United States
Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128

Version 3.0.0
March 2013
Tracking Number ICCBBA IG-002

Published by:
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Acknowledgement

ICCBBA thanks the members of the Americas Technical Advisory Group (ATAG) for their contributions in the development of this consensus standard.

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Abbreviations and Acronyms

2-D	Two dimensional
ASCII	American Standard Code for Information Interchange
ATAG	Americas Technical Advisory Group
CCD	Charged Coupled Device
CFR	Code of Federal Regulations
DIN	Donation Identification Number
FDA	Food and Drug Administration
FIN	Facility Identification Number
GS1	An international organization involved in setting standards for supply chain information
IEC	International Electrotechnical Commission
ISBT	International Society of Blood Transfusion
ISO	International Organization for Standardization
PLT	Platelets
RBC	Red Blood Cells
RFID	Radio Frequency Identification Tag
US	United States
WB	Whole Blood
WBC	White Blood Cells

1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance on labeling requirements in the US for blood and blood components.

1.2 Scope

ISBT 128 is an international information standard for human blood, tissue, cellular therapy, organ, and milk products. A balance exists between what information on a product label must be strictly standardized in order to achieve the goals of an international standard and what must be left to the discretion of national authorities because of variations in language and regulatory requirements. Broadly, this can be divided as follows:

Internationally defined: The definitions of data structures and the placement of bar codes, as well as the corresponding data content text that appears immediately beneath a bar code, are strictly standardized. These label elements must appear exactly as specified in the *ISBT 128 Standard Technical Specification*.

Nationally defined: Bar code text (the interpretation of the information in the bar code) and additional text are generally left to national authorities to define. Additionally, the use of some data structures, such as the collection date on the label, is nationally defined. These decisions are codified by national working groups established for this purpose unless superseded by regulatory authority. In the US this working group is the Americas Technical Advisory Group (ATAG) of ICCBBA.

This document, *The United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128*, provides specific instructions for the US where there is flexibility in the *ISBT 128 Standard Technical Specification*.

What it contains:

This document provides specific information for the text that must appear on US labels and provides many example labels meeting the requirements in the US. While it is not possible to provide an example of every type of product label, this document should provide enough examples to enable users to develop their own label.

Text shown in example labels and on various tables in this document represents ICCBBA's recommendations. Other variations of the wording, capitalization, or punctuation may also be acceptable. Users are advised to consult the FDA to determine if a proposed variation is acceptable.

What it does not contain:

It does not provide detailed guidance for final labels on smaller pediatric containers. Smaller labels should follow the principles outlined for larger labels, but will have to be designed with the smaller size taken into consideration.

It does not cover details about the required quality of bar codes nor their precise placement. This information is contained in the *ISBT 128 Standard Labeling of Blood Components.*

It does not provide detailed information about product coding. Specific information about product coding may be found in a document called *Use of Product Code Data Structure [003] – Blood*. Specific information about the terminology used in product coding is found in a document called *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*.

1.3 Intended Audience

The intended audience of this document is transfusion medicine facility staff (management, information technology, quality, validation, and laboratory), auditors, software developers, and vendors of equipment and consumables. It is intended to help these people understand labeling requirements and to standardize to the extent possible labeling of blood and blood components in the US.

1.4 Normative References

ICCBBA
ISBT 128 Standard Technical Specification (ST-001)
ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions (ST-002)
ISBT 128 Standard Labeling of Blood Components (ST-005)

AABB
Standards for Blood Banks and Transfusion Services

FDA
21 CFR 606.121
21 CFR 610.40
21 CFR 610.53
21 CFR 610.60
21 CFR 640.3
21 CFR 640.70
21 CFR 640.3(d)
21 CFR 640.120
Federal Register/Vol 48, No. 64/Friday, April 1, 1983/Notices

1.5 Other References and Additional Reading

ICCBBA Website (www.iccbba.org)
AABB Website (www.aabb.org)
FDA Website (http://www.fda.gov/BiologicsBloodVaccines/default.htm)

Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics (FDA, November 2008)

Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007)

Implementation Guide: Use of Product Code Data Structure [003] – Blood (IG-021)
Implementation Guide: Use of the Manufacturer's Data File (IG-015)
Technical Bulletin 9: Blood Bag Identification Using ISBT 128 and GS1 (IG-012)
Technical Bulletin 10: Valid and Invalid Bar Codes for Use in ISBT 128 Validations (IG-013)
Technical Note 1: Case Conversion (IG-016)
Technical Note 2: Length of the Product Code Bar Code and Concatenation (IG-017)
Technical Note 4: Manufacturer Catalog Number and Lot Number (IG-019)

1.6 Background

A specification for ISBT 128 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. Around the world, implementation in blood establishments began soon after the standard was issued, with a steady increase in adoption since that time. The model originally developed by the WPADP has demonstrated its suitability by accommodating local and regional changes without requiring substantial structural change. The standard has since been expanded for use with cellular therapy and tissue products.

In the US, blood centers have been converting to ISBT 128 over the past decade, led by the Department of Defense and the Community Blood Center of Greater Kansas City. In 2008, AABB required the use of ISBT 128 by its accredited facilities.

1.7 Changes in this Version

Version 3.0.0 of this document is considerably reorganized and expanded from Version 2.0.0. Many more examples of labels and text are included to help US users standardize labels while meeting the requirements of the FDA, AABB, and the ISBT 128 Standard. While Table 1 notes specific changes and corrections, the document must be read in its entirety.

ISBT 128 is a "living system." This document, and other documents important to ISBT 128, will be subject to a continual revision process. Care is taken to ensure any changes are backward compatible. Users should be sure that they have the most recent version of any document; a listing of current versions is maintained on the ICCBBA Website.

Table 1 Changes and Corrections Between Version 2.0.0 and Version 3.0.0

	Section in Version 2.0.0	Section in Version 3.0.0	Change	Rationale
1		Throughout	Version 3.0.0 includes changes in organization as well as many more examples and explanations.	Response to questions posed to the ICCBBA office since the publication of version 2 of this document.
2		Throughout	On example labels throughout the document, capitalization has changed on three warning phrases. It is now: • Properly identify intended recipient. • See circular of information for indications, contraindications, cautions, and methods of infusion. • Rx only	To be in compliance with CFR.
3		Throughout	On label examples throughout the document, the option has been provided to abbreviate two statements for test results: Anti-CMV Neg. Hgb S Neg.	To reduce the amount of space needed to print this information.
4		2.6.2	Indicated 2-D bar codes could be used on blood labels, but that they cannot be the sole means of communicating electronic information for the DIN, product code, ABO/Rh, and expiration date.	While it is expected that facilities will move toward the use of 2-D bar codes in the future, time must be allowed for facilities to obtain appropriate scanners to be purchased and software to be updated to read this critical information.
5	Throughout	Throughout	The term “eye-readable text” was changed to “data content text”	Consistent with other ISBT 128 documents. “Eye-readable text” had a common definition different from that used within the ISBT 128 standard and this could be confusing.

6	1	3.1	A variance from the FDA is no longer required to use ISBT 128 proper names.	Change in regulations
7	3.5.2.1.2	4.1.1.2	The Donation Identification Number must be printed such that all characters are of the same font, point size, and color.	All characters of the DIN are equally important. Printing some characters with a different prominence may give the incorrect impression that only the emphasized numbers need to be recorded.
8	3.5.2.1.3	4.1.1.3	Flag characters in the DIN will be rotated 90 degrees clockwise.	The direction of the rotation was not stated in Version 2.0.0. This is now standardized.
9	Table 3	Table 3	Added coding options for para-Bombay phenotypes Moved pooled product blood groups from Special Messages table to ABO/Rh table.	Requested by international users More logical placement. *Note: The codes for these pooled blood groups have not changed; only the table in which they appear has changed.*
10		4.3.1.1	Added national Product Description Codes B7000 through B9999.	Allow the US to create national Product Description Codes if needed.
11	3.5.5.3.1		Previous version stated "Platelets Pheresis – 7d is the Proper Name"	Version 2.0.0 incorrectly stated the proper name of this product is Platelets Pheresis - 7d. While Apheresis Platelets – 7d was the proper name, this was deleted in Version 3 because this product is no longer available in the US.
12	3.5.5.3.3	4.3.1.4	Autologous donations must be encoded with a "1" or an "X".	Version 2.0.0 incorrectly stated that "V" may be used if one of the optional codes is not used. "V" may only be used for allogeneic donations.
13	3.5.5.3.3	4.3.1.4	Added the code 0 (zero) for when the donation type is not specified.	Error correction. 0 may be used in the US for recovered plasma, source plasma, and source leukocytes (but for no other blood products).

14	3.5.5.3.3	4.3.1.4	Added a note that while the use of “D” in the Product Code is optional in Version 3.0.0, it will become mandatory in the next published version of this document.	This was a decision of the Americas Technical Advisory Group (ATAG) to improve the likelihood that a directed unit will be associated with the appropriate recipient.
15	4.1.4.1		Deleted the requirement to right justify the Donation Identification Number.	Decision of ATAG to allow printing the Donation Identification Number in a larger type size.
16	4.1.4.1, Figure 4	5.1.3.1, Figure 14	Caution statement must read, “This product may transmit infectious agents.”	Version 2.0.0 incorrectly printed this statement without the words “This product”.
17	4.1.4.1 Figure 5	5.1.3.1 Figure 16	Right justified collection date bar code.	To be consistent with international design.
18	4.1.4.4	5.1.3.4	The name of the facility that modified or further processed a product must be on the label ONLY if the product leaves the facility.	The inclusion of the name of the modifying facility is optional if the product does not leave the facility.
19		5.1.3.4	The phrases DONOR TESTED WITHIN THE LAST 30 DAYS or DONOR UNTESTED (autologous units) appears in the lower right quadrant, when appropriate.	This wording is required by the FDA if the donor unit is not tested. This was not detailed in version 2.0.0.
20		5.1.3.4	The phrase SEE TIE TAG FOR TEST RESULT INFORMATION (allogeneic units) appears in the lower right quadrant, when appropriate.	Ensure the information regarding incomplete test status is clearly indicated to the user.
21	5.3.1, Figures 10-13	7.2.2, Figure 27 and Figure 28	Examples were changed to show only the minimum required ISBT 128 information on the base label.	Non-ISBT 128 information on base labels has not been standardized.
22	5.4, Figure 13; 5.4, Figures 14-17	7.2.3, Figure 29; 7.3, Figure 30	Caution statement must read, “This product may transmit infectious agents.”	Version 2.0.0 incorrectly printed this statement without the words “This product”.
23	5.6, Figure 23	7.5, Figure 64	On the example label for POOLED CRYOPRECIPITATED AHF, POOLED is printed as part of the Class name.	In Version 2.0.0, POOLED was incorrectly printed as a Modifier.

24	5.6, Figure 25	7.8.17, Figure 98	The word “Therapeutic” should appear beneath the bar code justified to the right edge of the bar code. Test results should appear in the lower right quadrant.	Consistency.
25	7		Deleted the chapter on other documents to consult.	This information is now found on the ICCBBA Website where it can be updated more frequently and in Sections 1.4 and 1.5.
26	Appendix B	6.2, Table 5	Platelet Rich is indicated to be part of the Class for “Platelet Rich Plasma.”	Version 2.0.0 indicated Platelet Rich was a Modifier. Platelet Rich is part of the Class, not a Modifier.
27	Appendix B	6.2, Table 6 and 7.8.16	For Leukocytes (whole blood derived), the following sentence appears, “If the product is to be used for further manufacturing, it will be labeled, ‘SOURCE LEUKOCYTES.”	FDA requirement.
28	Appendix C	6.3, Table 7	The words OPEN SYSTEM will be printed on the label if the product is made in an open system.	Unless otherwise stated, the default value of an Attribute group is assumed. For the System Integrity Attribute group, the default is “closed.” Therefore, it is assumed the product was made in a closed system unless otherwise stated. This change to US requirements is required to allow facilities to determine appropriate dating on thawed products. For example, if an apheresis FFP was made in a closed system, it may be converted to Thawed Plasma and given a 5-day outdate. If it is made in an open system, the dating on the thawed product may not be extended to 5 days.
29	Appendix C	6.3, Table 7	Added Donor Exposure group	New Attribute group
30		6.4, Table 8	Included instructions for labeling platelets with platelet additive solutions.	Platelet additive solutions may be used in the US.

