



ISBT 128 STANDARD

Labeling of Cellular Therapy Products

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1 Introduction

1.1 Purpose

This document is intended to help facilities, label vendors, and software developers design appropriate ISBT 128 labels for cellular therapy products.

1.2 Scope

This document provides guidance in the design of labels for cellular therapy products following the standards described in the *ISBT 128 Standard Technical Specification (ST-001)*. Because container sizes for these products vary considerably, only a sampling of possible label designs is provided.

This document addresses affixed labels in the ISBT 128 format. It does not address the design of attached labels or accompanying documents.

1.3 Intended Audience

The intended audience of this document is staff at facilities of cellular therapy collection and processing centers, as well as the hospitals that receive these products (management, information technology, quality, validation, and laboratory), auditors, software developers, and label vendors.

1.4 Normative References

ISBT 128 Standard Technical Specification ([ST-001](#))

ISBT 128 Standard Terminology for Medical Products of Human Origin ([ST-002](#))

ISO 8601:2004(E): Data elements and interchange formats — Information interchange — Representation of dates and times

1.5 Other References

ICCBBA

Implementation Guide: Product Coding [Data Structures 003 and 032] - Cellular Therapy ([IG-022](#))

Implementation Guide: Use of Flexible Date and Time [Data Structure 031] ([IG-024](#))

AABB

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

FACT

Foundation for the Accreditation of Cellular Therapy (FACT) Standards
<https://www.factglobal.org/standards/hct-standards/>

JACIE

Joint Accreditation Committee of ISCT and EBMT Standards
<http://www.jacie.org/>

NetCord-FACT Standards

<https://www.factglobal.org/standards/hct-standards/>

WMDA

World Marrow Donor Association (WMDA) Standards
<https://www.wmda.info/professionals/quality-and-accreditation/wmda-standards/>

WBMT

The Worldwide Network for Blood and Marrow Transplantation Position Paper can be found at: <https://www.wbmt.org/>

1.6 Background

A Specification, ISBT 128, for labeling blood products was developed by the International Society of Blood Transfusion Working Party on Automation and Data Processing (WPADP) [now called the Working Party on Information Technology] and published by ICCBBA in 1995. Countries around the world are in various stages of implementation, and the model originally developed by the WPADP has demonstrated its suitability by accommodating regional changes without substantial structural change.

It was recognized almost immediately that the ISBT 128 Standard would be useful for cellular therapy products as well as blood products. A small number of facilities began using ISBT 128 for these products in the late 1990s. However, greater international standardization in terminology and labeling was needed to allow the use of the Standard to become widespread. This goal was met through the co-operative endeavor of the following organizations:

- AABB
- American Society for Transplantation and Cellular Therapy (ASTCT)
- American Society for Apheresis (ASFA)
- Asia-Pacific Blood and Marrow Transplantation Group (APBMT)
- European Society for Blood and Marrow Transplantation (EBMT)
- Foundation for the Accreditation of Cellular Therapy (FACT)
- ICCBBA
- International Society of Blood Transfusion (ISBT)
- International Society for Cell and Gene Therapy (ISCT)
- Joint Accreditation Committee of ISCT and EBMT (JACIE)
- National Marrow Donor Program (NMDP)
- World Marrow Donor Association (WMDA)

Representatives from these organizations, as well as additional technical experts and regulatory liaisons, comprise the Cellular Therapy Coding and Labeling Advisory Group

(CTCLAG). Through this group, global consensus is reached for the on-going development of terminology and label design for cellular therapy products using the ISBT 128 Standard.

Standard terminology will help to ensure a common understanding of product definitions. Use of the ISBT 128 Standard will provide:

- Unique global identification of cellular therapy products
- An international reference table for product descriptions
- Label designs that are consistent worldwide

The organizations supporting this Standard believe that its adoption will significantly improve the quality, safety, and traceability of cellular therapy products.

1.7 Changes in This Version

The following table indicates the major changes between Version 2.0.0 and Version 2.0.1. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print.

	Version 2.0.0 Chapter, Section, Table, or Figure	Version 2.0.1 Chapter, Section, Table, or Figure	Change	Rationale
1.	1.4 & 1.5	1.4 & 1.5	Links were added to the reference document's tracking numbers. Links for the FACT and NetCord-FACT Standards were updated.	For consistency and to give a quick link to the reference documents.

2 Data Structures

The data structures that are commonly used to label cellular therapy products include:

- Donation Identification Number [Data Structure 001]
- Blood Groups [ABO and RhD] [Data Structure 002]
- Product Code [Data Structure 003]
- Expiration Date and Time [Data Structure 005]
- Collection Date [Data Structure 006] or Collection Date and Time [Data Structure 007]
- Compound Message [Data Structure 023]

Detailed information for all data structures is found in the *ISBT 128 Standard Technical Specification* (ST-001).

3 General Labeling Considerations

3.1 General Principles

There are two general types of labels to consider for cellular therapy products:

- The base label that is applied by the manufacturer of the container.
- Product labels that are applied by cellular therapy facilities. Different types of product labels include:
 - The label at the completion of product collection
 - The label at the completion of processing
 - The label at distribution for administration
 - A partial label that can be either an in-process product label or the label on a product that is ready for administration

The following general principles apply to label design:

- Primary considerations in label design shall include improving the safety of the product and the efficiency of processing/administering. If these two considerations conflict, safety shall take precedence over efficiency.
- Critical information on the container shall dominate the label via position and prominence and shall take precedence over information that is of less importance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

Because of differences in languages and regulations, text that appears on the label, as well as the location of that text, is left to national authorities. However, examples are provided for guidance in determining where text may be placed. Bar code placement is more strictly standardized.

