

BT No.: 0425	Ver. 6
IRISH BLOOD TRANSFUSION SERVICE	

TITLE: TRACEABILITY USER MANUAL

Supersedes Version: 5

Change Description:

- Revise BT - 0425. Update traceability user manual.
- In section 4.7 include re-routing from Cork mater Private to Mater Private Dublin.
- In case of Mater Private transfers, the BT - 0396 will be removed from the component at th point when the units are being transferred to the Mater Private Dublin.
- The haemovigilance officer at Mater Private Cork will remove the labels. The label to be stamped 'transferred to stock, Mater Private Dublin' the label will be initialled & dated by the HVO.
- Mater Private Dublin will confirm receipt of units by emailing/faxing blood component transfer form to Traceability, MRTC. Document reference MPC-PP-HAE-022.
- Transferred units are reconciled & fated in eTraceline as per IBTS/DIAG/SOP/01150
- Include CUH process for labels & confirmation of transfer in traceability manual also, CUH ref MF-C-BTR-VPBOSIV.

Reason for Change:

- To include re-routing from Mater Private Cork to MP Dublin.
- To include total CUH process, reconciliation not referred to.

Change order No.:

IBTS/CO/0055/17

Referenced Procedures

SOP's, Policies, Guidelines, User Guides, PMF, BT, Specification, Codes etc.

SmartTrain Roles

N/A

SmartSolve Document Category

Category	Mobile	Cryobiology	Website
Yes / No	No	No	Yes

This BT form may be printed directly from EQMS/Internet for use.

TRACEABILITY USER MANUAL

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*** This service issue applies to the Munster Region only**

1. Introduction

- 1.1 SI 547 of 2006 requires that the IBTS, 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%). This statutory instrument requires that, inter alia, **(Regulation 4)** “each blood establishment, hospital blood bank and facility shall ensure the compatibility traceability of blood/ blood components with accurate identification procedure, record maintenance and appropriate labelling”. **(Regulation 7)** “each blood bank should have a system in place for each blood unit or blood component received whether or not locally processed and the final destination of that unit whether transfused, discarded or returned to the distributing blood establishment ...”
- And - in relation to verification –
- (Regulation 9)** “each blood establishment/ blood bank must have in place a procedure, when it issues units of blood or blood components for transfusion to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify subsequent disposition”
- And
- (Regulation 10)** “each blood establishment/ hospital blood bank and facility shall retain the data set in the first schedule here to for at least 30 years in an appropriate readable storage medium in order to ensure compatibility traceability.”
- Where the first schedule sets out requirement for facilities as
blood component supplier/ unit identification or lot number/ transfusion recipient identification/ date of transfusion or disposition/ and for blood units not transfused confirmation of subsequent disposition.
- 1.2 The IBTS Diagnostic services will comply by use of the ‘Bag & Tag’ compatibility traceability system. This involves the tagging of a compatibility/ traceability label (BT 396) to the component and the subsequent manual entry of the date 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 eTraceline patient record from the information returned (part C of BT 396) from the user hospital **and** the retention of a hard copy of part C of BT 396 for 30 years.
- 1.3 The Traceability Programme was implemented to fulfil the requirements of *SI 547 of 2006 European Community (Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations 2006*.
The regulations require unambiguous traceability of all blood and blood components from donor to patient and documentation of final fate if not transfused.
- 1.4 The intent is to identify all transfusion linked donors and patient therefore where a patient is exposed to **any** portion of a donor’s blood component this link must be identified. This includes where a few mls is transfused or indeed where the line has tissue.

- 1.5** The Compatibility/ Traceability Label (BT 396) will be issued with all blood and blood components from the IBTS to patients in facilities where the IBTS acts as their blood bank in the provision of a routine compatibility service. Return of the Compatibility/ Traceability Label (BT 396) allows unambiguous traceability and the final fate of the blood component.
- 1.6** It is the responsibility of the Haemovigilance Officer/Nominee to ensure the prompt return of fully completed section C (blue) of the compatibility/ traceability labels.

2. Compatibility/ Traceability Label (BT 396)

A Compatibility/ Traceability Label (BT 396) is issued with all* blood and blood components from the IBTS to patients in facilities where the IBTS acts as their blood bank in the provision of a routine compatibility service.

