

2.4 Description of the Data Structures

2.4.1 Donation Identification Number [Data Structure 001]

Note: This is the only data structure in which the second character of the data identifier shall be part of the data content.

Purpose: Data Structure 001 shall specify a Donation Identification Number that is a unique identification of a donation event [collection or recovery] or a product pool from anywhere in the world over a one hundred year period.

Structure: =αppppyynnnnnff

Element	Length	Type
=	1	data identifier, first character
α	1	data identifier, second character alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A–N, P–Z, 0–9}; second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future (e.g., if α = A and pppp = BC12, the αpppp will be ABC12)
yy	2	numeric {0–9}
nnnnn	6	numeric {0–9}
ff	2	numeric {0–9}

The fifteen (15)-character data content string, **αppppyynnnnnff**, shall be encoded and interpreted as follows:

αpppp shall specify the Facility Identification Number (FIN) and shall be encoded and interpreted by reference to the ICCBBA Registered Facilities database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website;

yy shall specify the last two digits of the year in which the donation was collected or recovered (or, in the case of a tissue processing facility assigning a DIN, this may be the year in which the first product from the donation event was processed);

2.4.12 Special Testing: Red Blood Cell Antigens — General [Data Structure 012]

Purpose: Data Structure 012 shall provide information regarding red blood cell phenotypes, CMV antibody, IgA, and Hemoglobin S status of the product.

Structure: =\aaaaaaaaaaaaaaaaaii.

Element	Length	Type
=	1	data identifier, first character
\	1	data identifier, second character
aaaaaaaaaaaaaaaa	16	numeric {0–9}
ii	2	numeric {0–9}

The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaaii**, shall be encoded and interpreted using Table 9, starting on page 85 and Table 12, Page 90.

Common Rh antigens may be encoded together as a phenotype (Rh column 1 on Table 9, page 85) or as individual Rh antigens (C,c,E,e, columns 14-16). If Rh antigens are encoded individually using positions 14, 15, and/or 16, then the value of column 1 shall be set to 9 (no information). Conversely, if the phenotype is present in column 1, then the values of the C,c,E,e antigens shall all be set to 9, ni (no information).

See Examples of Use in 8.3, page 130.

If there are Red Blood Cell Antigens that have been tested for, but that are not encoded using Table 9 and Table 12, positions 17 and 18 may be set to 00 (see Table 12) and information concerning the status of those antigens may be indicated on the label text. Alternatively, red cell antigens not found on these tables may be encoded using the Red Cell Antigens with Test History (Data Structure 030). For information on this data structure, see 2.4.30 on page 73.

2.4.28 Product Consignment [Data Structure 028]

Purpose: Data Structure 028 shall transfer information about product shipments.

Structure: =&appppyynnnnccdd

Element	Length	Type
=	1	data identifier, first character
\$	1	data identifier, second character
α	1	alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A-N, P-Z, 0-9}, second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future.
yy	2	Numeric {0-9}
nnnnn	5	Numeric {0-9}
cc	2	Numeric {0-9}
dd	2	Numeric {0-9}

The sixteen character data string **appppyynnnnccdd** shall be encoded and interpreted as follows:

apppp	shall specify the Facility Identification Number (FIN) and is encoded and interpreted by reference to the ICCBBA Registered Facility table (see 4.3, page 107) published and maintained by ICCBBA in the password-protected area of the ICCBBA Website
yy	shall specify the year
nnnnn	shall specify a serial number
cc	shall specify the number of the container within consignment. For dispatch documentation (paper or electronic), this field shall be set to 00
dd	shall specify the total number of containers in consignment

2.4.30 Red Cell Antigens with Test History [Data Structure 030]

Purpose: Data Structure 030 shall transfer information about red cell antigen phenotypes, including whether the test has been performed more than once and if the results represent current or historical data. It is anticipated that this data structure will be used in electronic communication or on documents accompanying the product rather than on the container label.

Structure: &%nnpppppprrss

Element	Length	Type
&	1	data identifier, first character
%	1	data identifier, second character
nnn	3	Numeric {0-9}
Repeating segment (repeats nnn times):		
pppppp	6	Numeric {0-9}
rr	2	Numeric {0-9}
ss	2	Numeric {0-9}

The character data string **nnpppppprrss** shall be encoded and interpreted as follows:

nnn Shall indicate the number of occurrences of the repeating segment in the data structure

Repeating segment (repeats nnn times):

pppppp ISBT-defined antigen as defined by the table described in 3.2.4, page 101

rr Result interpretation as defined by Table 22, page 100 (numeric, 0-9)

ss Number of tests as defined by Table 23, page 100 (numeric, 0-9)

There is no requirement for the order in which antigens may appear in the data string. Software shall be written to place an antigen in the appropriate field based on the value of pppppp.

When utilizing this data structure to express more than one test result, the results shall be concordant.

Information in the Red Cell Antigen with Test History Data Structure shall be firmly linked to the Donation Identification Number to which it corresponds. It is strongly recommended that a Compound Message Data Structure [023] that

3 Reference Tables

3.1 Reference Tables Maintained in This Document

Table 3 Data Structure 001: Donation Identification Number Flag Digits, ff [RT004]

Value of ff	Meaning When Used in the Donation Identification Number
00	Flag not used; null value
01	Container 1 of a set
02	Container 2 of a set
03	Container 3 of a set
04	Container 4 of a set
05	Second (or repeated) "demand-printed" label
06	Pilot tube label
07	Test tube label
08	Donor record label
09	Sample tube for NAT testing
10	Samples for bacterial testing
11	Match with Unit label
12–14	Reserved for future assignment
15	Container 5 of a set
16	Container 6 of a set
17	Container 7 of a set
18	Container 8 of a set
19	Container 9 of a set
20-59	Reserved for assignment and use by each local facility. Therefore the meaning and interpretation of flag values 20–59 may differ with each FIN and should not be interpreted at any other site
60–96	ISO/IEC 7064 modulo 37-2 check character on the preceding thirteen (13) data characters, appppyynnnnnn including the FIN, year and the unit serial number — value is assigned as 60 plus the modulo 37-2 checksum
97–99	Reserved for future assignment

