Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Review

Review: IBTS DOC REVIEW AND APPROVAL

Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	GERMAN CARRARA CALMELS	GERMAN CARRARA CALMELS
2	DIAGNOSTICS WRITER IBTS	AILEEN GRIFFIN	AILEEN GRIFFIN
3	DIAGNOSTICS REVIEWER MRTC	EIMEAR REARDON	EIMEAR REARDON
4	DIAGNOSTICS HEAD OF DEPT MRTC	KEVIN SHEEHAN	KEVIN SHEEHAN
4	LABS HEAD OF TESTING IBTS	PADRAIG WILLIAMS	PADRAIG WILLIAMS
5	QUALITY ASSURANCE REVIEWER IBTS	SIOBHAN CREEDON	SIOBHAN CREEDON

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/0383/23

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

TITLE: DIAGNOSTICS CUSTOMER MANUAL

Change Description:

1. Revise IBTS/DIAG/CM/0001 Update as per changes made to IBTS/RCI/CM/0001 ver. 3 and associated CO IBTS/CO/0221/23.
2. Section 2. Quality Policy Updated.
3. Contact Information Updated.
4. Section 4.1 updated to refer reader to the section of the manual detailing specimen and request form labelling requirements.
5. Section 5.3.1 updated to include that if electronic labelling system is used for specimen labelling, the label must contain a unique identifier that can be used to trace the sample taker.
6. Section 7.2 Updated Elution TAT to 5 days.
7. Section 7.2 Updated to provide clarity on management of referral laboratories report queries.
8. Section 8.2 updated to include Neutralisation and DTT treatment Inter-Laboratory Comparison schemes.
9. Section 11 Incorporate BT-0425 into the CM. The SAE and SAR section 11 are also updated.
10. Consultant Haematologist has changed.
11. Chief Medical Scientist has changed.

Reason for Change:

1. To ensure the CM is current
2. To come in line with quality policy outlined in IBTS/DIAG/LM/0001
3. Consultant Haematologist has changed
4. To provide clarity to reader
5. Many hospitals use BloodTrack or other suitable means for electronically labelling Blood Transfusion samples. Updated to provide clarity on specimen taker identity requirements for specimens labelled by electronic means.
6. To provide clarity to reader. Information regarding issue of paper report not previously included for this request type. Elution performed as part of antibody investigation. Antibody investigation TAT is 5 days
7. Not previously addressed in CM
8. Schemes in place but not previously documented in previous version of CM
9. BT-0425 is out of date and no longer required by RCI. Diagnostics (Diag) require it so it has been incorporated
10. To ensure correct contact information is available to customers
11. To ensure correct contact information is available to customers

Change Order No.:

IBTS/CO/0383/23

Referenced Documents

IBTS/MED/SOP/0050	IBTS/DIAG/LM/0001	IBTS/EXT/DOC/0021
IBTS/DIAG/FORM/0001	IBTS/EXT/DOC/0007	IBTS/EXT/DOC/0020
BT - 0007	IBTS/EXT/DOC/0009	IBTS/EXT/DOC/0025
BT – 0597	IBTS/EXT/DOC/0012	IBTS/DIAG/SOP/0115
BT – 0396	IBTS/EXT/DOC/0017	IBTS/DP/POL/0002
IBTS/DIAG/SOP/0063	IBTS/QA/SOP/0063	IBTS/DIAG/SOP/0055
IBTS/DIAG/SOP/0030	IBTS/QA/QM/0001	IBTS/QAV/SOP/0002

SmartSolve Roles

DIAG MS MRTC	DIAG THOD MRTC	MED SMO MRTC
DIAG SMS MRTC	MED CON MRTC	MED SPEC REG MRTC

Training Type

All Roles	Read and Understand

SmartSolve Document Category

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

Table of Contents

TITLE: DIAGNOSTICS CUSTOMER MANUAL

1 INTRODUCTION

1.1 This manual is designed to provide an overview of the services available from the Irish Blood Transfusion Service (IBTS) Diagnostics Laboratory at the Munster Regional Transfusion Centre (MRTC). 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 Diagnostics 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 Diagnostics 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 (S.I. No. 360 of 2005, S.I. No. 547 of 2006, S.I. No. 562 of 2006).

1.5 The laboratory complies with S.I. No. 547 of 2006 incorporating Articles 14 and 15 of Directive 98/2002/EC (Traceability Requirements, Notification of SAR/E).

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

1.7 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 and compatibility services undergo continuous review through quality assurance and audit activities.

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

1.9 This manual should be read in conjunction with the IBTS product master files and the Diagnostics laboratory manual. The laboratory manual and product master files may be viewed on the giveblood.ie website.

1.10 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 Diagnostics laboratory processes/procedures where the results or their interpretation could be significantly different, prior to implementation.

1.11 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 customer guide will not be supplied.

1.12 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.

1.13 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.

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

1.15 The term 'Hospital Blood Bank' is used to describe the situation where the Diagnostics laboratory act as an institution's Hospital Blood Bank.