3.2 Label Size

The size of an ISBT 128 label for cellular therapy products will vary primarily depending upon the size of the container. Factors such as the amount of information that a facility wants to encode using ISBT 128 data structures, the symbology (linear bar codes versus 2-D symbols) chosen to convey electronically readable information, the number of languages that may be required for text, and the requirements for other information on the label may influence the size of the label.

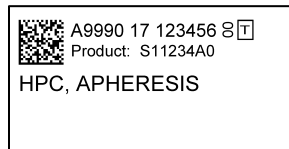
The ISBT 128 Standard, therefore, does not specify a particular size of label. However, a 100 mm x 100 mm label is considered a routine label size when the size of the container permits. This allows label stock typically used for blood banks to be used for cellular therapy products.

3.3 Minimum Requirements for ISBT 128 Labels

Regardless of the size of the label, the minimum ISBT 128 information content of the label shall be:

- Electronically readable Donation Identification Number (DIN). If a 2-D symbol is used, both the DIN and the Product Code shall be electronically readable.
- The eye-readable Donation Identification Number, flag characters when required (rotated 90° clockwise), and the boxed manual check character.
- The eye-readable Product Code (Product Description Code, Collection Type Code, and Division Code). If this text does not appear in conjunction with a bar code (e.g., there is no linear bar code for Product Code or a 2-D symbol is used), the word “Product” shall precede the Product Code, see Figure 1 and Figure 2.
- The product Class name.

Figure 1 Minimum ISBT 128 Information



3.4 Other Minimum Label Requirements

Applicable regulations and standards should be consulted for other minimum requirements for labels, see Section 1.5. Typically, intended recipient information is required. Labeling requirements may vary based on the stage of the product (at completion of collection, at completion of processing, and at distribution for administration).

Figure 2 Minimum ISBT 128 Requirements and Additional Information – Linear

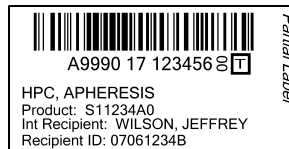


Figure 3 Minimum ISBT 128 Requirements and Additional Information – 2-D

3.5 National Labeling Guidelines

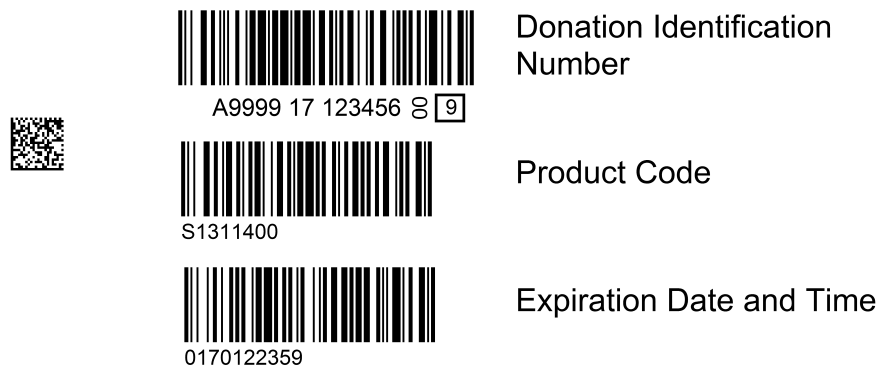
National bodies may publish guidelines for labeling which adhere to the ISBT 128 Standard. ICCBBA maintains on its website examples of such national documents. For assistance in creating such national guidelines, or to share a national guideline on the ICCBBA website, contact the ICCBBA office (tech.manager@iccbba.org).

4 Electronically Readable Symbols

Either linear bar codes (Code 128) or two-dimensional (2-D) symbols (Data Matrix), or both, may be used to label cellular therapy products. 2-D symbols have the advantage of allowing a great deal of information to be encoded into a very small amount of space, see Figure 4. They require a more modern type of scanner, an imaging scanner, to read them and may require changes to the receiving system software. Imaging scanners are becoming more widely available in hospitals.

Specifications (quality, dimensions, etc.) for the printing of electronically readable symbols are found in the *ISBT 128 Standard Technical Specification* (ST-001).

Figure 4 Comparison of 2-D and Linear Bar Codes



All of the information contained in the three linear bar codes on the right is contained within the 2-D symbol on the left.

5 Bar Code and 2-D Symbol Placement

5.1 100 mm x 100 mm Product Label

When space permits, the size of the product label is 100 ± 2 mm x 100 ± 2 mm. The affixed label may be applied as a single 100 mm x 100 mm label or may be built up with smaller labels applied at different stages during the process.

- The bar codes for the Donation Identification Number [Data Structure 001] and Product Code [Data Structure 003] shall be present.
- When known at the time of labeling, the bar code for the Blood Groups [ABO and RhD] [Data Structure 002] shall be present.
- The inclusion of the bar code for the Expiration Date and Time [Data Structure 005] or the Flexible Date and Time [Data Structure 031], if known at the time of labeling, is strongly recommended. It is anticipated this will be a requirement in the future.

The product label design shall be based upon the concept of four equal quadrants, 50 ± 1 mm x 50 ± 1 mm each. The bar codes shall be placed in these quadrants as indicated in Table 1.

