United States Consensus Guidance for the Uniform Labeling of Cellular Therapy Products Using ISBT 128

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1 Introduction

1.1 Purpose

Some aspects of label design using ISBT 128 are internationally standardized, while other aspects are left to national authorities to determine. Examples of internationally standardized aspects are the placement and content of bar codes. Examples of nationally determined aspects are the text which appears on the label and whether certain information (such as a collection date) must appear.

The *ISBT 128 Standard Technical Specification* (ST-001) addresses aspects of the standard that are internationally defined. The purpose of the *US Consensus Guidance for the Uniform Labeling of Cellular Therapy Products Using ISBT 128* is to provide guidance for users, software developers, and label vendors in the US in those areas of cellular therapy product labeling that are not internationally defined.

1.2 Scope

This document provides background information and label examples for using ISBT 128 in cellular therapy facilities in the US. It outlines where information may be placed on an affixed label in order to standardize the label within the US as much as possible. Such standardization will make it easier for users to find information on labels when receiving products from multiple sources.

This document does not provide specific information about the content of attached labels or accompanying documents, or how information on these labels and documents must be formatted or secured to the product container.

Other ICCBBA documents provide more detailed information about data structures, bar code requirements, terminology, and databases. These documents, listed in Section 1.4 and found on the ICCBBA Website, must be consulted for a more complete understanding of ISBT 128.

Accrediting Organization Requirements
This document takes into consideration the requirements of accrediting organizations (AABB, FACT, Netcord-FACT, and WMDA) in label design but does not list all their labeling requirements. The Alliance for Harmonization of Cellular Therapy Accreditation (AHCTA) has published a convenient crosswalk of labeling requirements of these organizations on its website http://www.ahcta.org. This crosswalk defines label content for partial labels, labels at the completion of collection, labels at completion of processing, and labels at distribution for administration. It also indicates whether information must be on the affixed, attached, or accompanying labeling.

FDA Requirements
This document takes FDA requirements into consideration in label designs. It provides guidance on information that should appear on the container label. It does not define a package label or how to secure the container within the package. There are a variety of ways to meet FDA requirements for securing the container within the package and users are encouraged to discuss their planned solutions with the FDA.

The user is advised to review all pertinent FDA regulations and guidelines (see Section 1.4 and 1.5 for references). In the event of a discrepancy, the Code of Federal Regulations and FDA guidelines take precedence over this and other ISBT 128 documents for labeling cellular therapy products in the US.

Compliance with this guidance document does not ensure labels will meet FDA requirements. Label content and layout for licensed products must be approved by the FDA.

1.3 Intended Audience

This document is intended for staff (management, laboratory, quality, validation, and information technology) of facilities using ISBT 128, software developers, auditors, and manufacturers of labels for cellular therapy products.

1.4 Normative Reference

ICCBBA (all ICCBBA documents are found at www.iccbba.org)**:**

ISBT 128 Standard Technical Specification (ST-001)
ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions (ST-002)
ISBT 128 Standard Labeling of Cellular Therapy Products (ST-004)
ISBT 128 Standard Product Description Code Database (ST-010)

AABB:
AABB Standards for Cellular Therapy Product Services (available from AABB at http://www.aabb.org)

Circular of Information for the Use of Cellular Therapy Products (http://www.aabb.org)

AHCTA:
Alliance for Harmonization of Cellular Therapy Accreditation (AHCTA) Labeling Crosswalk at http://www.ahcta.org/documents.html

FACT:
Foundation for the Accreditation of Cellular Therapy (FACT) Standards
http://www.factwebsite.org/Standards/

Netcord-FACT Standards http://www.factwebsite.org/Standards/

ISO
(ISO references may be purchased on their Website at http://www.iso.org/iso/en/prods-services/ISOstore/store.html)

ISO/IEC 15417: 2007(E): Information technology—Automatic identification and data capture techniques—Code 128 bar code symbology

ISO/IEC 16022:2006(E): Information technology—International symbology specification—Data Matrix

ISO/IEC 7064:2003(E): Information technology—Security techniques—Check character systems

NMDP:
National Marrow Donor Program (NMDP) Standards
https://network.bethematchclinical.org/

WMDA:
World Marrow Donor Association (WMDA) Standards
http://www.worldmarrow.org/

US Food and Drug Administration (FDA):
Code of Federal Regulations (The following references may be found on the FDA Website Search Page
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm)

21 CFR 201.56
21 CFR 201.57
21 CFR 312.6
21 CFR 610.60
21 CFR 610.61
21 CFR 1271.55
21 CFR 1271.60
21 CFR 1271.65
21 CFR 1271.90
21 CFR 1271.290
21 CFR 1271.370

1.5 **Other References**

ICCBBA:
Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)
Implementation Guide: Use of the Manufacturers Data File (IG-015)
Implementation Guide: Use of Product Code [Data Structure 003] – Cellular Therapy (IG-022)
Implementation Guide, Use of Product Divisions [Data Structure 032] (IG-023)
Implementation Guide: Use of Flexible Date and Time [Data Structure 031] (IG-024)
Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)
Implementation Guide: ISBT 128 Facility Identification Number (IG-034)

FDA:

Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System (http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM357135.pdf)

Guidance for Industry and FDA Staff: IND Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System (http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm388218.htm)

Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)) (http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM285223.pdf

FDA Resources for Data Standards
http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

ISBT:
Knels R, Davis R, Ashford P, et al: Guidelines for the use of RFID technology in transfusion medicine. Vox Sang 2010; 98(s2):1-24.

WMDA:
WMDA Position Paper: Introduction and Importance of a globally unique identify and labeling format (ISBT 128). http://www.worldmarrow.org (Found under Regulatory and Legal Affairs Committee tab.)

1.6 **Background**

ISBT 128 coding for cellular therapy products was initially developed during the 1990s. Since that time, the field of cellular therapy has grown dramatically. Recognizing the need to expand and revise the existing coding system, an international advisory group, the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG), was created. CTCLAG includes representatives from the following organizations: AABB, Asia-Pacific Blood and Marrow Transplantation group (APBMT), American Society for Blood and Marrow Transplantation (ASBMT), American Society for Apheresis (ASFA), European Group for Blood and Marrow Transplantation (EBMT), Foundation for the Accreditation of Cellular Therapy (FACT), ICCBBA, International Society of Blood Transfusion (ISBT), International Society for Cellular Therapy (ISCT), Joint Accreditation Committee of ISCT and EBMT (JACIE), National Marrow Donor Program (NMDP), and the World Marrow Donor Association (WMDA). The US Food and Drug Administration (FDA) also provided a liaison to work with the group. These representatives developed the terminology and label design for cellular therapy products using ISBT 128.

Shortly after the publication of the international standard, a group of individuals representing US organizations met to define those elements left to national discretion. Organizations involved in this effort included AABB, ASBMT, ASFA, FACT, ICCBBA, ISCT, and NMDP (see Acknowledgement). Again, FDA provided a liaison. A variety of interested vendors also participated in these discussions. The output of that work was the first version of this document. This document was updated in 2012 to reflect the licensure of cord blood products.

Following the change to ISBT 128 Cellular Therapy terminology in August 2013, this document has again been updated.

This is a guidance document. Where “shall” is used it reflects requirements found in Standards documents (either ISBT 128 or elsewhere). Where “should” is used, it reflects recommendations. Where “may” is used it reflects suggestions.

1.7 New in this Version

Bolded items indicate changes to the ISBT 128 Standard or to guidance provided since Version 1.2.0 of this document. Items that are not bolded represent formatting changes to the document or clarifications.

	Chapter, Section or Table in Version 1.3.0	Chapter, Section or Table in Version 1.3.1	Change	Rationale
1	8.4, Table 23	8.4, Table 23	The donation type code for a paid research collection was changed from an "R" to an "r". The donation type code for a paid source collection was changed from an "S" to an "s".	This was a correction of a typographical error.

1.8 New in Future Versions

Two new data structures have been approved and published in the *ISBT 128 Standard Technical Specification* (ST-001). These data structures are:

- Processing Facility Information Code [Data Structure 033], which will allow bar coding of the facility that processed the product. When the appropriate location for the bar code relating to this data structure on a cell therapy 100mm x 100 mm label is determined, it will be added to this document.
- The Product Divisions [Data Structure 032], which will allows the encoding of more than 26 first level divisions. This has been published for software developers to begin to introduce it into their software. If used, this data structure is required for traceability making it essential that all users can read and interpret it. Because this is a critical function, it should not be used until all users can read it. Therefore, when it can be implemented will be determined by the technical advisory groups of ICCBBA. See *Implementation Guide: Use of Product Divisions [Data Structure 032]* (IG-023) for more information.

2 ISBT 128 Basics

This chapter contains a very brief description of basic information about the use of ISBT 128. More detail can be found in the *ISBT 128 Standard Technical Specification* (ST-001).

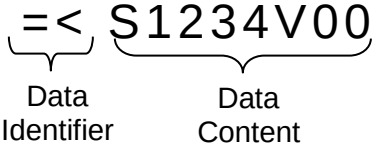
2.1 Encoding Information

In order for information about cellular therapy products to be transferred electronically (via bar codes, two-dimensional symbols, etc.), the information must first be encoded into a format that makes electronic transfer easy. Data structures provide this format.

Data structures define the way in which information is presented in ISBT 128. There are many data structures, only some of which are used on product labels. Consult the *ISBT 128 Standard Technical Specification* (ST-001) for a complete list of data structures.

Each data structure consists of data identifiers and data content (see Figure 1) and is very precisely defined in terms of its length and permissible characters.

Figure 1 Data Structure



2.1.1 ISBT 128 Data Identifiers

Each data structure begins with a two- or three-character code, the data identifier, that defines the type of information contained within the bar code.

The first character will always be "=" or "&". By international agreement these characters are reserved for ISBT 128 data structures.

The second (and sometimes third) character distinguishes the type of ISBT 128 information to be conveyed. For example, the two characters "=%" at the beginning of a data structure indicate that the bar code carries information about the ABO/RhD Blood Groups whereas "=<" means the bar code carries information about the Product Code.

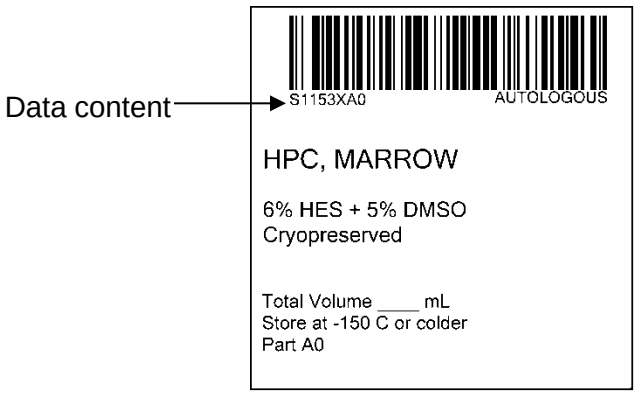
For a complete listing of ISBT 128 data structures and their data identifiers, see the *ISBT 128 Standard Technical Specification* (ST-001).

2.1.2 **Data Content**

Data content is the information to be conveyed; for example, the data content is a code indicating that the product is A RhD Positive. This information is encoded to allow it to be efficiently transferred electronically. The code for A RhD Positive (with no information encoded for extended Rh, Kell or Miltenberger phenotypes) is 6200. International reference tables are used to encode and decode information. Some of these reference tables are found in the *ISBT 128 Standard Technical Specification* (ST-001); others are databases and are found on the ICCBBA Website.

The data content appears in an eye-readable form beneath a linear bar code on an ISBT 128 label.

Figure 2 Example of Data Content on a Label



Data characters are the individual ASCII characters that make up the data content.

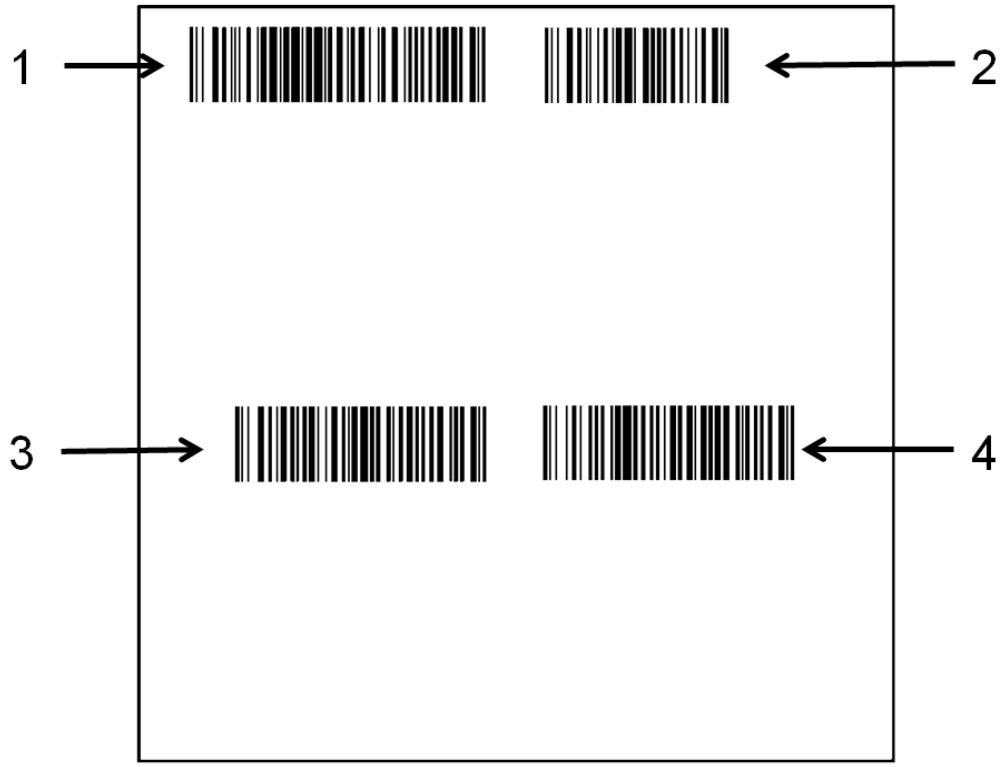
2.2 **Concatenation**

Concatenation is the scanning of two bar codes as a single message [see *ISBT 128 Standard Technical Specification* (ST-001) for specific details]. It requires that the bar codes be placed side by side with the right edge of the bar code on the left within a specific distance (9 mm +/- 4mm) of the left edge of the bar code on the right. The design of a 100 mm by 100 mm ISBT 128 label allows concatenation of two pairs of bar codes:

- The Donation Identification Number and Blood Groups (ABO/RhD)
- The Product Code and the Expiration Date and Time

See Figure 3.

Figure 3 Label Showing Placement of Bar Codes for Concatenation



1 Donation Identification Number
2 ABO/RhD
3 Product Code
4 Expiration Date/Time

Concatenation can provide better process control. By concatenating pairs of bar codes, it can be assured that information is being read from the same label. In some situations one type of data is dependent on another. For example, the expiration date/time is dependent

on the Product Code. In this situation, concatenation and appropriate software may be used to ensure the expiration date/time is changed if the Product Code is changed.

The following is a list of bar code pairs that are commonly concatenated. The list is not exhaustive and it must be emphasized that the Standard allows any pair of ISBT 128 codes to be concatenated. Reference to the corresponding data structure is given in brackets.

Donation Identification Number [001] and Blood Groups [ABO and RhD] [002];

Product Code [003] and Expiration Date and Time [005];

Donation Identification Number [001] and Product Code [003];

Donation Identification Number [001] and Donor Identification Number [019];

Container Manufacturer and Catalog Number [017] and Container Lot Number [018];

Manufacturer and Catalog Number: Items Other Than Containers [021] and Lot Number: Items Other Than Containers [022]:

Patient Date of Birth [024] and Patient Hospital Identification Number [025]

2.3 **Delivery Systems**

The information in ISBT 128 data structures can be delivered using a number of different technologies including Code 128 linear bar codes, Data Matrix two-dimensional (2-D) bar codes, wireless radio frequency identification transponders (RFID tags), and Electronic Data Interchange (EDI) messages. This makes ISBT 128 highly flexible for the unique requirements of cellular therapy products.

Some requirements depend on the delivery mechanism used.

2.3.1 **Linear bar codes**

Code 128 is the only linear bar code symbology approved for ISBT 128. The bar code shall comply with the industry standard ISO/IEC 15417: 2007I: Information technology—Automatic identification and data capture techniques—Code 128 bar code symbology specification. Additional rules regarding Code 128 bar codes used to deliver ISBT 128 data structures are given in the *ISBT 128 Standard Technical Specification* (ST-001).

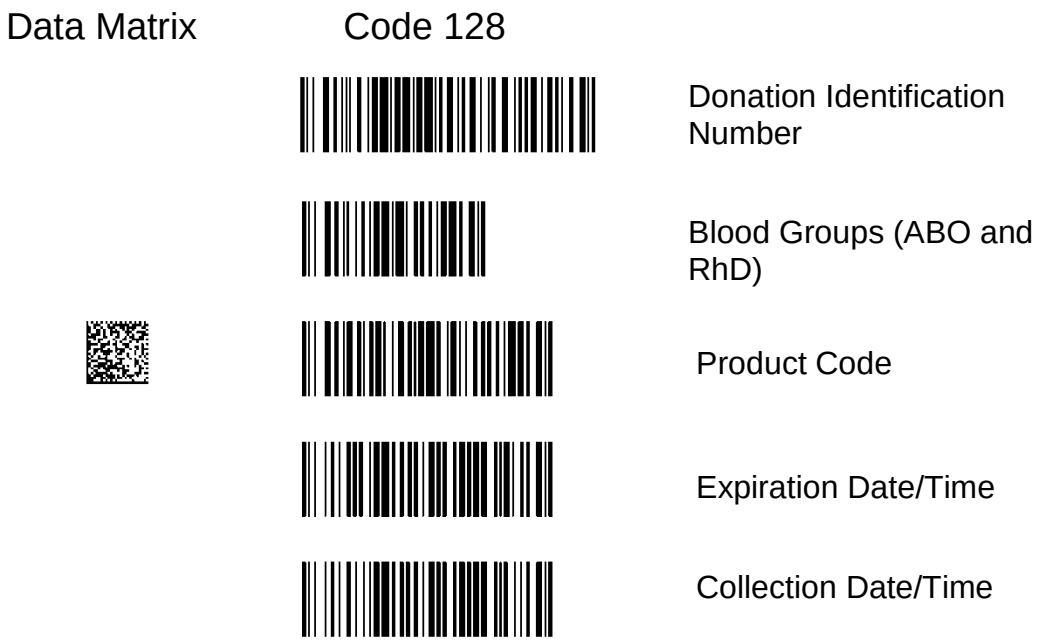
2.3.2 **Two-dimensional bar codes**

Data Matrix is the only two-dimensional (2-D) symbology approved for label applications for ISBT 128. The bar code shall comply with the industry standard ISO/IEC 16022:2006I: Information technology—International symbology specification—Data Matrix. Additional rules regarding Data Matrix bar codes used to deliver ISBT 128 data structures are given in the *ISBT 128 Standard Technical Specification* (ST-001). An additional ICCBBA document, *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014), provides examples of how Data Matrix may be used with ISBT 128.

Other 2-D symbologies may be used for non-label applications, such as donor records, that are not used outside the facility that applies them.

2-D barcodes are very useful when space is limited. In Figure 4, the amount of data in the Data Matrix symbol on the left is equal to that found in the five linear bar codes on the right.

Figure 4 Comparison of 2-D and Linear Bar Codes



2.3.3 **RFID**

The ISBT Working Party on Information Technology (ISBT WPIT) is currently evaluating issues related to the application of RFID to transfusion medicine and have published their findings in Knels R, Davis R, Ashford P, et al: Guidelines for the use of RFID technology in transfusion medicine. Vox Sang 2010; 98(s2):1-24. These guidelines recommend:

- The use of passive HF (13.56 MHz)
- That the user follow ISO 18000-3 tag standard and the ISO 15961 and ISO 15962 data encoding rules.
- That ISBT 128 data structures be used within the message.

Use of RFID with cellular therapy products may require additional studies beyond that needed for blood products.

When available, ICCBBA will consider these recommendations for inclusion in the ISBT 128 Standard. In the interim, implementers wishing to use these or any other novel technologies should contact ICCBBA for advice before proceeding. Use must comply with the appropriate industry standard.

2.3.4 **Electronic Data Interchange (EDI) Messages**

Rules for incorporating ISBT 128 data structures into EDI messages will normally be specified by the body responsible for the message standard. The only restriction placed by ICCBBA is that data identifier characters are a required part of the data field unless the message standard provides an alternative means of unambiguously identifying a data field as containing a specific ISBT 128 data structure. In this case, data identifiers may be omitted.

3 ISBT 128 Data Structures

This document reviews those data structures for which there are US-specific instructions and those data structures which have unique applications for cellular therapy products. Detailed information on all ISBT 128 data structures may be found in the *ISBT 128 Standard Technical Specification* (ST-001).

3.1 Donation Identification Number [Data Structure 001]

This data structure provides for the unique identification of any collection or product pool worldwide for a one hundred year period.

This data structure is unique in that the second character of the data identifier is also the first character of the data content.

The data structure has 16 characters:

=αppppyynnnnnnff

where:

=	is the first character of the data identifier.
αpppp	shall specify the Facility Identification Number (FIN) of the facility that assigned the DIN and shall be encoded and interpreted by reference to the ICCBBA Registered Facilities database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. (Note: α is also the second character of the data identifier.)
yy	shall specify the last two digits of the year in which the DIN was assigned.
nnnnnn	shall specify a sequence number indicating the particular collection, recovery or product pool within the given year for the facility identified by the FIN.
ff	shall specify flag characters.

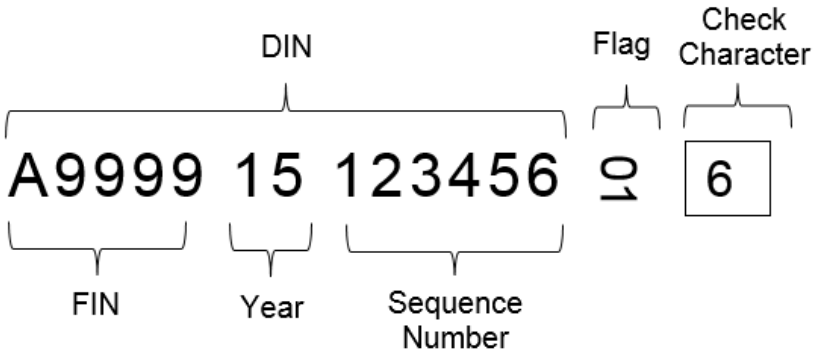
Flag characters may be used to assist in process control (such as identifying materials used in the collection process — container 1, container 2, tube 1, tube 2, etc. — permitting verification that the correct bar code has been scanned, i.e., the bar code actually attached to container 1, etc.) or to support additional checks for accurate data transmission. Flag characters are the last two characters of the DIN data structure, but

they are not part of the DIN itself. Flag characters are to be used in process control; it is not intended that they be recorded as part of the DIN.

An additional check character (not the same character that is integral to every Code 128 bar code) is calculated on the 13 data characters (αppppyynnnnnn) of the DIN. It is printed enclosed in a box to the right of the DIN and flag characters. The ISO modulo 37,2 method is used to compute this check character. This check character can be used to ensure the accuracy of keyboard data entry when supported by the appropriate computer software.

The first 13 characters of the data content comprise the DIN (see Figure 5).

Figure 5 Donation Code



3.1.1 **US Specification**

Usage: The DIN shall be both machine and eye-readable.

3.1.1.1 **Applying the DIN**

Usually, the DIN is the first label applied to product containers and should not afterwards be removed or defaced. To prevent potential errors, it is recommended that the DIN not be over-labeled during processing of the product. However, with extremely small labels this may be unavoidable. Should it become necessary to over-label the DIN, mechanisms shall be in place to ensure that the DIN on the new label matches the DIN on the original label.

