ISBT 128 Cellular Therapy Label Design

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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

2 - Blood Groups [ABO and RhD] (when applicable)

5 - Collection (or Production) Date and Time

3 - Product Code

4 - Expiration Date and Time (when applicable)
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

![Barcode Image]

- **S0020** 13 015114 φ H
- **RhD**
- **pos**
- **Tapp. datum**
  - 0150460738
  - 15 FEB 2009 07:38
- **S1128200**
- **Använd senast**
  - 0150481314
  - 17 FEB 2015 13:14
- **HSC, aferes**
  - Mobiliserade
- **Volym** 108 mL
- **Lösning** Citrat
- **Lagringstemp 2-6C**
# Upper Left Quadrant (ULQ)

<table>
<thead>
<tr>
<th>Information Elements</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation Identification Number</td>
<td>Machine-readable</td>
</tr>
<tr>
<td>Donation Identification Number</td>
<td>Text</td>
</tr>
<tr>
<td>Facility (collection, pooling, or cord blood processing) name and address</td>
<td>Text</td>
</tr>
<tr>
<td>Collection date and time if pertinent</td>
<td>Machine-readable</td>
</tr>
<tr>
<td>Collection date and time if pertinent</td>
<td>Text</td>
</tr>
<tr>
<td>Cautions and warnings:</td>
<td></td>
</tr>
<tr>
<td>Do Not Irradiate</td>
<td>Text</td>
</tr>
<tr>
<td>Do Not Use Leukoreduction Filters</td>
<td>Text</td>
</tr>
<tr>
<td>Rx Only</td>
<td>Text</td>
</tr>
</tbody>
</table>
Upper Left Quadrant

- Appearance of DIN:

\[
A99999\ 12\ 123456 \overset{\text{K}}{\sim}
\]

- Facility Identification Number (FIN)
- Collection Year (+/- 1 month)
- Serial Number

A9999 12 123456

Donation Identification Number (DIN)
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 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 Α
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
When trying to maintain confidentiality, the facility name should not appear (e.g., matched unrelated donors).

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

Do Not Irradiate
Do Not Use Leukoreduction Filters
Rx Only
## Lower Left Quadrant (LLQ)

<table>
<thead>
<tr>
<th>Information Elements</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code</td>
<td>Machine-readable</td>
</tr>
<tr>
<td>Product Code</td>
<td>Text</td>
</tr>
<tr>
<td>Product name and description</td>
<td>Text</td>
</tr>
<tr>
<td>Anticoagulant/preservative and its concentration</td>
<td>Text</td>
</tr>
<tr>
<td>Volume</td>
<td>Text</td>
</tr>
<tr>
<td>Recommended storage temperature</td>
<td>Text</td>
</tr>
<tr>
<td>Division number</td>
<td>Text</td>
</tr>
<tr>
<td>US License Number, if product is FDA licensed</td>
<td>Text</td>
</tr>
<tr>
<td>Warning statement: “Caution: New Drug—Limited by United States law to investigational use.” If product is distributed under an IND</td>
<td>Text</td>
</tr>
</tbody>
</table>
Lower Left Quadrant (LLQ)

Product Description Code

Donation Type

Division Code

S1234V00

ISBT 128 Product Code
Lower Left Quadrant – Example Labels

HPC, MARROW
6% HES + 5% DMSO
Cryopreserved

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

HPC, APHERESIS
Mobilized

Total Volume 198 mL containing
approx 11 mL Citrate

Store at 1 to 10 C
### Upper Right Quadrant (URQ)

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

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

<table>
<thead>
<tr>
<th>RhD Group</th>
<th>ABO text</th>
<th>RhD text</th>
</tr>
</thead>
<tbody>
<tr>
<td>RhD Positive</td>
<td>Solid black</td>
<td>Black on white</td>
</tr>
<tr>
<td>RhD Negative</td>
<td>Outline black</td>
<td>White on black</td>
</tr>
</tbody>
</table>

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

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

FOR AUTOLOGOUS USE ONLY
Upper Right Quadrant – Label Examples

For Use by Intended Recipient Only

Unrelated Donor
Donor # W0000 1236549

For Use by Intended Recipient Only

Related Donor
John P. Smith
Donor # W0000 1236549
Date of Birth: 17 NOV 1983
## Lower Right Quadrant (LRQ)

