor agreement to comply with the confidentiality requirements of ISO 15189 is managed through the IBTS On-line Induction process. All other visitors to the laboratory are required to agree to comply with the confidentiality requirements of ISO 15189 on entering the laboratory. This is managed by laboratory staff. (IBTS/LABPT/SOP/0002).

1.19 It is the responsibility of Laboratory Director; Head of Testing; RCI CMS or designee to communicate Residual Risk to Users. Where appropriate communication may be through amended patient reports (IBTS/RCI/SOP/0002), via the complaints process (IBTS/QA/SOP/0063), or at the Consultant Haematologist's discretion.

1.20 Laboratory procedures include time limits for requesting additional examinations on the same sample. These limits are based on working limits for red cell / plasma samples. The time between sample collection and examination is specified and monitored where relevant. If the validity period of the sample has expired, the user will be informed on the patient report.

1.21 The RCI complies with policies set out by the IVDR whereby any reagents used in the laboratory shall bear a CE marking. Where the laboratory changes the original reagent to resuspend a red cell reagent in a different medium a log of such changes is kept and available to view upon request.

2 QUALITY POLICY

The RCI management team will ensure the laboratory complies with the IBTS Quality Policy laid out in IBTS/QA/QM/0001. In addition the RCI Laboratory will comply with the standards set by, AML-BB, S.I. No. 360 of 2005 European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 and EU Directive 2002/98/EC (setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components) for the services and tests defined in this manual and is committed to:

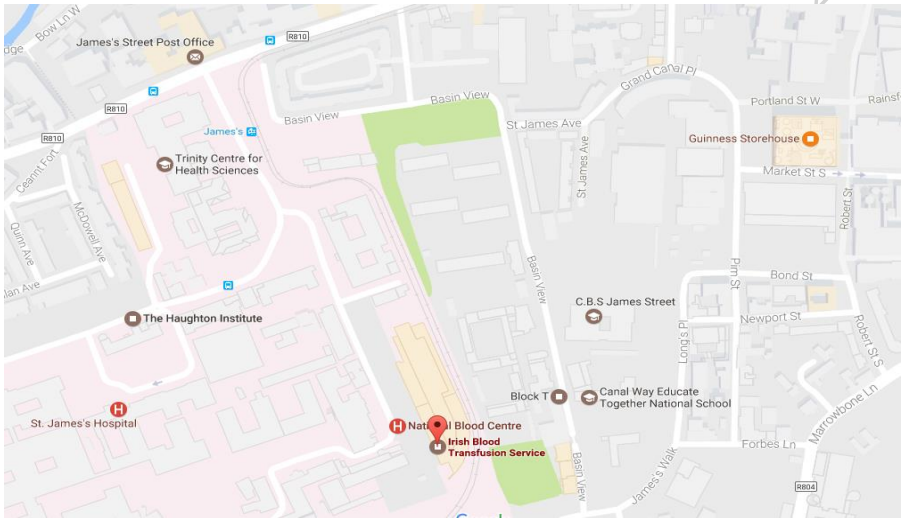
- Staff recruitment, training and development at all levels to provide an effective and efficient service to its users.
- Providing and managing resources to ensure that all examinations are processed to produce the highest quality results possible.

- Reporting results in ways, which are timely, confidential, accurate and are supported by clinical advice and interpretation when required,
- Implementation of Internal Quality Control, External Quality Assessment, Audit and Assessment of Customer Satisfaction to continuously improve the quality of the service
- Compliance with relevant environmental legislation.
- Adherence to appropriate technical and professional standards.
- Management and staff are committed to creating a quality culture within the Department by continuously improving our services based on the results of performance through data review, internal quality audits, equipment maintenance, Quality Control programmes and the assessment of customers' needs.

3 GENERAL INFORMATION

3.1 RCI LABORATORY

Location: The RCI Laboratory is based at the National Blood Centre (NBC) in Dublin. The NBC is located on the site of St James Hospital (see map below):



Postal Address:
Red Cell Immunohaematology Laboratory
National Blood Centre
James's Street
Dublin 8
D08 NH5R

Tel: (01) 4322800
Fax: (01) 4322709
Email: rci@ibts.ie

Scope of Activity: The RCI Laboratory provides a specialist red cell immunohaematology service to hospital blood transfusion laboratories. It is the national centre for antenatal antibody quantitation testing.
It also provides hospital blood bank services to 3 organisations:
Royal Victoria Eye & Ear Hospital, Dublin
Our Lady's Hospice & Care Services,
Harold's Cross & Blackrock Hospice.

Sample Reception: Sample Reception for the RCI Laboratory is located at Security. The entrance to Security is located approximately 20 metres to the left of the main entrance doors to the building (see picture below).

3.2 Laboratory Director

The RCI Laboratory is directed by Consultant Haematologist; Dr Kieran Morris.

3.3 Service Operating Times

Table 1.1 of RCI operating times

Department / Activity	Opening Hours RCI
Routine Laboratory	Monday to Friday 8.00 - 19:00 Excluding Bank Holidays
Emergency Out of Hours Service* (On-Call Service)	Monday to Friday: 19:00 - 8:00 (Scientist On-call**) Saturday, Sundays & Bank Holidays: Scientist On-Call 24 hrs.**
Sample Reception	Security: 24 Hrs

* The out-of-hours service is for emergency referrals only and where immediate blood component transfusion is clinically indicated.

** The Scientist on-call for the RCI Laboratory is not on-site & is called in as/when required.

3.4 Key Personnel and Contact Details

Table 1.2 of Key Personnel Contact Details

SECTION	RCI, NBC
Consultant Haematologist	Dr Kieran Morris 01-4322800 or Specialist Medical Officer / Registrar on duty 01-4322800
Chief Medical Scientist	Conor Galvin 01-4322966
Laboratory (Routine Hours)	01-4322972 01-4322973
Laboratory (Out of Hours)	01-4322800 (Switch) Ask for Registrar On-call. The IBTS Medical Registrar will determine if a sample is to be processed on call and will in turn contact the RCI scientist.
Clinical issues (Out of Hours)	01-4322800 (Switch) Ask for registrar on duty/call.
For Hospital Blood Bank Service ONLY *	During Routine hours contact the RCI laboratory. Out of hours, contact SSCD Department via Switch (01-432 2800) Hospital Services staff will contact RCI staff and notify them of the request.
Laboratory Fax No.	01-4322701
Switch	01-4322800
Emergency Contact No. (Hospital Services Department)	01-4540131

*All other platelet orders (i.e. from Hospital Blood Transfusion Laboratories) are handled by the Components Issue Laboratory

3.5 Sample Testing Schedule

3.5.1 Routine Service

3.5.1.1 Hospital Blood Bank Service

The RCI laboratory will accept and process samples for routine and compatibility testing throughout the day Monday to Friday. Sample testing on any day is prioritised based on clinical need. The cut off time for receipt of samples for group & hold / routine crossmatch on the same day is 5pm.

3.5.1.2 Hospital Blood Transfusion Laboratories (referral service)

Samples should be received by RCI by day 4 post bleed to allow for sufficient time to perform the required testing. If the sample is >4 days old on receipt, the laboratory will determine whether the sample can be accepted or not. The referring laboratory will be contacted if the sample is rejected.
Samples are processed based on clinical need (except for batched tests – see below). Samples which are referred for antibody investigation and provision of blood will be prioritised for testing during the routine working day.

The cut off time for sample receipt for provision of blood during the routine working day is 2pm (please ensure that samples for crossmatching are sent without delay and directly to the laboratory to meet this cut off time).

Please note: all requests for crossmatch must be phoned in advance to the RCI laboratory and be accompanied with a clinical request for blood. All ''add on'' requests for crossmatch must be followed with a clinical request and a copy of BT-0345 specifying the total number of units requested and any special requirements, this can be emailed to the laboratory using RCI@IBTS.ie.

In an urgent situation the RCI laboratory should be contacted by telephone and provision will be made to process the sample urgently or out of hours if required. All out of hour's requests are approved by the Medical Team in the IBTS and must be clinically urgent. Samples for antenatal antibody titration/ quantitation will be batched and processed to meet the test turnaround times specified in Section 7.1.1.

3.5.2 Emergency Service

3.5.2.1 Hospital Blood Bank Service

The RCI laboratory provides an emergency blood group and compatibility service, both routine and out of hours, for organisations where the IBTS acts as their Hospital Blood Bank and have in place a service level agreement (SLA). The RCI Laboratory maintains a supply of 2 units of O RhD negative, un-crossmatched blood at the NBC for issue in emergency issue to the Royal Victoria Eye & Ear Hospital. In this instance the units are labelled as Emergency Stock on the BT - 0396 Compatibility label.

3.5.2.2 Referral Service for Hospital Transfusion Laboratories

The RCI Laboratory provides an emergency immunohaematology / compatibility testing referral service for Hospital Blood Transfusion Laboratories.

3.5.2.3 Requesting Emergency Services

If a sample is urgent, please indicate this on the request form by completing the 'Treat as Emergency' box to ensure that the request is prioritised by the laboratory.
Please contact the laboratory to discuss the urgent requirement.

- Routine Hours: Contact the laboratory directly (refer to Section 3.4 for contact details).
- Out of hours: Contact switch and request to speak to the medical personnel on-call (refer to Section 3.4 for contact details).

Requests for emergency services / compatibility testing out of hours will be assessed in accordance with the urgency of the request by the IBTS Specialist Medical Officer (SpMO) / Registrar / Consultant Haematologist.

3.5.2.4 Procedure for Urgent Requests

All urgent requests must be phoned to the laboratory and the priority of the sample indicated on the BT-345 request form. Urgent samples must be transported as urgent with clear instructions on delivery of the sample. The turnaround time for the sample will be as indicated in Section 7 below. Where multiple urgent samples are received, samples will be triaged by the Medical Team.

