ISBT 128 Standard

Labeling of Blood Components

Version Number 2.0.1

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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 blood products.

1.2   Scope

This document provides guidance in the design of labels for blood products following the Standards described in the *ISBT 128 Standard Technical Specification* (ST-001).

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 blood collection and processing centers and transfusion services (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 for Base Labels (ST-023)

ISO 8601-2004 Data elements and interchange formats — Information interchange — Representation of dates and times

1.5   Other References

ICCBBA:
ICCBBA publications are maintained on the ICCBBA Website. It is the responsibility of registered and licensed establishments to ensure that they have the most recent version of all ICCBBA publications by regularly consulting the listing maintained on the ICCBBA Website. A subscription email notification system is available on the ICCBBA Website. The following listing is current as of the date on the front cover of this document.

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

Implementation Guides
        Use of Product Code [Data Structure 003], Blood (IG-021)
        Use of Red Cell Antigens with Test History [Data Structure 030] (IG-027)

1.6   Background

A specification for the use of ISBT 128 for the labeling of 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.

International standardization of labeling is a key element of ISBT 128. Standardized bar codes allow blood products to be shipped internationally with clear, unambiguous labeling and can be used to overcome language barriers.

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. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

Version Control: Version 2.0.0 vs. Version 2.0.1

	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 documents' tracking number text.	For consistency and to provide quick access to the reference documents.

2 Data Structures

The data structures that will commonly be used for affixed labels on blood 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]
- Production Date [Data Structure 008] or Production Date and Time [Data Structure 009]
- Special Testing: General [Data Structure 010]
- Special Testing: Red Cell Antigens [Data Structure 012]
- Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]
- Compound Message [Data Structure 023]
- Dimensions [Data Structure 029]
- Red Cell Antigens with Test History [Data Structure 030]

Detailed information for all data structures is found in the *ISBT 128 Standard Technical Specification*.

3 Electronically Readable Symbols

Linear bar codes (Code 128) are used currently to label blood products. Two-dimensional (2-D) symbols (Data Matrix) are encouraged to be used instead of, or in addition to, linear bar codes on blood labels to improve efficiency. 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 1) and allowing a single scan to convey a great deal of information.

Figure 1 Comparison of 2-D and Linear Bar Codes

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

Data Matrix   Code 128

Donation Identification Number

Blood Group (ABO/RhD)

Product Code

Expiration Date/Time

Special Testing Results
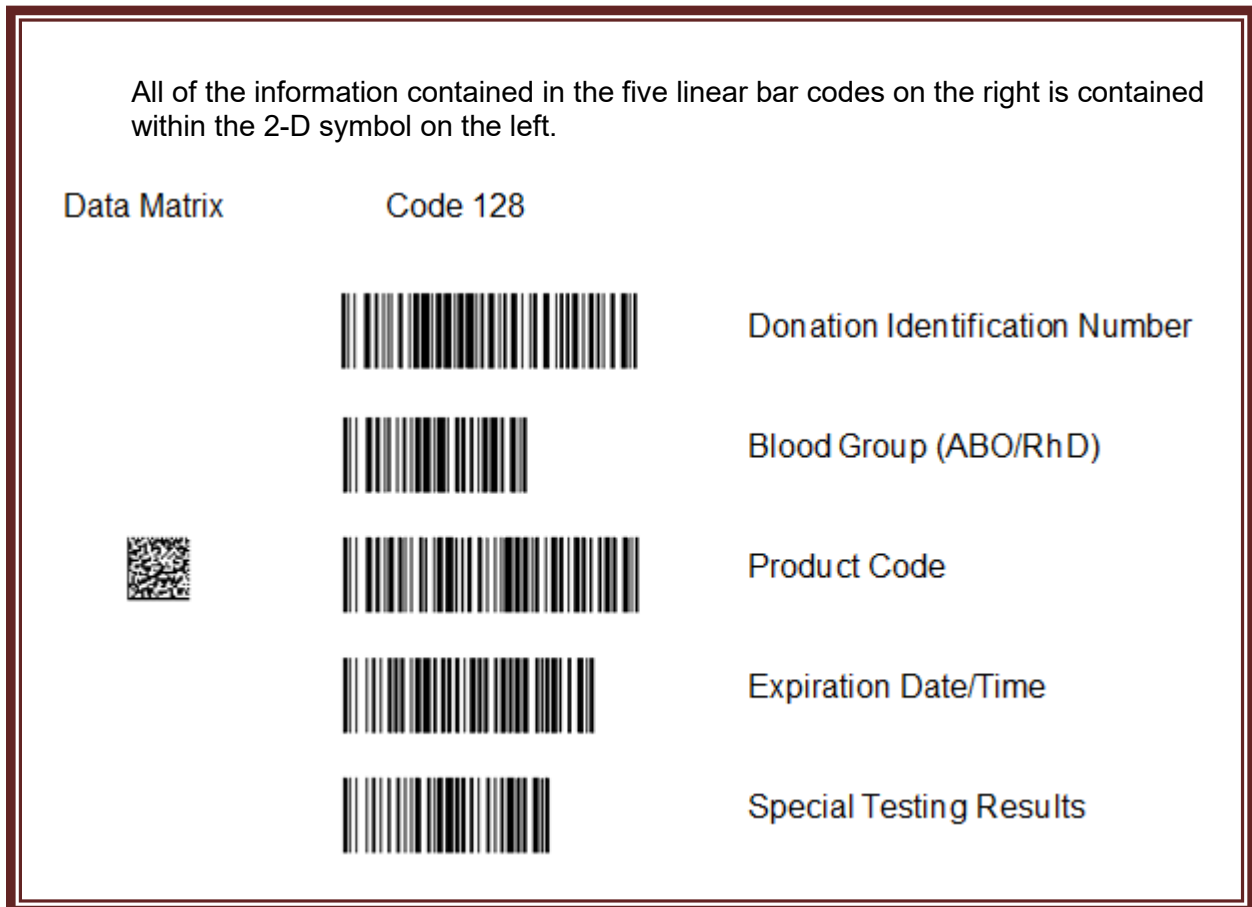
The use of RFID technology for blood components should comply with the guidelines published in Vox Sanguinis [Knels R, Davis R, Ashford P, et al: Guidelines for the use of RFID technology in transfusion medicine. Vox Sang 2010; 98(S2):1-24]. These guidelines recommend:

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

Additional guidance will be provided as this, or similar, technology develops.

4 Labeling Considerations

4.1 National Labeling Guidelines

National bodies may publish guidelines for labeling which adhere to the ISBT 128 Standard, as well as the rules set forth in this document. 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).

4.2 General Principles

Two general label types are specified in ISBT 128:

- Base label - the label applied by the manufacturer of the container.
- Final label - the label placed on a product container by the processing facility.

    Note: Facilities may also apply intermediate or in-process labels.

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 little importance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

- The use of color (for example, for ABO) is neither prohibited nor encouraged.

4.3 Printing of Bar Codes

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

4.4 Final Label Dimensions

4.4.1 100 mm by 100 mm Final Label

The default size of the final label is 100 (+/-2) mm by 100 (+/-2) mm. The final 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.

Recognizing the potential for overlap between the limits of tolerance for the base label dimensions (refer to ST-023) and final label dimensions, the final label dimensions should be no larger than the base label.

4.5   Final Label Bar Code Placement

When linear bar codes are used, the final label design shall be based upon the concept of four equal 50 (+/-1) mm by 50 (+/-1) mm quadrants.

The bar codes shall be placed in these quadrants as shown in Table 1.

When linear bar codes are used, Data Structures 001, 002, 003 and 005 shall be present and positioned as described in Table 2. These requirements place the bar codes in an ideal position for concatenation.

No vertical lines may appear between pairs of bar codes that are meant to be concatenated.

Linear bar codes for other Data Structures found on the final label, and the Data Matrix symbol, are optional and if used should be positioned as described on Table 3.

When present, the Data Matrix symbol shall include the four data structures (001, 002, 003, and 005) required for linear bar codes. Additional ISBT 128 data structures (excluding nationally defined structures) may also be included.

Figure 2, page 13, shows final label printed according to these tables.

Table 1 Final Label Quadrants and Bar Codes [RT022]

Quadrant	Data Structure [Reference number]
Upper Left	Donation Identification Number (required) [001]
	Collection Date and Time (optional) [006, 007] or Production Date and Time (optional) [008, 009]
Lower Left	Product Code (required) [003]
	Dimensions (optional) [029]
Upper Right	ABO/RhD Blood Group (required) [002]
Lower Right	Expiration Date and Time (required) [005]
	Special Testing (optional) [010,011,012,013,014,015,016]

Table 2 Required Positioning of Bar Codes on Final Labels [RT023]

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

* Concatenation distances must also be maintained

Table 3 Recommended Positioning of Bar Codes on Final Labels [RT024]

While these barcodes shall be placed in the quadrants indicated, their exact placement within the quadrant is not mandated.

Bar Code	Vertical Alignment	Horizontal Alignment
Collection Date (and Time) [006, 007] or Production Date (and Time) [008, 009]	20 mm ± 2mm from top of Upper Left Quadrant*	Bar code right edge should be at 4 mm ± 2mm from right edge of Upper Left Quadrant*
Special Testing [one of several alternative data structures]	20 mm ± 2mm from top of Lower Right Quadrant*	Bar code left edge should be at 4 mm ± 2mm from left edge of Lower Right Quadrant*
Dimensions [029]	As close to the bottom of the label as practical*	Bar code right edge should be at 4 mm ± 2mm from right edge of Lower Left Quadrant*
Data Matrix symbol (for transition labels)	Nationally defined	Nationally defined
Data Matrix symbol	The exact vertical placement of the Data Matrix symbol is variable based on the size of the symbol	The horizontal placement of the Data Matrix symbol should be along the vertical center line within the upper half