Table 16 Data Structure 015: Special Testing: HLA-A and -B Alleles, Position 17 (CMV Antibody Status) [RT015]

Value	CMV Antibody Status
0	nt
1	neg
2	pos

Superseded

Table 17 Data Structures 024 and 025: Patient Date of Birth and Patient Identification Number [RT018]

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

Superseded

Table 18 Data Structure 027: Infectious Markers: Positions 1 through 9 [RT019]

Position	1		2		3		4		5		6		7		8		9	
Antibody	HIV-1/2			HCV			HBc			HTLV-I/II	Syphilis	CMV				Parvo B19		Chagas
Antigen		HIV-p24			HCV			HBs										
Genome Value			HIV			HCV			HBV				CMV	EBV	WNV		Parvo B19	
0	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
1	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg
2	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos
3	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos

neg — negative; pos — positive; na — information not available

Table 19 (continued) Data Structure 027: Infectious Markers: Positions 10 through 18

Position	10		11		12		13		14		15		16		17		18	
Antibody																		
Antigen																		
Genome Value																		
0	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		

neg — negative; pos — positive; na — information not available

Note: Positions 10 through 18 have been reserved for future use.

Table 19 Data Structure 029: Symbols [RT037]

Value	Description
01	Dimension is equal to the expressed value within a tolerance defined by the facility
02	Dimension is greater than the expressed value
03	Dimension is greater than or equal to the expressed value
04	Dimension is less than the expressed value
05	Dimension is less than or equal to the expressed value
06	Dimension is the nominal value as defined within a circular of information/package insert for the product

Table 20 Data Structure 029: Dimensions [RT038]

Value	Units	Description
0001	mL	Volume of the associated product including the anticoagulant/additive
0002	mm	Length of the associated product
0003	mm	Width of the associated product
0004	mm	Height of the associated product
0005	mm	Particle size of the associated product
0006	cm ²	Area of the associated product
0007	10log9	Total number of platelets in the container of the associated product
0008	g	Weight of associated product excluding the container but including the anticoagulant/additive

Table 21 Data Structure 029: Decimal Point [RT039]

Value	Meaning	Example
0	Integer value	12345
1	Decimal point between fourth and fifth numbers	1234.5
2	Decimal point between third and fourth numbers	123.45
3	Decimal point between second and third numbers	12.345
4	Decimal point between first and second numbers	1.2345
5	Decimal point is in the first position	.12345

Table 22 Data Structure 030: RBC Serological Results [RT040]

Value	Meaning
01	Negative
02	Positive

Table 23 Data Structure 030: Number of Tests [RT041]

Value	Meaning
01	Tested once on this donation
02	Tested once on prior donation
03	Tested \geq twice on different donations (current and historic) with concordant results
04	Tested \geq twice on different donations (historic only) with concordant results
05	Tested \geq twice on this donation only, different samples, with concordant results

Superseded

4.3 Facility Identification Number Identification Code

This database shall contain the names and locations of all ICCBBA registered facilities. It is published in the password-protected area of the ICCBBA Website. This file shall be a Microsoft Excel® file and be named:

Registered Facilities – xls

It shall also be available on the Website as a tab delimited text file (Registered Facilities – Text).

Table 29 Registered Facilities [RT030]

Field Name	Field Size	Field Description
FIN	5	Facility Identification Number
Firm Name	60	Legal name of facility
City	30	Mailing address details of facility
State/Province	20	Mailing address details of facility
Country	20	Mailing address details of facility
Postal Code	10	Mailing address details of facility
Website	100	Website of the facility

5 Delivery Mechanisms for ISBT 128 Data Structures

ISBT 128 data structures can be delivered using a number of different technologies including linear bar codes, two-dimensional (2-D) bar codes, wireless radio frequency identification transponders (RFID tags), and EDI messages. Rules for such uses of ISBT 128 data structures will depend on the delivery mechanism.

5.1 Linear Symbols

5.1.1 General Requirements

ISBT 128 data structures represented as linear bar codes shall use Code 128 symbology and be compliant with ISO/IEC 15417. Implementations shall ensure that a switch is made to subset C of the Code 128 symbology where appropriate in order to reduce bar code length.

5.1.2 Symbol Print Quality

As described in ISO/IEC 15416, print quality of a Code 128 symbol shall be 1.5/6/670 where 1.5 is the overall quality, 6 is the measuring aperture reference number (corresponding to a 0.15 mm diameter aperture) and 670 is the peak response wave length in nanometers. A 1.5 corresponds to a C grade in the ANSI standard X3.182 – 1990.

5.1.3 Symbol Dimensions

Nominal module width (X): The X dimension shall be constant throughout a given symbol. The X dimension is the width of the narrowest bar within the bar code symbol.

Whenever possible, ISBT 128 bar codes used on a container label should be printed using a nominal X dimension of 0.25 mm, and in no case shall they be printed at a nominal X dimension smaller than 0.17 mm.

Note: Printers and scanners need to be compatible with the X dimension selected.

Any use of an ISBT 128 data structure as a linear printed bar code (i.e., not only on container labels, but on test tubes, etc.) should use an X dimension that meets these criteria.

Non-ICCBBA defined bar codes (such as national use bar codes) should meet the criteria listed above.

For further information on implementation of 2-D symbols, see Implementation Guide: *Use of Data Matrix symbols with ISBT 128*.

5.3 RFID Tags

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 technology develops.

5.4 EDI Messages

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

For messages following the HL7 Standard, see Chapter 11.