3.1.1.2 **Facility Identification**

Cord Blood Facilities: In the situation of cord blood facilities, a processing lab may be administratively responsible for collections and assignment of DINs. In this situation, the DIN that appears on the

product, as well as the text identity of the organization appearing below the DIN, shall be that of the processing facility. If the DIN is not affixed until the donation reaches the processing laboratory, it is essential that suitable mechanisms be in place to ensure the accurate identification and traceability of the product prior to the application of the DIN.

Cord blood facilities applying for licensure of their product with the FDA must have a unique facility identifier (the FIN within the DIN) if they want to use ISBT 128 identifiers in lieu of the National Drug Code (NDC) on the product label.

Assignment of an ISBT 128 DIN to a non-ISBT 128 Labeled Unit: If a facility receives a unit that is not already labeled with ISBT 128, the donation number on the unit may not be unique. The receiving facility may want to assign an ISBT 128 DIN to the product to ensure uniqueness. In this case, the facility should assign one of its own DINs (with its own FIN) to the product. The FIN reflects the receiving facility in this situation.

The original DIN shall not be obscured, altered, or removed. If space does not permit adding the new DIN to the affixed label, it should be attached to the container.

Records shall be kept mapping the original donation number, product, and the facility from which it was received to the new DIN.

Facility Confidentiality with Matched Unrelated Donor Products: See section 5.7.2.2, page 61.

3.1.1.3 **Flag Characters**

Flag characters may be used in the US as detailed in the *ISBT 128 Standard Technical Specification* (ST-001). The default or null value, 00, shall always be present as part of the DIN bar code if other flags are not used. An example of how these flag characters may be used is found in Section 5.1, beginning on page 51.

3.1.1.4 **Keyboard Entry Check**

Although keyboard entry of the DIN into a computer system is strongly discouraged, there will be times when it is necessary. Computer system software should be designed to recognize keyboard entry of the DIN and to require verification of data entry by use of the additional check character. Details of the algorithm used to calculate the ISO 37,2 check character may be found in the *ISBT 128 Standard Technical Specification* (ST-001).

3.1.1.5 **Avoiding Label Waste**

Preprinted DINs may be used over a fourteen month period to reduce waste. For example, labels bearing the year “15” may be used from December 1, 2014 through January 31, 2016. It is expected that collection/processing centers will be careful in their label orders so that this practice is used to the minimum extent necessary.

Collection/processing facilities shall maintain an accurate record of the actual date of collection. The rationale behind the 14-month tolerance in the collection year is that the donation year in this data structure exists only to ensure uniqueness of the DIN every 100 years. It does not in any way replace the collection or expiration date on the label.

3.1.1.6 **Pooled Products**

Pooled products should be assigned a unique DIN. See Figure 82, page 126. This number should be assigned by the pooling facility and reflect its Facility Identification Number. The name and location in the Upper Left Quadrant, beneath the unique identifying number, should be that of the pooling facility. Facility records shall reflect the identification numbers of the various units within the pooled product.

Pooling often involves multiple products of the same Class from the same donor collected on different days (e.g., multiple units of HPC, APHERESIS from the same donor collected on different days).

In the US, unique pool numbers should also be assigned when units of the same product Class from the same donation are divided, stored, and then pooled. That is, if a product is first divided and stored, then subparts of the donation are recombined, a unique DIN should be assigned to the recombined product. See Section 5.3, page 53, for an example. This is required so that each pooled product is uniquely identified when multiple pools from the same donation exist.

Note that in the situation where, as part of initial processing, a portion of the product is removed and added back, the product is not considered to be pooled. For example, a portion of the original product is set aside before processing, T/B-cell depletion is performed on the remainder of the product, and at the end, based on the final T-cell dose required, the non-depleted part is added back to the final depleted product. This is not considered “pooling” and the product is not assigned a new DIN.

3.1.1.7 **Multiple Births**

Each cord blood product from a multiple birth (twins, triplets, etc.) should each be assigned a unique DIN.

3.2 **Blood Groups (ABO/RhD) [Data Structure 002]**

This data structure has six characters:

=%ggre

where:

=% is the data identifier.

gg shall EITHER

specify ABO and RhD blood groups and type of donation or collection information and shall be encoded and interpreted by reference to Table 1, beginning on page 31.

OR

specify a range of special messages as shown in Table 2, page 33.

r shall specify Rh and Kell or Miltenberger phenotypes. A value of 0 (zero) shall be used if the data structure does not contain information about these phenotypes. (See US Specification 3.2.1.1.)

e is reserved for future use.

3.2.1 **US Specification**

Usage: The ABO/RhD is not always known at the time a product is cryopreserved and it may not be applicable. However, if known at the time of freezing and applicable, it may be included on the affixed label.

3.2.1.1 **Blood Group**

Data characters “r” and “e” are not used in the US and should always be shown as “00”.

On a 100 mm x 100 mm label, units without an intended recipient (e.g., public cord blood donations), the text should be printed as follows when ABO/RhD is present on the label:

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

See illustrations in Section 7.1.3.1, beginning on page 76.

The ABO/RhD status of units intended for autologous or designated use is printed in much smaller print. Because of this smaller size print, outline fonts should not be used for RhD negative products.

3.2.1.2 **Type of Donation or Collection**

In the US, information about the type/intended use of a donation or collection (e.g., Autologous or Designated Collection) should be included in the ABO/RhD Blood Groups bar code when the bar code is present. Values for "gg" should be used as shown on Table 1. The ABO/RhD label should look very different from that of a unit not designated for a particular patient (see illustrations in Section 7.1.3.1, beginning on page 76).

If the product is not intended for a specific recipient(s), then the default "gg" value for the ABO/RhD blood groups should be used.

Table 1 Data Structure 002: Blood Groups [ABO and RhD], Including Optional Type of Donation or Collection Information

Note: Shaded columns are included for the purpose of completeness. These codes are part of the ISBT 128 Standard Technical Specification (ST-001) and may be used for blood or other products. These codes should not be used to label Cellular Therapy products in the US. However, software should be written to read and interpret these codes since products could be received from countries using these codes.

ABO and RhD Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only/Urgent Medical Need	Directed (Dedicated/ Designated) Collection/ Biohazard	Directed (Dedicated/ Designated) Collection/ Eligible for Crossover	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazard
O RhD negative	95	91	92	93	94	96	97	98
O RhD positive	51	47	48	49	50	52	53	54
A RhD negative	06	02	03	04	05	07	08	09
A RhD positive	62	58	59	60	61	63	64	65
B RhD negative	17	13	14	15	16	18	19	20
B RhD positive	73	69	70	71	72	74	75	76
AB RhD negative	28	24	25	26	27	29	30	31
AB RhD positive	84	80	81	82	83	85	86	87
O	55	P2	P3	P4	P5	P7	P8	P9
A	66	A2	A3	A4	A5	A7	A8	A9
B	77	B2	B3	B4	B5	B7	B8	B9
AB	88	C2	C3	C4	C5	C7	C8	C9
para-Bombay, RhD negative	D6	D2	D3	D4	D5	D7	D8	D9
para-Bombay. RhD positive	E6	E2	E3	E4	E5	E7	E8	E9

ABO and RhD Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only/Urgent Medical Need	Directed (Dedicated/ Designated) Collection/ Biohazard	Directed (Dedicated/ Designated) Collection/ Eligible for Crossover	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazard
Bombay, RhD negative	G6	G2	G3	G4	G5	G7	G8	G9
Bombay, RhD positive	H6	H2	H3	H4	H5	H7	H8	H9
O para-Bombay, Rh D negative	I6	I2	I3	I4	I5	I7	I8	I9
O para-Bombay, RhD positive	J6	J2	J3	J4	J5	J7	J8	J9
A para-Bombay, RhD negative	K6	K2	K3	K4	K5	K7	K8	K9
B para-Bombay, RhD negative	L6	L2	L3	L4	L5	L7	L8	L9
AB para-Bombay, RhD negative	M6	M2	M3	M4	M5	M7	M8	M9
A para-Bombay, RhD positive	N6	N2	N3	N4	N5	N7	N8	N9
B para-Bombay, RhD positive	O6	O2	O3	O4	O5	O7	O8	O9
AB para-Bombay, RhD positive	Q6	Q2	Q3	Q4	Q5	Q7	Q8	Q9

Table 2 Data Structure 002: Special Messages

gg	Interpretation
Ma	Autologous collection
Mb	Biohazard
Md	Discard (to be destroyed)
Mf	For fractionation use only
Mq	Quarantine/hold for further testing or processing
Mr	For research use only
Mx	Not for transfusion based on test results

3.3 **Product Code [Data Structure 003]**

The Product Code data structure has 10 characters:

=<αooootds

where:

=<	is the data identifier.
αoooo	shall specify the Product Description Code and shall be encoded and interpreted by reference to the Product Description Code Database table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.
t	shall depend on the value of α.
ds	shall specify whether the unit has been divided.

For cellular therapy products, α is S. For other values of α, see *ISBT 128 Standard Technical Specification* (ST-001).

oooo can only be interpreted when combined with α, and through reference to the Product Description Code Database.

The coding and interpretation of tds depends upon the value of α. For cellular therapy products:

t specifies the type of donation and is encoded and interpreted by reference to Table 23, page 96.

ds provides information on whether the unit has been divided.

- If the unit has not been divided, ds should be set to the default value of 00 (zero, zero).
- If the Product Divisions [Data Structure 032] is used, **ds** shall be set to 99. Software shall require that when a 99 appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions Data Structure shall be scanned and recorded. [See *ISBT 128 Standard Technical Specification* (ST-001) for information about the Product Divisions Data Structure.]
- If divisions are encoded in the Product Code:

  d may encode the first division. First level divisions (up to 26) of the primary collection shall be encoded using capital letters (See note in text box below)

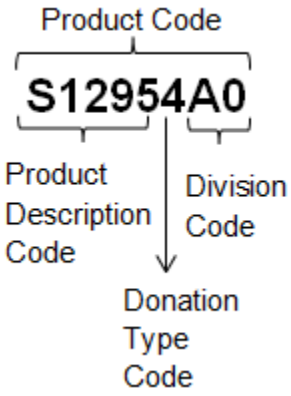
s may encode the second division. Second level subdivisions (up to 26) shall be encoded using lower-case letters (See note in text box below)

Note: Divisions need not be equal and this nomenclature does not require this.

Note: For cellular therapy products, until the Product Divisions [Data Structure 032] is implemented, d and s may be used to uniquely identify divisions without regard to hierarchal level. Facilities utilizing this option shall ensure that each product is uniquely identified (i.e., multiple products with the same DIN and Product Description Code shall have a unique division code).

For examples of use, see Section 5.2, page 52.

For interpretation of tds for other values of α, see the *ISBT 128 Standard Technical Specification* (ST-001).



3.3.1 A-D National or Local Codes

The block of Product Description Codes A0000-D9999 shall be reserved for use as nationally or facility defined Product Description Codes. There shall be no international interpretation associated with these values.

These codes should ONLY be used where there is not an appropriate international code and there is good reason why an international code should not be allocated. For example, local codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty whether the code assigned to a product should be international or local/regional/national, the user should contact the ICCBBA office.

National agencies may reserve a range of these values for national assignment. Where this is done it shall be the responsibility of the national agency to ensure that definitions are provided for use within the country and that products bearing such codes are not transferred outside the national boundary.

Individual facilities may also assign codes for their own use provided that these do not conflict with codes assigned at the national level. Where such codes are used, the facility shall ensure that definitions are provided for use within their service region, and that products bearing such codes are not transferred outside their normal distribution network. Care shall be taken in interpreting the product description from a local code as this will be specific to the supplier.

In all cases, the product definition for nationally or facility assigned codes shall be retained permanently for traceability purposes. Once assigned, codes shall not be reassigned.

3.3.2 US Specification

Usage: The Product Code and a product description shall appear in text on the product. If linear bar codes are used, the Product Code bar code shall appear on a full label and should appear if space permits on a partial label. If 2-D symbols are used, the Product Code should be encoded in the bar code.

National Product Description Codes: The US has reserved the following codes for national use: **B7000 through B9999**. These codes may not be used for local use.

The ISBT 128 database is intended for international use. Not all products and additives listed in the database may be commercially available for use in the US. Some of the products and additives may require pre-marketing approval by the FDA. It is the responsibility of the user to be knowledgeable about US regulations and standards and to produce only products that meet these requirements.

The ISBT 128 Product Description Code database contains many retired codes for cellular therapy products. ICCBBA recommends these codes not be used for the labeling of new products, although they are retained in the database for backward compatibility. Please see *ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions* (ST-002) for more information about retired codes.

3.4 Expiration Date and Time [Data Structure 005]

If the expiration date is provided in a machine-readable format, Data Structure 005 must be used. This data structure has 12 characters:

&>cyyjjjhhmm

where:

&>	is the data identifier.
c	shall specify the century of the year in which the product expires.
yy	shall specify the year within the century in which the product expires.
jjj	shall specify the ordinal (Julian) date on which the product expires.
hh	shall specify the hour at which the product expires (00 to 23).
mm	shall specify the minute at which the product expires (00 to 59).

A day is defined as beginning at midnight (00:00) and ending at 23:59.

3.4.1 US Specification

Usage: Expiration date and time are not required to be machine-readable. (A good practice would be to have either the collection date or the expiration date, or both, machine-readable when space permits.)

Expiration dates may not be established for all cellular therapy products. When required or applicable, the expiration date (and time) shall be on the container label. If it is not physically possible to include the expiration date on the container label, it shall appear on the attached label.

For information on printing dates, see 5.7.2.4, page 63.

3.5 Collection Date (and Time) [Data Structures 006 and 007]

If collection date is machine-readable, one of two data structures may be used. Where time is not important, use Data Structure 006; where time is important, Data Structure 007 may be used.

Data Structure 006 has 8 characters:

=*cyyjjj

where:

=*	is the data identifier.
c	shall specify the century of the year in which the product was collected.
yy	shall specify the year within the century in which the product was collected.
jjj	shall specify the ordinal (Julian) date on which the product was collected.

Data Structure 007 has 12 characters.

&*cyyjjjhhmm

where:

&*	is the data identifier.
c	shall specify the century of the year in which the product was collected.
yy	shall specify the year within the century in which the product was collected.
jjj	shall specify the ordinal (Julian) date on which the product was collected.
hh	shall specify the hour at which the product was collected (00 to 23).
mm	shall specify the minute at which the product was collected (00 to 59).

A day is defined as beginning at midnight (00:00) and ending at 23:59. For cellular therapy products, “collection time” is defined as the end time of the collection.

3.5.1 **US Specification**

Usage: Collection date (and time) is (are) not required to be machine-readable (although good practice would have either the collection date or the expiration date machine-readable where space permits). Collection date (and time) is (are) not required on the affixed label.

3.6 Manufacturer's Information Data Structures

Some cellular therapy containers will bear information pertaining to the manufacturer of the container on the base label. There are two data structures for this as described in the following sections.

3.6.1 Container Manufacturer and Catalog Number [Data Structure 017]

The data structure has 12 characters:

=)bqqwwwwwww

where:

=)	is the data identifier.
b	shall specify the container identification character in a container or transfer set. The value of b is set as follows: • For whole blood and other non-apheresis collection sets, 1-9 shall be used. 1 shall be reserved for the primary collection container. • For apheresis collection sets, A-Z shall be used. • For transfer container/sets, 0 (zero) shall be used. If more than one type of container is present in the transfer set, numeric characters 2-9 may also be used. (The number 1 shall be reserved for the primary bag of a whole blood collection set.)
qq	shall specify the identity of the container set manufacturer and is encoded and interpreted from the Manufacturer Identifier Codes table [RT016] that can be found on the ICCBBA Website.
wwwwwww	shall specify the manufacturer's catalog number. This must be interpreted from information provided by the manufacturer. If the catalog number is less than seven (7) characters, it should be padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 0027QzE).

Used in conjunction with the Manufacturers Data file [*see ISBT 128 Standard Technical Specification* (ST-001) and *Implementation Guide: Use of Manufacturers Data File* (IG-015)], this data structure can be a powerful tool for process control. With use of appropriate software and downloading of the data file, much information about the container set can be determined automatically. This information includes such things as the number of bags in the set.

3.6.2 **Container Lot Number [Data Structure 018]**

The data structure has 12 characters:

&)xxxxxxxxxx

&) is the data identifier.

The ten (10)-character data content string, xxxxxxxxxx, encodes the manufacturer's lot number. If the lot number is less than ten (10) characters, it shall be padded with zeroes at the beginning of the string (i.e., the lot number 1234rZ would be transmitted as 00001234rZ).

Because lot numbers can be padded with zeroes, ideally they should not begin with a 0 (zero). If the lot number begins with 0 (zero), the manufacturer shall have a mechanism to ensure correct identification of the lot number when a problem is reported and the lot number is indicated without the leading 0 (zero).

3.7 **Donor Identification Number [Data Structure 019]**

A **Donor** (not "Donation") Identification Number may be needed for the labeling of cellular therapy products. It may either be a locally assigned number (local format), a registry-assigned number, or a number in the ISBT 128 format. If a number in the ISBT 128 format is used and it is to be machine-readable, Data Structure 019 should be used. This data structure has 23 characters:

=;αppppvvvvvvvvvvvvvvv

where:

=;	is the data identifier.
αpppp	shall specify the Facility Identification Number (FIN) and is encoded and interpreted by reference to the ICCBBA Registered Facility table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.
vvvvvvvvvvvvvvv	shall specify a facility-assigned or nationally-assigned donor identification number. The interpretation of the assigned number requires knowledge of how such numbers are assigned in the country specified by the FIN. If the number assigned is not sixteen (16) characters, it should be padded with zeroes at the beginning of the string (i.e., the donor identification number 395421746 would be transmitted as 0000000395421746). However, in some countries, the assigned number can begin with zero; therefore the specific length of the assigned number must be known in order to correctly interpret this data structure.

3.7.1 **US Specification**

Usage: The use of the ISBT 128 format for the donor number is optional. The decision of which donor number format to use (local, registry, or ISBT 128) is made by the facility that assigns the number.

3.8 **Compound Message [Data Structure 023]**

Because of the size of some cellular therapy containers, there is inadequate space for multiple linear bar codes. Considerably more information can be machine-readable if two dimensional (2-D) bar codes are used.

In order to encode multiple data structures into a single symbol, the Compound Message [Data Structure 023] is used. This is a variable length data structure. The 7-character data structure shall be encoded and interpreted as follows:

=+aabbb

where:

=+ is the data identifier.

aa shall specify the number of ISBT 128 data structures that follow.

bbb shall be either:

- all zeroes – indicating this is an undefined message, i.e. only the number of data structures is identified, but not what each one is; or
- a three-digit number referencing an entry in an ICCBBA maintained table that defines the sequence of the data structures within a compound message. This reference table is found on the ICCBBA Website.

Rules for constructing compound messages:

1. A compound message shall comprise a string of ISBT 128 data structures (excluding nationally defined structures), beginning with the Compound Message [Data Structure 023];
2. Data structures shall be combined with no intervening characters in the order shown on Table RT017 for the ICCBBA-specified message selected, and each data structure shall begin with its data identifier characters;
3. The string shall only contain ISBT 128 data structures;
4. The number of data structures following the Compound Message data structure shall be indicated in element aa of the Compound Message data structure;
5. If an ICCBBA-specified sequence is used in the compound message, the reference number of the structure shall be included in element bbb of the Compound Message Data Structure;

6. If the sequence of the message is not specified by ICCBBA, the Compound Message Data Structure shall have element bbb set to zeroes, but element aa will be set as specified in rule 4.

ICCBBA-specified compound messages are defined in a table on the ICCBBA Website called:

ICCBBA-Specified Compound Messages [RT017]

Requests for additional entries to this table should be submitted to the ICCBBA office (tech.director@iccbba.org).

Reading software should always verify the integrity of the data string, including checking that the correct number of data structures appears. Data should only be interpreted if the integrity of the entire data string has been confirmed.

See Section 5.4, page 54 for examples of the use.

3.8.1 US Specification

Usage: The use of this data structure is optional. It is intended to be used with high capacity delivery systems such as 2-D bar codes, RFID, or electronic messaging.

3.9 **Patient Date of Birth [Data Structure 024]**

The patient (recipient) date of birth structure may be used in a variety of places, including on the labeling (affixed, attached, or accompanying) of cellular therapy products, patient wristbands, and/or documentation associated with the collection. The use of a machine-readable patient date of birth is optional, but may improve process control.

The data structure has 12 characters:

=#aayyyymmdd

where:

=# is the data identifier.

aa shall specify a location code identifying where this occurrence of the information is held. For acceptable values see Table 3, below.

yyyy shall specify the year of birth.

mm shall specify the month of birth.

dd shall specify the day of birth.

Table 3 Data Structures 024 and 025: Patient Date of Birth and Patient Identification Number location codes

Code	Location
00	Not used
01	Wrist band
02	Order form
03	Sample Tube
04	Working list/Lab list/form
05	Test report
06	Delivery note/issue documentation
07	Intended recipient label (attached to container)
08	Affixed label
09-79	Reserved
80-99	For local or national use

3.9.1 **US Specification**

Usage: The use of this data structure is optional.

3.10 **Patient Identification Number [Data Structure 025]**

The patient (recipient) identification number may be used in a variety of places, including on the labeling (affixed, attached, or accompanying) of cellular therapy products, patient wristbands, and/or other documentation. The use of a machine-readable patient identification number is optional, but may improve process control.

This structure allows for a variable length number, and, while it is called a "number", either numbers or letters may be used. This allows for maximum flexibility in utilizing identification numbers already in use within a facility.

This is a variable length data structure:

&#aallxx…xx

where:

&#	is the data identifier.
aa	shall specify a location code identifying where this occurrence of the information is held. For acceptable values, see Table 3, page 45.
ll	shall specify the length of the following patient number field.
xx…xx	shall specify the patient identification number, alpha numeric only, punctuation characters and spaces are not permitted.

Note: The patient (recipient) identification number may only be unique within the facility in which it was assigned. There may be duplicate numbers if a patient moves from one facility to another.

Reading software should always verify the integrity of the data string, including checking that the correct number (as defined by ll) of characters appears in the patient identification number.

3.10.1 **US Specification**

Usage: The use of this data structure is optional.

3.11 **Infectious Markers [Data Structure 027]**

There may be a need to convey information pertaining to infectious disease testing in a manner that is very accurate and unambiguous. The Infectious Markers data structure provides a means to accomplish this. It is expected that this information will appear in electronic communications or on accompanying documentation rather than on the affixed label of a product.

The data structure has 20 characters:

&"nnnnnnnnnnnnnnnnnn

where:

&"	is the data identifier.
nnnnnnnnnnnnnnnnnn	shall specify a string of digits, each of which identifies the result status of a pair of markers as indicated in the *ISBT 128 Standard Technical Specification* (ST-001). Test results that may be encoded include: antibodies to HIV-1,2, HCV, HBc, HTLV-I/II, Syphilis, CMV, Parvo B19, and Chagas; HIV-p24, HCV, and HBs antigens; and genomic testing for HIV, HCV, HBV, CMV, EBV, WNV and Parvo B19.

The information is specific to a particular donation and thus must be provided in a manner that can be securely linked to the DIN. Facility records will, in turn, link the DIN and its test results to a donor.

This information may be coded by the use of a Compound Message structure containing both the DIN and Infectious Marker screening, concatenated bar code reading, or by other mechanisms that secure association of the information with the DIN.

The results provided in the data string should be the final outcome of the approved screening process of the testing facility.

Because cellular therapy products often cross international borders, where testing requirements may not be the same, this data structure provides a mechanism to communicate which tests have been performed and the results of those tests.

3.11.1 **US Specification**

Usage: The use of this data structure is optional. This data structure is not sufficient to meet FDA regulatory requirements and therefore may not be used in lieu of the summary of records [1271.55(b)]. Review of the summary of records is needed to ensure testing meets US requirements.

3.12 **Flexible Date and Time [Data Structure 031]**

Data Structure 031 shall convey information about date and time, including the type of time (collection, recovery, production, cross clamp, etc.) and the time zone (local or UTC).

