ISBT128 Standards for Blood and Blood Components: How it Translates to Patient Safety

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Declaration of Conflict of Interest

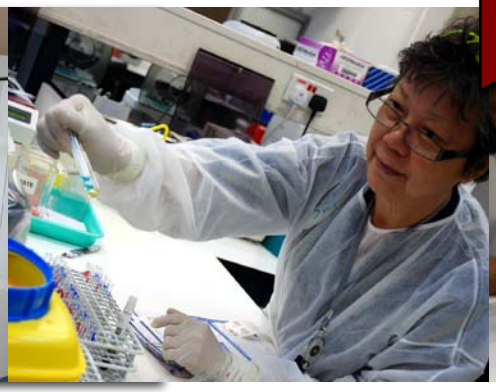
- Member of the ICCBA Board of Directors
- ICCBBA is a non-profit organisation that manages, develops and licenses ISBT 128
- ICCBBA is organised and operated exclusively for charitable, scientific and educational purposes
- ICCBBA Board of Directors are volunteers and do not receive any compensation

The Blood Transfusion Chain

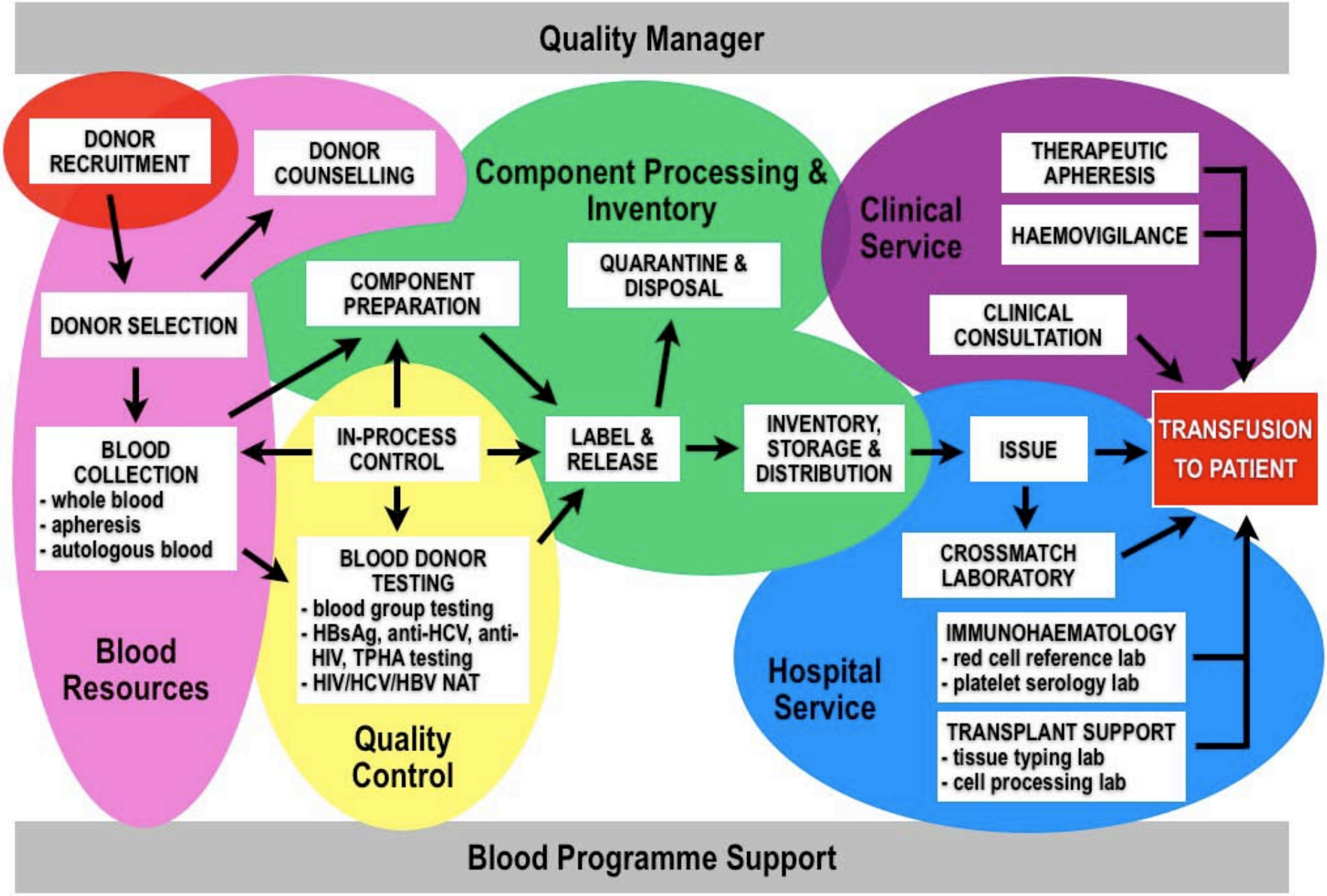
Blood Transfusion Chain

Vein to Vein

Donor Recruitment → **Blood Collection** → **Processing / Testing / Storage** → **Pre-Transfusion Testing** → **Issue / Transfusion**



VEIN TO VEIN ORGANISATION



Separation of Blood into Components

Production of Modified Components

Cryoprecipitated AHF
Fresh Frozen Plasma
Fibrinogen Concentrate
Liquid Plasma

Derivative Production

5% Albumin
20% Albumin
Intravenous Immune Globulin
Factor VIII Concentrate
Factor IX Concentrate

Further Modification

Leucocyte-Reduced Red Cells
Irradiated Blood
Washed Red Cells
Frozen Cellular Components

Apheresis Technology

Using apheresis machines, individual blood components can be collected from the donor

Patient Transfusion Safety

Haemovigilance

Defined as :

A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow up of its recipients), intended to collect and assess information on unexpected or undesirable events resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence

How Haemovigilance Contributes to Patient Transfusion Safety

- Provides medical community with reliable source of information about untoward effects of blood transfusion
- Indicates corrective measures required to prevent recurrence of some accidents/dysfunctions in transfusion process
- Alerts hospitals and blood services about adverse events that could involve more than a single recipient, including those related to :
  - Transmission of infectious diseases
  - Blood bags, solutions or blood processing

Recipient Haemovigilance

- Adverse transfusion reactions :
  - Immediate reactions during transfusion, e.g. haemolysis, febrile non-haemolytic reactions, rash, bacterial contamination, etc
  - Delayed untoward effects after transfusion - haemolysis, acute GVHD, etc
  - Occurrence of allo-immunisation against red cell, HLA or platelet antigen
- Identification of transfusion transmitted infections through trace-back and lookback activities

