



Document Detail

Type: DIAG IBTS UG
Document No.: IBTS/DIAG/UG/0002[1]
Title: **USER GUIDE FOR DIAGNOSTICS LABORATORY, MRTC**
Owner: QA DOC CON QA DOC CONTROL
Status: CURRENT
Effective Date: 24-Mar-2020
Expiration Date: 24-Mar-2022

Review

Review: IBTS DOC REVIEW AND APPROVAL

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	DEBBIE MAC RORY	DEBBIE MAC RORY
2	DIAGNOSTICS WRITER MRTC	AILEEN GRIFFIN	AILEEN GRIFFIN
3	DIAGNOSTICS HEAD OF DEPT MRTC	KEVIN SHEEHAN	KEVIN SHEEHAN
3	DIAGNOSTICS HEAD OF DEPT NBC	EDEL SCALLY	EDEL SCALLY
4	IT QM REVIEWER IBTS	ELIZABETH GORDON	REBECCA WALDEN
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN O'LEARY	COLIN O'LEARY

Review: IBTS DOC REVIEW AND APPROVAL

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	DIAGNOSTICS WRITER MRTC	AILEEN GRIFFIN	AILEEN GRIFFIN
3	DIAGNOSTICS HEAD OF DEPT NBC	EDEL SCALLY	SMARTCOMM
3	DIAGNOSTICS HEAD OF DEPT MRTC	AILEEN GRIFFIN	AILEEN GRIFFIN
3	Head of Testing IBTS	PADRAIG WILLIAMS	PADRAIG WILLIAMS
4	IT QM REVIEWER IBTS	ELIZABETH GORDON	REBECCA WALDEN
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN O'LEARY	COLIN O'LEARY

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/0026/19

TITLE: USER GUIDE FOR DIAGNOSTICS LABORATORY, MRTC**Change Description:**

Create new document IBTS/DIAG/UG/0002 which is “USER GUIDE FOR DIAGNOSTICS LABORATORY, MRTC”

Reason For Change:

- To have separate user guides for Diagnostics MRTC and RCI Lab NBC
- Introduce new version of user guide which details the services provided by the Diagnostics laboratory, MRTC
- Create a user friendly document for service users.

Change Order No.:

IBTS/CO/0026/19

Referenced Procedures

BT – 0007
 BT – 0311
 BT – 0345
 BT – 0597
 IBTS/MED/SOP/0050
 IBTS/QA/SOP/0068

SmartSolve Roles

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

Training Type

Staff Trained in Previous Version	New Staff
Read Only	Procedural Training (Read Through with Trainer)

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
No	No	No	Yes	No

TITLE: USER GUIDE FOR THE DIAGNOSTICS LABORATORY, MRTC

1.0 INTRODUCTION

- 1.1** This guide is designed to provide an overview of the services available from the Diagnostics Laboratory at the Munster Regional Transfusion Centre. It is intended for the users of both the routine compatibility services and of the referral immunohaematology service provided by the Diagnostics Laboratory MRTC.
- 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 Areas covered by The Munster Regional Transfusion.
- 1.3** This guide specifies the minimum requirements for the labelling of samples and for the completion of request forms to ensure sufficient information is received for the requested service to be optimally delivered. The IBTS will accept correctly completed blood request forms / service requests from designated facilities requesting its service provided the pertinent details are completed and the samples accompanying the forms meet the current specified criteria. Authorised personnel will review test request documentation to determine suitability of tests requested (standard investigations, reference investigations and urgent requests).
- 1.4** The 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 (SI 360 of 2005, SI 547 of 2006, SI 562 of 2006).
- 1.5** The laboratory complies with SI 547 of 2006 incorporating Articles 14 and 15 of Directive 98/2002/EC (Traceability Requirements, Notification of SAR/E). The laboratory is committed to obtaining the International Standard ISO 15189.
- 1.6** The laboratory operates to internal policies and procedures for all activities as defined by the IBTS Quality Management System. This manual is a controlled document as part of that System. All red cell referral & compatibility services undergo continuous review through quality assurance and audit activities.
- 1.7** Samples are disposed of by the IBTS laboratories in accordance with IBTS Health and Safety procedures and, in compliance with waste management regulations.
- 1.8** This user guide should be read in conjunction with the IBTS product master files.
- 1.9** IBTS laboratory management is committed to the provision of a full and effective service. To this end it ensures:
- Optimum staff recruitment, training, development and retention at all levels.
 - Procurement, validation and maintenance of appropriate equipment /resources.
 - Maintaining sample integrity and thereby the correct performance of laboratory examinations.
 - Use of examination procedures that are fit for purpose and ensure the highest achievable quality.
 - Timely, confidential, accurate and clinically useful reporting of examination

results.