2 QUALITY POLICY

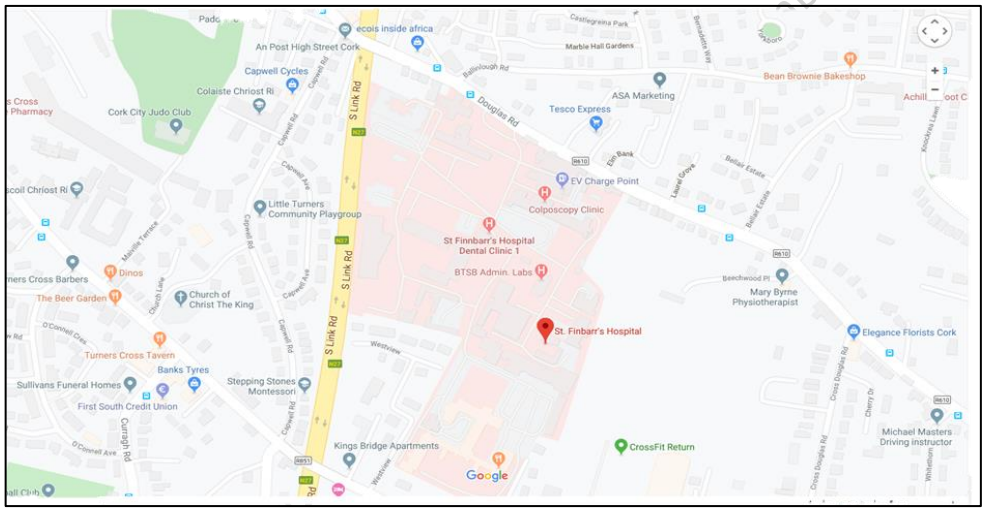
The Diagnostics management team will ensure the laboratory complies with the IBTS Quality Policy laid out in IBTS/QA/QM/0001. In addition the Diagnostics Laboratory will comply with the standards set by ISO 15189, AML-BB, S.I. No. 360 of 2005 European Communities (Quality and Safety of Human Blood and 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 Diagnostics laboratory

Location: The Diagnostics Laboratory is based at the Munster Regional Transfusion Centre (MRTC). The MRTC is located on the site of St Finbarr's Hospital in Cork (see map below, the main entrance to the St Finbarr's Hospital site is via the Douglas Road).



Postal Address: Diagnostics Laboratory
Munster Regional Transfusion Centre
St. Finbarr's Hospital
Douglas Road
Cork
T12 Y319

Tel.: (021) 4807400
Fax: (021) 4323315

Scope of Activity: The Diagnostics Laboratory provides a specialist red cell immunohaematology service to hospital blood transfusion laboratories in Munster.

It also provides hospital blood bank services to 4 hospitals;

- South Infirmary Victoria University Hospital
- St Finbarr's Hospital
- Cork Mater Private Hospital
- Marymount University Hospital & Hospice

Sample Reception: Sample reception for the Diagnostics Laboratory at the MRTC is located in the Despatch Department. The entrance is located directly across from the church on the ground of St Finbarr's Hospital (see picture below).

3.5 Laboratory Director

The Diagnostics Laboratory is directed by Consultant Haematologist Dr Sorcha NíLoingsigh.

3.6 Service Operating Times

Department / Activity	Opening Hours DIAGNOSTICS MRTC
Routine Laboratory	Monday to Friday 07:00 to 19:00 Excluding Bank Holidays
Emergency Out of Hours Service* (On-Call Service)	Monday to Friday: 19:00 to 07:00 (Scientist on Site) Saturday, Sundays & Bank Holidays: Scientist On-Site 24 Hours
Sample Reception	Security: 24 Hours

The out-of-hours service is for emergency referrals only and where immediate blood component transfusion is clinically indicated. Requests for elective surgical procedures will not be processed out of hours.

3.7 Key Personnel and Contact Details

SECTION	DIAGNOSTICS, MRTC
Consultant Haematologist	Dr Sorcha NíLoingsigh. 021-4807400 or Specialist Medical Officer on duty 021-4807400
Chief Medical Scientist	Ms Eimear Reardon 021-4807400
Laboratory (Routine Hours)	021-4807417 021-4807418 021-4807440
Laboratory (Out of Hours)	021-4807400 (Switch) or 021-4807419 (Despatch) Ask for Medical Scientist on Duty
Clinical issues (Out of Hours)	021-4807400 (Switch) or 021-4807419 (Despatch) Ask for doctor on duty/call.
Laboratory Fax No.	021-4323315
Switch	021 4807400
Emergency Contact No. (Despatch)	021-4807419

3.5 Sample Testing Schedule

3.5.1 **Routine Service**

3.5.2.1 Hospital Blood Bank Service

The MRTC Diagnostics Laboratory operates an automated batch testing system. Two batches are run daily: at 09:00 hours and at 13:00 hours (Friday at 13.30hrs). Samples received after these times will be processed in the next scheduled batch unless they are to be treated as an emergency and the laboratory has been phoned to inform them of the urgency of the request. Samples tested in the batch system will not accrue an additional emergency charge.

3.5.2.2 Referral service for Hospital Blood Transfusion Laboratories

Samples are processed based on clinical need (with the exception of batched tests – see below). In general, Samples for serological investigation received before 09.00 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 Monday to Thursday is 13:00 and on Friday 13.30 (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 advised of same, provision will be made to process the Sample urgently or out of hours if required.

3.5.2 Emergency Service

3.5.2.1 Hospital Blood Bank Service

The Diagnostics 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 Diagnostics Laboratory at the MRTC maintains a stock of O RhD Negative un-crossmatched blood at the South Infirmary Victoria University Hospital and the Cork Mater Private Hospital only. In this instance the units are labelled as emergency stock on the BT-396 traceability label.

3.5.2.2 Referral Service For Hospital Transfusion Laboratories

The Diagnostics laboratory also 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 ticking 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 relevant laboratory directly (refer to Section 3.4 for contact details).
- Out of hours: Contact switch and request to speak to the medical scientist or 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)/Consultant Haematologist.

3.5.2.4 Procedure 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 number/emergency 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 and if the patient is bleeding or not
- 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 Diagnostics 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 Diagnostics 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/ 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/SpMO following consultation with the patient's attending clinician (in accordance with IBTS/MED/SOP/0050).

3.6 Turnaround Times

For turnaround times for response to routine and emergency requests see Section 7.2

3.6.1 Non-compliance with turnaround times

- Turnaround times are routinely monitored monthly.
- 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.