* Concatenation distances must also be maintained

Figure 2 Placement and Nominal Size of Bar Codes on Final Label
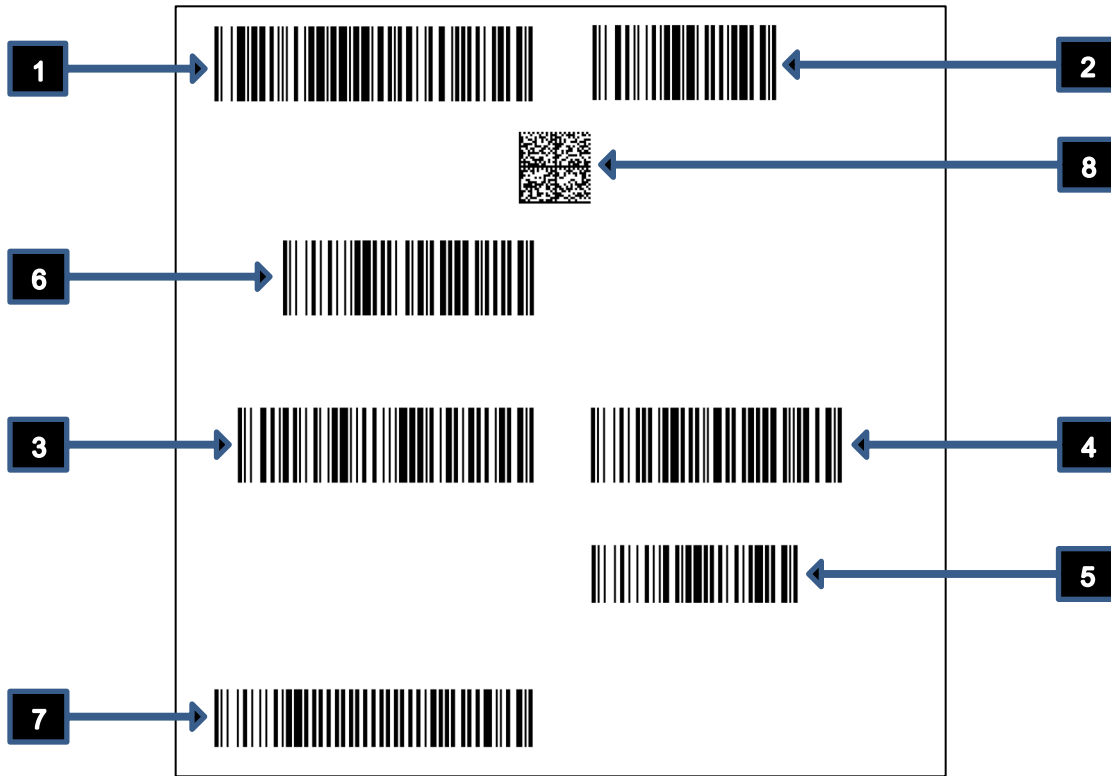
Required Bar Codes
1 – Donation Identification Number
2 – ABO/RhD
3 – Product Code
4 – Expiration Date and Time

Optional Bar Codes and Symbols
5 – Special Testing
6 – Collection (or Production) Date or Date and Time
7 – Dimensions
8 – Data Matrix symbol

To assist in label design, if more than one linear bar code is to be placed in a quadrant, e.g., Expiration Date and Special Testing, some adjustment of the absolute position of bar codes other than those for Data Structures 001, 002, 003, and 005 is permissible. Additionally, depending on the amount of text that is required, it may be necessary to reduce bar code height in accordance with bar code height requirements described in the *ISBT 128 Standard Technical Specification.*

A library of example labels from different countries is posted on the ICCBBA Website.

4.5.1 Small Final Label

Some containers for distribution within a facility may require a smaller final label. In designing such labels the principles outlined in this chapter should be applied to the extent possible.

If the design includes use of linear bar codes with an X dimension of less than 0.25 mm, care should be taken to ensure that all scanners that will be used to read the label are able to do so.

At a minimum:
1) Every ISBT 128-labeled product shall carry an electronically readable Donation Identification Number and Product Code.
2) Every ISBT 128-labeled product shall carry a text Donation Identification Number and Product Code.
3) If linear bar codes are used and the affixed label is too small to carry both bar codes, then the DIN bar code shall appear on the affixed label, along with text DIN and Product Code. The DIN and Product Code bar codes shall also be carried together on an attached label or on accompanying documentation (*Note: For traceability, both the ISBT 128 DIN and the full Product Code, which includes the Product Description Code and the Division Code, are required on the affixed label.*)

When using small affixed labels, additional required information shall appear on an attached or accompanying labeling meeting national requirements.

4.6   2-D Label Design

When the 2-D Data Matrix symbol is used in place of linear bar codes, the 2-D label shall be divided into three regions: 1) upper half, 2) lower left, and 3) lower right.

Figure 3 2-D Label Design

```
┌─────────────────────────────────────┐
│                                      │
│            Upper Half                │
│         (100mm x 50mm)               │
│                                      │
│                                      │
├──────────────────┬───────────────────┤
│                  │                   │
│                  │                   │
│   Lower Left     │   Lower Right     │
│  (50mm x 50mm)   │  (50mm x 50mm)    │
│                  │                   │
│                  │                   │
└──────────────────┴───────────────────┘
```

The upper half region shall contain the Donation Identification Number, Product Code, product name, ABO/RhD, expiry date, volume, and the Data Matrix symbol.

The lower left region shall contain (as applicable) the collection date, storage conditions, regulatory text, static information, and collection facility.

The lower right region shall contain (as applicable) test result information and the processing facility (if different than the collection facility).

5 Text

5.1   Types of Label Text

There are three types of text for ISBT 128 labels:

- Text corresponding to data content: The eye-readable representation of the encoded data characters. For linear bar codes, it is printed left justified immediately below the bar code, unless otherwise specified.

