Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin Eireann

User Guide for the Red Cell Immunohaematology Laboratory

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TITLE: USER GUIDE FOR THE RED CELL IMMUNOHAEMATOLOGY LABORATORY

Change Description:
Introduction of new document IBTS/RCI/UG/0001 which is the "User Guide for the Red Cell Immunohaematology laboratory".

Reason For Change:
- Introduce new version of user guide which details the services provided by the RCI laboratory.
- Create a user friendly document for service users.

Change Order No.:
IBTS/CO/0373/18

Referenced Procedures
IBTS/MED/SOP/0050
IBTS/QA/SOP/0006

SmartTrain Roles

RCI MS NBC	MED CON IH NBC
RCI SMS NBC	MED CON MSD IBTS
RCI THOD NBC	MED CON BMR HLA NBC
MED SMO NBC	RCI REAG SMS NBC
MED SPEC REG NBC	

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
No	No	No	Yes	No

TITLE: USER GUIDE FOR THE RED CELL IMMUNOHAEMATOLOGY LABORATORY

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TITLE: USER GUIDE FOR THE RED CELL IMMUNOHAEMATOLOGY LABORATORY

1.0 INTRODUCTION

1.1 This guide 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 users of both the routine compatibility 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 guide 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 IBTS will accept correctly completed blood request forms / service requests 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 (standard investigations, reference investigations and urgent requests).

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). The laboratory is committed to obtaining the International Standard ISO 15189.

1.6 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 IBTS laboratories in accordance with IBTS Health and Safety procedures and, in compliance with waste management regulations.

1.8 This user guide should be read in conjunction with the IBTS product master files.

1.8 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 user satisfaction, in addition to internal audit and external quality assessment.
- Notification to users of significant changes to IBTS laboratory processes/procedures where the results or their interpretation could be significantly different, prior to implementation.

2.0 USING THIS GUIDE

2.1 A copy of this manual is available on the internet at: https://www.giveblood.ie/Clinical-Services/Red-Cell-Immunohaematology-Diagnostics/. Hard copies of the User Manual will not be supplied.

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

2.3 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.

2.4 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.

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

3.0 RCI LABORATORY QUALITY POLICY

The RCI Laboratory strives to be a centre of excellence.

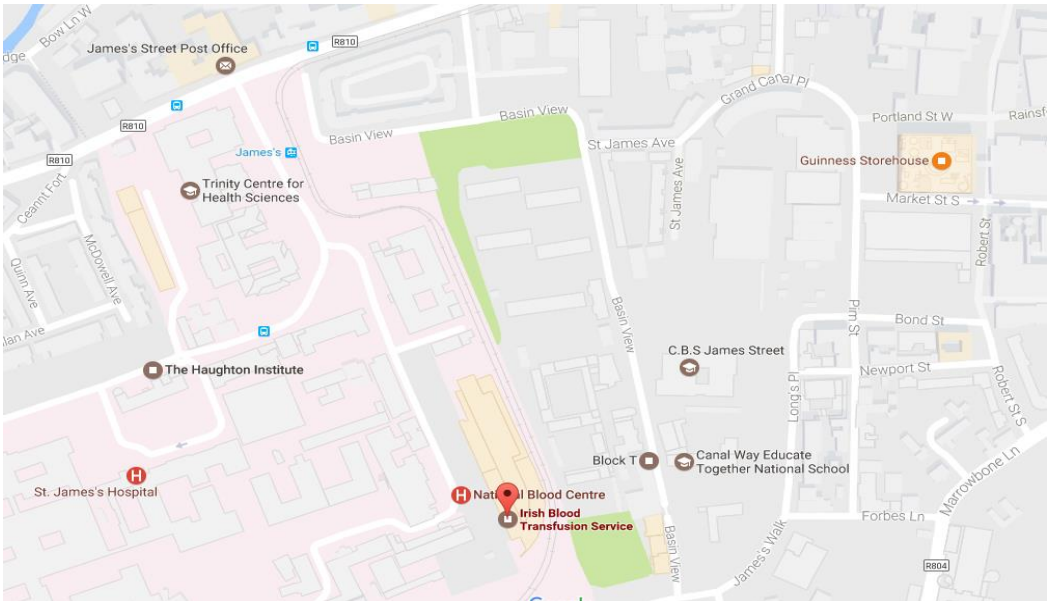
In order to ensure that the needs and requirements of laboratory users (and ultimately patient's needs) are appropriately met, the IBTS RCI Laboratory will:

