



ISBT 128 STANDARD

Labeling of Collection Products for Cellular Therapy Manufacturing

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1 Introduction

1.1 Purpose

This document provides instructions for the labeling of apheresis collection products for sponsor cellular therapy clinical trials and manufacturing.

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification (ST-001)*. It defines the labeling requirements for cellular therapy apheresis collection products for further processing by a clinical trials sponsor or a manufacturer. The Standard can be used for labeling collection products for further manufacturing into clinical trials products or approved products.

The Standard is for use only in situations where the sponsor/manufacturer has adopted this Standard and has provided the necessary information to populate the sponsor/manufacturer section of the label. While designed for apheresis collection products, the use of the label on collection products for further processing from other sources is not prohibited. Future versions of this Standard may be extended to cover other sources of collection products.

This label is not to be used on products for direct infusion.

Users are advised to consult regulatory authorities in their own countries for information regarding regulations and accrediting organizations for information concerning standards other than ISBT 128. Regulatory requirements supersede requirements of the ISBT 128 Standard.

1.3 Intended Audience

The intended audience of this document is: clinical trials sponsors, manufacturers, staff at clinical trials facilities, apheresis collection centers, hospitals that receive clinical trials or manufactured products, software developers, and label/software vendors.

1.4 Normative References

ISBT 128 Standard Technical Specification (ST-001)

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

1.5 Other References

ICCBBA website (www.iccbba.org)

1.6 Background

Apheresis collection of starting products for use in cellular therapy manufacturing for clinical trials and commercial therapy is performed in blood center or hospital apheresis suites that are often under contractual arrangements with sponsors or third-party manufacturers. Currently, sponsors/manufacturers have different labeling requirements for these apheresis collections. This causes challenges for the collection centers, particularly in situations where a collection center collects on behalf of multiple organizations. The complexity of multiple label formats carries the potential for error, and associated near-miss events have been reported (13th Cell Therapy/FDA Liaison Meeting, Oct 2016).

By providing standardized, consistent labeling to all apheresis collection bags destined for further manufacturing by a sponsor/manufacturer, the risk of misinterpretation of patient data can be reduced.

ISBT 128 is a well-established and widely used international coding system for Medical Products of Human Origin (MPHO). It provides a comprehensive and highly flexible system for describing products and assigning product codes suitable for use in bar codes and other electronic communication. ISBT 128 is very widely used for labeling of cellular therapy products and is required by FACT-JACIE and AABB accreditation standards.

This Standard was developed by ICCBBA in collaboration with industry partners including: bluebird bio, GlaxoSmithKline plc., Gilead Sciences, Johnson & Johnson, Juno Therapeutics, Kite Pharma, Legend Biotech, National Marrow Donor Program (NMDP/Be The Match), Deloitte, AABB, FACT, Standards Coordinating Body for Regenerative Medicine, Trakcel, Vineti, and subject matter experts in apheresis nursing and quality assurance.

The Standard builds on the existing ISBT 128 standards for cellular therapy and uses compatible label dimensions. It retains the essential ISBT 128 traceability information while also accommodating sponsor/manufacturer information in a standardized manner.

2 Label Design

2.1 General Principles

The following general principles for ISBT 128 labeling shall 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 little importance to the end-user.

In the label design specification below, statements using the word “shall” are obligatory for compliance with this Standard, statements using the word “should” are optional but represent best practice, and statements using the word “may” are optional.

Where text is printed it shall comply with the text requirements specified in Section 4.

The following resources are available on the ICCBBA website to assist those designing labels:

- *ISBT 128 Standard Technical Specification (ST-001)* for information on the general requirements and supplementary guidance.
- *ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)* for information on the structure of the terminology and terms definitions.
- ISBT 128 Product Description Code Database (in the password-protected area) for a comprehensive list of the Product Description Codes (PDCs).
- ISBT 128 Product Lookup Web Application (in the password-protected area) to search for existing Product Description Codes (PDCs). If a suitable international code is not available, a Clinical Trials PDC may be requested.

2.2 Labeling Requirements

The label printed to affix to an apheresis collection set base label shall be an ISBT 128 standard nominal 4” x 4” (100mm x 100mm) label.