When making an urgent request the following details will be requested and confirmed (by reading back to the person giving the information):

- Referring Hospital
- Name of person making the request
- Patient's name (if known), hospital / emergency / trauma number and date of birth.
- The urgency of the request (date and time required) and estimated time of sample arrival

In addition, the following details will be confirmed to the medical scientist:

- Number and type of blood component requested including any special requirements (CMV- / Irradiated)
- Blood Group, ABO/ Rh/ K type, if known (from referral

laboratory only), serology results at the referring site & details of known antibodies
- Reason for transfusion
- Transfusion history (if known)
- Relevant clinical condition
- Current haemoglobin
- Name and contact details of doctor looking after patient (this is required where a sample will be processed out of hours)

Note:

1. Where a clinical condition dictates that a transfusion is required prior to the completion of testing, the transfusion support may vary depending on the degree of clinical urgency, the availability of an emergency stock of red cells on site at the hospital and prior availability of the patient's sample and validated blood group at the RCI laboratory.
2. Where blood is required urgently but prior to the completion of compatibility testing and the patient's sample is not known to contain clinically significant antibodies, transfusion support will be provided by the RCI laboratory or issued from the hospital's own stock.
3. Where antibodies are detected in the patient's sample, the relative risks of abbreviated testing prior to emergency transfusion will need to be discussed between the IBTS Consultant Haematologist/ Registrar/ SpMO and the clinician in charge at the hospital.
4. Where there is concessionary release of a product/component or a deviation from standard procedure a concessionary release will be authorised by the IBTS Consultant Haematologist/ Registrar/SpMO following consultation with the patient's attending clinician (in accordance with IBTS/MED/SOP/0050).
5. If a verbal request is received for additional units or testing the referring hospital must send a completed BT-345 or BT – 0007 request form for the additional testing required. Where a verbal request for testing is received, testing may commence prior to receipt of the request form but a request form must be received for every requested test.

3.6 Turnaround Times

For turnaround times for routine and emergency requests see Section 7.1.1.

3.6.1. Non-compliance with turnaround times

- Turnaround times are monitored monthly.
- Turnaround times are discussed at monthly Senior meetings, monthly laboratory meetings and at the RCI AQMR
- Should there be a significant delay in the expected turnaround times, the requestor will be notified in the instances where the delay could compromise patient care.
- The requesting facility must inform the laboratory of any change in the urgency of the blood so that appropriate action can be taken.

- Monthly turnaround times are available on request from the CMS / designee.

Note:

Overuse of the urgent service will adversely affect the turnaround time of all urgent tests.

3.7 Service Fees and Charges

A list of current services fees and charges, with detailed information regarding out of hours service charges, are available from: Director of Finance - 01 4322800. The cost list of service is emailed to all hospitals at the beginning of each year and is available from the IBTS on request.

3.8 Data Protection

Under the General Data Protection Regulation (GDPR) (EU) 679/16 and the Data Protection Act 2018, the RCI Laboratory acts as a DATA PROCESSOR for the referring laboratory/organisation when samples are referred for testing to IBTS. This testing provides diagnostic testing for patients of the referring laboratory. The referring laboratories are the DATA CONTROLLERS.

3.9 Advisory activities

The laboratory ensures that appropriate laboratory advice and interpretation are available to meet the needs of patients and users. The laboratory has established arrangements for communicating with laboratory users on the following when applicable:

3.9.1. Advising on choice and use of examinations based on the clinical indication of the patient and best practice guidelines. The request form indicates the type of sample required for each test method by the referring hospital, based on the results obtained, the RCI laboratory may perform additional reflex test. Where relevant the clinical indications and limitations of examination methods are listed in the customer manual. The frequency of requesting the examination is based on best practice guidelines and is advised on the patient report.

<u>Clinical indications for testing</u>

Referral to the RCI laboratory is usually prompted by complex or unresolved serological cases, where advanced Immunohaematology testing is needed:

- Investigation of complex/ multiple red cell antibodies
- Autoimmune haemolytic anaemia
- Suspected transfusion reactions (Positive DAT/eluate)
- Crossmatch incompatibility
- Pre-transfusion testing in patients with rare blood groups
- Alloimmunisation in pregnancy (e.g. anti-D, anti-K, Anti-c)

- Requirement for antigen-negative or rare donor units
- when standard laboratory tests are insufficient or inconclusive

Limitations of examination methods

- Sample Quality; mislabelled/unlabelled samples can compromise results.
- Haemolysed and/or lipemic samples may cause inaccurate test results due to the presence of free haemoglobin and/or fatty plasma, particularly when using automated equipment.
- Passive antibodies – may complicate interpretation (e.g. IVIG or maternal antibodies in neonates).
- Autoantibodies – can mask underlying alloantibodies, requiring adsorption studies that are time-consuming and sometimes inconclusive.
- Turnaround Time – Referral testing may take longer than stated TAT which can impact urgent transfusion need.
- False negatives (low-titre antibodies may not be detected).
- DAT can be positive in non-transfusion-related conditions
- Crossmatching does not eliminate all risks, haemolytic reactions can still occur.
- Massive transfusion can cause dilution effect in samples.
- Antigen typing- strong DAT positive samples can limit phenotyping.
- Rare antibodies, identification may require international collaboration.
- Cards / cassettes which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminium foil should not be used as this may produce false positive results.
- Failure to properly mix the cell suspension may result in the use of heavy or weak red cell suspensions which may cause aberrant results.
- Fibrin residues may be trapped at the top of the gel after centrifugation appearing as a fine pink line with bulk of the red cells at the bottom of the microtube and should be interpreted with caution.
- The use of other suspending media rather than ID-Diluent 2 may modify the reactions when utilising the Bio-Rad CAT.
- Bacteria may cause false positive or negative results.
- Potential sources of variation also include incubation times/temperature, centrifugation speeds/ times.

3.9.2. Providing professional judgements on the interpretation of the results of examinations. Patient reports are signed by the Chief Medical Scientist or designee and where clinical advice and guidance is required a Consultant Haematologist signature is also present on the patient report.

3.9.3. Advising on scientific and logistical matters such as instances of failure of sample(s)to meet acceptability criteria. In the event a sample is rejected the referring hospital is phoned and a patient report is subsequently issued.

3.9.4. Promoting the effective utilisation of laboratory examinations, the laboratory ensures that the appropriate reflex tests are performed based on the clinical information provided. The laboratory has procedures in place, if abbreviated testing is performed or blood is required for a patient before the completion of an investigation.

3.10 Communication of risk

The RCI laboratory identifies potential risks to patient care in the pre-examination, examination and post-examination processes. These risks are assessed and mitigated to the fullest extent possible. The residual risk is communicated to users as appropriate. Communication may be through amended patient reports via the complaints process or at the discretion of the Consultant Haematologist.

The identified risks and effectiveness of the mitigation processes is monitored and evaluated according to the potential harm to the patient. The RCI risk log is reviewed and updated as required. An action plan is developed when the risk score assigned is above a specific threshold. The laboratory also identifies opportunities for improvement patient care and has a framework to manage these opportunities.

4 REQUEST FORMS

4.1 General Information:

Samples and Forms

- It is the policy of the IBTS laboratories to treat all samples as potentially infectious or high risk. Therefore, we advise that universal precautions be taken in the collection, packaging and the delivery of samples being sent to the laboratories for analysis.
- All materials used in the collection of samples should be treated as potentially hazardous and discarded according to the hospital guidelines for waste management and in compliance with relevant regulations.
- Samples for referral should be freshly drawn venous samples without dilution by intravenous fluid.
- Referred samples should not have been tested/sub-sampled at the referring hospital; exceptions can be made for patients that are difficult to sample e.g. poor veins, following discussion with the RCI laboratory.
- When two samples are recommended for referral, they should be collected during the same phlebotomy (<15 minutes apart) to ensure adequate sample volume for testing, if samples are taken >15 minutes apart they are considered separate samples.

- All patient samples must be labelled at the bedside applying positive patient identification.
- Sending haemolysed and/or lipaemic samples should be avoided where possible as free haemoglobin and/or fatty plasma can produce test result errors (especially when using automated equipment). Such samples may have to be rejected. However, it is recognised that there are situations when haemolysis is the result of the patient's condition.
- Samples referred to the RCI laboratory should conform to the requirements for the timing of sample collection, as defined in Section 5.3.6.
- Samples should be transported promptly to the RCI laboratory (Samples should not be stored overnight in transport vehicles).
- Samples must not be exposed to direct sunlight or extremes of temperature; samples should be transported in an ambient temperature range (2 – 25°C) unless otherwise specified in Section 7.1.1. If samples are required to be stored prior to referral to the RCI laboratory, they should be stored at 2-8ºC (exceptions are details in Section 7.1.1). This is the responsibility of the referring hospital / institution.
- Sample forms / packaging, date and time stamped on receipt at the IBTS Security.
- On receipt in the laboratory, samples are registered with a unique RCI sample number and all stored aliquots from the primary sample are labelled with the assigned RCI sample number.
- RCI scientific staff will review request forms and samples against pre-defined acceptance criteria to determine if they are suitable for the tests requested (See Sections 4.4 and 5.3 for request form and specimen labelling requirements, respectively). Where it is determined that the request form and/or sample is not suitable, the requesting hospital will be informed.
- Please note: the request form is considered an agreement.

Note:

1. **Incorrect or incomplete forms/ samples may result in the tests not being undertaken and may require a second sample to be submitted resulting in increased turnaround times with service delay.**
2. **Requests for test(s) where the RCI Laboratory acts as a Hospital Blood Bank must be made by a registered medical practitioner or an appropriately qualified healthcare professional acting on the instructions of a medical practitioner.**
3. **Requests for referral services by Hospital Blood Transfusion Laboratories may be made by a Medical Scientist.**
4. **All crossmatch requests must be accompanied by a clinical request for blood.**
5. **Request for tests not processed in the RCI Laboratory are referred to specialist external laboratories. See Section 7 and section 7.2 for further details.**

4.2 RCI Laboratory Request Forms

The laboratory service request must be accompanied by duly completed & legible RCI Laboratory Request form. Several different request forms are available. These are used as outlined below.

Referral Service for Hospital Blood Transfusion Laboratories

BT - 0345 Request for Red Cell Immunohaematology Investigation Form

This form is used by referring Hospital Blood Transfusion Laboratories when they require the RCI Laboratory to undertake specialised investigations e.g. to resolve blood group serological anomalies, perform antibody investigations; or to request compatibility testing on these patients. This form may also be used by hospital blood transfusion laboratories to request ante-natal investigations, e.g. antibody titre and Anti-D/c quantitation.