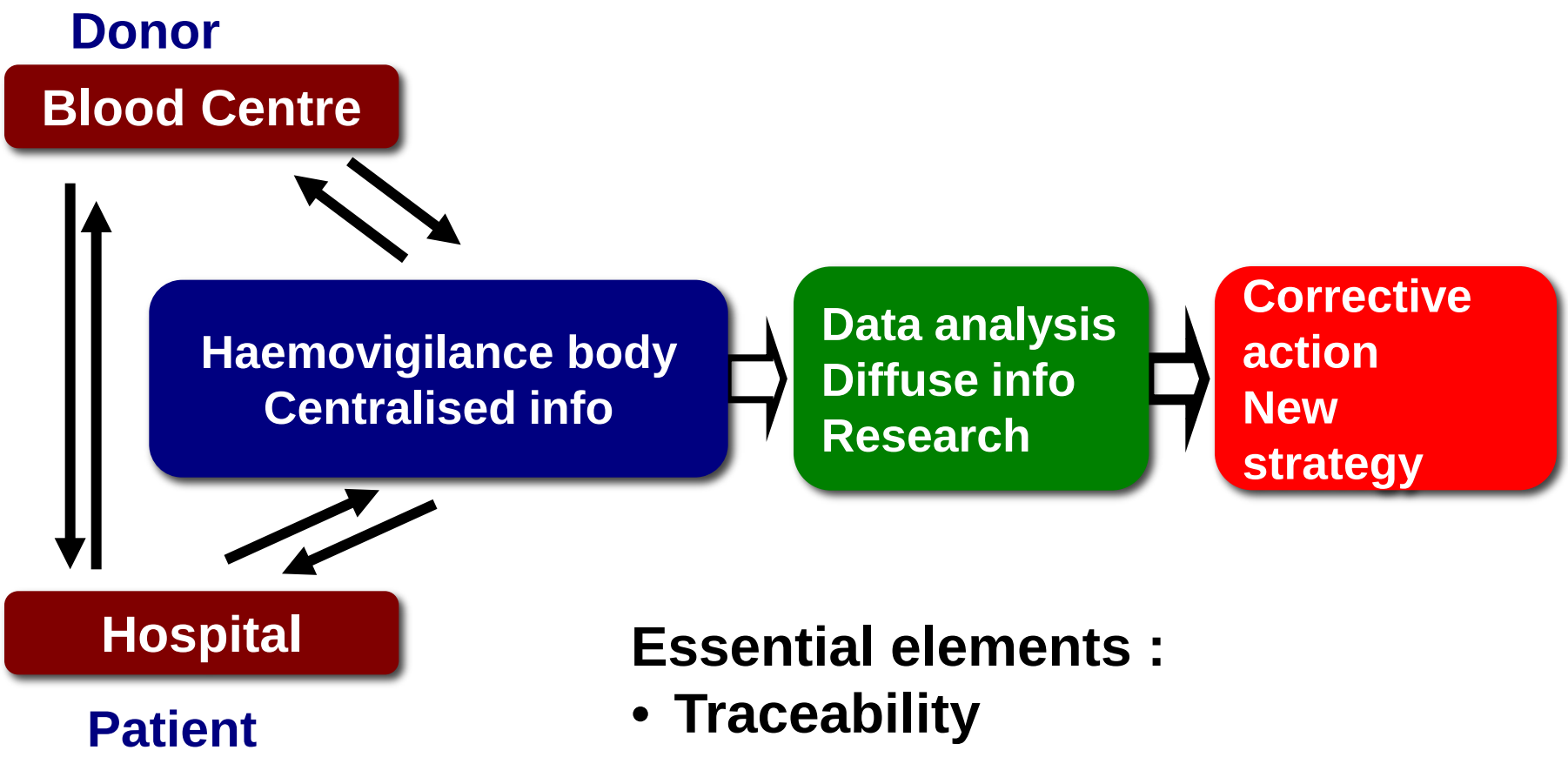
Process Haemovigilance

- Surveillance of errors in the process of both production and transfusion of blood components
  - Systematic surveillance of errors and near misses
  - Monitoring traceability of blood products
  - Surveillance of blood utilisation
- Near miss - any error, which if undetected, could result in the determination of wrong blood group, or issue, collection, or administration of an incorrect or unsuitable component but which was recognised before the transfusion took place

Donor Haemovigilance

- Untoward events observed during blood donation
- Data related to donor selection, such as frequency and causes of blood donation exclusion
- Epidemiologic data on the donors found positive in marker screening

Schematic of Haemovigilance



Essential elements :

- **Traceability**
- **Cooperation**
- **Homogeneous reporting**
- **Data analysis**

Traceability

- Ability to trace each individual unit of blood or blood components derived thereof from the donor to its final destination, whether this is a patient, a manufacturer of medicinal products or disposal, and vice versa
- Final destination may be:
  - Patient
  - Manufacturing of medicinal products
  - For research and investigational purposes
  - Disposed of
- Essential element is a unique identification numeric or alphanumeric code for each donation, with subsidiary code for each component prepared for that donation - linked with data identifying both the donor and recipient

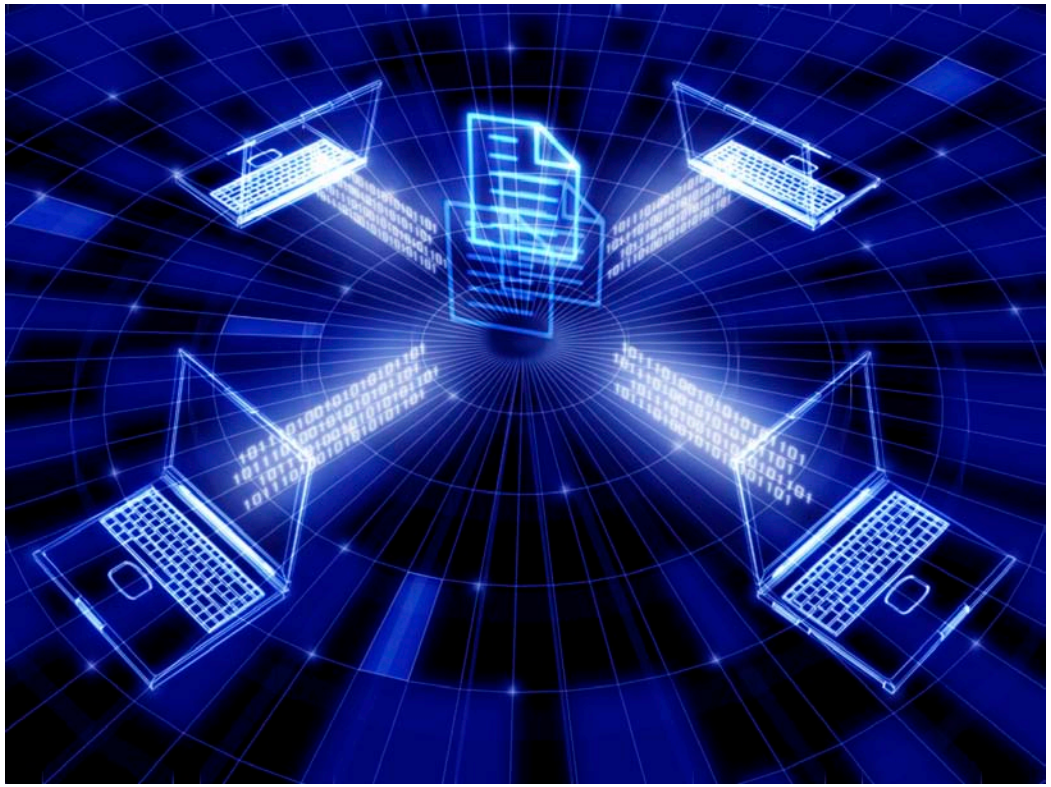
International Movement of Blood, Cell, Tissue Products

