



# Use of *ISBT 128* in the Labeling of Cellular Therapy Products

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# What is *ISBT 128*?

- International standard for the transfer of information associated with tissue, cellular therapy and blood products
- Provides
  - globally unique donation numbering system
  - Internationally standardized product definitions
  - Standard data structures for bar coding and electronic data interchange
- Independent of delivery mechanism (linear bar code, 2-D bar codes, RFID, electronic data interchange)

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# What is ICCBBA?

- Formerly International Council for Commonality in Blood Bank Automation
- Not-for-profit US-based organization
- Develops and manages *ISBT 128* Standard
- Works with advisory groups of experts in the fields of tissues, cellular therapy and blood
- Interacts with other standard setting and regulatory organizations to ensure compatibility of the *ISBT 128* Standard with existing standards and regulations

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# Status of *ISBT 128*

- In use for almost 10 years for cell therapy, blood and tissue
  - Cellular Therapy: Some US and European Cellular Therapy facilities using *ISBT 128*. Used in cord blood banks all over the world
  - Blood: Blood banks in many countries are using *ISBT 128* since 1997
  - Tissue: UK is using *ISBT 128* for tissue banking; being evaluated for use with tissues in the US
- International standard setting organizations have committed to using *ISBT 128* for cellular therapy products

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# Organizations Committed to *ISBT 128* Standard for Cellular Therapy

- **AABB**
- American Society for Apheresis (**ASFA**)
- American Society for Blood and Marrow Transplant (**ASBMT**)
- European Group for Blood and Marrow Transplantation (**EBMT**)
- Foundation for Accreditation of Cellular Therapy (**FACT**)
- International Society for Blood Transfusion (**ISBT**)
- International Society for Cellular Therapy (**ISCT**)
- **ISCT Europe**
- Joint Accreditation Committee for ISCT and EBMT (**JACIE**)
- National Marrow Donor Program (**NMDP**)
- World Marrow Donor Association (**WMDA**)

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# Cellular Therapy Coding and Labeling Advisory Group

- Formed in 2005 to broaden the use of *ISBT 128* in the area of cellular therapy
- Have defined terminology and label designs
- Will publish work this winter for public review
- An FDA liaison is invited to all meetings

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# ***ISBT 128* Process Steps**

- Identify experts in the field
- Define terminology
- Encode information
- Create common databases
- Design standardized label

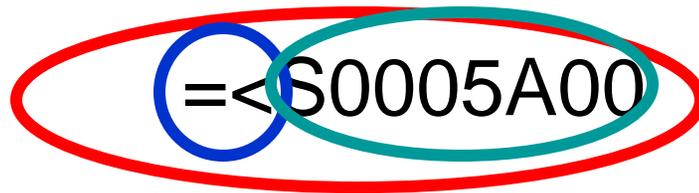
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# Common Terminology

- Select terminology through consensus
- Define selected terms
- Publish for broad input