6 Product Labeling

6.1 Tissue Labeling

This chapter applies to blood and cellular therapy products. For information on labeling tissue products, see *ISBT 128 Standard Labeling of Human Tissues*.

6.2 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 the *ISBT 128 Standard Product Code Structure and Labeling* documents (Cellular Therapy and Blood Components). ICCBBA maintains on its Websites 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.director@iccbba.org).

6.3 General Principles

Two label types are specified in ISBT 128: the label applied by the manufacturer of the container referred to as the base label and the label placed on a product container by the processing facility referred to as the final label.

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).

6.4 Base Label Bar Code Placement

6.4.1 Standard Base Label Bar Code Placement

Where the container is of sufficient size, it shall carry a 100 ± 2 mm by 106 ± 2 mm base label.

The base label should carry the two manufacturer's information bar codes: the Container Manufacturer and Catalog Number [017] bar code in the lower left quadrant and the Manufacturer's Lot Number [018] bar code in the lower right quadrant. The recommended position for these bar codes on 100 ± 2 mm by 106 ± 2 mm label is indicated in Table 30, page 113.

Table 30 Positioning Bar Codes on the Base Labels [RT020]

Bar Code	Vertical Alignment	Horizontal Alignment
Container Manufacturer and Catalog Number [017]	3 mm from bottom of Left Quadrant [or 9 mm from bottom of label]	Bar code right edge should be at 4 mm from right edge of Left Quadrant
Container Lot Number [018]	3 mm from bottom of Right Quadrant [or 9 mm from bottom of label]	Bar code left edge should be at 4 mm from left edge of Right Quadrant

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



Required Bar Codes
1 - Container Manufacturer and Catalog Number
2 - Container Lot Number

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

6.4.2 Small Base Label Bar Code Placement

The size of some containers does not allow a 100 ± 2 mm by 106 ± 2 mm base label. In designing such labels the principles outlined in this chapter should be applied to the extent possible.

An alternative label design may be used if the container will accommodate a 50 mm x 75 mm label. This base label shall carry the two manufacturer's information bar codes. The Container Manufacturer and Catalog Number [017] bar code shall be printed vertically in the upper half of the label and the Manufacturer's Lot Number [018] shall be printed vertically in the lower half of the label. The recommended position for these bar codes is indicated in Table 31, and is illustrated in Figure 6, page 115. This places the bar codes in an ideal position for concatenation.

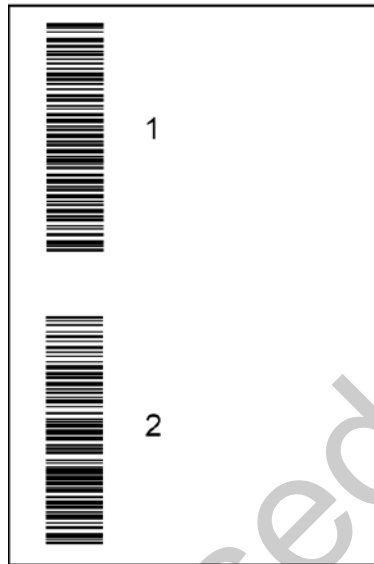
In order to accommodate the smaller size of the 50 mm x 75 mm label, and allow for concatenation of the bar codes, an X dimension as small as 0.17 mm may be used. Users should ensure that scanners selected will be able to accommodate this X dimension.

The bar code height may also be reduced to 8 mm in order to accommodate required text as long as the requirement for a height equal to or greater than 15% of bar code length is met.

Table 31 Positioning Bar Codes on 50 mm by 75 mm Containers [RT021]

Bar Code	From vertical center of label	From left side of label
Container manufacturer and catalog number	The right edge of the bar code is 4 mm above the vertical center of the label	Lower edge of the bar code is 6 mm from the left side of the label
Lot number	The left edge of the bar code is 4 mm below the vertical center of the label	The lower edge of the bar code is 6 mm from the left side of the label

Figure 6 Placement and Nominal Size of Bar Codes on a 50 mm by 75 mm Base Label



1 - Container Manufacturer and Catalog Number
2 - Container Lot Number

6.5 Final Label Bar Code Placement

6.5.1 100 mm by 100 mm Final Label

The default size of the final label is 100 (+/-2) mm by 100 (+/-2) mm. Where the container size does not support this size of label, special consideration will need to be given.

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.

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 32 on page 117.

Linear bar codes for Data Structures 001, 002, 003 and 005 shall be present and positioned as described in Table 32, page 117 and Table 33, page 117. These requirements place the bar codes in an ideal position for concatenation.

Linear bar codes for other Data Structures found on the final label, and the Data Matrix symbol, should be positioned as described on Table 34, page 117.

When present, the Data Matrix symbol shall include the four data structures (DIN, Product Code, ABO/RhD, and Expiration Date and Time) required for linear bar codes. Any additional ISBT 128 data structures (excluding nationally defined structures) may also be included.

Figure 7, page 118, shows final label printed according to these tables.

