United States Consensus Standard for the Uniform Labeling of Cellular Therapy Products using *ISBT 128*

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1 Introduction

ISBT 128 is an international information standard for blood, tissue, and cellular therapy products. A balance exists between what information on a product label must be strictly standardized in order to achieve the goals of an international standard and what may be left to the discretion of national authorities. These elements are defined in the *ISBT 128 Standard Technical Specification.*

Essentially, the definition of data structures and the placement of bar codes, and their corresponding eye readable text (the text version of the data content of the bar code) that appears immediately beneath a bar code, are strictly standardized. These label elements must appear exactly as specified in the *ISBT 128 Standard Technical Specification*. Bar code text (the interpretation of the information in the bar code) and other text are generally left to national authorities to define in order to accommodate different languages and regulatory requirements. Additionally, the use of some data structures (e.g., collection date) are nationally defined.

The United States Consensus Standard for the Uniform Labeling of Cellular Therapy Products Using ISBT 128 defines for the United States the areas that are the prerogative of national authorities. It must be used in conjunction with the *ISBT 128 Standard Technical Specification* to design labels for cellular therapy products. Every effort has been made to ensure label designs suggested in this document are in compliance with AABB, FACT, NMDP, and FDA requirements. However, cellular therapy is very much an evolving field and requirements are still being developed. This document will be updated regularly to ensure compliance with new requirements. It is important to note that applicable FDA regulations take precedence over any requirements in this document. For newer products, it would be advisable to confirm labeling requirements with the FDA during the product development process.

1.1 Unresolved Issue

At the time of releasing this document, the mechanism(s) for maintaining the confidentiality of the collection facility for products shipped through a Registry has not been determined. At a minimum, the name of the collection facility will not appear in text on the label. Various options to further increase confidentiality are still being explored by the Cellular Therapy Coding and Labeling Advisory Group. When a decision is reached about the labeling of these products, the information will be shared immediately.

1.2 Requesting an Exemption or Alternative to an FDA Requirement

In some instances, a facility may request an exemption from, or alternative to, an FDA requirement discussed in subpart C or D of 21 CFR 1271 and as illustrated in this document. This might be relevant, for example, in the case where the inclusion of the donor name, when the donor is not a first- or second-degree blood relative, is felt to add a measure of safety for the recipient to prevent mix-ups or improper release. Such a request to the FDA would have to be accompanied by supporting information including a description of the proposed alternative

method of meeting the regulatory requirements. The regulations for requesting such an exemption are found in Sec. 1271.155.

US Consensus Standard for Uniform Labeling of Cellular Therapy Products using *ISBT 128* Version Control

	Chapter, Section or Table in Version 1.0.0	Chapter, Section or Table in Version 1.1.0	Change	Rationale
1	8.4.1, Table 4	8.4.1, Table 4	Added intended recipient information to requirements for partial label	FACT requirement

2 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 to review and expand the standard. CTCLAG included representatives from the following organizations: AABB, 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), ISCT Europe, 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* and published it in July 2007 (Ashford P, Distler P, et. al. Standards for the terminology and labeling of cellular therapy products. Transfusion 2007;47:1319-1327).

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, and NMDP. Again, FDA provided a liaison. A variety of interested vendors also participated in these discussions. The output of that work is this document.

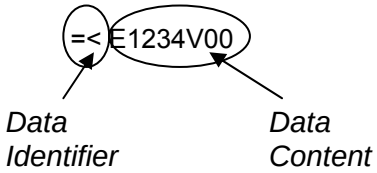
3 *ISBT 128* Data Structures

In order for information about cellular therapy products to be transferred electronically (via bar codes, two-dimensional symbols, radio frequency tags, etc.), the information must first be coded into a format that makes electronic transfer easy. Data structures are 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. Examples of data structures which encode information that does not appear on the label include Staff Member Identification Number and Patient Identification Number. Consult the *ISBT 128 Standard Technical Specification* for a complete list of data structures.

Each data structure consists of data identifiers and data content (see Figure 1, Page 13) and is very precisely defined in terms of its length and permissible characters.

Figure 1 Data Structure



3.1 *ISBT 128* Data Identifiers

Each data structure begins with two characters, the data identifier. Data identifiers define the type of information the bar code contains.

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

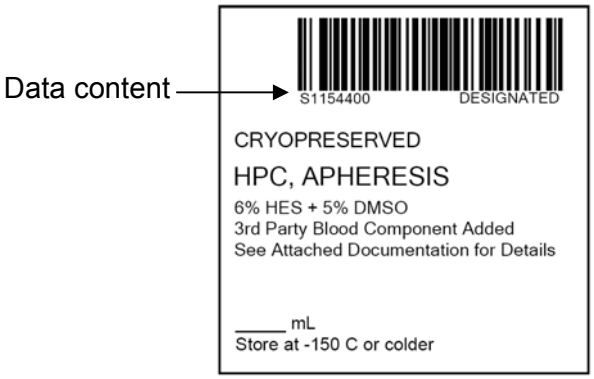
The second character distinguishes the type of *ISBT 128* information to be conveyed. For example, the two characters "=%" at the beginning of a data structure indicate that the bar code carries information about the ABO/Rh Blood Groups whereas "=<" means the bar code carries information about the product code. Consult the *ISBT 128 Standard Technical Specification* for more information.

3.2 Data Content

Data content is the information to be conveyed. For example, the information to be communicated is that the product is A Rh Positive. This information is encoded to allow it to be efficiently transferred electronically. For example, A Rh Positive is encoded as 6200. Internationally agreed upon reference tables are used to encode and decode information. Some of these reference tables are found in the *ISBT 128 Standard Technical Specification*; 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

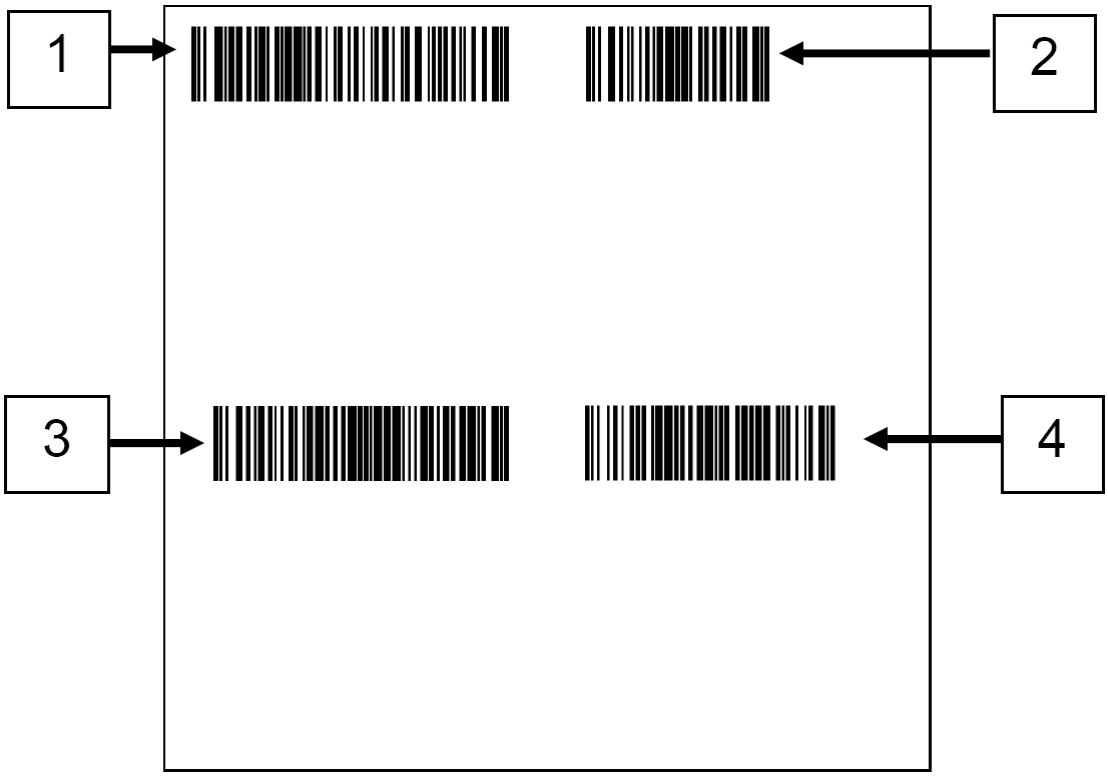


Data characters are the individual ASCII characters that make up the data content.

4 Concatenation

Concatenation is the scanning of two bar codes as a single message (see *ISBT 128 Standard Technical Specification* 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 the ABO/Rh; and the Product Code and the Expiration Date (see Figure 3).

Figure 3 Label Showing Placement of Bar Codes for Concatenation



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

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 a function of another. For example, the expiration date is a function of the product code. In this situation, concatenation 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 parentheses.

- 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 Birth Date (024) and Patient Hospital Identification Number (025)

It is possible to concatenate other pairs of *ISBT 128* bar codes and these can be specified within some scanner systems (see Technical Bulletin 5 found on the ICCBBA Website at www.iccbba.org).

5 Delivery Systems

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

Rules for uses of *ISBT 128* data structures will depend on the delivery mechanism.

5.1 Linear bar codes (Code 128 required)

Code 128 is the only linear bar code format approved for *ISBT 128*. The code must comply with the industry standard ISO/IEC 15417: 2007(E): 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*.

5.2 Two-dimensional bar codes (Data Matrix Recommended)

Two-dimensional (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

While many 2-D symbologies are available, ICCBBA recommends Data Matrix (ECC 200) as the 2-D symbology for *ISBT 128*. The ISO/IEC 16022 Information technology—International symbology specification—Data Matrix should be followed.