* For exceptions to this see Section 4.5

Components include

- (i) Red Cell Preparations
- (ii) Platelets
- (iii) Plasma Components inc. Fresh Frozen Plasma and Cryoprecipitate
(Solvent Detergent (SD) plasma is not within the scope of the regulation)


Care should be exercised when handling the unit to ensure that the label is not detached from the unit.

In the unlikely event that the label becomes detached from the unit, it should not be transfused.

The Crossmatch Laboratory should be advised and the unit returned.

2. Compatibility/ Traceability Label (BT 396)

The compatibility/ traceability label (BT 396) holds service related information on the face and instructions on the back as below

STOP, SEE BACK OF THIS TAG BEFORE TRANSFUSION		
 Irish Blood Transfusion Service Seirbhís Fulastrúcháin Éireann		NBC 01 4322800 Fax 01 4322930 MRTC 021 4807400 Fax 021 4323315 BT396-2 Oct-13
Donation Component: Signature 1: _____ Date Given: _____ Signature 2: _____ Time Given: _____		
Peel off label above and place in patient's Medical Records		
Surname:	Forename:	
DOB:	Gender:	
Hospital:		
Ward:		
Hospital No:	Suitable for Transfusion Unit:	
Patient's Blood Group:	Component:	Comments:
Special Requirements / Transfusion Protocol:		
Donation Number:		
Once transfusion has been started, you must send the completed section below back to the Hospital Transfusion Laboratory as per local policy. This is a legal requirement		
Surname:	Forename:	
Hospital No:	Lab Sample No:	
Donation Number:	DOB:	
Component:		
Date Given:	Time Given:	
I confirm that the above named patient received this blood component.		
Sign and Print Name	Hosp. Wd.	

PRE ADMINISTRATION
<p>STEP 1: Check the component has been prescribed Check any special requirements e.g. irradiated Check if concomitant drugs prescribed e.g. diuretic.</p> <p>STEP 2: Check and document baseline observations.</p> <p>STEP 3: Check expiry date and time of component. Check pack for leaks, discolouration or clumping.</p>
ADMINISTRATION
<p>STEP 1: Ask the patient to tell you their Surname, Forename and Date of Birth. Be especially vigilant with unconscious or compromised patients, refer to your local hospital policy.</p> <p>STEP 2: Check their Surname, Forename and Date of Birth and Patient Identity Number against their wristband and the compatibility label.</p> <p>STEP 3: Check that the information on the compatibility label matches the details on the blood component i.e. donation number, blood group.</p> <p>If there are any discrepancies – DO NOT PROCEED - contact your Hospital Transfusion Laboratory and HVO.</p> <p>If you suspect a transfusion reaction- STOP the transfusion immediately, seek medical advice, and contact the HVO and Transfusion Laboratory.</p> <p style="text-align: center;">Under SI # 547 of 2006 European Communities (Human Blood and Blood Components Traceability Requirements and Notifications of Serious Adverse Reactions) Regulations 2006. IT IS A LEGAL REQUIREMENT that this section of the label be completed and returned to the Transfusion Laboratory</p> <p style="text-align: right;">© Irish Blood Transfusion Service BT396-2</p>

The information will be printed by the laboratory (or handwritten in the event of a technology failure)

3. Ties

The Compatibility/ Traceability Label (BT 396) is attached to the pack by way of a plastic tie (as shown).



This should be received in your hospital with the tie uppermost (as shown below) at the open end of the overwrap and stored in this position.



This is to prevent the tie causing a pack tear from pressure on the pack.



4. Management of Compatibility/ Traceability Label (BT 396)

4.1 Overview

The Crossmatch Laboratory may issue components:-

- To assigned patients – this may be transfused to the intended or an unintended recipient.
Such components could be transferred with a patient to another facility and within Cork City such components could be rerouted to CUH.
- Labelled as emergency stock to be held on hospital site (non-assigned).
Such components could be transferred with a patient to another facility and within Cork City such components could be rerouted to CUH.
- Unlabelled in case of life threatening emergency.

The following section details the appropriate management for each circumstance.