- Risk of duplication of identifiers
- Misidentification of products resulting in wrong blood, cells or tissue graft being transfused or implanted
- Weak traceability path
- Need to renumber units when products are received from outside a local area
- Slow or non-existent alert in situations of adverse events requiring product recall

Need for Standardisation

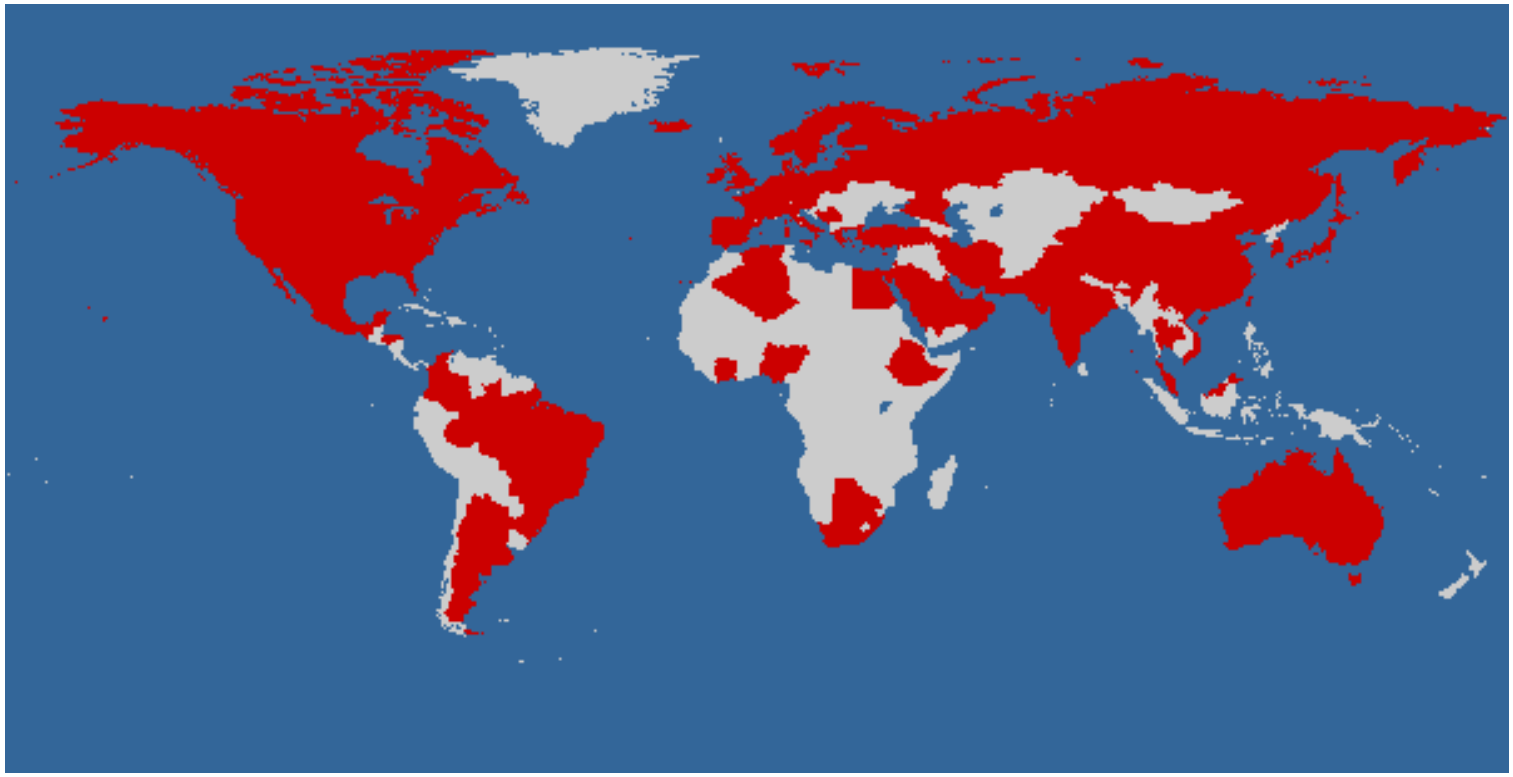
- Bar codes have same meaning globally, thus eliminating language barriers
- Eliminates need to renumber units because identifiers are globally unique
- Improved safety because receiving facility can understand detailed product characteristics
- Reduces software costs
- Facilitates movement into newer technology data transfer mechanisms

ISBT 128



ISBT 128

- Initially developed by working party of the International Society of Blood Transfusion (ISBT)
- First used in blood bank in Estonia in 1997