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

Verify when in Use. Status CURRENT Effective 24 March 2020

Table of Contents

Training Type	2
2.0 USING THIS GUIDE.....	6
3.0 DIAGNOSTICS LABORATORY QUALITY POLICY.....	6
4.0 GENERAL INFORMATION.....	7
4.1 Diagnostics Laboratory, MRTC	7
4.2 Laboratory Directors	8
4.3 Service Operating Times	8
4.4 Tests & Services Provided	9
4.5 Key Personnel & Contact Details	10
4.6 Sample Testing Schedule	11
4.7 Turnaround Times	12
4.8 Service Fees and Charges	13
4.9 Data Protection where samples are referred to IBTS	13
5.0 LABORATORY REQUEST FORMS, SAMPLE TUBES AND CONTAINERS.....	13
5.1 General Information: Re Samples and Forms.....	13
5.2 General Information Re Sample Collection.....	14
5.4 Sample Labelling.....	17
5.5 Sample / Request Card Acceptance / Rejection.....	18
5.6 Non-Conforming Samples / Request Forms or Sample Quality Issues	18
5.7 Exceptions.....	19
5.8 Timing of Sample Collection	19
5.9 Sample Storage.....	20
6.0 SAMPLE DELIVERY, PACKAGING AND TRANSPORT REQUIREMENTS	20
6.1 Sample Delivery.....	20
6.2 Sample Packaging and Transport	20
7.0 EXTERNAL AND INTERNAL QUALITY ASSESSMENT PROGRAMMES	21
7.1 External Quality Assessment Programmes (EQA)	21
7.2 Internal Quality Assessment Programme	21
7.3 Licensing / Accreditation	22
7.4 Major Non-Conformance / Failure in an External Quality Assurance Scheme	22
8.0 LABORATORY TESTS AND SERVICES.....	22
8.1 Services provided by the MRTC Diagnostics Laboratory	22
8.2 Pre-transfusion Compatibility & Specialised Immunohaematological Testing.....	22
8.3 Referral Test Services	26
8.4 Provision of Blood Components.....	30
8.5 Medical & Scientific Consultancy Service	34
8.6 Haemovigilance Advisory Service.....	34
8.7 Repeat Examination.....	34
8.8 Further Examination of the Primary Sample.....	34
9.0 REPORTING OF TEST RESULTS.	35
9.1 Approval of Test Results and Issuing Reports.....	35
9.2 Issuing Reports on Critical Samples where the Results are delayed	36
9.3 Reporting of Results by Fax	36
9.4 Telephoned Results	36
9.5 Archiving of Patients Records:	37
10.0 REVIEW & ASSESSEMENT OF CUSTOMER SATISFACTION	37
10.1 Service Level Agreements	37
10.2 Customer Complaints	37
10.3 Quality Management Review	38
10.4 Customer Liaison	38
10.5 Hospital Transfusion Committees	38
10.6 Continuous Improvement.....	38
11.0 TRACEABILITY AND REPORTING OF SERIOUS ADVERSE REACTIONS (SARS) AND SERIOUS ADVERSE EVENTS (SAES)	38
11.1 Traceability	38
11.2 Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs)	39

2.0 USING THIS GUIDE

- 2.1 A copy of this User Guide is available on the internet at:
<https://www.giveblood.ie/Clinical-Services/Red-Cell-Immunohaematology-Diagnostics/Diagnostic-Laboratory-User-Guide.pdf>

Hard copies of the User Guide will not be supplied.

- 2.2 When key changes are made to either the tests or the services identified in this manual, the customer will be notified in writing. The electronic copy of the manual will be modified and made available to the customer.
- 2.3 The term ‘BSH Guidelines 2012’ shall refer to ‘Guidelines for pre-transfusion compatibility Procedures in Blood Transfusion Laboratories’ British Committee for Standards in Haematology, 2012, throughout the document.
- 2.4 The term ‘Hospital Blood Transfusion Laboratory’ is used to describe the Blood Transfusion Laboratories in hospitals to which the Diagnostics Laboratory provides a referral service.
- 2.5 The term ‘Hospital Blood Bank’ is used to describe the situation where the Diagnostics Laboratory acts as an institution’s Hospital Blood Bank.

3.0 DIAGNOSTICS LABORATORY QUALITY POLICY

The Diagnostics Laboratory strives to be a centre of excellence.

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

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

4.0 GENERAL INFORMATION

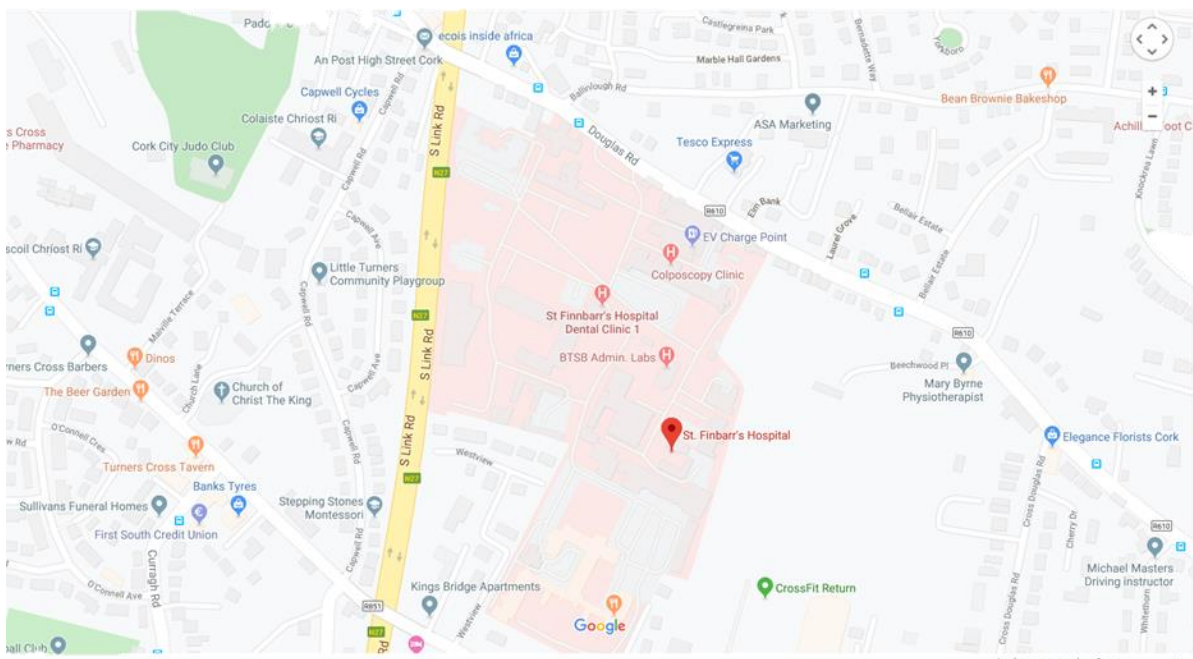
4.1 Diagnostics Laboratory, MRTC

These user manual details the services provided by the:

- Diagnostics Laboratory, Munster Regional Transfusion Centre

4.1.1 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).