Table 1 Positioning of Bar Codes on a 100 mm x 100 mm Cellular Therapy Label [RT062]

Quadrant	Bar Codes
Upper Left	<p><u>Required to be printed:</u></p> <ul style="list-style-type: none"> • Donation Identification Number [Data Structure 001] <p><u>Optional:</u></p> <ul style="list-style-type: none"> • Collection Date [Data Structure 006] • Collection Date and Time [Data Structure 007] • Production Date and Time [Data Structure 009] • Flexible Date and Time [Data Structure 031] - Encoding the collection or production date and time
Lower Left	<p><u>Required to be printed:</u></p> <ul style="list-style-type: none"> • Product Code [Data Structure 003]
Upper Right	<p><u>Required to be printed when known at the time of labeling:</u></p> <ul style="list-style-type: none"> • Blood Groups [ABO and RhD] [Data Structure 002] <p><u>Optional:</u></p> <ul style="list-style-type: none"> • Global Registration Identifier for Donors [Data Structure 039]

Lower Right	<p><u>Strongly recommended to be printed when known at the time of labeling:</u></p> <ul style="list-style-type: none">• Expiration Date and Time [Data Structure 005] or• Flexible Date and Time [Data Structure 031] - Encoding the expiration date and time
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The recommended alignment of bar codes on a 100 mm x 100 mm label is described in Table 2. This design places the bar codes in an ideal position for concatenation.

Table 2 Recommended Bar Code Alignment on a 100 mm x 100 mm Cellular Therapy Label [RT063]

Bar Code	Vertical Alignment	Horizontal Alignment
Donation Identification Number [001]	3 ± 2 mm from top of Upper Left Quadrant*	Bar code right edge should be 4 ± 2 mm from right edge of Upper Left Quadrant*
Product Code [003]	3 ± 2 mm from top of Lower Left Quadrant*	Bar code right edge should be 4 ± 2 mm from right edge of Lower Left Quadrant*
Blood Groups [ABO and RhD] [002]	3 ± 2 mm from top of Upper Right Quadrant*	Bar code left edge should be 4 ± 2 mm from left edge of Upper Right Quadrant*
Expiration Date and Time [005 or 031]	3 ± 2 mm from top of Lower Right Quadrant*	Bar code left edge should be 4 ± 2 mm from left edge of Lower Right Quadrant*
Collection Date (and Time) [006, 007, or 031] or Production Date and Time [009 or 031]	20 ± 2 mm from top of Upper Left Quadrant	Bar code right edge should be 4 ± 2 mm from right edge of Upper Left Quadrant

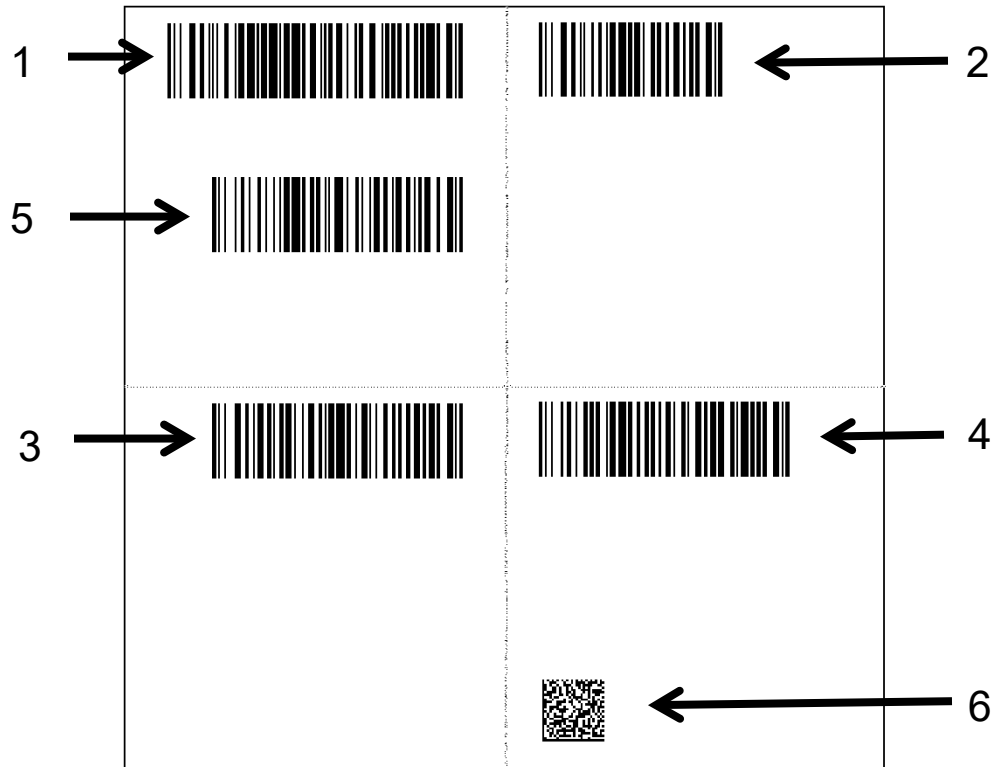
*Concatenation distances must also be maintained

When present, the Data Matrix symbol shall include the Donation Identification Number and Product Code Data Structures. It should also include the Blood Groups [ABO and RhD] and the Expiration Date and Time Data Structures when this information is available. Any additional ISBT 128 data structures (excluding nationally defined structures) may also be included.

Where a Data Matrix symbol is used, it should be positioned as close to the bottom of the label as practical in the lower right quadrant.

Depending on the amount of text that is required on a label, it may be necessary to reduce the bar code height in accordance with bar code height requirements described in the *ISBT 128 Standard Technical Specification* (ST-001).

Figure 5 shows the placement and nominal size of bar codes on a final label.