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

3.8 Data Protection

Under the General Data Protection Regulation (GDPR) (EU) 679/16 and the Data Protection Act 2018, the Diagnostics 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.

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 Diagnostics laboratory.
- All patient samples must be labelled at the bedside applying positive 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, in particular, is a result of the patient's condition.
- Samples referred to the Diagnostics 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 Diagnostics 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 7.2 and 7.3.
- If samples are required to be stored prior to referral to the Diagnostics laboratory, they should be stored at 2-8ºC (exceptions are detailed in Section 7.2 and 7.3). This is the responsibility of the referring hospital /

institution.

- Sample forms / packaging are date and time stamped on receipt at the IBTS.
- On receipt in the laboratory, samples are registered with a unique Diagnostics sample number and all stored aliquots from the primary sample are labelled with the assigned Diagnostics sample number.
- Diagnostics scientific staff will review request forms and samples against pre-defined acceptance criteria to determine if they are suitable for the tests requested (See section 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

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 Diagnostics 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 Diagnostics Laboratory are referred to specialist external laboratories. See Section 7.3**

4.2 Diagnostics Laboratory Request Forms

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

BT – 0007 - Blood Group and Compatibility Request Form
This form should be used for Samples submitted for blood group and compatibility testing. The form may be used for all referrals to the Diagnostics Laboratory at the MRTC.

IBTS/DIAG/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 Diagnostics 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/ 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

The BT-0007 and BT-0597 forms are available on request from the IBTS by contacting personnel in the following departments:

Despatch Department (021-4807419 / 021-4807420)
Diagnostics Laboratory (021-4807417 / 021-4807418)

IBTS/DIAG/FORM/0001 can be printed from giveblood.ie website using the following link:
https://healthprofessionals.giveblood.ie/clinical-services/transfusion-transplantation/red-cell-immunohaematology-diagnostics/ibts_diag_form_0001.pdf

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

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.
20. In the situation where a sample is being referred, it is acceptable for referring laboratory staff to complete the BT - 0007 Request Form. Laboratory staff should ensure that all details on the BT - 0007 form correspond with the sample and their own request form details.
    - The requesting hospital must submit a copy of their own completed request form along with the completed BT - 0007 and sample.
    - The Sample declaration will be signed on the requesting hospital's form. This declaration will be acceptable.

Note: Addressograph labels are not acceptable on any request form.

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

5 SAMPLE INFORMATION

5.1 Sample Collection

The collection of the blood sample from the patient and the subsequent labelling of the sample tubes should be performed as one continuous, uninterrupted event at the patient's (bed)side, involving one patient and one member of staff only.

All staff involved in sample collection should be competency assessed.

Local policies or guidelines should clearly identify which staff are authorised to collect blood samples for pre-transfusion compatibility testing**.**

Where the Diagnostics laboratory acts as Hospital Blood Bank;

Samples for group and antibody screening and cross-matching, one sample will suffice.

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

Where Diagnostics laboratory is providing a referral service, two samples are required if possible. They do not need to be taken independently of each other, in other words they can be collected at the same time by the same person. 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 Diagnostics Laboratory

On a case-by-case basis and following discussion with the Diagnostics 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. Segments must be labelled with the ISBT no. of the donor unit
The Crossmatch report issued will give the outcome of the segments crossmatched. The report will state in the comments section of the report that the segments labelled with donor unit id no are compatible/incompatible/suitable/least incompatible or whatever the result obtained is. Responsibility for ensuring that the segments are from the correct units will lie with the referring hospital.

5.2 Service Requestor Responsibilities

- Obtaining consent from the patient for the tests required at the Diagnostics 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 Diagnostics 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 Diagnostics 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 Diagnostics 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
7. Where the time of sample collection is not provided the sample time will be registered at the Diagnostics 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.
- The use of such on demand printed labels by hospitals must be pre-arranged by agreement with the Diagnostics Laboratory. Otherwise labels on samples must be handwritten.
- All patient samples and forms must be labelled at the bedside applying positive patient identification.
- **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

Diagnostics 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.

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). 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.

5.3.5 Exceptions

Exceptions may be made for samples from the following groups:

5.3.5.1 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:

- A unique identification number
- Gender
- 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.

3.5.3.2 Where a repeat sample would be difficult to obtain and the result of testing is not to be used for transfusion purposes.

3.5.3.3 Where the delay in acquiring a new sample might seriously prejudice a successful clinical outcome.

3.5.3.4 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.

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 hours 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. This decision is agreed between the Diagnostics 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 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

5.3.8 Guidelines for the Storage of Samples: Pre-testing

BSH 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

5.3.9 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 7.2 and 7.3.

6 SAMPLE PACKAGING AND TRANSPORT

6.1 Sample Delivery

Diagnostic Samples will be accepted by MRTC laboratories at any time. They should be delivered to Despatch.
Refer to Section 3.1 for map & picture of locations.

Note:

THE DIAGNOSTICS 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.

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. The requirements stated below apply to all diagnostic samples directed to the Diagnostics 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.**
- 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 TESTING PROVIDED

The table below lists the test procedures provided by the Diagnostics Laboratory, tests that are further referred and other services available to customers.

Test / Service
Diagnostics 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
Direct Antiglobulin Test
Elution
Extended RBC Phenotyping
Investigate Monoclonal Antibody Interference
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)
Investigation of Cold Reactive Antibodies
Paroxysmal cold haemoglobinuria (PCH)/ Donath-Landsteiner

Referral Test Services
MBG, NBC: Weak D genotype & full RBC genotype
IBGRL: Complex Immunohaematological Investigation
NHSBT: Investigation of IgA Deficiency & IgA Antibodies
NHSBT: Cold Agglutinin Titre and Thermal Range
Other Services
Provision of Blood Products & Components
Clinical & Scientific Consultancy Services
Haemovigilance 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
- Referral Test Services
- Provision of Blood/Blood Components for Transfusion
- 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

7.2 Pre-Transfusion Compatibility and Specialised Testing

The table that follows provides details of the tests available at the DIAG 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.