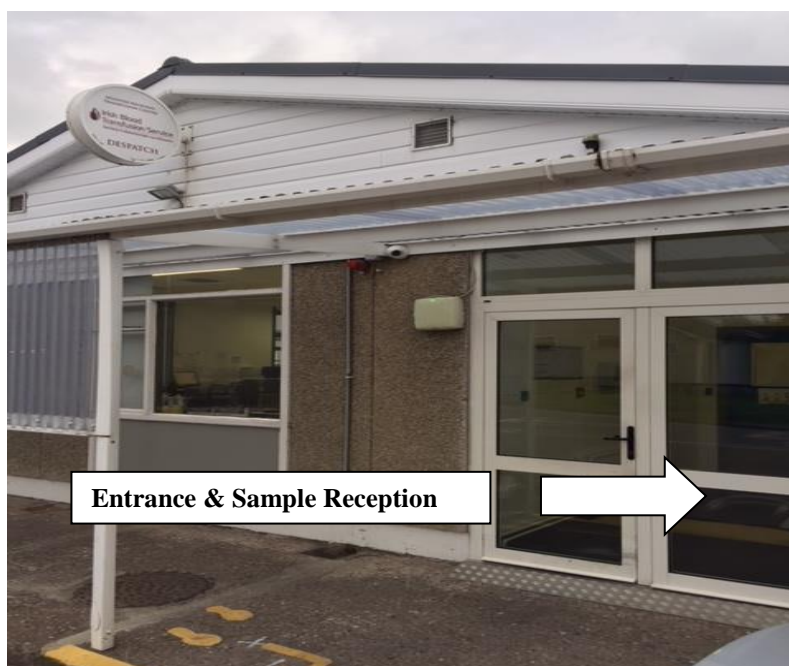


Postal Address: Diagnostics Laboratory
Munster Regional Transfusion Centre
St. Finbarr's Hospital
Douglas Road
Cork
T12 Y319
Tel.: (021) 4807400
Fax: (021) 4323315

Scope of Activity: The Diagnostics Laboratory at the MRTC provides a specialist red cell immunohaematology service to hospital blood transfusion laboratories in the Munster area. It also provides hospital blood bank services to 4 hospitals:

1. South Infirmary Victoria University Hospital
2. St Finbarr's Hospital
3. Cork Mater Private Hospital
4. Marymount University Hospital & Hospice

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



4.2 Laboratory Directors

The Diagnostics laboratory is directed by a Consultant Haematologist:

Diagnostics Laboratory (MRTC): Dr Joan Power/Professor Ian Hann

4.3 Service Operating Times

Department/Activity	Opening Hours MRTC
Routine Laboratory	Monday to Friday 7:00am to 19:00pm Excluding Bank Holidays
Emergency Out of Hours Service* (On-Call Service)	Monday to Friday: 19:00 to 7:00 am (Scientist on Site) Saturday, Sundays & Bank Holidays: Scientist On-Site 24 hours
Sample Reception	Despatch: 24 Hours

* The emergency out-of-hours service is for non-deferrable tests that are necessary for patient management. Requests for elective surgical procedures will not be processed out of hours.

4.4 Tests & Services Provided

The table below lists the test procedures provided by the Diagnostics Laboratories and identifies the site(s) at which the test is available. **(Ctrl & Click on the page no. indicated to move to the relevant section of this manual where full details are provided)**

Test / Service	Page
Antenatal Antibody Titration	24
Antibody Investigation	24
Investigation of Autoimmune Haemolytic Anaemia (AIHA)	24
Blood Group/Antibody Screen	24
Blood Group/Compatibility Testing	24
Blood Group/Compatibility Testing for Patients with Red Cell Antibodies	24
ABO Blood Group Anomaly Investigation	24
Direct Antiglobulin Test	25
Eluate	25
Extended RBC Phenotyping	25
Investigate Monoclonal Antibody Interference	25
Investigation of Haemolytic Disease of the New-born (Where maternal red cell antibodies are implicated / suspected)	25
Transfusion Reaction Investigation (Where crossmatch performed at IBTS)	25/26
Transfusion Reaction Investigation (Sample Referred for Transfusion Reaction Investigation)	26
Investigation of Cold Reactive Antibodies	26
Referral Test Services	27
BGGL, NBC: Weak D genotype & full RBC genotype	28
IBGRL: Complex Immunohaematological Investigation	28
NHSBT: Investigation of IgA Deficiency & IgA Antibodies	28
NHSBT: Cold Agglutinins/CHAD Investigation	29
Other Services	
Provision of Blood Products & Components	30
Clinical & Scientific Consultancy Services	
Haemovigilance Advisory Services (Hospital Blood Bank Service ONLY)	

4.5 Key Personnel & Contact Details

SECTION	MRTC
Consultant Haematologist	Dr Joan Power/Prof Ian Hann 021-4807400 or Specialist Medical Officer on duty 021-4807400
Chief Medical Scientist	Mr Kevin Sheehan 021-4807400
Laboratory Office	021-4807409/ 4807427
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.
Platelet Issue	<u>Hospital Blood Bank Service ONLY</u> *(see below) Routine Hours (07:00 am – 19:00 pm): 021-4807417/ 4807418 Out-of-Hours: 021-4807400 (Switch) or 021-4807419 (Despatch)
Laboratory Fax No.	021-4323315
Switch	021 4807400
Emergency Contact No. (Despatch)	021-4807419

* All other platelet orders (i.e. from Hospital Blood Transfusion Laboratories) are dealt with through the Electronic Online Ordering System,
<https://www.giveblood.ie/Clinical-Services/Hospital-Services/Online-blood-ordering-system.pdf>

4.6 Sample Testing Schedule

4.6.1 Routine Service

4.6.1.1 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.

4.6.1.2 Hospital Blood Transfusion Laboratories (Referral Service)

Samples are processed based on clinical need (with the exception of batched tests – see below). In general, Samples for serological investigation received before 9am will be processed on the same day. Samples which are referred for antibody investigation and provision of blood will be prioritised for testing during the routine working day. **The cut off time for sample receipt for provision of blood during the routine working day is 1 pm (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.