31	Appendix D	6.6, Table 9	Added the code 0 (zero).	This code may be used in the US for Recovered Plasma and Source Plasma, as well as Source Leukocytes.
32	Appendix D	5.1.3.3	For donation types with "Biohazard", the word "Biohazard" should appear before the phrases "For Designated Recipient Only" or "For Autologous Use Only.	This had been inconsistently presented in Version 2.0.0.
33		7.8.9	Added that in the US, apheresis plasma divided into multiple ADULT doses may be labeled either with different Product Description Codes (indicating different containers) or as division codes (7th and 8th characters of the Product Code).	Decision of the ATAG to increase flexibility and to allow for plasma apheresis collection kits that have multiple bags for collection and storage of plasma.
34		8.1	Added that the facility name/location that appears in the ICCBBA Facility Identification Number database should be the legal name and location of the facility. For FDA-licensed facilities, it should be the name and location on the FDA license. For FDA-registered (but not licensed) facilities, it should be the name and location as it appears on the FDA registration.	Clarity.

Please note that this table represents only major changes and corrections to Version 2.0.0. The document must be read in its entirety because of the expansion of many sections.

2 Overview of the ISBT 128 Standard

2.1 Need for an International Standard

A great deal of important information is presented on a blood product label. This information varies from country to country according to regulations, language differences, and local transfusion practice. In today's world of multinational disaster relief programs and multinational military operations, blood collected and processed in one country may be used in another. It is essential that critical information such as ABO and Rh, expiration date, and product description be clearly understood by medical personnel transfusing the blood product. Given the concerns about safety and traceability, it is also important that these data be easily captured by a computer system and that each product is uniquely identified on a global basis. These goals are easier to achieve if there is standardization in blood product labeling.

However, ISBT 128 is more than a labeling system; it is an information standard. This means it is designed to transfer information about blood and other products of human origin electronically and is independent of the mechanism of transfer. ISBT 128 supports information transfer by a variety of mechanisms such as linear bar codes, two-dimensional (2-D) symbols, radio frequency identification (RFID) tags, and electronic messaging.

2.2 Summary of the ISBT 128 Standard Technical Specification

The *ISBT 128 Standard Technical Specification* defines the rules for the use of ISBT 128 internationally. It:

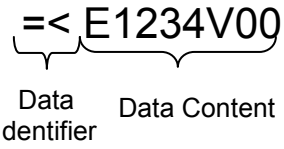
- defines the data identifiers used in the transfusion and transplantation environments;
- defines the data structures that carry information, i.e., how a particular bar code will be recognized by a reader, how many characters are present, and whether the characters are letters, numbers, or both;
- includes tables that define how bar codes should be translated;
- describes the layout for a blood product label, including the precise placement of bar codes;
- defines technical details for the Code 128 and Data Matrix bar codes, such as the width of the narrowest bars and print quality requirements; and
- describes the variation made in Code 128 to support specialized concatenation.

2.3 ISBT 128 Data Structures

Data structures define the way in which information is presented in ISBT 128. There are many data structures, only some of which are used on blood labels. Examples of data structures which encode information that does not appear on the label include Staff Member Identification Number and Patient Identification Number. Table 2, page 22, is a list of the ISBT 128 defined data structures that was complete at the time this document was published. Consult the *ISBT 128 Standard Technical Specification* for the most recent list.

Each data structure consists of data identifier characters and data content (see Figure 1) and is very precisely defined in terms of its length and permissible characters (see Table 2, page 22).

Figure 1 Data Structure



2.3.1 ISBT 128 Data Identifiers

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

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

The second character distinguishes the type of ISBT 128 information to be conveyed. For example, the two characters "=%" at the beginning of a data structure indicate that the bar code carries information about the ABO/Rh Blood Groups whereas "=<" means the bar code carries information about the Product Code. Table 2 indicates the data identifier for each ISBT 128 data structure. Consult the *ISBT 128 Standard Technical Specification* for the most recent list.

2.3.2 Data Content

Data content is the information to be conveyed. For example, the information to be communicated is that the product is A, Rh Positive. This information is encoded to allow it to be efficiently transferred electronically so that A, Rh Positive becomes 62. Internationally agreed upon reference tables are used to encode and decode information. See Table 3, page 37, for an example of such a reference table. Some

of these reference tables are found in the *ISBT 128 Standard Technical Specification*; others are found on the ICCBBA Website.

The data content appears in an eye-readable form beneath a linear bar code on an ISBT 128 label.

Figure 2 Example of Data Content on a Label

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

Table 2 ISBT 128 Data Structures

Ref	Data Structure Name	First Character of the Data Identifier		Second Character of the Data Identifier		Data Content
			ASCII Value		**ASCII Value**	
001	Donation Identification Number	=	61	A–N; P–Z; 1–9		αppppyynnnnnnff
002	Blood Groups [ABO and RhD]	=	61	%	37	ggre
003	Product Code	=	61	<	60	αooootds
004	Expiration Date	=	61	>	62	cyyjjj
005	Expiration Date and Time	&	38	>	62	cyyjjjhhmm
006	Collection Date	=	61	*	42	cyyjjj
007	Collection Date and Time	&	38	*	42	cyyjjjhhmm
008	Production Date	=	61	}	125	cyyjjj
009	Production Date and Time	&	38	}	125	cyyjjjhhmm
010	Special Testing: General	&	38	(	40	zzzzz
011	Special Testing: Red Blood Cell Antigens **[Retired]**	=	61	{	123	aaaaaaaaaaaaaaaii
012	Special Testing: Red Blood Cell Antigens -- General	=	61	\	92	aaaaaaaaaaaaaaaii

Ref	Data Structure Name	First Character of the Data Identifier		Second Character of the Data Identifier		Data Content
			ASCII Value		ASCII Value	
013	Special Testing: Red Blood Cell Antigens -- Finnish	&	38	\	92	aaaaaaaaaaaaaaaii
014	Special Testing: Platelet HLA and Platelet-Specific Antigens	&	38	{	123	AAAABBBBCCCCCCCCDE
015	Special Testing: HLA-A and -B Alleles **[Retired]**	=	61	[	91	EEEEFFFFGGGGHHHHLM
016	Special Testing: HLA-DRB1 Alleles **[Retired]**	=	61	"	34	IIIIJJJJMMMMMMMMMM
017	Container Manufacturer and Catalog Number	=	61	)	41	bqqwwwwwww
018	Container Lot Number	&	38	)	41	xxxxxxxxxx
019	Donor Identification Number	=	61	;	59	αppppvvvvvvvvvvvvvv
020	Staff Member Identification Number	=	61	'	39	αppppuuuuuu
021	Manufacturer and Catalog Number: Items Other Than Containers	=	61	-	45	NNOOOOOOOO
022	Lot Number: Items Other Than Containers	&	38	-	45	PPPPPPPPPP
023	Compound Message	=	61	+	43	aabbb
024	Patient Date of Birth	=	61	#	35	aayyyymmdd
025	Patient Identification Number	&	38	#	35	aallxx…xx
026	Expiration Month and Year	=	61	]	93	yyyymm
027	Infectious Markers	&	38	“	34	nnnnnnnnnnnnnnnnn

Ref	Data Structure Name	First Character of the Data Identifier		Second Character of the Data Identifier		Data Content
			ASCII Value		**ASCII Value**	
028	Product Consignment	=	61	$	36	αppppyynnnnnccdd
029	Dimensions	&	38	$	36	nnaabbbbccccccdee… aabbbbccccccdee
030	Red Cell Antigens with Test History	&	38	%	37	nnnpppppprrss…pppppprrss
	Data structures not defined by ICCBBA	&	38	a-z		These data identifiers may be assigned by a facility or a regional, national, or super national authority,
	Reserved Data Identifiers for a Nationally-Specified Donor Identification Number	&	38	;	59	Defined nationally
	Confidential Unit Exclusion Status Data Structure	&	38	!	33	Defined nationally

2.4 ISBT 128-Specified Label

The ISBT 128 blood product label is divided into four quadrants of equal size, 50 mm (2") wide by 50 mm (2") long. Regardless of site of collection worldwide, the bar codes should be placed in the same relative positions. The *ISBT 128 Standard Technical Specification* defines the placement of the following bar codes (see Figure 3, page 26).

Base Label:

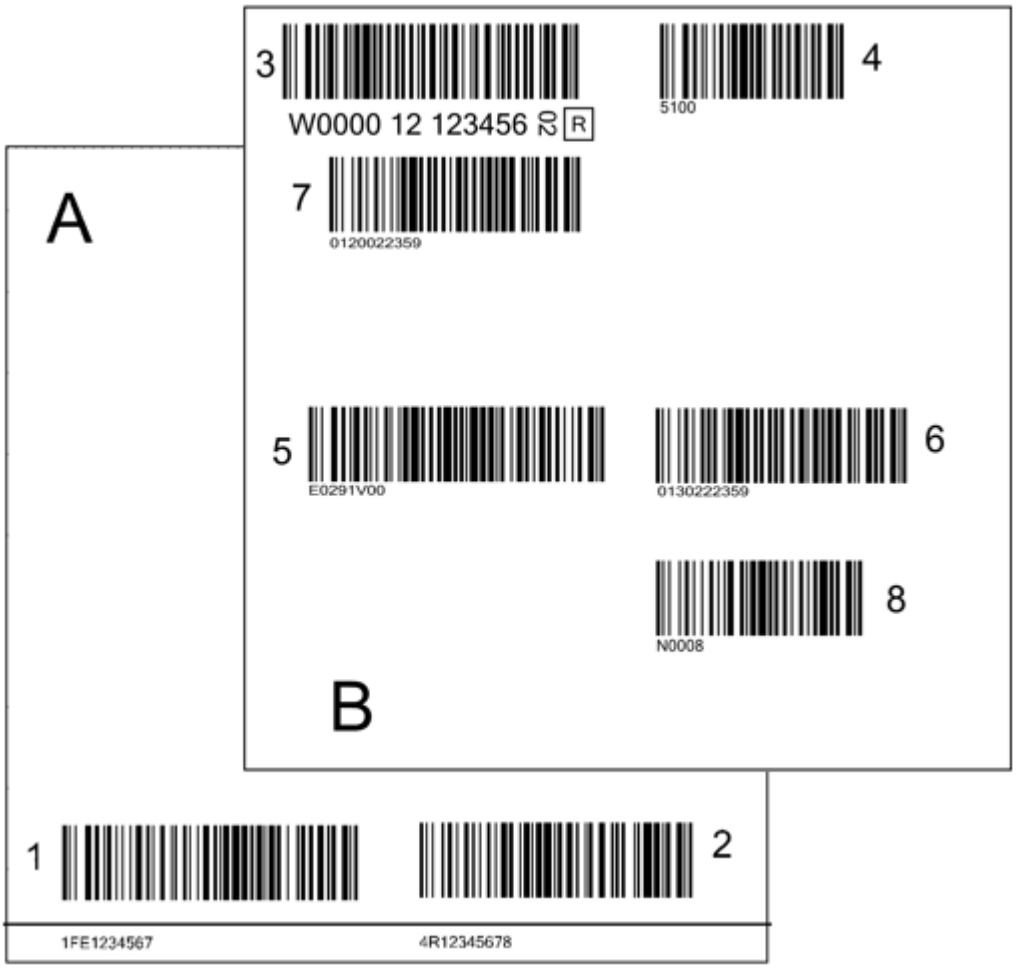
- Container Manufacturer Identity and Catalog Number
- Container Lot Number

Final Label:

- Donation Identification Number
- ABO/Rh Blood Groups [Kell and Rh phenotypes] [Type of Donation or Collection]
- Product Code [Type of Donation or Collection]
- Expiration Date and Time
- Collection Date or Collection Date and Time
- Special Testing

Not all bar codes must appear on all US products. Requirements are defined in sections for US Specifications for each data structure in Chapter 4.

Figure 3 ISBT 128-Specified Label



A — Base label
B — Final container label

Key:
1 Container Manufacturer Identity and Catalog Number
2 Container Lot Number
3 Donation Identification Number
4 ABO/Rh Blood Groups
5 Product Code
6 Expiration Date and Time
7 Collection Date (and Time)
8 Special Testing

The Container Manufacturer Identity and Catalog Number bar code and the Container Lot Number bar code are part of the container manufacturer's base label (A on Figure 3). Both of these bar codes will be covered by final labeling, although the data content text below the bar codes should remain visible.

Bar codes 3 through 8 are part of final labeling (B on Figure 3). Bar code 6 is the Expiration Date and Time; this information is not required to be bar coded in the US. Bar code 7 is the Collection Date or Collection Date and Time, it is only used on certain products (e.g., Recovered Plasma), and this information is not required to be bar coded in the US. Bar code 8 (Special Testing) is optional information and may or may not appear on the final label.