Hospital Blood Bank Service Forms

BT - 0007 Blood Group and Compatibility Request Form
This form is used solely by facilities to which the laboratory provides Hospital Blood Bank services.

IBTS/RCI/FORM/0001 Request for Transfusion Reaction Investigation

This form is used by organisations, to whom the IBTS laboratory, acting as a Hospital Blood Bank has supplied compatible blood, when they wish to report a suspected transfusion reaction and request investigation of same.

BT- 0597 Haemovigilance Clinical Review Form

This form is used by the Haemovigilance Officer in facilities where the RCI laboratory acts as a Hospital Blood Bank, to document the patient information obtained following an adverse reaction or event. It should be forwarded to the IBTS SpMO/Registrar/Consultant Haematologist. It should include the details of the reaction/event, other relevant clinical information and results of haematology, biochemistry and microbiology tests performed as part of the adverse reaction investigation.

4.3 Ordering IBTS Request Forms

Request Form BT - 0345 **'Request for Red Cell Immunohaematology Investigation'** can be printed from the giveblood.ie website (https://healthprofessionals.giveblood.ie/clinical-services/transfusion-transplantation/red-cell-immunohaematology-diagnostics/rci-test-request-forms/)

All of the other forms are available on request from the RCI Laboratory by contacting personnel in the department.

4.4 Completion of Request Forms

A request form must accompany all samples referred for testing. Adequate completion of requests should include clinical information (e.g. obstetric history, transfusion history, reason for transfusion) so that work may be prioritised and processed accordingly in the laboratory; and to facilitate accurate result interpretation. As per BSH Guidelines the following mandatory patient personal identifiers must be provided on the request form and must be documented in a legible manner to be accepted for testing:

1 Patient's Surname
2. Patient's Forename
3. Patient's Date of Birth
4. Hospital number *****

* **Where the patient does not have a hospital number e.g. sample being referred from a GP (and the sample is not for compatibility testing purposes); an address will suffice as a third patient identifier in place of the hospital number.**

The following information should also be documented on the request form:

5. Patient's gender
6. Patient's ethnicity
7. Location [referring hospital and ward (if given)]
8. Patient's address (* mandatory requirement if hospital number not applicable – see above)
9. Details of the requesting clinician (& their contact details)
10. Date and time of sample collection (This is required for Hospital Blood Bank requests only)
11. Test(s) required
12. Number of units of blood required and date/time required (if for crossmatching)
13. Specific transfusion requirements for individual patients i.e. requirement for CMV negative and / or Irradiated blood

Where possible please provide the following information:

14. Relevant clinical information appropriate to the test(s) requested (e.g. clinical condition, medication)
15. Transfusion history (including results of serological investigations obtained by the referring centre, details of date of last transfusion, most recent haemoglobin level, historical antibodies, transplant history)
16. Antenatal history (including details of expected delivery date, anti-D administration, history of haemolytic disease of the foetus and new-born, history of intrauterine transfusions)
17. The specific clinical indication for a transfusion request
18. A clear indication as to whether the tests/services requested are urgent or routine
19. The compatibility request from the clinical area must also accompany the request form.

The Declaration(s) Must Be Signed:

20. The declaration regarding the correct labelling of the sample/request form and its validity must be completed (signed) by:
    - the person who took the sample (when the laboratory is acting as the sites Hospital Blood Bank)
    - the person referring the sample (Hospital Blood Transfusion Laboratory Referrals) Failure to complete the declaration may result in the sample not being processed.

Note:

Requests must be telephoned in advance if the service requested is urgent.

5 SAMPLE INFORMATION

5.1 Sample Collection

Where the RCI laboratory acts as Hospital Blood Bank;

- For group and antibody screening one sample will suffice.
- For crossmatch requests, two samples collected at different times are required, where there is no known historical ABO group, unless a secure bedside electronic patient identification system is in place. This is a recommendation from the BSH Guidelines 2012 to avoid transfusion of ABO incompatible blood due to misidentification of the patient at the time of sample collection. The exception is an emergency requirement for blood where one sample will suffice so as to not to unduly delay the transfusion. In this case group O blood will be selected for non-group O patients. It is important that the second sample is taken prior to transfusion so that the ABO/RhD group can be confirmed on the patient's cells without interference by transfused cells.

Where the RCI laboratory provides a Referral Service to Hospital Blood Transfusion Laboratories

Where RCI laboratory is providing a referral service, one sample is sufficient; however the responsibility for checking the historical group will reside with the referring Hospital Blood Transfusion Laboratory. If no historical group is available then the referring Hospital Blood Transfusion Laboratory should ensure the patient's ABO/RhD group has been verified on two separate samples prior to blood product issue.

Note: Re referral of compatibility requests to the RCI Laboratory

On a case-by-case basis and following discussion with the RCI Laboratory, the referring Hospital Blood Transfusion Laboratory may send segment(s) from suitable unit(s) for compatibility testing in conjunction with a patient sample(s). This is to expedite the provision of blood to the patient or where units of a particular phenotype are

required and are already available from the referring hospital's blood stocks.

N.B. Segment line must be labelled with the ISBT no. of the donor unit and the segment number must be visible on the line as both these numbers will be listed on the patient report.

Please note: only segments that are deemed suitable/compatible for transfusion will be listed on the report.

5.2 Service Requestor Responsibilities

- Obtaining consent from the patient for the tests required at the RCI Laboratory.
- Positively identifying the patient from whom the sample is taken.
- Safely disposing of the materials used in the collection of samples.
- Ensuring that samples containers meet the labelling requirements of the RCI Laboratory and that the request form has been completed to an acceptable standard.
- Ensuring that the test / services requested are appropriate.
- Ensuring that sufficient sample volume has been referred for testing.
- Ensuring that samples are delivered to the RCI Laboratory within a timeframe appropriate to the nature of the tests requested.
- Ensuring that appropriate transport containers are used (for the safety of all handlers).
- Ensuring that patient confidentiality is maintained.
- Ensuring that if referring unit segment(s) that the segment(s) are labelled with the unit ISBT No. and that the units meet the requirements of the patient's transfusion protocol.

5.3 Sample Labelling

5.3.1. Mandatory Requirements

The following essential information is MANDATORY on all samples referred to the RCI Laboratory and should be documented in a legible manner on the sample container:

1. Patient's Surname
2. Patient's Forename (initials are not acceptable)
3. Date of birth
4. Hospital number *
   * Where the patient does not have a hospital number e.g. out-patient / antenatal GP referrals (and the sample is not for compatibility testing purposes); an address/partial address will suffice as a third patient identifier in place of the hospital number
5. Date (and time where blood is requested ¥) of sample collection

6. The initials/ signature of the person collecting the sample or in the case of an electronic labelling system, the label must contain unique identifier that can be used to trace the sample taker.

¥ Where the time of sample collection is not provided the sample time will be registered at the RCI Laboratory as 00:00 on the date of collection indicated.

Note:

All patient samples and forms must be labelled at the bedside applying positive patient identification.

5.3.2. Labels on Sample Tubes

- Sample tubes must never be pre-printed or pre-labelled.
- The Service Requestor's responsibility is to ensure that all printed labels for samples for blood transfusion testing are generated at the bedside and are compliant with BSH Guidelines (The administration of blood components: a British Society for Haematology Guideline, 2018).
- **Only labels that are printed 'On Demand'** next to the patient and immediately attached to the sample tube at the time of phlebotomy by the individual who took the sample are acceptable.
- **Labels pre-printed** away from the bedside or taken from the patient's notes (e.g. **addressograph** labels) are **not** acceptable on samples for processing. A repeat sample will be required.

5.3.3. Sample / Request Form Acceptance / Rejection

RCI Laboratory staff follow written standard operating procedures for the receipt and incoming inspection of samples and request forms. This is to ensure that samples taken for laboratory analysis can be accurately and unambiguously identified and that all necessary information is supplied for appropriate and timely analysis, interpretation and reporting. Where the requirements with respect to labelling of the request form/sample container or sample quality issues are not met, this may result in the rejection of the request or a delay in sample processing.

Samples are accepted for testing if they are:

1. Of appropriate sample type for the tests required
2. Of sufficient volume for testing
3. If the information on the request form and sample are correctly matched
4. The sample & request card meet the mandatory labelling requirements.

Samples may be rejected in the following circumstances:

1. They are of an inappropriate sample type
2. They have leaked in transit
3. They are insufficient for testing
4. They are grossly haemolysed
5. They have been separated prior to referral
6. The sample and request form are mismatched, or the information is not correct
7. There is insufficient information on the sample and/or the request form.
8. There is significant delay in receipt of sample from date/time of collection resulting in sample invalidity/instability. Note: Samples must be ≤ 7 days old on receipt with the exception of samples which fall under 72hr rule.

5.3.4. Non-Conforming Samples / Request Forms or Sample Quality Issues

If a sample/request is identified as unacceptable, the referring laboratory/location or requestor (as appropriate) will be contacted and advised of any required corrective action or the need for a repeat sample in accordance with laboratory SOP. On occasion, rejected samples may be tested (see Section 5.3.5 Exceptions). In these instances, results reported will bear an appropriate caveat indicating the nature of the problem. A report will be generated for all rejected samples stating the reason for rejection. Sample rejection figures are monitored in the laboratory, if repeated issues are identified the referring hospital will be notified.

5.3.5. Exceptions

Exceptions may be made for samples from the following groups:

- Trauma, unconscious, or Emergency Department patients where the identity is not yet established. It is the responsibility of the referring laboratory to have a procedure in place for labelling of samples of unidentified patients. Ideally the minimum clinical information supplied should include: (1) a unique number, (2) gender and (3) approximate age. It is helpful to be informed of the ethnicity of the patient. Samples will be registered using the patient details on the sample tube. The sample details on the sample tube and request form must match.
- Where a repeat sample would be difficult to obtain and the result of testing is not to be used for transfusion purposes.
- Where the delay in acquiring a new sample might seriously prejudice a successful clinical outcome.
- Where the sample cannot be replaced, e.g. pre transfusion samples post transfusion reaction, samples taken at specific time periods e.g. foetal samples.