Figure 5 Placement and Nominal Size of Bar Codes on Final Label

Gray lines marking quadrants are for reference only and should not be printed on the label

Required Bar Codes

- 1 – Donation Identification Number
- 2 – Blood Groups [ABO and RhD]
- 3 – Product Code

Strongly Recommended

- 4 – Expiration Date and Time

Optional Bar Codes and Symbols

- 5 – Collection (or Production) Date and Time
- 6 – 2-D symbol with all five data structures

5.2 Partial Labels

When the container size is small, partial labels must be used. The placement of electronically readable information on a partial label will be entirely dependent on the size and shape of the label. For linear labels, the DIN bar code should appear before (above) the Product Code bar code (if present). Because of size constraints, 2-D symbols may be preferred. Appropriate regulations and standards should be followed when determining what information will appear on the partial affixed label and what information will be carried on attached labels or accompanying documentation.

5.3 Location of the GRID on a 100 mm x 100 mm Label

The Global Registration Identifier for Donors (GRID) may be encoded in a linear bar code or a 2-D symbol.

When encoded in a linear bar code or as standalone information in a 2-D symbol, it shall be placed in the upper right quadrant.

When encoded along with other product information in a 2-D symbol, the eye-readable GRID shall be placed in the upper right quadrant, and the 2-D symbol should be positioned as close to the bottom of the label as practical in the lower right quadrant.

For an example of the GRID in a linear bar code and as standalone information in a 2-D symbol, see Section 7, Figure 20 and Figure 21.

6 Text

Fonts selected for labels shall allow differentiation between similar characters (e.g., 0/O and 1/l).



Particular font sizes and types are not specified, but designers shall ensure clarity of all text and use larger fonts to emphasize critical information. The use of color (e.g., for ABO) is neither prohibited nor encouraged.

Unless otherwise specified, every ISBT 128 linear bar code on a container label shall be accompanied by text that corresponds to the data content. It shall be printed left justified immediately below, but not touching, the linear bar code, unless otherwise specified. Text shall be in font that differentiates similar characters with a maximum height of 2 mm.

Data identifiers shall not appear in text, unless otherwise specified.

At a minimum, data labels (i.e., text indicating the meaning of the data item) should be used when the purpose of the code is not apparent by its position on the label or by its context, see Figure 6. Appropriate abbreviations may be used when space is limited.

Figure 6 Examples of Data Labels (in Red Boxes)

	A9996 17 123456 8 S
	Product: S11226D0
HPC, MARROW	
10% DMSO Cryopreserved Store at -150 C or colder Part D0	
	Collection Date: 2017-02-12
	Expiration Date: 2018-02-12 23:59 CET (2018-02-12 22:59 UTC)
<i>Partial label</i>	
	BIOHAZARD For Use by Intended Recipient Only
Intended Recipient: PATIENT, JOHN Q MRN: 123456789 Date of Birth: 31 DEC 1984	
Processing Facility 2nd Line of Name City, State, Zip Code	

6.1 Donation Identification Number [Data Structure 001]

All data characters in the thirteen (13)-character DIN shall be printed. This includes the second data identifier character as, in this specific case, the second character of the data identifier is also a data content character. A national authority should determine how the DIN should be displayed, for example:

W1234 17 123456

V0043 17 499 999




The flag characters “ff” may be used to convey specific information other than the unique identification of the product and shall be distinguished from the Donation Identification Number.

When the default value (00) is used for flag characters, it does not have to be printed.

When Type 1 or Type 2 flag characters are used, they shall be printed as either:

- **Numeric Presentation:** The two-digit values of flags “ff” shall be printed rotated 90° clockwise to make them visually different from the Donation Identification Number.

Figure 7 Representation of Flag Characters

W0000 17 123456  

 Flag Characters

- **Non-numeric Presentation:** A graphical icon or other representation of the value of “ff.” For example, for flag “07” printing, an icon showing a small test tube may be used.

Type 3 flag characters shall not be printed.

An additional check character is calculated on the thirteen data characters of the DIN. It is printed enclosed in a box to the right of the DIN and flag characters, see Figure 7. The check character system ISO/IEC 7064 Mod 37-2 method is used to compute this check character. The manual check character should be used to ensure the accuracy of keyboard data entry.

When linear bar codes are used, the DIN shall be printed beneath the corresponding bar code, but it does not need to be left justified. This allows the DIN to be printed in a larger font.

6.2 Facility

The name and the address of the facility that corresponds to the Facility Identification Number (FIN) may appear beneath the DIN in text.

Figure 8 Upper Left Quadrant Facility Text



In the situation of a Matched, Unrelated Donor where confidentiality of the collection facility is needed, it is recommended by the WMDA (<https://www.wmda.info/>) that the facility name NOT appear in text on the label, see Figure 9.

Note: It is also recommended that facilities not publish their FINs on their websites or other materials in order to keep the link between FIN and facility name less easily discoverable.

Figure 9 Upper Left Quadrant for Matched, Unrelated Donor



6.3 Blood Groups [ABO and RhD]

The ABO and RhD blood groups should be printed beside (Autologous, Directed, or Designated collections) or beneath (collection type not specified, such as a public Cord Blood collection) the corresponding bar code in the upper right quadrant.

Figure 10 Upper Right Quadrant for Designated or Directed Collection

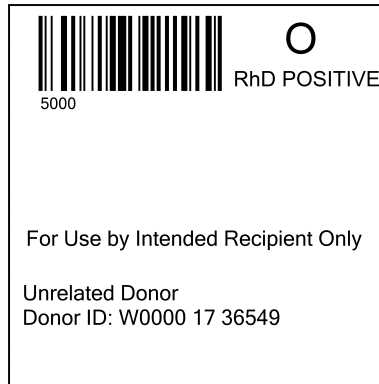


Figure 11 Upper Right Quadrant for “Non-Specified” Collection



6.4 Product Descriptions

On a 100 mm x 100 mm label, product description text shall be in the lower left quadrant beneath its corresponding bar code. It shall be left justified.