4.2 Management of BT 396 - Assigned Patient

1. Hospital procedures cover the issue of components for transfusion and management in the clinical area.
2. On completion of independent identification checks and pack inspection as per hospital procedure, Practitioner (1) and Practitioner (2) sign the Pink Section of the Compatibility/ Traceability Label (BT 396) before commencing the transfusion.

Space is limited on the blue section of the Traceability Label. Where a patient has lengthy forenames, first and second forenames will be printed, but a third is unlikely to be. The complete name is present on the 6000 Report.

3. Once the transfusion has commenced, the completed “peel off” pink portion of the Compatibility/ Traceability Label (signed by both practitioners) is attached to the relevant place in the patient’s medical notes.
4. Once the transfusion is under-way, the practitioner signs the Blue Section (c) of the Compatibility/ Traceability Label. The time given should be documented using the 24 hour time format with day ending at 23:59 and new day commencing at 00:00. This section must be returned to the Crossmatch Laboratory as per the procedures in hospitals for which the IBTS acts as a blood bank.
(Remember the donor-patient link must be made once the transfusion has **commenced**)
5. The White Section of the Compatibility/ Traceability Label should be retained with the component until disposal of the pack. In the event of a patient adverse event the laboratory require this for pack inspection verification.

4.3 Blood Component Which was not Transfused to the Patient for Whom it was Originally Labelled, but Transfused to a Different Patient

On completion of pack inspection as per hospital procedure, prior to commencing transfusion Practitioner (1) and Practitioner (2) sign the Pink Section of the Compatibility/ Traceability Label (BT 396).

Once transfusion has commenced the Pink Section should be retained in the patient's chart, as per hospital procedure.

Where a blood component not transfused to the patient for whom it was originally labelled was transfused to a different patient,

The *Traceability Form for Transfusion Confirmation of Non-Assigned Blood Components* (IBTS/DIAG/SOP/0030 Att. 6.1) should be completed with

- (1) The patient details of the patient to whom the blood component was transfused
- (2) Transfusion details
- (3) Confirmation of transfusion

The Blue Section (c) of the Compatibility/ Traceability Label (BT 396) should be affixed to the designated area.

NB No patient, practitioner details, date or signature should be completed in the blue section.





If the staff member completing the Traceability Form was not a witness to transfusion, then prior to completing the Traceability Form, she/he must have reviewed the patient's chart to confirm transfusion to the named patient.

IBTS/DIAG/SOP/0030 Att. 6.1.

This service issue applies to the Munster Region only

4.4. Blood Component Issued Labelled as Emergency Stock (non-assigned Blood Component)

4.4.1 Compatibility/ Traceability Label BT 396 labelled as emergency stock

STOP, SEE BACK OF THIS TAG BEFORE TRANSFUSION	
 Irish Blood Transfusion Service Seirbhís Fuiláistríocháin Éireann	
NBC 01 4322800 Fax 01 4322930 MRTC 021 4807400 Fax 021 4323315 BT396-2 Oct-13	
Donation: 4224159	
Component: 04333 Red cells in A.S.leucodepleted CPD SAGM	
	
Signature 1:	Date Given:
Signature 2:	Time Given:
Peel off label above and place in patient's Medical Records	
Surname: EMERGENCY STOCK	Forename: SIVH
DOB:	Gender:
Hospital: South Infirmary/Victoria	
Ward: UNKNOWN	
Hospital No:	Suitable for Transfusion Until: 18/06/2014 23:59
Patient's Blood Group: O RhD Negative	Component: 04333 Red cells in A.S.leucodepleted CPD SAGM
Comments:	
Special Requirements / Transfusion Protocol: Patient should receive, C-, E-, K-. Rh Negative. CMV-, Red Cells	
Donation Number: 4224159	
	
Once transfusion has been started, you must send the completed section below back to the Hospital Transfusion Laboratory as per local policy. This is a legal requirement.	
Surname: EMERGENCY STOCK	Forename: SIVH
Hospital No:	Lab Sample No:
Donation Number: 4224159	DOB:
	
Component: 04333 Red cells in A.S.leucodepleted CPD SAGM	
Date Given:	Time Given:
I confirm that the above named patient received this blood component.	
Sign and Print Name	Hosp Wd.