- Text associated with electronically-readable information: The interpretation of the encoded data content.

- Text not associated with electronically-readable information: All other information on the label that is not associated with an encoded message.

Figure 4 Text Terminology Used in ISBT 128

A9999 17 123456 9

Accurate Blood Center
Anywhere, Worldwide

Text Not Associated with Electronically-Readable Information (previously called additional text)

Volunteer Donor

Text Corresponding to Data Content in a Linear Bar code (previously called Data content text)

E0311V00

RED BLOOD CELLS

ADENINE-SALINE (AS-1) ADDED
LEUKOCYTES REDUCED

_____ mL from 450 mL CPD Whole Blood
Store at 1 to 6 C

Text Associated with Electronically-Readable Information(previously called Barcode text)

5.2 Text Corresponding to Data Content

Every Code 128 (linear) bar code on a container label shall be accompanied by text corresponding to the encoded data content.

Data identifiers shall not appear as part of the label text.

Except for the DIN, text corresponding to the data content shall appear immediately below, but not touching, the linear bar code.

It shall commence in line with the leftmost bar of the bar code (left justified).

It shall be represented in a typeface that differentiates characters from numbers with a maximum height of 2 mm.

The DIN and Product Code shall appear in text when Data Matrix symbols are used. This is necessary to ensure adequate traceability since a product is uniquely identified based on the DIN and the Product Code. It is therefore essential that this information be available to the receiving facility in a human-readable format.

For other information that may be encoded in the 2-D symbol that is not in linear bar codes (e.g., Red Cell Antigens with Test History or Dimensions), text corresponding to the data content may appear in attached or accompanying documentation.

5.2.1 Donation Identification Number [Data Structure 001]

The text for a Donation Identification Number is unique in that it is the sole means of presenting the data content of the bar code, i.e., it serves the dual role of data content text and bar code text.

As bar code text, it shall be printed using a typeface that differentiates characters from numbers. A national authority should determine the grouping of characters in the DIN presentation, for example:

V4043 12 499999

B404 212 123 456

All data characters shall be printed. (The DIN is the only data structure for which the second data identifier character is also a data character).

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 (see *ISBT 128 Standard Technical Specification* and *Technical Bulletin 7: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution* (IG-010) for information about the use of flag characters).

When Type 1 or Type 2 flag characters are used (see *ISBT 128 Standard Technical Specification*) 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.

A9999 12 123456 ㄥ K

⇩

Flag Characters

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

A9999 12 123456 ▮ K

5.2.2 Keyboard Entry Check Character K

Refer to the *ISBT 128 Standard Technical Specification* for when a keyboard entry check character **K** shall be used in conjunction with specific data structures.

In the case of Donation Identification Number [Data Structure 001], the calculation shall be based on the Donation Identification Number only, i.e., excluding the flag characters.

Wherever the keyboard check character is printed, it shall be clearly distinguished from data content. When printed in association with the data content text, a box shall be printed around the keyboard entry check character.

For example, a Red Cell phenotype would be printed:

959789997599924799 D

It shall be printed in a typeface that clearly distinguishes alphabetic and numeric characters; e.g., there shall be no confusion between 1 (one) and I (capital letter I), or between 0 (zero) and O (capital letter O).

5.3   Text Associated with Electronically-Readable Information

This type of text is the interpretation of the data content (the data content of the bar code) in terminology meaningful to the user (see Figure 4). The text associated with electronically-readable information is nationally defined to allow for differences in language, regulatory requirements, and preferences.

Particular font sizes and types are not specified for bar code text but designers shall ensure clarity of all text and use larger fonts to emphasize critical information.

The font chosen should clearly differentiate between similar characters (e.g., O and 0; I and 1).

Text associated with electronically-readable information shall appear on the label.

If this is not possible (e.g., on a small syringe label or information corresponding to the Red Cell Antigen with Test History data structure), appropriate regulations and requirements of standard setting organizations should be consulted to determine what information shall appear on the affixed label and what information may be on an attached label or accompanying documentation.

5.3.1   Facility

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

Figure 5 Upper Left Quadrant Facility Bar Code Text

5.3.2   Blood Groups [ABO and RhD] [Data Structure 002]

ABO status may be printed black on white if RhD positive, and outline black on white if RhD negative, but this is not required.

RhD status for the Blood Groups [ABO and RhD] bar code text may be printed black on white if RhD positive; white on black if RhD negative, but this is not required.

