



# Introduction to *ISBT 128*

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# ICCBBA



ICCBBA enhances safety for patients by managing the *ISBT 128* international information standard for use in transfusion and transplantation.

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# Role of ICCBBA

- Not-for-profit organization, funded from license fees
- development and maintenance of the standard
- assignment of new codes
- technical support
- educational material
- promotion

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# The Objective

To provide a standard information environment that:

- ❑ supports the open movement of blood, tissues and cellular therapy products around the world in such a way that critical information is rapidly, accurately and unambiguously communicated;
- ❑ satisfies regulatory requirements for traceability and retention of information.

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# What is *ISBT 128*?

- *ISBT 128* is an international standard for the coding and labeling of blood components, cellular therapy products and tissue transplant products.
- Developed for transfusion by ISBT in 1994
- Extended to support Tissue Banking and Cellular Therapy in 2000
- Extended to support Solvent Detergent Plasma in 2006

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# ***ISBT 128* for Blood Transfusion**

- 3,500 Licensed Facilities worldwide
- 30 million units of blood *ISBT 128* labeled each year
- Extensive use in Europe and Middle East
- Rapid rollout in N. America to 2008 deadline
- Chinese Society of Blood Transfusion recommend use of *ISBT 128*. Already implemented in Shanghai and Zhejiang Province.
- Australian NBA decision to implement by July 2011

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# ***ISBT 128* in Cellular Therapy**

- New *ISBT 128* Terminology and Labeling Standards published by the International Cellular Therapy Coding and Labeling Advisory Group
  - ❑ Transfusion 2007:47 1312-1327,
  - ❑ Bone Marrow Transplantation (2007) 40, 1075-1090
  - ❑ Journal of Clinical Apheresis (2007)
- Terminology being widely accepted
- Implementation in facilities across the world
- Over 180 CT Facilities registered in 28 countries

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# ***ISBT 128 for Tissues***

- ISBT 128 Standard extended to support Tissue Products in UK in 2000
- Adopted for coding and labelling of all tissues provided by the UK NHSBT
- CEN (European) Workshop Agreement recommends *ISBT 128* standard with addition of “key code”
- AATB/ICCBBA North American Tissue Technical Advisory Group developing terminology









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# Key Elements of *ISBT 128*

- Unique donation numbering system (global)
- Standard structures and formats for information
- International product list, definitions and codes
- Standard data structures for other key information (status information, expiry, HLA profiles etc.)
- Mechanism for development and maintenance of the standard

# ISBT 128 Labeling

 W1234 02 123456 	 5100
<hr/> <b>Accurate Blood Center</b> Anywhere, Worldwide <hr/>	 <b>Rh(D) Positive</b>
<small>Properly Identify Intended Recipient See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.</small> <b>Rx only</b> <b>VOLUNTEER DONOR</b>	
 E0291V00	 0022062359 <b>Expiration Date</b> <b>31 JUL 2002</b>
<b>RED BLOOD CELLS</b> <b>ADENINE-SALINE (AS-1) ADDED</b>	
From 450 mL CPD Whole Blood	

Donation  
Identification  
Number

Blood Group

Product Code

Expiration  
Date

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# Donation Identification Number

G1517 02 123456 8 M

- Comprises 4 elements:
  - ❑ Facility identification code
  - ❑ Year indicator
  - ❑ Sequential number
  - ❑ Flag characters
- Manual entry check character

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# Facility Identification Code

- Assigned by ICCBBA to ensure global uniqueness
- Assigned to Collection Facilities at the time of Registration and Licensing
- Reference Lookup Table available to Registered Facilities and Vendors
- Provides a key to donation tracing

