Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

Type: DIAG IBTS GDE
Document No.: IBTS/DIAG/GDE/0001[4]
Title: **IBTS PRIMARY SPECIMEN AND USER MANUAL DIAGNOSTICS / COMPATIBILITY LABORATORIES**
Owner: 1895 REBECCA WALDEN
Status CURRENT
Effective Date: 15-Feb-2016
Expiration Date: 15-Feb-2020

Review

Review: IBTS DOC REVIEW AND APPROVAL

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Change Orders

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

Document Detail

Change Orders - Incorporated

Changes as described on Change Order:

Change Order No.
IBTS/CO/0406/14

TITLE: IBTS PRIMARY SPECIMEN AND USER MANUAL DIAGNOSTICS / COMPATIBILITY LABORATORIES

Change Description:
Revise IBTS/DIAG/GDE/0001.
(1) Update section 5.4.3 to deal with situation where lab completes BT7 form but sample has been taken in by someone else. Declaration will have been signed on referring hospital request form and photocopy of this to be submitted with completed BT7. (Applying to samples sent to MRTC only)
(2) Add in that where samples are referred to IBTS: Under data protection acts 1988 and 2003, IBTS Diagnostics laboratories acts as a data processor for the referring lab, providing diagnostic testing for its patients. The referring lab are the data controllers.

Reason For Change:
(1) To provide clarity to labs referring samples to us and where we require a BT7 form from them.
(2) Data protection clarification.

Change Order No.:
IBTS/CO/0406/14

TITLE: **IBTS PRIMARY SPECIMEN AND USER MANUAL DIAGNOSTICS / COMPATIBILITY LABORATORIES**

CONTENTS **PAGE**

TITLE: IBTS PRIMARY SPECIMEN AND USER MANUAL DIAGNOSTICS / COMPATIBILITY LABORATORIES

1.0 INTRODUCTION

1.1 This manual is designed to provide an overview of the services available from the diagnostics / compatibility laboratories of the IBTS and is intended for the users of both the routine diagnostics / compatibility services and of the reference immunohaematology service.

1.2 This manual identifies the services provided by the IBTS diagnostic/compatibility laboratories to their customers/users: namely the hospitals, hospital blood banks and medical practitioners in the public and private health care sectors.

1.3 This manual specifies the minimum requirements for the labelling of specimens 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 specimens 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 IBTS diagnostics /compatibility laboratories are subject to regular scheduled inspection by the IMB 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 IBTS diagnostics /compatibility laboratories comply with S1 547 of 2006 incorporating Articles 14 and 15 of Directive 98/ 2002/EC (Traceability Requirements, Notification of SAR/E). The laboratories are committed to obtaining and maintaining the International Standard ISO 15189 (current version).

1.6 The IBTS diagnostics /compatibility laboratories operate 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 diagnostics /compatibility services undergo continuous review through quality assurance and audit activities. CE marked IVD kits, controls and reagents are used in accordance with manufacturer's instructions. Likewise all validated technology and systems used are CE marked with the appropriate documentation supplied. Validated methods and procedures are used. A calibration and maintenance schedule is in place for all equipment.

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

1.8 IBTS laboratory management is committed to the provision of a full and effective service.

- Optimum staff recruitment, training, development and retention at all levels.
- Procurement, validation and maintenance of appropriate equipment /resources.
- Maintaining specimen integrity and thereby the correct performance of laboratory examinations.
- Use of accredited examination procedures/methods ensuring 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 diagnostics/compatibility laboratories processes/procedures where the results or their interpretation could be significantly different, prior to implementation.

2.0 GUIDE TO USING THIS MANUAL

2.1 A copy of this manual is available on the internet, www.giveblood.ie under 'Clinical Services' – 'Clinical and Diagnostic Services' – 'IBTS Primary Specimen User Manual - Diagnostics/Compatibility Laboratories"

2.2 A hard copy of the IBTS Diagnostic / Compatibility Laboratories Primary Specimen and User Manual will only be supplied to customers of the IBTS on request. All obsolete versions of the hard copies of the User Manual will be recalled by the IBTS.

2.3 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. The hospital hard copy will be withdrawn and returned to the IBTS.

2.4 The term "BCSH 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.

3.0 DIAGNOSTICS LABORATORIES QUALITY POLICY

3.1 The Diagnostics Laboratories strive to be centres of excellence for Red Cell Immunohaematology.

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

- Operate a Quality Management System to continuously improve the quality of services provided.
- Operate to the requirements of ISO 15189 Medical Laboratories –Particular Requirements for Quality and Competence (ISO 15189, current version).
- 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 Policies, Guidelines and Procedures relevant to their work.
- Ensure that Laboratory examinations are processed to provide the highest quality results possible.
- Report results of examinations that are timely, confidential and accurate and are supported by clinical advice and interpretation when required.
- Implement internal Quality Control, External QA, audit and assessment of user satisfaction to continuously improve the quality of service provided.
- Uphold professional values and good professional practice and conduct.

Approved by:

Marie O'Connell
Director of Quality and Compliance
Date: 16th July 2014

Dr. Sorcha Ni Loingsigh
Consultant Haematologist (Locum)/
Director of Diagnostics Laboratory, NBC
Date: 17th July 2014

Dr. Joan Power
Consultant Haematologist/
Director of Diagnostics Laboratory, MRTC
Date: 17/07/2014.

4.0 GENERAL INFORMATION

4.1 Laboratory Directors

National Blood Centre: Dr, Sorcha Ni Loingsigh, Consultant Haematologist

Munster Regional Transfusion Centre: Dr Joan Power, Consultant Haematologist

4.2 IBTS Laboratory Personnel– Medical/Medical Scientific

The laboratories welcome your queries. For Medical and /or Medical Scientific advice please contact the personnel as tabulated below.

CONTACTS	NBC	MRTC
Chief of Diagnostics Laboratory.	Mr Barry Doyle 01-4322800	Mr Kevin Sheehan 021-4807400
Consultant Haematologist	Dr Sorcha Ni Loingsigh 01-4322800 or Specialist Medical Officer /Registrar on duty 01-4322800	Dr Joan Power 021-4807400 or Specialist Medical Officer on duty 021-4807400

4.3 Service Operating Times

Department/activity	Opening Hours NBC	Opening Hours MRTC
Specimen Reception	**Security: 24 Hrs**	**Despatch: 24 Hrs**
Routine Laboratory Diagnostic/Compatibility Service	Monday to Friday 9.00 am – 7.00 pm Excluding bank holidays	Monday to Friday 9.00 am –5.00pm Excluding bank holidays
Emergency out of hours service (on-call diagnostic service)	Contact scientist on -call / duty (24hrs) 01 4322800 (switch)	Contact scientist on-call / duty (24hrs) 021 4807400
Bank holidays (on-call diagnostic service)	Contact scientist on -call / duty (24hrs) 01 4322800 (switch)	Contact scientist on-call / duty (24hrs) 021 4807400