- Operate a Quality Management System to continuously improve the quality of services provided
- Operate to the requirements of SI 547 of 2006 incorporating Articles 14 and 15 of Directive 98/ 2002/EC (Traceability Requirements, Notification of SAR/E)
- Set quality objectives and plans in order to implement the Quality Policy
- Ensure that all staff are familiar with this quality policy and all RCI Laboratory policies, guidelines and procedures relevant to their work
- Ensure that laboratory examinations that are timely, confidential and accurate; and are supported by clinical advice and interpretation when required
- Implement internal quality control, external quality assurance, audit and assessment of user satisfaction to continuously improve the quality of the service provided
- Uphold professional values and good professional practice and conduct.

4.0 GENERAL INFORMATION

4.1 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:
RCI Laboratory
National Blood Centre
James's Street
Dublin 8
D08 NH5R
Tel: (01) 4322800
Fax: (01) 4322930
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 2 organisations:

1. Royal Victoria Eye & Ear Hospital, Dublin
2. Our Lady's Hospice & Care Services, Harold's Cross & Blackrock

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

4.2 Laboratory Director

The RCI Laboratory is directed by a Consultant Haematologist; Dr Stephen Field

4.3 Service Operating Times

Department/Activity	Opening Hours RCI
Routine Laboratory	Monday to Friday 8.30 am – 19:00 pm Excluding Bank Holidays
Emergency Out of Hours Service* (On-Call Service)	Monday to Friday: 19:00 pm to 8:30 am (Scientist On-call**) Saturday, Sundays & Bank Holidays: Scientist On-Call 24 hrs.**
Sample Reception	**Security: 24 Hrs**

* The emergency out-of-hours service is for non-deferrable tests that are necessary for patient management.

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

4.4 Tests & Services Provided

The table below lists the test procedures provided by the RCI Laboratory. **Click on the page number indicated to jump to the relevant section of this manual where full details are provided)**

4.5 Key Personnel & Contact Details

SECTION	NBC
Consultant Haematologist	Dr Stephen Field 01-4322800 or Specialist Medical Officer / Registrar on duty 01-4322800
Chief Medical Scientist	Mr Barry Doyle 01-4322800
Laboratory Office	01-4322966
Laboratory (Routine Hours)	01-4322972 01-4322973
Laboratory (Out of Hours)	01-4322800 (Switch) Ask for Medical Scientist On-call.
Clinical issues (Out of Hours)	01-4322800 (Switch) Ask for doctor on duty/call.
Platelet Issue Hospital Blood Bank Service ONLY *	Routine Hours (08:30 am – 19:00 pm): Contact Hospital Services (01-4322970) (Hospital Services staff will contact staff in the RCI Laboratory to fill the order) Out-of-hours: 01 4322800 (Switch)
Laboratory Fax No.	01-4322709
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**

4.6 Sample Testing Scheduling

4.6.1 Routine Service

4.6.1.1 Hospital Blood Bank Service

The RCI laboratory will accept and process samples for routine compatibility testing throughout the day Monday to Friday. Sample testing on any particular 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.

4.6.1.2 Hospital Blood Transfusion Laboratories (Referral Service)

Samples are processed based on clinical need (with the exception of batched tests – see below). In general, samples for serological investigation received before 9am will be processed on the same day. 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).**
In an urgent situation the IBTS laboratory should be contacted by telephone and provision will be made to process the sample urgently or out of hours if required.
Samples for antenatal antibody titration/quantitation will be batched and processed to meet the test turnaround times specified in Section 8.2.