Figure 6 Linear Label Upper Right Quadrant for Designated or Directed Donation

Figure 7 Linear Label Upper Right Quadrant for Autologous Donation
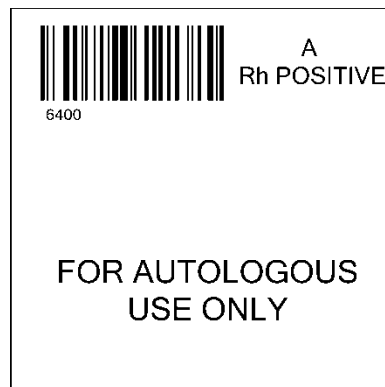
Figure 8 Linear Label Upper Right Quadrant for "Non-Specified" Donation
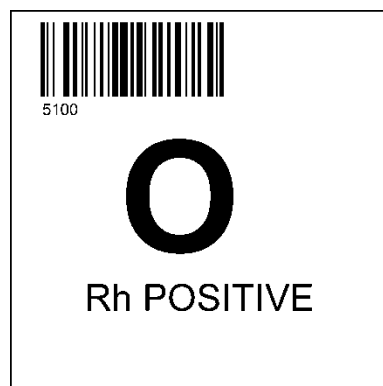
Figure 9 Linear Label Optional Differentiation of RhD Negative Units
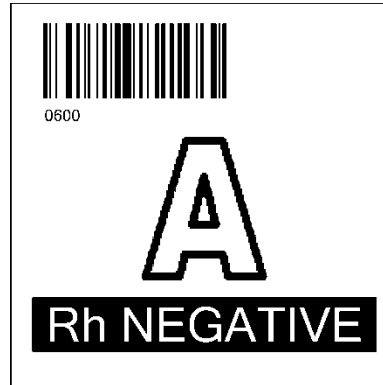
5.3.3 Product Descriptions [Data Structure 003]

Where space permits, the Class, Modifier, and Attributes (except default Attribute variables) text shall be printed on the label. See *Standard Terminology for Medical Products of Human Origin* for default attribute variables.

Product description bar code text should be printed with the Modifier proportionally smaller than the Class name and Attribute(s) text should be proportionately smaller than Modifier text.

Figure 10 Relative Text Size of Class, Modifier, and Attributes

WASHED
RED BLOOD CELLS
IRRADIATED
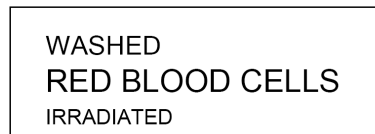
5.3.4 Dates [Data Structures 004, 005, 006, 007, 008, 009, 024]

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

Expiration Date:

2017-03-17
OR
17 MAR 2017

Note: Abbreviations for month shall comply with relevant national standards where applicable.

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

Time:
15:15

5.3.5 Month-Year [Data Structure 026]

The date shall be printed in compliance with ISO 8601-2004 extended format or in the format month — year. In the latter case, the month alphabetical expression shall use a three-letter abbreviation. The year shall be a four-digit numerical representation.

<div align="center">

2017-03

OR

MAR 2017

</div>

Note: Abbreviations for month shall comply with relevant national standards where applicable.

5.3.6 Special Testing, Red Blood Cell Antigens [Data Structures 011, 012, and 013]

Note: Data Structure 011 has been retired.

National guidelines should be consulted for specific information regarding the printing of this bar code text. As an example, rather than the complete red blood cell phenotype associated with Data Structure 012, the bar code text may read:

<div align="center">

Phenotype provided in
accompanying documentation.

</div>

or some similar phrase. Alternatively, the antigen profile relevant to the recipient may be emphasized with the notation that the remainder of the interpretation of the bar code is presented elsewhere.

5.3.7 Donor Identification Number [Data Structure 019]

The Facility Identification Number comprises the first five characters of the 21-character Donor Identification Number. The next 16 characters are defined by the facility.

When the facility-defined portion of Donor Identification Number is less than 16 digits, it shall be padded with zeros at the beginning of the actual number.

If desired, software developers may routinely strip off padding and present the actual number when printing the number or displaying the number on a screen.

For example:

In Denmark, a possible data content string would be: **000000 080656 1665**, a ten (10)-digit number with six (6) leading zeroes as padding. This number might display on a screen as **080656 1665.**

In France, it might be: **0 1 56 05 18 033 087 78**, a fifteen (15)-digit number with a single (1) leading zero as padding. This number might display on the screen as **1 56 05 18 033 087 78.**

5.4 Text Not Associated with Electronically-Readable Information

This type of text is defined as text not associated with a bar code or 2-D symbol. Additional text includes warnings (e.g., "This product may transmit infectious agents") and information such as Volunteer Donor or a platelet count on a platelet apheresis product.

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

If not nationally defined, facilities may add text not associated with electronically-readable information to the label where space permits and there is need.

Particular font sizes and types are not specified for text not associated with electronically-readable information but designers shall ensure clarity of all text and use larger fonts to emphasize critical information.