With the exception of the Donation Identification Number, for which the eye-readable information is presented in a specialized way, the data characters in the bar code are printed immediately below each linear bar code symbol. This text is called data content text (to understand text terminology used in this document, see Figure 103, page 151) and is standardized globally.

The eye-readable representation of the interpreted bar coded information, called bar code text in this document, and any other text on the label, called additional text in this document (again, see Figure 103, page 151), are defined by each country to meet its own requirements. This document defines the bar code text and additional text for the US.

2.5 Concatenation

Concatenation is the term used to describe the reading of two (or more) bar codes as if they were a single bar code. Details are given in the *ISBT 128 Standard Technical Specification*. There is no US requirement that concatenation be used, but it does provide improved process control.

The value of concatenation is the ability to check that two bar codes are attached to a single unit. This is accomplished by requiring that the second bar code be read within a time period too short to permit reading a bar code not on the same unit. In designing ISBT 128, two pairs of bar codes are placed in horizontal alignment for ease of concatenation. The first pair, the Donation Identification Number and the ABO/Rh Blood Groups bar codes, ensures that the ABO/Rh label applied is correct according to the data in the host computer for the particular unit. The second pair, the Product Code and the Expiration Date and Time bar codes, should also be consistent since the Product Code can change during further manufacturing requiring a corresponding change in the Expiration Date and Time.

The ISBT 128 label was designed specifically so that these two pairs of bar codes could be concatenated. However, in applications other than the standard blood label, different pairs of bar codes may be concatenated if desired.

2.6 Delivery Mechanisms

ISBT 128 data structures are symbology-independent allowing them to be used with new bar code symbologies or other data capture technologies.

2.6.1 Linear Symbology: Code 128

The linear symbology selected for ISBT 128 bar code labeling is Code 128. Code 128 was chosen for several reasons. First, it is a secure symbology. In addition to each Code 128 character being self-checking (three different ways), there is a built-in check digit. Misreads due to a single substitution error are extremely rare; scanning errors (when they occur) generally produce no-reads rather than misreads. Security of data capture is thereby increased dramatically.

Next, Code 128 has three subsets, A, B, and C. Alphabetic characters are available in subsets A and B and allow more flexibility in coding highly variable information. The double-density coding of numeric characters supported by subset C allows more information to be encoded in a given space. This is important because of the limited space on blood container and sample tube labels.

Finally, Code 128 is used extensively by many industries making it easy to find scanners capable of reading it.

2.6.2 Two Dimensional Symbologies

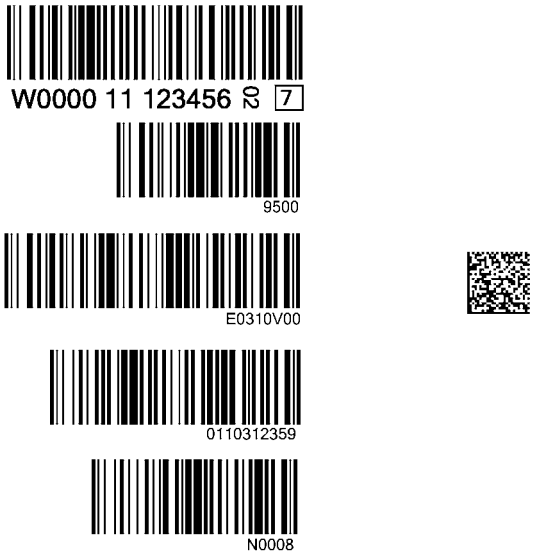
2-D symbologies are used where there is a great deal of information to convey and little space on the label. See Figure 4. All of the information encoded into the five Code 128 linear bar codes on the left side of this figure is encoded into the single Data Matrix symbol on the right.

There are a variety of 2-D symbologies available. If an ISBT 128 2-D symbol is used on a blood, cellular therapy, or tissue product label, then Data Matrix must be used. For technical details about the use of Data Matrix, see the *ISBT 128 Standard Technical Specification, Implementation Guide: Use of Data Matrix Symbols with ISBT 128,* and ISO/IEC 16022:2006(E): Information Technology—International Symbology specification—Data Matrix. Currently there are no specific recommendations for the use of Data Matrix symbols on blood labels in the United States. The use of 2-D symbols on cellular therapy labels is described in the *United States Consensus Standard for the Uniform Labeling of Cellular Therapy Products Using ISBT 128*.

Reading the 2-D symbols requires an imaging scanner. Imaging scanners are able to read both 2-D and linear bar codes such as Code 128. Because 2-D symbols may be used in the future on cellular therapy products, derivatives, patient wristbands, and even blood labels, facilities may wish to consider purchasing imaging scanners when their current scanners are replaced.

In the US, a 2-D bar code may not be the sole means of communicating electronic information for the DIN, product code, ABO/Rh, or expiration date on blood products at this time.

Figure 4 Comparison of Code 128 and Data Matrix Symbols



2.6.3 Radio Frequency Identification Tags

The use of Radio Frequency Identification (RFID) tags in transfusion medicine is being explored at the current time. If RFID technology proves suitable for transfusion medicine, ISBT 128 data structures can be used to transfer information through this technology.

For further information on the use of RFID technology, see: 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.

3 Use of ISBT 128 in the US

This *US Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128* blends the requirements of the AABB and FDA with the ISBT 128 international model. Individuals from FDA and AABB participate in the Americas Technical Advisory Group (ATAG) of ICCBBA to ensure this document continues to reflect the requirements of FDA and AABB.

3.1 FDA Position

FDA first recognized the ISBT 128 Standard in an FDA guidance published in 2000. In 2006, FDA published the updated *US Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128*, Version 2.0.0, as a guidance document (this document was written at the end of 2005).

ISBT 128 was developed as an international standard. Therefore the ISBT 128 component name (with any appropriate Modifiers and Attributes) does not always match the proper names of components in the Code of Federal Regulations (CFR). A specific instance of this is Cryoprecipitated AHF. In the international database, this product is called Cryoprecipitate. Other examples of US proper names that are different from ISBT 128 class names appear in Section 6.2.

FDA licensed establishments should submit copies of their ISBT 128 labels for licensed products to the FDA for approval.

FDA does not require ISBT 128. However, it does require that certain information on the label [unique facility identifier, lot number relating to the donor (called Donation Identification Number in this document), ABO/Rh of the donor, and Product Code] be machine readable. In publishing the *US Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128* as a guidance document, FDA has recognized that ISBT 128 labels meet these requirements.

The Code of Federal Regulations takes precedence over this and other ISBT 128 documents for blood product labeling in the US.

The inclusion of example labels in this consensus document for any given product does not necessarily mean that the product is an FDA-licensable product.

3.2 AABB Position

The AABB Standards require that blood be labeled using ISBT 128 in its accredited facilities (both within and outside the US).

4 Data Structures

The *ISBT 128 Standard Technical Specification* describes all ISBT 128 data structures. The following sections discuss those data structures with unique US specifications.

4.1 Donation Identification Number [001]

This data structure provides for the unique identification of any donation or product pool worldwide for a one hundred year period.

The Donation Identification Number (DIN) has 13 data characters:

αppppyynnnnnn

where:

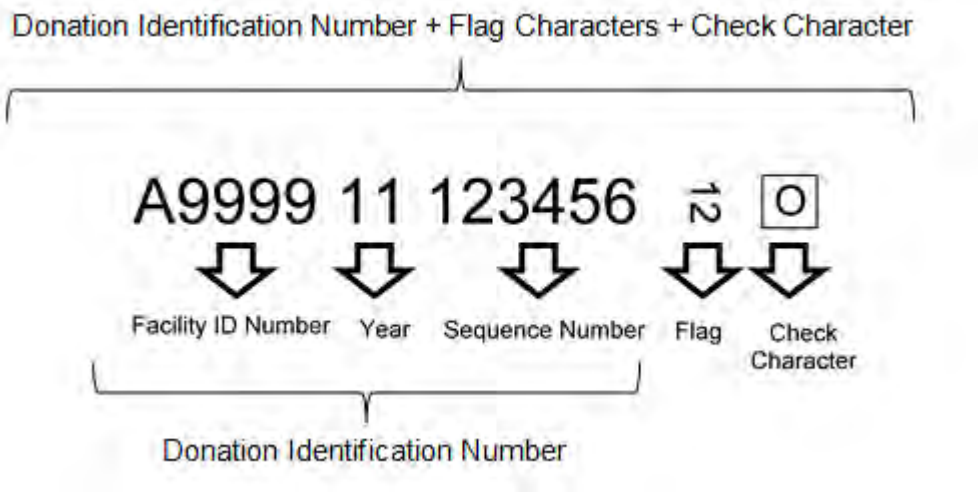
αpppp	designates the collection or pooling facility;
yy	designates the year in which the donation or collection was made;
nnnnnn	is a serial number associated with the donation, collection, or pooled product.

Other data characters incorporated into this bar code are “flag” characters. These may be used to assist in process control (such as identifying materials used in the collection process — container 1, container 2, tube 1, tube 2, etc. — permitting verification that the bar code has been scanned from the expected location — from container 1, etc.) or to support additional checks for accurate data transmission. The specific meaning associated with flags is defined in the *ISBT 128 Standard Technical Specification*. Flag characters are the last two characters of the DIN data structure. However, they are not part of the DIN itself. Flag characters are to be used in process control; it is not intended that they be recorded as part of the DIN in facility documents.

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

An additional check character (not the same check character integral to every Code 128 bar code) calculated on the entire 13 data character DIN (αppppyynnnnnn) will be printed, enclosed in a box, to the right of the DIN. The ISO modulo 37-2 method is used to compute this check character. This check character can be used to ensure the accuracy of keyboard data entry when appropriately supported by computer software.

Figure 5 Donation Numbering



4.1.1 US Specification

4.1.1.1 Application

The DIN must be machine and eye-readable.

Usually, the DIN is the first label applied to collection containers intended to contain blood products. It is applied before whole blood or apheresis products are collected.

For pooled products, a unique identification number must be assigned. This number should be in the same format as the DIN and reflect the Facility Identification Number of the pooling facility.

4.1.1.2 Printing the DIN

The eye-readable DIN, flag and check characters will appear as follows:

W0000 12 123456 98 R

The DIN is divided into three parts (Facility Identification Number, year, and serial number) in its eye-readable form for ease in reading. This should facilitate checking and recording the DIN into records when the bar code is not scanned.

No portion of the 13-character DIN shall be emphasized. That is, the entire number must appear in the same size, font, and color.

4.1.1.3 Flag Characters

Flag characters may be used as detailed in the *ISBT 128 Standard Technical Specification.* The default or null value, 00, should always be present as part of the DIN bar code when other flags are not used.

As shown in Figure 5, page 32, flag characters are printed in a way that identifies their special role, either rotated 90 degrees clockwise (i.e., printed vertically rather than horizontally) or in "pictorial" or "iconized" format (e.g., a picture of a test tube).

4.1.1.4 Keyboard Entry Check

Although keyboard entry of the DIN into a computer system is strongly discouraged, there will be times when it is necessary. Computer system software should be designed to recognize keyboard entry of the DIN and to require verification of data entry by the additional check character described above.

Keyboard check characters should be printed within a box as shown in Figure 5, page 32.

4.1.1.5 Avoiding Label Waste

Preprinted DINs may be used over a fourteen month period to cut down on waste. For example, labels bearing the year "14" may be used from December 1, 2013 through January 31, 2015. The collection facility must have an accurate record of the actual date of collection. The rationale behind allowing the 14-month tolerance in the collection year appearing in the DIN is that this year notation is present only to ensure uniqueness of the DIN every 100 years. It does not in any way replace the expiration date (or collection date, as appropriate) on the label.

4.2 ABO/Rh Blood Groups (002)

This data structure has four (4) data characters:

ggre

where:

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

r specifies Rh and Kell or GP-Mur (Miltenberger III) phenotype information;

e is reserved for future use.

Special messages, e.g., FOR LABORATORY RESEARCH USE ONLY, and other information may be encoded instead of ABO and Rh blood group information if appropriate (see Table 4, page 39).

4.2.1 US Specification

The ABO/Rh must be machine and eye-readable.

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

The type of donation or collection should be specified in this bar code in accordance with Table 3, page 37.