4.6.2 Emergency Service

4.6.2.1 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 situations to the Royal Victoria Eye & Ear Hospital.

4.6.2.2 Hospital Blood Transfusion Laboratories (Referral Service)

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

4.6.2.3 To Request 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 4.5 for contact details).
* Out of hours: Contact switch and request to speak to the medical scientist or medical personnel on-call (refer to Section 4.5 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.

4.6.2.4 Procedure to be followed for Urgent Requests

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

- Hospital / ward
- Name of person making the request and contact details
- The urgency of the request (date and time required) and estimated time of sample arrival

- Patients name (if known), hospital / emergency / trauma number and date of birth

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

- Number and type of component requested
- 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

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 IBTS.
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 IBTS 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).

4.7 Turnaround Times

For turnaround times for routine and emergency requests see Section 8.2.

4.7.1 Non Compliance with the Turnaround Times

- Turnaround times are routinely monitored as part of the laboratories quality improvement programme.
- 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.

Note:

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

4.8 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

4.9 Data Protection where samples are referred to IBTS

Under data protection acts 1988 and 2003, 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 laboratory are the DATA CONTROLLERS.

5.0 LABORATORY REQUEST FORMS, SAMPLE TUBES AND CONTAINERS

5.1 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.
- Sending haemolysed and/or lipaemic samples should be avoided where possible as free haemoglobin and/or fatty plasma can produce test result errors (especially when using automated equipment). Such samples may have to be rejected. However, it is recognised that there are situations when haemolysis, in particular, is a result of the patient's condition.
- Samples referred to the RCI laboratory should conform to the requirements for the timing of sample collection, as defined in Section 5.8.
- 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 8.2. 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 8.2).
- Sample forms/ packaging are date and time stamped on receipt at the IBTS.
- On receipt in the laboratory, samples are registered with an 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. Where it is determined that the request form and/or sample is not suitable, the requesting hospital will be informed.

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. Request for tests not processed in the RCI Laboratory are referred to specialist external laboratories. See Section 8.3.

5.2 General Information Re Sample Collection

5.2.1 Where the RCI laboratory acts as Hospital Blood Bank;

- **For group and antibody screening one sample will suffice.**
- **For cross-match 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 (see section 5.4.2).**
  This is a recommendation from the 2012 BCSH Guidelines 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.

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

Where IBTS 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 crossmatch 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 segments from suitable units for crossmatching at the RCI laboratory in conjunction with the sample. 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. Segments must be labelled with the ISBT no. of the donor unit.

5.2.3 Service Requestor responsibilities include:

- 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 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 segments that the segments are labelled with the unit ISBT No. and that the units meet the requirements of the patient's transfusion protocol.

5.3 RCI Laboratory Request Forms

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

Hospital Blood Transfusion Laboratories (Referral Service)

BT. 345 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.7 Blood Group and Compatibility Request Form
This form is used solely by facilities to which the laboratory provides Hospital Blood Bank services.

BT.311 Transfusion Reaction Investigation Form
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.597 Haemovigilance Clinical Review Form
This form is used by the Haemovigilance Officer in facilities where the IBTS 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.

5.3.2 Process for ordering the IBTS Request Forms.

Note: Request Form BT345 'Request for Red Cell Immunohaematology Investigation' can be printed from the giveblood website (https://www.giveblood.ie/Clinical-Services/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 following departments:

(a)	**NBC:**	**RCI Laboratory**	**(01-4322972 / 01-4322973)**
		RCI Laboratory Office	**(01-4322966)**
		email	**rci@ibts.ie**

5.3.3 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 BCSH 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

The Declaration(s) Must Be Signed:

19. 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.

5.4 Sample Labelling

5.4.1 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

¥ 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 to prevent misidentification and labelling errors.