# Encode information (data structures)



*Data  
Structure*

*Data  
Identifiers*

*Data Content*

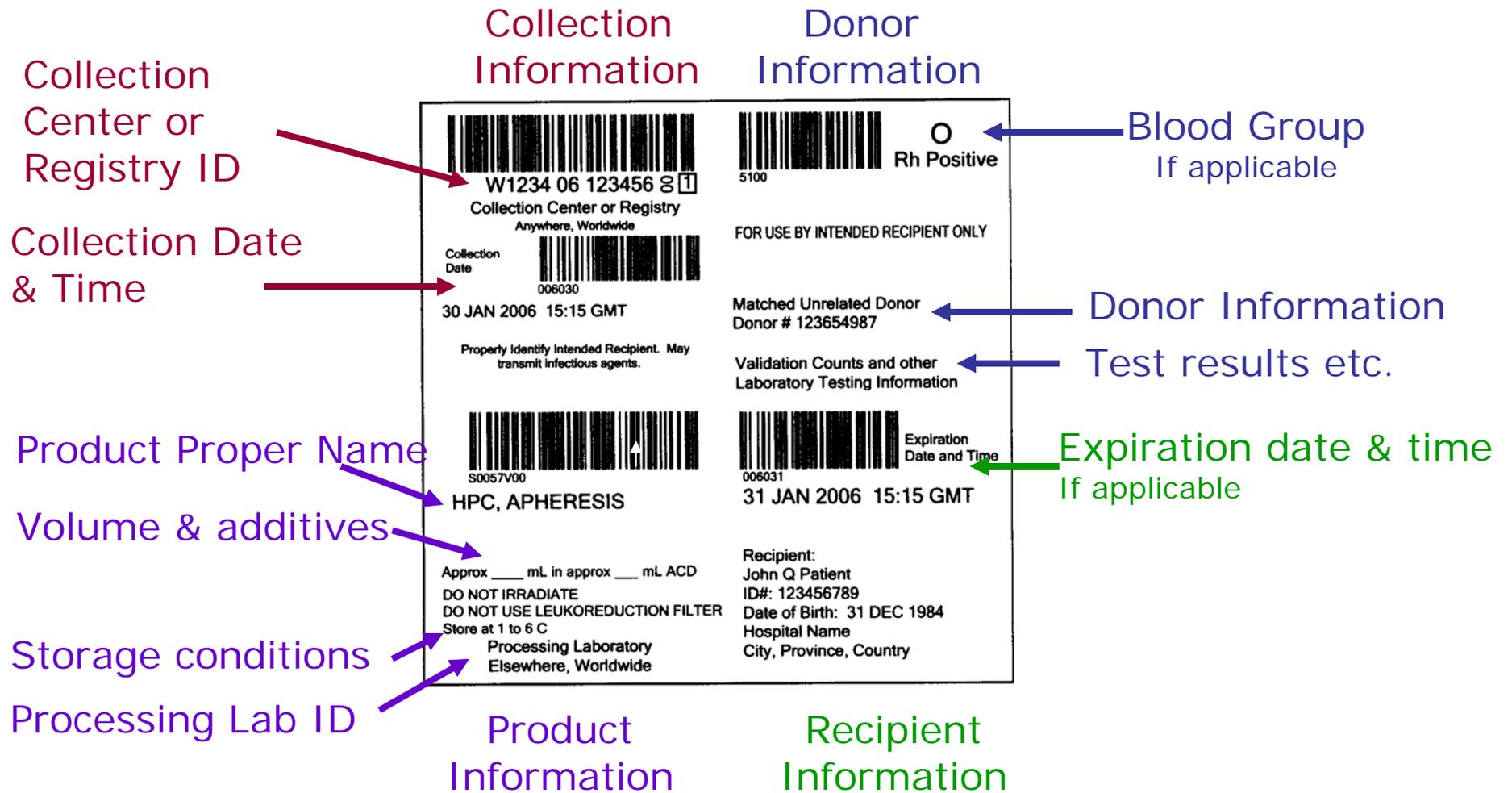
*(product, donation  
type, divisions if any)*

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# Common ICCBBA-maintained database

- Found on ICCBBA website
  - Accessible to users
  - Accessible to regulatory and standard setting organizations
- Reference tables for codes
  - For example, product code S0005 = Thawed HPC, Marrow|DMSO/XX/<-120C|Open|10% DMSO

# Design standardized label



 <b>90003</b> 05 2171348 <b>H</b> <b>上海市血液中心</b> 血站执业许可证： 沪卫血站字(2001)第001号 临床适应症：适用于贫血且需要补充血容量的患者。  注意事项：输注前请检查包装是否完好无损，外观是否正常；除0.9%的生理盐水外不得与任何药剂在同一输液器内输注。	 8400  <b>AB</b>  <b>Rh 阳性</b>
 <b>Z0203000</b> <b>病毒灭活冷沉淀凝血因子原料浆预制品</b> 容量：100mL ± 10% 保养液：ACD-B 储存条件：2-6℃ 制备者：1234	 200511221200 失效期： 2005-11-22 12:00 保存期：21天 制备时间： 2005-11-02 12:00

# Cryo Vial Label



TC-T Cell

Smith, John F.

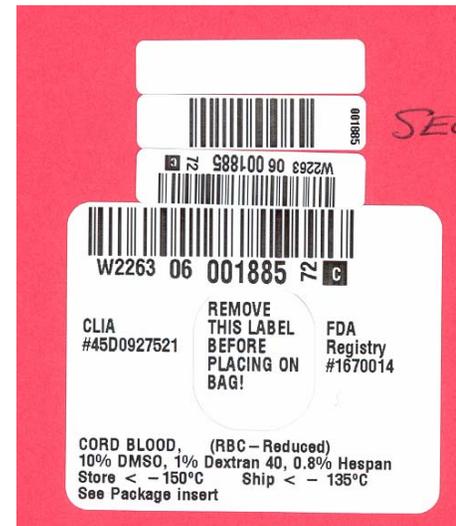
TCH MRN #: 98705324

DOB: 14 NOV 1936

# BioArchive™ Cord Blood Labels



Courtesy of Thermogenesis



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# Importance of International Standardization

*Products commonly cross international borders  
(39% of NMDP products cross an  
international border)*

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# What information can be encoded?