In the above exceptional circumstances, non-compliant samples may be accepted for testing with a documented authorised concession (e.g. written confirmation from the requestor verifying the patient identity) where delay in acquiring a new sample may seriously prejudice a successful clinical outcome for a patient, or where the sample cannot be replaced. In such cases the IBTS will not be responsible for errors made as a result of unacceptable labelling and/or samples issued by the referring facility. This may impact on the labelling and release of the suitable component, such that the component will be issued for transfusion at the discretion of the patient's clinician.

The decision to process the sample may require approval by the consultant at the IBTS. In all those instances the test report will identify and reflect the non-conforming issue.

5.3.6. Timing of Sample Collection

Samples for compatibility testing should be referred to the laboratory without delay to facilitate timely testing of the samples and processing of requests.

Transfusions or pregnancy may stimulate the production of unexpected antibodies through either a primary or secondary response. The timing of samples selected for crossmatching or antibody screening must take account of this.

Table 1.3 Guidelines for the Collection of Samples

Patient Category	Sample to be taken not more than
Patient transfused or pregnant in the last 3 months Patients receiving Anti-CD38 (with current or historical allo-antibodies)	72 hours before transfusion[1]
Patient not transfused or pregnant in the last 3 months Patients receiving Anti-CD38 therapy (no current/historical allo-antibodies)	7 days before transfusion [1]
On-going cases	A formal deviation from the 3 day rule may be considered for patients that are being repeatedly transfused (e.g. AIHA, Myelodysplastic Syndromes, patient's receiving anti-CD38 therapy) and have not become allo-immunised (i.e. have not formed clinically significant alloantibodies) allowing samples to remain acceptable for up to 7 days. This decision is agreed between the RCI Consultant Haematologist & the referring Hospital Consultant Haematologist, where a transfusion management plan is agreed.

[1] This is the time between the sample being taken and the subsequent transfusion

5.3.7. Sample Storage

Whole-blood samples will deteriorate over a period. Problems associated with prolonged storage include red cell lysis, bacterial contamination, loss of complement in serum and decrease in potency of red cell antibodies, particularly IgM class antibodies.

5.3.8. Guidelines for the Storage of Samples: Pre-testing

Routine Referrals

Where samples are not being referred to the laboratory on the date collected, they should be refrigerated at 2-8°C prior to transport.
Once accepted in the RCI separated Red Cell samples are stored at 4ºC for a minimum seven days. Separated plasma samples are stored between -30ºC and -50ºC for one month. Anti-D, and anti-c quantitation and titration samples are held in the plasma trays (for parallel testing) for up to 10 months (duration of pregnancy).

Please note: Red cell work (i.e. phenotyping, blood grouping, DAT) can be performed up to 7 days post phlebotomy.

Any change to pre-examination or examination procedures will be communicated to customers via email, including how biological reference intervals / clinical decision limits are defined. The thresholds for antibody quantitation and antibody titration utilised in the RCI laboratory are as detailed by the BSH guidelines.

6 SAMPLE DELIVERY, PACKAGING AND TRANSPORT

6.1 Sample Delivery

Samples will be accepted by RCI laboratory at any time. They should be delivered to:

- Security at the National Blood Centre

Refer to Section 3.1 for map & picture of locations.

Note:

THE RCI LABORATORY MUST BE TELEPHONED IN ADVANCE OF URGENT REQUESTS AND THE SAMPLES DELIVERED AS PROMPTLY AS POSSIBLE.

6.2 Sample Packaging and Transport

It is advised that universal precautions be taken in the collection, packaging and delivery of the sample to the IBTS and that the patient's confidentiality is protected.

Please note: RCI staff will contact the referring hospital should a sample leak in transit. It is the responsibility of the referring hospital for evaluation of the sample transport system as required by ISO 15189:22 7.2.5 (4 c).

6.2.1. International carriage of dangerous goods by road

It is the responsibility of the service requestor to ensure the packaging; labelling and transportation of all samples comply with current European Agreement concerning Carriage of Dangerous Goods by Road Regulations. Legislation requirements are available from the Health & Safety Authority website www.hse.ie. The requirements stated below apply to all diagnostic samples directed to the RCI laboratory.

6.2.2. Universal Packaging Procedure for the Transport of Diagnostic Samples

- Samples to be sent should be stored in a secure (preferably plastic) primary container.
- Wrap the sample tube/container in tissue or cotton wool which will act as absorbent material in the event of spillage.
- Place the sample tube/container in a biohazard bag.

- Place the biohazard bag with the sample tube and the request form in a padded envelope or an approved transport container.
- Label the envelope with a hazard warning label, "Diagnostic Sample, Category B UN 3373".
- Place the name, address and contact number of the destination laboratory on the outside envelope. *Note: It is very important to ensure that the address is correct and complete to ensure delivery to the correct location.*

Address labels (BT -0685) are available on giveblood.ie, these labels are printed by the hospital and attached to sample boxes being referred to the RCI.

BT-0685
Sample label:
FAO: Red Cell Immunohaematology
National Blood Centre
James's St.
Dublin 8 Routine / Urgent
D08 NH5R
Referring Hospital…… Date……
Store between 2ºc and 8ºc

This label is available for printing from the following link: https://healthprofessionals.giveblood.ie/media/eidhqq0w/postage-labels.pdf

- Samples should be forwarded to the laboratory as soon as possible to preserve the integrity of the sample.
- Where blood is required the same day or it is an URGENT request, samples must be sent directly to the laboratory (see Note 2 below).
- The sample and the request form should be packaged so as to ensure patient confidentially at all times during transportation.

Note 1:

There is no requirement for a licensed courier to transport non-infectious diagnostic samples; however, An Post prohibits the sending of diagnostic samples by regular post.

Note 2:

Please contact the laboratory regarding all urgent samples. Ensure the transport box for urgent samples is marked 'Urgent'.

7 TESTING PROVIDED

The table below lists the test procedures provided by the RCI Laboratory, tests that are further referred and other services available to customers. For further information on referral centres and consultants, refer to section 7.2. The RCI do not claim accreditation for 'referral test services'.

Table 1.4 of list of tests provided by RCI

Test / Service
RCI Laboratory
Antenatal Antibody Titration
Antibody Investigation
Investigation of Autoimmune Haemolytic Anaemia (AIHA)
Blood Group/Antibody Screen
Blood Group/Compatibility Testing
Blood Group/Compatibility Testing for Patients with Red Cell Antibodies
ABO Blood Group Anomaly Investigation
RhD Blood Group Anomaly Investigation (Serological)
Direct Antiglobulin Test
Elution
Extended RBC Phenotyping
Investigate Monoclonal Antibody Interference (crossmatch requests only)
Investigation of Haemolytic Disease of the Foetus and New-born (Where maternal red cell antibodies are implicated / suspected)
Transfusion Reaction Investigation (Laboratory acting as Hospital Blood Bank)
Transfusion Reaction Investigation (Referred Sample)
Anti-D Quantitation
Anti-c Quantitation
Investigation of red cell polyagglutination

Table 1.5 of Refer tests sent to other centres

Samples may be further referred to other centres listed below
IBGRL: for complex Immunohaematological Investigation
NHSBT: for Investigation of IgA Deficiency & IgA Antibodies
NHSBT: for Cold Agglutin Titre and Thermal Range
NHSBT: for Paroxysmal cold hemoglobinuria (PCH) / Donath – Landsteiner

Table 1.6 of additional services offered by RCI

Other Services
Clinical & Scientific Consultancy Services
Haemovigilance Clinical Advisory Services (Hospital Blood Bank Service ONLY)
Provision of HBB services including traceability and haemovigilance

7.1 Services Provided

- Pre-transfusion Compatibility / Specialised Immunohaematological Testing
- Provision of Rare Donor Red Cell Components from International Rare Blood Programmes.
- Concessionary Release of Blood Components
- Medical and Scientific Consultancy Service
- Haemovigilance Advisory Service
- Samples may be further referred to other centres where the testing is not performed in RCI or additional testing is required to support findings
- Specialist support to the ADG Laboratory in areas such as blood group confirmation, ABO anomaly investigation, red cell phenotyping, and antibody investigation for donor samples.

7.1.1. Pre-Transfusion Compatibility and Specialised Testing

The table that follows provides details of the tests available at the RCI Laboratory, sample requirements, any special requirements and turnaround times for test results.

- Initial verbal reports will be provided where emergency testing is performed or critical results are being reported.

Note 1

Turnaround time is defined as the time from sample reception at the IBTS to the time results/products are available for issue.

Note 2

Tests marked with an '*'are available out of hours for clinically urgent orders.