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	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)	1x 6 ml	Routine requests processed on next scheduled batch (See section 3.5) Emergency: Processed immediately on receipt Contact Diagnostics laboratory in advance	Routine: Results usually available in 24 hrs. Report will follow in 5 working days Emergency: ASAP - within 2 hours of receipt of Sample if no antibodies detectable

Test Profile	Sample type (fresh venous Sample)	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 Diagnostics lab 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)
Blood Group and Compatibility Testing (Patients with red cell antibodies) ROUTINE or EMERGENCY *	EDTA (WB)	2 x 6 ml Minimum	Contact Diagnostics laboratory in advance Progress can be discussed by telephoning the Diagnostics laboratory (See above re unit segments)	2-6 hours Please note 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

Test Profile	Sample type (fresh venous Sample)	Sample volume	Service details and requirements	Turnaround time test
Investigate Monoclonal Antibody Interference	EDTA (WB)	1 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 3.5) Must be telephoned in advance	Results phoned within 1 working day from availability of result
Transfusion Reaction Investigation * Where the IBTS acts as a Hospital Blood Bank or where our lab has provided crossmatched blood as part of our reference service.	EDTA (WB) Post transfusion And Clotted post transfusion sample The implicated unit must be sealed and returned to the IBTS.	2 x 6 ml 1 x 6 ml clotted (if required)	Must be telephoned in advance. Contact medical consultant / medical SpMO 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 (BT-396) 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

Test Profile	Sample type (fresh venous Sample)	Sample volume	Service details and requirements	Turnaround time test
Transfusion Reaction Investigation * (Referred Samples from Hospital Blood Transfusion Laboratories where the initial crossmatch was performed by the Referring Laboratory)	EDTA (WB) Pre Transfusion Post transfusion And A clotted post transfusion sample should also be referred where possible	1 x 6 ml (Pre) 2 x 6 ml(Post) 1 x 6 ml clotted (if required)	Must be telephoned in advance. Progress will be discussed with requestor The sealed unit and/or segments from pack affected should be submitted where a crossmatch has to be done. he segment will need to be labelled with the IBTS Number of the donor unit.	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 Note: Where bacteriological screening of the implicated units is required, or immunological investigation is necessary, the turnaround time may be extended beyond 7 days
Investigation of Cold Reactive Antibodies (Investigation comprises antibody screen & identification at 18ºC as necessary) See also Investigation for Cold Agglutinins/CHAD under Referral Service	EDTA (WB) (Sample for investigation to be taken @ 37˚C and remain @ 37˚C during transportation/until separated) Recommended to be transported in validated thermal flask	1 x 6 ml	Contact the laboratory in advance	5 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.

7.3 Referral Test Services

A variety of molecular tests are available at the IBTS Molecular Biology and Genetics Laboratory, NBC including:

- Fetal RHD Screen (from maternal blood)
- Full RBC Genotype Investigation
- Weak D genotype Investigation

Samples for the following tests will be referred to the International Blood Group Reference Laboratory (IBGRL)

- Molecular Investigation of Other Blood Groups
- Complex Immunohaematology Investigation where results are inconclusive at Diagnostics or confirmation of findings is required.

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 MRTC Diagnostics Laboratories 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/.
The IBGRL user guide may be accessed at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/16584/inf1136.pdf
Please complete the BT - 0007 request form when sending samples to the Diagnostics Laboratory for onward referral to the relevant referral laboratory.
If you wish to query the information on a report for a sample that was referred out by Diagnostics, please contact the Diagnostics laboratory who can follow up with the referral laboratory and / or Consultant on your behalf.

Note 1:

Please note that the IgA deficiency, IgA Antibody and Cold Agglutinin Testing provided by NHSBT are only providing partial testing on particular aspects of these complex issues as outlined on Pages 33/ 34.
Further testing for example for other associated or intrinsic immunological or haematological disorders would require expert immunological and haematological input and opinion.

Note 2:

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 3:

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 Diagnostics 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 Diagnostics 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 the lab prior to sending	In cases of anaphylactic transfusion reactions, or other indications Samples for investigation should be directed to the Diagnostics 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 Barnsley	EDTA (WB) Serum sample * (separated at 37C)	2 x 6 ml 1 x 6ml * Contact Laboratory prior to referring samples."	* 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 Diagnostics Laboratory following receipt of same.

7.4 Provision of Blood Components

7.4.1 For Hospital Blood Transfusion Laboratories

At the MRTC orders for blood components are handled by Hospital Services and the Diagnostics Laboratory.
Requests are initially made by using the Electronic Online Ordering System.

Note:

The Hospital Service Department must be phoned when placing an Emergency Order on the Electronic Ordering System.

Refer to the User Guide available at this link:
https://healthprofessionals.giveblood.ie/research/home/clinical-services/blood-components-hospital-services/hospital-services/user-guide-for-ibts-online-ordering-system.pdf

Note:

For all components manufactured / supplied by the IBTS, please refer to the Product Master File for instructions for use and storage detail specifications.