# Facility Code Lookup

G1517 02 123456 M

G0116	Scottish National Blood Transfusion Service	Edinburgh		Scotland	EM17 7QT	<a href="http://www.scotblood.co.uk">www.scotblood.co.uk</a>
G0117	Scottish National Blood Transfusion Service	Edinburgh		Scotland	EM17 7QT	<a href="http://www.scotblood.co.uk">www.scotblood.co.uk</a>
G0118	Scottish National Blood Transfusion Service	Edinburgh		Scotland	EM17 7QT	<a href="http://www.scotblood.co.uk">www.scotblood.co.uk</a>
G0337	Isle of Man Blood Transfusion Service	Douglas	Isle of Man	United Kingdom	IM1 4QA	
G0915	National Blood Service	Sheffield	Yorkshire	England	S5 7JN	<a href="http://www.blood.co.uk">www.blood.co.uk</a>
G0916	National Blood Service	Edgware	Middlesex	United Kingdom	HA8 9BD	<a href="http://www.blood.co.uk">www.blood.co.uk</a>
G1016	Scottish National Blood Transfusion Service	Edinburgh		Scotland	EM17 7QT	<a href="http://www.scotblood.co.uk">www.scotblood.co.uk</a>
G1517	Welsh Blood Service	Pontyclun	Wales	United Kingdom	CF72 9WB	<a href="http://www.welshblood.org.uk">www.welshblood.org.uk</a>
G1618	Northern Ireland Blood Transfusion Service	Belfast		N. Ireland	BT9 7TS	
G1703	Scottish National Blood Transfusion Service - Tissues	Edinburgh		Scotland	EM17 7QT	<a href="http://www.scotblood.co.uk">www.scotblood.co.uk</a>
G1704	Scottish National Blood Transfusion Service	Edinburgh		Scotland	EM7 7UT	<a href="http://www.scotblood.co.uk">www.scotblood.co.uk</a>

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# Product Code

- Provides an international reference table of products
- Clear unambiguous definitions
- Structured presentation of information using concepts of class, modifier and attributes
- Simple process for requesting new codes
- Regular updates are published by ICCBBA

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# Product Code Hierarchy

- **CLASS** – a description of the product type
  - A product belongs to only one class
- **MODIFIER** – describes the physical state of the product
  - A product may have up to one modifier
- **ATTRIBUTES**
  - A product may have many attributes
  - Each attribute group has a range of possible values
  - A combination of attribute values describes the product to the level of detail **required by the user.**

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# Example

- CLASS
  - Ground Bone
- MODIFIER
  - Freeze Dried
- ATTRIBUTES
  - Irradiated
  - Medium Granule



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# Benefits of the structure

- Flexible system supports future developments in tissue banking and CT
- Structured
- Supports analysis of information at various levels
- Allows the user to specify the degree of detail in the definition

# Other *ISBT 128* Data Structures

- ABO/Rh D Blood Group
- Expiration Date (and Time)
- Collection Date (and Time)
- Special Testing (General)
- Red cell Phenotypes
- Platelet Specific Antigens and HLA Phenotypes
- HLA Genotypes
- Manufacturers Code and Catalogue Number
- Manufacturers Lot No
- Donor Identification Number
- Staff Identification Number
- ***Potential to add new structures as required***

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# ISBT 128 Identification of Derivatives

- Donation Identification Number provides unique identification. FIN assigned to the fractionator
  - ❑ X0001 08 123456
- Product Code identifies the specific derivative product
  - ❑ X0004000 - SOLVENT DETERGENT POOLED PLASMA Group AB
- Lot Number and Expiry Date data structures



# Identification of Blood Derivatives



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# Background

- Initial approach from blood transfusion institutions and derivative manufacturers
- Discussion over labeling of solvent detergent plasma
  - Product is processed by plasma fractionator but distributed as frozen plasma product
  - Unique identification essential to manage post thaw control of product

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# Background

- Australian NBA decision to label plasma derivatives with GS1
- Québec request for ISBT 128 labelling of plasma derivatives
  - ❑ Customer complaint from APCSTQ (Association professionnelle des chargés de sécurité transfusionnelle du Québec) to Government of Québec
- Introduction of ISBT 128 for solvent detergent plasma in Finland

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# Background

- ICCBBA/GS1 Memorandum of Understanding
- Desire to achieve global standardization
- Need to explore the needs of relevant stakeholders
  - Users (hospital and blood center)
  - Manufacturers
  - Regulators

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# Key Issues

- Requirement for unique identification
- Dual path for derivative management
- Blood product or drug?



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# Unique Identification

- Current situation
  - Derivatives identified by
    - Product name
    - Lot number
    - Expiry date

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# Why unique ID?

- Individual containers in a lot are identical at the point of release from manufacturer
- Following release, their history changes:
  - Different recipient organizations
  - Different storage conditions
  - Different time of use
- In order to follow product history unique identification is essential

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# Dual path

- Hospital level management of derivative products follows two paths
  - Management through Blood Bank
  - Management through Pharmacy
- The former approach is based on treating derivatives as blood products
- The latter approach is based on treating derivatives as drugs

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# Blood Product or Drug?

- Product is batch produced, and in most cases has a long shelf life
- Source for blood derivatives is human blood donations
- Different regulatory framework
- Haemovigilance and traceability requirements mean there is a need to maintain the donor – recipient pathway for a period of at least 30 years