5.4.2 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 BCSH 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.
- The use of such on demand printed labels by hospitals must be pre-arranged by agreement with the RCI Laboratory. Otherwise labels on samples must be handwritten.
- 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.

5.5 Sample / Request Card 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.

5.5.1 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.

5.5.2 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

5.6 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 5.7 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.

5.7 Exceptions

5.7.1 Exceptions may be made for samples from the following groups:

- Trauma, unconscious, or Emergency Department patients where the identity is not yet established. The minimum clinical information supplied must include: (1) a unique number, (2) gender and (3) approximate age. It is helpful to be informed of the ethnicity of the patient.

- 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. a fax/other 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.

5.8 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.

Guidelines for the Collection of Samples from Previously Transfused Patients

Patient Category	Sample to be taken not more than
Patient transfused or pregnant in the last 3 months	72 hrs before transfusion[1]
Patient not transfused or pregnant in the last 3 months	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) and have not become allo-immunised (i.e. have not formed clinically significant alloantibodies) allowing samples to remain acceptable for up to 7 days. A risk assessment should be performed and transfusion management plan agreed by the IBTS and referring Hospital Consultant Haematologists.

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

5.9 Sample Storage

Whole-blood samples will deteriorate over a period of time. 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.

5.9.1 Guidelines for the Storage of Samples: Pre-Testing

BCSH 2012 recommended working limits for the storage of blood testing samples (pre-analysis) are detailed below:

Patient Category	18 – 25 º C	2-8º C	-30º C
Patients transfused or pregnant in the last 3 months	Up to 48 hrs	Up to 3 days[1]	NA
Patients not transfused and not pregnant in the last 3 months	Up to 48 hrs	Up to 7 days	3 months

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

5.9.2 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 unless otherwise specified in Section 8.2.

6.0 SAMPLE DELIVERY, PACKAGING AND TRANSPORT REQUIREMENTS

6.1 Sample Delivery

Diagnostic samples will be accepted by IBTS laboratories at **any time.** They should be delivered to:

- Security at the NBC

Refer to Section 4.1 for map & picture of locations.

Note:

THE IBTS MUST BE TELEPHONED IN ADVANCE OF URGENT REQUESTS AND THE SAMPLES DELIVERED TO THE IBTS 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.

6.2.1 International Carriage of Dangerous Goods by Road

The packaging, labelling and transportation of all samples must comply with current European Agreement concerning Carriage of Dangerous Goods by Road Regulations. 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 for samples boxes being referred to the RCI Laboratory are available at: - ***https://www.giveblood.ie/Clinical-Services/Red-Cell-Immunohaematology-Diagnostics***
- The sample can be transported or posted as appropriate (see Note 1 below).
- 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'.

7.0 EXTERNAL AND INTERNAL QUALITY ASSESSMENT PROGRAMMES

7.1 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
- Lab Quality (Finnish External Quality Assurance Scheme)

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.

7.2 Inter-laboratory Comparison Scheme

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

7.3 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.

7.4 Licensing / Accreditation

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

7.5 Major Non–Conformance / Failure in an External Quality Assurance Scheme

Major 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 users of the service will be notified.

8.0 LABORATORY TESTS AND SERVICES

8.1 Services provided by the RCI Laboratory

- **Pre-transfusion Compatibility / Specialised Immunohaematological Testing**
- **Referral Test Services**
- **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**

8.2 Pre-transfusion Compatibility & Specialised Immunohaematological 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 laboratory to the time results/products are available for issue.