Refer to the Product Master files available at this link:
https://healthprofessionals.giveblood.ie/clinical-services/blood-components-hospital-services/our-products-components/

Service Provided	Contact
Red Cells with no special requirements	Hospital Services (021) 480 7419 / 021 4807400
Plasma Components including SD Plasma	Hospital Services (021 480 7419 / 021 4807400)
Blood with special requirements: • Blood suitable for neonatal transfusions • CMV Negative & Irradiated Blood • Phenotyped Units	Diagnostics during routine hours (021-4807417/ 4807418) Out of hours: Phone Hospital Services in order to contact Diagnostics (021 4807419 / 4807400)
Fibrinogen Concentrate	Hospital Services (021 480 7419 / 021 4807400)
Platelet components (Including CMV Negative / Irradiated / Washed)	Diagnostics during routine hours (021-4807417/ 4807418) Out of hours: Phone Hospital Services in order to contact Diagnostics (021 4807419 / 4807400)
Red cells (CMV negative / Irradiated)	Diagnostics during routine hours (021-4807417/ 4807418) Out of hours: Phone Hospital Services in order to contact Diagnostics (021 4807419 / 4807400)

7.4.1.1 General Information re Red Cell Components with Special Requirements

• CMV Negative & Irradiated Red Cells

The IBTS do not carry a large stock of pre-irradiated red cells. MRTC have a stock of A RhD Positive, O RhD Positive pre-irradiated. Please allow sufficient time to prepare the order. In rare instances if the required ABO/RhD type or the required quantity is not available, this information will be relayed by telephone to the requesting hospital. If not available, the request may be relayed to IBTS medical staff for direction. If the hospital agrees to accept a different ABO or D type, then the electronic order will be amended by the IBTS Scientist and this will be returned electronically to requesting hospital to accept the changes.

• Phenotyped (Antigen Typed) Red Cells

The IBTS endeavour to hold a limited stock of phenotyped units that are readily available for issue. However this is dependent on stock levels, patient demand and the complexity of the antigen type(s) required. Where the required antigen type is available from stock blood supplies please allow 20-30 minutes to prepare the order. When the required phenotype(s) is not available from current stocks screening of suitable units will be required. Staff in the Diagnostics laboratory will be requested to screen suitable units for the required phenotype. If screening is required the turn-around time will be dependent on the complexity of screening required.

In some cases where the required phenotype/high incidence antigen negative units are not available in the MRTC, they may need to be sourced from the other IBTS centre (NBC). Transport time will then need to be factored in when estimating the delivery time of the requested units.

If the required units are not available in either centre approval must be sought from the medical consultant / medical registrar to call up donors or to obtain suitable units from the International Blood Bank Rare Donor Programme. Timescale is dependent on the availability of blood and the urgency of the request.

7.4.1.2 General Information re Platelet Components

• Platelet components without special requirements (i.e. not CMV negative):

If available on shelf: allow 20-30 min to prepare order for issue.
If not available: the request may be relayed to IBTS Medical staff for direction.

- **Platelet components with special requirements**
  CMV Negative Platelets:
  If the required ABO/Rh type is available on the shelf: allow 20-30 min to prepare order for issue
  - If not available: the request may be relayed to the IBTS Medical staff for direction.

- **HLA Matched Platelets:**
  - First time requests for such components must be made in advance to the SpMO/Registrar on duty at the IBTS to facilitate the call-up of a suitable donor or to allow for the database search of suitable components already bled. The hospital will be notified by the medical personnel as to the availability of the component.
  - An electronic order should be generated
  - IBTS laboratory staff will agree service supply with medical staff at NBC and collate supply logistics.

- **HPA matched Platelets:**
  - In cases where Foetal Neonatal Alloimmune Thrombocytopenia (FNAIT) is suspected or confirmed the delivery should be planned in communication with the IBTS to try and ensure appropriate antigen negative platelets are available. The maternal and paternal ABO and Rhesus group and sex of the baby should be identified.
  - Medical staff will liaise with laboratory staff to ensure the HPA matched platelets are available for the time that they are required.

7.4.2 For Hospitals where the Diagnostics, MRTC is the direct provider of Hospital Blood Bank Services, the following services are provided:

Service Provided	Contact
Red Cells (with/without special requirements)	Diagnostics Laboratory during routine hours (021-4807417/ 4807418) Out of hours: Phone Hospital Services in order to contact Diagnostics (021 4807419 / 4807400)
Platelets * (with/without special requirements)	Diagnostics Laboratory during routine hours (021-4807417/ 4807418) Out of hours: Phone Hospital Services in order to contact Diagnostics (021 4807419 / 4807400)
Fibrinogen Concentrate	Diagnostics during routine hours (021-4807417 / 4807418) Out of hours: Phone Hospital Services in order to contact Diagnostics (021 4807419 / 4807400)
Emergency stock of O Rh D Negative Blood ∞	Diagnostics during routine hours (021-4807417/ 4807418) Out of hours: Phone Hospital Services in order to contact Diagnostics (021 4807419 / 4807400)

* If the blood group of the patient has not been previously tested by the Diagnostics Laboratory a blood Sample is required for blood group investigation. The orders are placed by phone.

∞ MRTC maintains a stock of O RhD Negative un-crossmatched blood at the South Infirmary Victoria University Hospital and Cork Mater Private Hospital only.

7.5 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:

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

7.6 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.

7.7 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.

7.8 Haemovigilance Advisory Service

All haemovigilance queries relating to situations where the Diagnostics 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.

7.9 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.

- Should additional samples be required the laboratory will contact the requesting location.

7.10 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 Titre samples can be held for parallel testing for up to 10 months

8. INTERNAL AND EXTERNAL EQA SCHEMES

8.1 External Quality Assessment Programmes (EQA)

The 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
External proficiency testing is performed by all staff working in the diagnostics laboratories on an annual frequency.

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

8.2 Intra-Laboratory Comparison Scheme

The Diagnostics Laboratory also participates in an intra-laboratory comparison scheme for DTT neutralisation and Ch/Rg neutralisation as no formal EQA programmes are available for these particular methods.