The data structure has 18 characters:

=(ZUTTYYYYMMDDhhmm

where:

=(	is the data identifier.
Z	shall specify local or UTC time. For acceptable values, see Table 4 below.
U	shall be reserved for future use. The value shall be set to 0.
TT	shall specify the type of time. For acceptable values, see Table 5 below.
YYYY	shall specify the year.
MM	shall specify the month (01-12).
DD	shall specify the day (01-31).
hh	shall specify the hour (00-23).
mm	shall specify the minute (00-59).

Table 4 Data Structure 031: Time Zone [RT045]

Value	Meaning
1	Local time zone of facility assigning the date
2	Coordinated Universal Time (abbreviated UTC)

Table 5 Data Structure 031: Type of Time [RT046]

Value	Meaning
01	Expiration date and time
02	Collection date and time
03	Production date and time
04	Cross Clamp date and time

For further information, see *Implementation Guide: Use of Flexible Date and Time [Data Structure 031]* (IG-014).

4 Databases and Reference Tables

4.1 Facility Code Database

This database contains the names and locations of all ICCBBA-registered facilities worldwide. Each facility is assigned a five-character Facility Identification Number (FIN) that for US facilities begins with “W”. This database is found on the ICCBBA Website and is called:

Registered Facilities

To assist users in identifying a facility associated with a given FIN, a look-up tool is available on the ICCBBA website.

4.2 Product Description Codes Database

This database provides a list of all Product Description Codes and product descriptions. This database is found on the ICCBBA Website and is called:

Product Description Codes Database

For ICCBBA licensed facilities, a look-up tool is available on the ICCBBA Website for finding Product Description Codes using this database.

Specific information about the Product Description Codes Database is found in the *ISBT 128 Standard Product Description Code Database* (ST-010) and in *Implementation Guide: Use of Product Code [Data Structure 003] – Cellular Therapy* (IG-022). The latter document also contains information about requesting new Product Description Codes when an appropriate code does not exist.

As noted earlier, and repeated here for emphasis, the ISBT 128 Product Description Code Database is intended for international use. Not all products and additives listed in the database may be commercially available for use in the US. Some of the products and additives may require pre-marketing approval by the FDA. It is the responsibility of the user to be knowledgeable about US regulations and standards and to produce only products that meet these requirements.

4.3 Special Testing

This database contains the test names and codes for data conveyed in the Special Testing, General [Data Structure 010] such as CMV. This database is found in the password-protected area of the ICCBBA Website and is called:

Special Testing, General

While this information is not routinely included on the affixed label of a cellular therapy product due to space constraints, bar coded information about such additional testing may be used on attached or accompanying labeling.

4.4 Manufacturers ID

This table contains the identification codes assigned to manufacturers for use in the Container Manufacturer and Catalog Number [Data Structure 017] and the Manufacturer and Catalog Number – Items other than Containers [Data Structure 021]. Some of the entries may not be in current use but are retained for use in look back situations. Licensed vendors who want to have a code assigned for use in these data structures should contact ICCBBA.

This table is published on the ICCBBA Website and is called:

Table W1 [RT016] – Manufacturer ID Codes

4.5 ICCBBA-Specified Compound Messages

The table contains the reference numbers and structures for ICCBBA-defined compound messages. When using these messages, the identifier is incorporated into the compound message structure. Requests for additions to this table should be submitted to the ICCBBA office (tech.director@iccbba.org).

This table is found on the ICCBBA Website and is called:

Table W2 [RT017] – ICCBBA-Specified Compound Messages

5 Examples of Data Structure Information Usage

5.1 Use Of Flag Characters [Data Structure 001]

An example of the use of flag characters is to link information from partial labels to full label information. There are two standardized flag characters for this purpose: the value 12 is defined as “Affixed Partial Label” and 13 is defined as “Attached label (intended to be used with affixed partial label).” *See the ISBT 128 Standard Technical Specification* (ST-001), Table RT004 for more information about standardized flag characters.

In practice, 12 would be assigned as the flag character for the partial label and 13 as the flag for the full label. If the DIN is A9990 15 123457, the partial label would have:

And the full label would have:

Manual and computerized systems could be set up to ensure that the affixed label matches the attached label (except for the flag characters). If software is used, it could require the processing facility scan the affixed label of the product. If the flag character 12 is present, software could require a scan of the second label (the attached full label) with a flag character of 13.

Alternatively, if the full label is scanned first, software could be designed to “see” the 13 flag and require a scan of a DIN with a 12 flag (an affixed label). Software could then confirm the two DINs and product codes agree.

A similar system could be used in the receiving facility to ensure the labels matched.

Thus a full label would be securely associated with the product electronically as well as being physically attached in some way to the product.

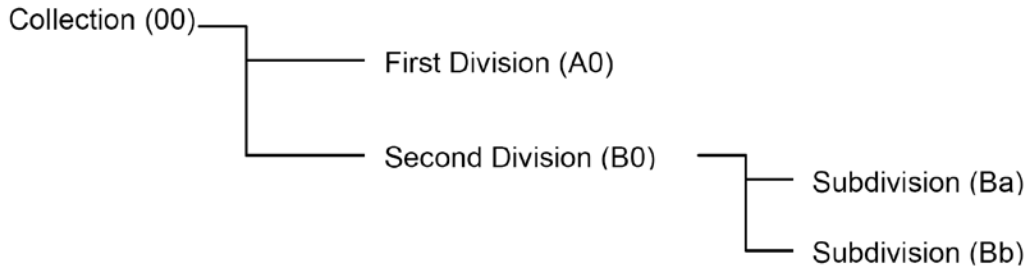
5.2 **Use of Product Division Codes [Data Structure 003]**

Coding of divisions from a single collection should be done using the 7th and 8th characters of the Product Code [Data Structure 003].

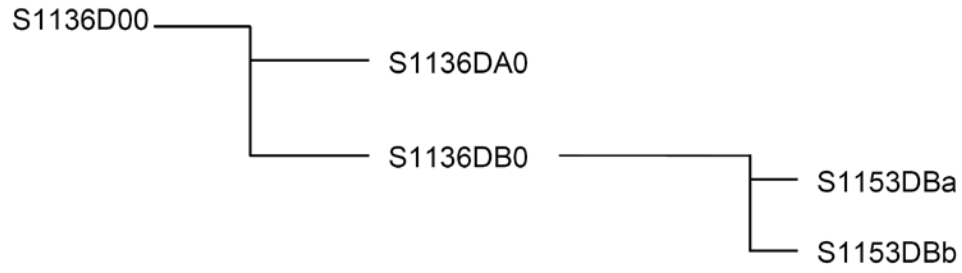
For example, consider a bone marrow harvest as diagrammed below. When collected and undivided, the 7th and 8th characters of the Product Code are 00 (zero, zero). The product is initially divided into two parts, one for further processing into the desired population of cells [this becomes A0 (A, zero)] and the other is for backup or rescue [this becomes B0 (B, zero)]. The first division changed the 7th character from 0 to an upper case letter.

The B0 portion is divided again later that day for freezing in separate aliquots, which become Ba and Bb. The 8th character changed from 0 to a lower case letter.

Figure 6 Product Division Coding



Or, using the Product Description Codes for a designated product:



S1136 = HPC, Marrow|Citrate/XX/refg

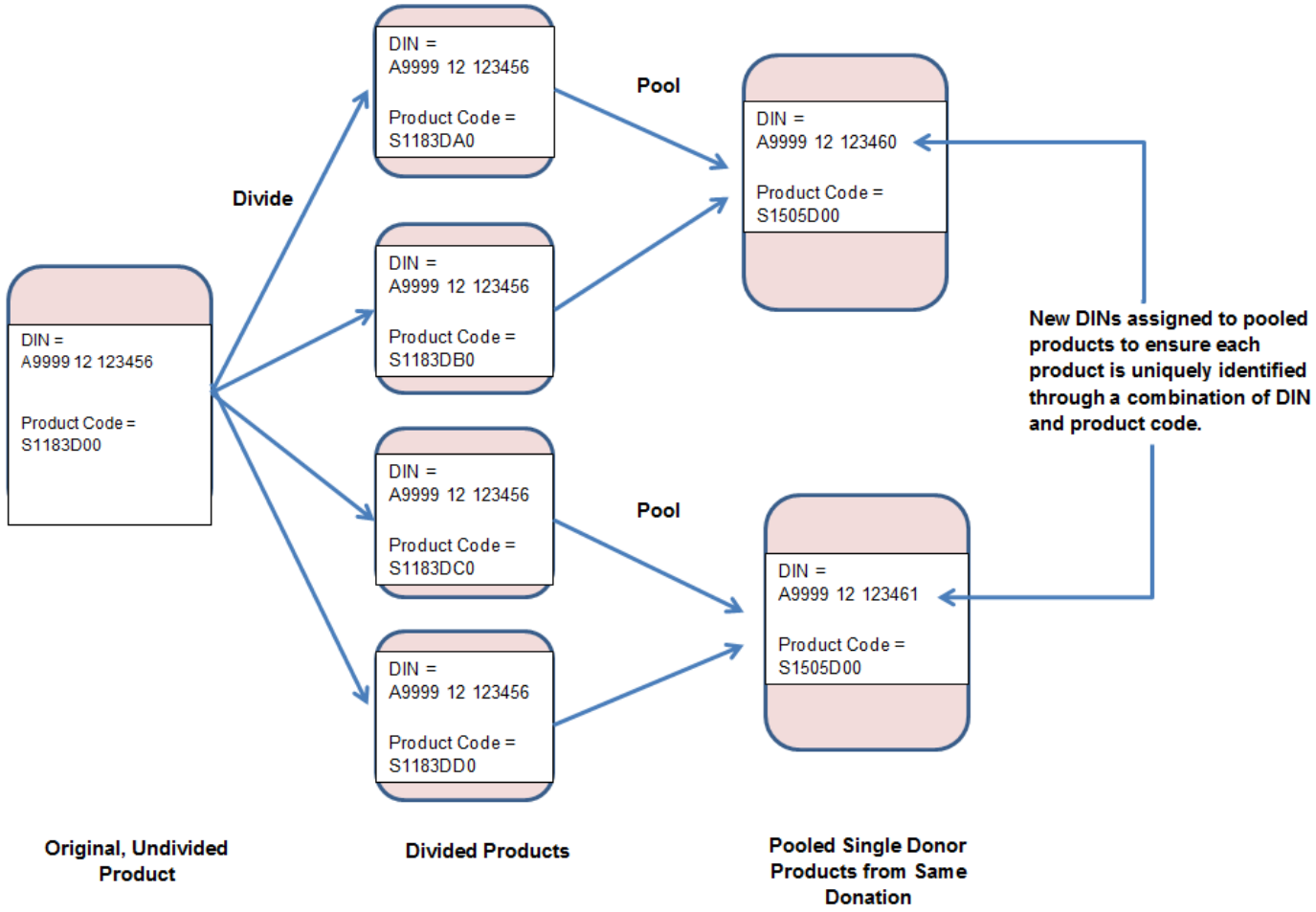
S1153 = HPC, Marrow|NS/XX/<=-150C|6%HES+5% DMSO|Cryopreserved

Note: Until software can be updated to accommodate the new Product Divisions [Data Structure 032], d and s may be used to uniquely identify divisions without regard to hierarchal level. Facilities utilizing this option shall ensure that each product is uniquely identified (i.e., multiple products with the same DIN and Product Description Code shall have a unique division code).

5.3 Recombining Parts of a Divided Product

In some instances, divided products are recombined. In this situation, a new DIN should be assigned to the pooled products to ensure unique identification of each product.

Figure 7 Recombining Divided Products



Product Codes Used in Example
S1183 = HPC, MARROW|Heparin/XX/refg
S1505 = HPC, MARROW|Heparin/XX/ref|Pooled, Single Donor:Yes

5.4 **Use of Compound Message [Data Structure 023]**

The Compound Message Data Structure is intended to be used whenever multiple messages are to be transmitted using a single 2-D symbol, RFID, or as part of an electronic message.

For example, a cord blood container may be very small and it may be desirable to have machine-readable information for DIN, Product Code, ABO/RhD, and expiration date and time. A 2-D bar code could be used to conserve space. To encode this information into a 2-D bar code, a Compound Message may be used. The coding for this data structure is described in 3.8 and the reference table for ICCBBA-defined messages, W2 ICCBBA-Specified Compound Messages (RT017), is found on the ICCBBA Website under Tech Library, Databases/Reference Tables, Reference Tables.

The actual coding would involve stringing the four data structures together within the Compound Message Data Structure (see Section 3.8, page 43).

Data Identifier	Code	Meaning of Code
=+	04003	There will be four messages conveyed. The four messages are defined by ICCBBA and are Donation Identification Number, ABO/RhD, Product Code, and expiration date and time
= (see note below table)	A99991512345600	Donation Identification Number is A9999 15 123456
=%	5100	The product is Group O, RhD Positive
=<	S1124V00	The product is HPC, CORD BLOOD|NS/XX/<=-150C|10% DMSO| Cryopreserved from a Volunteer Donor and is not divided
&>	0250222359	The product expires on January 22, 2025 at 23:59

Note: In the case of the DIN, the first character (in this case “α”) is also the second character of the data identifier.

The message would then look like:

=+04003=A99991512345600=%5100=<S1124V00&>0250222359

When encoded into a Data Matrix symbol, with an X dimension of 35 mm [see *ISBT 128 Standard Technical Specification* (ST-001)], the information would be contained in an approximately 10 mm square symbol. It would appear as in Figure 8. For more information consult *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014) found on the ICCBBA Website.

Figure 8 Compound Message Example within a Data Matrix (2-D) Symbol

5.5 General Label Design and Text

There are different types of labels to consider for cellular therapy products.

- The base label which is applied by the manufacturer of the container.
- The product label that is applied by cellular therapy facilities. Different types of product labels include:
  - The label at the completion of product collection
  - The label at the completion of processing
  - The label at distribution for administration
  - A partial label, which FACT defines as "The minimum essential elements that must be affixed to all cellular therapy product containers at all times." The partial label can either be an "in process" product label or the label on a product that is ready for administration.

(Note: Please refer to 21 CFR 610.60(c) for the partial label requirements for biological products that are licensed.)

Base Label: The design of the ISBT 128 base label is described in the *ISBT 128 Standard Labeling of Cellular Therapy Products* (ST-004). The design includes two bar codes, the Container Manufacturer and Catalog Number [Data Structure 017] and the Container Lot Number [Data Structure 018]. The exact placement of the bar codes is defined in the *ISBT 128 Standard Technical Specification* (ST-001) to permit concatenation of the two bar codes.

5.6 Design Concepts of ISBT 128 Product Labels

5.6.1 100 mm by 100 mm Label Design

The original ISBT 128 design for the product label is a 100 mm by 100 mm label. It is divided into 4 quadrants, each of which is 50 mm by 50 mm. In subsequent sections these four quadrants will be referred to by their locations: Upper left quadrant (ULQ), lower left quadrant (LLQ), upper right quadrant (URQ), and lower right quadrant (LRQ).

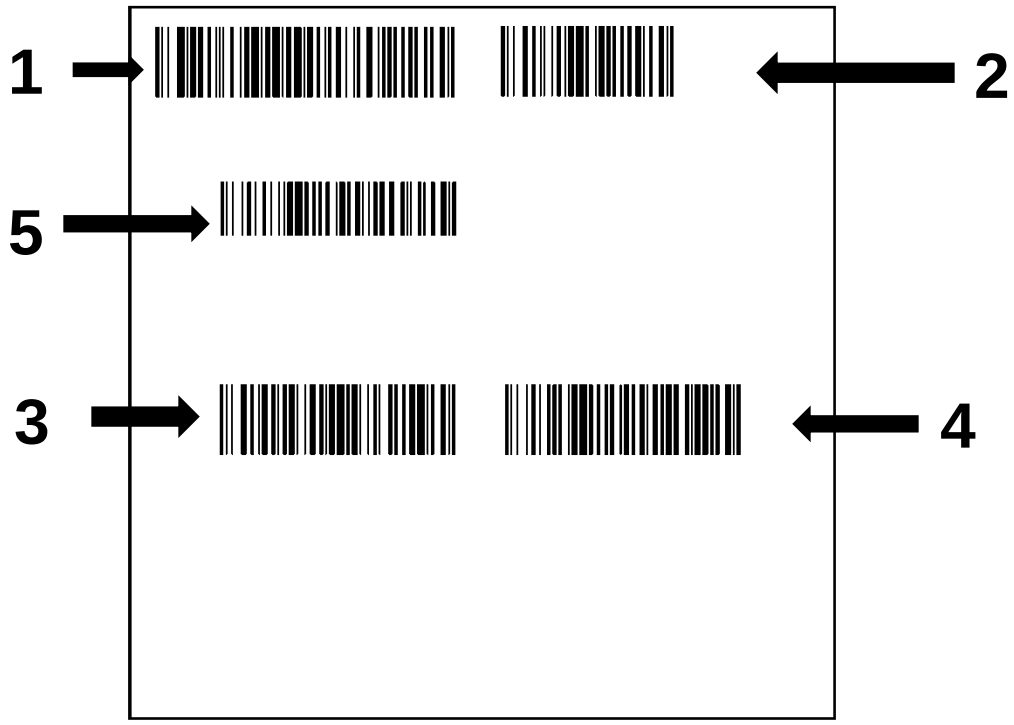
It is designed such that the label can be applied sequentially as 50 mm by 50 mm quadrants; in 50 mm by 100 mm strips (either vertically or horizontally); or as a full 100 mm by 100 mm label. This allows flexibility for each facility to determine how its process will flow.

ISBT 128 is rigid where the placement of the bar codes is concerned (see Figure 9). The exact positions are defined in the *ISBT 128 Standard Technical Specification* (ST-001). This placement is critical to permit

concatenation and to overcome language barriers. Concatenation is explained in Section 2.2, Page 19.

By always placing the bar codes in precisely the same position, users know which bar code to scan to read particular information (e.g., the Product Code) despite being unable to understand the language in text on the label. Because users of ISBT 128 share a common database, all internationally standardized bar codes may be interpreted to the local language (see Figure 10 for an example of a Swedish label).

Figure 9 Location of Bar Codes on a 100 mm x 100 mm Label



1 Donation Identification Number
2 Blood Group (ABO and RhD)
3 Product Code
4 Expiration Date/Time
5 Collection Date/Time

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

Figure 10 Using ISBT 128 to Overcome Language Barriers

Swedish label for:
HPC, APHERESIS
Volume: Variable (text on label)
Anticoagulant: Citrate
Storage Temperature: Refrigerated
Mobilized

PRODDESCRIPCODE	PRODDESCRIPCODEFORM	PRODDESCRIP0
S1127	S005S@29SG2 SL5SM2	HPC, APHERESIS|NS/XX/<=-150C|6% HES + 5% DMSO|Cryopreserved|Mobilized
S1128	S005S@34SM2	HPC, APHERESIS|Citrate/XX/refg|Mobilized
S1129	S005S@30SM2	HPC, APHERESIS|Citrate/XX/rt|Mobilized

5.6.2 **Small Label Design**

The design of a small label is completely dependent on its size. When linear bar codes are used, the DIN bar code should appear first, followed by the Product Code bar code (when space permits). A number of possible designs are shown in Chapter 9.

There is frequently inadequate space on a small label for all required information and thus many are “partial labels”. The required information that does not fit onto the partial label must go onto attached or accompanying labeling (AABB and FACT) or package label (FDA). See the Glossary for definitions of these terms. Chapter 6 discusses the information that must appear on the partial label.

The use of 2-D symbols permits most commonly needed information to be encoded into a space of approximately 10 mm square. Use of the 2-D bar code may thus allow machine-readable information on labels that otherwise would be too small. Since all machine-readable information is present in a single symbol, and users are not reliant on location to select the right bar code for scanning, placement of a 2-D symbol on a small label does not have to be strictly standardized.

5.7 **Label Text**

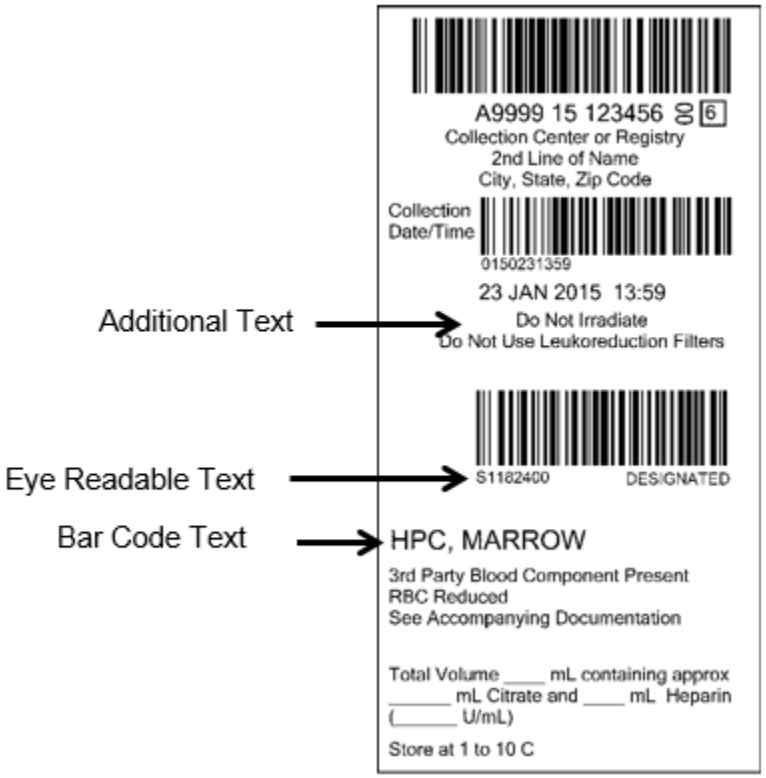
There are three types of text for ISBT 128 labels:

Data content text: The eye-readable representation of the data characters in a bar code printed left justified immediately below a linear bar code (unless otherwise specified). For two-dimensional symbols, data content text will only be present for the DIN and Product Code.

Bar code text: The interpretation of the data content of the bar code.

Additional text: All other information on the label that is not associated with a bar code.

Figure 11 Text Terminology



5.7.1 Data Content Text

Linear Bar Codes: Every Code 128 linear bar code on a container label shall be accompanied by data content text. Data identifiers shall appear only in the bar codes, not in the text. Except for the DIN and donation type beneath the product code, data content text shall appear immediately below, but not touching, the bar code; commence in line with the leftmost bar of the bar code and be represented in sans serif type with a maximum height of 2 mm. The minimum size will depend upon the printer; some printers cannot distinguish between certain letters (for example, an “o” and an “e”) below a height of about 1.5 mm.

2-D Bar Codes: While data content text generally is not associated with Data Matrix (2-D) symbols, the DIN and Product Code data content text shall appear when Data Matrix symbols are used. This is necessary to ensure adequate traceability because a product is uniquely identified based on these codes. It is therefore essential that this information can be entered manually should the electronic capture of information not be possible.

5.7.2 **Bar Code Text**

Bar code text is the interpretation of information encoded in the bar code. It is nationally defined to allow for differences in language, regulatory requirements, and preferences. Where needed, bar code text may appear in multiple languages on a label.

Sans serif fonts should be used. Particular font sizes are not specified for bar code text but designers shall ensure clarity of all text and use larger fonts to emphasize critical information. The font chosen should clearly differentiate between similar characters (e.g., O and 0; I and 1).

US Specification:
A font size of at least 8 should be used for all bar code text on a 100 mm x 100 mm label.

5.7.2.1 **Donation Identification Number [001]**

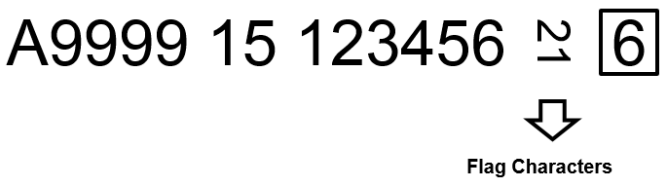
The data content text for a DIN is unique in that it is the sole means of presenting the data content of the bar code, i.e., it serves the dual role of data content text and bar code text. As bar code text it shall be printed using a sans serif typeface. A national authority should determine how it should be displayed, and in the US it should be displayed as shown in Figure 12.