- Unique identifier including the manufacturer or registry name
- Product description
- Donation type
- ABO/Rh
- Biohazard if applicable
- Expiration date and time
- Collection date and time
- Special testing results (CMV or HLA)
- Donor identifier
- Patient identification number and date of birth

W1234 07 123456 8 S



Five character facility ID code  
Year  
Serial number  
Flags (number or icon)  
Check digit



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# Facility Identification Number

All facilities in the world are assigned a unique Facility ID code by ICCBBA

- May also encode a donor registry
  - ❑ Required by 42 U.S.C. 274K (f) (5) to ensure donor confidentiality
  - ❑ Registry maintains identity of collection facility
- Key (database) on ICCBBA website
  - ❑ Accessible to users and regulatory agencies
- Once assigned, the Donation Identification Number doesn't change improving trackability
  - ❑ Exception: products from multiple donors are pooled into one container and a pool number is assigned



W1234 06 123456 8 1

Collection Center or Registry  
Anywhere, Worldwide



5400

○  
Rh Positive



BIOHAZARDOUS  
FOR AUTOLOGOUS USE ONLY

Collection Date  
30 JAN 2006 15:15 GMT

Properly Identify Intended Recipient. May  
transmit infectious agents.

Validation Counts and other  
Laboratory Testing Information



S0057X00

AUTOLOGOUS

HPC, APHERESIS

Expiration Date and Time  
31 JAN 2006 15:15 GMT

Approx \_\_\_\_ mL in approx \_\_\_\_ mL ACD  
DO NOT IRRADIATE  
DO NOT USE LEUKOREDUCTION FILTER  
Store at 1 to 6 C

Donor/Recipient:  
John Q Patient  
ID#: 123456789  
Date of Birth: 31 DEC 1984  
Hospital Name  
City, Province, Country

Processing Laboratory  
Elsewhere, Worldwide

# Blood type, donation type and biohazard information encoded

 W1234 06 123456 8 1 Collection Center or Registry Anywhere, Worldwide	 5400 Rh Positive
Collection Date 30 JAN 2006 15:15 GMT	 BIOHAZARDOUS FOR AUTOLOGOUS USE ONLY
Properly Identify Intended Recipient. May transmit infectious agents.	Validation Counts and other Laboratory Testing Information
 S0057X00 AUTOLOGOUS HPC, APHERESIS	Expiration Date and Time 31 JAN 2006 15:15 GMT
Approx ____ mL in approx ____ mL ACD DO NOT IRRADIATE DO NOT USE LEUKOREDUCTION FILTER Store at 1 to 6 C	Donor/Recipient: John Q Patient ID#: 123456789 Date of Birth: 31 DEC 1984 Hospital Name City, Province, Country
Processing Laboratory Elsewhere, Worldwide	

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# ***ISBT 128* Product Codes**

- Define the product in terms of its cellular content, anticoagulant, storage temperature and other attributes
- Do not include highly variable information (cell counts or amount of active/inactive ingredients) in bar coded information
  - ❑ This would create too many product codes to be manageable
  - ❑ Would require assigning of product codes on a very urgent basis
  - ❑ Would lose the benefit of standardization since receiving facility wouldn't have the "key" to the code
  - ❑ Information is human readable on the label

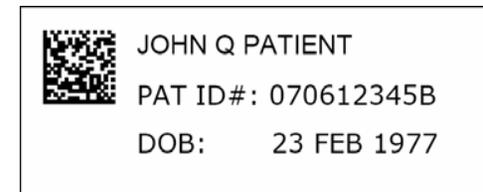
# Safety at Bedside

- Patient Identification Number
- Patient birth date

## Unit Label



## Patient Wristband



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# Advantages of *ISBT 128* vs. NDC

- Designed for international use overcoming language barriers
- Provides collection, processing or registry ID
- Tracking number does not change during subsequent processing
- Provides specific product information but does not encode highly variable information
- Product codes are assigned in advance of need
- Delivers safety to patient bedside

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# Summary

## ***ISBT 128*** is:

- **Comprehensive** system designed for cellular therapy products
- **Proven** system (in use for 10 years in CT labs, tissue banks and blood banks)
- **Flexible** enough to accommodate technological advances
- **Structured** enough to maintain global standardization