4.4 Diagnostics/Compatibility Laboratories Contact Details

SECTION	NBC	MRTC
Laboratory office/Switch Board	**01-4322966**	**021-4807418 / 021 4807400**
Diagnostics Laboratory Routine Mon-Fri	**01-4322972, 4322973**	**021-4807417, 021-4807418**
Out of hours	**01-4322800 (Switch) Ask for medical scientist on duty/call.**	**021-4807400 (Switch) Ask for medical scientist on duty/call.**
Clinical issues Out of hours contact number	**01-4322800 (Switch) Ask for doctor on duty/call.**	**021-4807400 (Switch) Ask for doctor on duty/call.**
Platelet issues (Hospital Blood Bank Requests only)	**01-4322972, 4322973, (Routine 9am – 7pm) 01 4322800 (out of hours)**	**021-4807417/ 4807418 (Routine-9am- 5.00pm) 021-4807400 (Switch) (out of hours)**
Laboratory Fax No.	**01-4322709 (Diagnostic laboratory) 01-4322942 Despatch (Product requests)**	**021-4323315 (Diagnostic laboratory)**
Main reception Fax No.	**01-4322930**	**Not applicable**

4.5 Specimen Testing Scheduling

4.5.1 Routine Compatibility Testing/ Hospital Blood Bank Service (list hospitals)

4.5.1.1 Munster Regional Transfusion Centre. (MRTC)

The MRTC diagnostics laboratory operates an automated batch testing system. Routine service requests are processed in the next batch (please refer to section 8.1.1 of this document). The MRTC laboratory operates a system of two batch runs daily - at 09:00 hrs and at 13:00 hrs and Friday at 13.30hrs. Specimens received before 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. Specimens tested in the batch system will not accrue an additional emergency charge.

4.5.1.2 National Blood Centre (NBC)

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

4.5.2 Referred Samples from Hospital Blood Banks to IBTS Laboratories (MRTC and NBC) for serological investigation/ provision of crossmatched blood for patients with antibodies

Specimens for serological investigation received before 9am will be processed on the same day as far as possible. Specimens which are referred for antibody investigation and provision of blood will be prioritised for testing during the routine working day. The cut off time for sample receipt for provision of blood during the routine working day is 2pm. However if the IBTS is contacted by telephone and advised of a clinical urgency, provision will be made to process the specimen urgently or out of hours if required.
Specimens for antenatal antibody titration and quantification will be batched and processed to meet the test turnaround times specified in Section 8.1.1.

4.6 EMERGENCY SERVICE

4.6.1 IBTS Diagnostics Laboratory acting as a Hospital Blood Bank

4.6.1.1 The IBTS provides an emergency blood group and compatibility service, both routine and out of hours, for hospitals where the IBTS acts as a hospital blood bank and have in place a service level agreement (SLA). A stock of O RhD negative, un-crossmatched blood will be held at the IBTS for issue in emergency situations.

To request these emergency services, contact switch and request to speak to the medical scientist or medical personnel on-call.

4.6.2 IBTS Diagnostics Laboratory acting as a Referral Service

4.6.2.1 The IBTS also provides a referral service for blood banks in other hospitals. Requests for emergency immunohaematology services / compatible blood out of hours from these hospitals will be assessed in accordance with the urgency of the request by the IBTS Specialist Medical Officer (SpMO) /Registrar /Consultant Haematologist.

To request these emergency services, contact switch and request to speak to the medical scientist or medical personnel on-call.

- **For turnaround times for response to emergency request for compatible blood see section 8.1**

4.6.3 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 also Medical Council Registration number (if possible).
- The urgency of the request (date and time required) and estimated time of specimen arrival
- Patients Name (if known), hospital / emergency / trauma number and Date of Birth.

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

- Number and type of component requested.
- Blood Group, ABO/ Rh/ K type, if known (from referral laboratory only)
- Reason for transfusion
- Transfusion history (if known)
- Relevant clinical condition.

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 specimen 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 specimen 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 specimen, 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 form will be authorised by the IBTS Consultant Haematologist/ Registrar/SpMO following consultation with the patient's attending clinician.

4.7 Service Fees and Charges

A list of current services fees and charges, with detailed information regarding out of hours service charges, is available from:

- Director of Finance, NBC (01 4322800)
- Administration, Munster Regional Transfusion Centre (021-4807490 /021-4807492)

4.7 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 lab when samples are referred for testing to IBTS. This testing provides diagnostic testing for patient's of the referring laboratory. The referring laboratory are the DATA CONTROLLERS.

5.0 LABORATORY REQUEST FORMS, SPECIMEN BOTTLES AND CONTAINERS

5.1 General Information: Re Specimens and Forms

- It is the policy of the IBTS laboratories to treat all diagnostic specimens as potentially infectious or high risk. Therefore, we advise that universal precautions be taken in the collection, packaging and the delivery of specimens being sent to the laboratories for analysis.
- Specimens for referral should be freshly drawn venous specimens without dilution by intravenous fluid, not exposed to direct sunlight or extremes of temperature, transported at room temperature (unless for referral for cold agglutinins) as expediently as possible to the IBTS laboratory.
- If specimens are required to be stored prior to referral to the IBTS laboratory, they should be stored at 4ºC. For exceptions to this see 6.3, "Storage of Specimens".
- Specimens referred to the IBTS laboratories should conform to the requirements for the timing of specimen collection, as defined in Section 5.6.1.
- Specimen forms/ packaging are date and time stamped on receipt at the IBTS.
- On receipt in the laboratory, specimens are registered with an IBTS specimen number and recorded in a registration log book, as per Standard Operating Procedures. All stored aliquots from the primary specimen are labelled with the IBTS specimen number.
- IBTS scientific staff will review request forms and specimens to determine if they are suitable for the tests requested. Where it is determined that the request form and/or specimen is not suitable, the requesting hospital will be informed.

Incorrect or incomplete forms/ specimens may result in the tests not being undertaken and may require a second specimen to be submitted resulting in increased Turnaround Times with service delay.

5.2 General Information Re Specimen Collection

5.2.1 IBTS acting as Hospital Blood Bank

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

5.2.2 IBTS acting as a Referral Service

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

5.2.3 Service Requestor responsibilities include;

- Obtaining consent from the patient for the tests required at the IBTS Diagnostics Laboratory.
- Positively identifying the patient from whom the specimen is taken.
- Safely disposing of the materials used in the collection of specimens.
- Ensuring that the test / services requested are appropriate.
- Ensuring that specimens are delivered to the IBTS 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 IBTS Laboratory Request Forms

5.3.1 The Laboratory service request must be accompanied by duly completed IBTS Laboratory Request form. A number of different request forms are available to hospitals. These are used for different diagnostics tests as outlined below.

BT.7 Blood Group and Compatibility Request Form
This form is used to accompany specimens to determine blood group (Group and antibody screen/ hold specimen) in order to have the option of ordering blood or blood components and requesting compatible units for a patient.

BT. 345 Request for Red Cell Immunohaematology Investigation Form
This form is used by referring hospitals when they require the IBTS to undertake special investigations to resolve blood group serological anomalies and antibody investigations. This form may also be used by hospital blood banks for Ante-Natal investigation, e.g. antibody titre and Anti-D/c quantitation.

BT.311 Transfusion Reaction Investigation Form
This form is used where the IBTS have supplied compatible blood to its users (see 1.2), who now wish to report a suspected adverse reaction to a blood transfusion and who request investigation for 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 to 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.

