Understanding ISBT 128 Labels

Linda Sledge, RN, HP(ASCP)
Quality Manager
Carolinas Cord Blood Bank
Duke University Medical Center
Why ISBT 128 Labeling?

- Emphasis on quality and safety
- Need for tracking and traceability of a specific unit of cellular products
  - The Donation Identification Number (DIN) combining with the Product Code provide unique identification for each unit
  - The ISBT 128 terminology & labeling standards are international regulatory requirements of bar-coding cellular products
- Choice of a method that could minimize clerical reading and transcribing errors and could transition into automated data handling
Understanding the Donation Identification Number (DIN)

- The DIN is specific to the donation/product/unit
- Remains the same for all products collected from donor during one collection
- Different DINs for different collections
- Not the same as Donor Number (or local identification #)
W0000 06 523457

- **W0000** = Identifies facility (assigned by ICCBBA)
- **06** = Year of collection
- **523457** = Sequential number associated with collection
Flags printed vertically for Process Control

20 as flag character = maternal blood
00 as flag character = cord blood unit

D = Checksum digit generated by computer based on the DIN & is used to verify manual entry of DIN
Understanding the Product Code (PC)

Product Code Criteria/Description Based on:
- ICCBBA standards and is assigned according to the ICCBBA database

S1128V00:
- S = Class of product (HPC)
- 1128 = Unique code that identifies class, attribute, modifier and product/additives as assigned by ICCBBA
- V = Donor type, V for Volunteer donor
- 00 = Unique identifier between bags
  - 00 is default where only 1 bag is collected
  - A0 is used for 1st bag, B0 for 2nd bag
Understanding the Number Assignments

- Donation Identification Number (DIN) and the Product Code (PC) create a unique identifier for the unit of HPC product.
- The label standards also apply to bone marrow products:
  - May require labeling capabilities by OR
  - Or more likely by cell processing laboratory
One Collection

08/06/07 Collection
1st Collection:
   DIN = W4321 07 123458 ☑ Y
   Local ID = R12341111
   PC = S1128V00

08/07/07 Collection
2nd Collection:
   DIN = W4321 07 123461 ☑ 9
   Local ID = R12341111
   PC = S1128V00
One collection, Two Products

08/06/07 Collection

1st Bag: DIN = W4321 07 123456  
Local ID # R12349999
PC = S1128VA0

2nd Bag: DIN = W4321 07 123456  
Local ID # R12349999
PC = S1128VB0
ISBT 128 Label Divided into Quadrants

1st Quadrant

Collection Center or Registry
Collection Date/Time:
29 JAN 2006 15:15
(29 JAN 2006 20:15 GMT)

Property Identify Intended Recipient:
May transmit infectious agents.

HPC, APHERESIS
Approx mL in approx mL ACD
DO NOT IRRADIATE
DO NOT USE LEUKOREDUCTION FILTER
Store at 1 to 10°C
Processing Laboratory Elsewhere, Worldwide

2nd Quadrant

FOR INTENDED RECIPIENT ONLY

Matched Unrelated Donor
Donor #: 123654987

Laboratory Testing Information
Additional Laboratory Testing Information

Expiration Date/Time:
31 JAN 2006 15:15
(31 JAN 2006 20:15 GMT)

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

3rd Quadrant

4th Quadrant

O RhD Positive
5100
Example of ISBT-128 Label for HPC, Apheresis Product

1st Quadrant DIN
W0000 = facility (W = US)
06 = year
523457 = sequential number
vertical # = process control code
Last character = check digit

If Collection date is required, date and time format
Warning Statements will be defined by US Labeling Standards when available

3rd Quadrant PC
ICCBBA assigns code
Barcode with eye readable
S = prefix for HPC products
Standard Language for storage and anticoagulant
Name and location of Processing facility if different from Collection facility

ABO/Rh Bar Code with eye readable
Testing Information to be set by US Stds
If Expiration date is required, date & time format
Recipient Information dependent of type of donation
Example Label
Biohazardous Autologous HPC, Apheresis

Collection Date
30 JAN 2007 15:15
(30 JAN 2007 20:15 GMT)

Expiration Date and Time
31 JAN 2007 15:15
(31 Jan 2007 20:15 GMT)

Processing Laboratory
Elsewhere, Worldwide

Donor/Recipient:
John Q Patient
ID#: 123456789
Date of Birth: 31 DEC 1984
Hospital Name
City, Province, Country
Example Label
Cyropreserved Cord Blood Unit
What are the benefits of ISBT 128?

- Standardized easy-to-read labels that included the requirements of the Regulations and Standards
- Staff’s awareness and acceptance of a needed standardization on terminology, data-structure and labeling guidelines for Cellular Therapy Products
- Elimination of handwritten labeling information that could lead to identification and labeling errors
Implementation Strategies for ISBT 128

- Promote acceptance of ISBT 128 as the standard
- Determine involvement of your facility
  - Collection
  - Processing
  - Storage
  - Distribution
  - Thawing
  - Infusion
- Determine level of automation
  - only manually
  - can scan but must make data entry manually
  - totally automated in data entry and data management
- Determine if an upgrade is necessary for your level of activities and your facility’s commitment to total automated data handling
Carolinas Cord Blood Bank (CCBB) Data Management System

- Uses AdvantageEDC™ for electronic record management
- System is maintained by the EMMES Corporation
- Accessed from any computer connected to the Internet
- System allows users to submit data forms using secure transmission technology

https://web.emmes.com/study/drc/
Welcome to the Carolinas' Cord Blood Bank Data Entry System

The Carolinas' Cord Blood Bank Data Entry System allows entry of data to the medical coordinating center securely and directly via the World Wide Web. The bank will be able to access and review their data directly.

Enter the Data System

Enter the Training System

CORD LISTINGS
Welcome to the Carolinas' Cord Blood Bank

Data Entry System

The Carolinas' Cord Blood Bank Data Entry System allows entry of data to the medical coordinating center securely and directly via the World Wide Web. The bank will be able to access and review their data directly.

Enter the Data System

Enter the Training System

CORD LISTINGS
BRC - Ver. 3.15

AdvantageEDC™ Login Screen

User ID: [Redacted]
Password: [Redacted]

Log In       Cancel

Notice: To protect the sensitive data this system handles, your browser connection will be automatically terminated if you remain on the same page longer than 20 minutes without an action that submits the page to the server. Upon termination, all data modifications to that page will be lost. Elapsed time on a page will be indicated by a timer in the browser's status bar.
ISBT unique identifier is scanned into EMMES data management system
Form to be entered is selected