Table 32 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 for blood) [005]
	Special Testing (optional) [010,011,012,013,014,015,016]
	Data Matrix (2-D) symbol

Table 33 Required Positioning of Bar Codes on Final Labels [RT023]

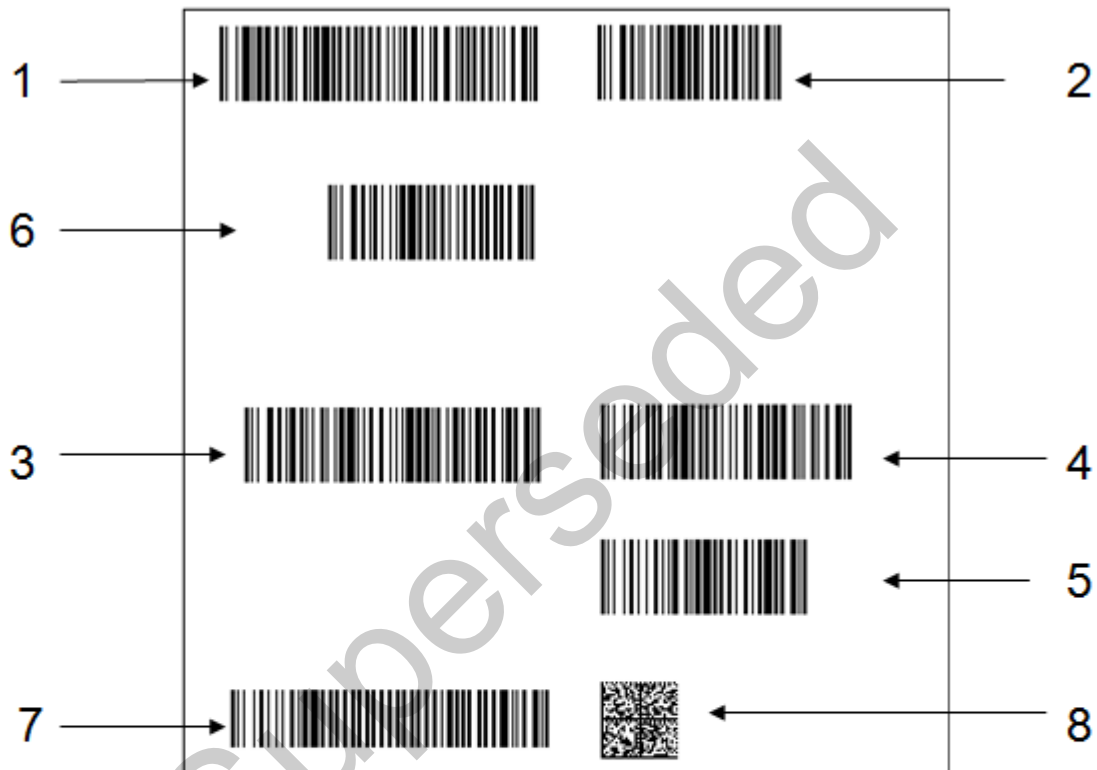
Bar Code	Vertical Alignment	Horizontal Alignment
Donation Identification Number [001]	3 mm from top of Upper Left Quadrant	Bar code right edge should be 4 mm from right edge of Upper Left Quadrant
Product Code [003]	3 mm from top of Lower Left Quadrant	Bar code right edge should be 4 mm from right edge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

Table 34 Recommended* Positioning of Bar Codes on Final Labels [RT024]

Bar Code	Vertical Alignment	Horizontal Alignment
Collection Date (and Time) [006, 007] or Production date (and Time) [008, 009]	20 mm from top of Upper Left Quadrant	Bar code right edge should be at 4 mm from right edge of Upper Left Quadrant
Special Testing [one of several alternative data structures]	20 mm from top of Lower Right Quadrant	Bar code left edge should be at 4 mm 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 from right edge of Lower Left Quadrant
Data Matrix symbol	As close to the bottom of the label as practical	Not specified.

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

Figure 7 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 5.1.3, beginning on page 108.

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

6.5.2 Small Final Label

Some containers 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 <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 must carry an electronically readable Donation Identification Number and Product Code
- 2) Every ISBT 128-labeled product must carry an eye readable text Donation Identification Number and Product Code
- 3) These (1 and 2 above) should appear on the affixed label whenever possible
- 4) 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, and the DIN and product bar codes shall also be carried together on an attached label or on accompanying documentation

6.6 Printing Label Text

6.6.1 Eye Readable Text for Linear Bar Codes

The eye-readable text is the representation of the data characters in a bar code that is printed left justified immediately below a linear bar code, unless otherwise specified (see Figure 10, page 156).

Every Code 128 bar code on a container label shall be accompanied by eye-readable text. Bar code data identifiers are non-data characters and therefore shall appear only in the bar codes, not in the eye-readable text.

6.6.1.1 Donation Identification Number [001]

The eye-readable 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 eye-readable text and bar code text. As bar

code text it shall be printed using a sans serif typeface. A national authority should determine how it should be displayed, for example:

V0043 99 499999



7004 203 123 456

All data characters shall be printed (in this instance only, 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 2.4.1).

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.

W0000 09 123456  

↑
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.

Type 3 flag characters shall not be printed.

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

When these bar codes are printed on the 100 mm by 106 mm base label, eye-readable text shall be printed in sans serif type in the 6 mm segment of the base label that will remain visible after the application of the final label. The height of this text shall not exceed 3 mm. It shall be centered vertically within the segment (see Figure 13, page 164) and commence in line with the leftmost bar of the bar code.

When these bar codes are printed on smaller base labels, the eye-readable text for these two bar codes shall be printed left justified immediately below the bar code. The eye readable text should remain visible after the base label is over-labeled with the final label. See Figure 14, page 165.

6.6.1.3 All Other Bar Codes

Eye-readable text shall appear immediately below, but not touching, the bar code; commence in line with the leftmost bar of the bar code and be represented in sans serif type with a maximum height of 2 mm (see Figure 10, page 156).

6.6.2 Keyboard Entry Check Character K

A keyboard entry check character **K** shall be used when eye readable text appears in conjunction with the following data structures in order to verify correct manual entry of the data content:

- Donation Identification Number [001]
- Special Testing: Red Blood Cell Antigens [011]
- Special Testing: Red Blood Cell Antigens — General [012]
- Special Testing: Red Blood Cell Antigens — Finnish [013]
- Special Testing: Platelet HLA and Platelet-Specific Antigens [014]
- Special Testing: HLA-A and –B Alleles [015]
- Special Testing: HLA-DRB1 Alleles [016]
- Donor Identification Number [019]
- Infectious Marker [027]

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

For other bar codes, the keyboard entry character may be used (see Table 35, page 122). Because the ISO/IEC 7064 modulo 37-2 checksum method does not allow for lower case alpha characters, it shall not be used in data structures that have lower case alpha characters.