4.4.2 Blood Component Issued Labelled as Emergency Stock Which has Been Transfused to a Patient

On completion of pack inspection as per hospital procedure, prior to commencing transfusion, Practitioner (1) and Practitioner (2) sign the pink section of the compatibility traceability label.

Once the transfusion has commenced the pink section should be retained in the patient's chart as per hospital procedure.

The hospital returning the Compatibility/ Traceability Label will fill out a *Traceability Form for Transfusion Confirmation of Non-Assigned Blood Components*

IBTS/DIAG/SOP/0030 (Att 6.1) containing the patient details of the patient to whom the blood component was transfused, transfusion details, and confirmation of transfusion.

The Traceability Form for Transfusion Confirmation of Non-Assigned Blood Components will be returned to the IBTS with the Blue Section of the Compatibility Traceability Label (BT 396) affixed to the designated section.

No patient, practitioner details, date or signature should be completed on the Blue Section.

If the staff member completing the Compatibility Traceability Form was not a witness to transfusion, then prior to completing the Compatibility Traceability Form, she/he must have reviewed the patient chart to confirm transfusion to the named patient.

4.5 Unlabelled Blood Component Issued in an Emergency

Red cell components of group O Rh D negative (Emergency Stock) may be issued in acute life threatening situations. In such emergencies these units will be issued as emergency stock with traceability label on them. Serological tests will not have been performed on these units prior to issue but will be done retrospectively.

4.6 Inter Hospital Transfer of Patient with Assigned Blood Components

Transfusion Commenced Prior to Transfer

Where transfusion is commenced prior to transfer, management should be as for an assigned patient, with Part C of the Compatibility/ Traceability Label (BT 396) returned to the Crossmatch Laboratory by the hospital from which the patient is being transferred. The Pink Section is to be completed and inserted in the hospital chart.

Transfusion during Inter-Hospital Transfer

Where a patient is transferred to another hospital with components, the Compatibility/ Traceability label (BT 396) is retained with the component on transfer.

Where transfusion is required for the patient in transit the RGN/MO accompanying the patient should complete the Pink Section and insert it in the hospital chart.

The Blue Section (c) should be completed and returned to the HVO in the hospital from which the patient was transferred by the RGN accompanying the patient.

Where transfusion is required for the patient in the receiving hospital prior to transfused units being entered into hospital inventory (stock), the RGN/MO accompanying the patient should complete the Pink Section and insert it in the hospital chart.

The Blue Section (c) should be completed and returned to the HVO in the hospital from which the patient was transferred by the RGN accompanying the patient to be sent on by the HVO to the Blood Bank from which the unit was issued / crossmatched.

Transfusion Post Hospital Transfer

On admission to the receiving hospital, where transferred units are entered into Hospital inventory (Stock) and managed as per hospital practice, traceability is the responsibility of the receiving hospital Blood Bank.

Confirmation of receipt of such components into hospital inventory should be sent to the relevant IBTS compatibility laboratory.

This service issue applies to the Munster Region only

4.7 Re-routed Blood Components

Red cell components may be re-routed to an approved hospital blood bank facility from a MRTC crossmatch facility under the approved re routing/ red cell optimisation scheme.

Where red cell components are re-routed to CUH, the BT 396 should be retained with the component on transfer. CUH will confirm receipt of such components into CUH Hospital inventory by fax. CUH will return the BT 396 directly to the compatibility laboratory at the Munster Regional Transfusion Centre.

Where red cell components are re-routed to Mater Private Dublin (MPD), the BT-396 is removed prior to transport by the HVO in Mater Private Cork (MPC). MPD will confirm receipt of components into inventory by e-mail. MPC will return the BT-396 directly to the Compatibility Laboratory at the Munster Region Transfusion Centre.

Returned labels are reconciled against the list of unit numbers sent by fax or e-mail and are then fated as facility to facility transfer on the laboratory information system.

This service issue applies to the Munster Region only

4.8 Unused Blood Components

Where a blood component is issued from the IBTS blood bank with the traceability label attached, **BUT** is not transfused/ used etc, this should be returned to MRTC or the Dublin Centre Laboratory with the tag attached to ensure appropriate fating. This applies to red cells, platelets, fresh frozen (not solvent detergent) plasma and cryoprecipitate.