Text should be printed:

	ABO text	Rh text	Example
Rh Positive	Solid black	Black on white	Figure 32, Page 101
Rh Negative	Outline black	White on black	Figure 33, Page 101
Rh not specified	Solid black	Not applicable	Figure 34, Page 101

Autologous and directed (dedicated, designated) units that cannot be crossed over do not follow the above format to distinguish Rh positive and Rh negative products because of the smaller size of the bar code text (see Figure 35 and Figure 36, page 102).

If the blood product is from an individual of the Bombay or para-Bombay phenotype, BOMBAY (O_h) or PARA-BOMBAY A_h (or B_h, AB_h, or O_h) will be printed in place of A, B, AB, or O (see Figure 38, page 103).

4.2.1.1 Application

Usually, the ABO/Rh label is the last applied after all testing of the donation or collection is complete.

4.2.1.2 Type of Donation or Collection/Intended Use

Information about the type of donation or collection/intended use [e.g., Autologous or Directed (Dedicated, Designated) Collection] is to be included in the ABO/Rh Blood Groups bar code when the blood product is to be used solely for a specific recipient (that is, it cannot be crossed over for use by another patient) or used for a special purpose. If the blood product is not intended solely for a specific recipient or is not one of the special purpose blood products listed in Table 4, Page 39, the default "gg" (n) value for the ABO/Rh blood groups should be used.

The default values of "gg" are shown as an "n" value in Table 3, Page 37. These "n" values are used to calculate the appropriate values of "gg" for other units. In the US, these values may be (n–4), (n–3), (n–2), n, (n+2) and (n+3).

One value allowed internationally is not used in the US.

- The value (n–1) (Directed, Eligible for Crossover) is currently not used in the US. This information can be encoded in the Product Code, however.

NOTE: IN THE NEXT VERSION OF THIS DOCUMENT, n-1 WILL LIKELY BE ALLOWED. A FORMAL CHANGE PROCESS WILL BE FOLLOWED TO ENSURE USER INPUT INTO THIS DECISION.

When the blood product is to be used for a specific recipient or for a special purpose, the ABO/Rh label should look very different from the appearance of a standard allogeneic unit (see Figure 35 and Figure 36, page 102).

If the unit is for autologous use, values "n+2" (For autologous use only) or "n+3" (For autologous use only/Biohazard) will be used. In both cases, the label will have FOR AUTOLOGOUS USE ONLY printed below the ABO/Rh bar code text as shown in Figure 35, page 102. The international biohazard symbol and the word BIOHAZARD will appear before the phrase FOR AUTOLOGOUS USE ONLY when "n+3" is used. In the US, the value "n+1" (for autologous use, eligible or crossover) is not used routinely because AABB Standards preclude the routine crossover of autologous units. US software is unlikely to support this option.

If the blood product is a directed, designated, or dedicated donation that is intended solely for a specific recipient, the "n–4" (Directed Only) or "n-2" (Directed Only/Biohazard) values may be used and FOR DESIGNATED RECIPIENT ONLY should be printed below the ABO/Rh bar code text as

shown in the illustration in Figure 36, page 102. The international biohazard symbol and the word BIOHAZARD will appear before FOR DESIGNATED RECIPIENT ONLY when “n-2” is used.

If the blood product is a directed, designated, or dedicated donation that may be crossed over, it should be labeled in the upper right quadrant as a routine allogeneic donations (“n” option). During the time that such a unit is reserved for a specific recipient, an intended recipient label or tie tag such as the ones illustrated in Figure 100, page 143, should be attached or affixed to the unit providing the appropriate information. When released for routine use, this label or tie tag should be removed.

If the product is being released by the collection or processing facility prior to completion of testing, the “n-3” (FOR EMERGENCY USE ONLY) should be used. See Figure 77, page 122 for an example. FOR EMERGENCY USE ONLY and the name of the patient and hospital where the patient is located should be on the label or labeling.

4.2.2 Rh, Kell, and GP-Mur (Miltenberger III) Phenotypes

As noted above, Rh, Kell, and GP-Mur (Miltenberger III) phenotypes should not be encoded as part of the ABO/Rh Blood Groups bar code in the US.

Table 3 ABO/Rh Blood Groups Data Structure: Values of "gg"

Note: Shaded column indicates a type of donation (autologous eligible for crossover) that is not commonly used in the US. It is included for the sake of completeness since it is not precluded by federal regulations. Software in the US is unlikely to support this option.

ABO and RhD Blood Groups	Default: Intended Use Not Specified (n)	Directed (Dedicated/ Designated) Collection Use Only (n-4)	For Emergency Use Only (n-3)	Directed (Dedicated/ Designated) Collection/ Biohazard (n-2)	Autologous Collection/ Eligible for Crossover (n+1)	For Autologous Use Only (n+2)	For Autologous Use Only/ Biohazard (n+3)
O RhD negative	95	91	92	93	96	97	98
O RhD positive	51	47	48	49	52	53	54
A RhD negative	06	02	03	04	07	08	09
A RhD positive	62	58	59	60	63	64	65
B RhD negative	17	13	14	15	18	19	20
B RhD positive	73	69	70	71	74	75	76
AB RhD negative	28	24	25	26	29	30	31
AB RhD positive	84	80	81	82	85	86	87
O	55	P2	P3	P4	P7	P8	P9
A	66	A2	A3	A4	A7	A8	A9
B	77	B2	B3	B4	B7	B8	B9
AB	88	C2	C3	C4	C7	C8	C9
para-Bombay, RhD negative	D6	D2	D3	D4	D7	D8	D9
para-Bombay. RhD positive	E6	E2	E3	E4	E7	E8	E9
Bombay, RhD negative	G6	G2	G3	G4	G7	G8	G9
Bombay, RhD positive	H6	H2	H3	H4	H7	H8	H9
O para-Bombay, Rh D negative	I6	I2	I3	I4	I7	I8	I9
O para-Bombay, RhD positive	J6	J2	J3	J4	J7	J8	J9

ABO and RhD Blood Groups	Default: Intended Use Not Specified (n)	Directed (Dedicated/ Designated) Collection Use Only (n-4)	For Emergency Use Only (n-3)	Directed (Dedicated/ Designated) Collection/ Biohazard (n-2)	Autologous Collection/ Eligible for Crossover (n+1)	For Autologous Use Only (n+2)	For Autologous Use Only/ Biohazard (n+3)
A para-Bombay, RhD negative	K6	K2	K3	K4	K7	K8	K9
B para-Bombay, RhD negative	L6	L2	L3	L4	L7	L8	L9
AB para-Bombay, RhD negative	M6	M2	M3	M4	M7	M8	M9
A para-Bombay, RhD positive	N6	N2	N3	N4	N7	N8	N9
B para-Bombay, RhD positive	O6	O2	O3	O4	O7	O8	O9
AB para-Bombay, RhD positive	Q6	Q2	Q3	Q4	Q7	Q8	Q9
Group A, Pooled Rh [Pooled Products]	A0						
Group B, Pooled Rh [Pooled Products]	B0						
Group AB, Pooled Rh [Pooled Products]	C0						
Group O, Pooled Rh [Pooled Products]	D0						
Pooled ABO, Rh Positive [Pooled Products]	E0						
Pooled ABO, Rh Negative [Pooled Products]	F0						
Pooled ABO, Pooled Rh [Pooled Products]	G0						
Pooled ABO [Rh not specified] [Pooled Products]	H0						

Table 4 Values of “gg” for ABO/Rh Data Structure for “Special Purpose” Blood Groups

Value of “gg”	Interpretation
Ma	Autologous collection
Mb	Biohazard
Md	Discard (to be destroyed)
Mf	For fractionation use only
Mq	Quarantine/hold for further testing or processing
Mr	For research use only
Mx	Not for transfusion based on test results

4.3 Product Code (003)

The Product Code data structure has eight (8) data characters:

αooootds

where:

αoooo specifies the Product Description Code and is encoded and interpreted by reference to the Product Description Code Database table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website (see 8.2, page 145).

α currently indicates the following product groups:

- E or F – blood components
- M – Other Therapies:
  - o Human milk - codes beginning with M0 (M0001 to M0999)
  - o Not assigned - codes beginning with M1 through M8 (M1000 to M8999)
  - o Topical use products of human origin - codes beginning with M9 (M9000 to M9999)
- N – Partially assigned:
  - o Organs for Transplant – codes beginning with N0 (N0001 to N0999)
  - o Not assigned – codes beginning with N1 through N9 (N1000 to N9999)
- R – Partially assigned
  - o Reproductive Tissue – codes beginning with R0 (R0001 to R0999)
  - o Not assigned – codes beginning with R1 through R9 (R1000 to R9999)
- S – cellular therapy products
- T – tissues
- V – ocular tissue
- X – derivatives
- A-D – national or local codes (see below).

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

A-D National or Local Codes

The block of Product Description Codes, A0000-D9999, has been reserved for use as nationally or facility defined Product Description Codes. There will be no international interpretation associated with these values.

These codes should ONLY be used where there is not an appropriate international code and there is good reason why an international code

αooootds

where:

should not be allocated. For example, local codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty about whether the code assigned to a product should be international or local/regional/national, the user should contact the ICCBBA office.

National agencies may elect to reserve a range of these values for national assignment (see 4.3.1.1 for US Product Description Codes). Where this is done it is the responsibility of the national agency to ensure that definitions are provided for use within the country and that products bearing such codes are not transferred outside the national boundary.

Individual facilities may also assign codes for their own use provided that these do not conflict with codes assigned at the national level. Where such codes are used, it is the responsibility of the facility to ensure that definitions are provided for use within their service region, and that products bearing such codes are not transferred outside their normal distribution network. Care will have to be taken in interpreting the product description from a local code as this will be specific to the supplier.

In all cases, the product definition for nationally or facility assigned codes must be retained permanently for traceability purposes. Once assigned, codes shall not be reassigned.

t — for blood products, designates the type of donation or collection/intended use (see Table 9, beginning on page 91);

ds — provides information about divisions of the blood product.

Data characters seven and eight (ds) are reserved for encoding information about divisions of blood products. When a blood product is divided into two or more parts, the seventh and eighth data characters are changed from “00” (zero, zero), the default values. See 7.8.3, page 118, for examples of how these characters may be used.

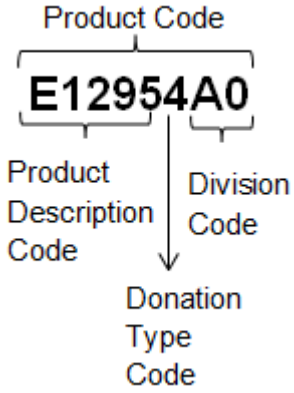
The 7th and 8th characters are generally used to indicate divisions when less than standard adult doses are involved (i.e., pediatric doses). When a donation is divided into multiple adult doses during collection (e.g., Apheresis Red Blood cells or Apheresis Platelets), this division is coded as part of the Product Description Code. Such an apheresis product could subsequently be divided into pediatric aliquots. These subsequent divisions into pediatric doses would be coded using the 7th and 8th characters of the Product Code (i.e., the Product Description Code could indicate, for example, 2nd Container, but there could be an A or B in the seventh position if the contents of the 2nd container were subsequently divided into pediatric aliquots).

For example:

E3087 is the Product Description Code for Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container. The full Product Code for a volunteer donor would be E3087V00.

When divided into two pediatric aliquots in a closed system, the Product Codes become E3087VA0 and E3087VB0.

Figure 6 Product Code Structure



4.3.1 US Specification

The Product Code must be machine and eye-readable.

The ISBT 128 Product Description Code database is an international data base and contains descriptions for blood products that are not used in the US. The approval for use of any blood product in the US remains the purview of the FDA. It should not be assumed that because a blood product description exists in the database that it is acceptable to produce and distribute the blood product within the US.

4.3.1.1 National Product Description Codes

In the US, Product Description Codes in the range **B7000 through B9999** have been reserved for national use. These codes should NOT be used for local Product Description Codes.

4.3.1.2 Proper Name

In order to simplify label design in a rules-based system, and to promote international harmonization, the proper name of a blood product in the US will generally be a reflection of the component Class and Modifiers as they appear in the ISBT 128 Product Description Code Database. Some exceptions are:

- Plasma for manufacture is either Source Plasma or Recovered Plasma;
- Cryoprecipitate is Cryoprecipitated AHF;
- Pooled Platelets with bacterial monitoring or bacterial testing following FDA guidelines for extension of dating are Pooled Platelets -5d;
- Red Cells to which plasma has been added are Reconstituted Red Blood Cells
- Leukocytes for manufacture (either apheresis or whole blood derived) are Source Leukocytes

Table 5, beginning on page 67, and Table 6, page 73, provide the proper names for products in the US.