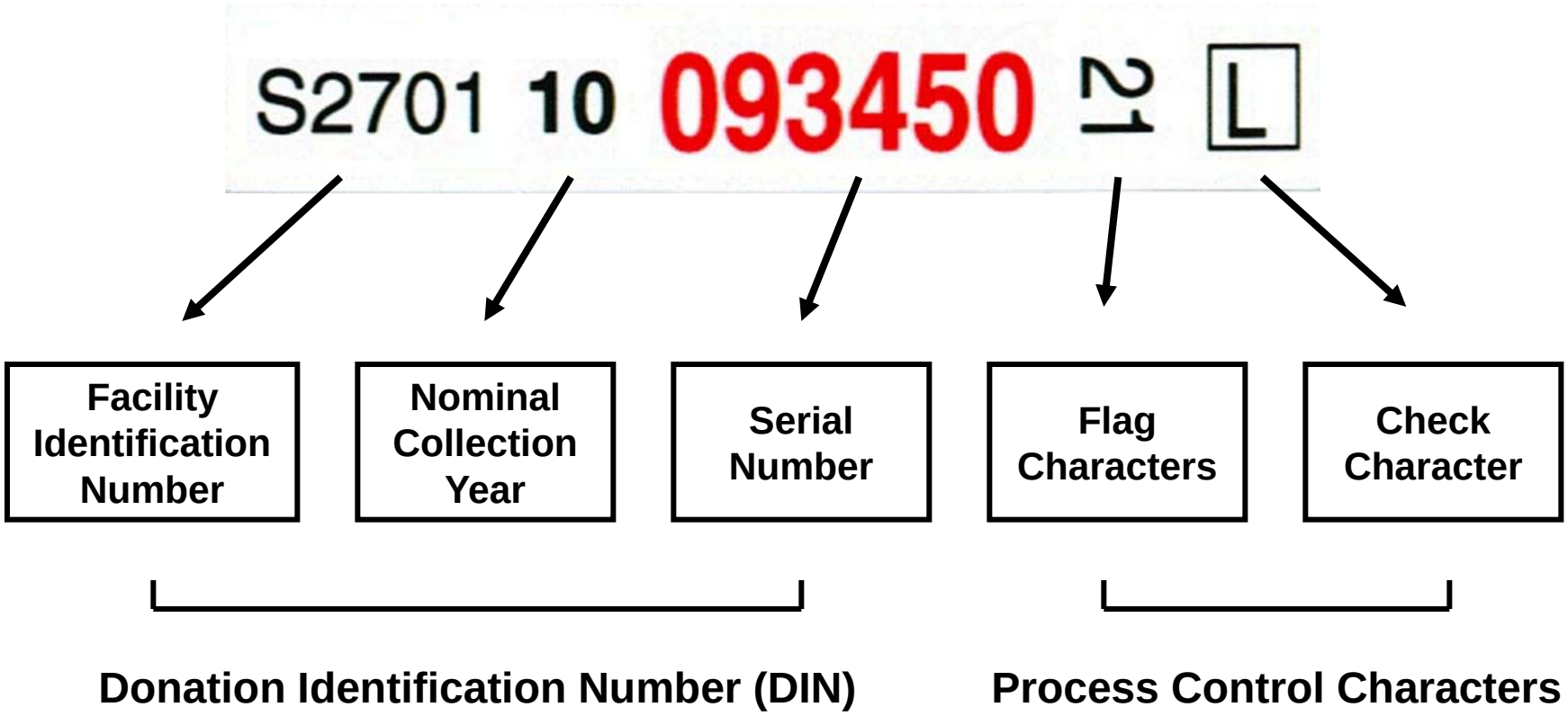
ISBT 128

- Global standard for identification, labelling, and information transfer of human blood, cell, tissue, and organ products
- Provides:
  - Globally unique donation numbering system
  - Internationally standardised product codes
  - Standard data structures for bar coding and electronic data interchange
  - Standardised labelling
- Intended for use across international borders and disparate health care systems
- Managed by ICCBBA

ISBT 128

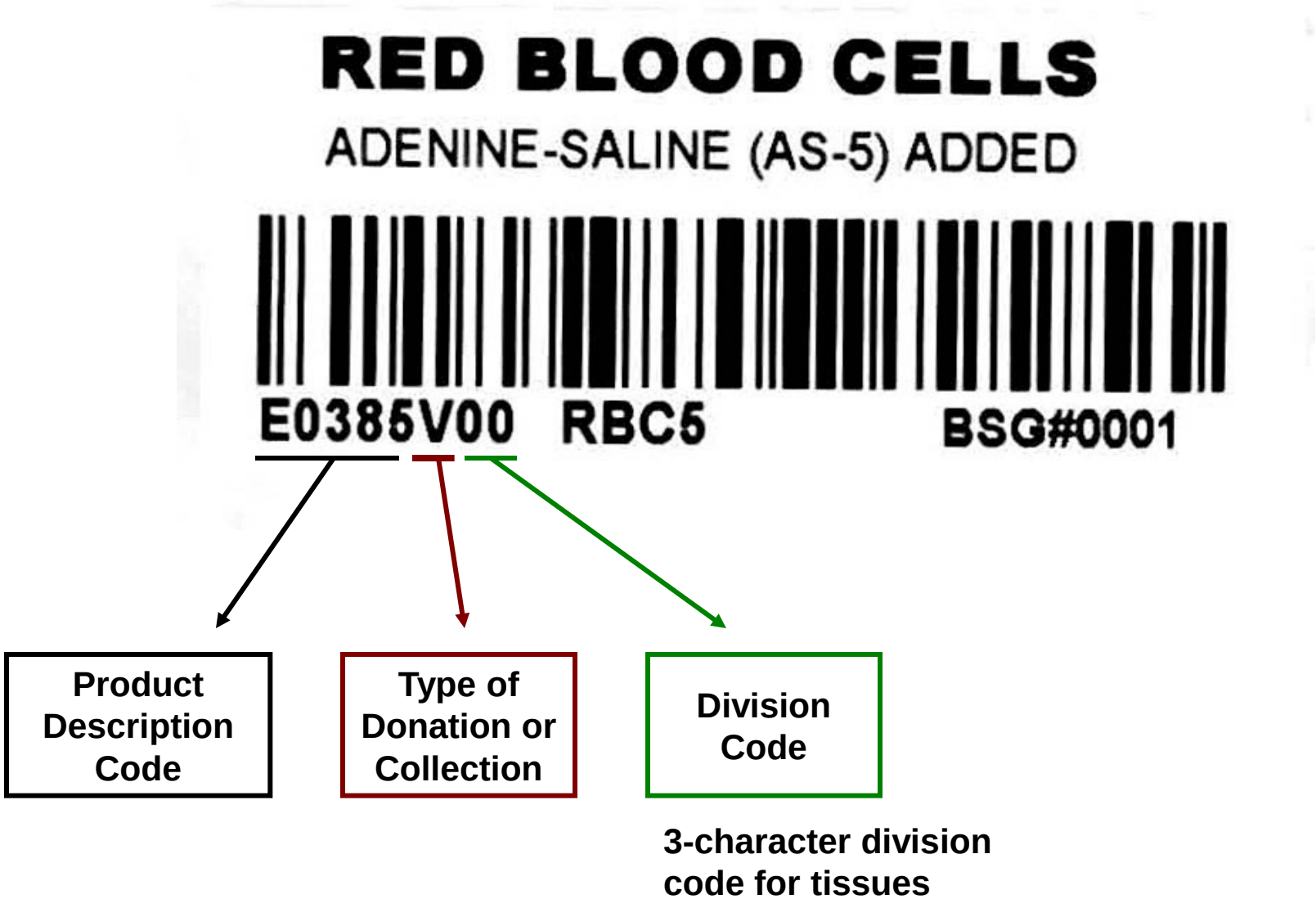
- Specifies:
  - Donation numbering system that ensures globally unique identification
  - Information to be transferred, using internationally agreed reference tables
  - International product reference database
  - Data structures in which this information is placed
  - Bar coding system (linear or 2-dimensional) for transfer of the information on the product label
  - Standard layout for the product label
  - Standard reference for use in electronic messaging