The above forms are available on request from IBTS centres by contacting personnel in the following departments:

(a) NBC: Diagnostics Department (01-4322972, 01-4322973)
Diagnostics Office (01-4322966)

(b) MRTC: Despatch Department (021-4807419, 021-4807420)
Diagnostics/Compatibility Dept (021-4807417, 021-4807418)

5.3.3 Completion of Request Forms

The following essential information must be documented in a legible manner on the request form

1. **Patient's Surname,***
2. **Patient's Forename***
3. **Patient's Date of Birth,***
4. **Hospital number,***
5. Patient's gender,
6. Referring hospital and ward
7. Patient's address
8. The name of the requesting clinician
9. Test(s) required
10. Number of units of blood required (if for crossmatching)
11. Date (and time where blood is requested) of specimen collection and the name of person taking the specimen
12. Relevant clinical information appropriate to the test(s) requested must be supplied
13. Transfusion history/ history of administration of Anti-D/Antenatal history etc, must be supplied.
14. Specific transfusion requirements for individual patients i.e. CMV negative and / or Irradiated, this should be indicated on the request form.
15. The specific clinical indication for a transfusion request must be documented on the transfusion form.
16. A clear indication as to whether the tests/services requested are urgent or routine.
17. A signed declaration by the person taking or referring the sample regarding its validity and completeness as indicated in 5.4.3 below.

*** These are the mandatory patient personal identifiers which must be provided on the request form and the specimen for acceptance for testing by the Diagnostics Laboratory as per BCSH 'Guidelines.**

Note:

The IBTS Diagnostics Laboratories must be telephoned in advance if the service requested is urgent

ADDRESSOGRAPH LABELS ARE NOT ACCEPTABLE BY MRTC ON ANY REQUEST FORM

5.4 Specimen Labelling

5.4.1 Mandatory Requirements

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

1. Patient's Surname
2. Patient's Forename
3. Date of birth
4. Hospital number (For out patients an address will suffice.)
5. Date and time of specimen collection
6. The initials/ signature of the person collecting the specimen

Note:

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

5.4.2 Labels on Specimen Bottles

- The Service Requestor's responsibility is to ensure that all printed labels for specimens for blood transfusion testing are generated at the bedside and are compliant with BCSH Guidelines.
- **Demand- printed** labels, produced by the use of hand-held bedside scanners and printers utilising bar-coded wristbands are acceptable and may even increase security during phlebotomy.*(BCSH Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories)*
- The use of such bedside printed labels by hospitals must be pre-arranged by agreement with the IBTS Diagnostics Laboratories.
- Labels **pre-printed** away from the bedside (commonly known as **addressograph** labels) are **not** acceptable on specimens for processing. A repeat specimen will be required.

5.4.3 Requirement to Sign the Declaration

The person referring the specimen (BT345 request form), or taking the specimen (BT7 request form) must complete the declaration section of the request form and ensure that the patients' details on the request form and on the specimen are correct. Failure to complete the declaration may result in the specimen not being processed.

5.4.3.1 Request Form where a sample is being referred to MRTC for Testing

In the situation where a sample is being referred to MRTC for Testing and Crossmatching, it is acceptable for the referring Lab Staff to complete the BT7 request form. Lab 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 BT7 and sample.

The specimen declaration will be signed on the requesting hospital form. This declaration will be acceptable to MRTC.

5.5 Exceptions:

5.5.1 Exceptions may be made for specimens from the following groups:

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

In the above exceptional circumstances, non compliant specimens may be accepted for testing with a documented authorised concession (e.g. a fax from the requesting clinician verifying the patient identity) where delay in acquiring a new specimen may seriously prejudice a successful clinical outcome for a patient, or where the specimen cannot be replaced. In such cases the IBTS will not be responsible for errors made as a result of unacceptable labelling and/or specimens 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 specimen may require approval by the consultant at the IBTS.

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

5.6 Quality of Blood Specimens (Vis–à-Vis Specimen Condition and Timing of Procurement)

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

5.6.1 Timing of Specimen Collection in relation to Previous Transfusion.

Transfusions or pregnancy may stimulate the production of unexpected antibodies through either a primary or secondary response. This timing of specimens selected for crossmatching or antibody screening must take account of this. See Section 12.1 and 12.2 of this manual.

5.6.2 Crossmatching Requests for Patients with Auto-Antibodies

The term 'Suitable' printed on the Compatibility Report, indicates the units are compatible/least incompatible for patients with auto-antibodies using adsorbed plasma, this term is recommended in the BCSH Guidelines 2012. In urgent situations or if unable to remove the auto antibody, phenotyped matched units will be issued where possible and the referring facility contacted.

5.6.3 Crossmatching Requests on Repeatedly Transfused Patients

In situations where patients are being repeatedly transfused (e.g. AIHA, MDS) and have not become alloimmunized (made clinically, significant alloantibodies) a deviation may be raised to accept samples beyond the 3rd day period up to 7 days with the agreement of IBTS and referring Hospital Consultant Haematologists. See also Section 12.1 and 12.2 of this manual.

5.7 Non-Conforming Specimen Bottles, Forms or Specimen Quality Issues

Where the requirements with respect to labelling of the request form/ specimen container or specimen quality issues are not met, the following will apply.

5.7.1 Specimens: Condition/Documentation and Appearance/Quality issues

5.7.1.1 Condition/Documentation

SPECIMEN ISSUES	ACTION REQUESTOR	ACTION IBTS DIAGNOSTICS LABORATORY
▪ No specimen received	A second specimen must be collected with a request form.	Hospital / GP will be phoned informing them of the event. This will be documented on the request form
▪ Specimen collected but date and time of collection not indicated	Where it is a life threatening emergency, requiring crossmatched units, the patient's Clinician must accept responsibility by providing a signed fax to that effect. A second specimen with a request form is requested in this situation In non urgent situations a second specimen must be collected with a new request form	If tested the report will show the non-conforming event. This will be recorded on the request form.
▪ Specimens unlabelled	A second specimen must be collected with a request form	Specimens will NOT be processed
▪ Absence of, or major discrepancy in any of the mandatory unique patient identifiers on the specimen ▪ Addressograph label on specimens	A second specimen must be collected with a request form.	Hospital / GP will be phoned informing them of the event. This will be documented on the request form. For urgent situations see Exceptions (Section 5.4) Concessionary release will require a signed fax to that effect.
Borderline examples: Single digit or letter discrepancy in any of the mandatory patient identifiers which is minor and is not associated with risk of patient misidentification	Fax accepting responsibility for the labelling of the specimen and or telephone confirmation may be required. Corrected data to be included (see 5.5 exceptions)	The laboratory will make a decision on whether or not the specimen is suitable for testing. A second specimen may be requested.
Miscellaneous specimen issues		Dealt with on a case by case basis

Specimen Appearance/ Quality Issues

SPECIMEN APPEARANCE / QUALITY ISSUES	ACTION - REQUESTOR	ACTION IBTS DIAGNOSTICS LABORATORY
▪ Evidence of Haemolysis ▪ Age of specimen. ▪ Integrity of specimen ▪ Miscellaneous quality issues	A second specimen will be requested as appropriate.	The Laboratory will make a decision whether or not the specimen is suitable for testing and may report results unaffected by the specimen quality, while not reporting test results that may be affected by the quality of the specimen. If tested and appropriate the report will show the non-conforming event
▪ Separated Specimens	A second specimen must be collected with a request form as appropriate	Hospital / GP will be phoned informing them of the event. This will be documented on the request form