This does not preclude the use of other symbologies. Use must comply with the appropriate industry standard. Implementers wishing to use other symbologies or novel technologies should contact ICCBBA for advice before proceeding.

5.3 RFID

ICCBBA has not as yet specified additional requirements for using RFID technologies, but these will be required in order to provide an adequate level of standardization. The ISBT Working Party on Information Technology is currently evaluating issues related to the application of RFID to transfusion medicine. 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.

5.4 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.

6 *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.

6.1 Donation Identification Number (Data Structure 001)

This data structure provides for the unique identification of any donation or collection worldwide for a one hundred year period. It has 13 data characters:

αppppyynnnnnn

where:

αpppp	designates the collection facility or registry. In the case of cord blood collections where the processing laboratory is administratively responsible for the collection, this number may reflect the processing laboratory;
yy	designates the year in which the donation or collection was made;
nnnnnn	is a serial number associated with the donation or collection.

Other characters incorporated into this bar code are “flag” characters. These 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 printed in a way that identifies their special role, either rotated 90 degrees clockwise (i.e., vertically rather than horizontally) or in “pictorial” or “iconized” format. Flag characters are the last two characters of the Donation Identification Number data structure. They are not part of the Donation Identification Number itself. Flag characters are to be used in process control; it is not intended that they be recorded as part of the Donation Identification Number.

An additional check character (not the same character that is integral to every Code 128 bar code) calculated on the entire 13 data characters (αppppyynnnnnn) will be printed, enclosed in a box, to the right of the Donation Identification Number (DIN) (see Figure 12, page 50). The ISO modulo 37,2 method will be 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.

6.1.1 US Specification

Usage: The Donation Identification Number is required to be both machine and eye readable.

6.1.1.1 Applying the DIN

Usually, the Donation Identification Number should be the first label applied to product containers. It is applied before a product is collected and should not afterwards be removed or defaced. To prevent potential errors, it is recommended that the Donation Identification Number 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 must be in place to ensure that the DIN on the new label matches the DIN on the original label.

6.1.1.2 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. 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.

Registry Collections: In some countries, the DIN may be assigned by the Registry for collections being shipped through the Registry. In this case, the FIN and the text beneath it will correspond to the Registry. The final decision on who (facility or the Registry) will assign the DIN in the US has not been made. When the decision is made, a new version of this document will be published

6.1.1.3 Data Characters

In the US the data characters should appear as follows:

W0000 08 123456

The Donation Identification Number is divided into three parts in its eye-readable form for ease in reading. This should facilitate reading, checking, and recording identification numbers.

No special emphasis (e.g., font, size, or color) should be given to any character(s) within the 13-character DIN.

6.1.1.4 Flag Characters

Flag characters may be used in the US as detailed in the *ISBT 128 Standard Technical Specification*. The default or null value, 00, should always be present as part of the Donation Identification Number bar code if other flags are not used. On product containers, the flag characters are printed rotated clockwise ninety degrees. Graphical icons can be printed on other materials used in the collection process (test tubes, donor registration form, etc.) if desired. Suggestions for how these flag characters may be used are found in Section 7.1, page 43.

The flag characters will be read by the bar code scanner and interpreted by the host computer software in collecting and/or processing facilities. Outside of the collection and/or processing facility, the flag characters may not be meaningful.

6.1.1.5 Keyboard Entry Check

Although keyboard entry of the Donation Identification Number 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 Donation Identification Number 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*.

6.1.1.6 Avoiding Label Waste

Preprinted Donation Identification Numbers may be used over a fourteen month period to cut down on waste. For example, labels bearing the year "09" may be used from December 1, 2008 through January 31, 2010. It is expected that collection/processing centers or registries will attempt to be careful in their label orders so that this permissive practice is used to the minimum extent necessary. Obviously, the collection facility should have 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 Donation Identification Number every 100 years. It does not in any way replace the collection or expiration date on the label.

6.1.1.7 Pooled Products

Pooled products should be assigned a unique Identification Number in the same format as the Donation Identification Number. See Figure 40, page 75. 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 should reflect the identification numbers of the various units within the pooled product.

6.2 ABO/Rh (Data Structure 002)

This data structure has four data characters:

ggre

where:

gg designates the ABO and Rh blood groups and certain other information (*see* below);

r specifies Rh and Kell or GP-Mur (Miltenberger III) phenotype information (*see* the *ISBT 128 Standard: Technical Specification*);

e is reserved for future use.

The ABO and Rh status of the product (e.g., A Rh positive, O Rh positive, O Rh negative) is defined by the first two (gg) of the four data characters of this bar code. In addition, the type of donation or collection (e.g., autologous, designated) may be encoded with these characters.

Alternatively, these characters (gg) may be used to encode a special message, such as For Research Use Only (see Table 2, page 26).

6.2.1 US Specification

Usage: The ABO/Rh is not required on the label.

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

Type of donation or collection should be specified in this bar code in accordance with Table 1, page 25.

For units with no intended recipient (e.g., public cord blood donations), if ABO/Rh is present on the label, the text should be printed as follows:

	ABO text	Rh text
Rh Positive	Solid black	Black on white
Rh Negative	Outline black	White on black

See illustrations in Section 8.3.3, page 55.

The ABO/Rh 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 Rh negative products.

6.2.1.1 Type of Donation or Collection/Intended Use

In the US, information about the type of donation or collection/intended use (*e.g.*, Autologous or Designated Collection) is to be included in the ABO/Rh Blood Groups bar code any time the product is to be used for a specific recipient.

If the product is intended for a specific recipient, values for “gg” should be used as shown on Table 1. The ABO/Rh label should look very different from the “normal” appearance (*see* illustrations in Section 8.3.3.1, beginning on page 55).

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

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

ABO and RhD Blood Groups	**Default: Intended Use Not Specified (n)**	**Directed (Dedicated/ Designated) Collection Use Only (n-4)**	**For Emergency Use Only (n-3)**	**Directed (Dedicated/ Designated) Collection/ Biohazardous (n-2)**	**For Autologous Use Only (n+2)**	**For Autologous Use Only/ Biohazardous (n+3)**
O RhD negative	95	91	92	93	97	98
O RhD positive	51	47	48	49	53	54
A RhD negative	06	02	03	04	08	09
A RhD positive	62	58	59	60	64	65
B RhD negative	17	13	14	15	19	20
B RhD Positive	73	69	70	71	75	76
AB RhD negative	28	24	25	26	30	31
AB RhD positive	84	80	81	82	86	87
O	55	P2	P3	P4	P8	P9
A	66	A2	A3	A4	A8	A9
B	77	B2	B3	B4	B8	B9
AB	88	C2	C3	C4	C8	C9
para-Bombay, RhD negative	D6	D2	D3	D4	D8	D9
para-Bombay. RhD positive	E6	E2	E3	E4	E8	E9
Bombay, RhD negative	G6	G2	G3	G4	G8	G9
Bombay, RhD positive	H6	H2	H3	H4	H8	H9

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

6.3 Product code (Data Structure 003)

The product code data structure has 8 data characters:

αooootds.

where:

αoooo specifies the Product Description Code and is encoded and interpreted by reference to the Product Description Code database table published and maintained by ICCBBA in the Registered User Area of the ICCBBA Website.

t depends on the value of α (see below)

ds provides information about divisions of the cellular therapy product

α currently indicates the following product groups:

- E or F – blood components;
- S – cellular therapy products;
- T – tissues;
- X – derivatives; and
- A-D – national or local codes (see 6.3.1, page 28)

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

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

t specifies the type of donation and is encoded and interpreted by reference to Table 11, page 69.

ds provides information as to 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).

d will encode the first division. First level divisions (up to 26) of the primary collection will be encoded using capital letters.

s will encode the second division. Second level subdivisions (up to 26) will be encoded using lower-case letters.

Third level subdivisions (and beyond) are not coded.

For examples of use, see Section 7.2, page 44.

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

For interpretation of tds for other values of α, see the *ISBT 128 Standard Technical Specification*.

6.3.1 A-D National or Local Codes

The block of product description codes, A0000-D9999, has been reserved for use as nationally or facility defined product codes. There will 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. 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 elect to reserve a range of these values for national assignment. Where this is done it is 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, it is the responsibility of the facility to 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 will have to 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 must be retained permanently for traceability purposes. Once assigned, codes should not be reused.

6.3.2 US Specification

Usage: A product description must appear in text on the product. The bar code should appear if space permits.

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 product coding system for cellular therapy was changed in 2007 (see *Cellular Therapy Product Coding Transition* found on the ICCBBA Website). Codes S0001-S1121 should not be assigned to new products. These codes are retained only in the database for backward compatibility.

6.4 Expiration Date and Time(Data Structure 005)

Expiration date and time are not required to be machine readable. If they are machine-readable, Data Structure 005 must be used. This data structure has 10 data characters:

cyyjjjhhmm

where:

c	designates the century (*e.g.*, 0 for 2000; 1 for 2100);
yy	designates the year of expiration;
jjj	is the Julian date (the number of the day in the year, *e.g.*, 022 is 22 JAN);
hh	specifies the hour (00–23);
mm	specifies the minutes (00–59).

Recognizing that there are national differences in how dates are printed, a single format for expressing the expiration date in eye-readable form, that is, 21 JUL 2006 (DD MMM YYYY — month in alpha characters, abbreviated) must be used. Time should be expressed based on a 24-hour clock with a colon between hour and minutes (HH:MM).