K is not part of the data content string but is calculated from it using the ISO/IEC 7064 modulo 37-2 checksum method. **K** is a character in the range {A-Z, 0-9, *} determined from the modulo 37 remainder of the weighted sum of the data content string as shown in Table 41 in Appendix A. For an example of the calculation for the 13-character string **αppppyynnnnnn** of the Donation Identification Number see Appendix A.

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

For example, an HLA genomic type would be printed:

0103 0201 0702 2705 19 **K**

1001 1501 9999 9999 99 **L**

Because of the significance of this particular character, 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).

Table 35 Keyboard Entry Check Character Requirements for ISBT 128 Data Structures Utilizing Code 128 [RT002]

Ref	Data Structure Name	Modulo 37-2 Keyboard Entry Check Character [K]
001	Donation Identification Number	Required
002	Blood Groups [ABO and RhD]	Not applicable
003	Product Code	Not applicable
004	Expiration Date	Optional
005	Expiration Date and Time	Optional
006	Collection Date	Optional
007	Collection Date and Time	Optional
008	Production Date	Optional
009	Production Date and Time	Optional
010	Special Testing: General	Optional
011	Special Testing: Red Blood Cell Antigens (withdrawn)	Required
012	Special Testing: Red Blood Cell Antigens — General	Required
013	Special Testing: Red Blood Cell Antigens — Finnish	Required
014	Special Testing: Platelet HLA and Platelet-Specific Antigens	Required
015	Special Testing: HLA-A and -B Alleles	Required
016	Special Testing: HLA-DRB1 Alleles	Required
017	Container Manufacturer and Catalog Number	Not applicable
018	Container Lot Number	Not applicable
019	Donor Identification Number	Required
020	Staff Member Identification Number	Optional
021	Manufacturer and Catalog Number: Items Other Than Containers	Not applicable
022	Lot Number: Items Other Than Containers	Not applicable
023	Compound Message	Not applicable
024	Patient Date of Birth	Optional
025	Patient Hospital Identification Number	Not applicable
026	Expiration Month and Year	Optional

Ref	Data Structure Name	Modulo 37-2 Keyboard Entry Check Character [K]
027	Infectious Marker	Required
028	Product Consignment	Optional
029	Dimensions	Optional
030	Red Cell Antigens with Test History	Not Applicable

6.6.3 Bar Code Text

Bar code text is the interpretation of the eye-readable text (the data content of the bar code) in terminology meaningful to the user (see Figure 10, page 156). Bar code text is nationally defined to allow for differences in language, regulatory requirements, and preferences.

Particular font sizes and types are not specified for bar code and additional 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). Sans serif fonts shall be used for Latin alphabets. The use of color (for example, for ABO) is neither prohibited nor encouraged.

Bar code text corresponding to information content of electronically readable information shall appear on the label. If the size of the label does not support the information content required by this standard, appropriate regulations and requirements of standard setting organizations should be consulted. Some required information may need to appear on secondary packaging.

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

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.

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

6.6.3.2 Product Descriptions [Data Structure 003]

Where space permits, the Class, Modifier, and Attributes (except default attributes) text shall be printed on the label.

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

Figure 8 Relative Text Size of Class, Modifier and Attributes



6.6.3.3 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:

2011-03-17

OR

17 MAR 2011

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.

For Cellular Therapy products with text expiration times, time zones shall be taken into consideration. If the product is to be shipped across time zones, FACT and 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 Universal Coordinated Time (UTC) when the product is to be shipped across an international time zone.

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

Expiration Date/Time:

15 JAN 2011 15:15 EST
(15 JAN 2011 20:15 UTC)

OR

2011-01-15 15:15 EST
(2011-01-15 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., EST can mean Eastern Standard Time in Australia, which is UTC+10 hours or Eastern Standard Time in North America, which is UTC -5 hours). However, the Cellular Therapy Coding and Advisory Group (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.

6.6.3.4 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.

2011-03

OR

MAR 2011

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

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

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:

Phenotype provided in
accompanying documentation

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.

6.6.3.6 Special Testing: HLA-A and -B Alleles [Data Structure 015] and Special Testing: HLA-DRB1 Alleles [Data Structure 016]

If alleles are determined genomically, the bar code text allele numbers shall be preceded by an asterisk (*).

HLA-A*0103,0201;B*0702,2705
DRB1*03,15

11 Use of ISBT 128 Data Structures in HL7 Messages

Per its Website (www.hl7.org), Health Level Seven International (HL7) is “a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7’s 2,300+ members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare.”

HL7 is an electronic messaging standard that allows communication between disparate computer systems. Within an HL7 message, there may be coded values. Some of these coded values are from HL7 maintained tables, some are from user defined tables, and others are from external tables. According to the HL7 standard, an external table is “a set of coded values defined and published by another standards organization.” ICCBBA is recognized by HL7 as such a standards organization. ICCBBA maintains tables, such as Table 40 [RT042], which is referenced in HL7 in its Vocabulary Table 0396 on the HL7 Website. This allows ICCBBA to specify how ISBT 128 data structures and other transfusion and transplantation information can be included in HL7 messages in a structured manner.

Table 40 [RT042] specifies identifiers that may be used in encoding ISBT 128 data structures into HL7 messages.