Note 2

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

Test Profile	Sample type (fresh venous sample)	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 *	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 ***	EDTA (WB)	3 – 6 ml	Routine requests processed on next scheduled batch (See section 4.6) Emergency: Processed immediately on receipt Contact RCI laboratory in advance	**Routine: Results usually available in 24 hrs.** **Report will follow group and hold period** **Emergency: ASAP - within 2 hrs of receipt of sample if no antibodies detectable**
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 hrs** **Urgent/emergency: ASAP (Within 2 hrs of receipt of sample)**

Test Profile	Sample type (fresh venous sample)	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 12.3 for additional information. (See above re unit segments)	**2-6 hrs** **<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**
Direct Antiglobulin Test	EDTA (WB)	1 x 6 ml	Next scheduled batch (See section 4.6)	**2 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 month or there is evidence of haemolysis (or a delayed haemolytic transfusion reaction). Telephone in advance if blood is required for patient	**2 working days**
Extended RBC Phenotyping	EDTA (WB)	1 x 6 ml	Extended phenotying is	**5 working days**

Test Profile	Sample type (fresh venous sample)	Sample volume	Service details and requirements	Turnaround time test
			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.	
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	**5 working days**
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**
Transfusion Reaction Investigation * (Where the IBTS acts as a Hospital Blood Bank)	EDTA (WB) Post transfusion + **Clotted 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	**ASAP 2-5 hrs 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**

Test Profile	Sample type (fresh venous sample)	Sample volume	Service details and requirements	Turnaround time test
			label (BT396) must not be removed from the units when returning to the IBTS.	
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 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 2-5 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 3 working days** **Written report -5-7 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**
T Cell antigen activation	EDTA (WB)	2-3 ml	Contact RCI Laboratory in advance Routine: Next scheduled Batch	**Routine: 2 - 3 working days**

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.

8.3 Referral Test Services

A variety of molecular tests that were formerly referred to the International Blood Group Reference Laboratory (IBGRL) are now available at the IBTS Blood Group Genetics Laboratory (BGGL); including:

- Full RBC Genotype Investigation
- Weak D genotype Investigation
- RHD Variant Investigation (includes normal RHCE determination)
- RHCE Variant Investigation
- Molecular Investigation of Other Blood Groups (by referral to the IBRGL)

Please refer to the Blood Group Genetic Laboratory User Guide for full details of the services provided (https://www.giveblood.ie/Clinical-Services/Blood-Group-Genetics/Customer-Resources/). Sample for molecular testing should be referred directly to the BGGL.

The IBTS act as the national facilitator for the referral of samples to NHSBT Sheffield 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 are inconclusive. The NHSBT user guide can be accessed at http://hospital.blood.co.uk./diagnostic-services/user-guides/. Please complete the BT345 request form when sending samples to the RCI Laboratory for onward referral to the relevant referral laboratory.

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).

Test profile /service	Centre	Sample type (fresh venous sample)	Sample volume	Service details and requirements	Turnaround time test
Complex Immunohaematology Testing	IBRGL	EDTA (WB)	2 x 6 ml	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.	The time between receipt of sample and reporting will depend on the urgency of the case and the number of samples in the laboratory at any given time (which is out of the control of the IBGRL). Priority is always given to urgent cases and therefore non-urgent investigations may be necessarily delayed. The referrer will be informed if there is to be undue delay in starting an investigation for this reason.
Investigation of IgA Deficiency & IgA Antibodies	NHSBT Sheffield	EDTA (WB)	2 x 6ml	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.	Results are generally available from the NHSBT within 7 - 14 working days of sample receipt Repeat testing will incur an extension to the turnaround time and possibly may require repeat sampling

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 Sheffield	EDTA (WB) Serum sample * (separated at 37C)	2 x 6 ml 1 x 6ml *	* Send the primary sample tube of the separated sample tube that is labelled with the patient identifiers The purpose of this test is to detect antibodies active at 4 °C. The two relevant cold antibodies most generally tested for are Anti-I and anti-i. If the antibody is able to bind to the red cells at 37°C, then haemolysis may result, giving rise to CHAD i.e. Cold Haemagglutinin disease. Cold agglutinin titres can be performed on request.	Result available within 5 working days of sample receipt by NHSBT. Report will be despatched by the RCI Laboratory following receipt of same.