ISBT 128 traceability information shall be printed on the left side and information specific to clinical trial/manufactured products shall be printed on the right side.

2.2.1 Left Side Labeling Requirements

Information on the left side of the label shall include:

- The electronically readable Donation Identification Number (DIN) [Data Structure 001].
- The eye-readable Donation Identification Number (DIN), flag characters when required (rotated 90° clockwise), and the boxed check character (see Section 4.1).
- The words “Do Not Irradiate” in bold print.
- The electronically readable Product Code [Data Structure 003].
- The eye-readable Product Code.
- Text corresponding to the Product Code (see Section 4.2).

The following additional information is optional, but may be required by regulators in some regions:

- The name/address of the collection center may be printed below the eye-readable DIN.
- The eye-readable Collection Date and Time should be printed. This shall be the date/time when the apheresis collection was completed. The requirements for the date/time format are given in Section 4.3.
- The Single European Code (SEC). When printed, this shall be printed as either the Donation Identification Sequence (DIS) only—on a single line--or as a full SEC in two lines at the bottom of the label as indicated in Figure 2.

Figure 1 shows a label example with the required ISBT 128 information on the left side, while Figure 2 shows a label with both required and optional information.

Figure 1 Left Side with Only Required Information



Figure 2 Left Side with All Information



2.2.2 Right Side Labeling Requirements

Information on the right side of the label shall include:

- If the product is part of a clinical trial, the words: For Clinical Trial Use Only.
- If the product is for autologous use only, the words: FOR AUTOLOGOUS USE ONLY.
- If the product is derived from an unrelated donor, the words: Unrelated Donor.
 - If the GRID of the unrelated donor is known, it should be printed below this statement.
- If the product is derived from a related donor, the words: Related Donor.
 - The Donor Identification Number and/or the name and date of birth may be printed below this statement.
 - The donor name should be in the format: family name(s) first, followed by a comma, and then given name(s).
 - The requirements for the date/time format are given in Section 4.3.
- Intended Recipient Identification Number:
 - This identifier is required if the product is an autologous or related donor therapy.
 - In all other cases, the identifier should be printed if assigned by the sponsor or manufacturer.
- Expiration date, and where appropriate, expiration time. The requirements for the date/time format are given in Section 4.3.
 - Expiration date is optional for cryopreserved products but may be required by regulators in some regions.
- Chain of Identity (COI) identifier assigned by sponsor/manufacturer.
- The sponsor/manufacturer Protocol Identifier if provided.
- Sponsor or manufacturer identification, indicated using a name or logo.

The following additional information is optional, but may be required by regulators in some regions:

- A Biohazard symbol may be printed in the top right corner of the label.
- The following may be printed below the Intended Recipient Identification Number:
 - The intended recipient name. This should be in the format: family name(s) first, followed by a comma, and then given name(s). For example: DOE, Charlie Alex.
 - The intended recipient date of birth. The requirements for the date/time format are given in Section 4.3.
- The following may be printed below the sponsor/manufacture Protocol Identifier:
 - Additional sponsor information that may include any of the following, but shall not exceed 4 lines of text with a minimum font size of 6:
 - A sponsor/manufacture allocated collection center site identifier.
 - A sponsor/manufacture allocated receiving facility identifier.
 - Other text specified by the sponsor/manufacture, for example: "Autologous Apheresis for Further Use in Manufacturing of XXXXXX Drug Product".
 - Other identifiers, such as the EudraCT clinical trial identifier.
- A Data Matrix two-dimensional (2-D) symbol should be included carrying an ISBT 128 Compound Message that includes the Donation Identification Number, Product Code, and Expiration Date/Time.

Figure 3 shows a label example for an autologous clinical trial product with only the required information on the right side. Figure 4 shows a label example with required and recommended information. Figure 5 shows a label example with required, recommended, and additional optional information.