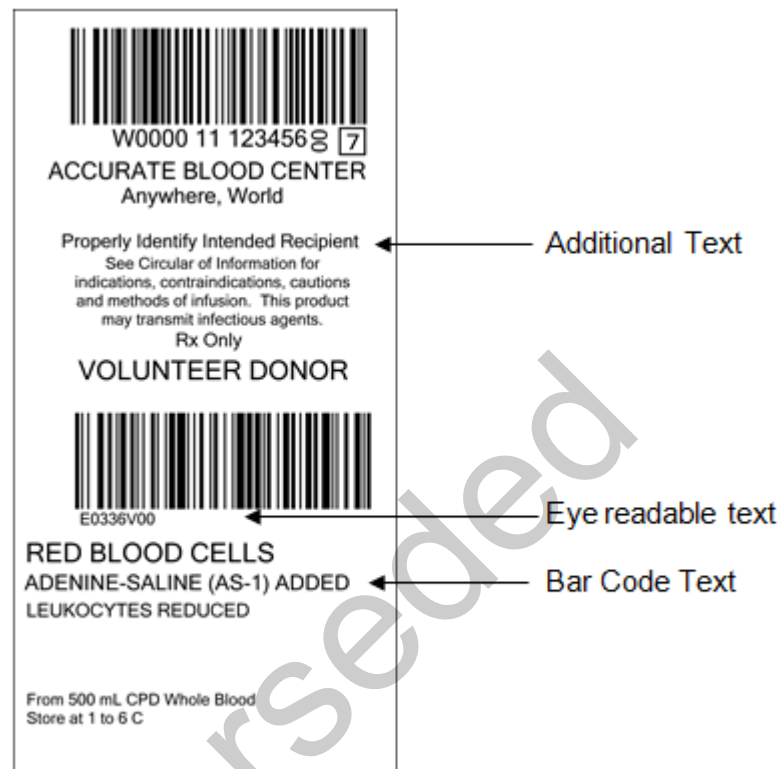
Table 40 IBT0001 Coding System Reference Table [RT042]

Identifier	Text Name	Description	Data example
IBT1-0001	Donation Number	Thirteen character donation number element from an ISBT 128 Donation Identification Number [Data Structure 001]. (In this case includes the second data identifier which is also the first data character)	G151708123456
IBT1-0002	Flag Value	Two character code corresponding to the flag characters from an ISBT 128 Donation Identification Number [Data Structure 001]. See Table 4 for acceptable values and their interpretation.	01
IBT1-0003	Donation and Flag	Fifteen-character code corresponding to an ISBT 128 Donation Identification Number [Data Structure 001] (In this case includes the second data identifier which is also the first data character). See Table 3 [RT004] for acceptable values of flag element and their interpretation.	G15170812345601

Data identifier	The first two characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined. (The Donation Identification Number is an exception to this rule. See 2.4.1, page 34.)	
Data structure	Information content comprising the data identifier and data content. When a data structure is represented as a bar code, the term data structure does not include the symbology-specific and always present start and stop codes, the modulo 103 check character, or any specified control characters.	
Dedicated donation	A collection arranged by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products).	
Designated donation	A unit collected from a donor called by the collecting facility to provide product (for example, HLA-compatible) to be used by a specific recipient (or for Cellular Therapy products, possibly a small group of recipients).	
Directed donation	A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide product to be used by that person.	
Facility	An organization that is responsible for the collection, processing, and/or distribution of ISBT 128-encoded products.	
Final label	Labeling as it appears on a product ready for release.	
Flag character	Part of the data content of a data structure used in process control or data transmission checking. Printed in eye readable format, but distinguished in some manner from the representation of the other data characters.	
ISBT 128	An international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. It provides for a globally unique donation numbering system, internationally standardized product definitions, and standard data structures for bar coding and electronic data interchange.	
Julian Date	See Ordinal Date.	
Label	An independent entity that carries one or more bar codes and also provides other 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.
Ordinal Date	A system for maintaining dates that numbers the first day of the year (January 1) as 1 and the last (December 31) as 365 or 366 (in a leap year). Also known as Julian Date.	
Primary container	The container into which the whole blood is drawn.	
Satellite container	A container other than the primary container in a container set.	
Text	(See Figure 10, page 156)	
	Eye-readable text	The eye-readable representation of the data characters in a bar code (printed left justified immediately below the bar code, unless otherwise specified).
	Bar code text	The interpretation of the eye-readable text (the data content of the bar code).
	Additional label text	All other information on the label that is not associated with a bar code.
Transfer container	A container intended for post-manufacturing connection to a container set.	
UTC	Universal Coordinated 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.	

Figure 10 Illustration of the Terms Eye-Readable Text, Bar Code Text, and Additional Label Text



Appendix A Donation Identification Number Check Character [K]

A.1 Keyboard Entry Check Character

ISBT 128 Donation Identification Numbers utilize checksum characters based on the ISO 7064 Mod 37-2 algorithm. This Appendix shows how to calculate the checksum character for any given Donation Identification Number. The calculation is based on the DIN thirteen (13)-character string (*i.e.*, excluding the leading = symbol and the flag characters).

The steps in the process are as follows:

1. For each character in the string determine its check value as required by ISO 7064 from Table 41;
2. For each character in the string determine its weighted check value by multiplying the check value from Table 41 by the *n*th power of 2 where *n* is the position of the character from the right hand end of the string;
3. Sum the weighted check values from step 2;
4. Find the modulus 37 value of the sum from step 3 (the value **remaining** when the weighted sum is divided by 37);
5. Subtract the value obtained in step 4 from 38;
6. Find the modulus 37 value of the result of step 5 (the value **remaining** when divided by 37);
7. Using the value in Step 6, determine the check character by again referring to Table 41 (this time read the character from the value) — this is the modulo 37-2 checksum character (referred to as K throughout this *Standard*).