The flag characters “ff” may be used to convey specific information other than the unique identification of the product and shall be distinguished from the DIN [see 3.1 and *ISBT 128 Standard Technical Specification* (ST-001) for more details].

Flag characters shall be printed as either:

Alphanumeric Presentation: The two-digit values of flags “ff” shall be printed rotated 90° clockwise to make them visually different from the DIN.

Figure 12 Numeric Representation of Flag Characters



Non-numeric Presentation: A graphical icon or other representation of the value of “ff”, e.g., for flag “07” printing an icon showing a small test tube.

Figure 13 Representation of Flag Characters with Icon

The keyboard check character shall be printed in a manner that clearly distinguishes it from data content. When printed in association with the data content text of a code, a box shall be drawn around the keyboard entry check character as shown in Figure 13.

5.7.2.2 **Facility**

The name and the address of the facility that corresponds to the Facility Identification Number (FIN) should appear beneath the eye-readable DIN, unless confidentiality is an issue.

Figure 14 Upper Left Quadrant Facility Bar Code Text

Facility Confidentiality with Matched Unrelated Donor Products: In general, eye-readable facility identifying information that corresponds to the FIN embedded in the DIN appears in the upper left quadrant beneath the DIN. However if the product is from a Matched Unrelated Donor, it is acceptable to omit the eye-readable facility information (see 7.1.1.2). This may be required when shipping product into some countries and is recommended by the World Marrow Donor Association (WMDA) in their position paper (see section 1.5). This paper also includes other recommendations for preserving confidentiality of the facility.

While the name of the facility that assigned the DIN does not appear in an eye-readable form, the facility may be identified from the first 5 characters of the DIN and should also be documented in the receiving facility's records.

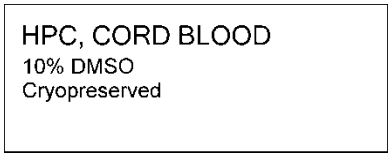
Because of the need to maintain facility confidentiality, it is strongly recommended that facilities do NOT publish their FIN (or examples of their labels which include their FIN) on their websites or other materials in order to keep the link between FIN and facility name less easily discoverable.

Figure 15 Upper Left Quadrant for Matched Unrelated Donor

5.7.2.3 **Product Descriptions**

Product description bar code text should be printed with the Attribute(s) text proportionately smaller than Class text on a 100 mm by 100 mm product label.

Figure 16 Text Size Relationships on Product Label



Text to be used in the US for various Classes or Attributes may be found in Chapter 8.

Class information should appear on the first line followed by the Attribute text where space permits, in the order that the Attributes appear in 8.3, beginning on page 86 (or as listed in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*). The phrase “See Accompanying Documentation” should appear beneath the Attributes when the Attribute is not specific (e.g., when the attributes Third Party Donor: Yes; Other Additives:Yes; or Genetically Modified:Yes are encoded). When multiple non-specific Attributes are present, a single “See Accompanying Documentation” is adequate (See Figure 17).

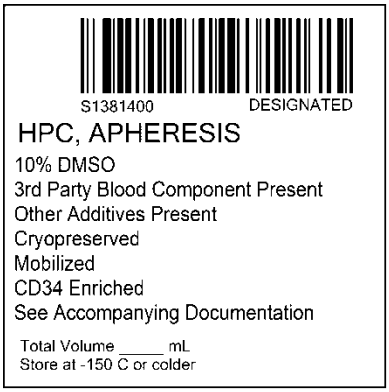
The phrase “See Accompanying Documentation” should also be used when there is inadequate space to print all attributes on the label. In this situation only the Class name should appear on the label with “See Accompanying Documentation” printed where Attributes would appear.

Note: The term “accompanying” in this content means “going together with”. The term includes anything that is affixed, attached, or accompanying the product.

Classes should be printed in all upper case letters, unless space does not permit.

More than one attribute may appear on a line, separated by commas, if this will allow space for printing more attributes

Figure 17 Multiple “Non-Specific” Attributes



5.7.2.4 **Dates**

Dates shall be printed in compliance with ISO 8601-2004 extended format (2010-03-17) or in the format day — month — year. If the latter, the day shall be numerical, the month alphabetical, using a three-letter abbreviation. The year shall be a four-digit numerical representation.

Times shall be printed based on a twenty-four hour clock with a colon placed between the hours and minutes.

2012-06-25 15:15

or

25 JUN 2012 15:15

When a product is being shipped across a time zone and time is pertinent, AABB, FACT, and JACIE standards require a local time zone designation. Similarly, ISBT 128 requires that the time

also be provided in Coordinated Universal Time (UTC) when the product will be shipped internationally across a time zone. When UTC is provided, it shall be printed beneath the local time in parenthesis with the designation “UTC”. Italics may also be used to clearly differentiate UTC from local time. For example:

Expiration Date/Time

15 JAN 2012 15:15 EST

(15 JAN 2012 20:15 UTC)

Note: It is recognized that local time zone designations may have little meaning internationally since two time zones may have the same abbreviation (e.g., EST can mean Eastern Standard Time in Australia, which is UTC+10 hours or Eastern Standard Time in North America, which is UTC -5 hours). However, the Cellular Therapy Coding and Advisory Group believed that local time zones are more readily interpreted within a country. For products shipped internationally, UTC should be used to interpret time.

In the US, if the expiration time is the default time of midnight (23:59) it is encoded into the bar code, and the data content text immediately beneath the bar code should also indicate 2359. However, inclusion of the 23:59 in the bar code text is optional.

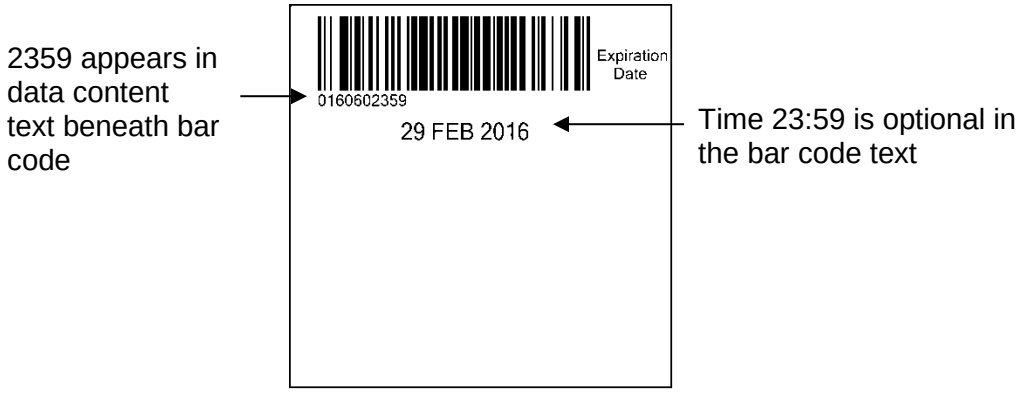
25 JUN 2012
or
2012-06-25

is acceptable, as is:

25 JUN 2012 23:59
or
2012-06-25 23:59

See Figure 18 for an example. (Terminology for text is explained in 5.7).

Figure 18 Text When Expiration is Default Time of 23:59



5.7.3 **Additional Text**

Additional text is defined as text not associated with a bar code. Additional text includes warnings (e.g., Do Not Irradiate) and information such as the address of the processing facility.

In designing their labels, facilities may add non-standardized additional text to the label when space permits.

US Specification:
A font size of at least 8 should be used for additional text on 100 mm x 100 mm labels.

6 Information Requirements on US Labels

6.1 General Requirements

Professional Organizations: Accrediting organizations such as AABB, FACT, NetCord-FACT, and WMDA have label content requirements for cellular therapy products in the United States.

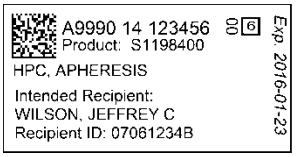
The Alliance for Harmonization of Cellular Therapy Accreditation (AHCTA) has published a convenient crosswalk of labeling requirements for these groups on its website http://www.ahcta.org. This crosswalk defines label content requirements for partial labels, labels at the completion of collection, labels at completion of processing, and labels at distribution for administration. It also indicates whether the information must be on the affixed, attached, or accompanying labeling.

FDA: FDA has requirements for labeling both licensed and non-licensed products. See the Reference Sections (1.4 and 1.5) for specifics. These references address content requirements for the container, package labels, and accompanying records. As noted in the scope, this document does not address formatting and placement of information that must be included on package labeling. The Code of Federal Regulations and FDA guidance documents must be consulted to determine all regulatory labeling requirements.

ISBT 128: The ISBT 128 Standard also has specific requirements for label content. The absolute minimum information which must appear on an ISBT 128 label, *regardless of its size,* to provide traceability is:

- Electronically-readable Donation Identification Number (DIN). If a 2-D label is used, both the DIN and the Product Code shall be electronically-readable.
- The eye-readable Donation Identification Number, flag characters (rotated 90° clockwise), and the boxed manual check character.
- The eye-readable Product Code (Product Description Code, Donation Type Code and Division Code). If this text does not appear in conjunction with a bar code (e.g., there is no linear bar code for Product Code), the word “Product” shall precede the text Product Code (see Figure 19).

Figure 19 Minimum Information – 2-D



For labels that are somewhat larger, but still too small to accommodate all elements of a product label, additional requirements are:

- Machine-readable Product Code (if linear bar codes are used)
- Text name of product (Class)
- Expiration date (if applicable)

Information content for full-sized (100 mm by 100 mm labels) is detailed in Section 7.1.

Compliance with this guidance document does not ensure labels will meet FDA requirements. Label content and layout for licensed products must be approved by the FDA.

6.1.1 Optional Information on Partial Labels

The following information should be included as space permits on an affixed partial label. If it does not fit on the partial label, it must be included on a package label.

- Recipient information, if applicable
- Donor information (code for non-related; name, date of birth, and identifying number for autologous, first, or second degree relatives)
- Biohazard symbol and “Biohazard” text, if applicable
- Collection date, if there is no expiration date
- Storage conditions
- Product attributes (e.g., CD34 Enriched), if space permits. If space does not permit all product attributes, the phrase “See Accompanying Documentation”
- Machine-readable Product Code
- ABO/RhD
- Collection facility information

The size of the print will be dictated by the size of the label. Rules followed for a 100 mm x 100 mm label (e.g., using a proportionately larger print for the Class name than for Attribute or printing the Class in all upper case letters) may not be practical for very small labels. See examples in Chapter 9.

7 Information Placement on US Labels

7.1 100 mm x 100 mm Product Label

In this section, information content of each of the four quadrants will be addressed in detail. This section describes where information should appear if it is needed, but will not discuss requirements for the stage (collection, processing, and/or at the time of distribution) at which information is needed.

7.1.1 Upper Left Quadrant (ULQ)

The information content that may be included in the ULQ of the 100 mm x 100 mm affixed label is shown in Table 6.

Table 6 Upper Left Quadrant Content

Information Elements	Format
Donation Identification Number	Machine-readable
Donation Identification Number	Text
Name and location of the facility assigning the DIN	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

7.1.1.1 **Donation Identification Number (DIN)**

The DIN shall appear in the ULQ. This information shall be both machine-readable and eye-readable. Corresponding text should appear immediately below a linear bar code.

7.1.1.2 **Facility Associated with the DIN**

The ULQ generally contains the text name of the facility that assigned the DIN. No text name is needed if the name of the collection facility is considered confidential. See Figure 20, page 71 and WMDA position paper referenced in Section 1.5.

If the name of the facility is printed, city, state, and Zip Code shall also appear as shown in Figure 23.

7.1.1.3 **Collection Date and Time**

If pertinent, the collection date (and time) should appear in the ULQ. Collection time is not required to be included. That is, either Data Structure 006 (Collection Date) or Data Structure 007 (Collection Date and Time) may be used.

Bar coding the collection date (and time) is not required, but aids in process control. (A good practice would be to have either the collection date or the expiration date, or both, machine-readable when space permits.) As stated in the *ISBT 128 Standard Technical Specification* (ST-001), it is permissible to reduce the height of a bar code to less than the standard 10 mm because of space limitations, but it should be no less than 15% of the length of the bar code. In order to print a collection date bar code in this quadrant, it is likely that the height of the bar code can be no more than 8 mm. The X dimension should not be changed.

If the product will be shipped across a time zone, the local time zone is required by AABB and FACT standards. The time should also be provided in Coordinated Universal Time (UTC) when the product will cross a time zone and an international border. See Section 5.7.2.4, page 63, for how to print dates.

See Figure 20 through Figure 24 for examples.

7.1.1.4 **Warning Statements**

The warning statements: Do Not Irradiate and Do Not Use Leukoreduction Filters should appear in the ULQ.

Rx Only will be printed at the bottom of the quadrant for licensed products.

Figure 20 Upper Left Quadrant – Facility Confidential

Figure 21 Upper Left Quadrant – Product with “Rx Only”

Figure 22 Upper Left Quadrant with Bar Coded Collection Date/Time

Figure 23 Upper Left Quadrant – Collection Time Not Needed

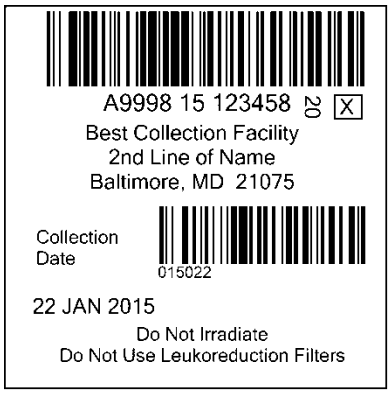


Figure 24 Upper Left Quadrant, Time Zone Not Needed

7.1.2 **Lower Left Quadrant (LLQ)**

The information content that may be included in the LLQ of the affixed 100 mm x 100 mm label is shown in Table 7.

Table 7 Lower Left Quadrant Content

Information Elements	Format
Product Code	Machine-readable
Product Code	Text
Product name and description	Text
Volume	Text
Anticoagulant/preservative and its concentration	Text
Storage temperature	Text
Division code	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

7.1.2.1 **Product Code Bar Code**

On a full 100 mm by 100 mm label, the Product Code shall be bar coded in the LLQ. The data content text of the Product Code shall appear immediately below the bar code and left justified. The donation type, when intended for a specific recipient (designated, autologous, etc.), should appear right justified beneath the bar code.

7.1.2.2 **Name of Product**

The printing of text product information (bar code text) is covered in 5.7.2.3, page 62. Wording is covered in Chapter 8.

7.1.2.3 **Volume**

The total volume of the product and the volume of the anticoagulant should appear beneath the product description.

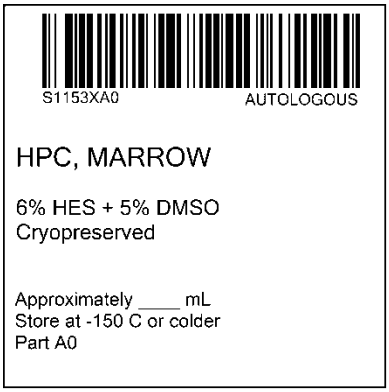
7.1.2.4 **Storage Temperature**

The storage temperature should appear beneath the volume on the label.

7.1.2.5 **Division Code**

If a Division Code applies (i.e., Part A0), it should appear beneath the storage temperature.

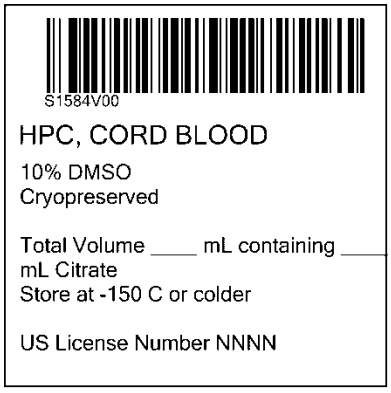
Figure 25 Lower Left Quadrant Divided Product Label



7.1.2.6 **US License Number**

If a product is FDA licensed, the US License Number may appear at the bottom of the LLQ. It must appear within the labeling for the product, but may be included in the package labeling instead of on the affixed (container) label.

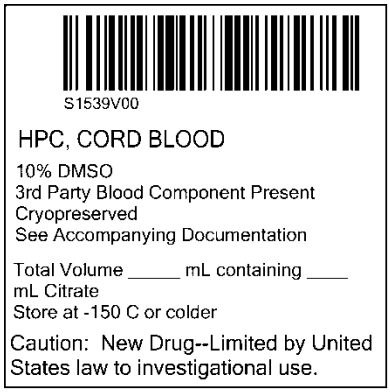
Figure 26 Lower Left Quadrant US License Number



7.1.2.7 **Warning Statement**

If the product is manufactured under an Investigational New Drug protocol, the following warning statement should appear at the bottom of the LLQ, “Caution: New Drug—Limited by United States law to investigational use.”

Figure 27 Lower Left Quadrant IND Warning Message



7.1.3 **Upper Right Quadrant (URQ)**

The information content that may be included in the URQ of the 100 mm x 100 mm affixed label is shown in Table 8.

Table 8 Upper Right Quadrant Information

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	Text
Donor name and date of birth, if donor is a first or second degree relative of the intended recipient	Text

7.1.3.1 **ABO and RhD**

The ABO and RhD (if applicable) may be bar coded on the final label of a full 100 mm by 100 mm label.

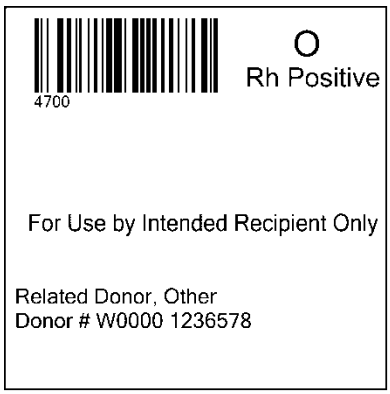
If ABO/RhD is printed and there is no known recipient (e.g., public cord blood bank), the ABO/RhD should be printed as large as possible. See Figure 28 and Figure 29.

Figure 28 Upper Right Quadrant ABO/Rh, No Intended Recipient, RhD Positive

Figure 29 Upper Right Quadrant ABO/Rh, No Intended Recipient, RhD Negative

If ABO/RhD is printed and the intended recipient is known, the ABO/RhD bar code text should be printed in a smaller font and appear to the right of the bar code. See Figure 30.

Figure 30 Upper Right Quadrant ABO/RhD Label with Intended Recipient



7.1.3.2 **Special Message in Place of ABO/RhD**

In place of an ABO/RhD, a special message may be given (see Table 2, page 33). An example of this would be when the product is intended to be used for nonclinical purposes rather than for infusion. Depending on whether or not positive test results exist, the product could be labeled as shown in Figure 31 or Figure 32.

Figure 31 Upper Right Quadrant Special Message for Nonclinical Use Product

Figure 32 Upper Right Quadrant Nonclinical Use Product with Positive Test Result

7.1.3.3 **Biohazard symbol**

The biohazard symbol, if appropriate, should appear immediately below the ABO and RhD. See Figure 33. The word “BIOHAZARD” should appear beside the symbol.

Figure 33 Upper Right Quadrant – Biohazard

7.1.3.4 **Warning statements**

If there is an intended recipient (other than the donor) the phrase, “For Use by Intended Recipient Only” should appear approximately two-thirds the way down the URQ and below the biohazard symbol, if present.

If the product is autologous, the phrase, “FOR AUTOLOGOUS USE ONLY” should appear approximately two-thirds the way down the URQ and below the biohazard symbol, if present.

When applicable (i.e., licensed products), the route of administration recommended or a reference to such directions in an enclosed circular may appear in this quadrant, although it is not required to be in this position.

For licensed cord blood, the sentence, “See package insert for full prescribing information and instructions for preparation.” must appear on the label. This quadrant is one place in which this statement may appear, although it is not required to be in this position.

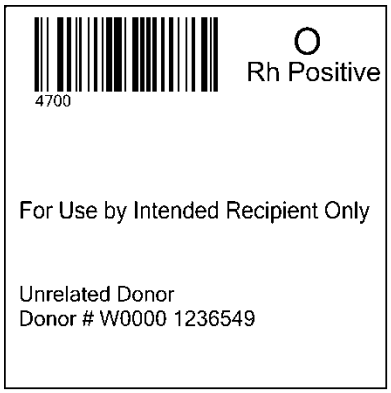
7.1.3.5 **Donor Information (When Recipient is Known)**

Designated Donations: Unrelated

If the donor is not related, the words “Unrelated Donor” and a donor identification number should appear in the lower portion of

the URQ. Other donor information shall remain confidential. See Figure 34.

Figure 34 Upper Right Quadrant – Unrelated Donor

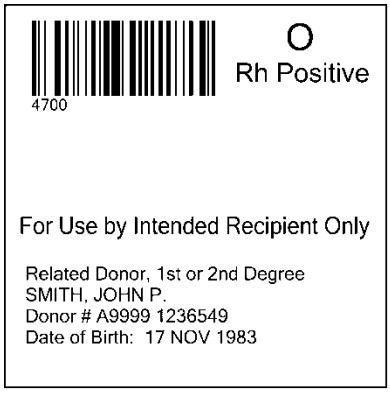


Designated Donations: Related, First or Second Degree

If the donor is a first or second degree relative, the words "Related Donor, First or Second Degree" (or "Related Donor, 1st or 2nd Degree) should appear in the lower portion of the URQ followed by:

- Last name, first name, middle initial of the donor (all upper case letters)
- Donor identification number (this may be either an ISBT 128 Donor Identification Number, a registry number, or a local number)
- Donor date of birth in the format YYYY-MM-DD (1974-11-07) following ISO Standard 8601 or DD MMM YYYY where the month will be a three letter abbreviation (e.g., the date will appear in the format 07 NOV 1944).

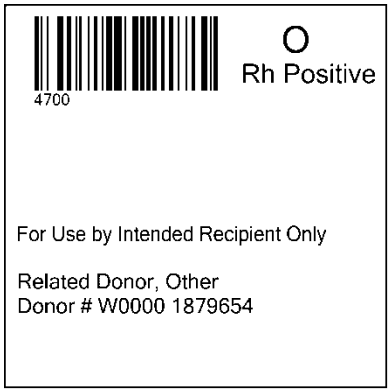
Figure 35 Upper Right Quadrant – Related Donor, First or Second Degree



Designated Donations: Related, Other than First or Second Degree

If the donor is related, but not first or second degree, the words "Related Donor, Other" should appear in the lower portion of the URQ followed by the donor number. Other donor information will remain confidential. See Figure 36.

Figure 36 Upper Right Quadrant – Related Donor, Other than First or Second Degree



Autologous Collections

For autologous donations, "FOR AUTOLOGOUS USE ONLY" should appear in the lower portion of the URQ. See Figure 37. (The Donor/Recipient information should appear in the LRQ, rather than in the URQ.)

Figure 37 Upper Right Quadrant – Autologous Donor, Biohazard

7.1.4 **Lower Right Quadrant (LRQ)**

The information content that may be included in the LRQ of the 100 mm x 100 mm affixed label is shown in Table 9.

Table 9 Information in Lower Right Quadrant

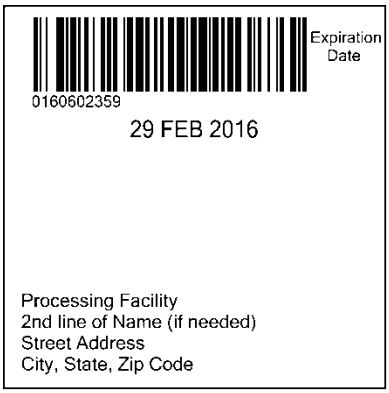
Information Elements	Format
Expiration date and time if applicable	Machine-readable
Expiration date (and time) if applicable	Text
Recipient name, identifier and date of birth if applicable	Text
Processing facility text if different from the facility identified in the ULQ	Text

7.1.4.1 **Expiration Date and Time**

Bar coding of the expiration date and time is not required, but aids in process control. (A good practice would be to have either the collection date or the expiration date, or both, machine-readable when space permits.)