4.3.1.3 Attributes

Table 7 (beginning on page 74) contains a listing of each Attribute Group used in the US (current as of the date of publication of this document) and its accompanying text.

4.3.1.4 Type of Donation or Collection/Intended Use

The type of donation or collection/intended use can be encoded in the sixth data character of the Product Code bar code. Codes that are acceptable for use in the US, as well as the wording of the label text, are shown in Table 9, beginning on page 91.

In the US, the following usage is mandatory:

Code	Required for
V	All blood products intended for transfusion that are collected from volunteer allogeneic donors if one of the optional codes is not used.
P	All blood products intended for transfusion that are collected from paid donors if one of the optional codes is not used.
T	Therapeutic collections if they are labeled for transfusion; it is not required if the collection is promptly discarded. Facilities may also use “V” rather than “T” if the facility has been granted approval from FDA for an alternative procedure to 21 CFR 640.3(d) under the provisions of 21 CFR 640.120 to distribute Whole Blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor’s disorder on the container label.
X or 1	Blood products collected from autologous donors that are not eligible for crossover.
A	Autologous unit eligible for crossover. However, because this crossover of autologous units is not a standard practice in the US, software may not be able to support the use of this code.

In the US, the following usage is optional:

R, S, D*, 2, 3, 4, or 5 may be used in place of V

> ** NOTE: WHILE THE USE OF "D" IN THE PRODUCT CODE FOR DIRECTED DONATIONS ELIGIBLE FOR CROSSOVER IS OPTIONAL IN VERSION 3.0.0 OF THE US CONSENSUS STANDARD, IT WILL BECOME MANDATORY WHEN THE NEXT VERSION OF THE US CONSENSUS STANDARD IS PUBLISHED.*

r, s, or d may be used in place of P

0 (zero) (meaning "not specified") may be used for Recovered Plasma, Source Plasma, or Source Leukocytes

When appropriate (see 4th column on Table 9, beginning on page 91) the donation or collection type which is encoded in the 6th character of the Product Code should be printed immediately below the bar code to the right of the required eye-readable information as illustrated in Figure 7. An example of an autologous unit is shown in Figure 69, page 111. The printing should be the same size and height as the required data content text. Bar code text to be printed may be found in Table 9, page 91.

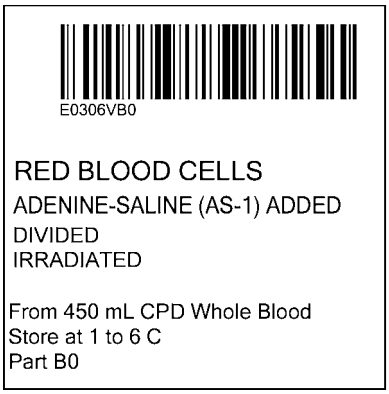
Figure 7 Donation Type Encoded in Product Code

When a unit that is labeled as a directed (or designated or dedicated) is to be crossed over, it is the prerogative of the facility to determine if the Product Code and the corresponding bar code need to be changed to reflect that the product is no longer reserved for the intended recipient.

4.3.1.5 Divisions

The scheme outlined in the *ISBT 128 Standard Technical Specification* will be used for identifying divisions. If the seventh and eighth data characters are other than "00," then the term DIVIDED should appear on the label in the first Attribute line, followed by Attributes such as IRRADIATED. If desired, a notation describing the division number may appear in the text below the storage temperature (see Figure 8, page 45).

Figure 8 Labeling of Divisions



Section 7.8.3 provides examples of how the system may be used to label pediatric aliquots.

4.3.1.6 Examples of Labels

Chapter 7 provides examples of labels based on these rules. From these illustrations, the logic to be used when designing a blood product description label can be seen. It is not intended that this document should provide an illustration of every possible combination — there are far too many — so it is important that the rules and logic behind the illustrations provided be clearly understood. ICCBBA will assist facilities, or their label vendors, in designing needed labels. If there are required labels that “will not fit” the logic and rules provided in this document, or when designing labels utilizing Classes, Modifiers, or Attributes that did not exist at the time of the printing of this document, please contact the ICCBBA office.

4.3.1.7 Obtaining a New Product Description Code

An on-line request form for new Product Description codes may be found on the ICCBBA website. Instructions for completion of this form are found in *Use of Product Code Data Structure [003] - Blood.*

4.4 Expiration Date and Time (005)

This data structure has 10 data characters:

cyyjjjhhmm

where:

c	designates the century (e.g., 0 for 2000; 1 for 2100)
yy	designates the year of expiration
jjj	is the ordinal (or Julian) date (the number of the day in the year, e.g., 022 is 22 JAN)
hh	is the hour (00–23) at which the product expires
mm	is the minute at which the product expires (00–59)

A day is defined as beginning at midnight (00:00) and ending at 23:59.

4.4.1 US Specification

The expiration date/time does not have to be machine readable, but this will improve process control. The expiration date must appear in text on the label. If the dating period for the product is 72 hours or less, the time of expiration must also appear on the label.

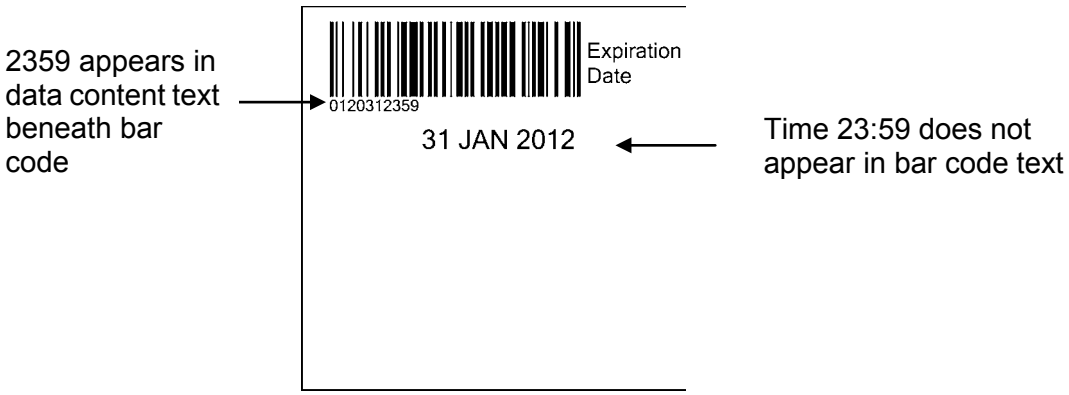
This format is DD MMM YYYY. For example:

21 JUL 2009

Abbreviations for month are: JAN; FEB; MAR; APR; MAY; JUN; JUL; AUG; SEP; OCT; NOV; DEC.

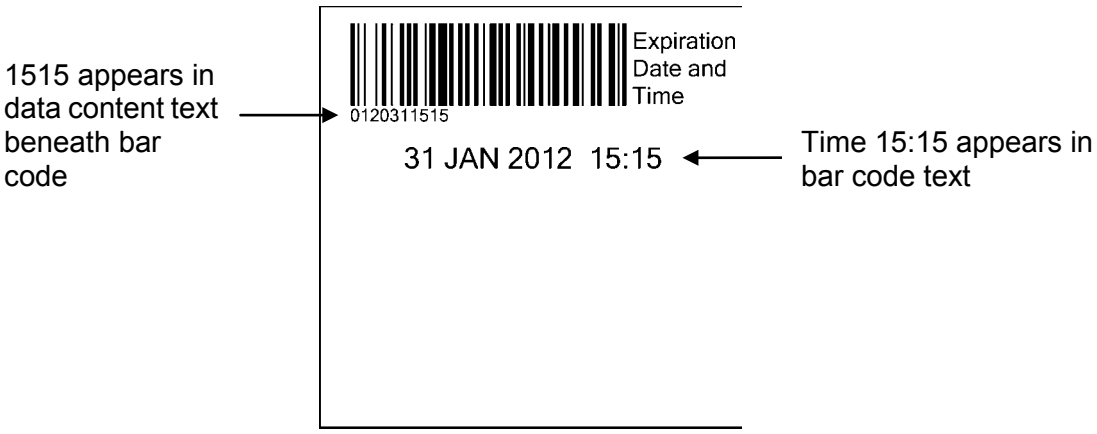
When a product outdates at midnight as a default, the time should be encoded into the bar code as 2359 and be displayed in the data content text as 2359, as shown in Figure 9. However, the time should not be shown in the bar code text; midnight expiration is assumed. (For an explanation of “text” terminology, see the Glossary.)

Figure 9 Text When Expiration is Default Time of 23:59



If the dating period for the product is 72 hours or less, the time of expiration must appear on the label. It should therefore be encoded in the bar code and printed in the data content text. In the bar code text, the time should be printed after the date with a colon separating hours from minutes in the bar code text. For example:

Figure 10 Expiration Date and Time



4.5 Collection Date (006)

This data structure has 6 data characters:

cyyjjj

Where:

c	is the century of the year in which the product was collected
yy	is the year within the century in which the product was collected
jjj	is the ordinal (or Julian) date on which the product was collected

The text is printed as described in 4.4.1.

4.5.1 US Specification

Collection date is not required to be machine readable, but this would improve process control.

Collection dates are not included on most product labels. Collection dates are utilized on Source Leukocytes and Recovered Plasma (and may be utilized on Source Plasma depending on contract requirements) when collection time is not critical.

Figure 11 Collection Date on Recovered Plasma Label

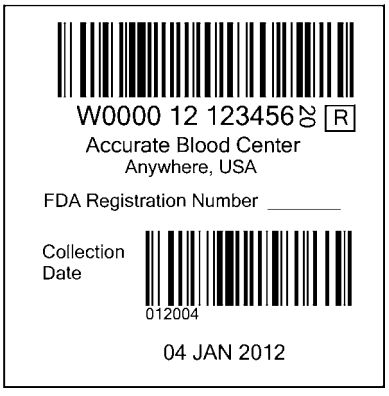
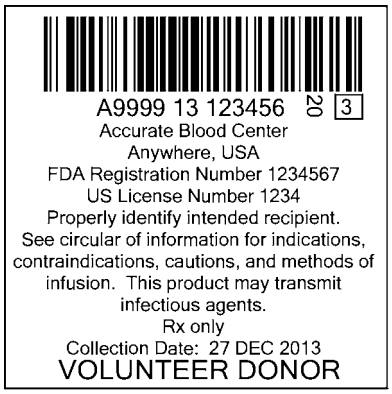


Figure 12 Collection Date on a Product for Transfusion



4.6 Collection Date and Time (007)

This data structure has 10 data characters:

cyyjjjhhmm

where:

c is the century of the year in which the product was collected

yy is the year within the century in which the product was collected

jjj is the ordinal (or Julian) date on which the product was collected

hh is the hour at which the product was collected (00 to 23)

mm is the minute at which the product was collected (00 to 59)

A day is defined as beginning at midnight (00:00) and ending at 23:59.

4.6.1 US Specification

Collection date and time are not included on most product labels. Collection date and time are utilized on Recovered Plasma (and may be utilized on Source Plasma depending on contract requirements) when collection time is critical. The text is printed as described in 4.4.1.

Collection date and time are not required to be machine readable but this would improve process control.

4.7 Special Testing: General (010)

An optional ISBT 128-specified data structure has been defined to contain the results of special or additional testing (e.g., CMV or Hemoglobin S). The codes appear in the Special Testing: General database maintained on the ICCBBA Website. See the *ISBT 128 Standard Technical Specification* for details.

4.7.1 US Specification

Examples of US labeling for this bar code are provided in Figure 66, page 109.

The code N0008 will be used to indicate the product is negative for antibodies to CMV based on testing of the current product (i.e., historical results for the donor may not be used). The text that will appear with this code is: Anti-CMV Neg. or Negative for Antibodies to CMV, or a similar phrase.

Special Testing information is not required to be machine readable.

4.8 Special Testing: Red Blood Cell Antigens (012)

An optional ISBT 128-specified data structure has been defined to contain the results of additional testing for red blood cell antigens, as well as CMV, Hemoglobin S, parvovirus B19, and IgA in conjunction with red cell antigen results. A description of the coding and the reference table can be found in the *ISBT 128 Standard Technical Specification*.

4.8.1 US Specification

Examples of US labeling for this bar code are provided in Figure 66 and Figure 67, page 109 and Figure 68, page 110.

Red blood cell antigen information is not required to be machine readable.