Samples for antenatal antibody titration/quantitation will be batched and processed to meet the test turnaround times specified in Section 8.2.

4.6.2 Emergency Service

4.6.2.1 Hospital Blood Bank Service

The IBTS 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 uncrossmatched blood at the South Infirmary Victoria University Hospital and the Cork Mater Private Hospital only.

4.6.2.2 Hospital Blood Transfusion Laboratories (Referral Service)

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

4.6.2.3 How to Request 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 4.5 for contact details).
- * Out of hours: Contact switch and request to speak to the medical scientist or medical personnel on-call (refer to Section 4.5 for contact details).
 - Requests for emergency services / compatibility testing out of hours will be assessed in accordance with the urgency of the request by the IBTS Specialist Medical Officer (Spume) / Registrar / Consultant Haematologist.

4.6.2.4 Procedure to be followed for Urgent Requests

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

- Hospital / ward
- Name of person making the request and contact details
- The urgency of the request (date and time required) and estimated time of Sample arrival
- Patients name (if known), hospital number and date of birth

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

- Number and type of component requested
- Blood Group, ABO/ Rh/ K type, if known (from referral laboratory only), serology results at the referring site & details of known antibodies
- Reason for transfusion
- Transfusion history (if known)
- Relevant clinical condition
- Current haemoglobin
- If the patient is bleeding or not

Note:

1. Where a clinical condition dictates that a transfusion is required prior to the completion of testing, the transfusion support may vary depending on the degree of clinical urgency, the availability of an emergency stock of red cells on site at the hospital and prior availability of the patient's Sample and validated blood group at the IBTS.
2. Where blood is required urgently but prior to the completion of compatibility testing and the patient's Sample is not known to contain clinically significant antibodies, transfusion support will be provided by the IBTS or issued from the hospital's own stock.
3. Where antibodies are detected in the patient's Sample, the relative risks of abbreviated testing prior to emergency transfusion will need to be discussed between the IBTS Consultant Haematologist/ Registrar/ SpMO and the clinician in charge at the hospital.
4. Where there is concessionary release of a product/component or a deviation from standard procedure a concessionary release will be authorised by the IBTS Consultant Haematologist/ Registrar/SpMO following consultation with the patient's attending clinician (in accordance with IBTS/MED/SOP/0050).

4.7 Turnaround Times

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

4.7.1 Non Compliance with the Turnaround Times

- Turnaround times are routinely monitored as part of the laboratories quality improvement programme.
- Should there be a significant delay in the expected turnaround times, the requestor will be notified. In the instances where the delay could compromise patient care, the medical/ clinical personnel will be notified.
- The requesting facility must inform the laboratory of any change in the urgency of the blood so that appropriate action can be taken.

Note:

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

4.8 Service Fees and Charges

4.9 Data Protection where samples are referred to IBTS

Under data protection acts 1988 and 2003, IBTS Diagnostics laboratories acts as a DATA PROCESSOR for the referring laboratory/organisation when samples are referred for testing to IBTS. This testing provides diagnostic testing for patients of the referring laboratory. The referring laboratory is the DATA CONTROLLER.

5.0 LABORATORY REQUEST FORMS, SAMPLE TUBES AND CONTAINERS

5.1 General Information: Re Samples and Forms

- It is the policy of the IBTS laboratories to treat all diagnostic 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 diagnostic 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 relevant IBTS laboratory.
- Sending haemolysed and/or lipaemic samples should be avoided where possible as free haemoglobin and/or fatty plasma can produce test result errors (especially when using automated equipment). Such samples may have to be rejected. However, it is recognised that there are situations when haemolysis, in particular, is a result of the patient's condition.
- Samples referred to the IBTS laboratories should conform to the requirements for the timing of Sample collection, as defined in Section 5.8.
- Samples should be transported promptly to the relevant IBTS laboratory. (Samples should not be stored overnight in transport vehicles.)
- Samples must not be exposed to direct sunlight or extremes of temperature; samples should be transported in an ambient temperature range (2 – 25°C) unless otherwise specified in Section 8.2. If Samples are required to be stored prior to referral to the IBTS laboratory, they should be stored at 2-8°C (exceptions are details in Section 8.2).
- Sample forms/ packaging are date and time stamped on receipt at the IBTS.
- On receipt in the laboratory, Samples are registered on our eTraceline Computer System. The system automatically creates a unique sample number. All Samples are also recorded in a registration log book, as per Standard Operating Procedures. All stored aliquots from the primary Sample are labelled with the assigned IBTS Sample number.
- IBTS scientific staff will review request forms and Samples against pre-defined acceptance criteria to determine if they are suitable for the tests requested. Where it is determined that the request form and/or Sample is not suitable, the requesting hospital will be informed.

▪ **Note:**

1. Incorrect or incomplete forms/ Samples may result in the tests not being undertaken and may require a second Sample to be submitted resulting in increased turnaround times with service delay.
2. Requests for test(s) in the Diagnostics Laboratories where they act 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 Laboratories are referred to specialist external laboratories.

5.2 General Information Re Sample Collection

5.2.1 Where the MRTC laboratory acts as Hospital Blood Bank

One sample is acceptable for requests for group and antibody screening / cross-matching.

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

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

Re referral of crossmatch requests to the Diagnostic Laboratory

- On a case-by-case basis and following discussion with the Diagnostics Laboratory, the referring Hospital Blood Transfusion Laboratory may send **segments** from suitable units for crossmatching at the Diagnostics laboratory in conjunction with the sample. This is to expedite the provision of blood to the patient or where units of a particular phenotype are required and are already available from the referring hospital's blood stocks. N.B. Segments must be labelled with the ISBT no. of the donor unit.
- 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.

5.2.3 Service Requestor responsibilities include:

- Obtaining consent from the patient for the tests required at the IBTS RCI/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 IBTS laboratories 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 IBTS RCI/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.