As noted in 5.7.2.4, page 63, if a product is being shipped across a time zone and time is pertinent, AABB, FACT, and JACIE standards require a local time zone designation. Similarly ISBT 128 requires that the time also be provided in Coordinated Universal Time (UTC) when the product will cross a time zone and an international border.

Figure 38 Lower Right Quadrant – Unknown Recipient



7.1.4.2 **Intended Recipient Information – Designated Donation**

When known, the phrase “Intended Recipient” should appear below the expiration date when the product is collected for an intended recipient (other than the donor). The recipient information should include:

- The last name, first name, middle initial (all upper case letters) of the recipient.
- The patient/recipient identifier number
- The date of birth of the patient/recipient in the format YYYY-MM-DD (1944-11-07) following ISO Standard 8601 or DD MMM YYYY where the month will be a three letter abbreviation (e.g., the date will appear in the format 07 NOV 1944).

See Figure 39, Figure 40, and Figure 41.

Because of confidentiality, this information does not appear on the label of a product from an unrelated donor at the time of collection.

Figure 39 Lower Right Quadrant – Expiration Date Not Bar Coded

Figure 40 Lower Right Quadrant – Expiration Date/Time Bar Code and Text

Figure 41 Lower Right Quadrant – Default Expiration Time of Midnight

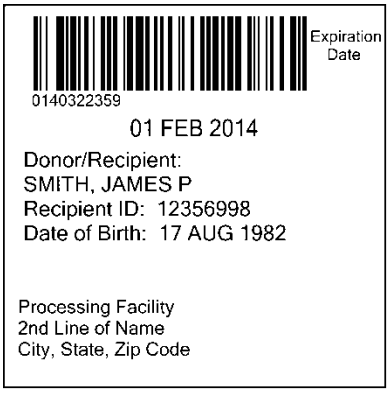
7.1.4.3 **Autologous Collections**

The words “Donor/Recipient” should appear in the lower portion of the LRQ followed by:

- Last name, first name, middle initial of the donor/recipient (all upper case letters),
- Donor/recipient identifier, and
- The date of birth of the patient/recipient in the format YYYY-MM-DD (1944-11-07) following ISO Standard 8601 or DD MMM YYYY where the month will be a three-letter abbreviation (e.g., the date will appear in the format 07 NOV 1944).

See Figure 42.

Figure 42 Lower Right Quadrant – Autologous Donation



7.1.4.4 **Processing Facility**

If different from the facility that assigned the DIN, the name, city, state, and Zip Code of the processing facility should appear at the bottom of the LRQ on a processed product.

7.2 **Smaller Labels**

The placement of information on smaller labels is guided by the size of the label. Facilities should design labels that best meet their needs while fulfilling regulatory and standard setting organization requirements.

8 Product Description Text on US Labels

Terminology undergoes regular review and may be updated once proposed changes are accepted. It is understood that any such changes will take time to implement. Every effort is made to ensure that all changes are backward compatible. Please see *ISBT 128 Standard Terminology for Blood, Cellular Therapy and Tissue Product Descriptions* (ST-002) for the most recent terminology.

8.1 Class Text

Class names will usually match the official class name in the ICCBBA database, as described in the document *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*. Changes to the terminology in 2013 were an effort to come into compliance with regulatory requests. **However, the internationally selected names that are listed in this document may not be acceptable to the FDA. Users are advised to consult the FDA when designing labels.**

Abbreviations listed in the *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions* may be used in standard operating procedures and in professional papers. Such abbreviations are not intended for use on product labels for licensed products.

8.2 Modifier Text

Modifiers are no longer used for cellular therapy. Facilities that have not yet implemented the new terminology, should refer to version 1.2.0 of this document for guidance on how Modifiers should be printed.

8.3 Attribute Text

8.3.1 Core Conditions

There are three parts to ISBT 128 core conditions: Anticoagulant added during collection, nominal volume (the targeted collection volume), and storage temperature.

Anticoagulant: If an anticoagulant is introduced during the collection process and is present in the product, the name of the anticoagulant should be listed on the label along with volume. In the case of heparin, the concentration of the original vial should also be included.

Volume: All cellular therapy products are coded with a nominal collection volume of “XX”, which means the actual targeted collection volume is not encoded in the product code. It is also not printed on the label.

Although the nominal collection volume does not appear on the label, the total volume of the product should appear in text on a full label, and whenever possible on a partial label. This information is not encoded within the Product Description Code.

The volume appears first. For example:

Total Volume ____ mL containing ____ mL Citrate

Total Volume _____ mL containing ____ mL Heparin (_____ U/mL)

Total Volume _____ mL containing ____ mL Citrate and _____ mL Heparin (_____U/mL)

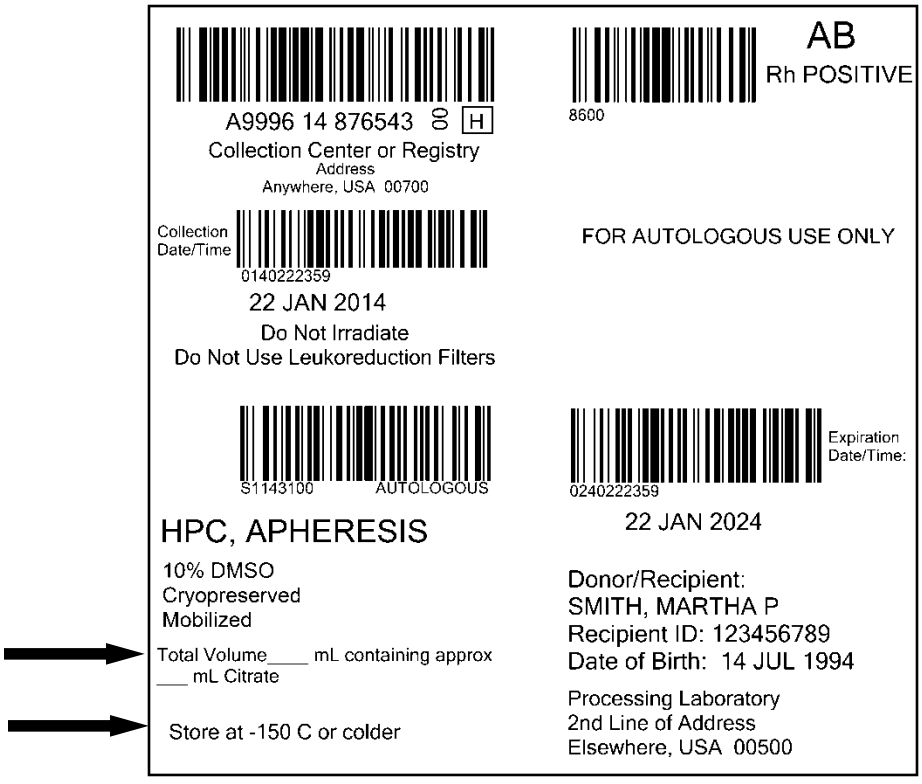
Storage temperature: The storage temperature should appear beneath the volume and anticoagulant on the full label. For example:

Store at -150 C or colder

Store at room temperature

Core conditions attributes appear beneath other attributes in the lower left quadrant of the label.

Figure 43 Core Conditions Labeling



8.3.2 **Groups and Variables**

Attribute text should be as it appears in the tables below. When the phrase “See Accompanying Documentation” is required (Third Party Component:Yes; Other Additives:Yes; or Genetically Modified:Yes), it needs to appear only one time if more than one of these attributes is present. The attached or accompanying documentation should include more detailed information about these attributes. If an attribute is not listed in this document, consult the ICCBBA office (tech.director@iccbba.org) for the appropriate text.

8.3.3 **Intended Use Group**

Table 10 Intended Use Group Text

Attribute Name	Definition	Label Text
Default: for administration	For patient use. The product is intended for administration to patients.	(None)
For further processing	For further processing into a product that may be administered; not intended for direct administration.	For Further Processing
For use in further processing donor’s cell product	Intended for use in further processing of cellular products from the same donor	For Use in Further Processing Donor’s Cell Product
Not for admin	Not for patient use; a product that is not intended for use in patient treatment.	For Nonclinical Use Only (in upper right quadrant)

8.3.4 **Manipulation Group**

Table 11 Manipulation Group Text

Attribute Name	Definition	Label Text
Default: Not Specified	No information about processing is specified in this Attribute group.	(None)
Electroporated	The use of an electric field to increase the permeability of the cell plasma membrane to introduce some substances (such as mRNA, drugs, etc.).	Electroporated
Filtered	Product after passage through a non-leukocyte reducing filter. (Note: The bone marrow harvest procedure includes a series of filters to obtain the collected product. This is not considered a separate manipulation step. The attribute “Filtered” should not be used. Select the attribute “Filtered” if an independent filtration is performed (e.g., filtered in the laboratory using a 170 - 260 micron filter).	Filtered
Lysed	The use of a process to disrupt the cell membranes (such as freezing cells without cryoprotectant, etc.).	Lysed
Pulsed	The loading of antigens (such as peptides, tumor antigens, etc.) on dendritic cells to increase the specificity of the immunotherapy.	Pulsed
PUV treated	Cells treated with psoralen/ultra violet light.	PUV Treated

8.3.5 **Cryoprotectant Group**

Table 12 Cryoprotectant Group Text

Attribute Name	Definition	Label Text
Default: No cryoprotectant	No cryoprotectant has been added.	(None)
5% DMSO	The concentration of the final product contains 5% dimethylsulfoxide by volume as the cryoprotective agent.	5% DMSO
7.5% DMSO	The concentration of the final product contains 7.5% dimethylsulfoxide by volume as the cryoprotective agent.	7.5% DMSO
10% DMSO	The concentration of the final product contains 10% dimethylsulfoxide by volume as the cryoprotective agent.	10% DMSO
6% HES + 5% DMSO	The concentration of the final product contains 5% dimethylsulfoxide by volume and 6% hydroxyethyl starch as the cryoprotective agents.	6% HES + 5% DMSO Or 6% HES and 5% DMSO
NS DMSO	The dimethylsulfoxide concentration of the final product is not specified in the coding. Additional information concerning the approximate amount of dimethylsulfoxide present will appear as text on the affixed, attached, or accompanying labeling.	DMSO Present. See Accompanying Documentation (This phrase is printed only if the concentration of DMSO is not on the affixed label.)
NS HES + NS DMSO	The final product contains unspecified concentrations of hydroxyethyl starch and dimethylsulfoxide. The concentrations of these additives may be specified in text on the affixed, attached, or accompanying label.	HES + DMSO Present. See Accompanying Documentation (This phrase is printed only if the concentration of additives is not on the affixed label.)
NS HES + 5% DMSO	The final product contains an unspecified concentration of hydroxyethyl starch and 5% dimethylsulfoxide by volume. The concentration of hydroxyethyl starch may be specified in text on the affixed, attached, or accompanying label.	HES + 5% DMSO or HES and 5% DMSO See Accompanying Documentation (This phrase is printed only if the concentration of the additives is not on the affixed label.)
NS HES + 10% DMSO	The final product contains an unspecified concentration of hydroxyethyl starch and 10% dimethylsulfoxide by volume. The concentration of hydroxyethyl starch may be specified in text on the affixed, attached, or accompanying label.	HES + 10% DMSO or HES and 10% DMSO See Accompanying Documentation (This phrase is printed only if the concentration of additives is not on the affixed label.)

8.3.6 **Blood Component from Third Party Donor Group**

Table 13 Blood Component from Third Party Donor Group Text

Attribute Name	Definition	Label Text
Default: 3rd party comp:No	No third party blood component added.	(None)
3rd party comp:Yes	Third party blood component added. See accompanying documentation.	3rd Party Blood Component Present. See Accompanying Documentation.

8.3.7 **Preparation: Other Additives Group**

Table 14 Preparation: Other Additives Group Text

Attribute Name	Definition	Label Text
Default: Other additives:No	No additives other than as part of the anticoagulant solution at the time of collection.	(None)
Concurrent Plasma	Concurrently collected plasma has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation.	Concurrently collected plasma present.
Concurrent plasma + other	Concurrently collected plasma has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation. Other additives are also present. See accompanying documentation.	Concurrently collected plasma and other additives present. See Accompanying Documentation.
Other additives:Yes	Other additives. See accompanying documentation.	Other additives present. See Accompanying Documentation.
Other additives: Yes incl animal src	Other additives present including animal source material. See accompanying documentation.	Other additives present including animal source material. See Accompanying Documentation.

8.3.8 **Genetically Modified Group**

Table 15 Genetically Modified Group Text

Attribute Name	Definition	Label Text
Default:Genetically Modified:No	Not genetically modified.	(None)
Genetically Modified:Yes	Genetically modified by the insertion of exogenous genetic material.	Genetically Modified. See Accompanying Documentation.

8.3.9 **Irradiation Group**

Table 16 Irradiation Group Text

Attribute Name	Definition	Label Text
Default: Irradiation:No	Product was not irradiated.	(None)
Irradiation:Yes	Product was irradiated.	Irradiated

8.3.10 **Modification Group**

Table 17 Modification Group Text

Attribute Name	Definition	Label Text
Default:Not Specified	Modifications are not specified in the coding.	(None)
Cryopreserved	Applies to cells in the frozen state after the addition of cryoprotectant(s).	Cryopreserved
Thawed	Applies to cryopreserved cells that have been thawed without washing prior to final issue for administration.	Thawed
Thawed Washed	Applies to cryopreserved cells that have been thawed and subsequently washed to remove cryoprotectant or other solution(s).	Thawed Washed
Washed	Applies to cells from a non-cryopreserved product that have been washed to reduce the amount of plasma, anticoagulant, and/or other solution(s).	Washed

8.3.11 **Mobilization Group**

Table 18 Mobilization Group Text

Attribute Name	Definition	Label Text
Default:Not Specified	Mobilization is not specified in the coding.	(None)
Mobilized	Applies to cells that have been obtained from a donor treated with an agent to increase the concentration of the target cell population(s).	Mobilized
Non-mobilized	Applies to cells that have been obtained from a donor not treated with an agent to increase the concentration of the target cell population(s).	Non-Mobilized

8.3.12 **Pooled Single Donor Group**

Table 19 Pooled Single Donor Group Text

Attribute Name	Definition	Label Text
Default:Not specified	Pooling of the product is not specified in the coding.	(None)
Pooled Single Donor: Yes	Product is a combination of multiple collections of the same product type from the same donor or aliquots from the same collection.	Pooled Single Donor

8.3.13 **Cultured Group**

Table 20 Cultured Group Text

Attribute Name	Definition	Label Text
Default:Cultured: No	Product was not cultured.	(None)
Cultured: Yes	Cells that have been maintained ex vivo to activate, expand, or promote development of a specified cell population in the presence of specified additive(s).	Cultured

8.3.14 **Enrichment Group**

Table 21 Enrichment Group Text

Attribute Name	Definition	Label Text
Default:Not Specified	No information about cell enrichment is specified in the coding.	(None)
Buffy coat enriched	Cells remaining after reduction of mature erythrocytes and plasma.	Buffy Coat Enriched
CD4 enriched	Product in which the CD4 cells have been enriched.	CD4 Enriched
CD34 enriched	Product in which the CD34 cells have been enriched.	CD34 Enriched
CD56 enriched	Product in which the CD56 cells have been enriched.	CD56 Enriched
CD133 enriched	Product in which the CD133 cells have been enriched.	CD133 Enriched
CTL enriched	Product in which the cytotoxic T lymphocytes have been enriched.	CTL Enriched
Monocyte enriched	Product in which the monocytes have been enriched.	Monocyte Enriched
Mononuclear cells enriched	Product in which the mononuclear cells have been enriched.	Mononuclear Cells Enriched
T Reg enriched	Product in which the T regulatory lymphocytes have been enriched.	T Reg Enriched
TIL enriched	A product in which autologous tumor infiltrating lymphocytes (TIL) have been enriched from the patient's tumor and cultured.	TIL Enriched
Viral specific T cells enriched	A product in which viral specific T cells have been enriched.	Viral Specific T Cells Enriched

8.3.15 **Reduction Group**

Table 22 Reduction Group Text

Attribute Name	Definition	Label Text
Default:Not specified	No information about cell or plasma reduction is specified in the coding.	(None)
αβ T cell reduced	The cells remaining after the Alpha Beta T cells have been reduced.	Alpha Beta T Cell Reduced
αβ T/B cell reduced	The cells remaining after the Alpha Beta T cells and B cells have been reduced.	Alpha Beta T/B Cell Reduced
B cell reduced	The cells remaining after B cells have been reduced.	B Cell Reduced
CD8 reduced	The cells remaining after CD8 cells have been reduced.	CD8 Reduced
Plasma reduced	The cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation.	Plasma Reduced
RBC reduced	The cells remaining after reduction of mature erythrocytes.	RBC Reduced
T cell reduced	The cells remaining after T cells have been reduced.	T Cell Reduced
T/B cell reduced	The cells remaining after T cells and B cells have been reduced.	T/B Cell Reduced
Tumor cell reduced	Cells remaining after tumor cells have been reduced.	Tumor Cell Reduced

8.4 **Donation types**

Table 23 Donation Types for Use with Product Code Data Structure

Note: Shaded lines are included for the purpose of completeness. These codes are part of the ISBT 128 Technical Specification and may be used for blood or other products. These codes should not be used to label Cellular Therapy products in the US. However, software should be written to read and interpret these codes since products could be received from countries using these codes. It is important to be aware when such products, if received, should not be used in the US (see the "When to Use" column).

Character	Type of Donation	Label Text (Appearing in URQ)	When to Use
0	Not specified		Default; no information is provided on the type of donation.
V	Voluntary allogeneic donation		When product is collected from a volunteer donor and is intended for administration to an unknown recipient.
R	Volunteer research donor	For Nonclinical Use Only	When product is collected from a donor for research purposes only.
S	Volunteer source donor		The code is intended for source products (products intended for further manufacture into products such as plasma derivatives). This should not be used with a cellular therapy product intended for administration.
T	Volunteer therapeutic collection		This code should not be seen on a cellular therapy product intended for administration.
P	Paid homologous (allogeneic) collection		Generally not applicable to cellular therapy products in the U.S. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.

Character	Type of Donation	Label Text (Appearing in URQ)	When to Use
r	Paid research collection		Generally not suitable for clinical use. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
s	Paid source collection		The code is intended for source products (products intended for further manufacture into products such as plasma derivatives) and is generally not applicable to cellular therapy products in the U.S. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
A	For autologous use, eligible for crossover		Allogeneic use of a product originally intended for autologous use is not generally acceptable for clinical use in U.S. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
1 (one)	For autologous use only	FOR AUTOLOGOUS USE ONLY	When product is for autologous use only.
X	For autologous use only, biohazard	BIOHAZARD FOR AUTOLOGOUS USE ONLY	When product is for autologous use and presents a known or suspected relevant communicable disease risk.

Character	Type of Donation	Label Text (Appearing in URQ)	When to Use
D	Volunteer Directed collection, eligible for crossover		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
d	Paid directed collection, eligible for crossover		Generally not acceptable for clinical use in U.S. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
L	For directed recipient use only, limited exposure		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
E	Medical exception, for specified recipient use only (allogeneic)		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
Q	A Special Testing bar code must be scanned		Would be used only for blood products, primarily Red Blood Cells to indicate additional information, usually about the red cell phenotype, is present in a Special Testing bar code.

Character	Type of Donation	Label Text (Appearing in URQ)	When to Use
2	For directed recipient use only		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
3	For directed recipient use only, biohazard		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
4	Designated collection	For Use by Intended Recipient Only (If there is more than one intended recipient, this should read, "For Use by Intended Recipients Only")	When product is intended for one recipient or a small group of recipients (e.g., siblings of a cord blood donor). This donation type would apply whether or not the intended recipient was known at the time of collection or processing.
5	Dedicated collection		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
6	Designated collection, biohazard	BIOHAZARD For Use by Intended Recipient Only (If there is more than one intended recipient, this should read, "For Use by Intended Recipients Only")	When product is intended for one recipient or a small group of recipients (e.g., siblings of a cord blood donor) and presents a known or suspected relevant communicable disease risk. This donation type would apply whether or not the intended recipient was known at the time of collection or processing.

Character	Type of Donation	Label Text (Appearing in URQ)	When to Use
F	Family reserved		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.
C	Replacement collection		Not generally used for Cellular Therapy products in the US. Should a product labeled with this code be received, the facility should contact the processing facility that labeled it to determine its suitability for use.

9 Label Examples

All labels in this section are example labels. They often contain more than the required information referred to in Chapter 6. Once the required information is on the label, as space permits facilities may include other information in addition to, or instead of, information shown on these label examples.

Text shown in italics is meant to indicate hand-written information (with the exception of the UTC date/time which may be printed in italics to differentiate it from local time).

These labels have not been approved by a regulatory authority. They serve as templates only.

Product names and attributes should be worded as they appear in Chapter 8. The exact wording of other information shall be as required by regulations and standards setting organizations. When precise wording is not required by these organizations (e.g., the phrase used to describe anticoagulant type and volume), this document represents recommendations, not requirements.