Unique Donation Identification Number (DIN)



Unique Donation Identification Number (DIN)

Product Codes



Product Codes

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED
LEUCO-REDUCED, IRRAD

E0307V00 RBC1ILR BSG#0023

FRESH FROZEN PLASMA

E4052V00 FFP BSG#0201

PLATELETS

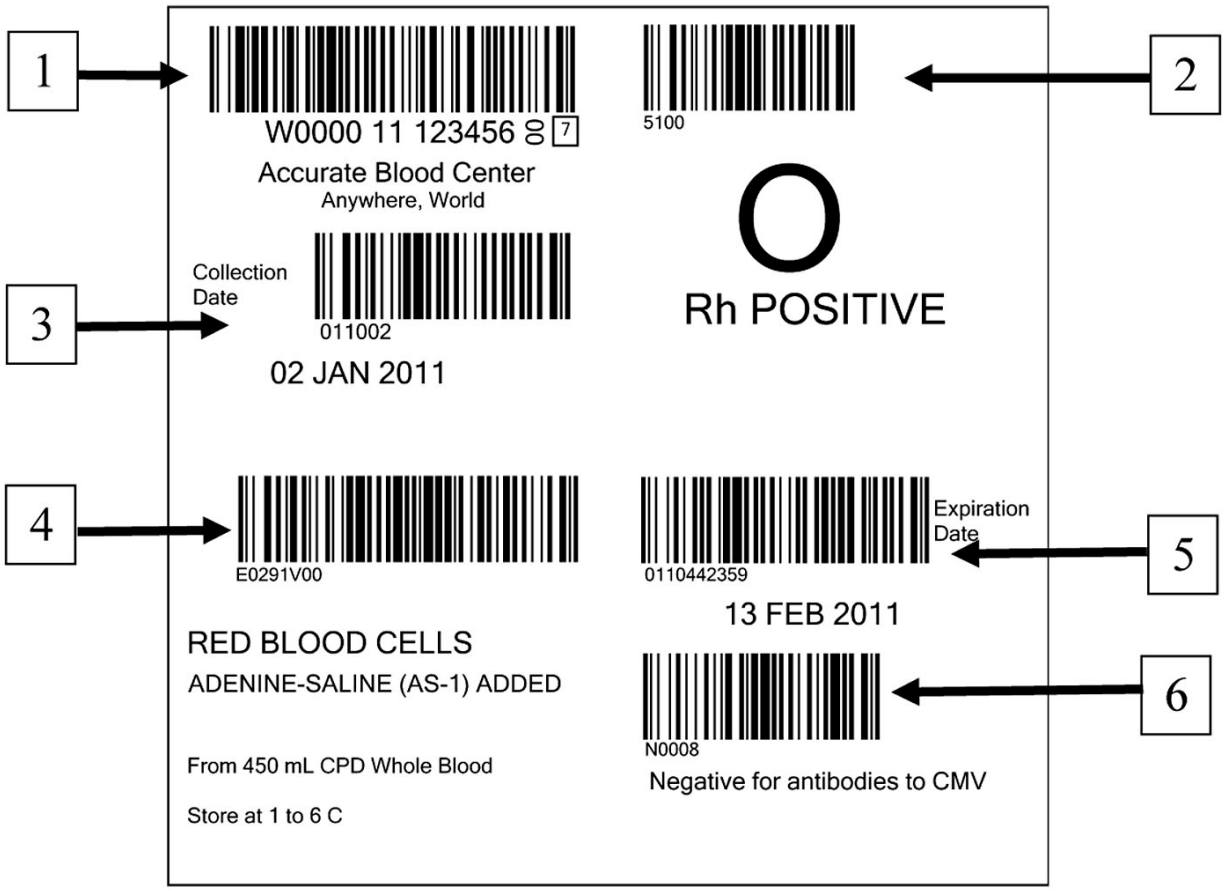
E2807V00 PLC5 BSG#0101

APHR PLATELETS
LEUCO-REDUCED, ACD-A

E3077V00 APLR BSG#0603

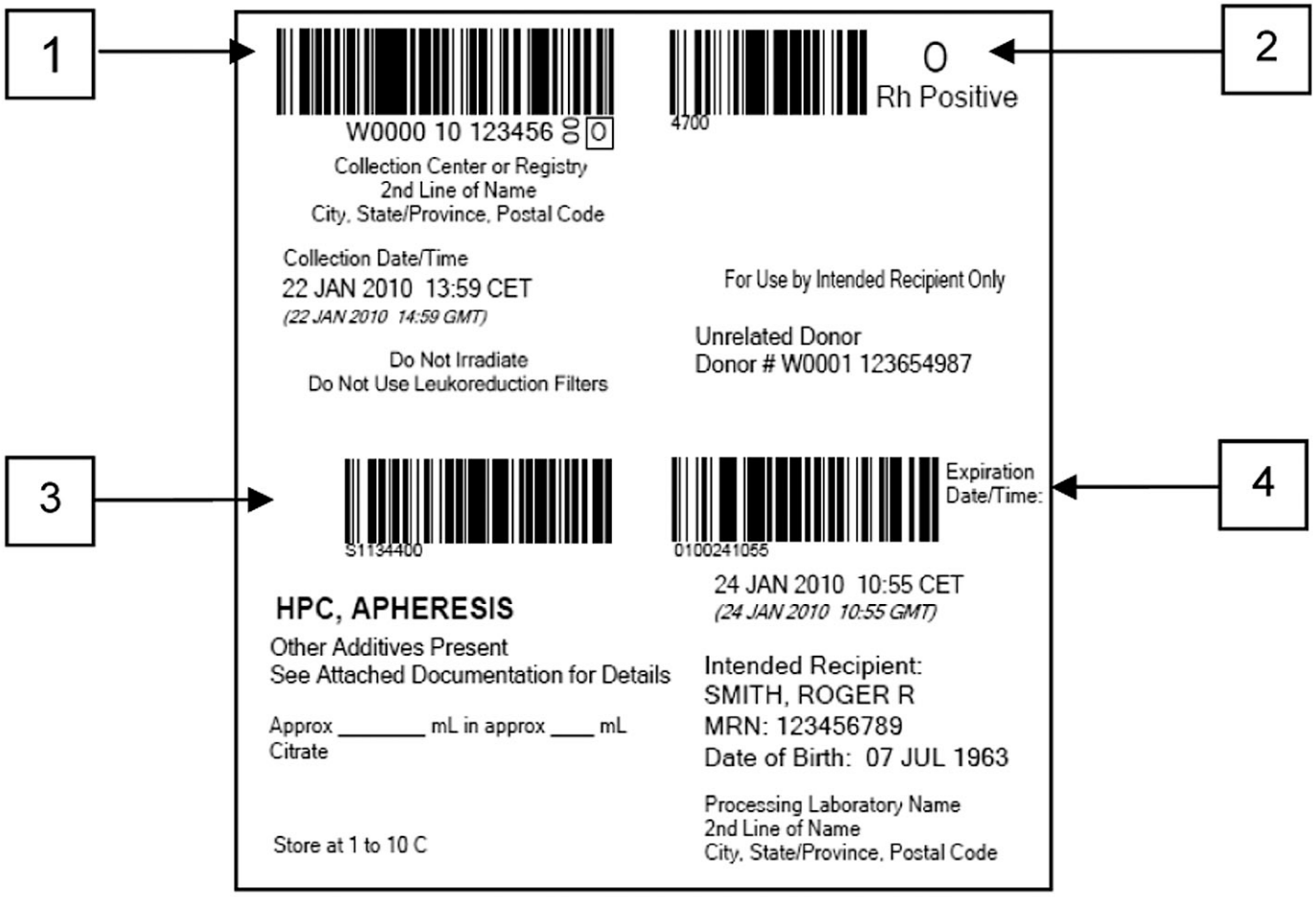
APHR PLATELETS
Leuco-Reduced **IRRAD** ACD-A

E3046V00 APLRI BSG#0606



Blood Product Label

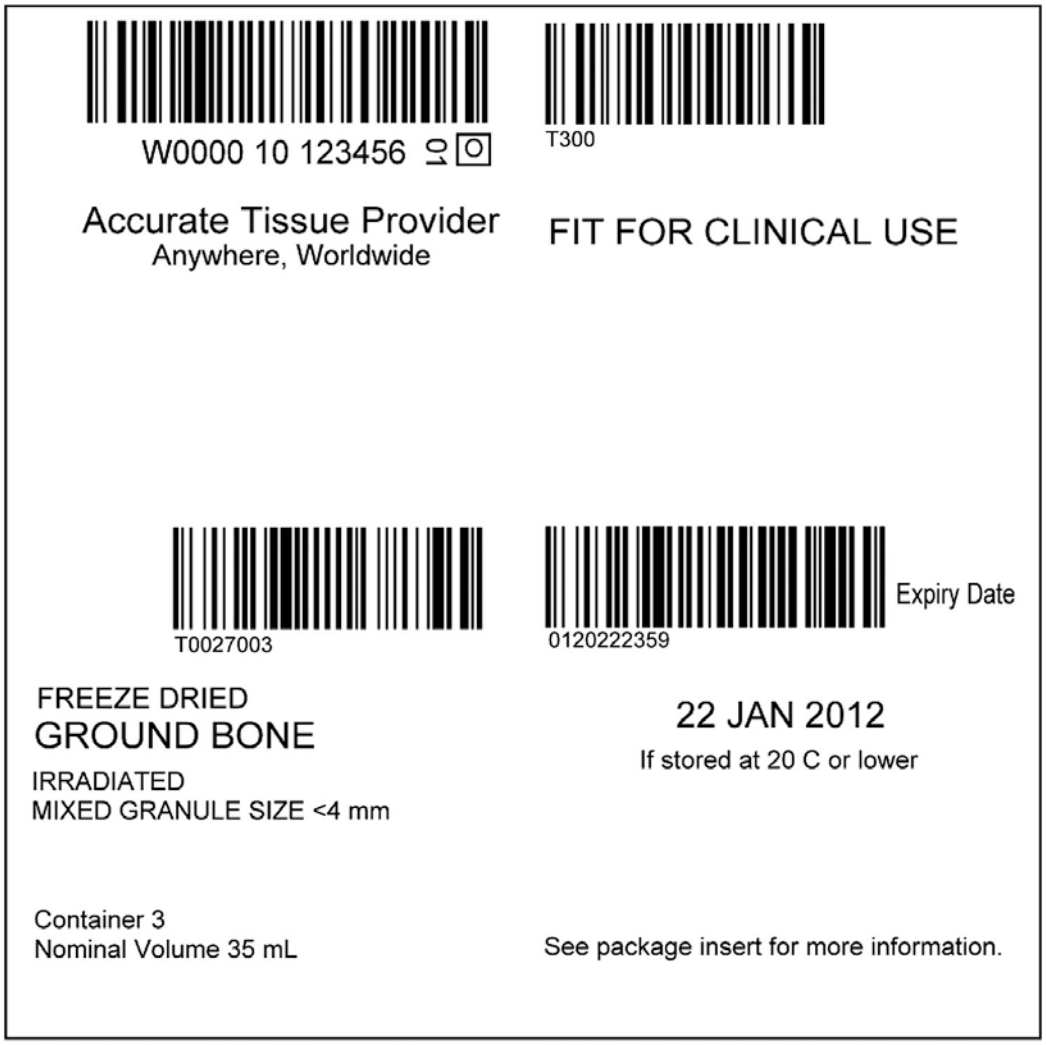
1 Donation Identification Number
2 ABO/Rh Blood Groups
3 Collection Date (optional)
4 Product Code
5 Expiration Date (and Time)
6 Special Testing (optional)



Cell Product Label

1 Donation Identification Number
2 ABO/RhD
3 Product Code
4 Expiration Date and Time

Tissue Product Label



Delivery Mechanisms

Comparative size of Code 128 and Data Matrix Symbols

Data Matrix Code 128

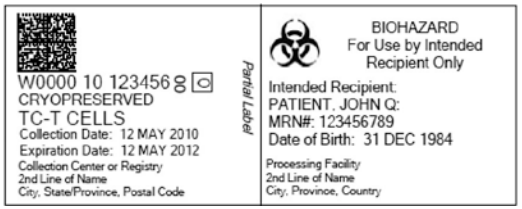
Donation ID number

ABO/Rh

Product Code

Expiration Date/Time

Special Testing results



Radiofrequency Identification

Vox Sanguinis (2009) **97**, 50–6

ORIGINAL PAPER

DOI: 10.1111/j.1423-0410.2009.001174.

