



*ICCBBA is a nongovernmental
organization in official relations with
the World Health Organization*

ISBT 128 Cellular Therapy Label Design

Erwin Cabana

Lead Information Standards Specialist

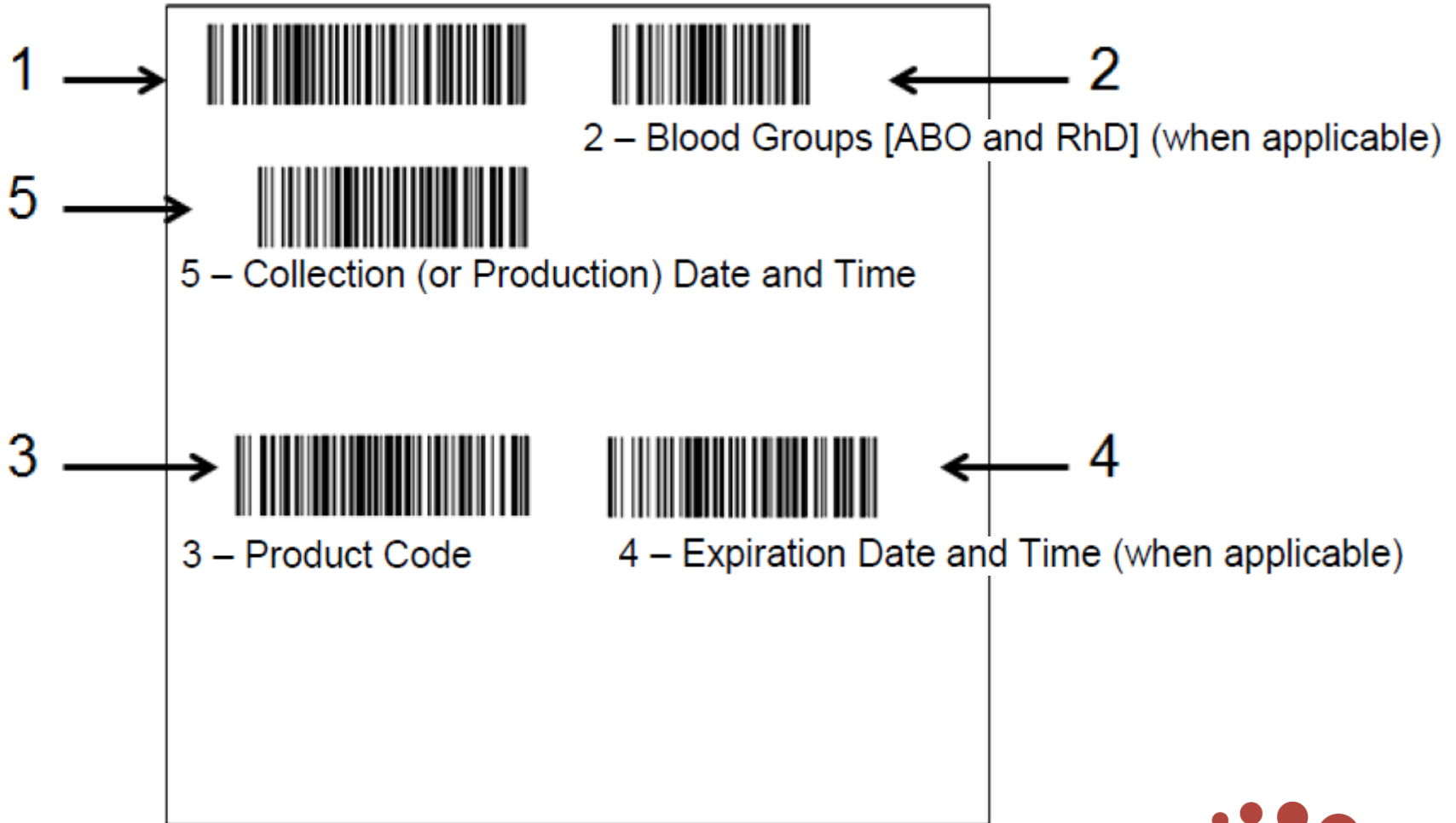
ICCBBA

Scope of Presentation

- ISBT 128 label design for final affixed label
- Full 100mm x 100mm label
- Designated locations for particular information
- Appearance of standardized text
- Examples of labels
- Partial labels