5.7.2 Request Form Issues

FORM ISSUES	ACTION REQUESTOR	ACTION IBTS DIAGNOSTICS LABORATORY
- No request form provided with the specimen.	A second specimen must be collected with a request form.	Hospital / GP will be phoned informing them of the event.
- Inadequate or incorrect patient details:- ▪ hospital number ▪ name (incomplete / incorrect spelling of forename or surname) ▪ date of birth	New specimen requested. Hospital will be informed that the specimen is invalid and IBTS requires the request to be repeated.	Where it is an emergency, the IBTS will allow the clinician responsible accept responsibility by providing a signed fax to the IBTS laboratory to that affect, detailing the corrected patient information (See 5.5 Exceptions)
- Borderline examples: • Single digit or letter discrepancy in any of the mandatory patient identifiers which is minor and is not associated with risk of patient misidentification • Clinical information (not supplied) ▪ Gender not provided ▪ Incorrect test requested ▪ No test requested ▪ Address (absent/incorrect) ▪ Ward or location (absent)	Fax accepting responsibility for the labelling of the specimen and or telephone confirmation may be required. Corrected data to be included (see 5.5 exceptions)	The laboratory will make a decision on whether or not the specimen is suitable for testing. A second specimen may be requested.
- Ordering physician not identified - Date and time of collection not indicated / not **correct**. - Miscellaneous form issues	Fax accepting responsibility for the labelling of the specimen may be required. Corrected data to be included. (see 5.5 exceptions)	The laboratory will make a decision on whether or not the specimen is suitable for testing. A second specimen may be requested. (See 5.5 Exceptions). Phone hospital and ask for clarification and / or fax accepting responsibility for omission / error.

5.7.3 General Information Re: Specimens and Forms

- It is the policy of the IBTS laboratories to treat all diagnostic specimens as potentially infectious or high risk.
- Specimens for referral should be freshly drawn venous specimens without dilution by intravenous fluids, not exposed to direct sunlight or extremes of temperature, transported at room temperature (unless for referral for cold agglutinins) as expediently as possible to the IBTS laboratory.
- If specimens are required to be stored prior to referral to the IBTS laboratory, they should be stored at 4ºC. For exceptions to this see 6.3 "Storage of Specimens".
- Specimens referred to the IBTS laboratories should conform to the requirements for the timing of specimen collection, as defined in Section 5.6.1.
- Specimen forms/ packaging are date and time stamped on receipt at the IBTS.
- On receipt in the laboratory, specimens are registered with an IBTS specimen number and recorded in a registration log book, as per Standard Operating Procedures (SOP's). All stored aliquots from the primary specimen are labelled with the IBTS specimen number.
- IBTS scientific staff will review request forms and specimens to determine if they are suitable for the tests requested. Where it is determined that the request form and/or specimen is not suitable, the requesting hospital will be informed.
- **Incorrect or incomplete forms/ specimens may result in the tests not being undertaken and may require a second specimen to be submitted resulting in increased Turnaround Times with service delay**

6.0 DELIVERY, PACKAGING, STORAGE AND TRANSPORT REQUIREMENTS OF DIAGNOSTIC SPECIMENS

6.1 Specimen Delivery

Diagnostic specimens will be accepted by IBTS laboratories at **any time** and left with security at the NBC and with despatch at the MRTC**.** Specimens for routine testing will be incorporated into the next routine batch.

Note:

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

6.2 Specimen Packaging and Transport

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

6.2.1 International Carriage of Dangerous Goods by Road.

The requirements stated below apply to all diagnostic specimens directed to the IBTS diagnostic laboratories. *(The packaging labelling and transportation of all specimens must comply with the Guidelines laid down for the International Carriage of Dangerous Goods by Road UNADR).*

6.2.2 Universal Packaging Procedure for the Transport of Diagnostic Specimens.

- Specimens to be sent should be stored in a secure (preferably plastic) primary container.
- Wrap the specimen bottle/container in tissue or cotton wool which will act as absorbent material in the event of spillage.
- Place the specimen bottle/container in a biohazard bag (supplied with the request form)
- Place the biohazard bag (attached to the request form) with the specimen bottle in a padded envelope or an approved transport container.
- Label the envelope with a hazard warning label, "diagnostic specimen, Category B UN 3373".
- Place the name, address and contact number of the destination laboratory on the outside envelope.

- The specimen can be transported or posted as appropriate
- The specimen and the request form should be so packaged so as to ensure patient confidentially at all times during transportation.

Note:

There is no requirement for a licensed courier to transport non infectious diagnostic specimens.

6.2.3 Samples for Molecular Testing.

Samples requiring molecular testing are referred externally (primarily to the International Blood Group Reference Laboratory {IBGRL}). Foetal Genotyping from Maternal Blood Sample is time sensitive to ensure that they are accepted by the referral Laboratory. **Notification to the Diagnostics laboratory in advance of referral for genotyping is desirable. Samples are not accepted in NBC on a Friday for Foetal Genotyping. Specimens submitted for Molecular Testing must not be refrigerated overnight and must be delivered to the IBTS diagnostic laboratories immediately after collection.**

6.2.4. Disposal of Waste Material Used in Specimen Collection.

All materials used in the collection of diagnostic specimens should be treated as potentially hazardous and discarded according to the hospital guidelines for waste management and in compliance with relevant regulations.

6.3 Specimen Storage

Whole-blood specimens 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. See section 12.3 for recommended working limits for the storage of blood testing specimens (pre-analysis). (BCSH Guidelines, 2012). See 6.2.3 for specimen storage for molecular testing.

7.0 EXTERNAL AND INTERNAL QUALITY ASSESSMENT PROGRAMMES

7.1 External Quality Assessment Programmes (EQA)

The Laboratories participate **in relevant available** external third party assessment schemes.
This includes schemes operated by:-
NEQAS (UK National External Quality Assurance Scheme) for Blood Transfusion Laboratory Practice (NBC/ MRTC)
UK AQQAS Scheme for Anti-D/c quantification (NBC)
Lab Quality (Finnish External Quality Assurance Scheme) (NBC/MRTC)
External proficiency testing is performed by all staff working in the diagnostics / compatibility laboratories on an annual frequency

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

7.2 Internal Quality Assessment Programmes.

The IBTS diagnostic /compatibility laboratories are 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

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 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 diagnostics laboratories (MRTC/NBC) 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 laboratories fail an external EQA scheme, all users of the service will be informed officially.

8.0 LABORATORY TESTS AND SERVICES

8.1 Services provided by the IBTS Diagnostics Laboratories:

- **Testing of blood specimens for Blood Group/Crossmatch/Antibody Investigation/Antigen Typing.**
- **Provision of Blood/Blood Components for Transfusion**
- **Medical and Scientific Consultancy**
- **Consultant Haematologist oversight of Haemovigilance**

8.1.1 Test Profiles and Turnaround times

This table provides guidelines for testing of specimens, special requirements and turnaround times for test results.

- Initial verbal reports will be provided where emergency testing is performed or critical values are being reported.
- Where no component has been issued and an antibody investigation has been carried out by the IBTS Laboratory, a written 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 Consultant Haematologist, this will incur a further delay in the reporting times.