Figure 3 Right Side with Only Required Information

	<p>For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI: 123ABC456DEF789GHI</p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;">Sponsor Info/Logo Area</div>
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Figure 4 Right Side with Required and Recommended Information




	<p>For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI: 123ABC456DEF789GHI Protocol: NCT99999999</p> <div style="text-align: center;"></div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 10px auto;">Sponsor Info/Logo Area</div>
--	---

Figure 5 Right Side with All Information

	For Clinical Trial Use Only  FOR AUTOLOGOUS USE ONLY
	Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01 Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC) COI: 123ABC456DEF789GHI Protocol: NCT99999999 Collection Center Site No: 47 Autologous Apheresis for Further Use in Manufacturing of XXXXXX Drug Product 
	Sponsor Info/Logo Area

3 Encoding Product Information

Product information shall be encoded within electronically readable symbols using ISBT 128 internationally defined data structures.

The Donation Identification Number [Data Structure 001] and the Product Code [Data Structure 003] shall be encoded using linear bar codes.

A Data Matrix 2-D symbol should be included. If present, this shall contain an ISBT 128 Compound Message that includes the Donation Identification Number [Data Structure 001], the Product Code [Data Structure 003], and, when known, the Expiration Date/Time [Data Structure 005].

All bar codes shall comply with the *ISBT 128 Standard Technical Specification* (ST-001).

4 Printing Label Text

Particular font sizes and types are not specified, but designers shall ensure clarity of all text.

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

Larger fonts shall be used to emphasize critical information.

4.1 Text Corresponding to the Donation Identification Number [Data Structure 001]

The Donation Identification Number (DIN), the flag characters (if non-zero), and the check character shall be printed.

The layout of the 13-character DIN may be nationally defined with spacing to provide blocks of characters for easier transcription.

The flag characters, if printed, shall be rotated 90° clockwise.

The check character shall be enclosed in a box.

Examples of DIN text are shown in Figure 6.

Figure 6 Examples of Printed Text for the Donation Identification Number [Data Structure 001]

A999920123456 9 K

A9999 20 123456 K

4.2 Text Corresponding to the Product Code [Data Structure 003]

Text corresponding to the Product Description Code (PDC) shall be printed on the label.

4.2.1 Products Labeled with an ISBT 128 International Product Description Code

The following shall be printed:

- Class name.
- Product attributes (except default attributes).
- Anticoagulant.
- Temperature at which the product should be stored.



The text does not have to match exactly with the product description found in the ISBT 128 Product Description Code Database. It may vary but should convey the same product information.

The order and size of text relating to the product description should be based on the importance of the information to the end user. In general, the class name will be in larger print than the attributes.

Text corresponding to the Division Code may be printed following the word “Part” (or equivalent term).

An example of text associated with an international PDC is shown in Figure 7.

Figure 7 Printed Text for the Product Code [Data Structure 003]

 A9996 20 123458 Z	
Do Not Irradiate  S13031A0	
Class Name Attribute Anticoagulant Storage Temperature..... Division Code	<ul style="list-style-type: none"> • MNC, APHERESIS • For Further Processing <p style="margin-left: 20px;">Total Volume ___ mL containing approx ___ mL Citrate</p> <ul style="list-style-type: none"> • Store at 1 to 10 C • Part A0

4.2.2 Products Labeled with a Clinical Trials Product Description Code

The sponsor/manufacturer product name shall be printed.

Text corresponding to the Division Code may be printed following the word “Part” (or equivalent term).

4.3 Dates and Times

Dates shall be printed in compliance with ISO 8601-2004 numeric extended format [YYYY]-[MM]-[DD]. For example, September 27, 2020 is represented as 2020-09-27.

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

When the default time of 23:59 is encoded, the text representation of the time is not required.

Example text for date and time is shown below:

2020-06-25 15:15

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:
2020-01-15 23:15 CST
(2020-01-15 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) believe that local time zones are more readily interpreted within a continent. For products shipped to different continents, UTC should be used to interpret time.)