Standard Bar Code Placement

1 – Donation Identification Number



Standard Bar Code Placement

Required Bar Codes on 100 mm x 100 mm label

- 1 – Donation Identification Number
- 3 – Product Code

Recommended Bar Code

- 4 – Expiration Date and Time (when applicable)

Optional Bar Codes and Symbols

- 2 – Blood Groups [ABO and RhD] (when applicable)
- 5 – Collection (or Production) Date and Time

Standard Bar Code Placement

- By always placing the bar codes in the same location, users know which bar code to scan for particular information.
 - Requires initial training to recognize bar codes
- Allows for concatenation

Standard Bar Code Placement

■ Overcome language barriers

The diagram illustrates the placement of four standard bar codes on a medication label. Each bar code is accompanied by its corresponding data:

- Top Left:** A large 1D bar code with data: S0020 13 015114 Ω \square H
- Top Right:** A smaller 1D bar code with data: 4700, followed by the text "O RhD pos".
- Middle Left:** A 1D bar code with data: 0150460738, followed by the text "Tapp. datum" and "15 FEB 2009 07:38".
- Middle Right:** A 1D bar code with data: 0150481314, followed by the text "Använd senast" and "17 FEB 2015 13:14".

Additional text on the label includes:

- HSC, aferes
- Mobiliserade
- Volym 108 mL
- Lösning Citrat
- Lagringstemp 2-6C

Upper Left Quadrant (ULQ)

Information Elements	Format
Donation Identification Number	Machine-readable
Donation Identification Number	Text
Facility (collection, pooling, or cord blood processing) name and address	Text
Collection date and time if pertinent	Machine-readable
Collection date and time if pertinent	Text
Cautions and warnings:	
Do Not Irradiate	Text
Do Not Use Leukoreduction Filters	Text
Rx Only	Text

Upper Left Quadrant

- Appearance of DIN:

A9999 12 123456 ≈ K

Facility
Identification
Number (FIN)

Collection
Year
(+/- 1 month)

Serial
Number

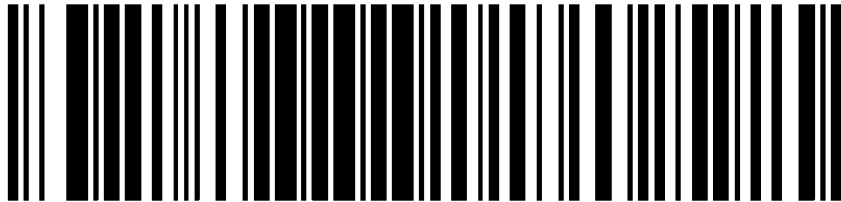
A9999 12 123456

Donation Identification Number (DIN)

Upper Left Quadrant

- Collection date/time not required to be machine readable or in text
- Rx Only text is required for licensed products.

Upper Left Quadrant – Example Label



A9999 12 123456 20 K

Best Collection Facility
2nd Line of Name
Boston, MA 02129

Collection Date/Time
22 JAN 2012 13:59 EST
(22 JAN 2012 18:59 UTC)

Do Not Irradiate
Do Not Use Leukoreduction Filters
Rx Only

Non-bar coded collection date

Upper Left Quadrant – Example Label



A9998 12 123458 ∞ A

Best Collection Facility
2nd Line of Name
Baltimore, MD 21075

Collection Date 
012022

22 JAN 2012
Do Not Irradiate
Do Not Use Leukoreduction Filters

Bar coded collection date

Upper Left Quadrant – Example Label

- When trying to maintain confidentiality, the facility name should not appear (e.g., matched unrelated donors).