If the product has an expiration time and is to be shipped internationally across time zones, the expiration date and time should also be provided in Greenwich Mean Time (GMT). When this is provided, it must be printed beneath the local time in parenthesis with the designation “GMT”. Italics may also be used to clearly differentiate GMT from local time. For example:

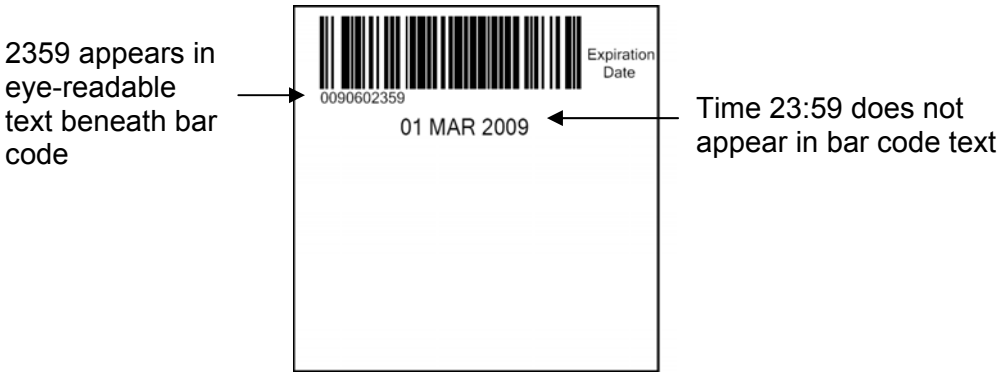
Expiration Date/Time
15 JAN 2008 15:15
(15 JAN 2008 20:15 GMT)

6.4.1 US Specification

Usage: Not all Cellular therapy products have an expiration date. If a product has an expiration date (and time), it must appear on the affixed label for 361 products. For 351 products, it should appear when space allows. This information does not have 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.)

If the expiration time is the default time of midnight, 2359 is encoded into the bar code. The eye-readable text immediately beneath the bar code should also indicate 2359. However, the bar code text should not give a time. See Figure 5 for an example. (Terminology for text is explained in the glossary, Figure 52.)

Figure 5 Text When Expiration is Default Time of 23:59



6.5 Collection Date (and Time) (Data Structures 006 and 007)

Collection date (and time) is(are) not required to be machine readable. If this information is machine readable, one of two data structures may be used.

Where time is not critical, Data Structure 006 may be used. This data structure has 6 data characters.

cyyjjj

where:

c	is the century of the year in which the product was collected;
yy	is the year within the century in which the product was collected;
jjj	is the Julian day of the year on which the product was collected

If time is important, Data Structure 007 should be used. This data structure has 10 characters.

cyyjjjhhmm

where:

c	is the century of the year in which the product was collected;
yy	is the year within the century in which the product was collected;
jjj	is the Julian day of the year on which the product was collected
hh	is the hour at which the product was collected (00 to 23);
mm	is 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.

Collection date (and time) is (are) not required to be on the affixed label by the *ISBT 128* Standard. However, this may be mandated by regulations or other standards in some countries. Even when mandated as label text, this information does not have 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.)

If the product has a collection time and is to be shipped internationally across time zones, the collection date and time should also be provided in Greenwich Mean Time (GMT). When this is provided, it must be printed beneath the local time in parenthesis with the designation “GMT”. Italics may also be used to clearly differentiate GMT from local time. For example:

Collection Date/Time
15 JAN 2008 15:15
(15 JAN 2008 20:15 GMT)

6.5.1 US Specification

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

6.6 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 an *ISBT 128* number is used and it is to be machine readable, Data Structure 019 should be used. This data structure has 21 data characters.

αppppvvvvvvvvvvvvvvv

where:

αpppp	specifies 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 Registered User Area of the ICCBBA Website.
vvvvvvvvvvvvvvv	is a facility- assigned or nationally-assigned donor identification number. 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).

6.6.1 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 (collection or processing) that assigns the number.

6.7 Manufacturer's Information Data Structures

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

6.7.1 Container Manufacturer and Catalog Number (Data Structure 017)

The data structure has 10 data characters.

bqqwwwwwww

where:

b — is 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 are used. 1 is reserved for the primary collection container;
- For apheresis collection sets A-Z are used.
- For transfer container/sets, 0 (zero) is 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 is reserved for the primary bag of a whole blood collection set.)

qq — specifies the identity of the container set manufacturer and is encoded and interpreted from the Manufacturer Identifier Codes table [RT018] that can be found in the *ISBT 128 Standard Technical Specification*.

wwwwwww — is 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 Manufacturer's Data file (*see ISBT 128 Standard Technical Specification*), 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, the anticoagulant/preservative, and the intended nominal collection volume.

6.7.2 Container Lot Number (Data Structure 018)

The data structure has 10 data characters

xxxxxxxxxx

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 should 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 must 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).

6.8 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 may be made machine readable if two dimensional (2-D), RFID, or other high density technologies are used.

In order to encode multiple data structures into a single symbol or RFID tag, the Compound Message Data Structure (023) is used.

This is a variable length data structure.

aabbb

where:

aa is the number of *ISBT 128* data structures that follow;

bbb is either:

- all zeros – indicating this is an undefined message, i.e. only the number of data structures is identified, but not what each one is;
- a three digit number referencing an entry in an ICCBBA maintained table that defines the content of this structured compound message.

Rules for constructing compound messages:

1. A compound message will comprise a string of *ISBT 128* data structures (excluding nationally defined structures), beginning with the Compound Message (CM) data structure (Data Structure 023);
2. Data structures will be combined sequentially with no intervening characters, and each will begin with its data identifier characters;
3. The string shall only contain *ISBT 128* data structures;
4. The number of data structures following the CM data structure will be indicated in element aa of the CM data structure
5. If an ICCBBA structured compound message format is used, the reference number of the structure shall be included in element bbb of the CM data structure;
6. If the message is not defined, the CM data structure will have element bbb set to zeros, but element aa will be set as specified in rule 4.

ICCBBA structured compound messages are defined in a table in the *ISBT 128 Standard Technical Specification* called:

Structured Compound Messages [RT017]

The reference table has been established with a small number of entries. Additional entries will be made on request to the ICCBBA office and with the approval of the Editorial Board.

See Section 7.3, page 45 for examples of the use.

6.8.1 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.

6.9 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 paperwork 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 10 data characters.

aayyyymmdd

where:

aa is a location code identifying where this occurrence of the information is held. For acceptable values see Table 3, page 39.

yyyy is the year of birth.

mm is the month of birth.

dd is the day of birth.

6.9.1 US Specification

Usage: The use of this data structure is optional.

6.10 Patient Identification Number (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 paperwork associated with the collection. 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:

aa	is a location code identifying where this occurrence of the information is held. For acceptable values, see Table 3 page 39.
ll	is the length of the following patient number field;
xx…xx	is the patient (recipient) 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.

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)
08-79	Reserved
80-99	For local or national use

6.10.1 US Specification

Usage: The use of this data structure is optional.

6.11 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 infectious marker structure has 18 data characters

nnnnnnnnnnnnnnnnnn

where

nnnnnnnnnnnnnnnnnn is a string of digits, each of which identifies the result status of a pair of markers as indicated in *ISBT 128 Standard Technical Specification*. 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.

Currently only values in the first eight positions have been defined and so positions 9-18 should always be set to a value of 0. For each marker there are three possible outcomes:

pos Reactive for specified marker in screening process

neg Specific marker not detected in screening process

na Information not available

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

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

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.

6.11.1 US Specification

Usage: The use of this data structure is optional.

6.12 Data Structures Defined for National or Regional Use

Data structures that fit in the *ISBT 128* model, but are not internationally defined, may be desirable nationally (or regionally). To support such data structures, the data identifiers &a through &z have been reserved.

There should be a national consensus regarding which data identifiers should be reserved for national use and which, if any, should be allowed for regional use.

Because the same codes can be assigned by multiple facilities and have different meanings, it is important that software only interpret these data structures within the context of the Facility Identification Numbers (FINs) that assigned them.

Non-ICCBBA defined data structures are not suitable for use in Compound Messages.

See the *ISBT 128 Standard Technical Specification* for details on how to use these data structures.

7 Examples of Data Structure Information Use

7.1 Use Of Flag Characters (Data Structure 001)

The *ISBT 128 Standard Technical Specification* includes a table giving the meaning of various flag characters that may be used in conjunction with the Donation Identification Number (Data Structure 001). Some of these values (00 through 19 and 97 through 99) have either been assigned by ICCBBA or are reserved for future assignment. Others (20-59) have been reserved for use by each local facility. The third group of numbers (60-96) have been set aside for use as check characters.

One unique use of local flag characters in cellular therapy facilities has been to differentiate between mother and infant samples for a cord blood collection. For example, both mother and infant samples have the same Donation Identification Number, e.g., W0000 08 123456, but the flag characters will vary depending on the source of the sample.

Samples from the mother may be labeled:

Samples from the infant may be labeled:

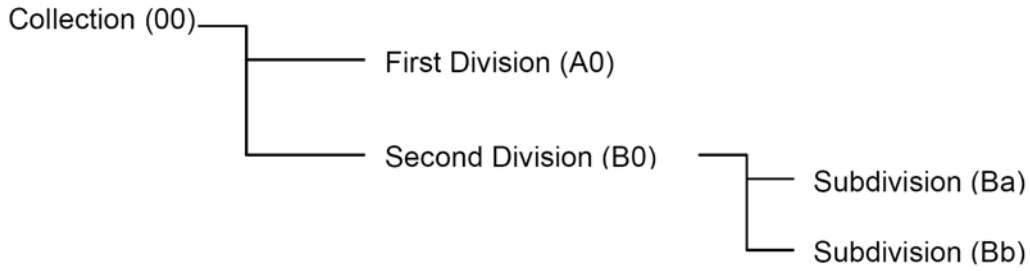
Further, the eye readable flag characters can be converted into icons.