The Class name shall be printed and Attributes (except default Attributes) text should be printed on the label when space allows. Product description text should be printed with the Attributes proportionally smaller than the Class name.

Modifiers are no longer used with cellular therapy products. For facilities that have not moved to the new terminology, please consult version 1.0.0 of this Standard for instructions on how to print modifiers. For version 1.0.0 of this document, please contact the ICCBBA office.

Figure 12 Example of Relative Size of Class and Attributes Text

HPC, CORD BLOOD 10% DMSO Cryopreserved
--

On smaller labels, the full product description may not fit on the label. The Class name or approved abbreviation shall appear. Abbreviations of Class names [described in the *ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)*] may be used on partial labels if space does not permit the full name and if allowed by regulatory authorities. If abbreviations are used, the full Class name shall be used in the accompanying documentation.

If space does not permit, the Attributes may be included on attached labels or in accompanying documentation. Where space allows, a phrase such as “See Attached Documentation for Details” should appear when the Attributes are not printed on the label. Relative size of Class and Attributes should be as described above, if space permits.

Two Attributes may appear on the same line to conserve space.

Some Attribute groups encode only “yes/no” information. For example:

Other Additives Group

Default: Other Additives:No	Default. No additives other than as part of the anticoagulant solution at the time of collection.
Other Additives:Yes	Other additives. See accompanying documentation.

In this situation, it would be appropriate to print a statement on the label such as “Other Additives Present” and “See Attached Documentation for Details,” see Figure 13.

Figure 13 Printing of “Yes/No” Attributes

Partial label

A9999 17 123503 § R

S1482400 DESIGNATED

HPC, APHERESIS
10% DMSO
3rd Party Donor Component Present
Other Additives Present
Cryopreserved, Mobilized
See Attached Documentation for Details
Expiration Date/Time: 06 FEB 2017 10:18

For Use by Intended Recipient Only

Intended Recipient:
PATIENT, JOHN Q
Recipient ID: 123456777
Date of Birth: 13 MAR 1984

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

6.5 Dates

When bar codes for dates (collection or expiration) are present, the corresponding text shall be printed in the upper left quadrant for the collection date/time and lower right quadrant for the expiration date/time. When linear bar codes are present, the information shall appear beneath the corresponding linear bar code.

If bar codes for dates are not present, text information for collection date/time, if present, should appear in the upper left quadrant and text information for expiration date/time, if present, should appear in the lower right quadrant.

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

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

2018-06-05 15:15
OR
05 JUN 2018 15:15

When the default time of 23:59 is encoded, the time does not have to appear as text, although it is acceptable if it does appear.

2018-06-05
OR
05 JUN 2018

or

2018-06-05 23:59
OR
05 JUN 2018 23:59

If the product is to be shipped across time zones, AABB and FACT-JACIE Standards require that the text expiration date and time include the local time zone. In addition, the ISBT 128 Standard requires that the label also include the Coordinated Universal Time (abbreviated UTC, previously known as Greenwich Mean Time, or GMT) when the product is to be shipped across an international time zone.

The UTC shall be printed beneath the local time in parentheses with the designation "UTC." Italics may also be used to clearly differentiate UTC from local time. For example:

Expiration Date/Time:

15 JAN 2018 09:15 CST
(15 JAN 2018 15:15 UTC)

OR

2018-01-15 23:15 CST
(2018-01-15 15:15 UTC)

Note: It is recognized that local time zone designations may have little meaning internationally since two time zones may have the same abbreviation [e.g., CST can be China Standard Time (UTC+08 hours) or Central Standard Time in North America (UTC-06 hours)]. However, the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) believes that local time zones are more readily interpreted within a continent. For products shipped to different continents, UTC should be used to interpret time.

The Flexible Date and Time [Data Structure 031] allows the UTC to be encoded. With the right software, the local date and time can be calculated from the UTC. For additional information on use, see *Implementation Guide: Use of Flexible Date and Time [Data Structure 031]* (IG-024).

6.6 Text Not Associated with Electronically Readable Information

Text not associated with electronically readable information includes warnings (e.g., Do Not Irradiate) and information, such as the name of the intended recipient.

The placement of this information is not internationally standardized but may be nationally standardized. Users should review national documents for additional information.

If not nationally defined, facilities may add additional text to the label where space permits and there is a need. While the placement of this information is not standardized, examples in Chapter 7 provide some suggestions.

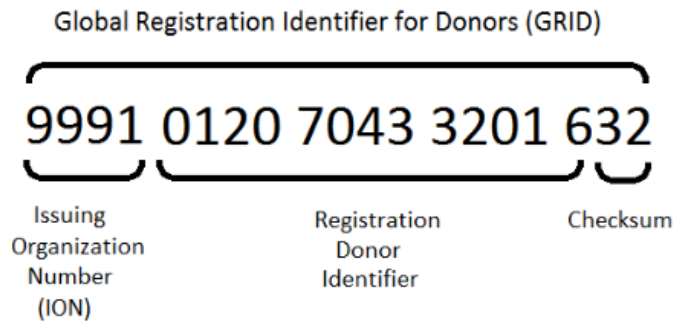
6.7 Global Registration Identifier for Donors

When printed in an eye-readable format, the GRID shall be divided into five blocks of 4,4,4,4,3 to assist manual transcription.

Spacing between the blocks shall be sufficient to ensure the blocks are clearly separated.

The GRID shall be printed in a font that allows differentiation between similar letters and digits (e.g., 0 and O, 1 and l).

An example of the full GRID eye-readable format is shown below.