4.9 Special Testing: Platelet HLA and Platelet-Specific Antigens (014)

An optional ISBT 128-specified data structure has been defined to contain the results of additional testing for platelet HLA and platelet-specific antigens, as well as CMV and high titer anti-A and B in conjunction with these results. A description of the coding and the necessary reference tables can be found in the *ISBT 128 Standard Technical Specification.*

4.9.1 US Specification

US labeling for this bar code should conform to the examples provided in the *ISBT 128 Standard Technical Specification*.

Platelet HLA and platelet-specific antigen information is not required to be machine readable.

5 Uniform Labeling Using ISBT 128

5.1 Concepts

5.1.1 Principles of Label Design

To remain within the “rules-based” system of ISBT 128, the following principles apply:

- 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 layout of the bar codes applied to primary, collection, satellite, or transfer containers shall conform to the quadrant design as outlined in the *ISBT 128 Standard Technical Specification* when space permits as follows:

  Upper left: Donation Identification Number / Collection Date (and Time)

  Upper right: ABO/Rh Blood Groups and Type of Donation or Collection/Intended Use

  Lower left: Product Code

  Lower right: Expiration Date and Time and Special Testing

- An eye-readable representation of the bar code data content shall appear beneath each linear bar code symbol on the container. It shall contain all data characters within the symbol, but shall not include the data identifier, start/stop characters, special characters (shift C, etc.), or the Code 128 modulo 103 check digit. With the exception of the Donation Identification Number, this representation will generally appear left justified with the first bar in the symbol.

- Being able to scan bar codes is of paramount importance. Quiet zones and bar heights shall conform to the *ISBT 128 Standard Technical Specification*. Bar codes must be positioned to allow use of any of the three common scanning technologies: contact wands, hand-held laser readers, and charge-coupled devices (CCDs).

5.1.2 US Specification for Bar Code Text and Additional Text

In general, this document will defer to the *ISBT 128 Standard Technical Specification* for typeface or type height of text. This will permit changes to occur in the *ISBT 128 Standard Technical Specification* without requiring a change in this document.

Text describing the product (Class, Modifiers, Attributes, and Additional Information) will be left justified. Other bar code and label text may be centered or left justified as appropriate (see illustrations in Chapter *7*), with the exception of the Donation Identification Number. For the printing of the Donation Identification Number, see 4.1.1.2, page 32. The DIN text may be right justified or centered under its bar code.

Fonts shall be sans serif. Compressed (condensed) fonts should be used before any text is abbreviated. Only approved abbreviations should be used (see the Appendix, page 147).

Color

- The full 13-character Donation Identification Number must be printed in the same color (see 4.1.1.2, page 32).
- The Biohazard symbol must be orange if preprinted labels are used, but may be black and white if an on-demand printer is used (see 5.1.3.3, page 58).
- The use of color for ABO/Rh or other labeling is neither prohibited nor encouraged.

The US License Number may be printed in either of two locations: the upper left quadrant or the lower left quadrant. It must not be printed in both locations. A US License Number is only applied by licensed facilities to blood products they are licensed to produce; a US License Number must not appear on unlicensed blood products.

Text shown in example labels and on various tables in this document represents ICCBBA's recommendations. Other variations of the wording, capitalization, or punctuation may also be acceptable. Users are advised to consult the FDA to determine if a proposed variation is acceptable.

5.1.3 Label Design

In applying these principles the design and arrangement for US labels is predicated on the following:

- The base label of primary collection, and satellite containers shall be 100 mm [4"] wide and 108 mm [4.25"] long

- The design of the final label shall cover an area 100 mm [4"] wide by 100 mm [4"] long

- Each 100 mm [4"] wide by 100 mm [4"] long label shall be divided into four equal 50 mm [2"] wide by 50 mm [2"] long quadrants

- The placement of the bar codes [Donation Identification Number, ABO/Rh Blood Groups, Product Code, Expiration Date and Time, and Special Testing] shall conform to the *ISBT 128 Standard Technical Specification* as illustrated in Figure 13, page 55

- Collection date, if included, shall be printed in the lower half of the upper left quadrant above “VOLUNTEER DONOR” or “PAID DONOR”

- Horizontal lines on base labels and on-demand labels are permitted to facilitate label application and reading

- Vertical lines are not permitted where they may interfere with the reading of concatenated bar codes. This means there shall be no vertical lines printed between the Donation Identification Number and ABO/Rh Blood Groups or the Product Code and Expiration Date and Time bar codes

- Although the satellite container is usually smaller, it is possible to apply labels of the same size as those used on the primary container

In specifying the print height and position of information to be used in labeling blood products, the following order of importance was used:

- Greatest importance: Donation Identification Number and the ABO/Rh Blood Group

- Intermediate importance: Expiration Date and Time, Product Description, and Volunteer Donor or Paid Donor statement

- Least importance: All other bar code and additional text

Note: No specifications are provided in this document for final labeling of pediatric doses of blood products. When consensus is reached for standardized labeling of these products, specifications will be included in future versions of this document. Until then, labeling of these containers should conform to the principles of ISBT128 labeling.

Figure 13 Final Label--Four Equally-Sized Labeling Quadrants: Placement of the Bar Codes

Donation Identification Number	ABO/Rh Blood Groups
Collection Date (when used) Donation Type (VOLUNTEER OR PAID)	
Product Code	Expiration Date and Time
	Special Testing
Container Manufacturer's ID and Catalog Number	Container Manufacturer's Lot Number

5.1.3.1 Upper Left Quadrant

The Donation Identification Number will be printed as described in 4.1.1.2, page 32.

The text information about the facility that collected (or pooled) the unit shall be printed below the DIN. This should include the full legal name of the facility and its location (city and state). The name printed in this location shall correspond to the Facility Identification Number in the Donation Identification Number above it. The FDA registration number may be printed in this quadrant.

Generally, the name of the facility is printed in title case (mixture of upper and lower case). For example:

Accurate Blood Center

However, if the facility has a "doing business as" (dba) name, then the legal name is printed in all capital letters, and the dba name is printed in title case. For example:

ACCURATE BLOOD CENTER
dba Midwest Community Blood Center

In Figure 14, page 56, the US License Number of the facility is shown in one of the two acceptable locations.

- See Figure 17, page 58, for the other acceptable location for the US License Number.
- See Section 7.8.18 for details on when the FDA License Number should appear on products collected by one facility and modified by another.

The required warning label text shall be printed in the lower third of this quadrant on blood components intended for transfusion. This text is:

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

For details on punctuation, consult the Code of Federal Regulations (CFR) or your FDA Consumer Safety Officer. Punctuation indicated in the CFR takes precedence over examples in this document.

There is no requirement for the size of this text, but it should be as large as space allows.

For products intended for transfusion, VOLUNTEER DONOR (or PAID DONOR) shall be printed at the bottom of the quadrant in no less prominence than the product name. If a collection date appears, it should be printed above VOLUNTEER DONOR (or PAID DONOR). See Figure 15, page 57.

Figure 14 Upper Left Quadrant--Standard

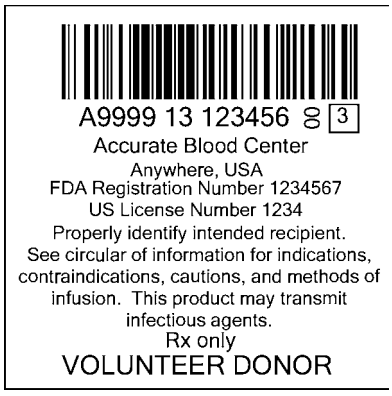
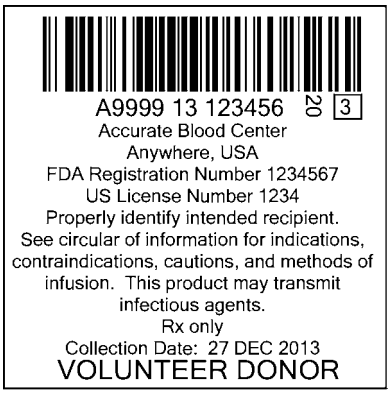
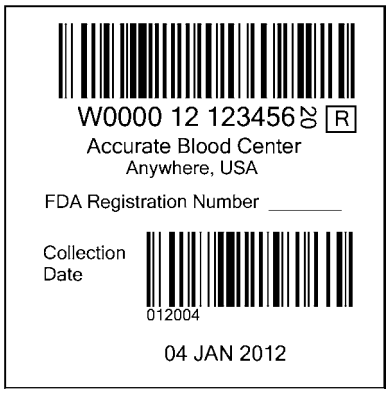


Figure 15 Upper Left Quadrant with Text Collection Date



Source Leukocytes, Recovered Plasma, and Source Plasma labels do not require the same label text as components intended for transfusion. Source Leukocyte and Recovered Plasma labels do, however, require the Collection Date, and Source Plasma labels may require a Collection Date depending on contract requirements. This date should appear in the lower half of this quadrant in place of the warning text required when a product is intended for transfusion.

Figure 16 Upper Left Quadrant – Recovered Plasma



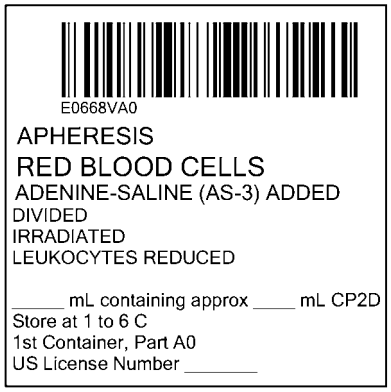
5.1.3.2 Lower Left Quadrant

Printing of this quadrant is covered in detail in Chapter 6.

The US License Number is shown in the other acceptable location in the illustration below. Applying the US license number in this location will allow it to be easily over-labeled if the product is modified into a non-licensed product.

- See Figure 14, Page 56, for the other acceptable location for the US License Number.
- See Section 7.8.18 for details on when the FDA License Number should appear on products collected by one facility and modified by another.

Figure 17 Lower Left Quadrant



5.1.3.3 Upper Right Quadrant

The ABO/Rh Blood Groups label text may be printed as large as space allows.

If the unit is an autologous collection and not eligible for crossover because it was obtained from an unsuitable donor (21 CFR 610.40 and 21 CFR 640.3), FOR AUTOLOGOUS USE ONLY shall be printed at the bottom of the quadrant.

Note: If the unit is eligible for crossover because it was obtained from a suitable donor, AUTOLOGOUS DONOR shall be printed at the bottom of the quadrant (instead of FOR AUTOLOGOUS USE ONLY). However, because crossover of autologous units is not routinely performed in the US, software may not support this option. Facilities may choose to continue to label all autologous donations FOR AUTOLOGOUS USE ONLY and not crossover any autologous units obtained from suitable donors.

If an allogeneic unit is designated solely for a specific recipient, FOR DESIGNATED RECIPIENT ONLY shall be printed at the bottom of the

quadrant (see illustrations in Figure 36, page 102) (see also 5.1.4.1, page 61).

In either of the latter two cases, the ABO/Rh label text should be very different as shown in the illustrations. If the unit is biohazard, the biohazard symbol with the word BIOHAZARD beneath it shall also appear in this quadrant (see Figure 18, page 59). OSHA permits the biohazard label to be black on white when produced by an on-demand printer as part of the ABO/Rh label. This does not preclude the use of the familiar orange biohazard label, and the orange label is still required for preprinted labels.

Figure 18 Upper Right Quadrant

5.1.3.4 Lower Right Quadrant

The Expiration Date and Time bar code and the bar code text shall appear in the upper third of this quadrant. The label text Expiration Date (and Time) may be printed to the right of the bar code; the bar code text (e.g., 01 JAN 2005 14:00) shall be printed below the bar code. The standard representation of date shall be DD MMM YYYY and the standard representation for time shall be HH MM. The local time (if other than the default 23:59) shall be printed in 24-hour format with a colon. As noted on Figure 9 page 47, if the expiration time is coded as the default 23:59, no bar code text relating to time should appear.

The name, location, and FDA registration number (and FDA license number, if applicable) of a modifying facility, if different from the collection facility, shall appear in the bottom half of this quadrant. This information is not required if:

- The product is shipped to another facility operating under the same FDA license
- The product is not distributed outside the facility in which it was modified
- A contractor of the firm performs the product modification

This information does not have to be machine readable.

If the product does not leave the facility in which it was modified, the identification of the facility that modified the product is not required, but may be included if the facility chooses to do so.

Special Testing information (if any of these optional bar codes are used) should be printed in the middle of this quadrant.

Additional text for the presence of red cell antibodies may appear in this quadrant.