Table 1.7 of Test profile, sample type, volume and TAT

Test Profile	Sample type (fresh venous sample)	Recommended Sample volume	Service details and requirements	Turnaround time test
Antibody Titration	EDTA Whole Blood (WB)	1 x 6 ml	Batched testing For urgent testing contact the lab in advance	**5 working days**
Antibody investigation * Including anti-G investigation	EDTA (WB)	2 x 6 ml	Progress will be discussed with requestor by telephone	**5 working days**
Investigation of Autoimmune Haemolytic Anaemia *	EDTA (WB)	2 x 6 ml	Progress will be discussed with requestor by telephone	**5 working days**
Blood Group / Antibody Screen ROUTINE or EMERGENCY * **(Where RCI act as a Hospital Blood Bank)**	EDTA (WB)	3 – 6 ml	Routine requests processed on next scheduled batch (See section 3.5) Emergency: Processed immediately on receipt Contact RCI laboratory in advance	**Routine: Results usually available in 24 hrs.** **Report will follow in 5 working days** **Emergency: ASAP - within 2 hrs of receipt of sample if no antibodies detectable**

Table 1.7 of Test profile, sample type, volume and TAT				
Test Profile	**Sample type (fresh venous sample)**	**Recommended Sample volume**	**Service details and requirements**	**Turnaround time test**
Blood Group and Compatibility Testing ROUTINE or EMERGENCY *	EDTA (WB)	1 x 6 ml	Routine requests processed on next batch Urgent/emergency requests: Processed immediately on receipt Contact the IBTS laboratory in advance Segments from suitable units may be sent with the sample to expedite the provision of blood or where units of a particular phenotype are required & already available from the referring hospitals blood stocks N.B. Segments must be labelled with the ISBT no. of the donor unit.	**Routine: 2-6 hours** **Urgent/emergency: ASAP (Within 2 hours of receipt of sample)**

Table 1.7 of Test profile, sample type, volume and TAT				
Test Profile	**Sample type (fresh venous sample)**	**Recommended Sample volume**	**Service details and requirements**	**Turnaround time test**
Blood Group and Compatibility Testing (Patients with red cell antibodies) ROUTINE or EMERGENCY *	EDTA (WB)	2 x 6 ml Minimum	Contact the RCI laboratory in advance Progress can be discussed by telephoning the RCI laboratory Refer to Section 3.5.2 for additional information. (See above re unit segments)	**2-6 hours** **<u>Please note</u> this is dependent on the complexity of antibodies detected.**
ABO Blood Group Anomaly Investigation (Serological)	EDTA (WB)	1 x 6 ml	Telephone in advance if blood is required for patient	**5 working days**
RhD Blood Group Anomaly Investigation (Serological)	EDTA (WB)	3 ml Cord Blood Sample	Serological testing will be performed on cord/neonate (<72 hrs old) samples only to determine maternal requirement for RhD Prophylaxis Progress will be discussed with requestor by telephone All other requests for RhD anomaly investigation should be referred to the Blood Group Genetics Laboratory at the NBC	**Results phoned within 1 working day**

Table 1.7 of Test profile, sample type, volume and TAT				
Test Profile	**Sample type (fresh venous sample)**	**Recommended Sample volume**	**Service details and requirements**	**Turnaround time test**
Direct Antiglobulin Test *	EDTA (WB)	1 x 6 ml	Next scheduled batch (See section 4.6) Note: there is no commercial IQC available for IgA and IgM portion of the monospecific DAT.	**5 working days** **Where antibodies are investigated please see above**
Elution *	EDTA (WB)	1 x 6 ml	An eluate is only warranted if the patient has been transfused within the last 28 days or there is evidence of haemolysis (or a delayed haemolytic transfusion reaction). Telephone in advance if blood is required for patient	**5 working days**

Table 1.7 of Test profile, sample type, volume and TAT				
Test Profile	**Sample type (fresh venous sample)**	**Recommended Sample volume**	**Service details and requirements**	**Turnaround time test**
Extended RBC Phenotyping	EDTA (WB)	1 x 6 ml	Extended phenotyping is recommended for transfusion dependant patients and patients with complex red cell antibodies. To be suitable for serological phenotyping the patient must not have been transfused within the previous 3 months.	**5 working days**
Paternal Phenotyping	EDTA (WB)	1 x 6 ml		**5 working days**
Investigate Monoclonal Antibody Interference *	EDTA (WB)	2 x 6 ml	Progress will be discussed with requestor by telephone. *Please note: antibody identification is only processed on these samples where a crossmatch has been requested.*	**2-6 hours** **<u>Please note</u> this is dependent on the complexity of antibodies detected.**

Table 1.7 of Test profile, sample type, volume and TAT				
Test Profile	**Sample type (fresh venous sample)**	**Recommended Sample volume**	**Service details and requirements**	**Turnaround time test**
Investigation of Haemolytic Disease of the New-born where maternal antibodies are implicated / suspected *	EDTA (WB) (Mother's sample) (Baby's sample)	1 x 6 ml 1-3 ml	Note: Investigations will be limited to Red Cell Serological studies Processed in next scheduled batch (See section 4.6) Must be telephoned in advance	**Results phoned within 1 working day from availability of result** **(Quantitation/ Antibody Titration)**

Table 1.7 of Test profile, sample type, volume and TAT

Test Profile	Sample type (fresh venous sample)	Recommended Sample volume	Service details and requirements	Turnaround time test
Transfusion Reaction Investigation * (Where the IBTS acts as a Hospital Blood Bank)	EDTA (WB) Post transfusion + Clot activated post transfusion sample The implicated unit must be sealed by a coupler and returned	2 x 6 ml + 1 x 6 ml	Must be telephoned in advance. Contact medical consultant / medical registrar on duty / on call, for direction **Please return implicated unit (if available) and the administration set (if possible).** (Even an 'empty pack' may provide a sample from an attached segment) The remaining un-transfused units must be quarantined at the hospital or returned to the IBTS, pending medical release. Part B (white) of the traceability label (BT396) must not be removed from the units when returning to the IBTS.	**ASAP 2-6 hours of receipt of sample for initial serological results** **Note: Where bacteriological screening of the implicated units is required, or immunological investigation is necessary, the turnaround time may be extended beyond 7 days A written report of the serological results only may be available within 5 working days**

Table 1.7 of Test profile, sample type, volume and TAT

Test Profile	Sample type (fresh venous sample)	Recommended Sample volume	Service details and requirements	Turnaround time test
Transfusion Reaction Investigation * (Referred samples from Hospital Blood Transfusion Laboratories)	EDTA (WB) Pre Transfusion (if crossmatch performed by referring hospital) Post transfusion + A clotted post transfusion sample should also be referred where possible	1 x 6 ml or 2 x 6 ml + 1 x 6 ml (if required)	Must be telephoned in advance. Progress will be discussed with requestor If pack culture is to be performed by the IBTS, the implicated unit must be sealed by a coupler and returned. Note: Testing may also be performed on the post-transfusion sample only, as requested by referring hospital.	**ASAP 2-6 hrs of receipt of sample for initial serological results.** **A written report of the serological results only may be available within 5 working days**
Anti- D Quantitation	EDTA (WB)	1 x 6 ml	Batched testing: Performed 2-3 times weekly Separated samples will not be processed	**Result phoned within 5 working days** **Written report 7 working days**
Anti-c Quantitation	EDTA (WB)	1 x 6 ml	Batched testing: Performed weekly Separated samples will not be processed	**Result phoned within 5 working days** **Written report 7 working days**

Table 1.7 of Test profile, sample type, volume and TAT				
Test Profile	**Sample type (fresh venous sample)**	**Recommended Sample volume**	**Service details and requirements**	**Turnaround time test**
Investigation of red cell polyagglutination	EDTA (WB)	1 x 6 ml	T poly agglutination may give rise to blood grouping anomalies and is associated with necrotising enterocolitis in paediatric practice These patients usually require transfusion and decision making in relation to component selection is complicated Urgent resolution of referred sample is required Contact RCI Laboratory in advance of referring a sample.	**5 working days**

***** Testing performed during both routine and out of hours service

Note: With regard to sample volume and number of samples required, exceptions may be made for patients where blood is difficult to obtain such as neonatal or paediatric patients.

7.2 Referral Test Services

The IBTS act as the national facilitator for the referral of samples to NHSBT Barnsley for the investigation of IgA deficiency, IgA antibodies and Cold Agglutinins. In addition, following investigation by the IBTS, samples may be requested for referral to the IBGRL for confirmatory testing or where the results obtained by the RCI laboratory are inconclusive. The NHSBT user guide may be accessed at http://hospital.blood.co.uk./diagnostic-services/user-guides/. The IBGRL user guide may be accessed at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/16584/inf1136.pdf Please complete the BT - 0345 request form when sending samples to the RCI Laboratory for onward referral to the relevant referral laboratory. RCI referral laboratories and Consultants from whom an opinion is sought are managed internally through IBTS/RCI/SOP/0013. They are reviewed annually. If you wish to query the information on a report for a sample that was referred out by RCI, please contact the RCI laboratory who can follow up with the referral laboratory and / or Consultant on your behalf.

All referral laboratories listed below are accredited to ISO 15189 for the tests described.

Note 1

Referrals to the external laboratories attract testing and transportation charges. Additional time will be incurred where samples are referred externally. In such cases the scientific staff at the IBTS will inform the requestor.

Note 2

The report from the external laboratory will be forwarded to the referring hospital (a copy of this report will be retained by the IBTS for reference).

Table 1.8 of tests referred to other referral centres					
Test profile /service	**Centre**	**Sample type (fresh venous sample)**	**Sample volume**	**Service details and requirements**	**Turnaround time test**
Complex Immunohaematology Testing	IBGRL	EDTA (WB)	Contact RCI laboratory prior to sending.	Samples are accepted from overseas reference laboratories ONLY. Service includes confirmation of rare specificities previously determined by the RCI laboratory and determination of possible underlying specificities. Larger samples are preferable and sometimes may be essential. Anti-coagulated samples should not be separated. Urgent referrals are defined as those where blood for transfusion is needed as quickly as possible. The RCI laboratory will contact the IBGRL by telephone to discuss reason for referral.	Due to the varying nature of the requests sent to Red Cell Reference a turnaround time cannot be specified. The time between receipt of sample and reporting will depend on the clinical situation of the patient, the complexity of the investigation and the number of samples in the laboratory at any given time. Cases are prioritised and therefore some investigations may be necessarily delayed.
Investigation of IgA Deficiency & IgA Antibodies	NHSBT Barnsley	EDTA (WB)	Contact RCI laboratory prior to sending.	In cases of anaphylactic transfusion reactions, or other indications Samples for investigation should be directed to the RCI laboratory for on-ward referral to the external laboratory.	5 working days from sample receipt Repeat testing will incur an extension to the turnaround time and possibly may require repeat sampling

Table 1.8 of tests referred to other referral centres					
Test profile /service	**Centre**	**Sample type (fresh venous sample)**	**Sample volume**	**Service details and requirements**	**Turnaround time test**
Cold Agglutinins/CHAD Investigation **(Investigation comprises DAT, room temperature screen, cold titre, thermal amplitude as necessary.)**	NHSBT Barnsley	EDTA (WB) Refer to User Guide in section 7.1 above	Contact RCI Laboratory prior to referring samples.	A DAT is performed and the plasma is investigated for the presence of clinically significant red cell alloantibodies at 20C. Subsequent tests may need to be performed at 4C and 30C where indicated to establish clinical significance and thermal amplitude. *It is not necessary to warm separate samples unless titration studies are required or specifically requested to do so by the RCI laboratory. Send the primary sample tube of the separated sample tube that is labelled with the patient identifiers Cold agglutinin titrations at 4°C can be performed on request in Cold Haemagglutinin Disease patients.	Result available within 5 working days of sample receipt by NHSBT. Report will be despatched by the RCI Laboratory following receipt of same.