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

Test profile	Centre	Specimen type (fresh venous specimen)	Specimen volume	Service details and requirements	Turnaround time test
Anti- D Quantitation	NBC	EDTA (WB)	7.5ml	Performed 2-3 times weekly Separated specimens will not be processed	Result phoned within 3 working days Written report - 5-7 working days.
Anti-c Quantitation	NBC	EDTA (WB)	7.5ml	Performed weekly. Separated specimens will not be processed	Result phoned within 5 working days Written report 7 working days
Antibody Titrations	NBC MRTC	EDTA (WB)	7.5 ml	For urgent testing contact the lab in advance.	5 -7working days
Antibody investigation *	NBC MRTC	EDTA (WB)	2 x 7.5ml	Progress will be discussed with requestor by telephone.	5 working days
Autoimmune Haemolytic Anaemia *	NBC MRTC	EDTA (WB)	2 x 7.5ml	Progress will be discussed with requestor by telephone.	5 working days
Blood Group / Antibody Screen ROUTINE	NBC MRTC	EDTA (WB)	3 – 7.5ml	Next scheduled batch (See section 4.5.1.1)	Results usually available in 24 hrs, report will follow group and hold period
Blood Group / Antibody Screen EMERGENCY	NBC MRTC	EDTA (WB)	3-7.5ml	Contact IBTS laboratory in advance. Processed immediately on receipt.	ASAP -Within 2 hrs of receipt of specimen if no antibodies
Blood Group and Compatibility Testing (Routine)	NBC MRTC	EDTA (WB)	7.5ml	Processed on next routine batch	Routine 2-6 hrs

Test profile / service	Centre	Specimen type (fresh venous specimen)	Specimen volume	Service details and requirements	Turnaround time test
Blood Group and Compatibility Testing (EMERGENCY)	NBC MRTC	EDTA (WB)	7.5ml	Contact IBTS laboratory in advance. Processed immediately on receipt.	ASAP - Within 2 hrs of receipt of specimen
Blood Group and Compatibility Testing for patients who have red cell immune antibodies (ROUTINE or in EMERGENCY situations)	NBC MRTC	EDTA (WB)	7.5ml Minimum	Contact IBTS laboratory in advance. Progress can be discussed by telephoning the IBTS laboratories.	2-6 hrs **Please note** this is dependent on the complexity of antibodies detected. Refer to Antibody investigation
Blood Grouping Anomalies (ABO/RhD)	NBC MRTC	EDTA (WB)	7.5ml	Progress will be discussed with requestor by telephone. Telephone in advance if blood is required for patient.	5 working days
Cold Agglutinins (Not available at NBC)	MRTC	EDTA (WB) (Specimen for investigation to be taken @ 37˚C and remain @ 37˚C during transportation)	7.5 ml	Contact MRTC laboratory if patient known to have CHAD.	5 working days
Direct Antiglobulin Test (Routine)	NBC MRTC	EDTA (WB)	3- 7.5ml	Next scheduled batch (See section 4.5.1.1)	2 working days Where antibodies are investigated please see above
Investigation of Haemolytic Disease of the Newborn where maternal antibodies are implicated / suspected.*	NBC MRTC	EDTA (WB) (Mothers) EDTA(WB) Baby's specimen	7.5 ml 1-3 ml	Note: Investigations will be limited to Red Cell Serological studies. Next scheduled batch (See section 4.5.1.1) Must be telephoned in advance	Results phoned within 1 working day

Note:

*** Indicates tests available out of hours for clinically urgent orders**

Test profile /service	Centre	Specimen type (fresh venous specimen)	Specimen volume	Service details and requirements	Turnaround time test
Molecular assay for Fetal (RH/K) typing from Maternal blood [1]	NBC MRTC To be tested at the IBGRL	EDTA (WB)	16ml Maternal 3ml Partner	To be referred for testing to IBGRL. Specimens need to be delivered to the IBTS laboratory immediately post collection (Mon-Thurs) for processing within 48 hrs of collection. This service should only be used for pregnancies which have progressed to at least 16-20 weeks gestation.	Results are generally available from the IBGRL within 7 - 14 working days of specimen receipt (travel time included). Repeat testing will incur an extension to the turnaround time and possibly may require repeat sampling
Molecular assay –Red blood cell genotyping [1]	NBC MRTC To be tested by the IBGRL	EDTA (WB)	3.5ml	To be referred for testing to IBGRL. Specimen should be as fresh as possible. (Samples should not be referred to IBTS on Fridays).	Results are generally available from the IBGRL within 7 - 14 working days of specimen receipt (travel time included and longer depending on complexity). Repeat testing will incur an extension to the turnaround time and possibly may require repeat sampling

Note: [1] Denotes a test referred to an external laboratory (please note such referrals attract testing and transportation charges): Additional time will be incurred where specimens are referred externally. In such cases the scientific staff at the IBTS will inform the requestor.

Test profile / service	Centre	Specimen type (fresh Venous specimen)	Specimen volume	Service details and requirements	Turnaround time test
Phenotyped Blood * (In stock) Request through the Electronic Order System	NBC MRTC	N/A	None	If screening required, time will be dependent on the complexity of screening required	10-20 mins to prepare order.
Phenotyped blood: multiple antigen - negative units * (In stock)) Request through the Electronic Order System	NBC MRTC	N/A	None	If screening required, time will be dependent on the complexity of screening required	10-20 mins to prepare order.
Phenotyped blood: High incidence antigen - negative units.*	NBC MRTC	N/A	None	Depending on the complexity of the screening required, compatible units may need to be sourced from the other IBTS centre and if not successful, approval to be sought from the medical consultant / medical registrar to call up donors.	Timescale dependent on availability of blood and urgency of request, e.g. out- of -hours testing require on -call services
Phenotyped blood: requiring importation of suitable units $_1$	NBC MRTC	N/A	None	If high incidence antigen negative red cells required, discussion with IBTS Consultant Haematologist/ Specialist Medical Officer/Registrar may be required to call up donors or to obtain suitable units from the International Blood Bank Rare Donor programme where the maximum notice will be required. The IBTS will also require adequate notification	Procurement of product dependent on the availability of the blood. A minimum of 48 hrs is required to import the blood.
T Cell antigen activation (ROUTINE)	MRTC	EDTA (WB)	2.7 ml	Contact MRTC Laboratory Next scheduled Batch	2 - 3 working days
T Cell antigen activation (EMERGENCY)	MRTC	EDTA (WB)	2.7 ml	Contact MRTC Laboratory in advance.	ASAP within 2 hrs of receipt of specimen

Note: $_1$ Denotes a test referred to an external laboratory. Please note such referrals attract testing and transportation charges: Additional time will be incurred where specimens are referred externally. In such cases the Scientific Staff at the IBTS will inform the requestor.

*** Indicates tests available out of hours for clinically urgent orders**

Test profile / service	Centre	Specimen type (fresh Venous specimen)	Specimen volume	Service details and requirements	Turnaround time test
Transfusion Reaction Investigation * Where the IBTS acts as a Hospital Blood Bank	NBC MRTC	EDTA (WB) Pre and Post transfusion **and a clotted post transfusion sample** The implicated unit must be sealed by a coupler and returned	7.5ml 7.5ml 7.5ml	Must be telephoned in advance. Contact medical consultant / medical registrar on duty / on call, for direction**.** **Please return** Implicated unit (if available)-(even an 'empty pack' may provide a sample from an attached segment),administration set (if possible). The remaining untransfused 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 hrs of receipt of specimen 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

Transfusion Reaction Investigation * Referred specimens	NBC MRTC	EDTA (WB) Pre and Post transfusion **A clotted post transfusion sample should also be referred where possible** The implicated unit must be sealed by a coupler and returned .	 7.5 ml 7.5ml 7.5ml (if required)	Must be telephoned in advance. Progress will be discussed with requestor.	ASAP 2-5 hrs of receipt of specimen for initial serological results. A written report of the serological results only may be available within 5 working days

Note:

[1] Denotes a test referred to an external laboratory (please note such referrals attract testing and transportation charges): Additional time will be incurred where specimens are referred externally. In such cases the scientific staff at the IBTS will inform the requestor

*** Indicates tests available out of hours for clinically urgent orders**

Please refer to the National Histocompatibility Immunohaematology Reference Laboratory (NHIRL) User Guide for Services provided by the NHIRL Laboratory NBC.