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 / Accreditation

The MRTC Diagnostics Laboratories 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 authorising body. The IBTS Blood Establishment is authorised under BE Number 0002.
The IBTS also authorised by the HPRA to distribute medicinal products under Wholesale Distribution Authorisation No. W00011/00001 & Authorisation No. W00011/00002.

8.5 Non–Conformance / Failure in an External Quality Assurance Scheme

Non-conformances are managed by controlled procedures, with investigation, corrective and preventative actions and review of practices, taken as appropriate. The laboratories 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 Diagnostics laboratory fails an external EQA scheme, all users of the service will be notified.

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 into the IBTS patient laboratory information system (eTraceline) 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 copy reports are printed and posted to the requesting laboratory/location. One hardcopy will be sent for each sample/request
- 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.
- 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 with the patient's neat plasma post DTT or other monoclonal antibody treatment.

- Where the Diagnostics laboratory has crossmatched segments from suitable units which were provided by the referring hospital, the unit numbers will be listed on the comments section of the report and identified as compatible/least incompatible/ suitable as appropriate. Responsibility for ensuring that the segments are from the correct units will lie with the referring hospital.
- Subsequent reports will only be sent in the event a report must be revised.
- Reports are also available to hospitals on demand (where urgently required) and are issued with all emergency requests.
- The Diagnostic laboratory 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 Diagnostics Laboratory, an antibody report will be issued within 5 working days.
- 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

Where clinically requested by the referring laboratory or the hospital clinician, the Diagnostics laboratory will issue results by fax. Where reports are requested to be faxed they will be signed by a scientist. Telephone verification

of the receipt of the faxed results is required. A hard copy of the report will follow in the post.

9.4 Telephoned Results

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

Criteria for telephoning results include 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 Diagnostic laboratory scientific staff.

The Diagnostic laboratory 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 report.

9.5 Archiving of Patients Records*:*

It is IBTS policy to store copies of original request forms and the reports issued by the Diagnostics laboratory 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 Diagnostics SMS Meetings and at the Diagnostics Annual Quality Review Meetings.

10.2 Customer Complaints / Compliments

Refer to IBTS/DIAG/LM/0001

10.3 Quality Management Review

Refer to IBTS/DIAG/LM/0001

10.4 Customer Liaison

10.4.1 Refer to IBTS/DIAG/LM/0001

10.4.2 Samples may be requested from the Diagnostics laboratory for validation purposes.

10.5 Hospital Transfusion Committees

Refer to IBTS/DIAG/LM/0001

10.6 Continuous Improvement

Refer to IBTS/DIAG/LM/000

11 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). See *IBTS/QA/QM/0001* for description of blood establishment traceability.

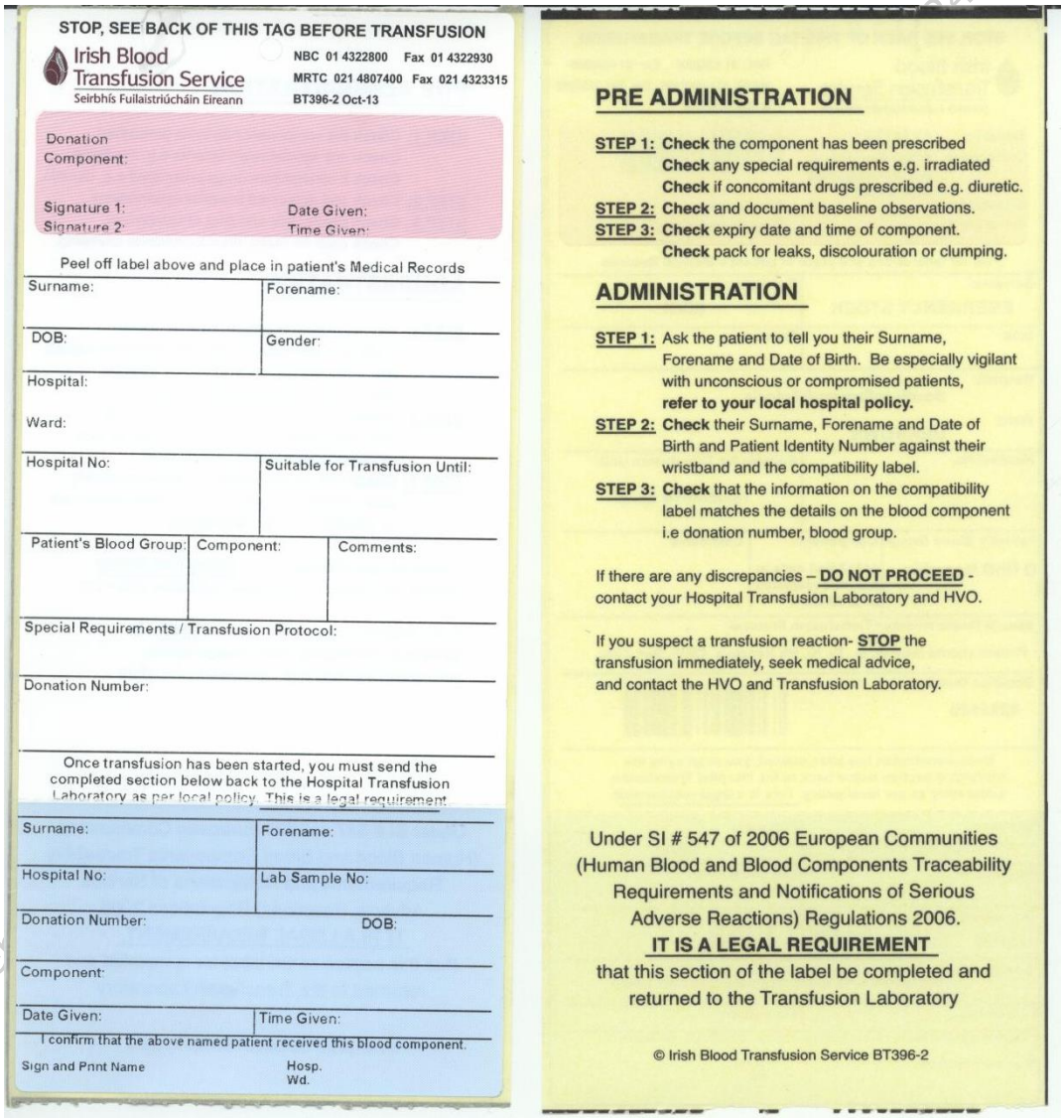
11.1.2 The IBTS maintains a system utilising a unique identification and labelling utilising both eProgesa and eTraceline. This is described in *IBTS/QA/QM/0001* for IBTS blood establishment (eProgesa) and *IBTS/DIAG/SOP/0030* for the Diagnostics laboratory (eTraceline).