<table>
<thead>
<tr>
<th>Information Elements</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration date and time if applicable</td>
<td>Machine-readable</td>
</tr>
<tr>
<td>Expiration date (and time) if applicable</td>
<td>Text</td>
</tr>
<tr>
<td>Recipient name, identifier and date of birth if applicable</td>
<td>Text</td>
</tr>
<tr>
<td>Processing facility text if different from the Collection or Pooling facility identified in the ULQ</td>
<td>Text</td>
</tr>
</tbody>
</table>
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
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

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

A
Rh NEGATIVE
0200

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

Expiration Date/Time:
0140241415
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

HPC, MARROW
10% DMSO, 3rd Party Blood
Component Present, Other Additives Present, Cryopreserved, Buffy Coat Enriched, See Attached Documentation for Details
Total Volume 60 mL containing approx 10 mL Heparin (1000 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

Collection Date/Time
27 Feb 2014 14:36 CST
(27 Feb, 2014 20:36 UTC)

Do Not Irradiate
Do Not Use Leukoreduction Filter

For Use by Intended Recipient(s) Only

Unrelated Donor
Donor ID: 1234-5678-9

Infuse Within 48 Hours of Collection or as Soon as Feasible

Intended Recipient
Tech, Mary
Recipient ID: 123-456-7

Total Volume 300 mL
containing 30 mL Citrate
Store at 1 to 10 C

Caution: New Drug—Limited by United States law to investigational use.
Full Label Examples

Collection Date/Time: 0140581444
27 Feb 2014 14:44 CST
(27 Feb, 2014 20:44 UTC)

For Use by Intended Recipient(s) Only

Unrelated Donor
Donor ID: 9876-5432-1

Do Not Irradiate
Do Not Use Leukoreduction Filter

HPC, MARROW
Other additives present

Infuse Within 48 Hours of Collection or as Soon as Feasible

Intended Recipient
Lab, Thomas
Recipient ID: 456-789-1

See Attached Documentation for Details
Total Volume: 600 mL
containing 2 mL Heparin (5000 units/mL)
Store at Room Temperature
Part: B0

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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

<table>
<thead>
<tr>
<th>Data Matrix</th>
<th>Code 128</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Donation Identification Number</td>
</tr>
<tr>
<td></td>
<td>Blood Groups (ABO and RhD)</td>
</tr>
<tr>
<td></td>
<td>Product Code</td>
</tr>
<tr>
<td></td>
<td>Expiration Date/Time</td>
</tr>
<tr>
<td></td>
<td>Collection Date/Time</td>
</tr>
</tbody>
</table>
Partial Labels - Examples

A9999 14 123503 [4]
Product: S1381400
HPC, APHERESIS
10% DMSO
3rd Party Blood Component Present
Other Additive Present
Cryopreserved, Mobilized, CD34 Enriched
See Attached Documentation for Details
20 mL
Expiration Date: 01 FEB 2024
Store at -150 C or colder

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 [4]
Product: S1381400
HPC, APHERESIS
10% DMSO
3rd Party Blood Component Present
Other Additive Present
Cryopreserved, Mobilized, CD34 Enriched
See Attached Documentation for Details
20 mL
Expiration Date: 06 FEB 2014 10:18
Store at -150 C or colder

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
Partial Labels - Examples

A9996 14 123456
Product: S1122600
HPC, MARROW
10% DMSO
Cryopreserved
Store at -150°C or colder

Collection Date: 2014-01-02
Expiration Date: 2016-01-02

BIOHAZARD
For Use by Intended Recipient Only

Intended Recipient: PATIENT, JOHN Q
Recipient ID: 123456789
Date of Birth: 31 DEC 1994
Processing Facility
2nd Line of Name
City, State, Zip Code

A9997 14 123456
Product: S11426Ba
HPC, APHERESIS
Intended Recipient: WILSON, JEFFREY
RID: 07061234B

Exp 18 APR 2015

A9999 14 123456
Product: S11424A0
HPC, Apheresis /Product S11424A0
Intended Recipient: WILSON, JEFFREY
RID: 07061234B
BIOHAZARD
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