7.2 Use of Division Codes (Data Structure 003)

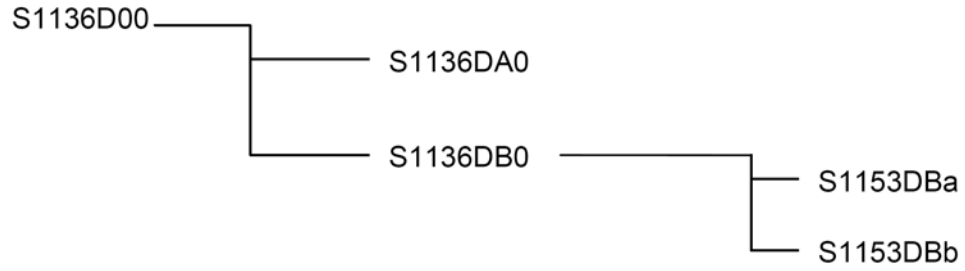
In 2007, coding of multiple cellular therapy products from a single collection became standardized. All such divisions should be encoded using the seventh and eighth characters of the Product Code Data Structure (Data Structure 003).

As a specific example of this scheme in practice, 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 B0 portion is divided again later that day for freezing in separate aliquots, which become Ba and Bb.

Figure 6 Product Division Coding



Or, using the product description codes for a designated product:



S1136 = HPC, Marrow|Citrate/XX/refg

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

7.3 Use of Compound Message Data Structure (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 (see Section 5, Page 17).

For example, a cord blood container is very small and it is desirable to have machine-readable information for Donation Identification Number, Product Code, ABO/Rh, and expiration date and time. A 2-D bar code could be used (see Figure 45, page 79). To encode this information into a 2-D bar code, Compound Message 003 (see the Structured Compound Messages Table in the *ISBT 128 Standard Technical Specification*) may be used.

The actual coding would involve stringing the four data structures together within the Compound Message Data Structure (see Section 6.8, page 36).

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/Rh, Product Code, and expiration date and time
= (see note below table)	W000008123456	Donation Identification Number is W0000 08 123456
=%	5100	The product is Group O, RhD Positive
=<	S1124V00	The product is Cryopreserved HPC, CORD BLOOD|NS/XX/<=-150C|10% DMSO from a Volunteer Donor and is not divided
&>	0100222359	The product expires on January 22, 2010 at 23:59.

Note: In the case of the Donation Identification Number, the first character of the Donation Identification Number (in this case, "W") is also the second character of the data identifier.

The message would then look like:

=+04003=W000008123456=%5100=<S1124V00&>0100222359

When encoded into a Data Matrix symbol, with an X dimension of 35 mm (0.013") (see *ISBT 128 Standard Technical Specification*), the information would be contained in an approximately 10 mm square symbol. It would appear as in Figure 7.

Figure 7 Compound Message Example within a Data Matrix (2-D) Symbol

8 Uniform Labeling Using *ISBT 128*

8.1 Concepts

There are two labels to consider. One is called the base label and is applied by the manufacturer of the container. The second label is called a final label. It is applied by either a collection or processing facility before a product is shipped to another facility or before the product is released for infusion.

The original *ISBT 128* design for the final label is a 100 mm by 100 mm label. It is divided into 4 quadrants, each of which is 50 mm by 50 mm. 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. This is critical to allow concatenation and to overcome language barriers. Concatenation is explained more fully in Chapter 4, Page 15

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 read the 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.

Figure 8 Using *ISBT 128* to Overcome Language Barriers

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

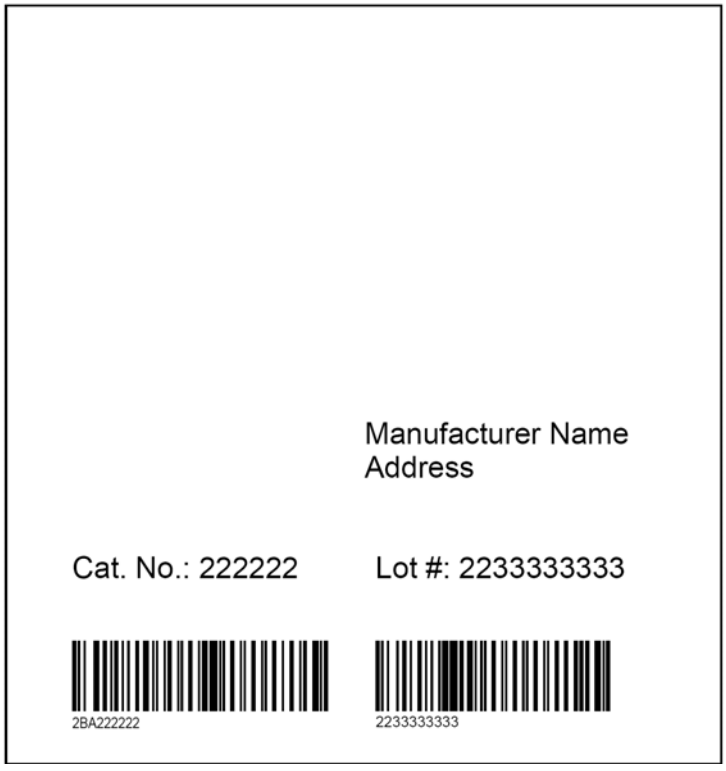
PRODDESCRIPCODE	PRODDESCRIPCODEFORM	PRODDESCRIP0
S1127	S006S@29SG2	Cryopreserved HPC, APHERESIS|N$/XX/<=-150C|6% HES + 5% DMSO
S1128	S005S@34	HPC, APHERESIS|Citrate/XX/refg
S1129	S005S@30	HPC, APHERESIS|Citrate/XX/rt

8.2 Base Label

8.2.1 100 mm x 106 mm Base Label

Some containers will have a base label affixed to the empty bag. When a base label is present, manufacturer's information may appear in both eye- and machine-readable formats. The manufacturer's identification, catalog number, and container identification bar code will be placed on the left. On the right, the bar code for the lot number of the bag will appear. The label is designed so that the eye readable text beneath the bar codes will be visible after the final label is affixed. The text information identifying the manufacturer and its location will appear on the label, but the position of this text is not standardized. The bar codes will be placed as specified in the *ISBT 128 Standard Technical Specification* to allow for concatenation.

Figure 9 100 mm x 106 mm Base Label



8.2.2 Small Base Label

On a smaller base label, the bar codes will be positioned vertically on the left side of the label to allow for concatenation. The label is designed so that the eye readable text beneath the bar codes will be visible after the final label is affixed. The bar codes will be placed as specified in the *ISBT 128 Standard Technical Specification* to allow for concatenation (see Chapter 4, page 15 for description of concatenation).

Figure 10 Small Container Base Label

8.3 Final Product - Full Label

8.3.1 Upper Left Quadrant

8.3.1.1 Donation Identification Number

The Donation Identification Number (DIN) must appear in the Upper Left Quadrant. This information must be machine readable. Corresponding text should appear immediately below the bar code. See 6.1.1.3, page 20 for details of how the number should be printed.

8.3.1.2 Facility Associated with the DIN

The Upper Left Quadrant contains the text name of the facility associated with the DIN. This may be:

- the collection facility, unless this information is considered confidential.
- no text name, if the name of the collection facility is considered confidential. See Figure 11, page 50.
- the processing facility in the case of a Cord Blood bank where the laboratory is administratively responsible for collections occurring at hospitals.
- the registry if the product is collected for a registry. In some countries, the DIN may be assigned by the Registry for collections being shipped through the Registry. In this case, the FIN and the text beneath it will correspond to the Registry.
- the pooling facility for a pooled product

Note: The final decision on who (facility or the registry) will assign the DIN in the US has not been made. When the decision is made, a new version of this document will be published

If the name of the collection or processing facility or the registry is printed, city, state, and Zip Code must also appear as shown in Figure 12.

8.3.1.3 Collection Date and Time

If pertinent, the collection date (and time) should appear in the Upper Left Quadrant 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*, it is permissible to reduce

the height of a bar code to less than the standard 10 mm because of space limitations. 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.

As noted earlier, if the product will be shipped internationally across a time zone, GMT should be printed beneath the local time. If GMT appears, it must be printed in parentheses (see Section 6.5) with the designation "GMT." Italics may also be used to further differentiate GMT from local time.

8.3.1.4 Warning Statements

The warning statements: Do Not Irradiate and Do Not Use Leukoreduction Filters will appear in the Upper Left Quadrant.

Rx Only will be printed at the bottom of the quadrant for licensed products subject to US 351 regulations. This phrase is optional on non-licensed 351 products and those subject to 361 regulations.

Figure 11 Upper Left Quadrant – Confidential Facility

Figure 12 Upper Left Quadrant – 351 Products (licensed product, with "Rx Only")

Figure 13 Upper Left Quadrant – 361 Products

Figure 14 Upper Left Quadrant - Collection Time Not Needed

Figure 15 Upper Left Quadrant with Bar Coded Collection Date/Time

8.3.2 Lower Left Quadrant

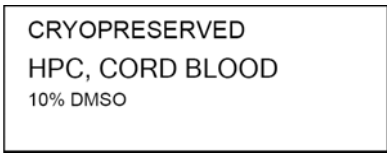
8.3.2.1 Product Code Bar Code

On a full 100 mm by 100 mm label, the product code must be bar coded in the Lower Left Quadrant. The eye readable text of the product will appear immediately below the bar code and left justified. The donation type, when intended for a specific recipient (designated, autologous, etc.), will appear right justified beneath the bar code.