11.1.3 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’.

11.1.4 It is the responsibility of these hospitals to have procedures in place when it issues units of blood or blood components for transfusion to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.

11.2 Compatibility/ Traceability Label (BT 396)

11.2.1 The Diagnostics laboratory utilises a 'Bag & Tag' traceability system. The Bag & Tag Label BT - 0396 is attached using a plastic tie onto all blood / blood components.



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:
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

© Irish Blood Transfusion Service BT396-2

11.2.2 The label allows for the tracking and tracing of the blood / blood product from the Diagnostics Laboratory to its final destination.

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11.3 Diagnostics Laboratory as Hospital Blood Bank

11.3.1 The Diagnostics laboratory provides a routine Blood Bank service for the following hospitals:

- South Infirmary/Victoria University Hospital
- Cork Mater Private Hospital
- St. Finbarr's Hospital
- Marymount University Hospital & Hospice

11.3.2 A senior Medical Scientist is responsible for establishing, maintaining and implementing a system to track donations issued by the Diagnostics

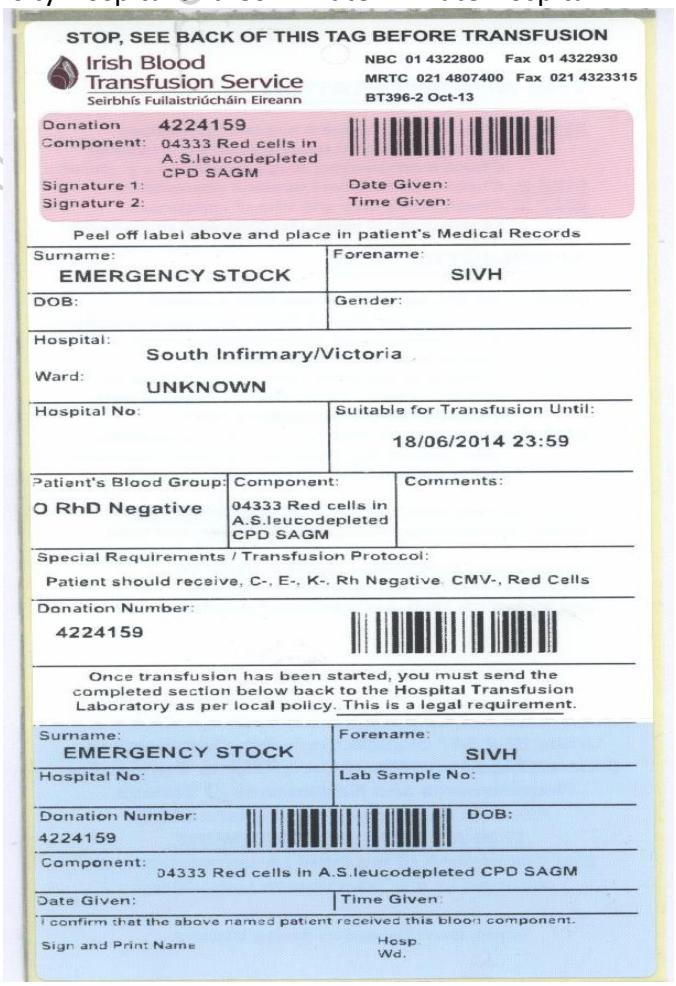
laboratory to the above hospitals for which the IBTS provides a routine hospital blood bank service. This is described in *IBTS/DIAG/SOP/0030.*

11.3.3 It is the responsibility of the hospital receiving the blood / blood component to perform the appropriate checks prior to administration of the blood / blood components as per their SOPs. On completion of these checks, Practitioner (1) and Practitioner (2) sign the pink section of the BT – 0396. Once transfusion has commenced this section is affixed to the patient's medical notes.

11.3.4 The Traceability Labels (blue section of *BT - 0396*) returned by the Hospital are inspected by the Diagnostics laboratory staff (refer to *IBTS/DIAG/SOP/0030*) to ensure that all of the relevant details have been completed.

11.3.5 When blood components have been transfused, the date & time of transfusion, name of hospital & ward and the signature of the Nurse/Doctor who administered the transfusion are completed on the blue section of the BT - 00396. It is the responsibility of the hospital haemovigilance officer/ nominee to ensure the prompt return of fully completed blue section to the Diagnostics laboratory.

11.3.6 Blood labelled as emergency stock is issued to South Infirmary/Victoria University Hospital and Cork Mater Private Hospital.