5. Records – How to Write and Correct Your Data

Records are detailed, written accounts of an operation. We are required by our quality system to keep accurate records of all our activities. We consider this to be a very important part of our practice.

**If the records are not correct, we cannot
guarantee that the fating is correct!!!**

There are forms provided for most activities. These will ensure that you record all relevant information. It is important that these forms are filled in correctly and accurately.

Black indelible pen should be used for all written records and forms. Pencil is not acceptable.

Handwriting should be neat and clear.

Information should be recorded such that it could be read and understood by someone less familiar with the operation.

Care should be taken not to make mistakes when recording information. However, if you do make a mistake, it should be corrected as follows:

- A single line should be marked through the incorrect information. This cross out should not make the initial information illegible, e.g., ~~mistake~~.
- The correct information should be written beside the error.
- You should insert your initials and date beside the correction, in some cases, it may be necessary to explain why you corrected the data (for example, if you changed a piece of data).

Records should always be filled in at the time the operation is performed. It is not good practice to “fill in the paperwork or enter the data afterwards”.

It is also important that records are kept on the official form. Recording information on notepaper in order to fill in the official documents later is not acceptable as it could lead to transcription errors or omissions.

**Appendix I - Table of Frequently Issued Product Codes
(Please refer to current Product Master File for comprehensive list)**

Product Code	Text on Tag	Text on Product Label
E7429V00	RC	RED CELLS
E7442V00	RC Irradiated	RED CELLS, Irradiated
E4999V00	RC Washed	RED CELLS, Washed
C7429V00	RC for NNU for 1st 5 days	RED CELLS, Suitable for Neonatal Use for 5 days after Date Drawn
C7429VA0	RC for NNU S1	RED CELLS, Neonatal Use, Split 1
C7429VB0	RC for NNU S2	RED CELLS, Neonatal Use, Split 2
C7429VC0	RC for NNU S3	RED CELLS, Neonatal Use, Split 3
C7429VD0	RC for NNU S4	RED CELLS, Neonatal Use, Split 4
C7429VE0	RC for NNU S5	RED CELLS, Neonatal Use, Split 5
C6296V00	Cryoprecipitate for NNU	CRYOPRECIPITATE for Neonatal Use
E6953V00	Platelet Pooled in Plas/PAS Irr	PLATELETS, Adult Dose with Plasma/PAS, Irradiated
E6645V00	Platelet Pooled in Plas/PAS Ext Life Irr	PLATELETS, Adult Dose with Plasma/PAS, Irradiated
E3929V00	Platelet Aph Irr	PLATELETS, Adult Dose, Irradiated
E3929VA0	Platelet Aph S1 Irr	PLATELETS, Adult Dose, Split 1, Irradiated
E3929VB0	Platelet Aph S2 Irr	PLATELETS, Adult Dose, Split 2, Irradiated
E3929VC0	Platelet Aph S3 Irr	PLATELETS, Adult Dose, Split 3, Irradiated
E7716V00	Platelet Aph Ext Life Irr	PLATELETS, Adult Dose, Irradiated
E7716VA0	Platelet Aph Ext Life S1 Irr	PLATELETS, Adult Dose, Split 1, Irradiated
E7716VB0	Platelet Aph Ext Life S2 Irr	PLATELETS, Adult Dose, Split 2, Irradiated
E7716VC0	Platelet Aph Ext Life S3 Irr	PLATELETS, Adult Dose, Split 3, Irradiated
C3929V00	Platelet Aph NNU Irr	PLATELETS, Adult Dose, Suitable for Neonatal Use, Irradiated
C3929VA0	Platelet Aph NNU S1 Irr	PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 1, Irradiated
C3929VB0	Platelet Aph NNU S2 Irr	PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 2, Irradiated
C3929VC0	Platelet Aph NNU S3 Irr	PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 3, Irradiated
C7716V00	Platelet Aph NNU Ext Life Irr	PLATELETS, Adult Dose, Suitable for Neonatal Use, Irradiated
C7716VA0	Platelet Aph NNU Ext Life S1 Irr	PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 1, Irradiated
C7716VB0	Platelet Aph NNU Ext Life S2 Irr	PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 2, Irradiated