9.1 **Label at Completion of Collection**

Figure 44 Full Collection Label – Unrelated Donor

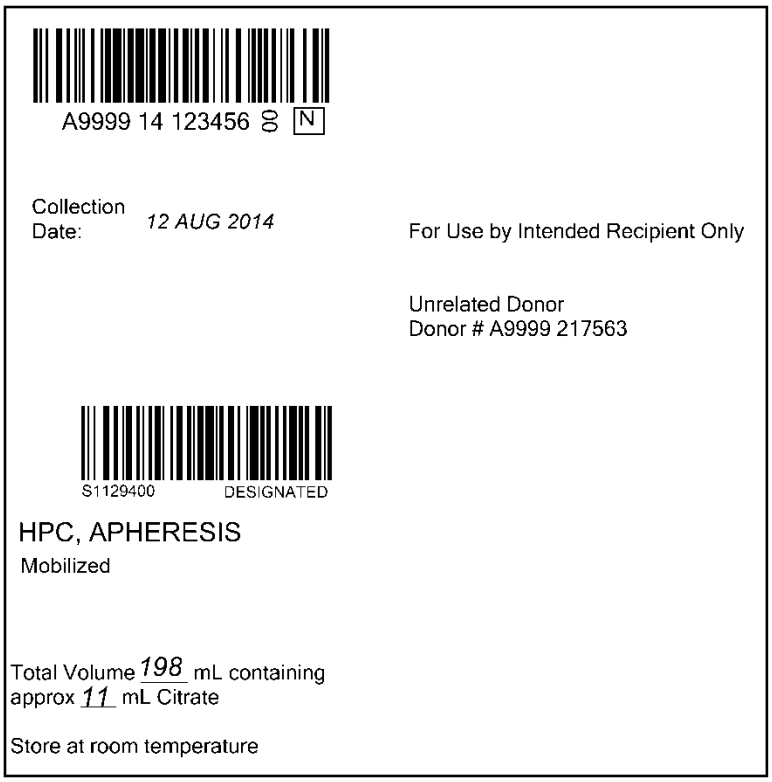


Figure 45 Full Collection Label – Related Donor 1st or 2nd Degree

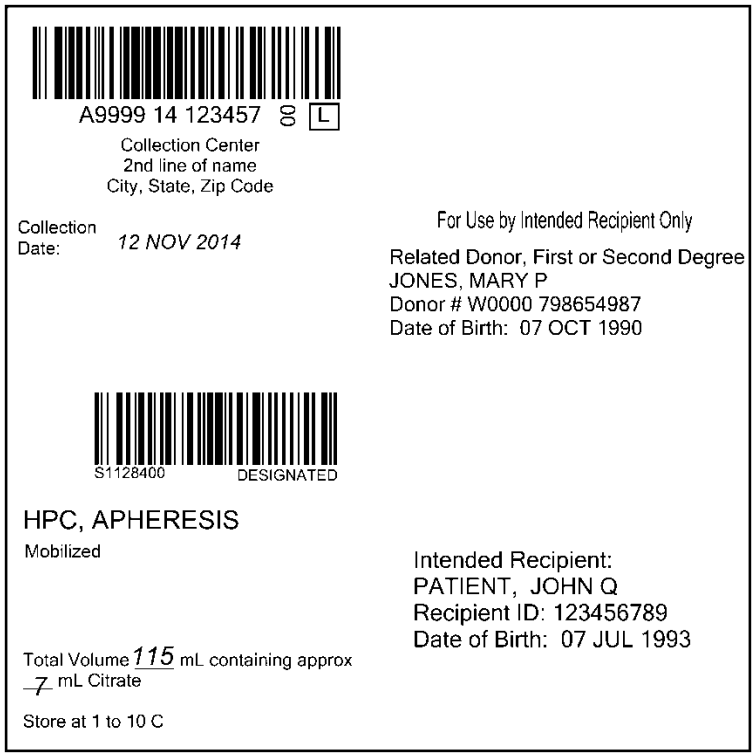


Figure 46 Full Collection Label – Related Donor Other

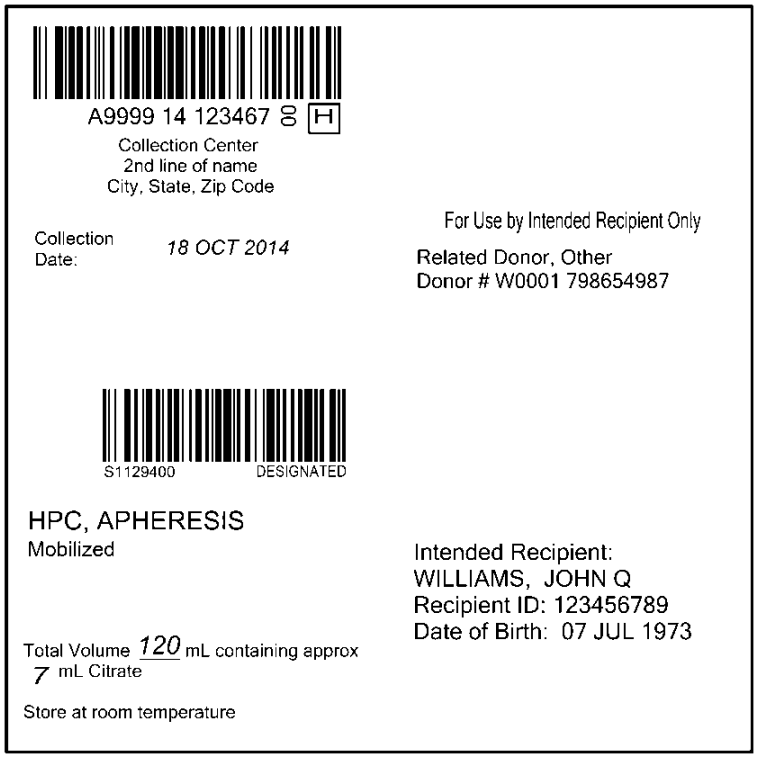


Figure 47 Full Collection Label – Autologous

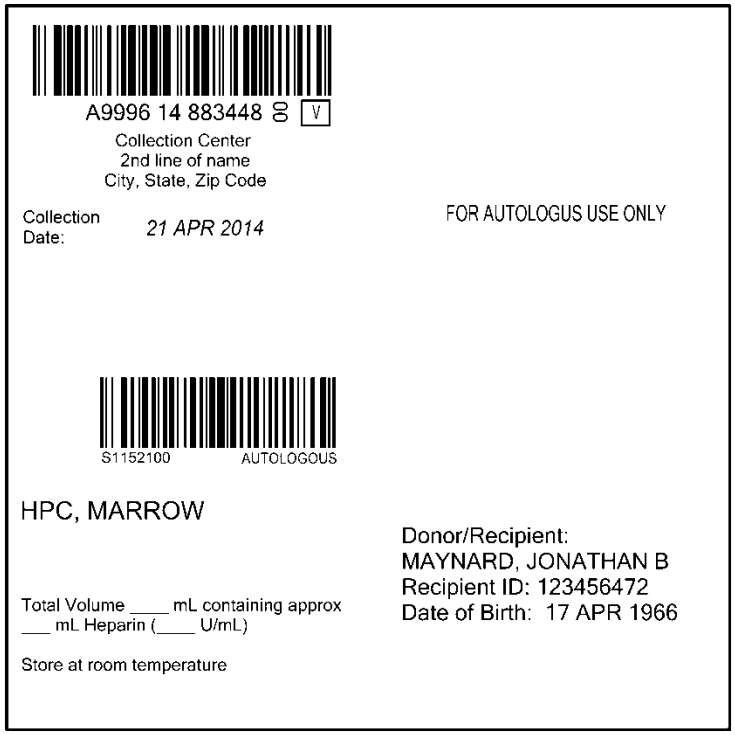


Figure 48 Full Collection Label – MNC, APHERESIS

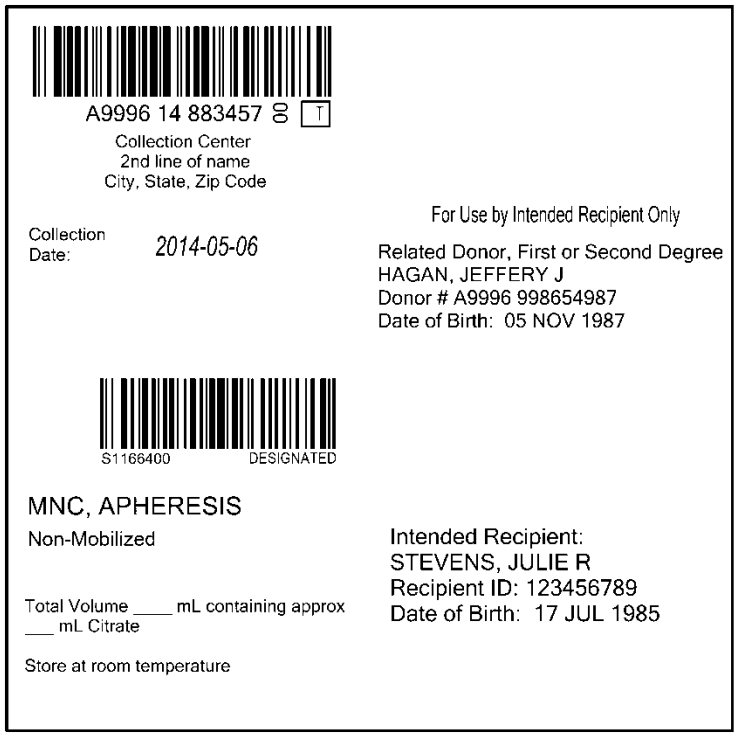


Figure 49 Full Collection Label – HPC, APHERESIS Collection

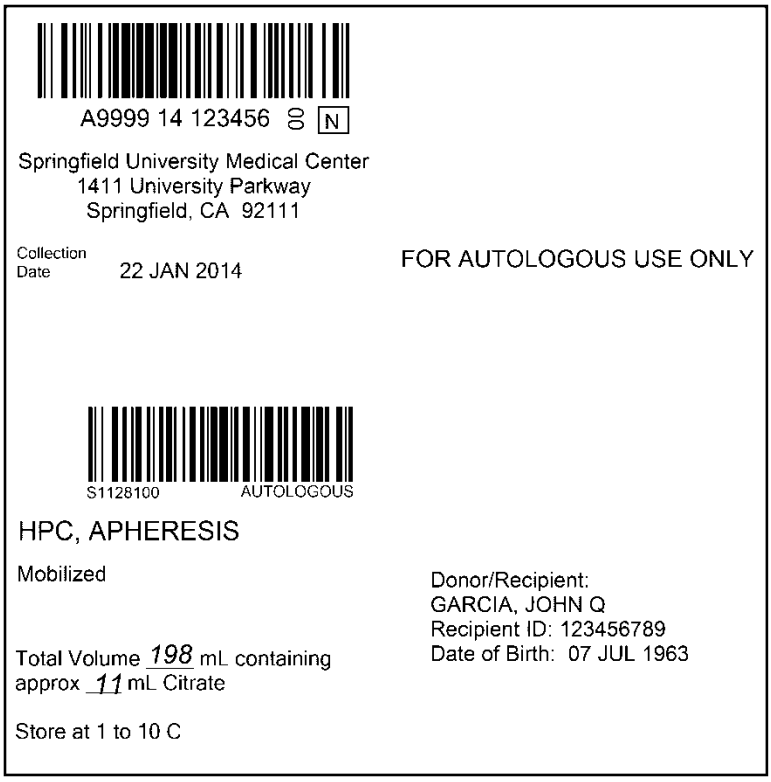


Figure 50 Full Collection Label – HPC, MARROW Collection

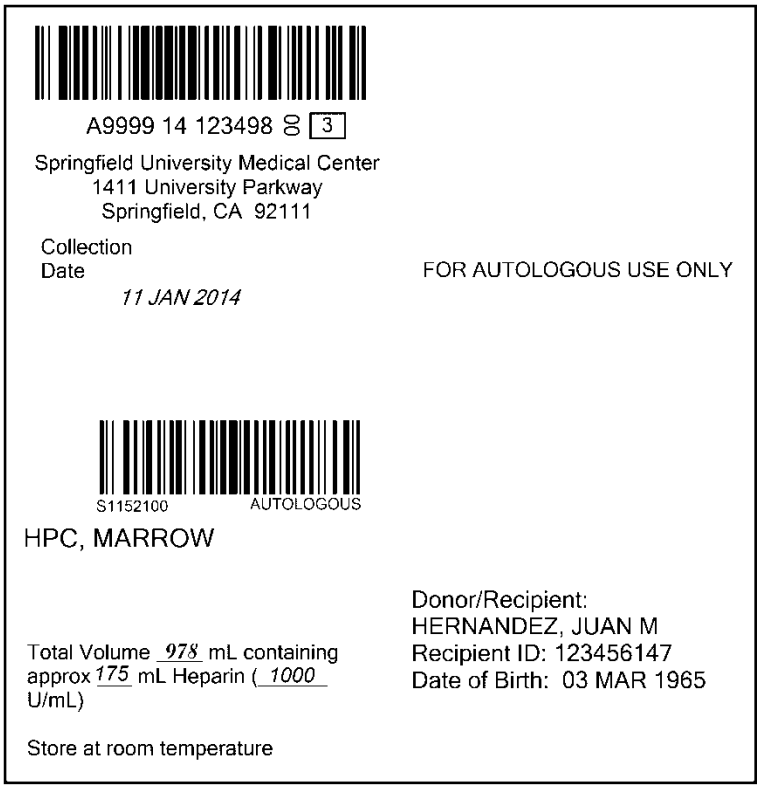
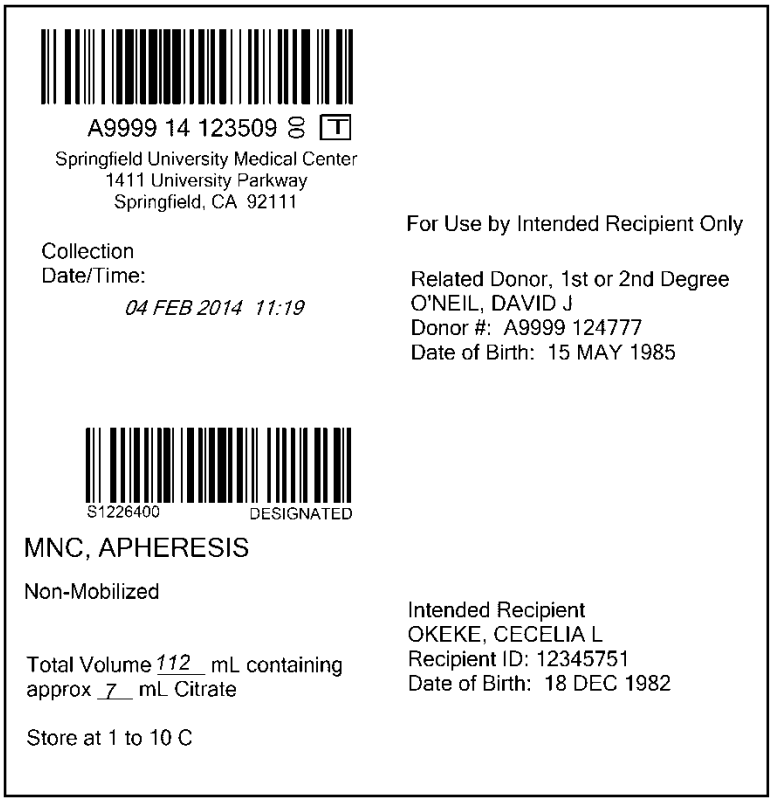


Figure 51 Full Collection Label – MNC, APHERESIS Collection



9.2 **Apheresis Products**

Figure 52 HPC, APHERESIS, Designated

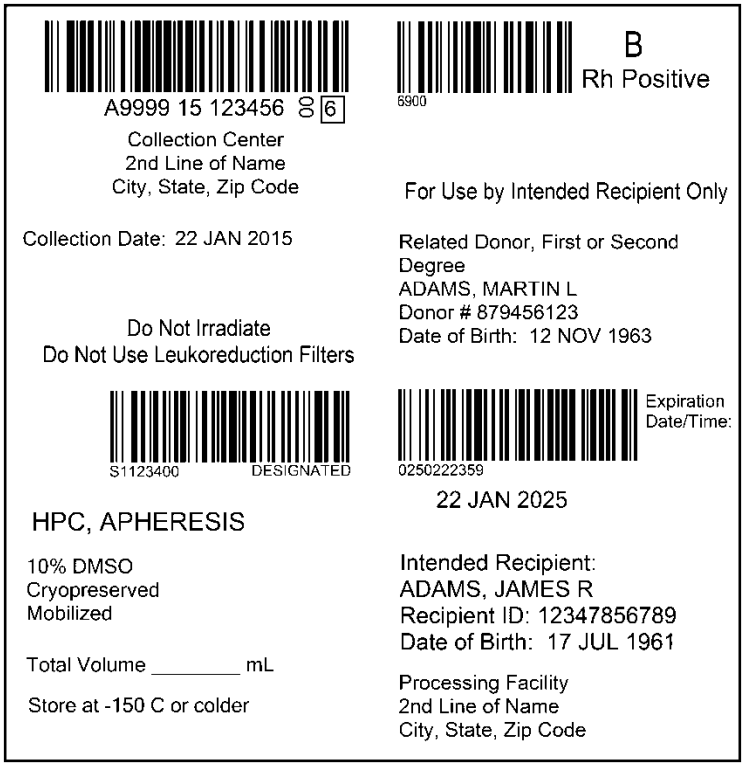


Figure 53 HPC, APHERESIS, Autologous

Figure 54 HPC, APHERESIS, Designated, Multiple Attributes

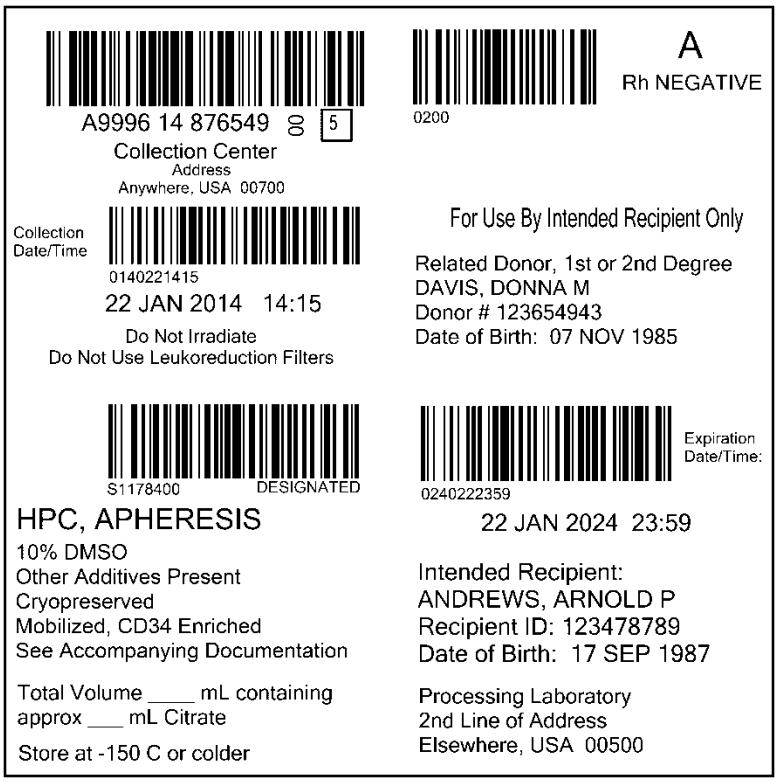


Figure 55 HPC, APHERESIS, Autologous, Multiple Attributes

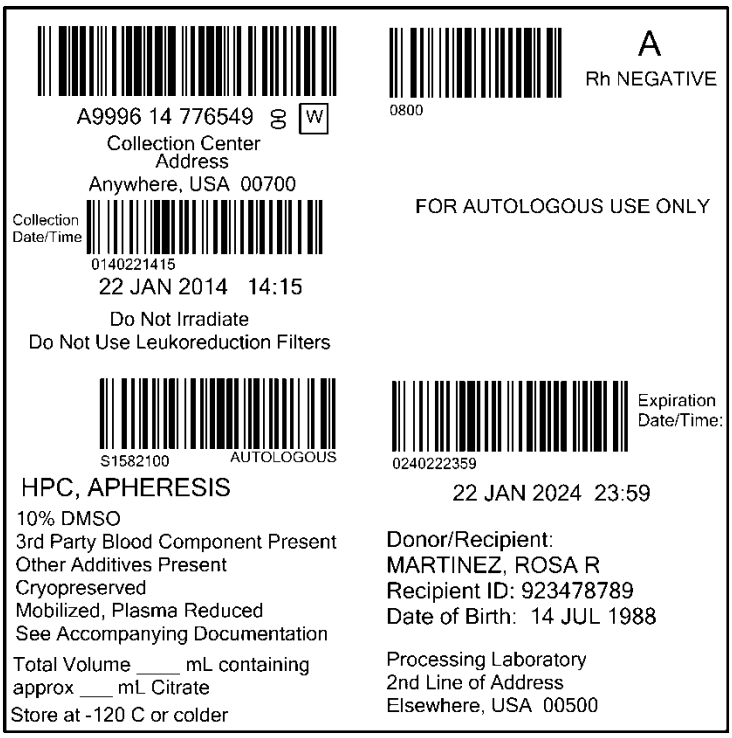


Figure 56 HPC, APHERESIS, Autologous, Multiple Attributes

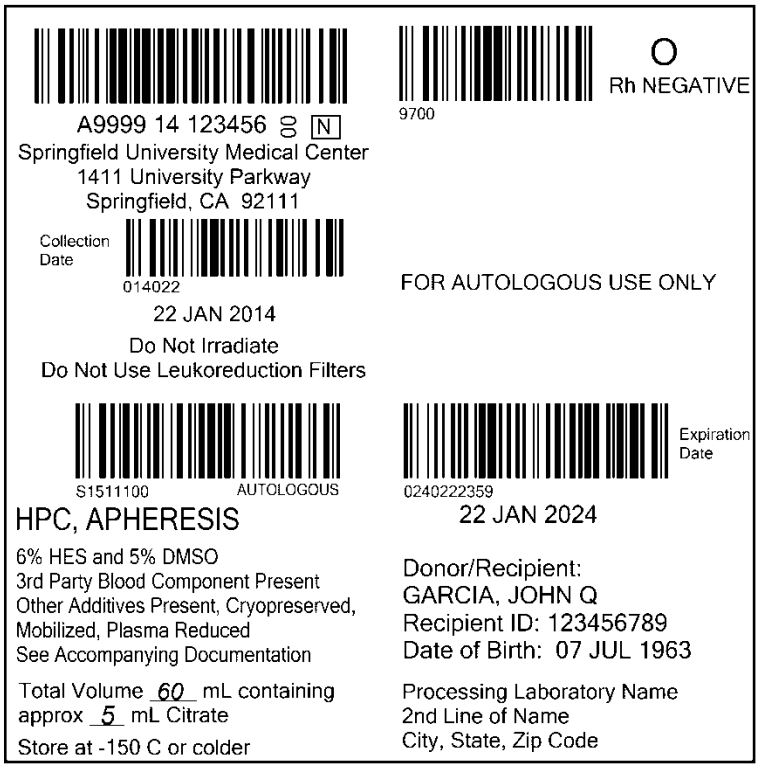


Figure 57 Cryopreserved HPC, APHERESIS Labels

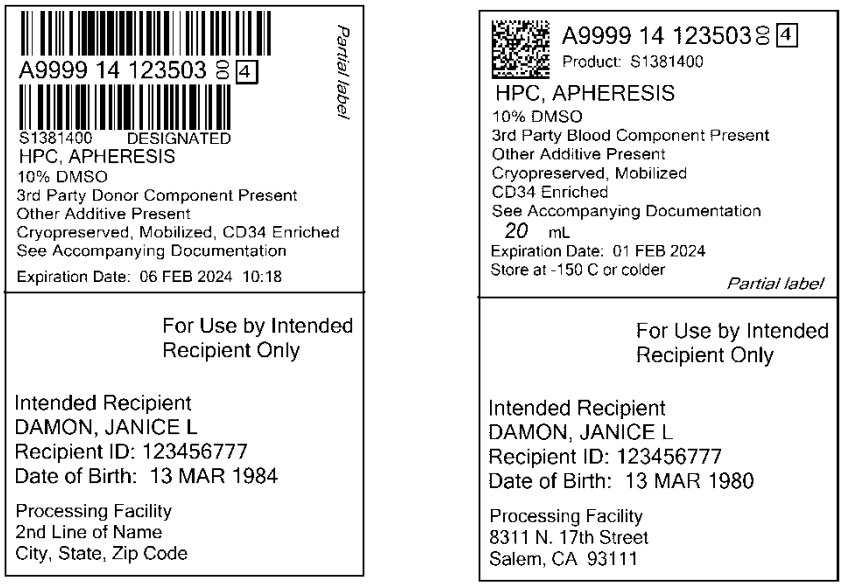
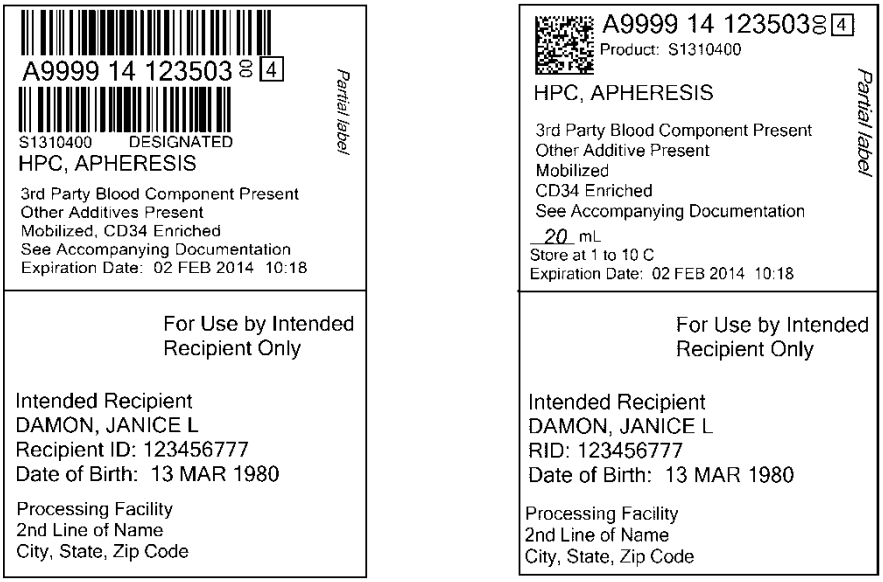