5.3 Diagnostic Laboratory Request Forms

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

Hospital Blood Transfusion Laboratories (Referral Service)

BT. 345 Request for Red Cell Immunohaematology Investigation Form

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

A BT7 form is also acceptable for sending reference samples.

Hospital Blood Bank Service Forms

BT.7 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.

BT.311 Transfusion Reaction Investigation Form

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

BT.597 Haemovigilance Clinical Review Form

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

5.3.2 Process for ordering the IBTS Request Forms.

All of the forms with the exception of the BT 345 are available on request from IBTS centres by contacting personnel in the following departments:

Despatch Department (021-4807419 / 021-4807420)

Diagnostics Laboratory (021-4807417 / 021-4807418)

The BT345 form may be printed from the IBTS website www.giveblood.ie by following the link:

<https://www.giveblood.ie/Clinical-Services/Red-Cell-Immunohaematology-Diagnostics/RCI-Test-Request-Forms/BT345>

5.3.3 Completion of Request Forms

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

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

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

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

5. Patient's gender
6. Patient's ethnicity
7. Location [referring hospital and ward (if given)]
8. Patient's address (* mandatory requirement if hospital number not applicable – see above)
9. Details of the requesting clinician and their contact details
10. Date (and time where blood is requested) 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 BT7 Request Form. Laboratory staff should ensure that all details on the BT7 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 BT7 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.

5.4 Sample Labelling

5.4.1 Mandatory Requirements

The following essential information is **MANDATORY** on all Samples referred to the IBTS and should be documented in a legible manner on the Sample container:

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

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

Note:

All patient Samples and forms must be labelled at the bedside to prevent misidentification and labelling errors.

5.4.2 Labels on Sample Tubes

- Sample tubes must never be pre-printed or pre-labelled.
- The Service Requestor's responsibility is to ensure that all printed labels for Samples for blood transfusion testing are generated at the bedside and are compliant with 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 MRTC Diagnostics Laboratories. Otherwise labels on samples must be handwritten.
- Labels **pre-printed** away from the bedside or taken from the patient’s notes (e.g. **addressograph** labels) are **not** acceptable on Samples for processing. A repeat Sample will be required.

5.5 Sample / Request Card Acceptance / Rejection

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.

5.5.1 Samples are accepted for testing if they are:

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

5.5.2 Samples may be rejected in the following circumstances:

1. They are of an inappropriate sample type
2. They have leaked in transit
3. They are insufficient for testing
4. They are grossly haemolysed
5. They have been separated prior to referral
6. The sample and request form are mismatched, or the information is not correct
7. There is insufficient information on the sample and/or the request form.
8. There is significant delay in receipt of sample from date/time of collection resulting in sample invalidity/instability

5.6 Non-Conforming Samples / Request Forms or Sample Quality Issues

If a sample/request is identified as unacceptable the referring laboratory/location or requestor (as appropriate) will be contacted and advised of any required corrective action or the need for a repeat sample in accordance with laboratory SOP. On occasion, rejected samples may be tested (see Section 5.7 Exceptions). In these instances, results reported will bear an appropriate caveat indicating the nature of the problem. A report will be generated for all rejected samples stating the reason for rejection.

5.7 Exceptions

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

- Trauma, unconscious, or Emergency Department patients where the identity is not yet established. The minimum clinical information supplied must include: (1) a unique number, (2) gender and (3) approximate age. It is helpful to be informed of the ethnicity of the patient.
- Where a repeat Sample would be difficult to obtain and the result of testing is not to be used for transfusion purposes.
- Where the delay in acquiring a new Sample might seriously prejudice a successful clinical outcome.
- Where the Sample cannot be replaced, e.g. pre transfusion Samples post transfusion reaction, Samples taken at specific time periods e.g. foetal Samples.

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

The decision to process the Sample may require approval by the consultant at the IBTS.

In all those instances the test report will identify and reflect the non-conforming issue.

5.8 Timing of Sample Collection

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

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

Guidelines for the Collection of Samples from Previously Transfused Patients

Patient Category	Sample to be taken not more than
Patient transfused or pregnant in the last 3 months	72 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. A risk assessment should be performed and transfusion management plan agreed by the IBTS and referring Hospital Consultant Haematologists.

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

5.9 Sample Storage

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

5.9.1 Guidelines for the Storage of Samples: Pre-Testing

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

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

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

5.9.2 Routine Referrals

Where samples are not being referred to the laboratory on the date collected they should be refrigerated at 2-8°C prior to transport unless otherwise specified in Section 8.2.

6.0 SAMPLE DELIVERY, PACKAGING AND TRANSPORT REQUIREMENTS

6.1 Sample Delivery

Diagnostic Samples will be accepted by MRTC laboratories at **any time**. They should be delivered to Despatch.

Refer to Section 4.1 for map & picture of locations.

Note:

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

6.2 Sample Packaging and Transport

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

6.2.1 International Carriage of Dangerous Goods by Road

The packaging, labelling and transportation of all Samples must comply with current European Agreement concerning Carriage of Dangerous Goods by Road Regulations. The requirements stated below apply to all diagnostic Samples directed to the MRTC 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 should be sent directly to the laboratory (see Note 2 below).
- The Sample and the request form should be packaged so as to ensure patient confidentiality at all times during transportation.

Note 1:

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

Note 2:

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

7.0 EXTERNAL AND INTERNAL QUALITY ASSESSMENT PROGRAMMES

7.1 External Quality Assessment Programmes (EQA)

The 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
- Lab Quality (Finnish External Quality Assurance Scheme)

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.

7.2 Internal Quality Assessment Programme

Internal controls are included in all tests: no tests can be accepted or reported unless control results are acceptable.

All test procedures are covered by Standard Operating Procedures and only trained and authorised staff may perform procedures. Staff competency is also assured before a staff member may perform a procedure. All procedures are regularly reviewed.

7.3 Licensing / 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 Licensing Authority. The IBTS Blood Establishment is licensed under BE Number 0002.