8.3.2.2 Name of Product

Product description bar code text will be left justified. It is recommended that product description bar code text should be printed with the Modifier and Attribute(s) proportionally smaller than the Class proper name (see Figure 16).

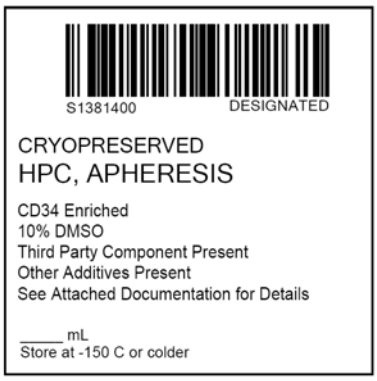
Figure 16 Text Size Relationships on Product Label



Text to be used in the US for various Classes, Modifiers, or Attributes may be found in Chapter 9. Figure 39, page 74, gives some examples of how Classes and Modifiers should appear.

Modifier information should appear on the first line, followed by the Class name on the second line. Attribute information should appear below the Class name of the product in the order that they appear in 9.3, beginning on page 65 (or as listed in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*). The phrase “See Attached Documentation for Details” should appear beneath the attributes when the attribute is not specific (i.e., 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 Attached Documentation for Details” is adequate.

Figure 17 Multiple "Non-Specific" Attributes



Note: When space is a problem, combining two statements on a single line for Attributes is acceptable and saves considerable space, provided that the reading of the statements is not compromised and that the general order of the statements is not changed.

8.3.2.3 Volume

The approximate volume of the product and anticoagulant must appear beneath the product description.

8.3.2.4 Storage Temperature

The recommended storage temperature must appear beneath the volume.

8.3.2.5 Division Number

If a division number applies (i.e., Part A0), it may optionally appear beneath the storage temperature.

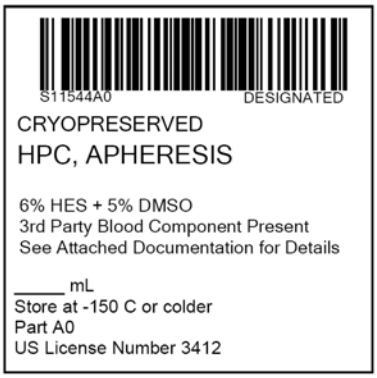
Figure 18 Divided Product Label

-

8.3.2.6 US License Number

If a product is FDA licensed, the US License Number may optionally appear at the bottom of the Lower Left Quadrant. It must appear within the labeling for the product, but may be included as attached or accompanying documentation instead of on the affixed label.

Figure 19 Lower Left Quadrant



8.3.2.7 Warning Statement

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

8.3.3 Upper Right Quadrant

8.3.3.1 ABO and Rh

The ABO and Rh (if known) should be bar coded on the final label of a full 100 mm by 100 mm label.

If there is no known recipient (e.g., public cord blood bank), the ABO/Rh should be printed as large as possible. See Figure 20 and Figure 21.

Figure 20 Upper Right Quadrant, No Intended Recipient, Rh Positive

Figure 21 ABO/Rh, No Intended Recipient, Rh Negative

If the intended recipient is known, the ABO/Rh bar code text should be printed in a smaller font and appear to the right of the bar code. See Figure 22.

Figure 22 ABO/Rh Label with Intended Recipient

8.3.3.2 Special Message in Place of ABO/Rh

In place of an ABO/Rh, a special message may be given. An example of this would be when the product is intended to be used for nonclinical purposes rather than for infusion.

Figure 23 Special Message in Place of ABO/Rh

8.3.3.3 Biohazard symbol

The biohazard symbol, if appropriate, should appear immediately below the ABO and Rh. See Figure 24. The word “BIOHAZARD” should appear beside the symbol.

Figure 24 Upper Right Quadrant – Biohazard

8.3.3.4 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 Upper Right Quadrant 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 Upper Right Quadrant and below the biohazard symbol, if present.

8.3.3.5 Donor Information (When Recipient is Known)

8.3.3.5.1 Designated Donations: Unrelated

If the donor is not related, the words “Unrelated Donor” and a donor identification number will appear in the lower portion of the Upper Right Quadrant. Other donor information will remain confidential. See Figure 25.

Figure 25 Upper Right Quadrant - Unrelated Donor

8.3.3.5.1 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” will appear in the lower portion of the Upper Right Quadrant 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.

Figure 26 Upper Right Quadrant - Related Donor, First or Second Degree

8.3.3.5.1 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” will appear in the lower portion of the Upper Right Quadrant followed by the donor number. Other donor information will remain confidential. See Figure 27.

Figure 27 Upper Right Quadrant - Related Donor, Other than First or Second Degree

8.3.3.5.2 Autologous Collections

For autologous donations,
“For Autologous Use Only” will appear in the lower portion of the Upper Right Quadrant. See Figure 28. (The Donor/Recipient information should appear in the Lower Right Quadrant, rather than in the Upper Right Quadrant.)

Figure 28 Upper Right Quadrant - Autologous Donor, Biohazard

8.3.3.6 Laboratory Results

Although allowed by the *ISBT 128* Standard, the US will not include laboratory test results on the affixed label because of space constraints.

8.3.4 Lower Right Quadrant

8.3.4.1 Expiration Date and Time

On a 361 product, the expiration date and time (if one exists) must appear in the Lower Right Quadrant. On 351 products, this information should appear (if an expiration date/time exits). 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 6.4, page 29, if the product will be shipped internationally across a time zone, GMT should appear beneath the local time. It must be printed in parentheses with the designation "GMT." Italics may also be used to further differentiate GMT from local time. As noted in 6.4.1, page 29, if the expiration time is the default time of 23:59 (midnight), no bar code text indication of time will appear (see Figure 29, page 60), although this information will appear as eye-readable text. (See Figure 52, page 88, for definitions of bar code text and eye readable text.)

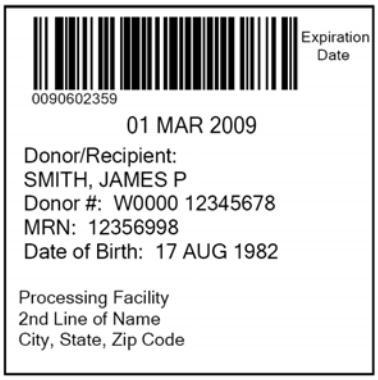
Figure 29 Lower Right Quadrant - Unknown Recipient

Figure 30 Lower Right Quadrant - Expiration Date Not Bar Coded

Figure 31 Lower Right Quadrant - Expiration Date/Time Bar Code and Text

Figure 32 Lower Right Quadrant – Default Expiration Time of Midnight

Figure 33 Lower Right Quadrant – Autologous Donation



8.3.4.2 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 (unique number)
- The date of birth of the patient/recipient in the format DD MMM YYYY. The month will be a three letter abbreviation (e.g., the date will appear in the format 07 NOV 1944).

See Figure 30, Figure 31, and Figure 32.

8.3.4.3 Autologous Collections

The words “Donor/Recipient” will appear in the lower portion of the Lower Right Quadrant followed by:

- Last name, first name, middle initial of the donor/recipient (all upper case letters),
- Donor number and/or the medical record number, and
- Date of birth.

See Figure 33.

8.3.4.4 Processing Facility

If different from the collection facility, the name, city, state, and Zip Code of the processing facility must appear at the bottom of the

Lower Right Quadrant on a processed product. This information would not appear at the time the product is collected.

8.4 Final Product – Partial Labels

Many cellular therapy product containers are very small, limiting the amount of information that may appear on the affixed label. For labels too small to bear the mandatory minimum information, users are advised to discuss possible alternatives with the FDA.

8.4.1 Minimum information

At a minimum, partial labels must include the information shown on Table 4.

Table 4 Minimum Information on Partial Labels

351 Products	361 Products
• A machine readable Donation Identification Number • Donation Identification Number in text • The proper name of the product (Class and Modifier) in text • Name of Manufacturer [21 CFR 610(c)] • Recipient information (if applicable)	• A machine readable Donation Identification Number • Donation Identification Number in text • The proper name of the product (Class and Modifier) in text • Expiration date (if any) [21 CFR 1271.370] • Recipient information (if applicable)

8.4.2 Optional information

The following information should be included as space permits on an affixed partial label.

- Processing facility information (required for 351 products, but optional on the affixed label for 361 products)
- Donor information
- Biohazard symbol and “Biohazard” text, if applicable
- Expiration date (if any, required for 361 products; optional on the affixed label for 351 products)
- Collection date, if there is no expiration date
- Storage conditions
- Product attributes (e.g., CD 34 Enriched), if space permits. If space does not permit all product attributes, the phrase “See Attached Documentation for Details”
- Machine-readable product code
- ABO/Rh
- Collection facility information

- US license number of the product for products that are FDA-licensed.

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 Modifier or printing the Modifier in all upper case letters) may not be practical for very small labels. See examples in Section 10.5, beginning on page 79.

8.4.3 Use of 2-D labels

The use of 2-D symbols permits more information to appear in a very small space. See Section 5.2, page 17. When used with Data Matrix symbology, the Compound Message Data Structure (Section 6.8) allows information from multiple Data Structures to be presented in a space of approximately a 10 mm square. Use of the 2-D label bar code may allow machine readable information on labels that otherwise would be too small.

8.5 Attached and Accompanying Labeling

Not all labeling information required by AABB, FACT, and FDA will fit on affixed labels. These organizations allow some of this information to appear on attached tags (tie tags) or accompanying paperwork. The current Standards of AABB and FACT, as well as the Code of Federal Regulations, should be consulted for details.

9 US Text Requirements

9.1 Class Text

Class names will match the official class name in the ICCBBA database, as described in the document *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*.