When printed on a product label, the GRID shall be preceded with the uppercase letters GRID and a colon (i.e., GRID:) and placed in the upper right quadrant. See an example of the eye-readable GRID in Section 7, Figure 19.

GRID: 9991 0120 7043 3201 632

7 Label Examples

The following labels are provided as examples only. National regulations and appropriate standards must be consulted to ensure full compliance with requirements.

7.1 Full 100 mm x 100 mm Label

Figure 14 Collection Label


	
A9996 17 883448  	
Collection Center 2nd line of name City, State/Province/Country, Postal Code	
Collection Date and Time	28 AUG 2017 14:14
	For Autologous Use Only
	
S1152100	
HPC, MARROW	
Total Volume ____ ml containing approx ____ mL Heparin (____ units/mL)	Donor/Recipient: MAYNARD, JONATHAN B Recipient ID: 123456472 Date of Birth: 17 APR 1966
Store at room temperature	

Figure 15 Label at Time of Release of Product (Designated)






 A9999 17 123456 8 9 Collection Center or Registry Anywhere, Worldwide	 4700 ○ RhD POSITIVE
Collection Date/Time  0170091330 09 JAN 2017 13:30 CET (09 JAN 2017 12:30 UTC)	FOR USE BY INTENDED RECIPIENT ONLY Related Donor: SMITH, JOHN P Donor ID: 123654987 Date of Birth: 17 NOV 1983
Do Not Irradiate Do Not Use Leukoreduction Filter  S1226400	 0170101330 10 JAN 2017 13:30 CET (10 JAN 2017 12:30 UTC) Expiry Date and Time
MNC, APHERESIS Total Volume <u>103</u> mL containing approx <u>6</u> mL Citrate Store at 1C to 10C	Intended Recipient: SMITH, MARTHA P Recipient ID: 123456789 Date of Birth: 12 Oct 1968 Processing Laboratory Elsewhere, Worldwide

Figure 16 Label at Time of Release of Product (Autologous Biohazard)












 A9999 17 123456 8 9 Collection Center or Registry Anywhere, Worldwide	 5400 ○ RhD POSITIVE
Collection Date and Time  0170351345 2017-02-04 13:45 EST (2017-02-04 18:45 UTC)	 BIOHAZARD FOR AUTOLOGOUS USE ONLY
Do Not Irradiate Do Not Use Leukoreduction Filter  S1143X00	 0270352359 2027-02-04 23:59 EST (2027-02-05 04:59 UTC) Expiry Date and Time
HPC, APHERESIS 10% DMSO Cryopreserved Mobilized Total Volume <u> </u> mL containing approx <u> </u> mL Citrate Store at -150 C or Colder	Donor/Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 Dec 1984 Processing Facility Elsewhere, Worldwide

Figure 17 Label at Time of Release of Product (Autologous, Not Biohazard)

		 RhD POSITIVE
A9999 17 123456 8 9	5300	
Collection Center or Registry Anywhere, Worldwide		
Collection Date and Time		FOR AUTOLOGOUS USE ONLY
	0170360915	
	2017-02-05 09:15	
Do Not Irradiate Do Not Use Leukoreduction Filter		
		Expiry Date and Time
S1123100	0270362359	2027-02-05 23:59
HPC, APHERESIS		
10% DMSO Cryopreserved Mobilized		Donor/Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 Dec 1984
Total Volume __ mL		
Store at -150 C or Colder		 Processing Laboratory Elsewhere, Worldwide

Note: This example shows both linear bar codes and a 2-D symbol. When space allows, this may be desirable. Linear bar codes are useful if the product is shipped to a facility that does not have imaging scanners; 2-D symbols are more efficient since all information is entered with a single scan.

Figure 18 Flexible Date and Time







 A9996 17 123456 S S Collection Center or Registry City, State, ZIP Code	 4700  RhD POSITIVE
 2002201703311015 Collection Date and Time 2017-03-31 12:15 CEST (2017-03-31 10:15 UTC)	For Use by Intended Recipient Only Related Donor, 1st or 2nd degree JOHNSON, MICHAEL A Donor ID: W0001 123654987 Date of Birth: 1972-03-04
Do Not Irradiate Do Not Use Leukoreduction Filter	
 S1697400 DESIGNATED	 2001201704021015 Expiration Date/Time 2017-04-02 12:15 CEST (2017-04-02 10:15 UTC)
HPC, MARROW 3rd Party Blood Component Present Other Additives Present Mononuclear Cells Enriched See Accompanying Documentation	Intended Recipient: JOHNSON, JOHN Q Recipient ID: 123456789 Date of Birth: 1996-01-03
Total Volume ___ mL containing approx ___ mL Heparin (___ U/mL)	Processing Laboratory Name 2nd Line of Name City, State, ZIP Code
Store at room temperature	

Figure 19 GRID in Eye-Readable Text Only







 A9996 17 123456 S S Collection Center or Registry City, State, ZIP Code	 4700  RhD POSITIVE
 2002201703311015 Collection Date and Time 2017-03-31 12:15 CEST (2017-03-31 10:15 UTC)	For Use by Intended Recipient Only
Do Not Irradiate Do Not Use Leukoreduction Filter	GRID: 9991 0120 7043 3201 632
 S1697400 DESIGNATED	 2001201704021015 Expiration Date/Time 2017-04-02 12:15 CEST (2017-04-02 10:15 UTC)
HPC, MARROW 3rd Party Blood Component Present Other Additives Present Mononuclear Cells Enriched See Accompanying Documentation	Intended Recipient: JOHNSON, JOHN Q Recipient ID: 123456789 Date of Birth: 1996-01-03
Total Volume ___ mL containing approx ___ mL Heparin (___ U/mL)	Processing Laboratory Name 2nd Line of Name City, State, ZIP Code
Store at room temperature	