8.2 Provision of Blood/Blood Components

8.2.1 IBTS Contact for provision of blood components

Services: Provision of Components	IBTS - Department
Blood suitable for neonatal transfusions	MRTC- Diagnostics NBC – Hospital Services
Plasma Components including SD Plasma	MRTC – Diagnostics / Hospital Services NBC Hospital Services
Prothrombin Complex Concentrate / Fibrinogen Concentrate (For Hospitals using IBTS Blood Bank Service only). Consultation with IBTS Medical Staff required	MRTC – Diagnostics/Hospital Services NBC – Diagnostics / Hospital Services
Platelet components (Including CMV negative /irradiated / washed)	MRTC – Diagnostics NBC- Diagnostics for Hospitals using IBTS Blood Bank Service NBC-Hospital Services (for stock requests)
Red Cells – Antigen Typed /Neonatal	MRTC – Diagnostics NBC- Hospital Services
Washed components/Red cells (CMV negative / irradiated)	MRTC –Components /Diagnostics NBC- Components/Hospital Services

Provision of EMERGENCY Blood where the IBTS act as the hospital blood bank

Services: Provision of Components	IBTS - Department
Emergency stock of O Rh D negative for Hospitals using the IBTS Blood Bank service	MRTC- Diagnostics NBC- Hospital services

Note:

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

8.2.2 Provision of Special Orders of red cells and platelets for Hospital Blood Banks.
Responsibility for all special orders of Red Cells and Platelets CMV Negative / Irradiated and also typed units for hospital blood banks lies with:
Diagnostics at **MRTC**
Issue Laboratory at **NBC**.

8.2.2.1 Requests are initially made by using the Electronic Online Ordering System.
The order type is filled in by the requesting hospital as:
1. Stock (next morning delivery)
2. Standard (will be issued when order is ready on same day)
3. Emergency (order will be prepared and issued ASAP).
4. Standing Order (same product is required on same days each week)

8.2.2.2 The IBTS do not carry a large stock of pre-irradiated red cells. 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**.**

Note: Red cells requiring antigen typing not available on the shelf:
The turnaround times for Antigen typed red cells, see Table in 8.1.1.

8.2.3 Provision of Platelet Components (See 8.2.2).

8.2.3.1 Platelet components without special requirements (i.e. not CMV negative):
- If available on shelf – allow 10 – 20 min to prepare order for issue.
- If not available, the request may be relayed to IBTS Medical staff for direction.

8.2.3.2 Platelet components with special requirements
CMV Negative Platelets:
- If the required ABO/Rh type is available on the shelf, allow 10-20 min to prepare order for issue
- If not available, the request may be relayed to the IBTS Medical staff for direction**.**

8.2.3.3 HLA Matched Platelets:
- Requests for such components must be made in advance to the SpMO/Registrar on duty at the IBTS (NBC/MRTC) to facilitate the call-up of a suitable donor or to allow for the database search of suitable components already bled. For MRTC an electronic order should be placed with MRTC who will agree service supply with medical NBC and collate supply logistics.
- The hospital will be notified by the medical personnel as to the availability of the component.

8.2.3.4 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.

8.2.3.5 For Hospitals where the IBTS acts as a Hospital Blood Bank
Patient Blood Group
Where the IBTS acts as a hospital blood bank, a blood specimen is required for blood group Investigation, if the blood group of the patient has not been previously tested by the Diagnostics laboratory. The orders are placed by phone and Diagnostics are involved in the issue of the product at both centres.

8.2.4 Provision of Rare Donor Red Cells 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 wet stock 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**.**

Note:

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

8.2.5 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.

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 and in accordance with IBTS/QA/SOP/0100 for planned deviations.

Section D of the **Concessionary release** form (Appendix 1) should include the name and designation of the requesting clinician who has agreed to accept the concession for the patient. A copy will be sent/faxed to the hospital blood bank or requesting clinician where the IBTS is the hospital blood bank.

8.3 Consultancy and Pathology services

The IBTS will provide medical and medical 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 4.2** of this manual.

8.4 Haemovigilance Advisory Service:

All haemovigilance queries relating to situations where the IBTS acts as a hospital bank should be directed to IBTS medical staff or directly to laboratory senior medical scientific staff. For contact names and numbers see **section 4.2** of this manual.

8.5 Repeat Examination due to Analytical Failure or Further Examination of the Primary Specimen

8.5.1 Repeat Examination due to Analytical Failure.

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

- Repeat the test using the back up procedure
  or
- Store the specimen in appropriate conditions until the cause of the analytical failure is identified and corrected and then repeat the test. The urgency of the outstanding specimen is reviewed by the relevant laboratory director or nominee.

8.5.2 Further Examination of the Primary Specimen

Where further testing is relevant to the investigation, then it is the policy of the laboratory to pursue further investigation using the primary specimen.

8.5.3 Referring Specimens to an External Laboratory for further investigations

Should additional testing be required on a specimen for analysis based on the results obtained by the IBTS laboratory, then the specimen may be referred on to an external reference laboratory. In such instances it may not be possible to use the initial specimen for analysis as age or size of specimen may impact on the validity of test results, so the hospital may be requested to submit another specimen.
Specimens should be referred directly to the IBTS (NBC/MRTC) laboratory where the specific test was performed – for onward referral to an external laboratory.
The Referring Hospital will be responsible for costs incurred through testing and transportation
All **Anti-D/c Quantitation** specimens should be referred directly from the hospital to the IBTS, NBC.

8.6 External Laboratory Testing

Some specimens are referred to external laboratories for testing such as the International Blood Group Reference Laboratory (IBGRL) in Bristol, for the identification of complex antibodies and molecular typing.
Specimens for investigation should be directed to the IBTS for referral to the external Laboratory for further investigation as the results may determine the appropriate transfusion component to be provided. The original report from the external laboratory will be forwarded to the referring hospital (Copy will be retained by the IBTS).

9.0 REPORTING OF TEST RESULTS.

9.1 Approval of Test Results and Issuing Reports.

- The results of all tests performed, including routine / emergency (out of hours) and complex investigations in the diagnostic laboratories at the IBTS are reviewed and approved by a medical scientist before release.
- Valid results are entered electronically into the IBTS computer system or, alternatively, if manually tested, the results will be entered by two medical scientists (or approved system during on-call hours). All results are validated by the IBTS computer system
- All results, once released, are available on the computer system. Hard copy reports are printed and are subsequently available to hospitals on demand and are issued with all emergency requests.
- A report will accompany blood / blood components that have been compatibility tested. The IBTS retains a copy of the report with the original request form. Where an interim report is issued, a final report will follow.
- Only scientific or medical staff may issue reports to the hospital. The report must be issued to the medical / clinical personnel responsible for the patient or to the senior medical scientist referring the specimen for investigation.
- 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 IBTS Laboratory an antibody report will be issued within 5 working days (See 8.1.1). Should the report be accompanied either by a clinical comment or a covering letter from the director of the laboratory this will incur a further delay in the reporting times.
- **A written report will be issued within 14 working days from the receipt of the specimen in all cases except where specimens have been referred to an external laboratory.**

9.2 Issuing Reports on Critical Specimens where the Results are delayed

Where a test is delayed the requestor will be notified. It is IBTS policy to immediately notify the referring hospital / team when there are indications that the results may be delayed. Information regarding contacting the referring hospital / team will be documented.