Table 1.8 of tests referred to other referral centres					
Test profile /service	**Centre**	**Sample type (fresh venous sample)**	**Sample volume**	**Service details and requirements**	**Turnaround time test**
Paroxysmal cold hemoglobinuria (PCH) / Donath – Landsteiner	NHSBT Barnsley	Refer to user guide in section above (note: a Separated serum sample which has been separated from a whole blood sample that has been allowed to clot at 37oC may be required).	Contact RCI Laboratory prior to referring samples.	Biphasic haemolysins as a cause of AIHA are extremely rare and mainly seen as a post-viral event in children. Routine investigations for AIHA do not include the test for biphasic haemolysins but where indicated, or on request, the Donath-Landsteiner test can be performed if paroxysmal cold haemoglobinuria (PCH) is suspected. If positive, the specificity of the antibody can be determined to confirm the diagnosis.	Result available within 5 working days of sample receipt by NHSBT. Report will be despatched by the RCI Laboratory following receipt of same.

7.3 Provision of Rare Donor Red Cell Components from International Rare Blood Programmes

Where the patient requires red cells of a specific red cell antigen profile that is not available in the IBTS stock supply or on the IBTS donor panels, where appropriate a request will be made to an International Rare Blood Bank Programme for the required number of units (either from current stock, following donor call up or frozen blood stocks).
Each individual case will be discussed with the IBTS medical staff and authorised on a Consultant to Consultant basis, to determine the exact requirements for individual patients and advise of associated difference in transfusion risk profile as appropriate. Procurement of product is dependent on the availability of the blood. Walk in whole blood donation and liquid red cell component transfusion is preferred and this requires scheduling. In clinical emergencies frozen recovered red cell components may be sourced Approval of medical consultant is required. Please provide the maximum notification possible for this service.

Note:

Direct consultation with the medical consultant on duty will be required.

7.4 Concessionary Release of Blood Components

Concessionary release of blood components, or acting contrary to an SOP, is sometimes the necessary and appropriate course of action in the best interest of patients. To act contrary to an SOP requires prior authorisation, or justifiable authorisation as soon after as is practicable, by the IBTS Consultant Haematologist or other suitably competent person who should discuss the clinical consequences with the clinicians in charge of the patient this process is proceduralised in IBTS/MED/SOP/0050.

Conditions which require concessionary release procedure:

- Use of D positive blood for a D negative patient who would normally be excluded from receiving D positive units.
- Use of antigen positive or un-typed red cells in patients with atypical red cell antibodies.
- Issue of red cells to patients with autoimmune haemolytic anaemia (AIHA) without the necessary exclusion of underlying antibodies.
- Issue of components that do not meet known special requirement, e.g. CMV negative or irradiated.
- Where it is necessary to act contrary to a Standard Operating Procedure in the best interest of a patient, this will be handled in accordance with relevant IBTS Quality Assurance documentation.

The event will be recorded on a Concessionary Release form. The name and designation of the requesting clinician who has agreed to accept the concession for the patient will be recorded along with the details of the IBTS Clinician who

has authorised the release of the blood product/component. A copy will be sent/faxed to the hospital blood transfusion laboratory; or to the requesting clinician where the IBTS laboratory provides Hospital Blood Bank services.

7.5 Medical and Scientific Consultancy Service

The IBTS will provide medical and scientific advice for all the above services. These services are available at all times with respect to blood transfusion practice. For contact names and numbers see Section 3.4 of this manual.

7.6 Haemovigilance Advisory Service

All haemovigilance queries relating to situations where the RCI laboratory acts as a facilities Hospital Blood Bank should be directed to IBTS medical staff, directly to laboratory senior scientific staff or to the IBTS Biovigilance Officer.

7.7 Repeat Examination

It is the policy of the laboratory, in the event of analytical failure to:

- Repeat the test using the relevant procedure(s)
  or
- Store the sample in appropriate conditions, until the cause of the analytical failure is identified and corrected; and then repeat the test. The urgency of the outstanding sample is reviewed by the relevant laboratory director or nominee.
- Samples are retained in accordance with local Guidelines for Storage of Examined Samples for Archive and Look Back Purposes.
- Should additional samples be required the laboratory will contact the requesting location.

7.8 Further Examination of the Primary Sample

Where further testing is relevant to the investigation, then it is the policy of the laboratory to pursue further investigation using the primary sample.
If additional investigations / blood products are required, please contact the laboratory to ensure that sufficient sample is available and that the sample is still valid. Red cell samples are stored at 4ºC for seven days or until the report is issued. Separated serum/plasma samples at stored at -20ºC or lower for 14 days. Antenatal samples: Anti-D, Anti-c quantitation and titre samples are held for parallel testing for up to 10 months.

7.9 Reference ranges for antenatal testing

7.9.1. Quantitation

Table 1.9			
Specificity	**Unlikely To Be Affected**	**Likely To Be Affected Refer To FAU**	
Anti-D	<4 IU/mL Low risk HDFN	4-15 IU/mL Moderate risk HDFN	>15 IU/mL High risk HDFN
Anti-c	<7.5 IU/mL Low risk HDFN	7.5- 20 IU/mL Moderate risk HDFN	>20 IU/mL High risk HDFN

7.9.2. Antibody titration

Table 1.10		
Antibody	**Unlikely to be affected**	**Likely to be affected Refer to FAU**
Clinically Significant antibodies	<32 Low risk HDFN	>32 Risk of HDFN
Kell System	Can cause HDFN at any titre	

7.10 Testing limitations

Haemolysed and/or lipaemic samples may cause inaccurate test results due to the presence of free haemoglobin and/or fatty plasma, particularly when using automated equipment. As a result, such samples may need to be rejected. However, it is acknowledged that in some cases—especially with haemolysis—these abnormalities may be due to the patient's underlying condition. Examination methods included testing limitations are available upon on request for all RCI methods.

8 EXTERNAL AND INTERNAL QUALITY ASSURANCE SCHEMES

8.1 External Quality Assessment Programmes (EQA)

The RCI Laboratory participates in relevant available external third party assessment schemes.

This includes schemes operated by:

- UK NEQAS (United Kingdom National External Quality Assurance Scheme) for Blood Transfusion Laboratory Practice
- UK AQQAS (Antibody Quantitation Quality Assurance Scheme) for Anti-D/c quantification
- Aurevia for Direct Antiglobulin Testing
- WASPS (Welsh Assessment of Serological Proficiency Scheme) for compatibility testing

External proficiency testing is performed by all staff working in the RCI laboratory on an annual frequency.

The laboratories are committed to participating in other schemes as they become available and are required to ensure comprehensive assessment of the test repertoire.

8.2 Inter-Laboratory Comparison Scheme

The RCI laboratory also participates in an inter-laboratory comparison scheme for elution, adsorption, neutralisation, and DTT treatment test methods as no formal EQA programmes are available for these particular test methods (with the exceptions of pilot exercises).

8.3 Internal Quality Assessment Programme

Internal controls are included in all tests: no tests can be accepted or reported unless control results are acceptable.
All test procedures are covered by Standard Operating Procedures and only trained and authorised staff may perform procedures. Staff competency is also assured before a staff member may perform a procedure. All procedures are regularly reviewed.

8.4 Authorisation

The RCI Laboratory is part of the IBTS quality management system, which is covered by GMP (Good Manufacturing Practice) and is inspected yearly by the HPRA (Health Products Regulatory Authority), the Blood Establishment Authorising Authority. The IBTS Blood Establishment is
Authorised under BE Number 0002.

8.5 Non-Conformance / Failure in an EQA Scheme

Non-conformances are managed by controlled procedures, with investigation, corrective and preventative actions and review of practices, taken as appropriate. The laboratory may be audited at any time provided that the IBTS Director of Quality and Compliance and the Laboratory Directors are notified in advance and that the time is agreed by all parties. Where the RCI Laboratory fails an external EQA scheme, all customers of the service will be notified.

8.6 Comparability

If it is determined that there is a difference in comparability between techniques, that cannot be resolved (i.e. This difference in results is not due to an error and will not be resolved), and the test method is to remain in use, users will be notified of a difference in comparability.

9 REPORTING OF RESULTS

9.1 Approval of Test Results and Issuing Reports

- All test results are reviewed and approved by a medical scientist before release.

- Valid results of automated testing are entered electronically into the IBTS computer system. Results of manual testing are entered by two medical scientists (or approved system during on-call hours). All results are validated by the IBTS computer system.
- Where relevant clinical advice and interpretative comments will be included on the test report.
- Clinical advice and interpretative comments are based on recommendation from BSH guidelines as standard.
- Where blood has been crossmatched and issued for a patient the units will be tagged with an IBTS compatibility tag and a hardcopy report will be issued with the blood.
- Routinely hard copy reports are printed and posted to the requesting laboratory/location. One hardcopy will be sent for each sample/request.
    - All reports are checked and signed by the Chief Medical Scientist or other senior person in charge once testing is complete.
    - Where blood has been issued for a patient the accompanying hardcopy report issued with the blood will be signed by the medical scientist who issued the blood.
    - Relevant reports are also reviewed and signed by the Consultant Haematologist.
- Compatibility results may be reported as compatible, least incompatible or suitable in accordance with BSH Guidelines and Daniels et al. The term 'Suitable' printed on the Compatibility Report, indicates the units are compatible/least incompatible for patients with auto-antibodies using adsorbed plasma, this term is recommended in the BSH Guidelines 2012. This term is also used to report that units were compatible following monoclonal antibody investigation.
- Where the RCI laboratory has crossmatched segments from suitable units which were provided by the referring hospital, the unit number and segment numbers will be listed on the report and identified as compatible/least incompatible/ suitable as appropriate.
- Reports are also available to hospitals on demand (where urgently required) and are issued with all emergency requests.
- The laboratory retains a copy of the report with the original request form. Where a preliminary or interim report is issued, a final report will follow.
- Only scientific or medical staff may issue reports to the hospital. The report must be issued to the medical / clinical personnel responsible for the patient or to scientific staff at the referring laboratory.
- Cumulative patient reports / worksheets for each patient are stored together.
- Where no component has been issued and an antibody investigation has been carried out by the RCI Laboratory an antibody report will be issued within 5 working days (Refer to Section 7.1.1). Should the report be accompanied either by a clinical comment or a covering letter from the director of the laboratory this will incur a further delay in the reporting times.