Table 41 Mapping from Characters to ISO/IEC 7064 Check Values and Calculated Values to the Checksum Character [RT035]

Character	0	1	2	3	4	5	6	7	8	9	A	B	C
Value	0	1	2	3	4	5	6	7	8	9	10	11	12
Character	D	E	F	G	H	I	J	K	L	M	N	O	P
Value	13	14	15	16	17	18	19	20	21	22	23	24	25
Character	Q	R	S	T	U	V	W	X	Y	Z	*		
Value	26	27	28	29	30	31	32	33	34	35	36		

Example of Calculation

Donation number G1234 89 654321

Position from right (n)	2 ⁿ (a)	Character	ISO 7064 value (step 1) (b)	Weighted value (step 2) (a x b)
13	8192	G	16	131072
12	4096	1	1	4096
11	2048	2	2	4096
10	1024	3	3	3072
9	512	4	4	2048
8	256	8	8	2048
7	128	9	9	1152
6	64	6	6	384
5	32	5	5	160
4	16	4	4	64
3	8	3	3	24
2	4	2	2	8
1	2	1	1	2
Step 3	sum of weighted values			148226
Step 4	modulo 37 (first MOD)			4
Step 5	subtract from 38			34
Step 6	modulo 37 (second MOD)			34
ISO/IEC 37-2 checksum				34
ISBT 128 check character (K)				Y

A.1 Computer Programs for Calculating K Using ISO 7064

This is an *informative* section designed to assist programmers by giving two representative methods for the calculation of the Donation Identification Number ISO 7064 modulo 37-2 check character. Both use the “*Pure system recursive method*” for calculation of the check character as documented in Section 7.1 of the ISO/IEC 7064 specification: “Information technology—Security techniques—Check character systems.”

Programmers must validate that their programs and algorithms comply with the normative ISO/IEC 7064 2003 specification and good programming practice.

Programs to generate the check character should also contain sufficient error checking to verify that the first character of the input Donation Identification Number is either an uppercase A–Z, or a digit 1–9 and that all subsequent characters in the input Donation Identification Number are digits.

The following PASCAL language function **ISOmod37_2** calculates and/or validates the ISO 7064 Mod 37-2 pure check character:

```

function ISOmod37_2(DonationInfo:string; K:integer) : char;
  {Calculate or validate ISO mode 37-2 pure check character}
  function ISOvalue(InputString:string; I:integer) : integer;
  begin {Convert ASCII character value to ISO 7064 value in range 0...36}
  case InputString[I] of
    '0' .. '9': ISOValue := (ord(InputString[I]) - 48);
    'A' .. 'Z': ISOValue := (ord(InputString[I]) - 55);
    '*': ISOValue := 36;
  end;
  end {function ISOvalue};
  var
    J,Sum,CharValue,CheckValue : integer;
  const
    ISOCharTable : string[37] = '0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*';
  begin
    Sum := 0;
    for J:= 1 to K do
      begin
        CharValue := ISOvalue(DonationInfo,J);
        Sum := ((Sum + CharValue)*2) mod 37;
      end;
    {Check character value is defined to be congruent to 1 mod 37}
    CheckValue := (38 - Sum) mod 37;
    ISOmod37_2 := ISOCharTable[CheckValue + 1];
  end {function ISOmod 37_2};

```

The following 'C' language function **CalculateMod37_2** also implements the "Pure system recursive method" documented in Section 7.1 of the ISO/IEC 7064: specification:

```
int CalculateISO7064Mod37_2(char *inputString)
{
int ch, sum, charValue, isDigit, isUpperAlpha;
static char iso7064ValueToCharTable[] =
"0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*";
// Read the characters from left to right.
for (sum = 0; ch = *inputString; inputString++)
{
// Ignore invalid characters as per ISO 7064.
isDigit = ((ch >= '0') && (ch <= '9'));
isUpperAlpha = ((ch >= 'A') && (ch <= 'Z'));
if (isDigit || isUpperAlpha)
{
// Convert the character to its ISO 7064 value.
if (isDigit)
charValue = ch - '0';
else
charValue = ch - 'A' + 10;
// Add the character value to the accumulating sum,
// multiply by two, and do an intermediate modulus to
// prevent integer overflow.
sum = ((sum + charValue) * 2) % 37;
}
}
// Find the value, that when added to the result of the above
// calculation, would result in a number whose modulus 37
// result is equal to 1.
charValue = (38 - sum) % 37;
// Convert the value to a character and return it.
return (iso7064ValueToCharTable[charValue]);
}
```

ICCBBA thanks Dr Clive Hohberger, Vice President of Technology Development at Zebra Technologies Corporation, Vernon Hills, Illinois, USA, for providing the PASCAL function ISOmod37_2, and Mr. Harold Boe, Vice President of Software Development at Seagull Scientific Systems, Inc, Bellevue, Washington, USA, for providing the C-language function CalculateISO7064Mod37_2.

Appendix B ISBT 128 Standard: Numbering of Versions of Documents and Databases

A three (3)-digit system shall be employed to distinguish versions of the ISBT 128 Standard documents and databases.

For documents:

ISBT 128 Standard documents shall include a version control sheet

- the third digit shall be increased by one whenever minor typographical errors are corrected or when language is clarified;
- the second digit shall be increased by one and the third digit returns to 0 whenever discreet new entries are made (e.g., a new data structure is inserted) or typographical errors with operational significance are corrected;
- the first digit shall indicate a major revision of the document.

For databases:

Databases shall have a version control sheet that shall be maintained on the ICCBBA Website.

For product description code database:

- the third digit shall be increased by one if the only change to the database is an addition to the Product Description table or minor corrections (e.g., spelling) in existing codes;
- the second digit shall be increased by one and the third digit returns to 0 if changes are made to the Class or Attribute tables;
- the first digit shall tie the database to the controlling major revision of the *ISBT 128 Standard Technical Specification*.

For Special Testing database:





- the third digit shall be increased by one if a typographical error is corrected;
- the second digit shall be increased by one and the third returns to 0 each time new item is added;
- the first digit shall tie the database to the controlling major revision of the *ISBT 128 Standard Technical Specification*.