6 Label Examples

Figure 11 Final Label Example – Red Blood Cells

W0000 15 123456 ⊗ [D]
Accurate Blood Center
Anywhere, World

5100

O

Rh POSITIVE

VOLUNTEER DONOR

E0291V00

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED

From 450 mL CPD Whole Blood
Store at 1 to 6 C

0150312359

Expiration Date

31 JAN 2015

N0008

Negative for antibodies to CMV
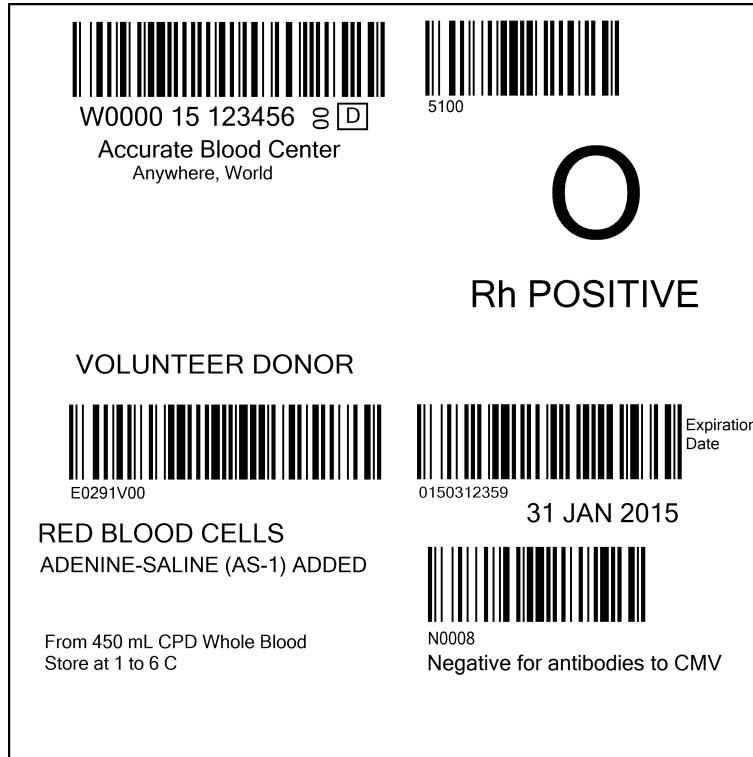
Figure 12 Final Label with Optional Collection Date

A9999 15 123456 ⊗ [6]
Accurate Blood Center
Anywhere, Worldwide

9500

Collection Date

0153542359

20 DEC 2015

O

Rh NEGATIVE

E0311V00

RED BLOOD CELLS

ADENINE-SALINE (AS-1) ADDED
LEUKOCYTES REDUCED

_____ mL from 450 mL CPD Whole Blood
Store at 1 to 6 C

0160312359

Expiry Date

31 JAN 2016

N0008

Negative for antibodies to CMV
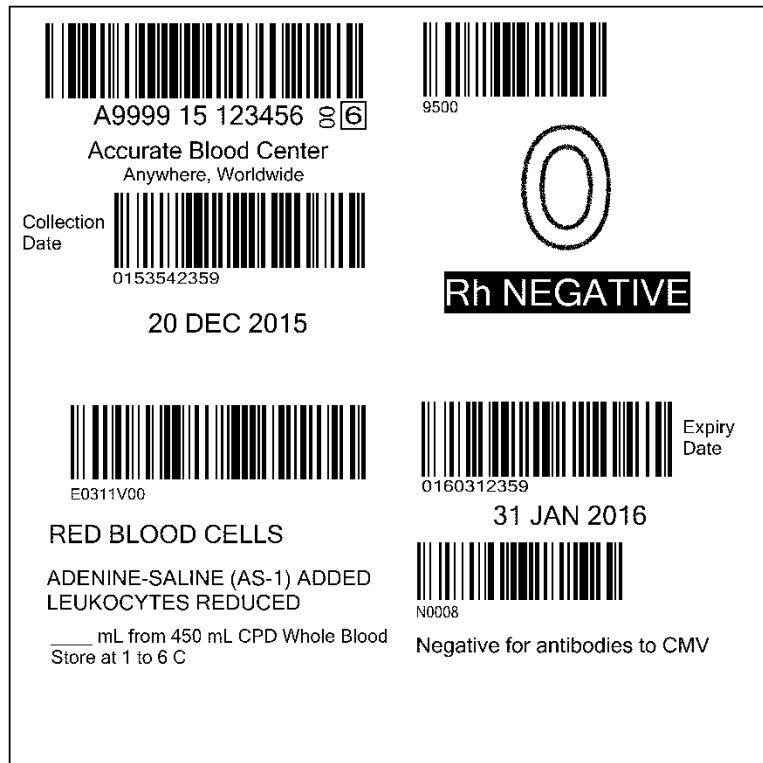
Figure 13 Example Transition Label with Linear Bar Codes and 2-D Symbol