5 Label Examples

Figure 8 Full Label – Refrigerated Product


 <p>A9996 20 123458 </p> <p>Collection Center City, State, Country, Postal Code</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S1303100</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p>	<p>For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI: 123ABC456DEF789GHI Protocol: NCT99999999</p> <p>Collection Center Site No: 47 Autologous Apheresis for Further Use in Manufacturing of XXXXXX Drug Product</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>Sponsor Info/Logo Area</p> </div>
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Figure 9 Full Label – Cryopreserved Product with No Expiration

 <p>A9996 20 123458 Ⓢ Z</p> <p>Collection Center City, State, Country, Postal Code</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S2535100</p> <p>MNC, APHERESIS 10% DMSO Concurrent plasma Cryopreserved</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at -150 C or colder</p> <p>SEC: GB000123A999620123458</p>	<p>For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01</p> <p>COI:123ABC456DEF789GHI Protocol: NCT99999999</p> <p>Collection Center Site No: 47 Autologous Apheresis for Further Use in Manufacturing of XXXXXX Drug Product</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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Figure 10 Full Label with Single European Code (SEC)

 <p>A9996 20 123458 Ⓢ Z</p> <p>Collection Center City, State, Country, Postal Code</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S1303100</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p> <p>SEC: GB000123A999620123458 A00S130300020200117</p>	<p>For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI: 123ABC456DEF789GHI Protocol: NCT99999999</p> <p>Collection Center Site No: 47 EudraCT: 2019-999999-01</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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Figure 11 Post Clinical Trial Approval

 <p>A9996 20 123458 Ⓢ Z</p> <p>Collection Center City, State, Country, Postal Code</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S1303100</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p>	<p>FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI: 123ABC456DEF789GHI Protocol: NCT99999999</p> <p>Collection Center Site No: 47 Autologous Apheresis for Further Use in Manufacturing of XXXXXX Drug Product</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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Figure 12 Full Label – Related Donor

 <p>A9996 20 123458 Ⓢ Z</p> <p>Collection Center City, State, Country, Postal Code</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S1303400</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p>	<p>For Clinical Trial Use Only Related Donor</p> <p>Donor Name: DOE, Alex Charlie Donor DOB: 2000-07-31</p> <p>Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI: 123ABC456DEF789GHI Protocol: NCT99999999</p> <p>Collection Center Site No: 47</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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Figure 13 Full Label – Unrelated Donor





 <p>A9996 20 123458 </p> <p>Collection Center City, State, Country, Postal Code</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S1303400</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p>	<p>For Clinical Trial Use Only Unrelated Donor</p> <p>GRID: 9991 0120 7043 3201 632</p> <p>Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI:123ABC456DEF789GHI Protocol: NCT99999999</p> <p>Collection Center Site No: 47</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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Figure 14 Full Label with Only Required Information




 <p>A9996 20 123458 </p> <p>Do Not Irradiate</p>  <p>S1303100</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p>	<p>For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI:123ABC456DEF789GHI Protocol: NCT99999999</p> <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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Figure 15 Full Label with Required and Recommended Information




 <p>A9996 20 123458 Ⓢ Z</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S1303100</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p> <p>SEC: GB000123A999620123458 A00S130300020200117</p>	<p>For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY</p> <p>Intended Recipient: Recipient ID: XXN127654</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI:123ABC456DEF789GHI Protocol: NCT99999999</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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Figure 16 Full Label with All Information

 <p>A9996 20 123458 Ⓢ Z</p> <p>Collection Center City, State, Country, Postal Code</p> <p>Collection Date and Time 2020-01-14 13:40</p> <p>Do Not Irradiate</p>  <p>S1303600</p> <p>MNC, APHERESIS For Further Processing</p> <p>Total Volume ___ mL containing approx ___ mL Citrate</p> <p>Store at 1 to 10 C</p> <p>SEC: GB000123A999620123458 A00S130300020200117</p>	<p>For Clinical Trial Use Only Related Donor </p> <p>Donor Name: DOE, Alex Charlie Donor DOB: 2000-07-31</p> <p>Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01</p> <p>Expiration Date/Time: 2020-01-17 13:40 EST (2020-01-17 18:40 UTC)</p> <p>COI:123ABC456DEF789GHI Protocol: NCT99999999</p> <p>Collection Center Site No: 47 EudraCT: 2019-999999-01</p>  <div style="border: 1px solid black; padding: 5px; text-align: center;">Sponsor Info/Logo Area</div>
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