Figure 58 HPC, APHERESIS Labels



9.3 **Marrow Products**

Figure 59 HPC, MARROW, Designated

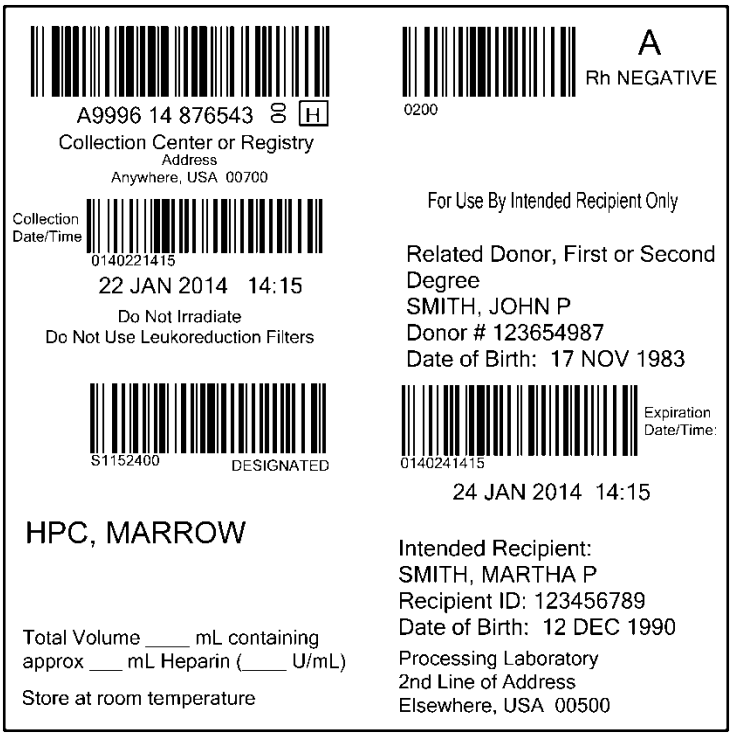


Figure 60 HPC, MARROW, Multiple Attributes

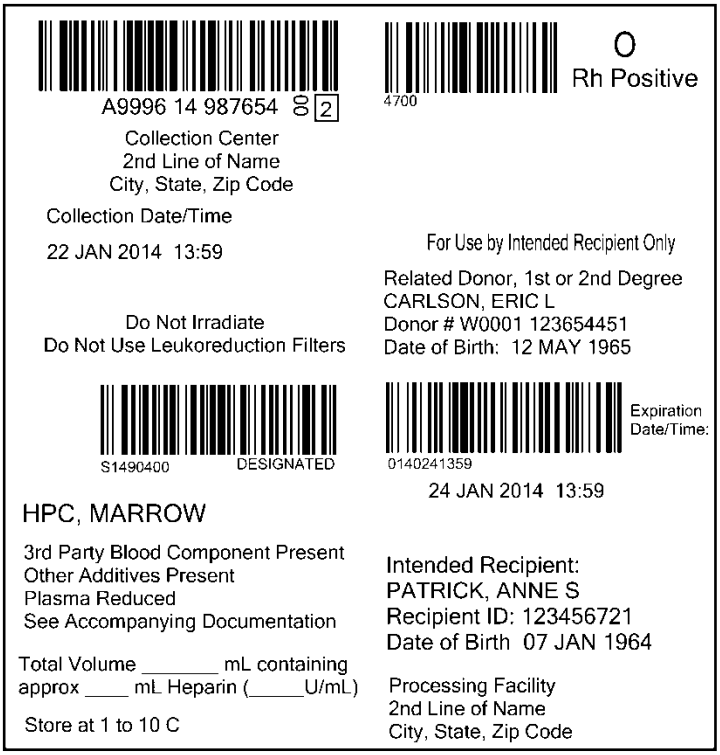


Figure 61 HPC, MARROW, Divided Product (Part A0)

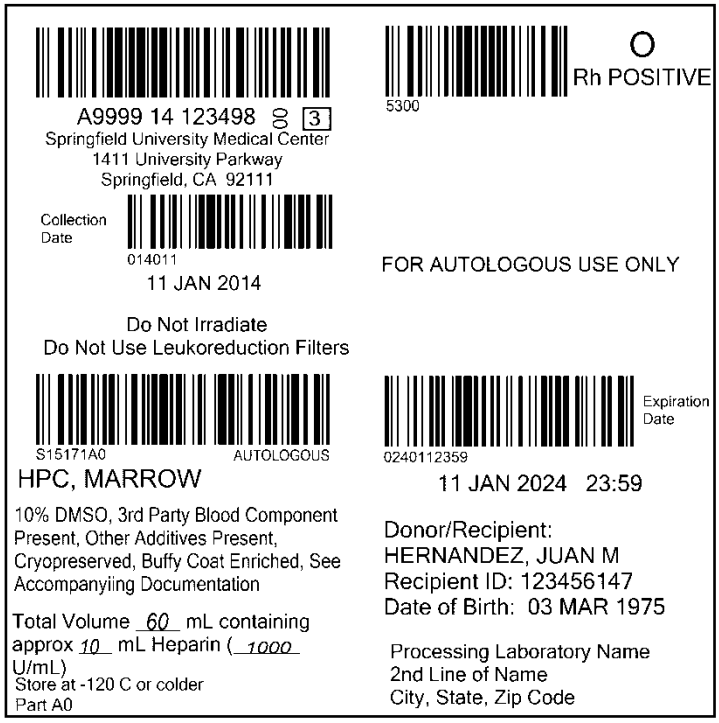


Figure 62 HPC, MARROW, Divided Product (Part C0)

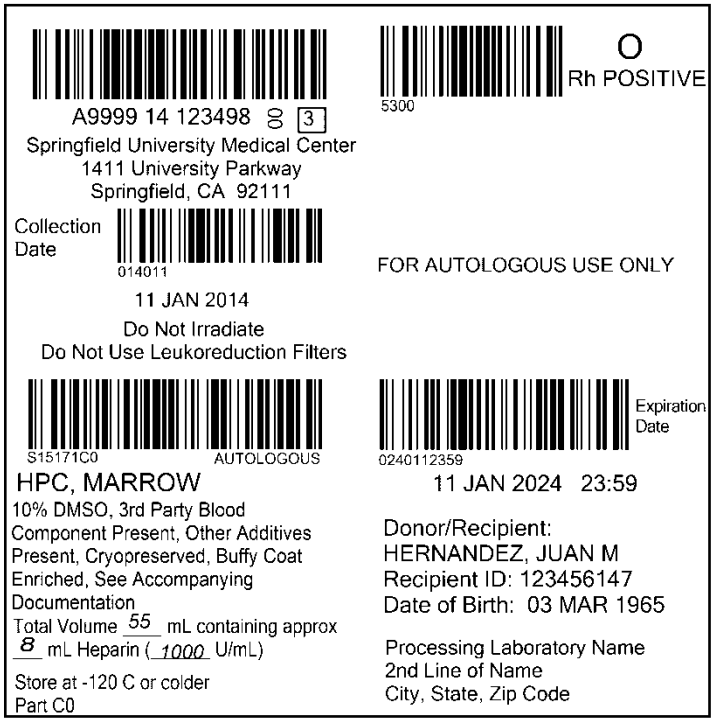
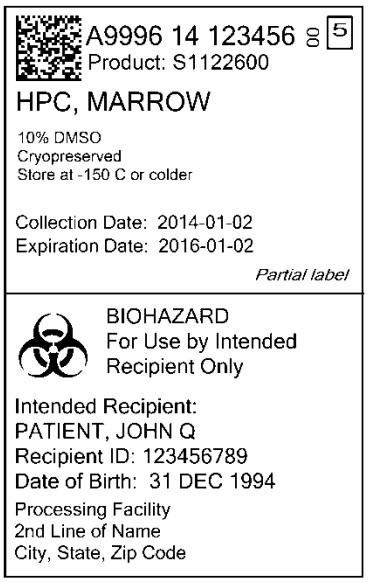


Figure 63 HPC, MARROW Label



9.4 Cord Blood Products

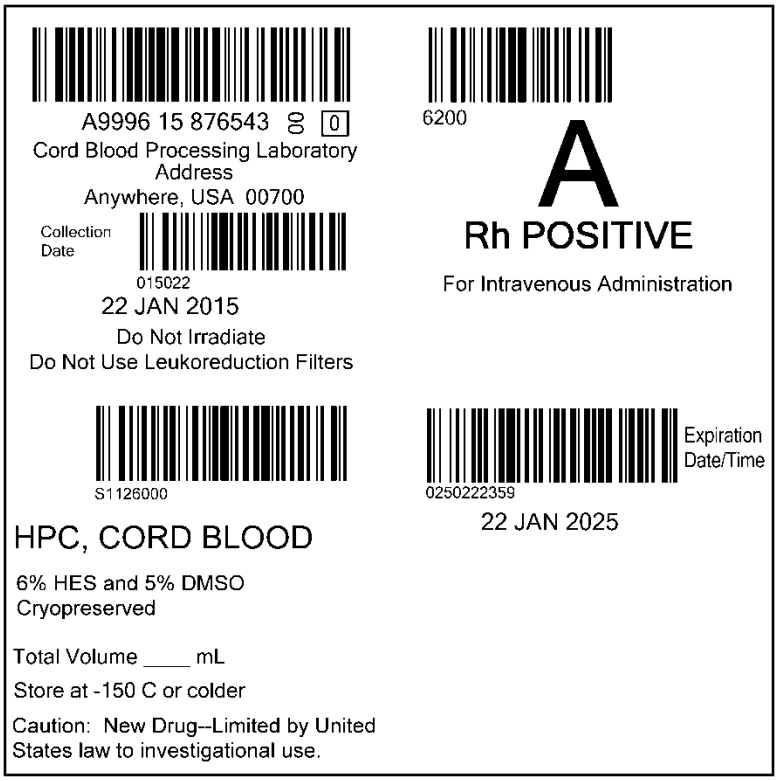
Compliance with this guidance document does not ensure labels will meet FDA requirements. Label content and layout for IND products must be discussed with the FDA and labels for licensed products must be approved by the FDA.

9.4.1 IND Cord Blood

Note: For labels too small to bear the mandatory caution statement for new drugs, users are advised to discuss with the FDA reviewer possible alternatives to placement of the statement.

Figure 64 Cord Blood Labels, IND

Figure 65 Cord Blood Label, IND

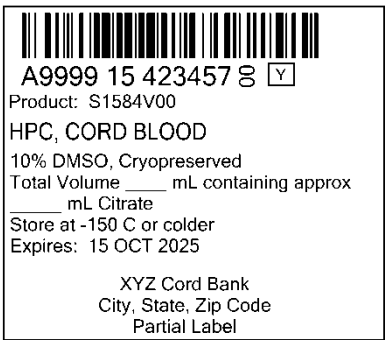


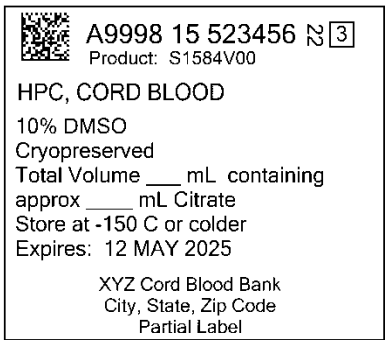
9.4.2 Licensed Cord Blood Products

Compliance with this guidance document does not ensure labels will meet FDA requirements. Label content and layout for licensed products must be approved by the FDA.

Licensed cord blood products are subject to the barcode label requirements (21 CFR 201.25). The barcode label at minimum must contain the appropriate National Drug Code (NDC). Cord blood banks that are applying for licensure and have fully implemented the ISBT 128 labeling must submit an exemption request from the barcode rule if they wish to use ISBT 128 labeling in lieu of NDC.

Figure 66 Cord Blood Labels, Licensed Products (Partial)





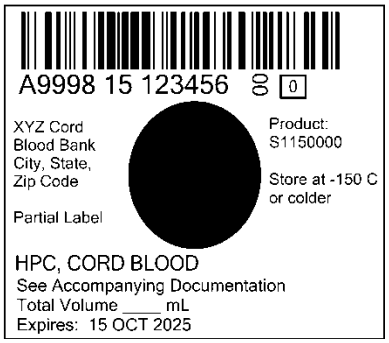
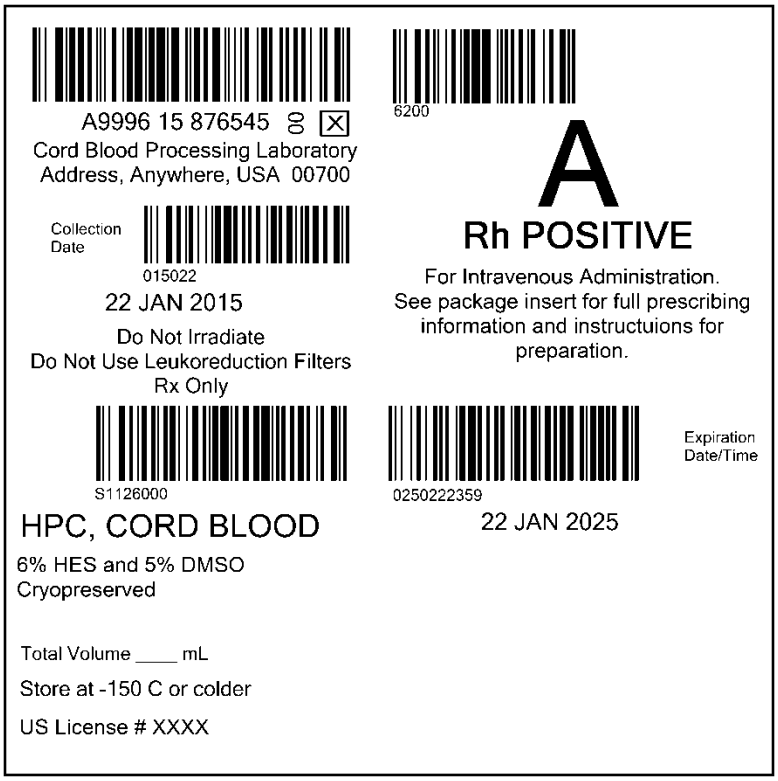


Figure 67 Cord Blood Label, Licensed Product



9.4.3 Licensure Status Unknown

It may not be known at the time of freezing if a product will meet the requirements of a licensed product. In this situation, as much of the required information as is known should be on the label, and the label should not bear license number or NDC.

At the time of shipment, when the licensure status is known, the package labeling (not necessarily the affixed label) should follow the appropriate label design for either licensed or IND.

Figure 68 Cord Blood, Licensure Status Not Known (Partial Label)

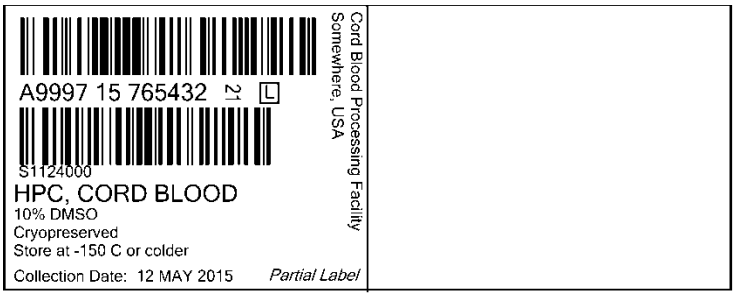
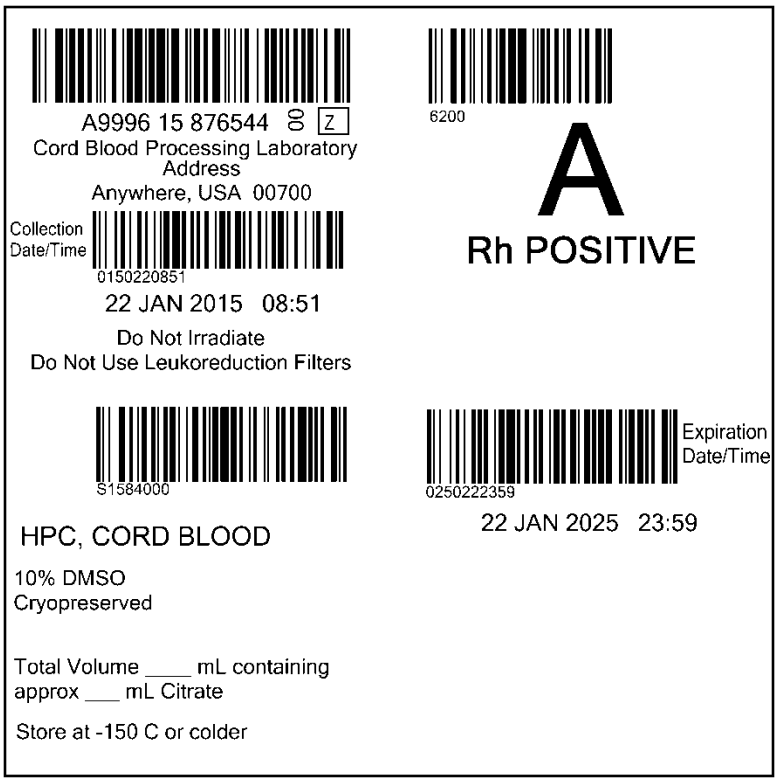
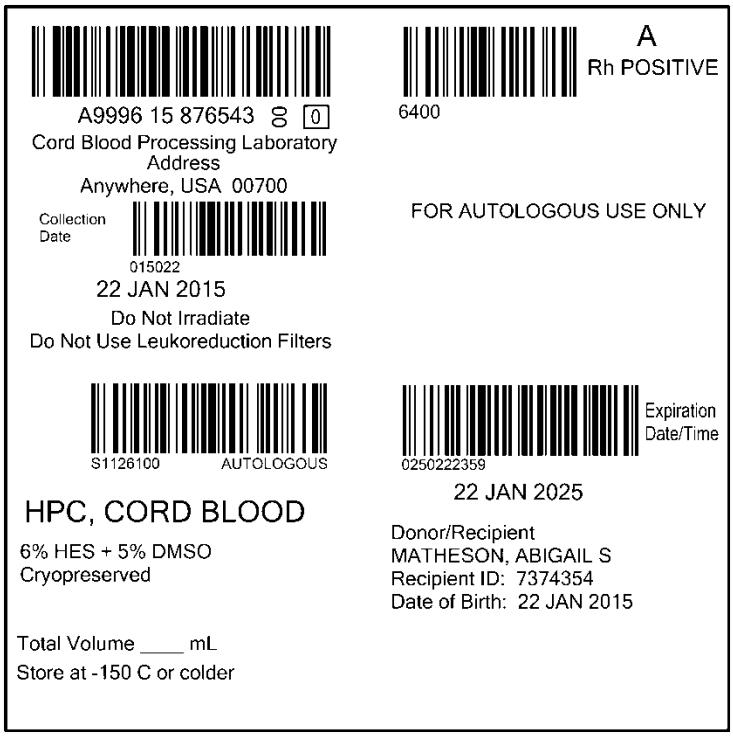


Figure 69 Cord Blood, Licensure Status Not Known (Partial Label)



9.4.4 **Cord Blood Products Neither Licensed Nor IND**

Figure 70 Cord Blood, Neither Licensed nor IND



9.4.5 **Cord Blood Prepared for Administration**

Figure 71 Cord Blood Prepared for Administration (Not IND)

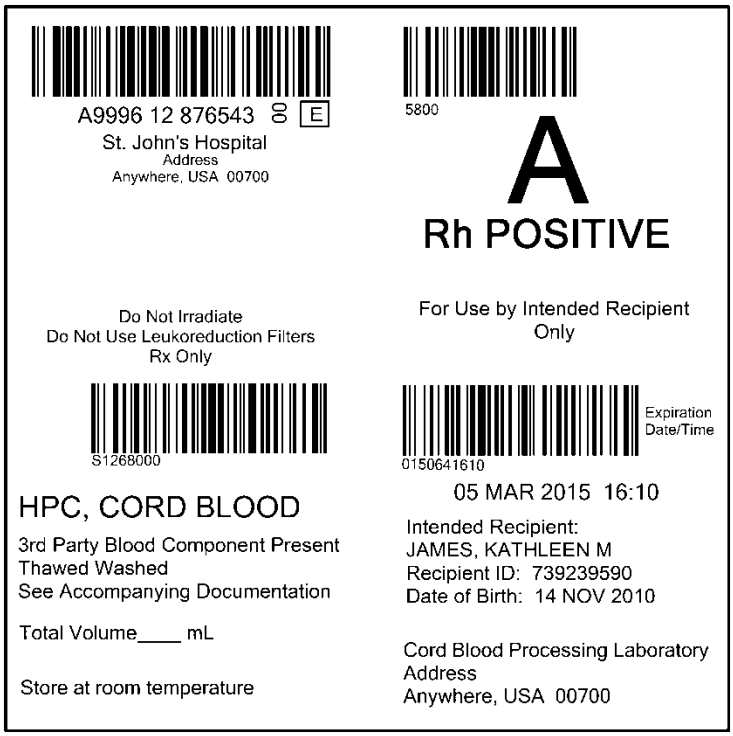
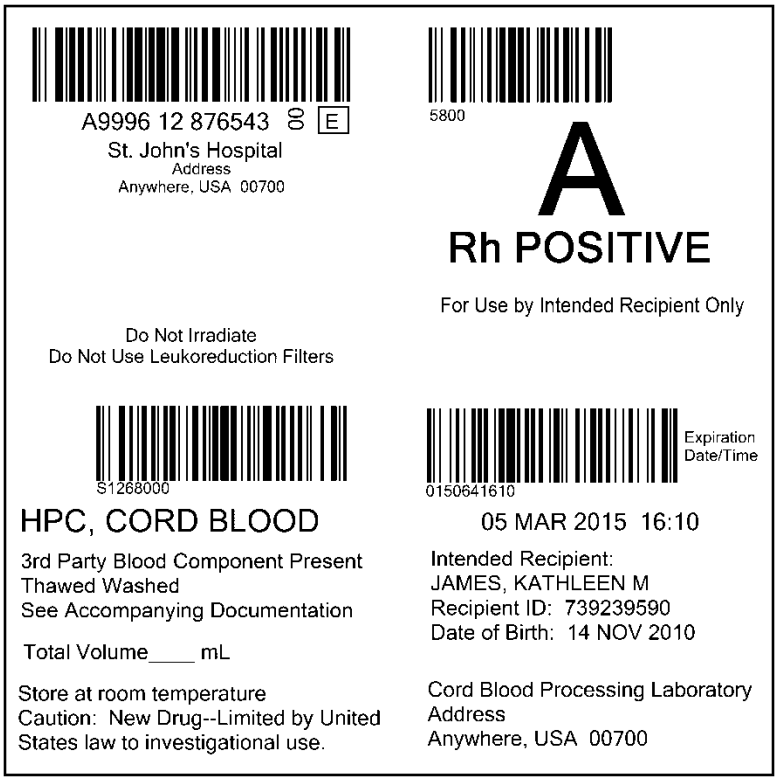


Figure 72 Cord Blood Prepared for Administration (IND)



9.5 MNC, NC, and T Cells Products

9.5.1 Full Label

Figure 73 MNC, APHERESIS Label (Unrelated Donor)