9.2 Modifier Text

Modifier names will appear above the class name on the label and match the modifier name in the document *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*.

9.3 Attribute Text

Attribute text will be as it appears in the tables below. When the phrase "See Attached Documentation for Details" is required (Third Party Component:Yes; Other Additives: Yes; or Genetically Modified:Yes) it need appear only one time if more than one of these attributes is present. The attached documentation will bear more detailed information about these attributes. If more space is needed (e.g., on a genetically modified unit), then "See Accompanying Documentation for Additional Information" should appear on the attached documentation.

9.3.1 Intended Use Group

Table 5 Intended Use Group Text

Attribute Name	Definition	Label Text
Default: for administration	For patient use: The product is intended for administration to patients	(None)
Not for admin	Not for patient use; a product that is not intended for use in patient treatment	For Nonclinical Use Only
For further processing	For further processing into a product that may be administered; not intended for direct administration	For Further Processing

9.3.2 Manipulation Group

Table 6 Manipulation Group Text

Attribute Name	Definition	Label Text
Default: no manipulation	No further processing has occurred following collection.	(None)
Diluted	A product to which an additional diluent (e.g. Concurrent Plasma) has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation	Diluted
Plasma Reduced	Cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation	Plasma Reduced
RBC Reduced	Cells remaining after reduction of mature erythrocytes	RBC Reduced
Buffy coat enriched	Cells remaining after reduction of mature erythrocytes and plasma.	Buffy coat enriched
Mono-nuclear cells enriched	Cells remaining after reduction or depletion of mature erythrocytes, granulocytes and plasma	Mononuclear cells enriched
T-cell reduced	Cells remaining after T cells have been reduced	T-cell reduced
B-cell reduced	Cells remaining after B cells have been reduced	B-cell reduced
T/B-cell reduced	Cells remaining after T&B cells have been reduced	T/B-cell reduced
CD8 reduced	Cells remaining after the CD8 cell population has been reduced	CD8 reduced
CD34 enriched	Product in which the CD34 cell population has been enriched	CD34 enriched
CD133 enriched	A product in which the CD133 cell population has been enriched	CD133 enriched
Tumor cells reduced	An identified tumor cell population has been reduced	Tumor cells reduced
PUV treated	Cells treated with psoralen/ultra violet light	PUV treated
Cultured	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
Monocyte enriched	Product in which the monocyte cell population has been enriched	Monocyte enriched

9.3.3 Cryoprotectant Group

Table 7 Cryoprotectant Group Text

Attribute Name	Definition	Label Text
Default: no cryoprotectant	No cryoprotectant has been added.	(None)
6% HES + 5% DMSO	The cells were frozen using 6% HES and 5% DMSO by volume as cryoprotective agents	6% HES + 5% DMSO
10% DMSO	The cells were frozen using 10% DMSO by volume as a cryoprotective agent	10% DMSO
7.5% DMSO	The cells were frozen using 7.5% DMSO by volume as the cryoprotective agent	7.5% DMSO
5% DMSO	The cells were frozen using 5% DMSO by volume as the cryoprotective agent	5% DMSO

9.3.4 Blood Component from Third Party Donor Group*

Table 8 Blood Component from Third Party Donor Group Text

Attribute Name	Definition	Label Text
Default: 3rd party comp:NO	Default. No third party blood component added	(None)
3rd party comp:YES	Third party blood component added. See attached documentation for details.	3rd Party Blood Component Present. See Attached Documentation for Details.

9.3.5 Preparation: Other Additives Group*

Table 9 Preparation: Other Additives Group Text

Attribute Name	Definition	Label Text
Default: other additives:NO	Default. No additives other than as part of the anticoagulant solution at the time of collection	(None)
Other additives:YES	Other additives present.	Other Additives Present. See Attached Documentation for Details.

9.3.6 Genetically Modified Group*

Table 10 Genetically Modified Group Text

Attribute Name	Definition	Label Text
Default: genetically Modified:NO	Default. Not genetically modified	(None)
Genetically Modified:YES	Genetically modified by the insertion of exogenous genetic material.	Genetically Modified. See Attached Documentation for Details.

**Note: The default values of the groups Blood Component from Third Party Donor, Other Additives, and Genetically Modified have been changed from those originally published. When initially published, "Not Specified" was the default value. The default value has been changed to that shown above to reflect the most common condition (the condition which would be expected unless otherwise noted).*

9.4 Donation types

Table 11 Donation Types for Use with Product Code Data Structure

Character	Type of Donation	Label Text	When to Use
V	Voluntary allogeneic donation		When product is collected from a volunteer donor and is intended for administration to an unknown recipient
0	Not specified		Default; no information is provided on the type of donation
R	Volunteer research donor	For Nonclinical Use Only	When product is collected from a donor for research purposes only
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.
E	For directed recipient, medical exception	For Use by Intended Recipient Only	When donor does not meet routine eligibility requirements, but does not have a positive infectious disease test result. For example, when donor has a hemoglobinopathy or has a travel history that would otherwise exclude him/her.
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. This donation type would apply whether or not the intended recipient was known at the time of collection or processing.
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 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.

10 Label Examples

10.1 Standard (100 mm by 100 mm labels)

10.1.1 Base label

See Section 8.2.

10.1.2 Final labels

Requirements set forth by AABB and FACT for what information must appear on full labels varies by the stage (collection, storage, or distribution) of the product. *ISBT 128* is intended for final labeling of a product. Final labeling is defined as: Labeling as it appears on a product ready for release. It is applied by either a collection or processing facility before a product is shipped to another facility or before the product is released for infusion.

Within the field of cellular therapy, products may be shipped at various stages for further processing at other facilities. Therefore, collection and storage labels are also shown in the examples of Final Labels. If products will not be shipped to other facilities prior to final labeling, then there is no requirement that such in-process labels be standardized.

When products are thawed at bedside, there is no need to re-label them as thawed products.

10.1.2.1 Collection Labels

Figure 34 Full Collection Label – Unrelated Donor (351 Product)

Figure 35 Full Collection Label – Related Donor 1st or 2nd Degree (361 Product)

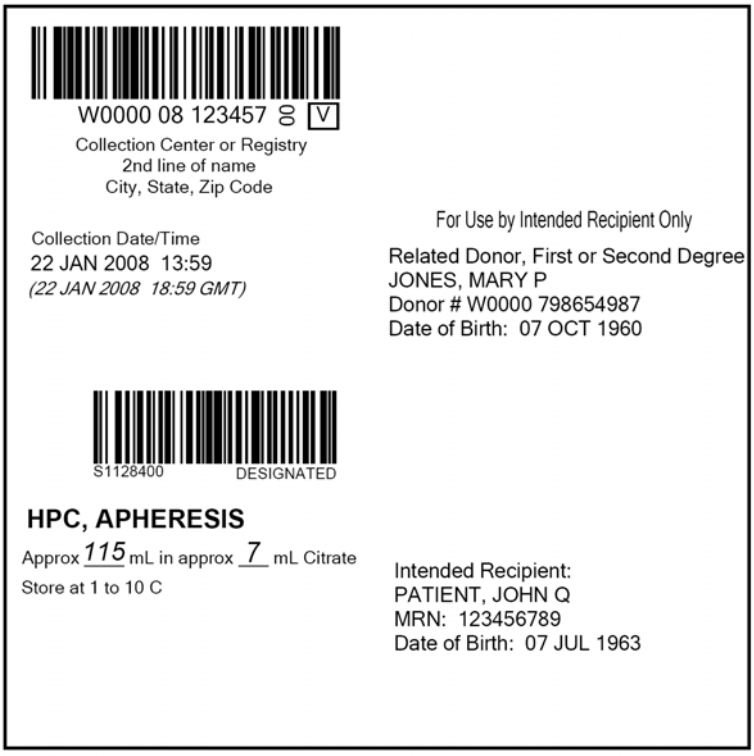


Figure 36 Full Collection Label – Related Donor Other (351 Product)

10.1.2.2 Distribution Labels

Figure 37 Full Distribution Label (351 Label)