Lower Left Quadrant (LLQ)

Information Elements	Format
Product Code	Machine-readable
Product Code	Text
Product name and description	Text
Anticoagulant/preservative and its concentration	Text
Volume	Text
Recommended storage temperature	Text
Division number	Text
US License Number, if product is FDA licensed	Text
Warning statement: "Caution: New Drug—Limited by United States law to investigational use." If product is distributed under an IND	Text

Lower Left Quadrant (LLQ)

Product
Description
Code

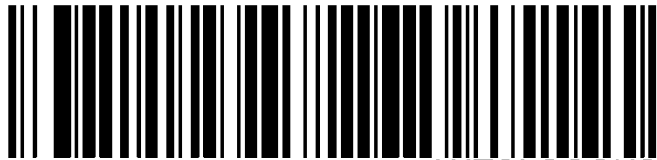
Donation
Type

Division
Code

S1234V00

ISBT 128 Product Code

Lower Left Quadrant – Example Labels



S1153XA0

AUTOLOGOUS

HPC, MARROW

6% HES + 5% DMSO
Cryopreserved

Total Volume _____ mL
Store at -150 C or colder
Part A0



S1128100

AUTOLOGOUS

HPC, APHERESIS

Mobilized

Total Volume 198 mL containing
approx 11 mL Citrate

Store at 1 to 10 C

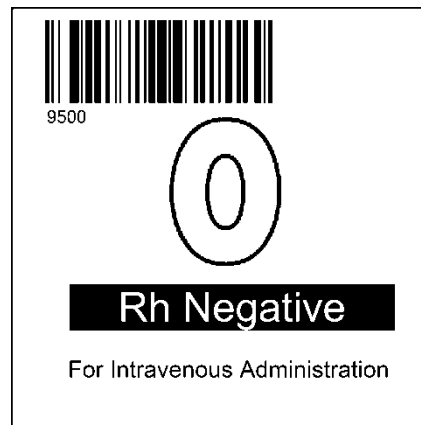
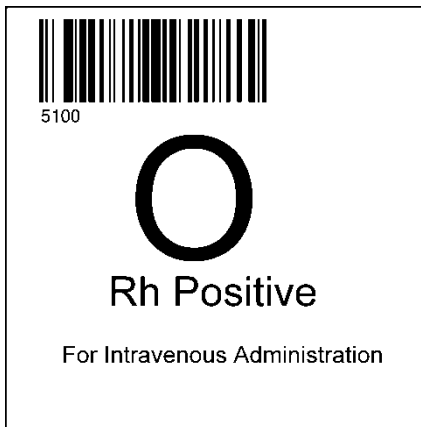
Upper Right Quadrant (URQ)

Information Elements	Format
ABO/RhD, if applicable	Machine-readable
ABO/RhD, if applicable	Text
Biohazard symbol if applicable (and if known at time of freezing on a cryopreserved product)	Symbol (information is also encoded into the machine readable ABO/RhD, if present)
Special message (e.g., For Nonclinical Use Only) if applicable	Text (This may also be encoded in the ABO/RhD data structure)
Warning message: For Autologous Use Only or For Use by Intended Recipient Only, if applicable	Text
Warning message: The route of administration recommended or a reference to such directions in an enclosed circular, if applicable	Text
Donor identifier, if recipient is known	Text
Donor name and date of birth, if donor is a first or second degree relative of the intended recipient	Text

Upper Right Quadrant

- The ABO/RhD may not be known or not applicable.
- If ABO/RhD is known:

RhD Group	ABO text	RhD text
RhD Positive	Solid black	Black on white
RhD Negative	Outline black	White on black




These examples would apply to cord bloods where the intended recipient is not known at the time of freezing

Upper Right Quadrant


- Format of donor ID number is up to the facility assigning the number
 - ISBT 128 donor number format is available (refer to Data Structure 019)
- For autologous units, donor information is included in the lower right quadrant as part of the recipient information.

Upper Right Quadrant – Label Examples



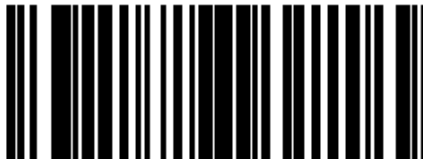
4900

○ Rh Positive




BIOHAZARD

For Use by Intended Recipient Only
Related Donor, First or Second Degree
SMITH, JOHN P
Donor # W0000 1236549
Date of Birth: 17 NOV 1983