Tracking blood products in blood centres using radio frequency identification: a comprehensive assessment

Rodeina Davis,[1] Bradley Geiger,[2] Alfonso Gutierrez,[2] Julie Heaser[2] & Dharmaraj Veeramani[2]

[1] *BloodCenter of Wisconsin, Milwaukee, WI, USA*
[2] *UW RFID Lab, University of Wisconsin*

Vox Sanguinis

Radiofrequency identification technology can standardize and document blood collections and transfusions

S. Gerald Sandler, Al Langeberg, Leo DeBandi, Joan Gibble, Charles Wilson, and Charles L. Feldman

Radio frequency identification for prevention of bedside errors

Sunny Dzik

"TO ERR IS HUMAN . . ."

In the landmark publication "To err is human," the Institute of Medicine brought attention to the conse-

BAR CODE OR RADIO FREQUENCY IDENTIFICATION (RFID) OR BOTH?

Bar code technology is an established technology within

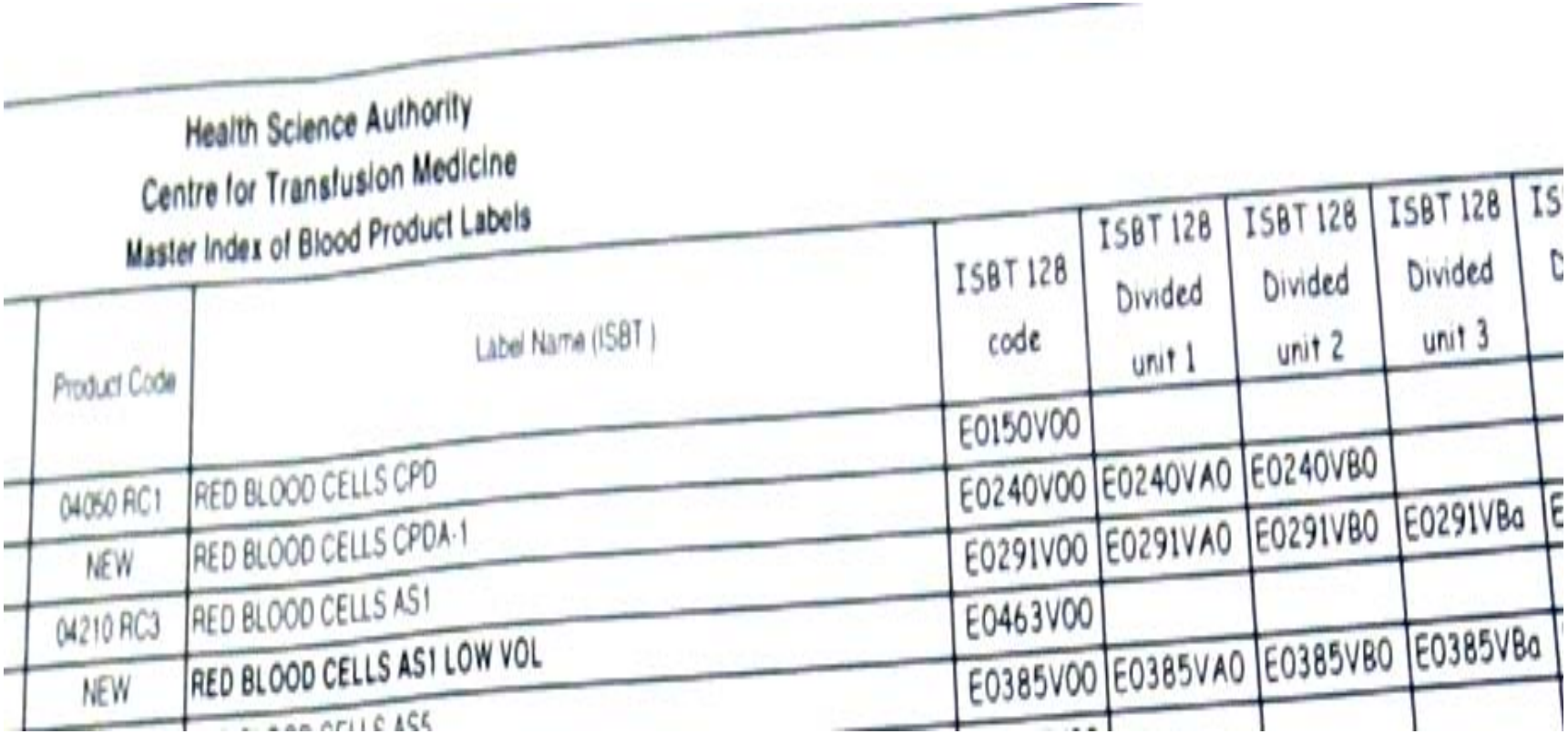
Using ISBT 128 in the Blood Service

Successful Implementation from Codabar to ISBT128 standard in 2006

Why Change ?

- Limitations of ABC Codabar standard
- Old component code system unable to systematically name modified products with multiple attributes, e.g. autologous deglycerolized leuco-reduced RBC irradiated divided unit
- Improved donation look back system with international DIN system
- ISBT 128 global standard for blood services in future