Figure 19 Lower Right Quadrant for Product Leaving the Facility

If allogeneic blood has not been tested for the required infectious markers, either (1) the results of infectious disease markers that have been performed and indication of which tests have not been completed shall appear on the affixed label or (2) this information shall appear on a tie tag and a phrase such as SEE TIE TAG FOR TEST RESULT INFORMATION should appear in this quadrant (see Figure 20).

Similarly, the message DONOR TESTED WITHIN THE LAST 30 DAYS should appear in this quadrant, when appropriate for a dedicated donor [21 CFR 610.40 (c)(1)(ii)] or an autologous donor [21 CFR 610.40 (d)(4)].

Figure 20 Lower Right Quadrant for Incompletely Tested Allogeneic Units

For untested autologous units, 21 CFR 610.40(d)(4) requires the phrase “DONOR UNTESTED” to appear on the label. This phrase should appear in the lower right quadrant.

Figure 21 Donor Untested Label for Autologous Units

For Source Leukocytes, if the product is released before completion of testing for infectious markers, the label must include the statement:

> Caution: Do not use contents until test results for HBsAg, STS, HCV RNA, HIV-1 RNA, HBV DNA, and antibodies to HIV, HCV, and HTLV-I/II have been received from the collection facility.

5.1.4 Additional Labels

5.1.4.1 Intended Recipient Labels

The identification of the intended recipient of a directed, autologous, designated, or dedicated collection may appear either on an affixed label on the container or on a tie tag. A label having the dimensions of no less than 65 mm [2.5"] by 25 mm [1"] long should be used, and if used as a label on the container, should not cover any other labeling. The label should have “INTENDED RECIPIENT INFORMATION LABEL” [21 CFR 610.40(c)(1)(ii)] printed on it. The remainder of the label should be arranged so that space is provided for the patient’s name, identification (e.g., medical record) number, birth date, the name of the hospital, and other information as shown in Figure 100, page 143.

Note: On a platelet storage container it may be inappropriate to place a label in the area above the base label because it reduces the breathable area for platelet storage and could result in decreased platelet viability. Please consult the manufacturer of the container for guidance.

5.1.4.2 Emergency Release Labels

When a unit is released before testing is completed, an additional label (either on an affixed label on the container or on a tie tag) shall indicate which tests have and have not been completed. For one possible design of such a tie tag, see Figure 101, page 144.

6 Printing ISBT 128 Product Description Labels

This chapter provides instructions for printing ISBT 128 product description labels for the most common blood products.

6.1 Rules for Printing ISBT 128 Product Description Label Text

Illustrations in this document follow a rules-based system for printing product description label text. In the US, these system rules reflect FDA requirements and are intended to present the needed information with as little abbreviation as possible given the constraints imposed by label size.

This chapter covers general rules. Instructions for products that may not follow the general rules are found in Section 7.8, beginning on page 112.

The general rules are:

- The ISBT 128 product description label design is based on a Component Class (Red Blood Cells, Whole Blood, Plasma, Platelets, etc.), a Modifier (Washed, Frozen, etc.), and Attributes (Irradiated, Leukocytes Reduced, etc.). The Component Class may be printed as large as space allows (not exceeding 4 mm [5/32"] in height).

The standard positioning scheme is:

MODIFIER
COMPONENT CLASS (or PROPER NAME if different)
ATTRIBUTE(S)

- The text size of Modifiers should be proportionally smaller than the Component Class (or proper name, if different) of the blood product unless otherwise specified in the CFR.

- The text size of the Attributes should be proportionately smaller than the text size of the Modifiers unless otherwise specified in the CFR.

- Proper names, if different from Component Class (e.g., SOURCE PLASMA), shall be printed in the same manner as Component Class.

- Class (or proper name if different), Modifiers, and Attributes should be printed in all upper case letters.

- Modifiers shall be printed on the line above the Component Class unless the additional text is such that abbreviation of the proper name would be necessary. In this case, the proper name can begin on the first line immediately after the Modifier(s) and "wrap" to the second line. Size difference should be maintained. See Figure 23, page 65.

- In general, Modifiers should be applied in reverse order of the procedures performed. For example, red blood cells are rejuvenated before they are frozen, so the correct order for the Modifiers is Frozen Rejuvenated.

- Additive solutions shall be listed on the line immediately after the Component Class (or proper name if different) and before the intended use cautionary statement, if applicable.

- Intended use information (in the form of a cautionary statement such as CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY) shall be printed the same size as the proper name and on the lines immediately following the proper name.

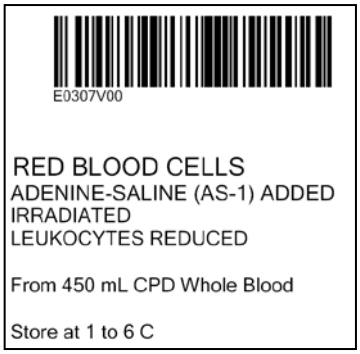
- If the unit is divided, DIVIDED shall appear before Attributes (see 4.3.1.5, page 44).

- Attributes shall be printed on the lines below the Component Class (or proper name, if different) and below the additive and the word DIVIDED, if present. If an additive and DIVIDED are not present, Attributes may be printed beginning immediately after the Component Class if space considerations dictate. Size difference should be maintained. Attributes shall appear in the same order as the Attribute Groups as listed in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions* (or as listed in the Product Description Code Database).

- Whenever the volume is shown (____ mL), it shall appear on the first line below the Attributes (the first "Additional Information" line).

- Anticoagulants and nominal collection volume (for example, From 450 mL CPD Whole Blood) shall be shown in the Additional Information lines, when appropriate.

Figure 22 Printing of Anticoagulant and Storage Temperature on Label



- Storage temperature shall be printed below the anticoagulant and nominal collection volume (when present).

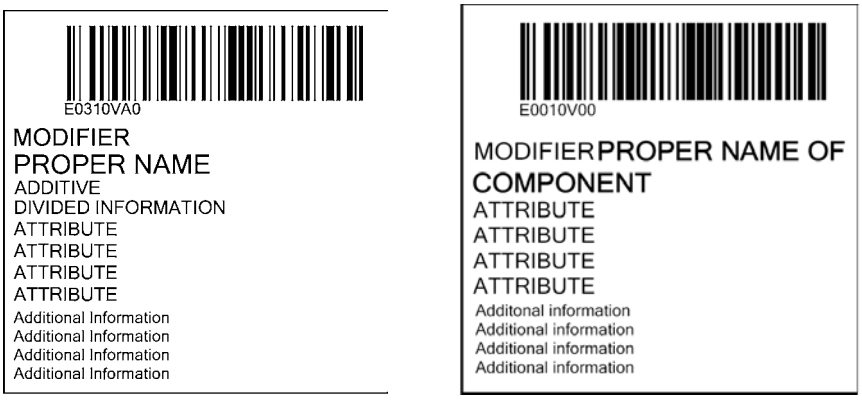
- Container and division text may optionally appear beneath the storage temperature if space permits. See Figure 50, page 105.

- The US License Number, when appearing in the lower left quadrant, is on the last Additional Information line. See Figure 50, page 105.

- Provided that small fonts are used, there is usually sufficient space to avoid abbreviation of any label or additional text with the exception of common abbreviations such as mL for milliliter(s) and C for degrees Celsius (Centigrade). Should abbreviations be absolutely necessary, they should conform to those listed in the Appendix. If there is no appropriate abbreviation in the Appendix, please consult the ICCBBA office for approval of the proposed abbreviation. ICCBBA will consult with the FDA and, if the abbreviation is acceptable, add it to the Appendix.

- In general, the position of the bar code, data content text, and the Component Class (or proper name, if different) are fixed. Modifiers, Attributes, and Additional Information are placed in relation to the Component Class (or proper name, if different).

Figure 23 Printing of Product Description Labels

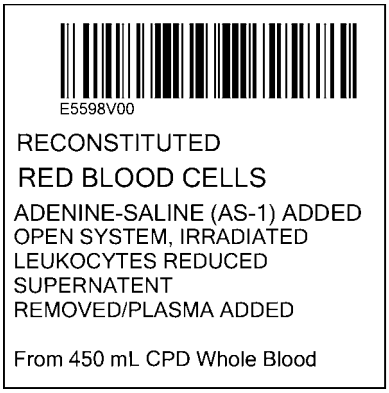


As can be seen from the two illustrations above, this placement generally permits a maximum of four (4) lines for Attributes and four (4) lines for Additional Information.

The Component Class (or proper name if different) should be placed above the middle of the label, as shown, and left justified. The size of the Component Class (or proper name if different) should be as large as possible (maximum height 4 mm [5/32"]), remembering that VOLUNTEER DONOR must be no less prominent. A compressed font that permits the height of the font to remain as large as possible is preferable to using a font that necessitates decreasing the height of the font.

Note: Combining two statements on a single line for Attributes or Additional Information is acceptable and saves considerable space, provided that the reading of the statements is not compromised and that the general order of the statements is not changed. See Figure 24.

Figure 24 Two Attribute Statements on a Single Line



6.2 Proper Names of Products

Note: The inclusion of a product in this chart does not necessarily mean that the product is an FDA-licensable product.

Table 5 Proper Name (Based on Class and Modifier)

Modifier	Component Class	Proper Name
	WHOLE BLOOD	WHOLE BLOOD
	RED BLOOD CELLS	RED BLOOD CELLS
WASHED	RED BLOOD CELLS	WASHED RED BLOOD CELLS
FROZEN	RED BLOOD CELLS	FROZEN RED BLOOD CELLS
FROZEN REJUVENATED	RED BLOOD CELLS	FROZEN REJUVENATED RED BLOOD CELLS
DEGLYCEROLIZED	RED BLOOD CELLS	DEGLYCEROLIZED RED BLOOD CELLS
DEGLYCEROLIZED REJUVENATED	RED BLOOD CELLS	DEGLYCEROLIZED REJUVENATED RED BLOOD CELLS
REJUVENATED	RED BLOOD CELLS	REJUVENATED RED BLOOD CELLS
APHERESIS	RED BLOOD CELLS	APHERESIS RED BLOOD CELLS
WASHED APHERESIS	RED BLOOD CELLS	WASHED APHERESIS RED BLOOD CELLS
FROZEN APHERESIS	RED BLOOD CELLS	FROZEN APHERESIS RED BLOOD CELLS
FROZEN REJUVENATED APHERESIS	RED BLOOD CELLS	FROZEN REJUVENATED APHERESIS RED BLOOD CELLS
DEGLYCEROLIZED APHERESIS	RED BLOOD CELLS	DEGLYCEROLIZED APHERESIS RED BLOOD CELLS

Modifier	Component Class	Proper Name
DEGLYCEROLIZED REJUVENATED APHERESIS	RED BLOOD CELLS	DEGLYCEROLIZED REJUVENATED APHERESIS RED BLOOD CELLS
REJUVENATED APHERESIS	RED BLOOD CELLS	REJUVENATED APHERESIS RED BLOOD CELLS
	FRESH FROZEN PLASMA	FRESH FROZEN PLASMA If the product is to be used for further manufacturing, it will be labeled: RECOVERED PLASMA
THAWED	FRESH FROZEN PLASMA	THAWED FRESH FROZEN PLASMA If the product is to be used for further manufacturing, it will be labeled: RECOVERED PLASMA
APHERESIS	FRESH FROZEN PLASMA	APHERESIS FRESH FROZEN PLASMA If the product was collected for transfusion, outdated, and then was converted for manufacturing use, it will be labeled: RECOVERED PLASMA

Modifier	Component Class	Proper Name
THAWED APHERESIS	FRESH FROZEN PLASMA	THAWED APHERESIS FRESH FROZEN PLASMA If the product was collected for transfusion, outdated, and then was converted for manufacturing use, it will be labeled: RECOVERED PLASMA
THAWED APHERESIS	PLASMA	THAWED APHERESIS PLASMA If the product was collected for transfusion, outdated, and then was converted for manufacturing use, it will be labeled: RECOVERED PLASMA
LIQUID APHERESIS	PLASMA	LIQUID APHERESIS PLASMA If the product was collected for transfusion, outdated, and then was converted for manufacturing use, it will be labeled: RECOVERED PLASMA