5400

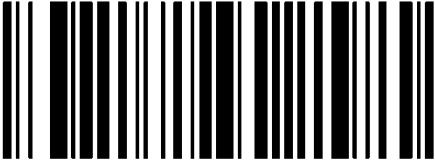
○ Rh Positive



BIOHAZARD

FOR AUTOLOGOUS USE ONLY

Upper Right Quadrant – Label Examples

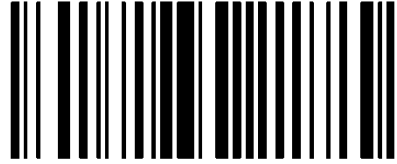


4700

O
Rh Positive

For Use by Intended Recipient Only

Unrelated Donor
Donor # W0000 1236549



4700

O
Rh Positive

For Use by Intended Recipient Only

Related Donor
John P. Smith
Donor # W0000 1236549
Date of Birth: 17 NOV 1983

Lower Right Quadrant (LRQ)

Information Elements	Format
Expiration date and time if applicable	Machine-readable
Expiration date (and time) if applicable	Text
Recipient name, identifier and date of birth if applicable	Text
Processing facility text if different from the Collection or Pooling facility identified in the ULQ	Text

Lower Right Quadrant

- Expiration date/time not required to be bar coded
- Recipient information (if known) appears below the expiration and is not required to be bar coded.
 - Donor/Recipient information if autologous

Lower Right Quadrant – Label Examples

Expiration Date and Time
01 MAR 2014 15:15 EST
(01 MAR 2014 20:15 UTC)

Intended Recipient:
SMITH, MARY L
Recipient ID: 123456778
Date of Birth: 31 DEC 1969

Processing Facility
2nd line of Name
City, State, Zip Code



0140322359

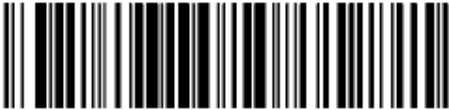




Expiration
Date

01 FEB 2014





Donor/Recipient:
SMITH, JAMES P
Donor #: W0000 12345678
Recipient ID: 12356998
Date of Birth: 17 AUG 1982

Processing Facility
2nd Line of Name
City, State, Zip Code




Full Label Examples

 A9996 14 876543 ♂ H Collection Center or Registry Address Anywhere, USA 00700	 0200 A Rh NEGATIVE
Collection Date/Time  0140221415 22 JAN 2014 14:15 Do Not Irradiate Do Not Use Leukoreduction Filters	For Use By Intended Recipient Only Related Donor, First or Second Degree SMITH, JOHN P Donor # 123654987 Date of Birth: 17 NOV 1983
 S1152400 DESIGNATED	 0140241415 Expiration Date/Time: 24 JAN 2014 14:15
HPC, MARROW	Intended Recipient: SMITH, MARTHA P Recipient ID: 123456789 Date of Birth: 12 DEC 1990 Processing Laboratory 2nd Line of Address Elsewhere, USA 00500
Total Volume ____ mL containing approx ____ mL Heparin (____ U/mL) Store at room temperature	

Full Label Examples

 A9999 14 123498 8 3 Springfield University Medical Center 1411 University Parkway Springfield, CA 92111	 5300 O Rh POSITIVE
Collection Date  014011 11 JAN 2014 Do Not Irradiate Do Not Use Leukoreduction Filter	FOR AUTOLOGOUS USE ONLY
 S15171A0 AUTOLOGOUS	 0240112359 Expiration Date 11 JAN 2024 23:59
HPC, MARROW 10% DMSO, 3rd Party Blood Component Present, Other Additives Present, Cryopreserved, Buffy Coat Enriched, See Attached Documentation for Details Total Volume <u>60</u> mL containing approx <u>10</u> mL Heparin (<u>1000</u> U/mL) Store at -120 C or colder Part A0	Donor/Recipient: HERNANDEZ, JUAN M Recipient ID: 123456147 Date of Birth: 03 MAR 1975 Processing Laboratory Name 2nd Line of Name City, State, Zip Code

Full Label Examples

 W0000 14 000042 S S	
Collection Date/Time	For Use by Intended Recipient(s) Only
 0140581436 27 Feb 2014 14:36 CST	Unrelated Donor
(27 Feb, 2014 20:36 UTC)	Donor ID: 1234-5678-9
Do Not Irradiate Do Not Use Leukoreduction Filter	
 S1128400	
HPC, APHERESIS Mobilized	Infuse Within 48 Hours of Collection or as Soon as Feasible
Total Volume 300 mL containing 30 mL Citrate Store at 1 to 10 C	Intended Recipient Tech, Mary Recipient ID: 123-456-7
Caution: New Drug--Limited by United States law to investigational use.	