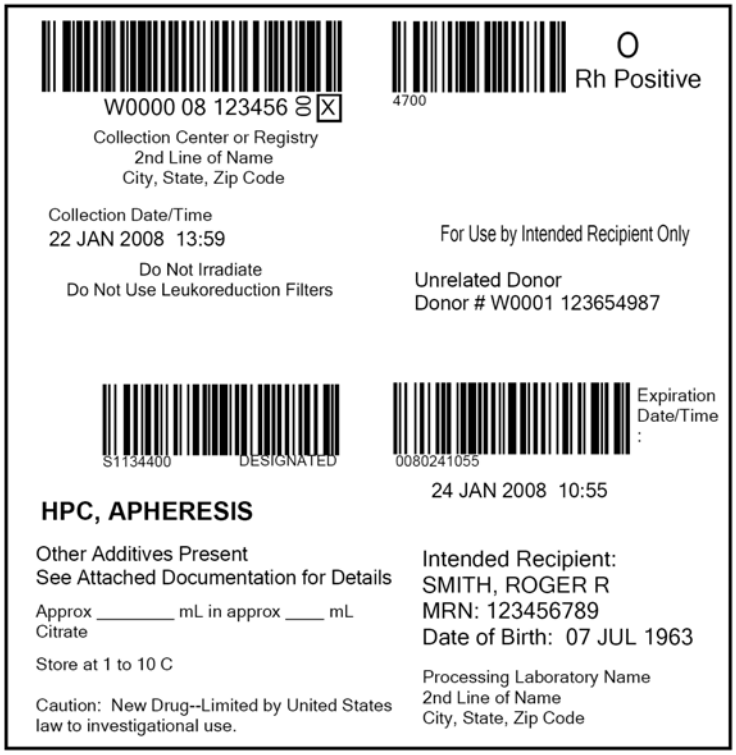
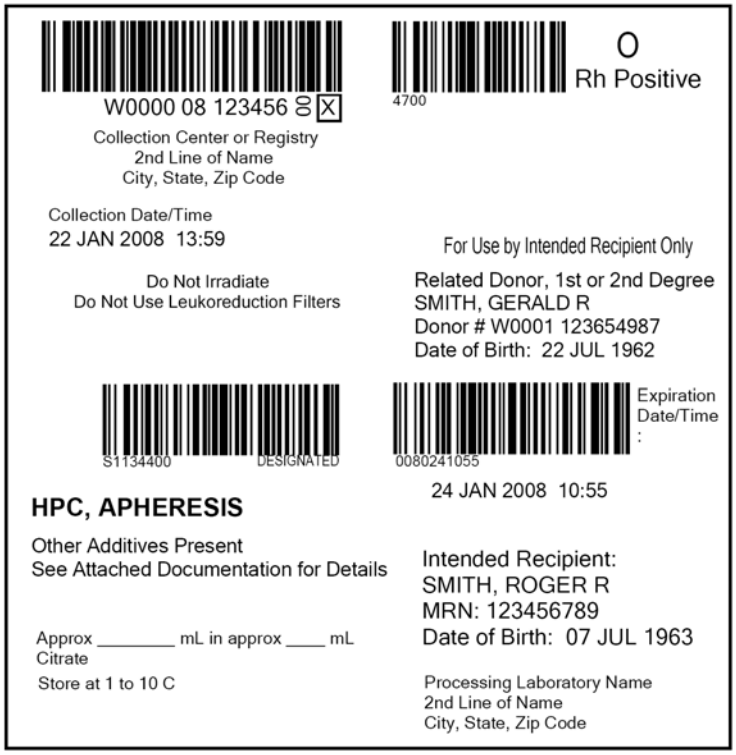
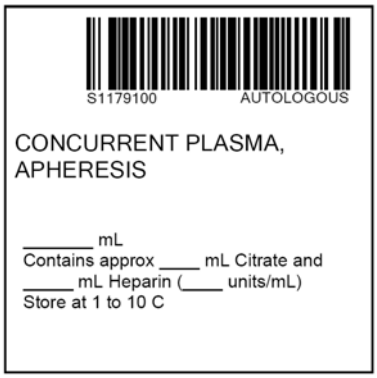


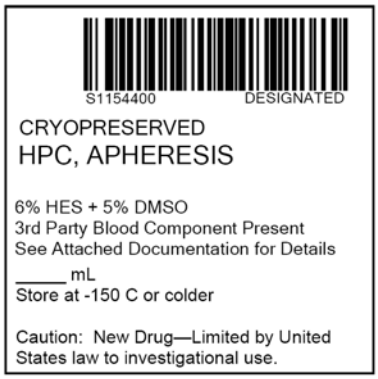
Figure 38 Full Distribution Label (361 Product)

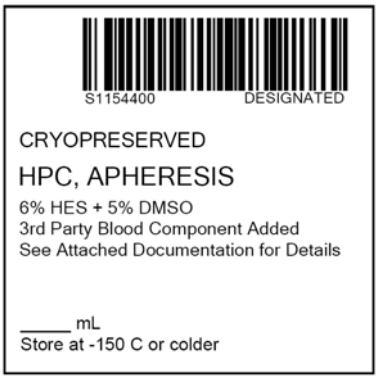


10.1.2.3 Product Code Labels

Figure 39 Sample Product Code Labels





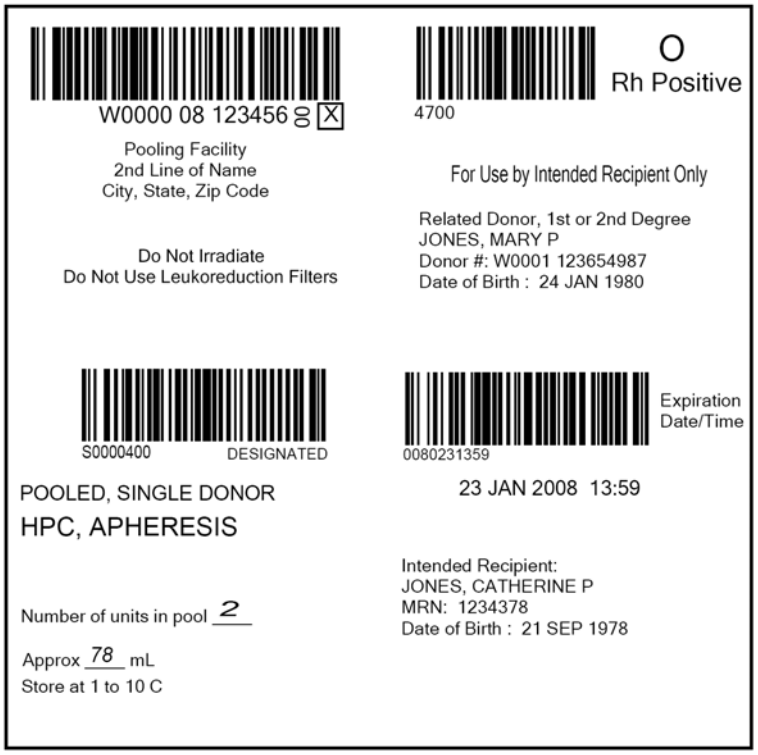


10.2 Pooled Products

Pooled products should be assigned a unique *ISBT 128* Identification Number. This should follow the same format as *ISBT 128* Donation Identification Numbers. 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. They should be given a new unique identification number and a pooled product description code as shown in Figure 40.

Figure 40 Pooled Product Label



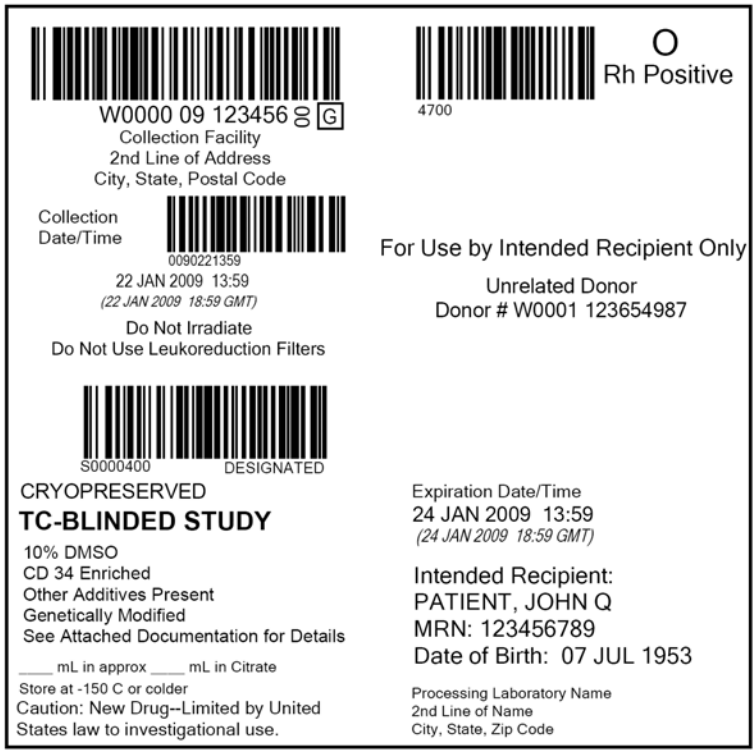
10.3 Products Collected Under Investigational Protocols

The sentence “Caution: New Drug—Limited by United States law to investigational use.” must appear in the Lower Left Quadrant.

10.3.1 Blinded Studies

When different products are collected for comparison under a blinded investigational protocol, all products should be labeled with the product class “TC-Blinded Study”. Because the test and control products are labeled identically, facility records must reflect the details of each product. *Note: One arm of the study may involve a placebo, which would be labeled identically to the active product.*

Figure 41 Investigational Product - Blinded Study



10.3.2 Non-Blinded Studies

When the product is collected under an investigational protocol, and is not part of a blinded study, it should be labeled with the product class “TC-INV” (Therapeutic Cells, Investigational). This class is used for a specific product. Throughout the study products labeled as TC-INV will be the same product, although the dose may vary within a specified range defined by the study.

Figure 42 Investigational Product – Non-Blinded Study

10.4 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" must appear in the Upper Right Quadrant.

A product code with the attribute "Not for Admin" should be selected.