8.4 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. A minimum of 48 hrs is required to import the blood. Please provide the maximum notification possible for this service.

Note:

This service may require up to several working days for patient transfusion. Direct consultation with the medical consultant on duty will be required

8.5 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 (ref 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.

8.6 Medical & 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 4.5 of this manual.

8.7 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.

8.8 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.

8.9 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.

9.0 REPORTING OF TEST 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 BCSH 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 BCSH Guidelines 2012. This term is also used to report that units were compatible with the patient's neat plasma post DTT treatment.
- Where the RCI laboratory has crossmatched segments from suitable units which were provided by the referring hospital, the unit 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 IBTS retains a copy of the report with the original request form. Where an 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 8.2). 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 the Results are delayed

It is IBTS 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:

It is not IBTS policy to release results of examinations performed directly to patients. If requested, the IBTS 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

Where clinically requested by the referring laboratory or the hospital clinician, the IBTS will issue results by fax. Where reports are requested to be faxed 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. Telephone verification of the receipt of the faxed 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 and designated responsibility e.g. clinician or scientist.

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.

10.0 REVIEW & ASSESSEMENT OF CUSTOMER SATISFACTION

Customer satisfaction is assessed through periodic survey of users, feedback received at Hospital Transfusion Committee meetings and processing of complaints. Customer complaints are reviewed regularly at the RCI Management Quality Review meetings. In addition representatives of the laboratory's customers are invited to attend the RCI Laboratory Annual Management & Quality Review.

10.1 Service Level Agreements

The IBTS enters into a Service Level Agreement (SLA) with all hospitals to which they supply blood/blood components and other services for patients of the hospitals. The SLA is subject to periodic review.

The objectives of the agreement include:

- The supply of blood / blood components in accordance with the Product Master File. The services provided including; blood grouping, crossmatching for named patients, antibody referral service, antibody quantification service, and such other services as agreed by the parties.
- The identification of the responsibilities of the IBTS and the said hospitals in the traceability of each unit issued from the IBTS and the need for a structure to deal with non-conforming issues.
- Notice of IBTS fees and charges; and the role of the IBTS and the said hospitals in the termination or amendment of the agreement.

10.2 Customer Complaints

The RCI Laboratory operates within the IBTS quality system incorporating blood components / services complaint defect procedures.

The objectives of our complaints handling system requires that:

- All complaints are rapidly and effectively handled; and fully investigated.
- The appropriate corrective and preventative actions are taken to reduce the risk of repeated errors.
- The relevant information is recorded and reported to the Consultant Haematologist & Quality Manager as appropriate.
- The customer receives a letter from the Quality Assurance / Medical Department in response to the complaint.
- Customer confidence is maintained in our service.

If the service provided is not satisfactory, or you have suggestions for service improvement please contact the IBTS personnel in your region.

10.3 Quality Management Review

Monthly quality reviews are performed of all aspects of the organisation including; customer complaints, non-conformances, sample turn-around times, sample volumes, EQA performance and significant changes. Non-conformances and complaints are also reviewed at weekly quality management review meetings and at monthly laboratory meetings. The RCI Laboratory hold an annual review meeting which reports on all aspects of the RCI Laboratory services and invites user representation.

10.4 Customer Liaison

The RCI Laboratory perform periodic surveys of customer satisfaction and also participate in IBTS User Symposia and National Haemovigilance Office Conferences. User issues are discussed and the IBTS inform their customers of new procedures and services at these events. The user is also afforded the opportunity to give the IBTS feedback on the service being provided to them. The RCI Laboratory welcomes site visits to the laboratory by their customers.

10.5 Hospital Transfusion Committees

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 IBTS continually monitors the suitability and effectiveness of the quality program which is in place in the organisation, through the Quality Management System

The Laboratories' Annual Management & Quality Review is a key element of the continuous improvement process.