A9999 16 123456 ☐Q

Accurate Blood Center
Anywhere, Worldwide

5100

O
RhD Positive

E0311V00

RED BLOOD CELLS

ADENINE-SALINE (AS-1) ADDED
LEUKOCYTES REDUCED

_____ mL from 450 mL CPD Whole Blood
Store at 1 to 6 C

0160312359

Expiry
Date

31 JAN 2016

950000008700027700 B

Negative for antibodies to CMV
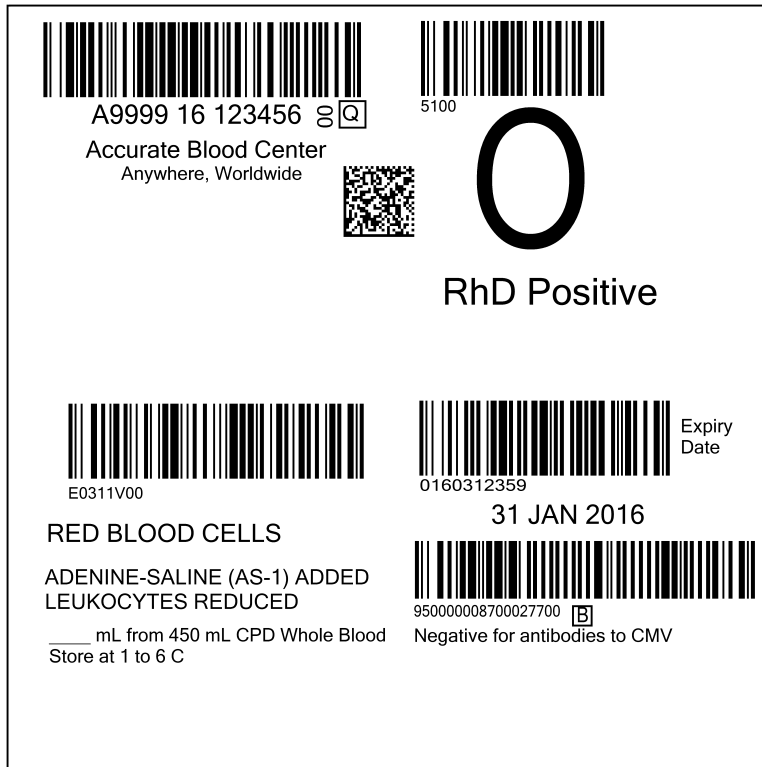
Figure 14 Final Label Example – Apheresis Platelets

A9999 15 123456 ☐6

Accurate Blood Center
Anywhere, Worldwide

5100

O
Rh POSITIVE

VOLUNTEER DONOR

E3046V00

APHERESIS
PLATELETS

IRRADIATED
LEUKOCYTE REDUCED

_____ mL containing approx _____ mL
ACD-A

Store at 20 to 24 C

0150312359

Expiration
Date

31 JAN 2015

022408279999999900 S

HLA-02,24;B08,27

Figure 15 Example 2-D Transition Label – Autologous Biohazard

W0000 14 123456 8 U

Accurate Blood Center
Anywhere, USA

Properly identify intended recipient.
See circular of information for indications,
contraindications, cautions, and methods
of infusion. This product may transmit
infectious agents.

Rx only
Collection Date   27 DEC 2014
VOLUNTEER DONOR

E0311X00   AUTOLOGOUS

RED BLOOD CELLS

ADENINE-SALINE (AS-1) ADDED
LEUKOCYTES REDUCED

From 450 mL CPD Whole Blood
Store at 1 to 6 C

O
Rh NEGATIVE
9800

BIOHAZARD
FOR AUTOLOGOUS
USE ONLY

0150312359

Expiration
Date

31 JAN 2015

Figure 16 Example 2-D Label

A9998 21 123456   8 0

Product: E4306V00

Apheresis
RED BLOOD CELLS

O
RhD POS

Exp: 31 MAY 2021 23:59

250 mL

Store at 2C to 6C
This component must not be used if
there are visible signs of deterioration.
Always check patient/component
compatibility/identity

Risk of infection including vCJD. Do not vent. This
component must be administered through a
transfusion set incorporating a 170 to 200um filter.
Contains pthalate (DEHP). Latex free.

This component was collected into 63ml of CPD
anticoagulant with the composition in. Anhydrous
Glucose 120 Sodium Citrate 89.4 Citric Acid
Monohydrate 15.6 Sodium Dihydrogen Phosphate
Dihydrate 16.1

Collection Facility:
Euro Blood Center
Megapolis, EU

Negative for:

C, E, K, Fy(a), Jk(a), S, Js(b)

CMV, HbS, H.T.

Figure 17 Example 2-D Label - Autologous

A9998 21 123456 8 [0]

O
RhD NEGATIVE

Product: E4306100

Apheresis

RED BLOOD CELLS

FOR AUTOLOGOUS
USE ONLY

Exp: 31 MAY 2021 23:59

250 mL

Store at 2C to 6C
This component must not be used if
there are visible signs of deterioration.
Always check patient/component
compatibility/identity

Risk of infection including vCJD. Do not vent. This
component must be administered through a
transfusion set incorporating a 170 to 200um filter.
Contains pthalate (DEHP). Latex free.

This component was collected into 63ml of CPD
anticoagulant with the composition in. Anhydrous
Glucose 120 Sodium Citrate 89.4 Citric Acid
Monohydrate 15.6 Sodium Dihydrogen Phosphate
Dihydrate 16.1