- A written report will be issued within 14 working days from the receipt of the sample in all cases; except where samples have been referred to an external laboratory.

9.2 Issuing Reports on Critical Samples where Results are Delayed.

It is policy to immediately notify the referring hospital / team when there are indications that the results may be delayed. The laboratory will maintain a record of all such correspondence.

A verbal report will be given as progress of the test becomes available, if required.

Note:

The RCI laboratory will not release results of examinations performed directly to patients. If requested, the laboratory will advise that the best practice is to issue the result to their clinician who can then discuss the implications of the test results with them.

9.3 Reporting of Results by Fax / Encrypted Email/ Sharefile

Where clinically requested by the referring laboratory or the hospital clinician, the IBTS will issue results by fax/encrypted email/Sharefile. Where reports are requested to be faxed/emailed or put on Sharefile they will be signed by a scientist. They may not have a Chief Medical Scientist or Consultant Haematologist signature and may be labelled as 'preliminary' if testing has not been fully completed or as 'interim' if the scientist is lone working. Telephone verification of the receipt of these results is required. A hard copy of the report will follow in the post.

Reports may be sent by email on request, only where a secure encrypted email process has been put in place with the requestor.

9.4 Telephoned Results

The RCI Laboratory provides telephoned results (to the patient's clinician / designated clinical personnel or to the referring laboratory) as clinically required.

Criteria for telephoning results includes the following:

1. Significant unexpected findings
2. When there is a significant delay in turnaround time
3. When blood / blood components are ready for issue/delivery
4. Relevant antenatal testing results.
5. When requested by the referring location

When requesting a verbal report, the patient's personal identifiers i.e. patient's name, date of birth and hospital number must be given to the RCI scientific staff.

The RCI staff will also require the details of the requestor i.e. their own name.

In accordance with laboratory procedures a record of all verbal reports is maintained by the laboratory. A hard copy of the report will follow all verbal reports.

9.5 Archiving of Patients Records

It is IBTS policy to store copies of original request forms and the reports issued by the IBTS laboratories for >30 years, either by electronic or paper record systems.

10 CUSTOMER SERVICE / SATISFACTION AND REVIEW

10.1 Service Level Agreements

Customer satisfaction is assessed through a yearly survey of users, feedback received at Hospital Transfusion Committee meetings and processing of complaints. Customer complaints are reviewed and discussed at the RCI SMS Meetings and at the RCI Annual Quality Review Meetings.

10.2 Customer Complaints / Compliments

The IBTS customer complaint form (IBTS/QA/SOP/0063 Attachment 6.2) for blood products, defects & testing / reporting of patient samples is available of the giveblood.ie website at the following link: https://healthprofessionals.giveblood.ie/clinical-services/quality-compliance/quality-documentation/quality-documentation.html. The form is completed by the user and emailed to qualityassurance@ibts.ie. A response will be received following investigation of the complaint.

The RCI laboratory welcome user feedback, this form is available from the following section of the website: https://healthprofessionals.giveblood.ie/clinical-services/transfusion-transplantation/red-cell-immunohaematology-diagnostics/ On completion of the patient, user and personnel feedback form, it is emailed to rci@ibts.ie . The laboratory will respond to the feedback once received.

10.3 Quality Management Review

Laboratory management review the management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness, including the stated policies and objectives.

10.4 Customer Liaison

The RCI Laboratory seeks feedback from its patients, users and personnel. Feedback is analysed and used to improve the management system, laboratory activities and services to users.

10.4.1. Records of feedback are maintained including actions taken. Communication is provided to personnel on actions taken arising from their feedback.

10.4.2. Samples may be requested from the RCI laboratory for validation purposes. Please email requests to rci@ibts.ie.

10.5 Hospital Transfusion Committees

10.5.1. The hospitals where the IBTS acts as a HBB arranges a Hospital Transfusion Committee meeting biannually. The following representatives from the IBTS are in attendance: Consultant Haematologist and RCI Chief Medical Scientist. SAEs and SARs are discussed at this meeting.

10.5.2. A review of Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR) is performed at the RCI Quality Review Meetings and should also be undertaken at each Hospital Transfusion Committee Meeting. The IBTS Consultant Haematologist will attend such meetings

10.5.3. It is the responsibility of the IBTS Biovigilance Officer to complete an ANSAE (Annual notification of serious adverse event) report on behalf of the IBTS Blood Establishment (may include SAEs relating to referral services) and also an ANSAE report where the IBTS acts as a hospital blood bank. While the hospital Haemovigilance Officer is responsible for reporting SARs occurring in the clinical setting, the IBTS Biovigilance Officer completes an ANSAR (Annual notification of a serious adverse reaction) report where the IBTS acts as a hospital blood bank.

10.5.4. The IBTS Biovigilance Officer submits the ANSAE and ANSAR reports to the National Haemovigilance Office (NHO) who submit this report to the competent authority, HPRA.

10.5.5. The IBTS Consultant Haematologist (designated nominee) / Chief Medical Scientist attend Hospital Transfusion Committees meetings, at hospitals where the laboratories provide hospital blood bank services; where issues of IBTS service and policy are discussed.

10.6 Continuous Improvement

The laboratory continually improves the effectiveness of the management system including pre-examination, examination and post examination processes as stated in objectives and policies and objectives. This is performed and documented through;

- Change Control
- Periodic Document Review
- Equipment Maintenance
- Monitoring of Turnaround times
- Management Review
- Internal Audits/External Audits
- Customer complaints or recommendations
- Assessment of Customer Satisfaction
- Assessment of Suppliers
- Training
- Further education and Continual Professional Development
- External Quality Assessment (EQA) reports
- The Non-Conformance System: Incident Reports and Complaints
- Risk Assessments
- Laboratory meetings

10.7 Traceability

Haemovigilance is defined as 'a set of surveillance procedures from the collection of blood / blood products to the follow up of recipients, to collect and access information on unexpected or undesirable effects resulting from the use of blood / blood products, and to prevent their re-occurrence'.

The information provided by Haemovigilance may contribute to improving the following:

- Provides the Medical professional with a reliable source of information about adverse events and reactions associated with blood collection and transfusion.
- Indicates corrective measures required to prevent a reoccurrence of incidents or dysfunctions in the transfusion process
- Warning system for hospitals and blood establishments about adverse events and reactions that could involve more individuals than a single recipient, including transfusion transmitted infections and defects related to packs, materials, solutions and blood processing.

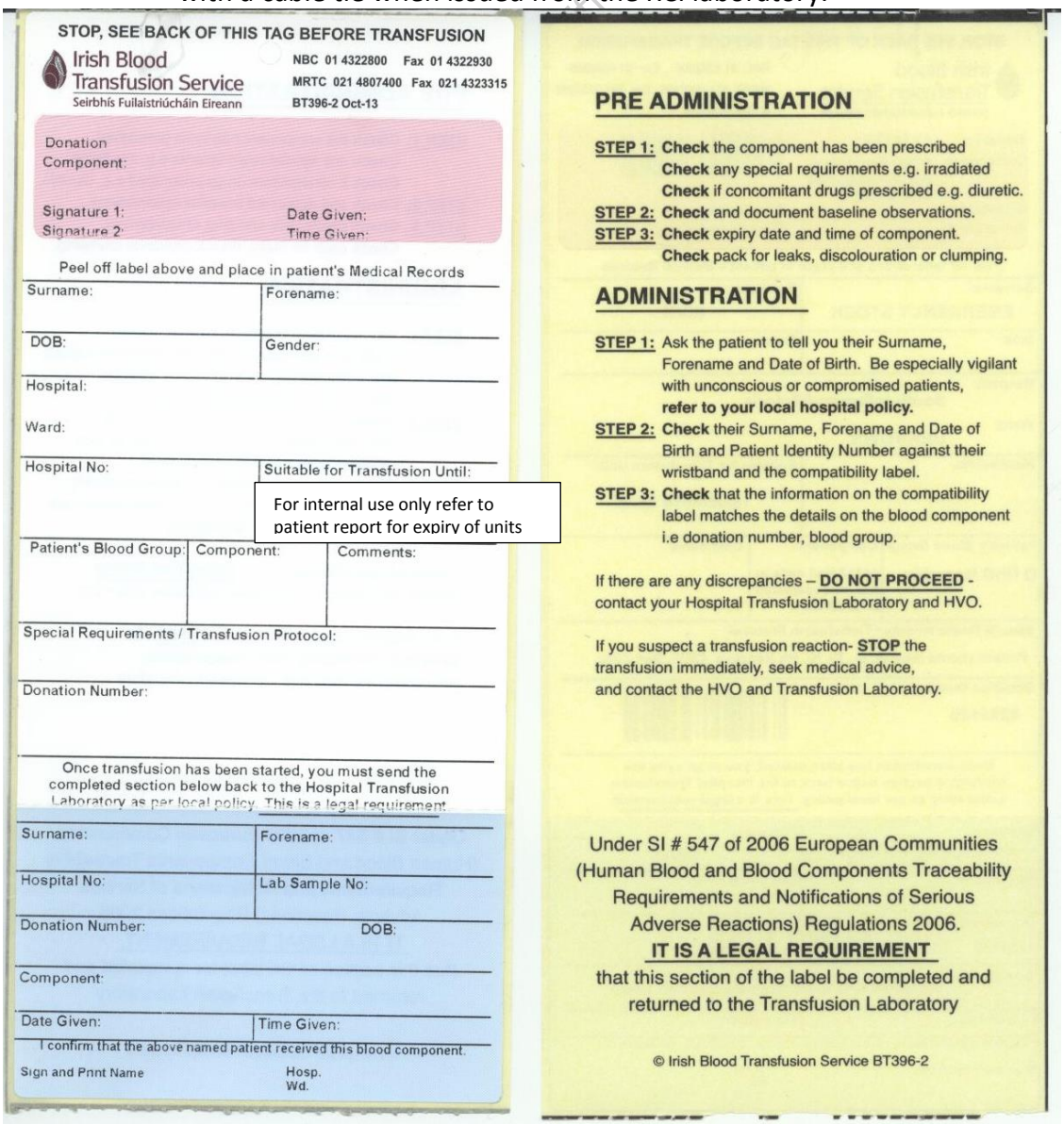
10.7.1. The RCI laboratory provides a routine Blood Bank service for the following hospitals;

- Our Lady's Hospice, Harold's Cross
- Blackrock Hospice
- Royal Victoria Eye & Ear Hospital.