11.0 TRACEABILITY AND REPORTING OF SERIOUS ADVERSE REACTIONS (SARS) AND SERIOUS ADVERSE EVENTS (SAES)

11.1 Traceability

11.1.1 SI 547 *European Community (Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations 2006* requires that the IRISH BLOOD TRANSFUSION SERVICE, where it acts as a hospital blood bank, has a system in place to trace the final fate of each and every unit of blood component supplied (i.e. 100% traceability).

11.1.2 The Irish Blood Transfusion Service in its agreement 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 traceability and storage. The Service Level Agreement (SLA) notes *inter alia* that "the hospital shall ensure the traceability of blood and blood components from the point of receipt of the blood or blood components by the hospital to its final use, or its return to the Irish Blood Transfusion Service for its disposal"; and that "where the IBTS acts as hospital blood bank, the hospital is required to notify IBTS of the final fate of each unit of blood and blood component supplied'. It is the responsibility of these hospitals to have procedures in place for those activities relative to the collection of samples and the procurement and transfusion of blood/blood products to their patients. In this instance the IBTS will review and approve these procedures.

11.1.3 The RCI laboratory complies by use of the 'Bag & Tag' traceability system. This involves the tagging of a compatibility/traceability label (BT 396) to the component and the subsequent manual entry of the date and time of transfusion together with the confirmation of transfusion (or any part thereof), recipient identification or other disposition (other patient/ transferred/ re-routed/ discarded), on the Irish Blood Transfusion Service IT system (eTraceline) patient's record. This information is taken from the traceability label, (part C of BT 396), which is returned from the user hospital, where we act as a Hospital Blood Bank only. A hard copy of this label is retained by the IBTS for 30 years. The Traceability User Manual is available on the Irish Blood Transfusion Service website.

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

11.2.1 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.

11.2.2 The Irish Blood Transfusion Service 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".

11.2.3 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). This includes where we act as a Hospital Blood Bank and as a referral laboratory.

11.2.4 The IBTS will report all SAEs occurring in relation to the diagnostic services provided to hospitals to the National Haemovigilance Office.

11.2.5 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. Where we act as a Hospital Blood Bank, the must liaise with the IBTS to prevent duplication of reporting.

11.2.6 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.

11.2.7 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.

11.2.8 Post transfusion samples (EDTA and clotted samples) for serological investigation must be submitted for investigation. All component packs from this event must be returned to the IBTS, if bacterial culturing is not performed local.

11.2.9 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.

11.2.10 A report will be issued to the hospital clinician outlining the results of all the investigations performed taking into account; the clinical history of the patient and any review carried out by the hospital Haemovigilance Officer. Advice on future transfusion support and management of the patient will be provided if requested.

11.2.11 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.

11.2.12 The IBTS Consultant Haematologist will send a copy of this communication (suitably anonymised) and results of the serological investigations to the NHO where relevant if the reaction fulfils the SAR criteria.

11.2.13 In the case of a Serious Adverse Event relating to RCI Laboratory services (e.g. testing or component selection) the IBTS Consultant Haematologist/ Specialist Medical Officer will inform the hospital clinician immediately.

11.2.14 In the case of an SAE that has occurred in the hospital, the hospital must inform the RCI Laboratory.

11.2.15 The IBTS Consultant Haematologist will advise on the clinical implications of the SAE for the patient by communication with the hospital clinician.

11.2.16 A review of serious adverse reactions and serious adverse events 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.

11.2.17 It is the responsibility of the IBTS Biovigilance Officer to identify, categorise and review SAEs according to the EU Directive 2005/61/EC and EU Directive 2002/98/EC. The IBTS Biovigilance Officer reports all SAEs to the National Haemovigilance Office who subsequently report these SAEs to the competent authority, HPRA.

11.2.18 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 and also an ANSAE report where the IBTS acts as a hospital blood bank. The IBTS Biovigilance Officer also completes an ANSAR (Annual notification of a serious adverse reaction) report where the IBTS acts as a hospital blood bank. 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.