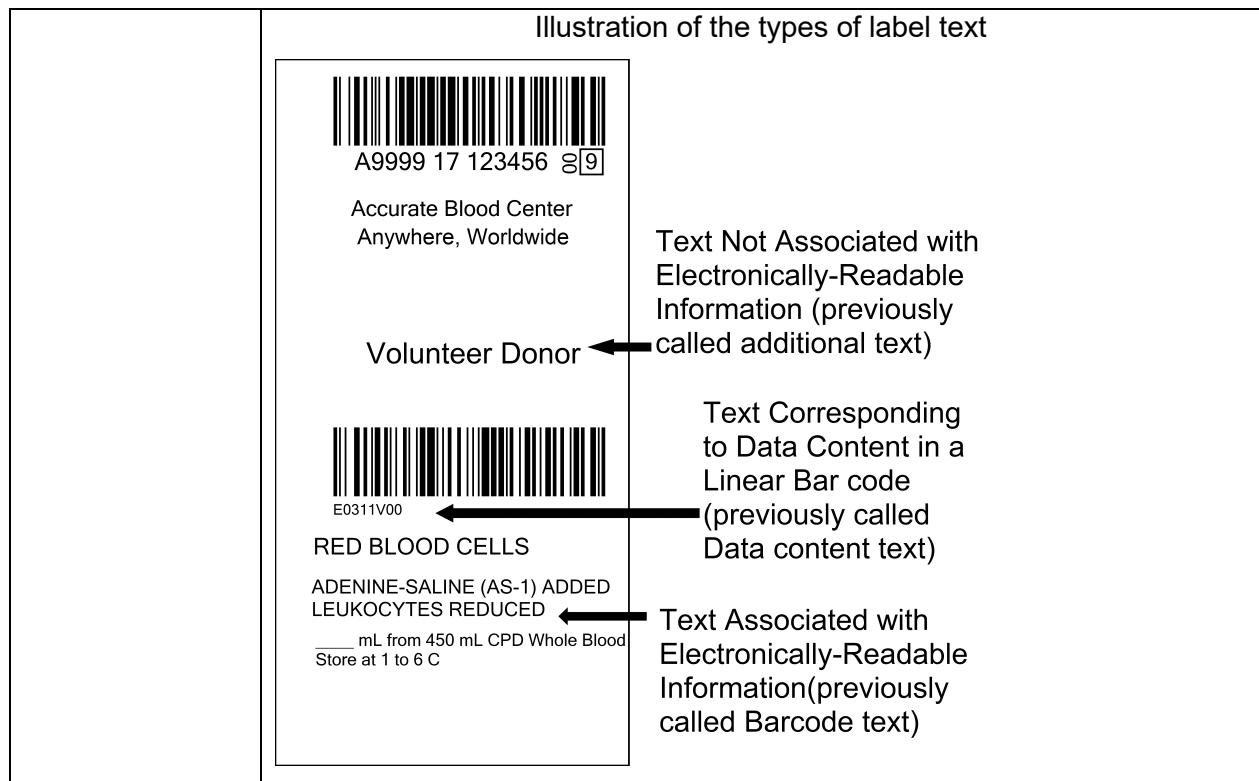Collection Facility:
Euro Blood Center
Megapolis, EU

Negative for:

C, E, K, Fy(a), Jk(a), S, Js(b)

CMV, HbS, H.T.

7 Glossary

General Terminology Used in ISBT 128 Coding and Labeling		
Data Content	The characters in a data structure that encode the desired message (a Product Code, for example).	
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. The second character of the data identifier can never be dropped because it is also part of the data content. See *ISBT 128 Standard Technical Specification*.)	
Data Structure	Defined format for information transfer within ISBT 128. The data structure defines the data identifiers, the data content, and the means to encode specific information within the data content. It specifies the context and structure and provides the links to the appropriate reference tables for conversion of codes to meaningful information. 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. (A different entity in this context means an institution with different ownership/leadership than the facility that labeled the product.)

Terminology Used in Donation Coding

Donation Identification Number + Flag Characters + Check Character

W0000 10 123456 12 [O]

FIN   Year   Sequence Number   Flag   Check Character

Donation Identification Number

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	A two-character code that is an element of the Donation Identification Number Data Structure. Flag characters can be used to identify the specific instance of a DIN label (e.g. identify a primary collection bag, a sample tube, or a donation record) and may be used to facilitate process control. They are not part of the unique 13-character Donation Identification Number (DIN) of the product.
Check Character	A character used to ensure the accuracy of the data in a data structure when such data is entered manually via a keyboard. The value is calculated by applying an algorithm to the appropriate data (see *ISBT 128 Standard Technical Specification* for details). The check character is most often used in association with the Donation Identification Number but may be used with some other ISBT 128 data structures. It is not part of the unique 13-character Donation Identification Number (DIN) of the product.

Terminology Used in Product Coding	
	Product Code E1212VA0 Product Description Code Division Code Donation Type Code
Product Code	An eight-character ISBT 128 code that comprises the Product Description Code, a Donation Type Code, and a Division Code. This 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.
Donation Type Code	A one-character alphanumeric code indicating the type of donation (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.
Text	

	Text corresponding to data content (previously called data content text)	The eye-readable representation of the data characters in a linear bar code. For linear bar codes, it is printed left justified immediately below the bar code, unless otherwise specified.
	Text associated with electronically-readable information (previously called Bar code text)	The interpretation of the data content of the bar code or 2-D symbol.
	Text not associated with electronically-readable information (previously called Additional text)	All other information on the label that is not associated with a bar code or 2-D symbol.

	Illustration of the types of label text
	A9999 17 123456 8⃞9⃞ Accurate Blood Center Anywhere, Worldwide Volunteer Donor ◄——— Text Not Associated with Electronically-Readable Information (previously called additional text) E0311V00 ◄——— Text Corresponding to Data Content in a Linear Bar code (previously called Data content text) RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED LEUKOCYTES REDUCED ◄——— Text Associated with Electronically-Readable Information(previously called Barcode text) ____ mL from 450 mL CPD Whole Blood Store at 1 to 6 C

END OF PUBLICATION

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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
ST-023 ISBT 128 Standard for Base Labels
IG-021 Use of Product Code [Data Structure 003] - Blood
IG-027 Use of Red Cell Antigens with Test History Data Structure [030]