3.2

Full Label Examples

 W0000 14 000044 8 0	
Collection Date/Time  0140581444 27 Feb 2014 14:44 CST (27 Feb, 2014 20:44 UTC)	For Use by Intended Recipient(s) Only
Do Not Irradiate Do Not Use Leukoreduction Filter	Unrelated Donor Donor ID: 9876-5432-1
 S12894B0 HPC, MARROW Other additives present	Infuse Within 48 Hours of Collection or as Soon as Feasible
See Attached Documentation for Details Total Volume <u>600</u> mL containing <u>2</u> mL Heparin (<u>5000</u> units/mL) Store at Room Temperature Part: B0	Intended Recipient Lab, Thomas Recipient ID: 456-789-1

Partial Labels

- For small containers, a partial label must be used
- Size of container will dictate the size of the partial label

Partial Labels

- Not all information will fit on a partial label

- Minimum information on a partial label:
 - Electronically readable DIN
 - Electronically readable Product Code too if 2D bar code
 - Eye readable DIN, flag characters, and check character
 - Eye readable product code
 - “Product: ” verbiage
 - Recipient information

Partial Labels

- The use of 2D bar codes is encouraged

Data Matrix



Code 128



Donation Identification
Number



Blood Groups (ABO and
RhD)



Product Code






Expiration Date/Time



Collection Date/Time



Partial Labels - Examples



 A9999 14 123503 8 4  S1381400 DESIGNATED HPC, APHERESIS 10% DMSO 3rd Party Donor Component Present Other Additive Present Cryopreserved, Mobilized, CD34 Enriched See Attached Documentation for Details Expiration Date: 06 FEB 2014 10:18	<i>Partial label</i>
For Use by Intended Recipient Only	
Intended Recipient DAMON, JANICE L Recipient ID: 123456777 Date of Birth: 13 MAR 1984 Processing Facility 2nd Line of Name City, State, Zip Code	

 A9999 14 123503 8 4 Product: S1381400 HPC, APHERESIS 10% DMSO 3rd Party Blood Component Present Other Additive Present Cryopreserved, Mobilized CD34 Enriched See Attached Documentation for Details <u>20</u> mL Expiration Date: 01 FEB 2024 Store at -150 C or colder	<i>Partial label</i>
For Use by Intended Recipient Only	
Intended Recipient DAMON, JANICE L Recipient ID: 123456777 Date of Birth: 13 MAR 1980 Processing Facility 8311 N. 17th Street Salem, CA 93111	

Partial Labels - Examples

 <p>A9996 14 123456 8 5 Product: S1122600</p> <p>HPC, MARROW</p> <p>10% DMSO Cryopreserved Store at -150 C or colder</p> <p>Collection Date: 2014-01-02 Expiration Date: 2016-01-02</p> <p style="text-align: right;"><i>Partial label</i></p>
 <p>BIOHAZARD For Use by Intended Recipient Only</p> <p>Intended Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1994 Processing Facility 2nd Line of Name City, State, Zip Code</p>

 <p>A9997 14 123456 $\frac{N}{4}$ B Product: S11426Ba</p> <p>HPC, APHERESIS</p> <p>Intended Recipient: WILSON, JEFFREY RID: 07061234B</p> <p style="text-align: right;"> BIOHAZARD</p> <p style="writing-mode: vertical-rl; text-orientation: mixed;">Exp 18 APR 2015</p>

 <p>A9999 14 123456 8 N</p> <p>HPC, Apheresis /Product S11424A0</p> <p>Intended Recipient: WILSON, JEFFREY RID: 07061234B</p> <p style="text-align: right;"> BIOHAZARD</p>
--

Other Labeling Considerations

- Facilities may add non-standardized additional text when space permits.
- A minimum font size of 8 should be used.

Other Labeling Considerations

- Acceptable text formats for the date:
 - 18 MAR 2014
 - 2014-03-18 (based on ISO 8601-2004)
- ISBT 128 requires that the time also be provided in Universal Coordinated Time (UTC) when the product will cross a time zone and an international border

Expiration Date/Time
15 JAN 2012 15:15 EST
(15 JAN 2012 20:15 UTC)

Questions

- Erwin Cabana
- erwin.cabana@iccbba.org