Figure 20 GRID in Linear Bar Code and Eye-Readable Text








 A9996 17 123456 ♂ [S] Collection Center or Registry City, State, ZIP Code	 4700  RhD POSITIVE
 2002201703311015 Collection Date and Time 2017-03-31 12:15 CEST (2017-03-31 10:15 UTC)	For Use by Intended Recipient Only  9991012070433201632 GRID: 9991 0120 7043 3201 632
Do Not Irradiate Do Not Use Leukoreduction Filter  S1697400 DESIGNATED	 2001201704021015 Expiration Date/Time 2017-04-02 12:15 CEST (2017-04-02 10:15 UTC)
HPC, MARROW 3rd Party Blood Component Present Other Additives Present Mononuclear Cells Enriched See Accompanying Documentation	Intended Recipient: JOHNSON, JOHN Q Recipient ID: 123456789 Date of Birth: 1996-01-03
Total Volume ___ mL containing approx ___ mL Heparin (___ U/mL)	Processing Laboratory Name 2nd Line of Name City, State, ZIP Code
Store at room temperature	

Figure 21 GRID in 2-D Symbol and Eye-Readable Text






 A9996 17 123456 ♂ [S] Collection Center or Registry City, State, ZIP Code	 4700  RhD POSITIVE
 2002201703311015 Collection Date and Time 2017-03-31 12:15 CEST (2017-03-31 10:15 UTC)	For Use by Intended Recipient Only  GRID: 9991 0120 7043 3201 632
Do Not Irradiate Do Not Use Leukoreduction Filter  S1697400 DESIGNATED	 2001201704021015 Expiration Date/Time 2017-04-02 12:15 CEST (2017-04-02 10:15 UTC)
HPC, MARROW 3rd Party Blood Component Present Other Additives Present Mononuclear Cells Enriched See Accompanying Documentation	Intended Recipient: JOHNSON, JOHN Q Recipient ID: 123456789 Date of Birth: 1996-01-03
Total Volume ___ mL containing approx ___ mL Heparin (___ U/mL)	Processing Laboratory Name 2nd Line of Name City, State, ZIP Code
Store at room temperature	

7.2 Labeling Containers Smaller than 100 mm x 100 mm

Figure 22 48 mm x 76 mm Final Label (Designated)



 A9996 17 123456 Ⓢ [S]  S1142400 HPC, APHERESIS Collection Date: 15 JUN 2017 Expiry Date: 15 JUN 2027 <i>Partial label</i>	Collection Center or Registry Anywhere, Worldwide	 A9996 17 123456 Ⓢ [S] Product: S1142400 HPC, APHERESIS 6% HES + 5% DMSO Cryopreserved Mobilized Store at -150 C or Colder Collection Date: 15 JUN 2017 Expiry Date: 15 JUN 2027 <i>Partial label</i>
Intended Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984 Processing Facility Anywhere, Worldwide	Intended Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984 Processing Facility Anywhere, Worldwide	

Figure 23 48 mm x 76 mm Final Label (Autologous Biohazard)

 A9996 17 123456 Ⓢ [S]  S1142X00 HPC, APHERESIS Collection Date: 15 JUN 2017 Expiry Date: 15 JUN 2027 <i>Partial label</i>	 A9996 17 123456 Ⓢ [S] Product: S1142X00 HPC, APHERESIS 6% HES + 5% DMSO Cryopreserved, Mobilized ___ mL containing ___ mL Citrate + ___ mL Heparin (___ units/mL) Store at -150 C or Colder Collection Date/Time: 15 JUN 2017 09:15 Expiry Date/Time: 15 JUN 2027 23:59 Collection Center or Registry Anywhere, Worldwide <i>Partial label</i>
 BIOHAZARDOUS FOR AUTOLOGOUS USE ONLY Donor/Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984 Processing Facility Anywhere, Worldwide	 BIOHAZARDOUS FOR AUTOLOGOUS USE ONLY Donor/Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984 Processing Facility Anywhere, Worldwide

Note: With linear bar codes, there is not enough space to include Attribute text.

Figure 24 96 mm x 38 mm Final Label (Designated)

 <p>A9999 17 123456 8 [9]</p>  <p>S1142400</p> <p>HPC, APHERESIS</p> <p>Collection Date: 15 JUN 2017 Expiry Date: 15 JUN 2027 <i>Partial Label</i></p>	<p>Intended Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984</p> <p>Processing Facility Anywhere, Worldwide</p>
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 <p>A9999 17 123456 8 [9] Product: S1142400</p> <p>HPC, APHERESIS</p> <p>6% HES + 5% DMSO Cryopreserved Mobilized Store at -150 C or Colder</p> <p>Collection Date/Time: 15 JUN 2017 10:15 Expiry Date/Time: 15 JUN 2027 23:59</p> <p>Collection Center or Registry Anywhere, Worldwide <i>Partial Label</i></p>	<p>Intended Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984</p> <p>Processing Facility Anywhere, Worldwide</p>
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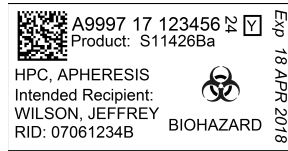
Figure 25 96 mm x 38 mm Final Label (Autologous, Biohazard)