Figure 43 Product Not for Administration

10.5 Partial Labels

Figure 44 48 mm x 76 mm Folded Label (Linear Bar Codes)

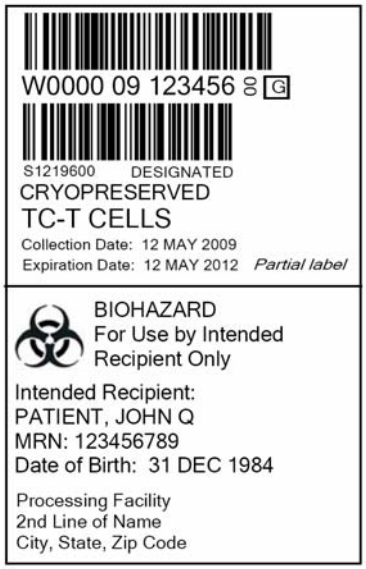


Figure 45 48 mm x 76 mm Folded Label (2-D bar code)

Figure 46 96 mm x 38 mm Folded Label (Linear Bar Codes)

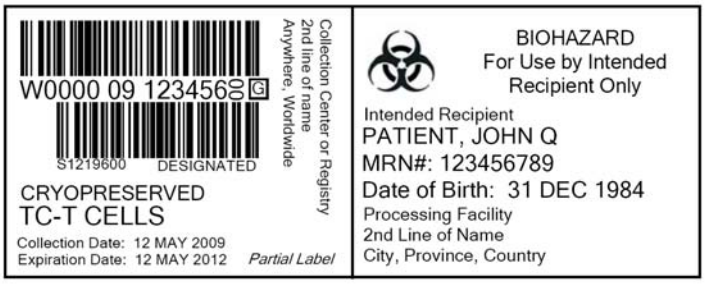
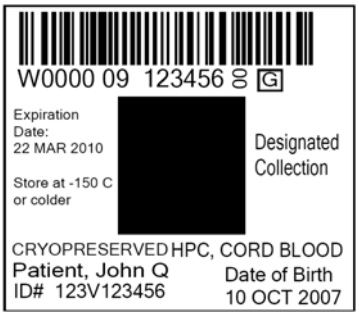


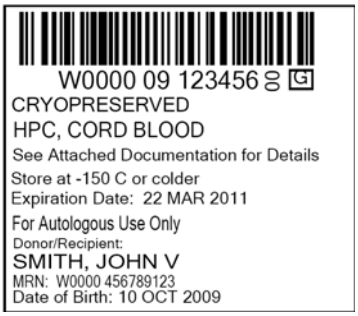
Figure 47 96 mm x 38 mm Folded Label (2-D Bar Code)

Figure 48 Cryo Vial Label (Linear Bar Codes)

Figure 49 Cryo Vial Labels (2-D Bar Codes)

Figure 50 Cryopreservation Labels





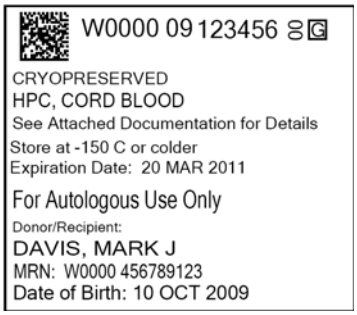
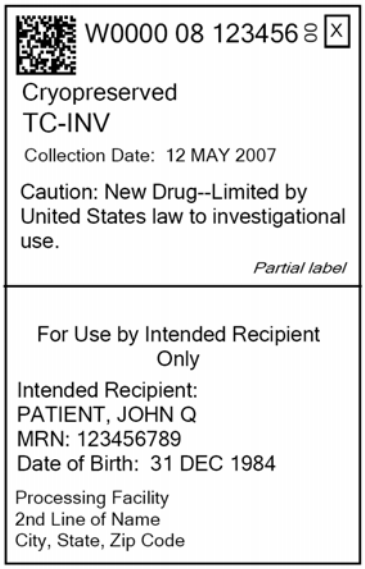
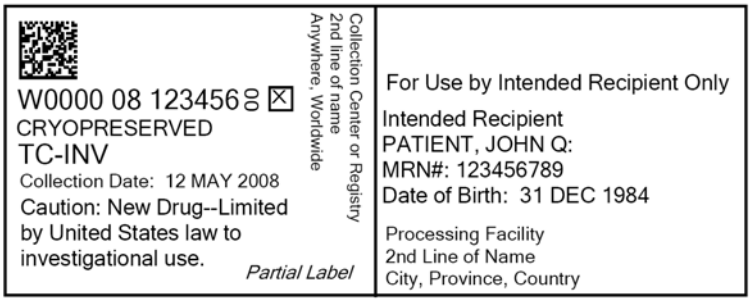


Figure 51 Investigation Products - Partial Labels

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.





11 Databases and Reference Tables

11.1 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 facility begins with "W." This database is found on the ICCBBA Website and is called:

Registered Facilities

11.2 Product Code Database

This database provides a list of all product codes and product code descriptions. A detailed description of the *ISBT 128* Product Description Code database can be found in the documents *ISBT 128 Standard: Technical Specification* and *Product Code Structure and Labeling – Cellular Therapy Products*. This database is found on the ICCBBA Website and is called:

Product Codes Database

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

Specific information about the Product Code database is found in *the ISBT 128 Technical Specification* and in *Product Code Structure and Labeling, Cellular Therapy Products*. The latter document also contains information about requesting new product codes when an appropriate code does not exist.

The *ISBT 128* Product 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.

11.3 Special Testing

This database contains the test names and codes for data conveyed in the Special Testing, General Data Structure (Data Structure 010) such as CMV and Hemoglobin S. This database is found in the Registered Users 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.

11.4 Manufacturers ID

The 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 wish to have a code assigned for use in these data structures should contact ICCBBA.

This table is published in the *ISBT 128 Standard Technical Specification*. It is called Data Structures 017 and 021: Manufacturer Identifier Codes [RT018].

11.5 Structured Compound Messages

The table contains the reference numbers and structures for structured *ISBT 128* compound messages. When using these messages, the identifier is incorporated into the compound message structure. Requests for additions to this table should be submitted through the ICCBBA Technical Advisory Groups.

This table is published in the *ISBT 128 Standard Technical Specification*. It is called Data Structure 023: Structured Compound Messages [RT017].

12 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
2-D bar code: Two-dimensional pattern of data cell

Base label 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.

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 eye readable text that verifies accurate keyboard entry.

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.

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)*

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 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*)

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.

Final label Labeling as it appears on a product ready for release. It is applied by either a collection or processing facility before a product is shipped to another facility or before the product is released for infusion.

Flag character Part of the data content of a data structure 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.

GMT Greenwich Mean Time, also known as Coordinated Universal Time (UTC), marks the starting point of every time zone in the World. See http://wwp.greenwichmeantime.com/ GMT does not change based on daylight saving time; thus, the relationship of local time to GMT changes if daylight saving time is observed.

ISBT 128 An international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. 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 A numbering 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).

Label

Affixed label: A self-adhesive independent entity that carries a bar code and also provides other eye-readable information.

Attached label: A label that is securely fastened to the product by means of a string or equivalent alternative

Accompanying label: Documentation that accompanies the product but is not affixed or attached.

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)]

Text

(See Figure 52, page 88)

Eye-readable text

The eye-readable representation of the data characters in a bar code (printed left justified immediately below the bar code, unless otherwise specified).

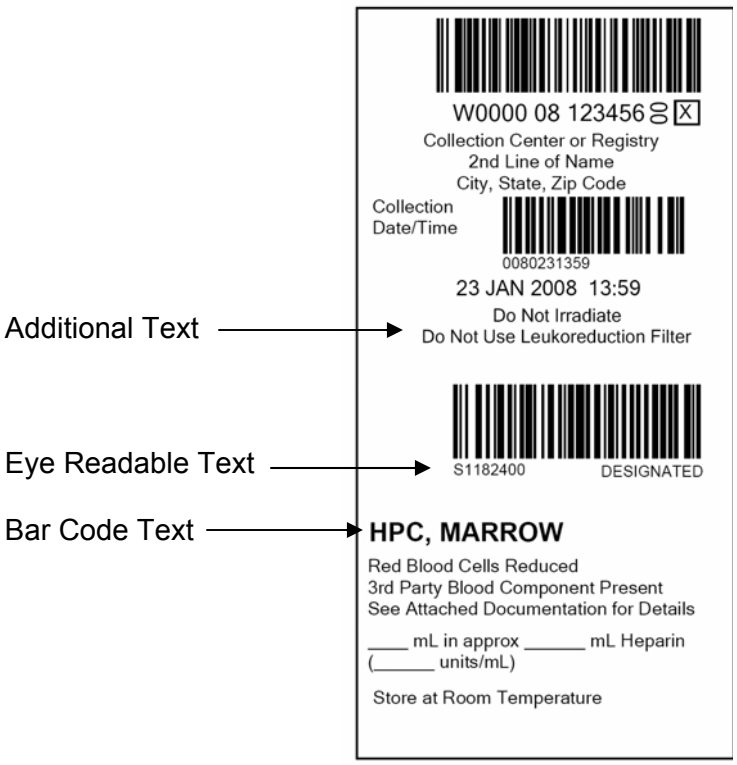
Bar code text

The interpretation of the eye-readable 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.

Figure 52 Illustration of the Terms Eye-Readable Text, Bar Code Text, and Additional Label Text



13 Abbreviations

Table 12 Abbreviations Used in This Document

2-D	Two-dimensional
CFR	Code of Federal Regulations
CMV	Cytomegalovirus
DIN	Donation Identification Number
EBV	Epstein-Barr Virus
FDA	Food and Drug Administration
FIN	Facility Identification Number
GMT	Greenwich Mean Time [also known as Coordinated Universal Time (UTC)]
HBc	Hepatitis B Core
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTLV	Human T-cell Lymphotropic Virus
NMDP	National Marrow Donor Program
RFID	Radio Frequency Identification
WNV	West Nile Virus

Table 13 Acceptable Abbreviations for Labeling Products

Abbreviation	Definition
#	Number
ACD	Acid Citrate Dextrose
ACD-A	Acid Citrate Dextrose Formula A
ACD-B	Acid Citrate Dextrose Formula B
Alb	Albumin
Approx	Approximately
C	Degree(s) Celsius (Centigrade)
CPD	Citrate Phosphate Dextrose
CPDA-1	Citrate Phosphate Dextrose Adenine Formula 1
CP2D	Citrate Phosphate Double Dextrose
DMSO	Dimethyl Sulfoxide
FDA	US Food and Drug Administration
Exp	Expiration Date
g	Gram(s)
h	Hour(s)
HES	Hydroxyethyl Starch
HSA	Human Serum Albumin
mg	Milligram(s)
mL	Milliliter(s)
MRN	Medical Records Number
room temp	Room temperature

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

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