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 IBTS will issue results by fax following authorisation by the consultant haematologist or chief scientific officer/ nominee with agreement with the customer. Telephone verification of results is required. A hard copy of the report will follow.

9.4 Telephoned Results:

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

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, for example from a clinician or scientist.

These details must be documented in a laboratory ledger which is dedicated to the documentation of all telephone calls into the laboratory. A hard copy of the report will follow.

9.5 Archiving of Patients Records:

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

10.0 REVIEW & ASSESSEMENT OF CUSTOMER SATISFACTION

Customer satisfaction is assessed through regular survey of users, feedback received at Hospital Transfusion Committee Meetings, processing of complaints and convening of annual user meetings (Annual User Symposia). There is also a regular review of Customer Complaints at the Diagnostics Management Quality Review meetings.

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

10.2 Customer Complaints

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

The objectives of our complaints handling system requires that: -

- All complaints are rapidly and effectively handled and fully investigated.
- The appropriate corrective and preventative actions are taken to reduce the risk of repeated errors.
- The relevant information is recorded and reported to the consultant haematologist & quality manager as appropriate.
- The customer receives a letter from the QA /Medical department in response to the complaint
- The customer confidence is maintained in our service.

If the service provided is not satisfactory, please contact the IBTS personnel in your region to process the complaint.

10.3 Quality Management Review

The IBTS quality groups conduct monthly reviews of all quality aspects of the organisation, in particular, customer complaints. The IBTS Diagnostics Management Quality Review group meetings includes an annual review meeting produce reports on all aspects of the Diagnostics Laboratories Service (including issue) and invites user representation This review forms part of the Quality Management Review. The laboratory Chief Scientists, Directors and Despatch/Hospital Services are also responsible for the investigation, root-cause analysis and risk assessment of complaints reported in their areas.

10.4 Customer Liaison

The NBC/MRTC Diagnostics Laboratories perform annual surveys of customer satisfaction and also participate in IBTS User Symposia and National Haemovigilance Office Conferences. User issues are discussed and the IBTS inform their customers of new procedures and services at these events. The user is also afforded the opportunity to give the IBTS feedback on the service being provided to them.

10.5 Hospital Transfusion Committees

The IBTS Consultant Haematologist / Chief Scientist for Diagnostics attend Hospital Transfusion Committees 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

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 (100%).

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 "where the Irish Blood Transfusion Service acts as a blood bank for hospitals without crossmatching facilities, the hospital is required to notify the Irish Blood Transfusion Service 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 Irish Blood Transfusion Service 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 (e.Traceline) patient's record. This information is taken from the Traceability label, (part C of BT 396), which is returned from the user hospital. A hard copy of this label is retained by the Irish Blood Transfusion Service 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 Irish Blood Transfusion Service conforms to Directive 2005/6/1/EC implementing Directive 2002/98/EC as regards notification of Serious Adverse Reactions (SARs) and Events (SAEs), transposed into Irish law by SI 547 of 2006.

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

11.2.3 It is the responsibility of the Irish Blood Transfusion Service as the 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).

11.2.4 The Irish Blood Transfusion Service diagnostics laboratories 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 blood bank, to have in place haemovigilance procedures for the clinical investigation and management of adverse events and reactions occurring in relation to transfusion of blood and blood components.

11.2.7 In the event of an adverse transfusion reaction relating to a component whether issued to a hospital blood bank or directly to 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 Irish Blood Transfusion Service 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 IBTS Consultant Haematologist will send a copy (suitably anonymised) of this communication and results of the serological investigations to the NHO if the reaction fulfils the SAR criteria.

11.2.13 In the case of a Serious Adverse Event relating to diagnostic 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 Irish Blood Transfusion Service 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 Irish Blood Transfusion Service Consultant Haematologist will attend such meetings.

12.0 GUIDELINES: MEDICAL/SCIENTIFIC

12.1 Antenatal Guidelines

Ante Natal Specimens

It is the policy of the IBTS Diagnostics Laboratories to follow the "Guidelines for Blood Grouping and Antibody Testing in Pregnancy (British Committee for Standards in haematology) 2006" which includes the timing of Ante-Natal sampling for patients with and without Red Cell Antibodies.

12.1.1. Specimens for Quantitation (Anti-D and Anti- c).

The Biological Reference Ranges for Patients with Anti-D and Anti- c are as follows,
*****

Anti-D level IU/ml	Risk of HDN	Recommendation	Comments
< 4	Low risk	Repeat specimens recommended every 4 weeks to week 28 gestation, then every 2 weeks to delivery.	
4 – 14	Moderate Risk	Recommend referral to a specialist Fetal Medicine Assessment Unit. Repeat specimens recommended every 4 weeks to week 28 gestation, then every 2 weeks to delivery. Note: Subsequent referral for Anti-D quantitation is of limited clinical value once Fetal Medicine Assessment has commenced.	Referral of maternal specimen to IBGRL for fetal RHD genotype may be helpful. Samples may be sent from 16 weeks gestation.
> / = 15	High Risk	Recommend referral to a specialist Fetal Medicine Assessment Unit. Repeat specimens recommended every 4 weeks to week 28 gestation, then every 2 weeks to delivery. Note: Subsequent referral for Anti-D quantitation is of limited clinical value	Referral of maternal specimen to IBGRL for fetal RHD genotype may be helpful, see above.

*

Anti-c level IU/ml	Risk of HDN	Recommendation	Comment
< 7.5	Low risk but monitor	Repeat specimens recommended every 4 weeks to week 28 gestation, then every 2 weeks to delivery.	
7.5 -19	Risk of moderate HDN	Recommend referral to a Specialist Fetal Medicine Assessment Unit. Repeat specimens recommended every 4 weeks to week 28 gestation, then every 2 weeks to delivery.	Referral of maternal specimen to IBGRL for fetal RH c genotype may be helpful, see above.
> / = 20	Risk of Severe HDN	Recommend referral to a specialist Fetal Medicine Assessment Unit. Repeat specimens recommended every 4 weeks to week 28 gestation, then every 2 weeks to delivery.	Referral of maternal specimen to IBGRL for fetal RH c genotype may be helpful, see above.