Appendix C Label Examples

Note: A library of example labels from different countries is posted on the ICCBBA Website. Additional label examples may be found in ISBT 128 Standard, Product Code Structure and Labeling documents (Cellular Therapy, and Blood Components).

Examples of tissue labels are included in the document ISBT 128 Standard Labeling of Human Tissue.

Figure 11 Cellular Therapy Example Labels

		O Rh Positive
W0000 11 123456 8 7	4700	
Collection Center or Registry 2nd Line of Name City, State, Zip Code		
Collection Date/Time 22 JAN 2011 10:55		For Use by Intended Recipient Only
Do Not Irradiate Do Not Use Leukoreduction Filters		Related Donor, 1st or 2nd Degree SMITH, GERALD R Donor # W0001 123654987 Date of Birth: 22 JUL 1962
		Expiration Date/Time
S1134400 DESIGNATED	0110241055	:
HPC, APHERESIS		24 JAN 2011 10:55
Other Additives Present See Attached Documentation for Details		Intended Recipient: SMITH, ROGER R MRN: 123456789 Date of Birth: 07 JUL 1963
Approx _____ mL in approx _____ mL Citrate		Processing Laboratory Name 2nd Line of Name City, State, Zip Code
Store at 1 to 10 C		

	Collection Center or Registry 2nd line of name Anywhere, Worldwide	For Use by Intended Recipient Only
W0000 11 123456 8 7 Product: S12174A0		Intended Recipient PATIENT, JOHN Q. MRN#: 123456789 Date of Birth: 31 DEC 1984
TC-T Cells DIVIDED, Part A0 Buffy Coat Enriched Store at 20 to 24 C Collection Date: 12 MAY 2011		Processing Facility 2nd Line of Name City, Province, Country
<i>Partial Label</i>		











	W0000 11 123456 8 7 Product: S11426Ba
HPC, APHERESIS, Part Ba Intended Recipient: WILSON, JEFFREY MRN: 07061234B	 BIOHAZARD

Figure 12 Blood Product Labels


 A9999 11 123456 
 Accurate Blood Center
 Anywhere, World
 Collection Date 
 011005
 05 JAN 2011
 VOLUNTEER DONOR

 E0472V00
 WASHED
 RED BLOOD CELLS
 IRRADIATED
 From 450 mL Whole Blood
 Store at 1 to 6 C

 5100

Rh POSITIVE

 0110311520
 Expiration Date/Time
 31 JAN 2011 15:20

 N0008
 Negative for antibodies to CMV












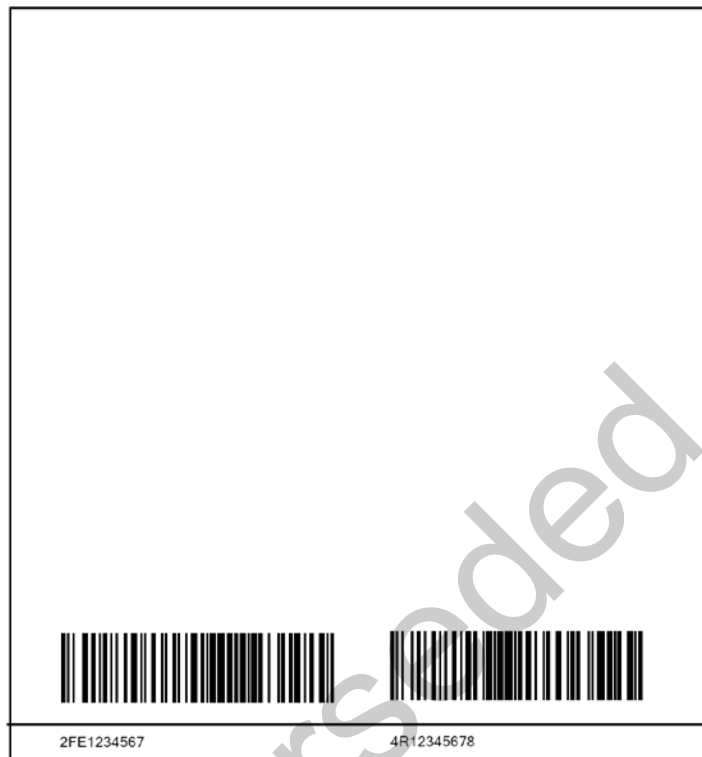

 W0000 10 123456 
 Accurate Blood Center
 Anywhere, Worldwide
 Collection Date 
 010354
 20 DEC 2010

 E0311V00
 RED BLOOD CELLS
 ADENINE-SALINE (AS-1) ADDED
 LEUKOCYTES REDUCED
 203 mL from 450 mL CPD Whole Blood
 Store at 1 to 6 C

 0101000100203000

 9500

Rh NEGATIVE

 0110312359
 Expiry Date
 31 JAN 2011

 880000008700000100 
 C-c+E-e+, K+k+;Fy(a+b+);Jk(a+b-)
 Negative for antibodies to CMV


Figure 13 Base Label



This example represents the minimum amount of ISBT 128 information that shall appear on the label. Manufacturers may include additional information such as:

- icons
- user friendly catalog numbers and lot numbers
- the intended use of the bag in text (e.g., For Platelet Storage)
- appropriate warnings (e.g., Not Suitable for Storage of Red Blood Cells or the number of days a platelet product can be stored within the container)

Figure 14 Small Base Label



This example represents the minimum amount of ISBT 128 information that shall appear on the label. Manufacturers may include additional information such as:

- icons
- user friendly catalog numbers and lot numbers
- the intended use of the bag in text (e.g., For Platelet Storage)
- appropriate warnings (e.g., Not Suitable for Storage of Red Blood Cells or the number of days a platelet product can be stored within the container)

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