 <p>A9999 17 123456 8 [9]</p>  <p>S1142X00</p> <p>HPC, APHERESIS</p> <p>Collection Date: 15 JUN 2017 Expiry Date: 15 JUN 2027 <i>Partial Label</i></p>	 <p>BIOHAZARD FOR AUTOLOGOUS USE ONLY</p> <p>Donor/Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984</p> <p>Processing Facility Anywhere, Worldwide</p>
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 <p>A9999 17 123456 8 [9] Product: S1142X00</p> <p>HPC, APHERESIS</p> <p>6% HES + 5% DMSO Cryopreserved Mobilized ___ mL containing ___ mL Citrate + ___ mL Heparin (___ units/mL) Store at -150 C or Colder Collection Center or Registry Anywhere, Worldwide Collection Date: 15 JUN 2017 Expiry Date: 15 JUN 2027 <i>Partial Label</i></p>	 <p>BIOHAZARD FOR AUTOLOGOUS USE ONLY</p> <p>Donor/Recipient: PATIENT, JOHN Q Recipient ID: 123456789 Date of Birth: 31 DEC 1984</p> <p>Processing Facility Anywhere, Worldwide</p>
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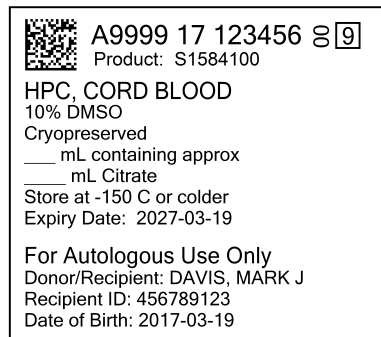
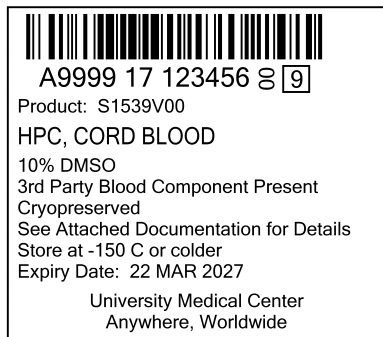
Note: With linear bar codes, there is not enough space to include Attribute text.

Figure 26 Cryo Vial Label



This label is 38 mm wide x 19 mm high. “Recipient Identification” has been abbreviated “RID.”

Figure 27 Other Small Labels



These labels are 50 mm wide x 44 mm high.

8 Glossary

General Terminology Used in ISBT 128 Coding and Labeling		
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 identifier. (The Donation Identification Number is an exception to this rule.)	
Data Identifier	The first two or three characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined. [The Donation Identification Number is an exception to this rule. The second character of the data identifier can never be dropped because it is also part of the data content. See <i>ISBT 128 Standard Technical Specification (ST-001)</i> .]	
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.	
Label	An independent entity that may carry one or more bar codes and also provides eye-readable information about the product.	
	Affixed Label	A label that adheres in physical contact with the product container.
	Attached Label	A label that is fastened securely to the product container by means of a tie-tag or comparable alternative.
	Accompanying Documentation	Documentation containing product information that is together with the product, or is available to the appropriate individual(s) electronically, but is not affixed or attached to the product.
	Final Label	Labeling as it appears on a product ready for release to another entity or for administration to a recipient.
	Partial Label	A label that because of size or other constraints does not contain all the required information.
	Product Label	Labeling applied to a product at various stages of processing by cellular therapy facilities.
UTC	Coordinated Universal Time, similar to GMT (Greenwich Mean Time), marks the starting point of every time zone in the World. UTC does not change based on daylight saving (summer) time; thus, the relationship of local time to UTC changes if daylight saving (summer) time is observed.	

Terminology Used in ISBT 128 Donation Numbering	
<p>Donation Identification Number + Flag Characters + Check Character</p> <p style="text-align: center;">Donation Identification Number</p>	
Donation Identification Number (DIN)	A thirteen-character code that identifies products from a single donation event. This identifier allows each donation event to be uniquely identified globally for a period of 100 years. The DIN comprises three elements: the Facility Identification Number (FIN), DIN year code, and DIN sequence number.
Facility Identification Number (FIN)	A five-character alphanumeric code assigned to facilities licensed to use ISBT 128 by ICCBBA. The code provides a globally unique identifier that is an essential element of a Donation Identification Number.
DIN Year Code	A two-character numeric code assigned by the facility that is used to ensure uniqueness of a Donation Identification Number for a period of 100 years.
DIN Sequence Number	A six-character numeric code assigned by a facility as part of the Donation Identification Number to ensure unique identification of each donation event.
Flag Character	Part of the data content of a data structure used in process control or data transmission checking. For ISBT 128, flag characters are used with the Donation Identification Number. Printed in eye-readable format, but distinguished in some manner from the representation of the other data characters.
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 and the ISO/IEC 7064 modulo 37-2 check character appended to text that verifies accurate keyboard entry.

Terminology Used in Product Coding	
	<p style="text-align: center;">Product Code</p> <p style="text-align: center;">S12124A0</p> <p style="text-align: center;">Product Description Code Division Code</p> <p style="text-align: center;">Collection Type Code</p>
Product Code	An eight-character ISBT 128 code that comprises the Product Description Code, a Collection Type Code, and a Division Code. The Product Code makes each product from a collection unique. This is the Data Content for the Product Code Data Structure.
Product Description Code	A five-character alphanumeric code assigned to each unique product type listed in the ISBT 128 database.
Collection Type Code	A one-character alphanumeric code indicating the type of collection (e.g., autologous, directed, or designated).
Division Code	A two-character code that uniquely identifies multiple products with the same Product Description Code and Donation Identification Number.

END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

[ST-001 ISBT 128 Standard Technical Specification](#)

[ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin](#)

[IG-022 Product Coding \[Data Structures 003 and 032\] - Cellular Therapy](#)

[IG-024 Use of Flexible Date and Time \[Data Structure 031\]](#)