Product Code Mapping – from old to new

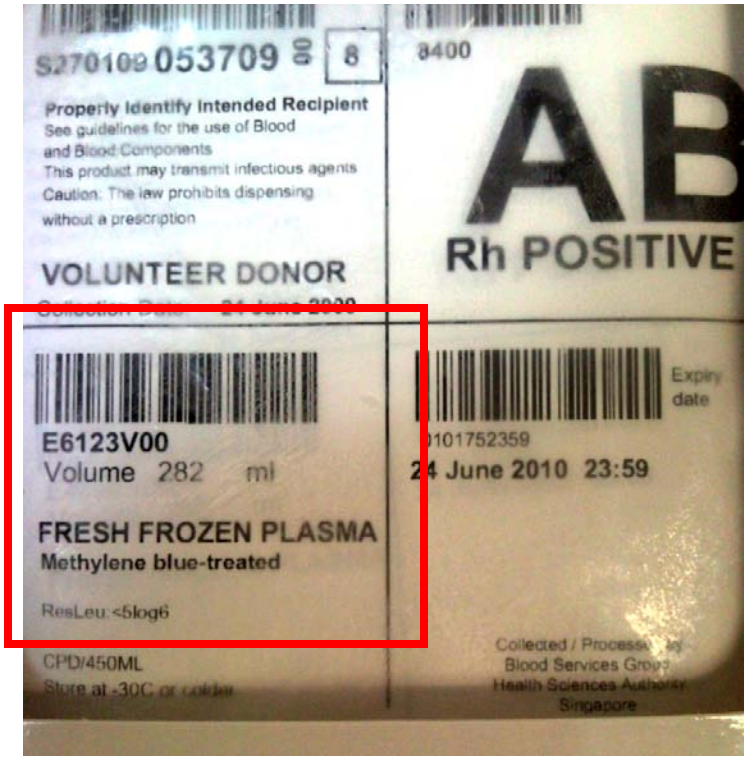


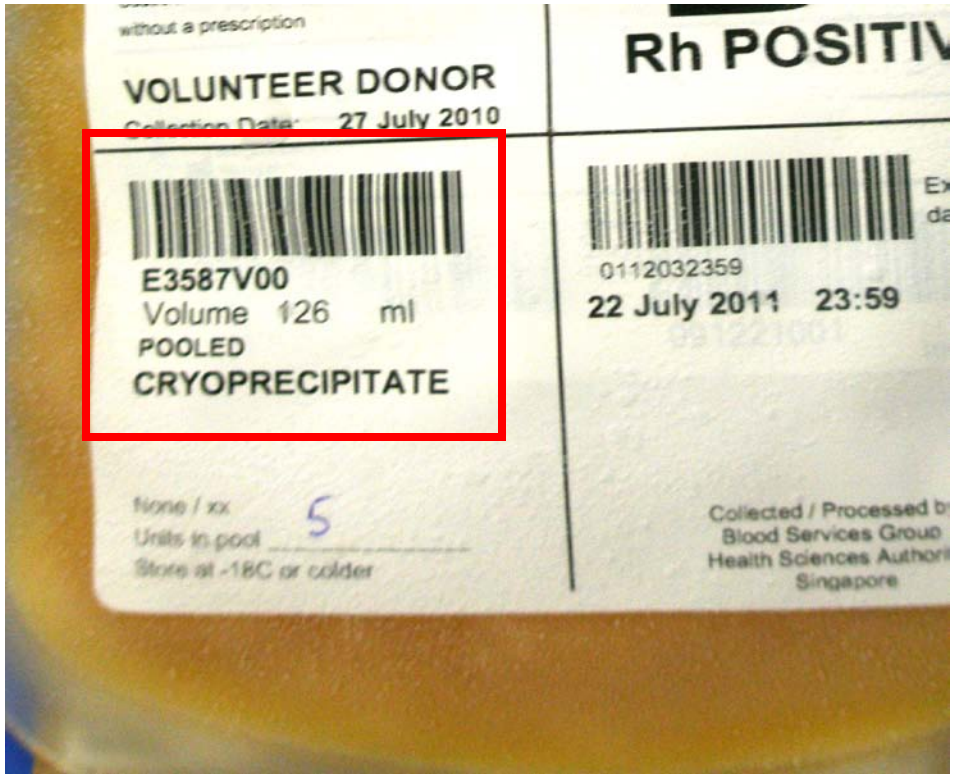
Health Science Authority
Centre for Transfusion Medicine
Master Index of Blood Product Labels

Product Code	Label Name (ISBT)	ISBT 128 code	ISBT 128 Divided unit 1	ISBT 128 Divided unit 2	ISBT 128 Divided unit 3	IS
		E0150V00				
04050 RC1	RED BLOOD CELLS CPD	E0240V00	E0240VA0	E0240VB0		
NEW	RED BLOOD CELLS CPDA-1	E0291V00	E0291VA0	E0291VB0	E0291VBa	E
04210 RC3	RED BLOOD CELLS AS1	E0463V00				
NEW	RED BLOOD CELLS AS1 LOW VOL	E0385V00	E0385VA0	E0385VB0	E0385VBa	

Blood Product Labelling

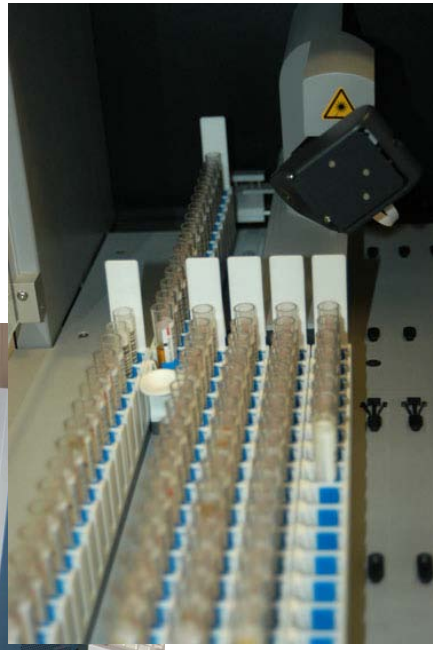
Ability to Incorporate Standard Label for New Blood Products

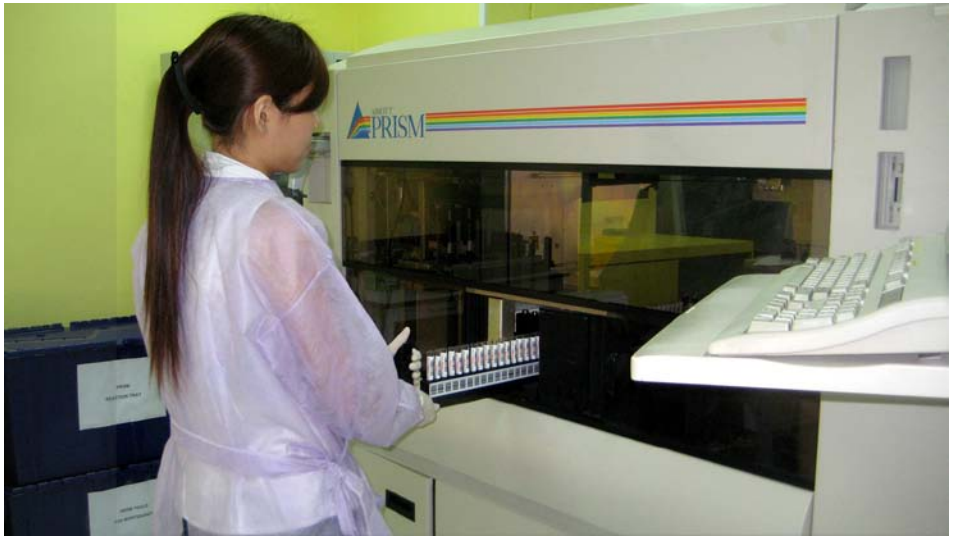




Blood Collection

Blood Donation Testing





Labeling of Blood - Final Confirmation of Suitability for Clinical Use

Issuing Blood for Patient


Thank You