10.7.2. These hospitals are responsible for managing Haemovigilance within the clinical area. The hospitals must employ a Haemovigilance officer on site. The IBTS Consultant Haematologist and other medical staff will provide guidance when / where required to hospital clinical staff on Haemovigilance issues. The IBTS has SLA's in place with these hospitals which clearly defines the Hospital's responsibilities in this regard.

10.7.3. The Hospital must ensure that the Haemovigilance activities meet the requirements of article 14/15 of the IMB/INAB, Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC in compliance with ISO 15189: 2022.

10.7.4. A traceability label, BT 396 is attached to all blood / blood components with a cable tie when issued from the RCI laboratory.



STOP, SEE BACK OF THIS TAG BEFORE TRANSFUSION

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin Eireann

NBC 01 4322800 Fax 01 4322930
MRTC 021 4807400 Fax 021 4323315
BT396-2 Oct-13

Donation Component:
Signature 1:
Signature 2:
Date Given:
Time Given:

Peel off label above and place in patient's Medical Records

Surname: | Forename:
DOB: | Gender:
Hospital:
Ward:
Hospital No: | Suitable for Transfusion Until:

For internal use only refer to patient report for expiry of units

Patient's Blood Group: | Component: | Comments:
Special Requirements / Transfusion Protocol:
Donation Number:

Once transfusion has been started, you must send the completed section below back to the Hospital Transfusion Laboratory as per local policy. This is a legal requirement.

Surname: | Forename:
Hospital No: | Lab Sample No:
Donation Number: DOB:
Component:
Date Given: | Time Given:
I confirm that the above named patient received this blood component.
Sign and Print Name Hosp. Wd.

PRE ADMINISTRATION

STEP 1: **Check** the component has been prescribed
Check any special requirements e.g. irradiated
Check if concomitant drugs prescribed e.g. diuretic.
STEP 2: **Check** and document baseline observations.
STEP 3: **Check** expiry date and time of component.
Check pack for leaks, discolouration or clumping.

ADMINISTRATION

STEP 1: Ask the patient to tell you their Surname, Forename and Date of Birth. Be especially vigilant with unconscious or compromised patients, **refer to your local hospital policy.**
STEP 2: **Check** their Surname, Forename and Date of Birth and Patient Identity Number against their wristband and the compatibility label.
STEP 3: **Check** that the information on the compatibility label matches the details on the blood component i.e donation number, blood group.

If there are any discrepancies – **DO NOT PROCEED** - contact your Hospital Transfusion Laboratory and HVO.

If you suspect a transfusion reaction- **STOP** the transfusion immediately, seek medical advice, and contact the HVO and Transfusion Laboratory.

Under SI # 547 of 2006 European Communities (Human Blood and Blood Components Traceability Requirements and Notifications of Serious Adverse Reactions) Regulations 2006.
IT IS A LEGAL REQUIREMENT
that this section of the label be completed and returned to the Transfusion Laboratory

10.8 Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs)

The IBTS conforms to Directive 2005/6/1/EC implementing Directive 2002/98/EC as regards notification of Serious Adverse Reactions (SARs) and Events (SAEs), transposed into Irish law by SI 547 of 2006.

10.8.1. It is the responsibility of the IBTS as a Blood Establishment to report all SAEs relating to collection, testing, processing, storage and distribution of blood and blood components by the Irish Blood Transfusion Service to the competent authority, the Health Products Regulatory Authority (HPRA). The IBTS also reports to the National Haemovigilance Office.

10.8.2. It is the responsibility of the IBTS as a referral laboratory and when acting as a HBB to report all SAEs relating to those activities, to the competent authority, the Health Products Regulatory Authority (HPRA). The IBTS also reports to the National Haemovigilance Office.

10.8.3. Where the IBTS acts as a referral laboratory for Hospital Blood Banks in its agreement (SLA) for the supply of blood and blood components and the provision of other services with its user hospitals has identified responsibilities for all parties in relation to the obligations to report Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs). The Service Level Agreement between the Irish Blood Transfusion Service and the hospital notes "The hospital shall report in writing and without delay all Serious Adverse Events and Serious Adverse Reactions to the National Haemovigilance Office of the Irish Blood Transfusion Service. The hospital should take note of the requirements under the regulations for mandatory reporting of Serious Adverse Events and Serious Adverse Reactions".

10.8.4. Where the RCI laboratory acts as a Hospital Blood Bank it is the responsibility of the hospital to have a haemovigilance system in place for the review of all blood transfusion adverse events / reactions occurring within the hospital and to ensure that all SAEs and SARs are reported to the National Haemovigilance Office (NHO) as defined by the NHO and in conformance with their protocols. The Hospital Haemovigilance Officer must liaise with the IBTS Biovigilance Officer to prevent duplication of reporting.

10.8.5. It is the responsibility of the hospital, for which the IBTS act as their Hospital Blood Bank, to have in place Haemovigilance procedures for the clinical investigation and management of adverse events and reactions occurring in relation to transfusion of blood and blood components.

10.8.6. In the event of an adverse transfusion reaction relating to a component, whether issued to a Hospital Blood Transfusion Laboratory or directly to a clinical transfusion facility where the IBTS acts as the hospital blood bank, the hospital must inform the RCI Laboratory immediately, by telephone, to ensure prompt recall of co-components where indicated.

10.8.7. The IBTS Consultant Haematologist / Specialist Medical Officer will provide immediate clinical advice on the investigation of such reactions and will liaise with the hospital clinical staff and Haemovigilance Officer in relation to the clinical events and investigation outcomes.

10.8.8. A report will be issued to the hospital clinician outlining the results of all the investigations performed.

10.8.9. If the criteria meet those for the reporting of a serious adverse reaction to the NHO the IBTS Consultant Haematologist will advise on the type of reaction and advise the hospital Haemovigilance Officer regarding reporting of the reaction to the NHO as per the NHO Handbook.

10.8.10. Where the RCI laboratory acts as a HBB, in the case of an SAE that has observed in the hospital, the hospital must inform the RCI Laboratory.

10.8.11. The IBTS Biovigilance Officer will assess all potential SAEs occurring in relation to the diagnostic services provided to hospitals by the RCI laboratory, both as a referral service or when acting as a HBB. These will be reported to the National Haemovigilance Office and/ or the HPRA if deemed necessary.

11 REFERENCES

11.1 Milkins, C. et al. (2013), Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. Transfusion Med, 23: 3-35. [IBTS/EXT/DOC/0025].

11.2 Blood Directive – Directive 2002/98/EC ~ "Setting the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood products and amending Directive 2001/83/EC". [IBTS/EXT/DOC/0012]

11.3 EU Directive 2004/33/EC Annex IV titled "Storage, Transport and Distribution Conditions for Blood and Blood Products". [IBTS/EXT/DOC/0012]

11.4 SI 360 / 05 - European Communities (Quality and Safety of Human Blood and Blood Products) Regulations 2005. This is the statutory instrument which adapts the EU Directives as defined above Into Irish law. [IBTS/EXT/DOC/0012]

11.5 Traceability SI 547/06 - Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC". [IBTS/EXT/DOC/0012]

11.6 Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC (AML-BB). [IBTS/EXT/DOC/0017].

11.7 Directive 2005/61/EC ~ "Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events". [IBTS/EXT/DOC/0012]

11.8 Directive 2005/62/EC ~ "Implementing Directive 2002/98/EC of the European Parliament and of the Council as regards community standards and specification relating to a quality system for blood establishments". [IBTS/EXT/DOC/0012]

11.9 ISO 15189. Medical Laboratories – Particular requirement for quality and competence, 2022. International Organisation for Standardisation. [IBTS/EXT/DOC/0033].

11.10 NHSBT user guide may be accessed at https://hospital.blood.co.uk/diagnostic-services/user-guides/

11.11 IBGRL user guide may be accessed at https://ibgrl.blood.co.uk/services/red-cell-reference/

11.12 IBTS/EXT/DOC/0034 INAB notification 45

12 ATTACHMENTS

12.1 List of customers for which RCI lab provide referral testing services

12.2 List of customers for which RCI lab provide HBB services

Customers for which RCI lab provide referral testing services
Cork University Hospital
General Hospital Cavan
Letterkenny University Hospital
St.Vincent's PUBLIC Hospital
St.James Hospital
Tallaght University Hospital
Beaumont Hospital
Mater PUBLIC Misericordiae Hospital
Mater PRIVATE Hospital
Temple Street Hospital
Crumlin Hospital
Coombe Women's Hospital
National Maternity Hospital
Rotunda Hospital
Bon Secours Hospital Dublin
Blackrock Clinic Blackrock Health
St.Mary's Hospital Cappagh
Connolly Hospital
St.Lukes Hospital, Rathgar
Beacon Hospital
Hermitage Clinic Blackrock Health
U.C.H. Galway
Portiuncula University Hospital
Bons Secours Hospital Galway
Galway Clinic Blackrock Health
Naas General Hospital
St.Lukes General,Kilkenny
Lady of Lourdes, Drogheda
University Hospital Limerick
Portlaoise Midland Regional Hospital
Our Lady's Hospital Navan
Mayo University Hospital
Tullamore Midland Regional Hospital
Roscommon University Hospital
Sligo University Hospital
University Hospital Waterford
Mullingar Regional Hospital
General Hospital Wexford

Customers for which RCI lab provide HBB services
Our Lady's Hospice, Harold's Cross
Royal Victoria Eye & Ear
Blackrock Hospice