12.1.2. Ante-Natal Specimens for Antibody Titration

*

Antibody	Titre	Recommendation	Comment
Anti-K	**N/A**	Anti-K can cause HDN irrespective of titre. Recommend referral to a Fetal Medicine Assessment Unit. Repeat specimens recommended every 4 weeks to week 28 gestation, then every 2 weeks to delivery. Check Partner's Kk type. If paternity can be confirmed and partner is Kell negative, repeat specimen recommended at 28 weeks gestation. If partner's Kell type is K positive or cannot be determined, then refer the maternal specimen for fetal K genotype and advise repeat specimens for antibody titration every 4 weeks to week 28 gestation, then every 2 weeks to delivery is recommended.	Check cord DAT at delivery and monitor infant for evidence of haemolysis.
* **Other Clinically Significant Antibodies**	**<32**	Antibody titres ≤32 are associated with a low risk of HDN. Check antibody levels at 28-32 weeks gestation. Referral of paternal specimen for antigen typing and / or maternal specimen for fetal genotyping (if appropriate)	Check cord DAT at delivery and monitor infant for evidence of haemolysis
	≥32	Antibody titres ≥32 are considered clinically significant for HDN. Referral to a Fetal Medicine Assessment Unit is advised. Referral of paternal specimen for antigen typing and /or maternal specimen for fetal genotyping (if appropriate) and repeat testing at appropriate intervals	Check cord DAT at delivery and monitor infant for signs of haemolysis

*** Please note:**
Antibody titration /quantitation levels with the correlation of the clinical risk for HDFN is based on heterozygous fetal antigen expression. Please note in the case of a pregnancy involving donor oocyte/embryo, there may be homozygous expression of the relevant antigen and possibly a risk of a more severe form of HDFN.

12.2 GUIDELINES FOR THE COLLECTION OF SPECIMENS FROM PREVIOUSLY TRANSFUSED PATIENTS.

Routine requests for crossmatching.

Patient transfused within;	Specimen to be taken not more than
Patient transfused or pregnant in the last 3 months	72 hrs before transfusion[1]
Patient not transfused or pregnant in the last 3 months	1 week before transfusion.[1]
On-going cases	A formal deviation from the 3 day rule may be considered for chronically transfused patients with no alloantibodies following multiple repeated transfusions 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

12.3 GUIDELINES FOR THE STORAGE OF SPECIMENS: PRE-TESTING

BCSH Task Force recommendations (2012) for the storage of specimens pre testing

	18 – 25 ° C	4° C	-30° 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

12.4 GUIDELINES FOR STORAGE OF EXAMINED SPECIMENS FOR ARCHIVE AND LOOK BACK PURPOSES

ID	Specimen Description	Storage Requirement	Storage Location	Minimum Retention Period	Responsibility
1.	Serum/ plasma for group/ antibody screen and crossmatch	-30°C	Designated laboratory freezer	14 days	Chief medical scientist
2	Serum/ plasma antibody titration / Anti-D/c quantitation	-30°C	Designated laboratory freezer	Duration of the pregnancy, for comparison	Chief medical scientist
3.	Whole blood	4°C	Designated laboratory 'fridges	3 days (after release of the report)	Chief medical scientist

12.5 GUIDELINES FOR PROCESSING SPECIMENS WITH SPECIAL REQUIREMENTS OUTSIDE OF THE ROUTINE WORKING DAY. THIS SERVICE IS CONFINED TO PATIENTS REQUIRING URGENT TRANSFUSION SUPPORT

	Result	Service provided
Patient Has	A single, clinically significant antibody	Antigen negative, crossmatched blood provided.
	Multiple antibodies Contact Specialist Medical Officer /Registrar on call and medical scientist on duty / call for direction.	If clinically significant antibodies are identified, antigen negative, crossmatched blood will be provided as per BCSH guidelines. If unable to identify the antibody/antibodies, units screened with patients plasma / serum, or units phenotypically matched to the patient are provided to the hospital for crossmatching. Crossmatching will be performed if specifically requested by the referring hospital blood bank and for hospitals where the IBTS acts as a blood bank.
	Autoantibody (all cells positive in IAT) AIHA Undefined antibody(s) Contact Specialist Medical Officer /Registrar and medical scientist on duty / call for direction.	Full investigation including auto or allo absorption to confirm the autoantibody and exclude underlying alloantibodies is performed depending on the time available. Patient specimen is phenotyped. On completion of these tests Rh and K phenotype matched units are selected and either issued to the hospital blood bank for crossmatching or are crossmatched prior to issue if specifically requested. Where the need for blood is urgent and there is insufficient time to complete the investigations, Rh and K phenotyped matched blood that may or may not be crossmatched is provided following discussion regarding the relative risks of transfusion or delaying the transfusion until tests are completed with the clinician in charge.

Turnaround times will vary on a case by case basis.
Contact diagnostics laboratory for updates on specimen investigation.

12.5.1 Non Compliance with the Turnaround Times

- 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.

13.0 INDEX OF TESTS AND SERVICES PROVIDED

13.1 Tests

13.1.1 Tests – Diagnostics MRTC and NBC

13.1.2 Tests – Diagnostics NBC Only

13.1.3 Tests – Diagnostics MRTC Only

13.1.4 Tests – Referred to IBGRL from both the MRTC and NBC Diagnostics Laboratories

Test Name	Page
Molecular Assay for fetal (Rh/K)typing from Maternal Blood	24
Molecular Assay – Red Blood cell genotyping	24

13.2 Services

13.2.1 MRTC Services

Service Name	Page
Platelet Components (CMV Negative/Irradiated/Washed)	29
Red Cells – Antigen Typed/ Neonatal/(CMV Negative/Irradiated)	29
Red Cells from Stock	29
Contact Details for Diagnostics /Medical and Hospital Services	8

Note: these services are covered by the Issue Laboratory, NBC.

13.2.2 NBC Services

Service Name	Page
Test Profiles	22 – 27
Contact Details for Diagnostics /Medical and Hospital Services	8

Appendix 1

Irish Blood Transfusion Service Diagnostics Laboratory
Concessionary Release Form

Section A- Patient details and concession information		
First Name	**Last Name**	**Hospital number**
Date of birth	**Hospital**	**Consultant**
Brief description of reasons for concession:		
IBTS Medical Scientist **Name** **Signature** **Date** **Time**		
Section B- Blood component details		
Description of component/product for concessionary issue		**Donation number**
Section C- Authorization		
Reason for Justification: **IBTS Consultant on duty:** **Name** **Signature** **MCRN** **Date** **Time**		
Section D- Informing patient's clinical team		
IBTS Consultant/ SpMO/SpR: **Name** **Signature** **MCRN** **Date** **Time** **Name of Doctor on the Clinical Team who has agreed to accept this concession for this patient:** **Name** **Grade** **Contact number**		
Section E- Confirmation of concessionary issue		
Diagnostic scientist: **Name** **Signature** **Date** **Time**		

Appendix 2

IBTS HAEMOVIGILANCE CLINICAL REVIEW REPORT

Patients Name		Hospital /Ward
Consultant	D.O.B	MRN
Unit N	Component	TxRx Date

Hospital Haemovigilance Officer's Report

REACTION INFORMATION OBTAINED FROM PATIENT'S CHART	
RELEVANT FURTHER INFORMATION	
Clinical History / Diagnosis	
Haematology Results: pre / post transfusion FBC	
Biochemistry Results: e.g. Bilirubin, LDH	
Patient Blood Cultures:	
Haemovigilance Officer:	**Date:**

SpMO / Consultant Haematologist's Report:

Comments and Conclusion (e.g. Type of Reaction / Imputability)
Special Transfusion Precautions
Consultant Haematologist **Date:**

Report Details: QC Number:

Date reviewed at Diagnostics meeting	
Lab report sent to patient's Consultant	
Chart to be flagged by HVO if required	
Letter sent to patient's Consultant (SAR+SAE)	
Report details logged in Progesa	

Reported to NHO ☐ IBTS Quality Department ☐ HTC ☐