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 4224159
Component: 04333 Red cells in A.S.leucodepleted CPD SAGM
Signature 1:
Signature 2:
Date Given:
Time Given:

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

Surname: EMERGENCY STOCK	Forename: SIVH
DOB:	Gender:

Hospital: South Infirmary/Victoria
Ward: UNKNOWN

Hospital No:	Suitable for Transfusion Until: 18/06/2014 23:59

Patient's Blood Group:	Component:	Comments:
O RhD Negative	04333 Red cells in A.S.leucodepleted CPD SAGM	

Special Requirements / Transfusion Protocol:
Patient should receive, C-, E-, K-, Rh Negative. CMV-, Red Cells

Donation Number: 4224159

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: EMERGENCY STOCK	Forename: SIVH
Hospital No:	Lab Sample No:

Donation Number: 4224159 DOB:
Component: 04333 Red cells in A.S.leucodepleted CPD SAGM
Date Given: Time Given:
I confirm that the above named patient received this blood component.
Sign and Print Name Hosp. Wd.

11.3.7 When emergency stock units have been transfused to a patient, the *Traceability Form for Transfusion Confirmation of Non-AssignedBlood Components* (IBTS/DIAG/SOP/0030 att. 6.1) must be completed. The following details must be included on the form:

- Patient name, DOB, MRN and address
- Hospital, ward, consultant
- Component code and unit number
- Date & Time of Transfusion

11.3.9 A hard copy of traceability labels are retained by the IBTS for 30 years as per IBTS/DP/POL/0002 and as required under SI 547.

11.4 Diagnostics Laboratory as Referral Laboratory

11.6.1 Where the Diagnostics laboratory acts as a referral laboratory, it is the responsibility of the referring Hospital Blood Bank to manage traceability of the unit.

11.5 Re-routing of blood

11.6.1 Where the Diagnostics laboratory acts as the HBB, crossmatched blood or Emergency stock O Negative blood that has not been transfused may be re-routed to an approved hospital blood bank under the Red Cell Optimisation scheme as detailed in IBTS/DIAG/SOP/0115.

11.6.2 When blood is re-routed to CUH, the BT – 0396 remains on the units for transfer. CUH confirm receipt of re-routed blood by sending a completed "Notification to MRTC of Intended Transfer of units / Receipt of Intended Transferred Units of Red Cells". Blood bank staff in CUH remove the BT – 0396 labels. Labels are then stamped, signed & dated before being returned to the Diagnostics laboratory.

11.6.3 When blood is re-routed to Mater Private Dublin, the HVO in Cork Mater Private removes the BT – 0396 prior to transfer. Labels are then stamped, signed & dated before being returned to the Diagnostics laboratory. Mater Private Dublin confirm receipt of re-routed blood by sending a completed "Blood Component Transfer Form".

11.6 Unused Blood Components

11.6.1 Where a blood component is issued by the Diagnostics laboratory as HBB but is NOT transfused and cannot be re-routed as per section 11.5, the unit and the attached BT – 0396 should be returned to the IBTS for discard. The traceability tag must be returned to the IBTS to ensure proper fating.

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

11.7.1 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.

11.7.2 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. Ref *IBTS/QA/QM/0001 and IBTS/QAV/SOP/0002.*

11.7.3 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. Ref *IBTS/QA/QM/0001 and IBTS/QAV/SOP/0002.*

11.7.4 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".

11.7.5 Where the Diagnostics 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.

11.7.6 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.

11.7.7 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 Diagnostics Laboratory immediately, by telephone, to ensure prompt recall of co-components where indicated.

11.7.8 Serological transfusion reaction investigations are undertaken as per *IBTS/DIAG/SOP/0063.* Blood component suspected adverse reactions are progressed through the IBTS Complaints Procedure as outlined in *IBTS/QA/SOP/0063*.

11.7.9 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.

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

11.7.11 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 as per the NHO Handbook.

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

11.7.13 The IBTS Biovigilance Officer will assess all potential SAEs occurring in relation to the diagnostic services provided to hospitals by the Diagnostics 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 according to *IBTS/QAV/SOP/0002.*

11.7.14 A review of serious adverse reactions and serious adverse events is performed at the Diagnostics Quality Review Meetings and should also be undertaken at each Hospital Transfusion Committee Meeting. The review is performed at the Diagnostics Quality Review Meetings as per IBTS/DIAG/SOP/0055. The IBTS Consultant Haematologist will attend such meetings.

11.7.15 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, Diagnostics Chief Medical Scientist & Biovigilance Officer. SAEs and SARs are discussed at this meeting.

11.7.16 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.

11.7.17 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.

11.7.18 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.

12 REFERENCES

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

12.2 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]

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

12.4 S.I. No. 360 / 05 - European Communities (Quality and Safety of Human Blood and Blood Products) Regulations 2005. [IBTS/EXT/DOC/0012].

12.5 S.I. No. 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].

12.6 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].

12.7 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].

12.8 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].

12.9 ISO 15189. Medical Laboratories – Particular requirement for quality and competence, 2012,. International Organisation for Standardisation. [IBTS/EXT/DOC/0033].

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

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

12.12 The administration of blood components: a British society for haematology guideline, 2018. [IBTS/EXT/DOC/0067]

13 ATTACHMENTS

13.1 List of Customers for which Diag Lab provide referral testing services

13.2 List of Customers for which Diag Lab provides blood bank services

List of Customers for which Diag Lab provide referral testing services

Customers for which Diagnostics Laboratory provide referral testing services
Cork University Hospital
Bon Secours Hospital Cork
Mercy University Hospital
University Hospital Kerry
Bon Secours Hospital Tralee
University Hospital Limerick
Mallow General Hospital
Tipperary University Hospital

List of Customers for which Diag Lab provides blood bank services

Customers for which Diagnostics Laboratory provide HBB services
Cork Mater Private
South Infirmary Victoria University Hospital
St Finbarr's Hospital
Marymount University Hospital and Hospice