7.4 Major Non-Conformance / Failure in an External Quality Assurance Scheme

Major non-conformances are managed by controlled procedures, with investigation, corrective and preventative actions and review of practices, taken as appropriate. The 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.

8.0 LABORATORY TESTS AND SERVICES

8.1 Services provided by the MRTC Diagnostics Laboratory

- **Pre-transfusion Compatibility / Specialised Immunohaematological Testing**
- **Referral Test Services**
- **Provision of Blood/Blood Components for Transfusion**
- **Medical and Scientific Consultancy Service**
- **Haemovigilance Advisory Service**

8.2 Pre-transfusion Compatibility & Specialised Immunohaematological Testing

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

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

Note 1

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

Note 2

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

Test Profile	Sample type (fresh venous Sample)	Sample volume	Service details and requirements	Turnaround time test
Antibody Titration	EDTA Whole Blood (WB)	1 x 6 ml	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 4.6) Emergency: Processed immediately on receipt Contact MRTC laboratory in advance	Routine: Results usually available in 24 hrs. Report sent next working day Emergency: ASAP - within 2 hours of receipt of Sample if no antibodies detectable
Blood Group and Compatibility Testing ROUTINE or EMERGENCY *	EDTA (WB)	1 x 6 ml	Routine requests processed on next batch Urgent/emergency requests: Processed immediately on receipt Contact MRTC laboratory in advance	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 MRTC laboratory in advance Progress can be discussed by telephoning the MRTC laboratory <i>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</i>	2-6 hours Please note this is dependent on the complexity of antibodies detected.

			<i>& already available from the referring hospitals blood stocks N.B. Segments must be labelled with the ISBT no. of the donor unit.</i>	
ABO Blood Group Anomaly Investigation (Serological)	EDTA (WB)	1 x 6 ml	Telephone in advance if blood is required for patient	5 working days
Direct Antiglobulin Test	EDTA (WB)	1 x 6 ml	Next scheduled batch (See section 4.6)	2 working days Where antibodies are present and need to be investigated, turnaround time will be 5 working days
Eluate	EDTA (WB)	1 x 6 ml	An eluate is only warranted if the patient has been transfused within the last month or there is evidence of haemolysis (or a delayed haemolytic transfusion reaction). Telephone in advance if blood is required for patient	2 working days
Extended RBC Phenotyping	EDTA (WB)	1 x 6 ml	Extended phenotyping is recommended for transfusion dependant patients and patients with complex red cell antibodies. To be suitable for serological phenotyping the patient must not have been transfused within the previous 3 months and must have a negative direct antiglobulin test. Samples not fulfilling these conditions will be forwarded for genotyping to	5 working days
Investigate Monoclonal Antibody Interference	EDTA (WB)	1 x 6 ml	Progress will be discussed with requestor by telephone	5 working days
Investigation of Haemolytic	EDTA (WB)	1 x 6 ml	Note: Investigations will be limited	Results phoned within 1

Disease of the New-born where maternal antibodies are implicated / suspected *	(Mother's Sample) EDTA (WB) (Baby's Sample)	1-3 ml	to Red Cell Serological studies Processed in next scheduled batch (See section 4.6) Must be telephoned in advance	working day
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 + 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 registrar on duty / on call, for direction Please return implicated unit (if available) and the administration set (if possible). (Even an 'empty pack' may provide a sample from an attached segment) The remaining un-transfused units must be quarantined at the hospital or returned to the IBTS, pending medical release. Part B (white) of the traceability label (BT396) must not be removed from the units when returning to the IBTS.	ASAP 2-5 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

<p>Transfusion Reaction Investigation * Referred Samples from Hospital Blood Transfusion Laboratories where the initial crossmatch was performed by the Referring Laboratory</p>	<p>EDTA (WB)</p> <p>Pre Transfusion Post transfusion + A clotted post transfusion sample should also be referred where possible</p>	<p>1 x 6 ml (Pre) 2 x 6 ml(Post)</p> <p>1 x 6 ml clotted (if required)</p>	<p>Must be telephoned in advance. Progress will be discussed with requestor</p> <p>Segments from pack affected should be submitted where a crossmatch has to be done. The segment will need to be labelled with the ISTB Number of the donor unit.</p>	<p>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</p>
<p>Investigation of Cold Reactive Antibodies</p> <p>(Investigation comprises antibody screen & identification at 18°C as necessary)</p> <p>See also Investigation for Cold Agglutinins/CHAD under Referral Services</p>	<p>EDTA (WB) (Sample for investigation to be taken @ 37°C and remain @ 37°C during transportation/until separated)</p> <p>Recommended to be transported in validated thermal flask</p>	<p>1 x 6 ml</p>	<p>Contact the laboratory in advance</p>	<p>5 working days</p>

Note: Where two samples are requested, exceptions may be made for patients where blood is difficult to obtain such as neonatal or paediatric patients.

8.3 Referral Test Services

A variety of molecular tests that were formerly referred to the International Blood Group Reference Laboratory (IBGRL) are now available at the IBTS Molecular Biology and Genetics Laboratory 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)

- RHD Variant Investigation (includes normal RHCE determination)
- RHCE Variant Investigation
- Fetal Blood Group Determination
- Molecular Investigation of Other Blood Groups

The IBTS act as the national facilitator for the referral of samples to NHSBT Sheffield for the investigation of IgA deficiency, IgA antibodies and Cold Agglutinins. In addition following investigation by the 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/>. Please complete the BT7 request form when sending samples to the Diagnostics Laboratory for onward referral to the relevant referral laboratory.