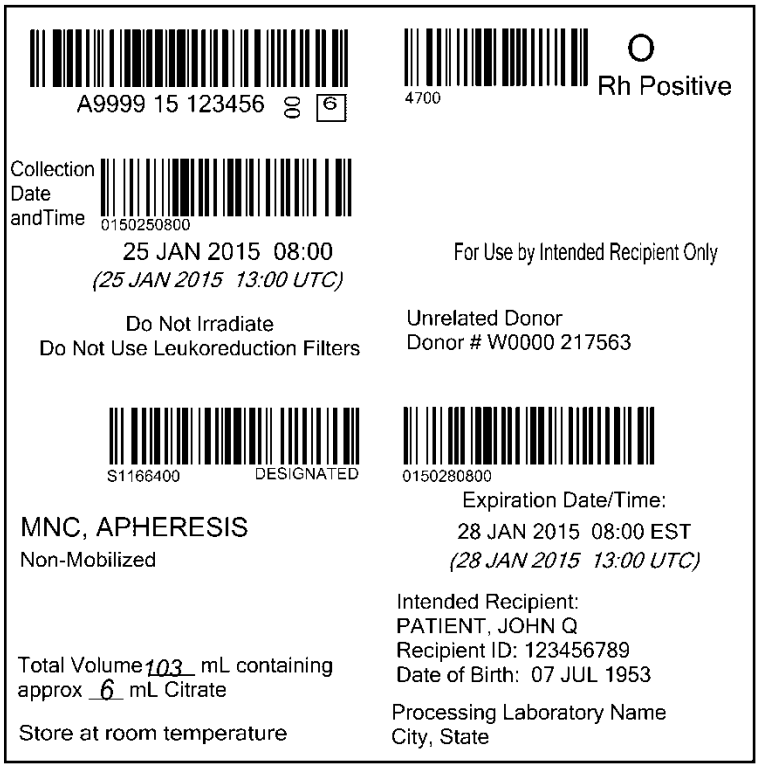
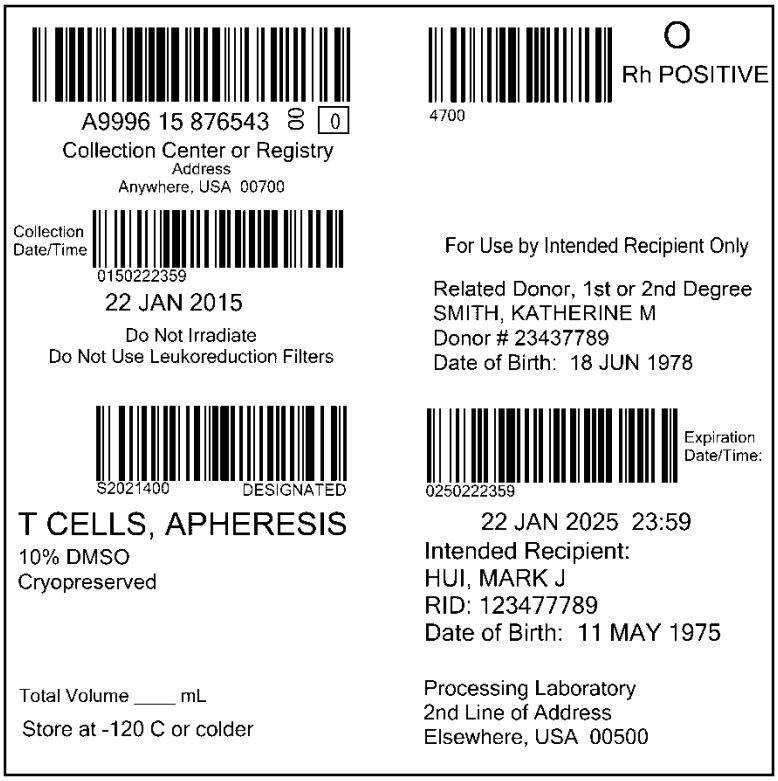


Figure 74 T CELLS, APHERESIS (Designated)



9.5.2 **Partial Label**

Figure 75 T CELLS, APHERESIS (Designated)

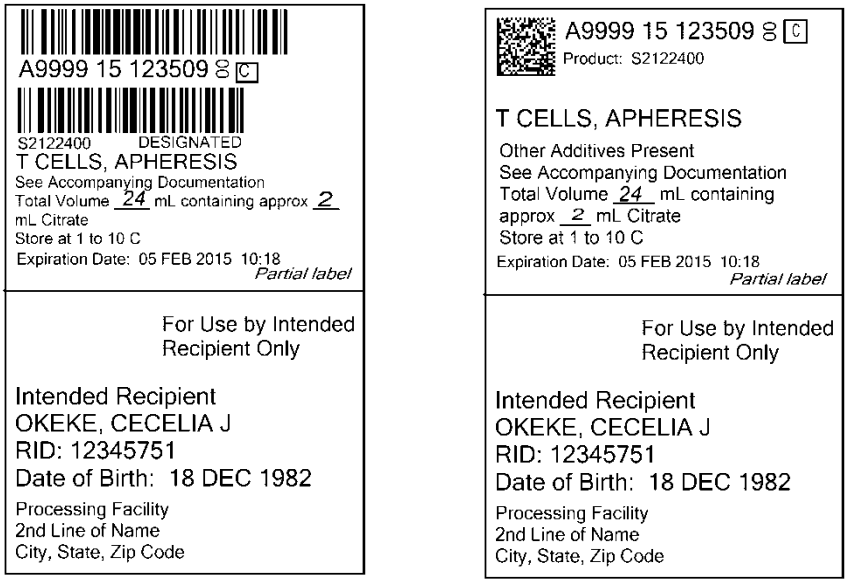


Figure 76 T CELLS, APHERESIS, Vertical Label

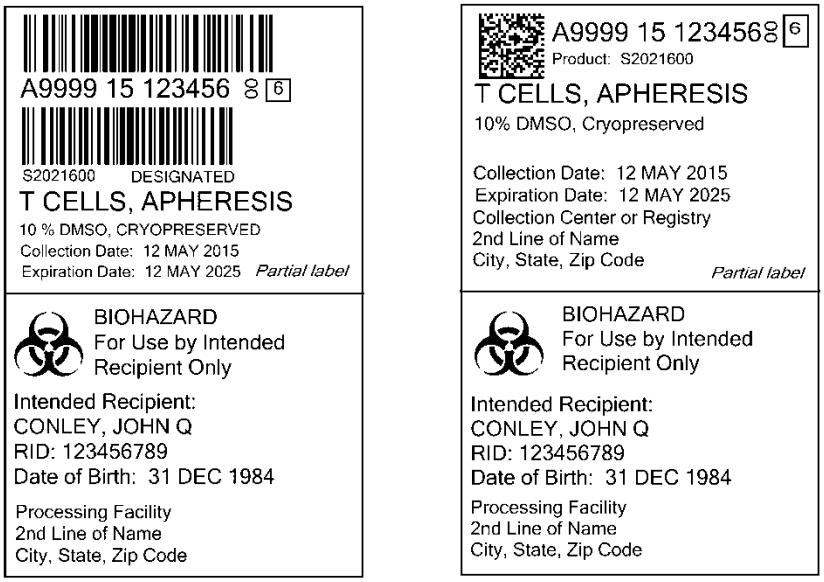


Figure 77 T CELLS, APHERESIS, Cryo Vial

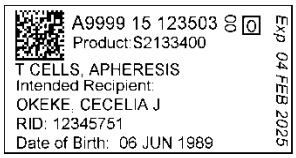


Figure 78 T CELLS, WHOLE BLOOD, Horizontal Label, Linear Symbol

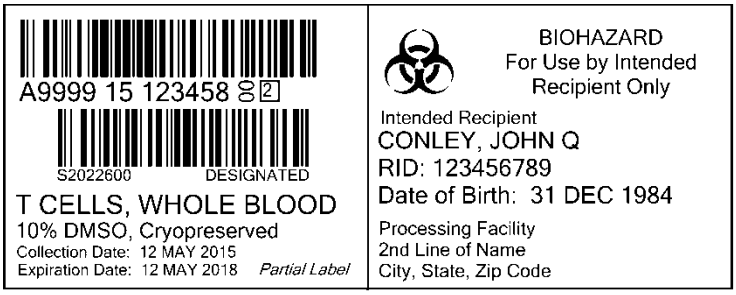
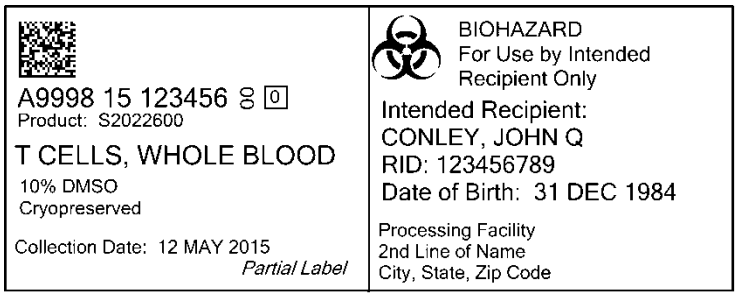


Figure 79 T CELLS, WHOLE BLOOD, Horizontal Label, 2-D



9.6 Products Collected Under Investigational Protocols

The sentence “Caution: New Drug—Limited by United States law to investigational use.” must appear on the label and should be in the LLQ.

Compliance with this guidance document does not ensure labels will meet FDA requirements. Label content and layout for products used under IND must be discussed with the FDA at the time of application review.

9.6.1 Investigational Products

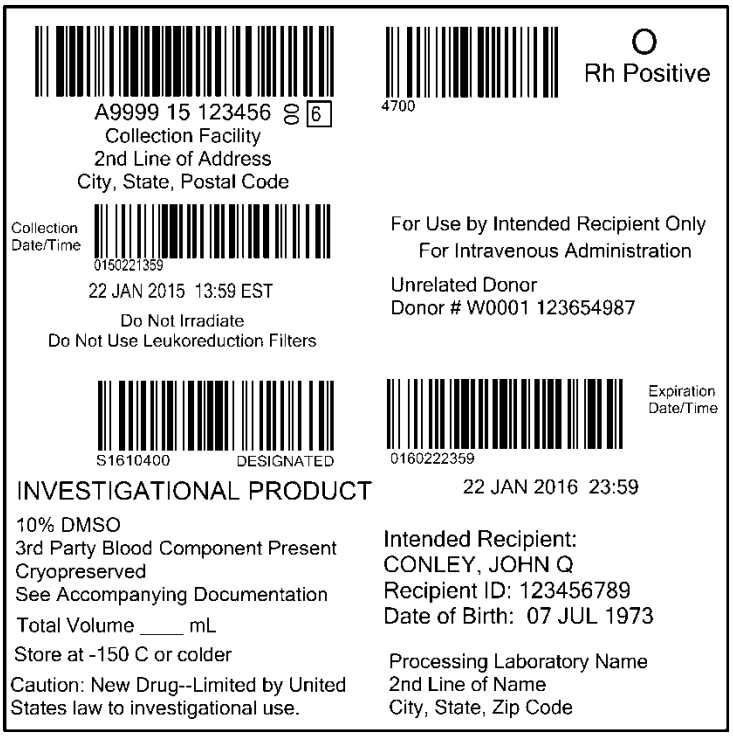
If a suitable class name for an investigational product exists, the product may be labeled using the applicable class name and the “Caution: New Drug…” statement.

When different products are collected for comparison under a blinded investigational protocol, or if the product is collected under an investigational protocol and is not part of a blinded study, products may be labeled with the product class “INVESTIGATIONAL PRODUCT”. In blinded study, the test and control products are labeled identically so facility records must reflect the details of each product.

Note for blinded studies: One arm of the study may involve a placebo, which would be labeled identically to the active product.

Note for non-blinded studies: Throughout the study products labeled as INVESTIGATIONAL PRDOUCT will be the same product, although the dose may vary within a specified range defined by the study.

Figure 80 INVESTIGATIONAL PRODUCT



9.7 **Products Not for Administration**

Products that are collected and not intended for administration should be given the special message code Mr in place of the ABO/Rh. The caution statement: “For Nonclinical Use Only” shall appear and should be in the URQ.

A Product Description Code with the attribute “Not for Admin” should be selected. In the example below, S1439 is MNC, APHERESIS|Citrate/XX/rt|Not for admin|Non-mobilized

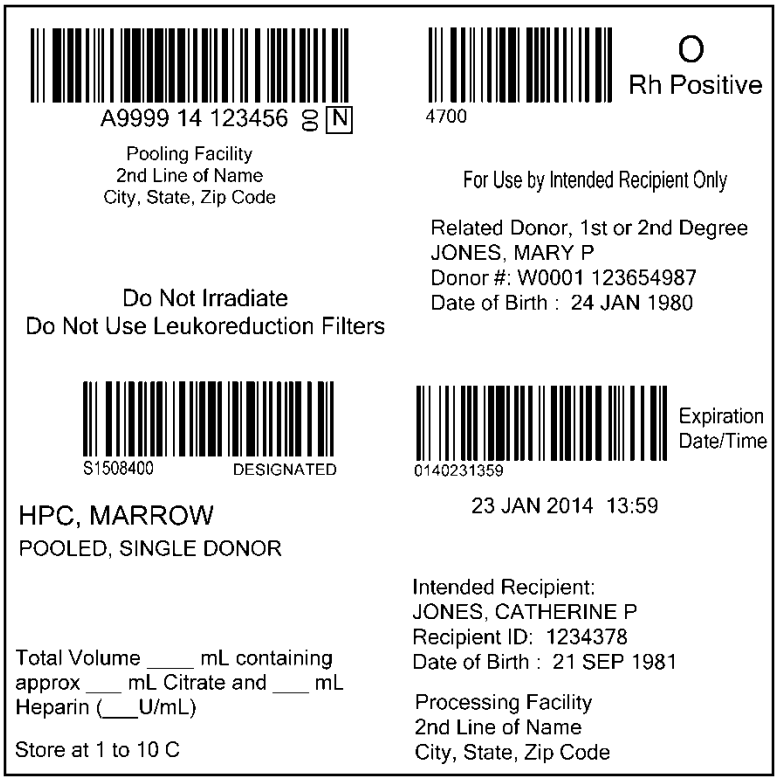
Figure 81 Product Not for Administration

9.8 **Pooled Products**

Pooled products should be assigned a unique DIN. The Facility Identification Number embedded in the unique number should be that of the pooling facility.

If a product is divided after collection, and two or more of the aliquots are subsequently recombined, they should be handled as any other pooled product. That is, they should be given a new unique identification number and a pooled Product Description Code as shown in Figure 82.

Figure 82 Pooled Product Label



9.9 **Cryo Vial Labels**

Figure 83 Cryo Vial Labels (Linear Bar Codes)

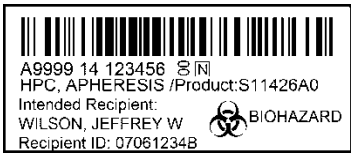
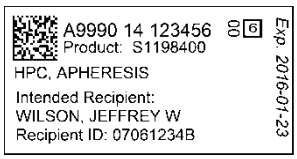
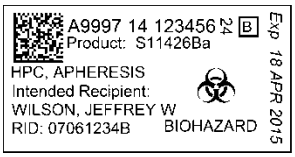


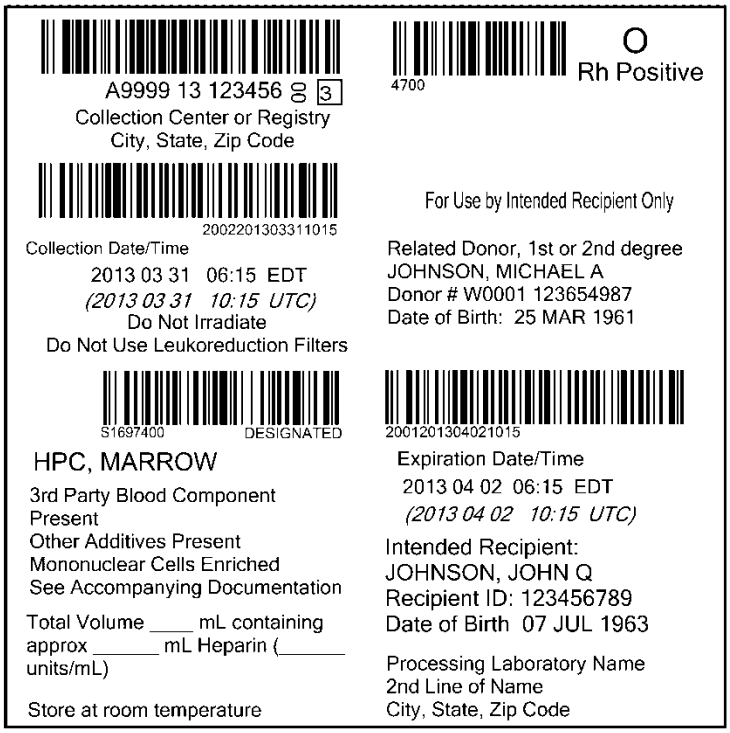
Figure 84 Cryo Vial Labels (2-D Bar Codes)





9.10 **Flexible Date and Time [Data Structure 031]**

Figure 85 Flexible Date and Time Data Structure



Bar codes for the Flexible Date and Time [Data Structure 031] are longer than other date and time bar codes so require some rearrangement of text.

10 Glossary

Bar code	A symbolic representation of a data structure that also includes the symbology-specific start and stop codes. In this document the unqualified use of bar code implies the use of Code 128 symbology with its associated modulo 103 check character.	
	Linear bar code	Single row of bars and spaces. In this document the unqualified use of linear bar code implies the use of Code 128 symbology with its associated modulo 103 check character.
	2-D bar code	Two-dimensional pattern of data cell. In this document the unqualified use of 2D bar code implies the use of Data Matrix.
Check character	A character used to ensure the accuracy of data. The value is calculated based on an algorithm applied to the data. Examples are • the modulo 103 check character internal to Code 128 • the ISO/IEC 7064 modulo 37-2 check character appended to data content text that verifies accurate keyboard entry.	
Concatenation	A method by which two bar codes can be read as if they were a single bar code. Provides a means for checking one bar code against the other to see that both are in place. Useful in labeling process control. ISBT 128 defines specific criteria for concatenation that must be enforced whenever concatenation is implemented. *(Note: ISBT 128 concatenation is a specific enhancement to the Code 128 Specification)*	
Container	The immediate unit, bottle, vial, ampule, tube or other receptacle containing the product as distributed for sale, barter, or exchange [21 CFR 600.3 (bb)].	
Container set	Any combination of containers, tubing, and other items as packaged by the manufacturer, intended for the collection of whole blood, marrow, cord blood, or apheresis products.	
Data characters	The individual ASCII characters that make up the data content.	
Data content	The characters in a data structure that encode the information for which the data structure is named. The data content does not include the data identifiers.	

Data identifier	The first two or three characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined. [The Donation Identification Number is an exception to this rule. *See ISBT 128 Standard Technical Specification* (ST-001).]	
Data structure	Information content comprising the data identifier and data content. When a data structure is represented as a bar code, the term data structure does not include the symbology-specific and always present start and stop codes, the modulo 103 check character, or any specified control characters.	
Dedicated Donation	A collection arranged by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products).	
Designated Donation	A unit collected from a donor called by the collecting facility to provide product (for example, HLA-compatible) to be used by a specific recipient (or for cellular therapy products, possibly a small group of recipients).	
Directed Donation	A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide product to be used by that person.	
Facility	An organization that is responsible for the collection, processing, and/or distribution of ISBT 128-encoded products.	
	Collection Facility	An entity providing the service of cellular therapy product collection. A Collection Facility may be part of the same institution as the Processing Facility and/or Clinical Program or may be part of another institution and perform cellular therapy product collection services through contractual agreement.
	Manufacturer	Any legal person or entity engaged in the manufacture of a product subject to license under the [Public Health Service] act; includes any legal person or entity who is an applicant for a license where the applicant assumes responsibility for compliance with the applicable product and establishment standards. (FDA)
	Processing Facility	A location where cellular therapy product processing activities are performed.

Flag character	Part of the data content of a Data Structure 001 used in process control or data transmission checking. Printed in eye-readable format, but distinguished in some manner from the representation of the other data characters.	
ISBT 128	An international standard for the transfer of information associated with medical products of human origin. It provides for a globally unique donation numbering system, internationally standardized product definitions, and standard data structures for bar coding and electronic data interchange.	
Julian Date	See ordinal date.	
Label	An independent entity that may carry one or more bar codes and also provides eye-readable information about the product.	
	Affixed	Information that adheres in physical contact with the cellular therapy product container.
	Attached	A label that is securely fastened to the product by means of a string or equivalent alternative. Any information required to be attached to a cellular therapy product container may alternatively be affixed.
	Accompanying	Documentation that goes with the product and is available to the appropriate individual(s), but not affixed or attached. For label text, this term is used when the documentation is either attached or accompanying the product.
	Base	The label placed on a container by a manufacturer. It carries the manufacturer's identity, the catalog number of the container (or container set), and the lot number of the container (or container set) encoded as ISBT 128 data structures.
	Container	Label affixed to the container (see definition of container)

	Final	Labeling as it appears on a product ready for release to another entity or for administration to a recipient. (A different entity in this context means an institution with different ownership/leadership than the facility that labeled the product.)
	Package	Labeling associated with the product package (see definition of package)
	Partial	The minimum essential elements that must be affixed to all cellular therapy product containers at all times.
	Product	Labeling applied to a product at various stages of processing by cellular therapy facilities
Manufacturing	Any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor [taken from the definition of "manufacture" found in 21 CFR 1271.3 (e).	
Ordinal Date	A system for maintaining dates that numbers the first day of the year (January 1) as 1 and the last (December 31) as 365 or 366 (in a leap year). Also known as Julian Date.	
Package	Immediate carton, receptacle, or wrapper, including all labeling matter therein and thereon, and the contents of the one or more enclosed containers. If no package, as defined in the preceding sentence is used, the container shall be deemed to be the package. [21 CFR 600.3 (cc)]	
Text	See 5.7 for an illustration of terms used to describe text.	
	Data content text	The eye-readable representation of the data characters in a bar code (printed left justified immediately below the bar code, unless otherwise specified).
	Bar code text	The interpretation of the data content text (the data content of the bar code).
	Additional label text	All other information on the label that is not associated with a bar code.
UTC	Coordinated Universal Time, similar to GMT (Greenwich Mean Time), marks the starting point of every time zone in the World. UTC does not change based on daylight saving (summer) time; thus, the relationship of local time to UTC changes if daylight saving (summer) time is observed.	

11 Abbreviations

Table 24 Abbreviations Used in This Document

Abbreviation	Definition
AHCTA	Alliance for Harmonization of Cellular Therapy Accreditation
2-D	Two-dimensional
CFR	Code of Federal Regulations
CMV	Cytomegalovirus
CTCLAG	Cellular Therapy Coding and Labeling Advisory Group
DIN	Donation Identification Number
DMSO	Dimethylsulfoxide
EBV	Epstein-Barr Virus
EDI	Electronic Data Interchange
FACT	Foundation for the Accreditation of Cellular Therapy
FDA	Food and Drug Administration
FIN	Facility Identification Number
HBc	Hepatitis B Core
HCV	Hepatitis C Virus
HES	Hydroxyethyl Starch
HIV	Human Immunodeficiency Virus
HTLV	Human T-cell Lymphotropic Virus
ICCBBA	Formerly known as the International Council for Commonality in Blood Banking Automation
IEC	International Electrotechnical Commission
IND	Investigational New Drug
ISBT	International Society of Blood Transfusion
ISO	International Organization for Standardization

Abbreviation	Definition
LLQ	Lower Left Quadrant
LRQ	Lower Right Quadrant
mL	Milliliter
mm	Millimeter
NDC	National Drug Code
NMDP	National Marrow Donor Program
RFID	Radio Frequency Identification
WMDA	World Marrow Donor Association
WNV	West Nile Virus
ULQ	Upper Left Quadrant
URQ	Upper Right Quadrant
UTC	Coordinated Universal Time

Table 25 Acceptable Abbreviations for Labeling Products

Abbreviation	Definition
#	Number
Alb	Albumin
Approx	Approximately
C	Degree(s) Celsius (Centigrade)
DMSO	Dimethylsulfoxide
FDA	US Food and Drug Administration
Exp	Expiration Date
g	Gram(s)
h	Hour(s)
HES	Hydroxyethyl Starch
HSA	Human Serum Albumin
Int	Intended (in context of Intended Recipient)
mg	Milligram(s)
mL	Milliliter(s)
PUV	Psoralen/ultra violet light
Recipient ID	Recipient Identification Number
RID	Recipient Identification Number
room temp	Room temperature
U	Units

Should additional abbreviations be needed for labels, user should contact the ICCBBA office (tech.director@iccbba.org).

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