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 Page 29. 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 IBGRL & NHSBT Sheffield 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	<p>Samples are accepted from overseas reference laboratories ONLY.</p> <p>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.</p> <p>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.</p>	<p>The time between receipt of sample and reporting will depend on the urgency of the case and the number of samples in the laboratory at any given time (which is out of the control of the IBGRL). Priority is always given to urgent cases and therefore non-urgent investigations may be necessarily delayed. The referrer will be informed if there is to be undue delay in starting an investigation for this reason.</p>
Investigation of IgA Deficiency & IgA Antibodies	NHSBT Sheffield	EDTA (WB)	2 x 6ml	<p>In cases of anaphylactic transfusion reactions, or other indications</p> <p>Samples for investigation should be directed to the MRTC Laboratory for on-ward referral to the external laboratory.</p>	<p>Results are generally available from the NHSBT within 7 - 14 working days of Sample receipt</p> <p>Repeat testing will incur an extension to the turnaround time and possibly may require repeat sampling</p>

Test profile /service	Centre	Sample type (fresh venous Sample)	Sample volume	Service details and requirements	Turnaround time test
<p>Cold Agglutinins/CHAD Investigation</p> <p>(Investigation comprises DAT, room temperature screen, cold titre, thermal amplitude as necessary.)</p>	NHSBT Sheffield	<p>EDTA (WB)</p> <p>Serum sample * (separated at 37C)</p>	<p>2 x 6 ml</p> <p>1 x 6ml *</p>	<p>* Send the primary Sample tube of the separated sample tube that is labelled with the patient identifiers</p> <p>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.</p> <p>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.</p> <p>Cold agglutinin titres can be performed on request.</p>	<p>Result available within 5 working days of Sample receipt by NHSBT.</p> <p>Report will be despatched by the Diagnostics Laboratory following receipt of same.</p>

8.4 Provision of Blood Components

8.4.1 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 on the website www.giveblood.ie

Note:

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

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: <ul style="list-style-type: none"> 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)
Washed components / 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)

8.4.1.1 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 and O RhD Positive only 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.

- **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 antigen profiles and where appropriate; a request will be made to an International Rare Blood Bank Programme for the required number of units (either from current stock, following donor call up or frozen blood stocks).

Each individual case will be discussed with the IBTS medical staff and authorised on a Consultant to Consultant basis, to determine the exact requirements for individual patients and advise of associated difference in transfusion risk profile as appropriate. Procurement of product is dependent on the availability of the blood. A minimum of 48 hours is required to import the blood. Please provide the maximum notification possible for this service.

Note:

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

8.4.1.2 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.

8.4.2 For Hospitals (Where the MRTC is the direct provider of Hospital Blood Bank Services)

Services are provided by the Diagnostics Laboratory:

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

* 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.

¥ Consultation with IBTS Medical Staff is required.

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

8.4.3 Concessionary Release of Blood Components or Blood Products

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

Conditions which require concessionary release procedure:

- Use of D positive blood for a D negative patient who would normally be excluded from receiving D positive units.
- Use of antigen positive or un-typed red cells in patients with atypical red cell antibodies.
- Issue of red cells to patients with autoimmune haemolytic anaemia (AIHA) without the necessary exclusion of underlying antibodies.
- Issue of components that do not meet known special requirement, e.g. CMV negative or irradiated.

- Where it is necessary to act contrary to a Standard Operating Procedure in the best interest of a patient this will be handled in accordance with relevant IBTS Quality Assurance Documentation.

The event will be recorded on a **Concessionary Release** form. The name and designation of the requesting clinician who has agreed to accept the concession for the patient will be recorded along with the details of the IBTS Clinician who has authorised the release of the blood product/component. A copy will be sent/faxed to the hospital blood transfusion laboratory; or to the requesting clinician where the IBTS laboratory provides Hospital Blood Bank services.

8.5 Medical & Scientific Consultancy Service

The IBTS will provide medical and scientific advice for all the above services. These services are available at all times with respect to blood transfusion practice. For contact names and numbers see **Section 4.5** of this manual.

8.6 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.

8.7 Repeat Examination

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

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

8.8 Further Examination of the Primary Sample

8.8.1 In-House Testing

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.

8.8.2 Referral to another Laboratory for Further Investigations

Should additional testing be required on a Sample based on the results obtained by the IBTS laboratory, e.g.:

- In the case of complex serology where the investigation by the IBTS laboratory is inconclusive or requires confirmation of the results obtained
- Or where molecular testing is required

the Sample may be referred on to the International Blood Group Reference Laboratory (IBGRL) or the Molecular Biology and Genetics Laboratory at the IBTS respectively. In such instances it may not be possible to use the initial Sample for analysis as age or size of Sample may impact on the validity of test results, so the hospital may be requested to submit another Sample.

Samples for referral to the IBRGL for serological testing should be referred directly to the Diagnostics laboratory for onward referral to the external laboratory as the results obtained may determine appropriate transfusion component to be provided. The Referring Hospital will be responsible for costs incurred through testing and transportation.

Samples for molecular Rh D testing should be referred directly to Molecular Biology and Genetics Laboratory at the IBTS.

9.0 REPORTING OF TEST RESULTS.

9.1 Approval of Test Results and Issuing Reports.

- All test results are reviewed and approved by a medical scientist before release.
- Valid results of automated testing are entered electronically into the IBTS computer system. Results of manual testing are entered by two medical scientists (or approved system during on-call hours). All results are validated by the IBTS computer system.
- Where relevant clinical advice and interpretative comments will be included on the test report.
- 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.
- All reports are checked by the Chief Medical Scientist or other senior person in charge once testing is complete. Reports are signed by two medical scientists.
- Routinely copy reports are printed and posted to the requesting laboratory/location. One hardcopy will be sent for each sample/request.
- 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 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 MRTC 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 (Refer to Section 8.2). Should the report be accompanied either by a clinical comment or a covering letter from the director of the laboratory this will incur a further delay in the reporting times.
- **A written report will be issued within 14 working days from the receipt of the Sample in all cases; except where Samples have been referred to an external laboratory.**

9.2 Issuing Reports on Critical Samples where the Results are delayed

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

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

Note:

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

9.3 Reporting of Results by Fax

Where clinically requested by the referring laboratory or the hospital clinician, the MRTC will issue results by fax. Where reports are requested to be faxed they will be signed by a scientist. A hard copy of the report will follow in the post.

9.4 Telephoned Results

The MRTC 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 IBTS scientific staff.

The IBTS staff will also require the details of the requestor i.e. their own name and designated responsibility e.g. clinician or scientist.

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

9.5 Archiving of Patients Records:

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

10.0 REVIEW & ASSESSEMENT OF CUSTOMER SATISFACTION

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

10.1 Service Level Agreements

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

The objectives of the agreement include:

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

10.2 Customer Complaints

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

The objectives of our complaints handling system require that:

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

- Customer confidence is maintained in our service.

If the service provided is not satisfactory, or you have suggestions for service improvement please contact MRTC personnel.

10.3 Quality Management Review

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

10.4 Customer Liaison

The Diagnostics Laboratory performs periodic surveys of customer satisfaction and also participates in IBTS User Symposia and National Haemovigilance Office Conferences. User issues are discussed and the IBTS inform their customers of new procedures and services at these events. The user is also afforded the opportunity to give the IBTS feedback on the service being provided to them.

10.5 Hospital Transfusion Committees

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

10.6 Continuous Improvement

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

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

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

11.1 Traceability

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

11.1.2 The Irish Blood Transfusion Service in its agreement for the supply of blood and blood components and the provision of other services with its user hospitals has identified responsibilities for all parties in relation to traceability and storage. The

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

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

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

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

11.2.2 The Irish Blood Transfusion Service in its agreement (SLA) for the supply of blood and blood components and the provision of other services with its user hospitals has identified responsibilities for all parties in relation to the obligations to report Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs). The Service Level Agreement between the Irish Blood Transfusion Service and the hospital notes “The hospital shall report in writing and without delay all Serious Adverse Events and Serious Adverse Reactions to the National Haemovigilance Office of the Irish Blood Transfusion Service. The hospital should take note of the requirements under the regulations for mandatory reporting of Serious Adverse Events and Serious Adverse Reactions”. Further information is available in the National Haemovigilance Office Handbook, BT 0566.

11.2.3 It is the responsibility of the IBTS as a Blood Establishment to report all SAEs relating to collection, testing, processing, storage and distribution of blood and blood components by the Irish Blood Transfusion Service to the competent authority, the Health Products Regulatory Authority (HPRA). This includes events in compatibility services where the IBTS acts as hospital blood bank or referral laboratory.

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

- 11.2.5** It is the responsibility of the hospital to have a haemovigilance system in place for the review of all blood transfusion adverse events / reactions occurring within the hospital and to ensure that all SAEs and SARs are reported to the National Haemovigilance Office (NHO) as defined by the NHO and in conformance with their protocols.
- 11.2.6** It is the responsibility of the hospital, for which the IBTS act as their Hospital Blood Bank, to have in place haemovigilance procedures for the clinical investigation and management of adverse events and reactions occurring in relation to transfusion of blood and blood components. In this case, the hospital must consult with the IBTS to prevent duplication of reporting to the National Haemovigilance Office.
- 11.2.7** In the event of an adverse transfusion reaction relating to a component, whether issued to a Hospital Blood Transfusion Laboratory or directly to a clinical transfusion facility where the IBTS acts as the hospital blood bank, the hospital must inform the Diagnostics laboratory immediately, by telephone, to ensure prompt recall of co-components where indicated.
- 11.2.8** Post transfusion samples (EDTA and clotted samples) for serological investigation and all component packs from this event must be returned to the MRTC Diagnostics laboratory for investigation.
- 11.2.9** The IBTS Consultant Haematologist / Specialist Medical Officer will provide immediate clinical advice on the investigation of such reactions and will liaise with the hospital clinical staff and Haemovigilance Officer in relation to the clinical events and investigation outcomes.
- 11.2.10** A report will be issued to the hospital clinician outlining the results of all the investigations performed, taking into account, the clinical history of the patient and any review carried out by the hospital Haemovigilance Officer. Advice on future transfusion support and management of the patient will be provided if requested.
- 11.2.11** If the criteria meet those for the reporting of a serious adverse reaction to the NHO the IBTS Consultant Haematologist will advise on the type of reaction and advise the hospital Haemovigilance Officer regarding reporting of the reaction to the NHO.
- 11.2.12** The hospital Haemovigilance Officer will send a copy of this communication (suitably anonymised) and results of the serological investigations to the NHO if the reaction fulfils the SAR criteria.
- 11.2.13** In the case of any Event relating to Diagnostics laboratory services (e.g. testing or component selection) the IBTS Consultant Haematologist/ Specialist Medical Officer will inform the hospital clinician immediately.
- 11.2.14** In the case of an SAE that has occurred in the hospital, the hospital must inform the MRTC Diagnostics laboratory.
- 11.2.15** The IBTS Consultant Haematologist will advise on the clinical implications of the SAE for the patient by communication with the hospital clinician.

- 11.2.16** A review of serious adverse reactions and serious adverse events is performed at the Diagnostics Quality Review Meetings and should also be undertaken at each Hospital Transfusion Committee Meeting. The IBTS Consultant Haematologist will attend such meetings.
- 11.2.17** It is the responsibility of the IBTS Biovigilance Officer to identify, categorise and review SAEs according to the EU Directive 2005/61/EC and EU Directive 2002/98/EC. The IBTS Biovigilance Officer reports all SAEs to the National Haemovigilance Office who subsequently report these SAEs to the competent authority, HPRA.
- 11.2.18** It is the responsibility of the IBTS Biovigilance Officer to complete an ANSAE (Annual notification of serious adverse event) report on behalf of the IBTS Blood Establishment and also an ANSAE report where the IBTS acts as a hospital blood bank. The IBTS Biovigilance Officer also completes an ANSAR (Annual notification of a serious adverse reaction) report where the IBTS acts as a hospital blood bank. The IBTS Biovigilance Officer submits the ANSAE and ANSAR reports to the National Haemovigilance Office (NHO) who submit this report to the competent authority, HPRA.

Verify when in Use. Status CURRENT Effective Date 2020