Modifier	Component Class	Proper Name
	PLASMA	PLASMA If the product is to be used for further manufacturing, it will be labeled: RECOVERED PLASMA
THAWED	PLASMA	THAWED PLASMA If the product is to be used for further manufacturing, it will be labeled: RECOVERED PLASMA
LIQUID	PLASMA	LIQUID PLASMA If the product is to be used for further manufacturing, it will be labeled: RECOVERED PLASMA
	PLATELET-RICH PLASMA	PLATELET-RICH PLASMA
	POOLED PLASMA	POOLED PLASMA
	PLATELETS	PLATELETS
WASHED	PLATELETS	WASHED PLATELETS
	POOLED PLATELETS	POOLED PLATELETS
WASHED	POOLED PLATELETS	WASHED POOLED PLATELETS
APHERESIS	PLATELETS	APHERESIS PLATELETS

Modifier	Component Class	Proper Name
FROZEN APHERESIS	PLATELETS	FROZEN APHERESIS PLATELETS
THAWED APHERESIS	PLATELETS	THAWED APHERESIS PLATELETS
WASHED APHERESIS	PLATELETS	WASHED APHERESIS PLATELETS
	CRYOPRECIPITATE	CRYOPRECIPITATED AHF
THAWED	CRYOPRECIPITATE	THAWED CRYOPRECIPITATED AHF
	POOLED CRYOPRECIPITATE	POOLED CRYOPRECIPITATED AHF
THAWED	POOLED CRYOPRECIPITATE	THAWED POOLED CRYOPRECIPITATED AHF
	GRANULOCYTES	GRANULOCYTES
APHERESIS	GRANULOCYTES	APHERESIS GRANULOCYTES
	POOLED GRANULOCYTES	POOLED GRANULOCYTES
APHERESIS	GRANULOCYTES/ PLATELETS	APHERESIS GRANULOCYTES/ PLATELETS
	LEUKOCYTES	LEUKOCYTES If the product is to be used for further manufacturing, it will be labeled: SOURCE LEUKOCYTES

Modifier	Component Class	Proper Name
APHERESIS	LEUKOCYTES	APHERESIS LEUKOCYTES If the product is to be used for further manufacturing, it will be labeled: SOURCE LEUKOCYTES

In a few situations, the proper name is based on the Component Class and an Attribute. These situations are:

Table 6 Proper Name (Based on Class and Attribute)

Component Class	Attribute	Proper Name
RED BLOOD CELLS	Plasma added	RECONSTITUTED RED BLOOD CELLS
POOLED PLATELETS	Bacterial Test or Bacterial Monitoring	POOLED PLATELETS -5d
PLASMA	For manufacture	RECOVERED PLASMA
APHERESIS PLASMA (when collected for further manufacturing)	For manufacture	SOURCE PLASMA
APHERESIS PLASMA (when collected for transfusion, but outdated and converted to plasma for further manufacturing)	For manufacture	RECOVERED PLASMA
APHERESIS LEUKOCYTES and LEUKOCYTES	For manufacture	SOURCE LEUKOCYTES

The proper name of one product is based on a combination of its Class (Plasma), Attribute (for further manufacturing, noninjectable) and its donation type (therapeutic). The proper name of this product is Therapeutic Exchange Plasma (Federal Register/Vol 48, No. 64/Friday, April 1, 1983/Notices). An example of a label for this product is seen in Figure 98.

6.3 Attribute Text

Table 7 Attribute Text

Note: Default values are associated with all Attribute Groups except Core Conditions. The label text accompanying a default value, such as FOR TRANSFUSION, NOT IRRADIATED, etc., is not printed on the label. Unless otherwise indicated, the default value is assumed.

Attribute Group	Attribute Variable	US Labeling Instructions
Core Conditions	Anticoagulant and additive if present Nominal volume of original collection Recommended storage temperature	Information associated with these variables shall be printed in the “Additional Information” Section of the lower left quadrant as required by the CFR. Exceptions: Additive text such as ADENINE-SALINE (AS-1) ADDED or ADENINE-SALINE (AS-3) ADDED or ADENINE-SALINE (AS-5) ADDED or PAS - C ADDED shall be printed in the “Attribute” Section on the line following the Component Class.
Intended Use	For further manufacture — injectable	CAUTION: FOR MANUFACTURING USE ONLY shall be printed in the “Attribute” Section on the lines following the Proper Name in the same font and print size as the Proper Name.

Attribute Group	Attribute Variable	US Labeling Instructions
Intended Use	For further manufacture — noninjectable	CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY shall be printed in the “Attribute” Section on the lines following the Proper Name in the same font and print size as the Proper Name. or CAUTION: FOR FURTHER MANUFACTURING INTO IN VITRO DIAGNOSTIC REAGENTS FOR WHICH THERE ARE NO ALTERNATIVE SOURCES shall be printed in the “Attribute” Section on the lines following the Proper Name in the same font and print size as the Proper Name if the unit has a reactive test for an infectious disease or if anti-HBc was not performed.
	For further manufacture — noninjectable restricted use	CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY shall be printed in the “Attribute” Section on the lines following the Proper Name in the same font and print size as the Proper Name. Below this, “Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act” shall appear.
		Or, if intended for use in a product that will be used as a reagent: CAUTION: FOR FURTHER MANUFACTURING INTO IN VITRO DIAGNOSTIC REAGENTS FOR WHICH THERE ARE NO ALTERNATIVE SOURCES shall be printed in the “Attribute” Section on the lines following the Proper Name in the same font and print size as the Proper Name if the unit has a reactive test for an infectious disease or if anti-HBc was not performed. Below this, “Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act” shall appear.
		Or, if intended for use in a product that will be used as a medical device:

Attribute Group	Attribute Variable	US Labeling Instructions
Intended Use		CAUTION: FOR FURTHER MANUFACTURING USE AS A COMPONENT OF A MEDICAL DEVICE FOR WHICH THERE ARE NO ALTERNATIVE SOURCES shall be printed in the “Attribute” Section on the lines following the Proper Name in the same font and print size as the Proper Name. Below this, “Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act” shall appear.
	For further manufacture — injectable restricted use	CAUTION: FOR MANUFACTURING USE ONLY shall be printed in the “Attribute” Section on the lines following the Proper Name in the same font and print size as the Proper Name. Below this, “Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act” shall appear.
	Not for transfusion or further manufacture	CAUTION: FOR LABORATORY RESEARCH USE ONLY shall be printed in the “Attribute” Section on the lines following the Component Class (or proper name if different) in the same font and print size as the Component Class (or proper name if different).
System Integrity	Open	OPEN SYSTEM shall be printed below the Component Class in the “Attribute” Section.
Irradiation	Irradiated	IRRADIATED shall be printed below the Component Class in the “Attribute” Section. No abbreviation is permitted.

Attribute Group	Attribute Variable	US Labeling Instructions
Residual Leukocyte Content	Residual leukocyte content <5 x 10^6 (ResLeu:<5E6)	LEUKOCYTES REDUCED shall be printed below the Component Class in the "Attribute" Section. *Note: Printing the actual number of leukocytes in the product is optional and is not recommended. If it is printed, it should appear beneath the storage temperature of the product*
	For PLATELETS prepared from WHOLE BLOOD Residual leukocyte content <8.3 x 10^5 (ResLeu:<8.3E5)	LEUKOCYTES REDUCED shall be printed below the Component Class in the "Attribute" Section. *Note: Printing the actual number of leukoocytes in the product is optional and is not recommended. If it is printed, it should appear beneath the storage temperature of the product.*
Altered	Albumin added	ALBUMIN ADDED shall be in Attribute line.
	Cryoprecipitate reduced	CRYOPRECIPITATE REDUCED shall be in Attribute line.
	Plasma added	Name of a red cell product to which plasma has been added shall be RECONSTITUTED RED BLOOD CELLS. PLASMA ADDED shall be in Attribute line.
	Plasma reduced	PLASMA REDUCED shall be in Attribute line.
	Plasma reduced/Albumin added	PLASMA REDUCED/ ALBUMIN ADDED shall be in Attribute line.
	Plasma reduced/Plasma added	Name of a red cell product to which plasma has been added shall be RECONSTITUTED RED BLOOD CELLS. PLASMA REDUCED/ PLASMA ADDED shall be in Attribute line.
	Platelets reduced	PLATELETS REDUCED shall be in Attribute line.
	Supernatant reduced	SUPERNATANT REDUCED shall be in Attribute line.

Attribute Group	Attribute Variable	US Labeling Instructions
	Supernatant removed/Plasma added	Name of product shall be RECONSTITUTED RED BLOOD CELLS. SUPERNATANT REMOVED/PLASMA ADDED shall be in Attribute line.
	Platelets/Cryoprecipitate reduced	PLATELETS and CRYOPRECIPITATE REDUCED shall be in Attribute line.
Final Content	Low volume	LOW VOLUME shall be printed in the "Attribute" Section. For WHOLE BLOOD: Approx ___ mL Whole Blood containing approx ___mL [anticoagulant] should appear on the first line of the "Additional Information" Section providing volumes as appropriate. (The volume of the product should be in the first blank; the volume of the anticoagulant should be in the second blank.) For RED CELLS: Approx ___ mL from ___ mL Whole Blood containing approx ___ mL [anticoagulant] should appear on the first line of the "Additional Information" Section providing volumes as appropriate. (The volume of the product should be in the first blank; the volume of the whole blood collection should be in the second blank; the volume of the anticoagulant should be in the third blank.)
	Final content <200 mL Final content ≥200 mL <400 mL Final content ≥400 mL <600 mL Final content ≥600 mL	Actual volume shall be printed as _____ mL in the "Additional Information" Section.

Attribute Group	Attribute Variable	US Labeling Instructions
Preparation: Additional Information	Plasma frozen ≤X hours X=15, 24, 48, 72, 120 or other number of hours	Print in the “Attribute” Section FROZEN WITHIN X HOURS AFTER PHLEBOTOMY *(Note: This Attribute is used primarily for Recovered or Source plasma.)*
	Granulocytes prepared using HES	___ mL Hydroxyethyl Starch Solution in the “Additional Information” Section together with any anticoagulant present. For example, ____ mL Na Citrate in 6% Hydroxyethyl Starch Solution. The percentage of the HES solution is optional.
	RT<=24h frozen <=24h	FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY HELD AT ROOM TEMPERATURE UP TO 24 HOURS AFTER PHLEBOTOMY
	RT<=24h refg	HELD AT ROOM TEMPERATURE UP TO 24 HOURS AFTER PHLEBOTOMY
Apheresis and container: Additional Information	1st container, 2nd container, etc.	1st Container (or 1st Container), 2nd Container (or 2nd Container), etc., may be printed beneath the storage temperature in the “Additional Information” section.
	Apheresis not automated	Prepared by a manual procedure should be printed in the “Additional Information” Section.
Quarantine: Additional Information		Not used in the US at this time.
Dosage: Additional Information	<3E11 plts	CONTAINS APPROX ____ X 10^{11} PLATELETS shall be printed in the “Additional Information” section. (Note: Some printers cannot print superscripts. In this situation, CONTAINS APPROX ___E11 PLATELETS is acceptable.)

Attribute Group	Attribute Variable	US Labeling Instructions
	X units (X number of units)	Indicate number of donor units in the pooled product in the “Additional Information” section.
Method of Treatment		Not used in the US at this time.
Hematocrit	0.5-0.6 0.5-0.7 .55-.75 >0.7	Either the range may be printed or the actual hematocrit may appear on the label in the “Additional Information” section. For example: Hematocrit 50 – 60% or Hematocrit ____%
Monitoring	Bacterial monitoring Bacterial test	5d shall be printed as part of the proper name for pooled platelets.
Donor Exposure	From X donors (X= number of donors)	Indicate number of donors whose components are present in the pooled product in the “Additional Information” section.

6.4 Core Conditions Text

Table 8 Core Conditions Text

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 65)
WB	Whole Blood, 450 mL	Approx 450 mL plus 63 mL [anticoagulant] Store at 1 to 6 C	Additional information line 1 Additional information line 2
WB	Whole Blood, 500 mL	Approx 500 mL plus 70 mL [anticoagulant] Store at 1 to 6 C	Additional information line 1 Additional information line 2
RBC	Red Blood Cells, 450 mL	From 450 mL [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2
RBC	Red Blood Cells, 500 mL	From 500 mL [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2
RBC	Red Blood Cells with additive, 450 mL	ADENINE-SALINE (AS-1, AS-3, or AS-5) ADDED From 450 mL [anticoagulant] Whole Blood Store at 1 to 6 C	Attribute line 1 Additional information line 1 Additional information line 2
RBC	Red Blood Cells with additive, 500 mL	ADENINE-SALINE (AS-1, AS-3, or AS-5) ADDED From 500 mL [anticoagulant] Whole Blood Store at 1 to 6 C	Attribute line 1 Additional information line 1 Additional information line 2
RBC	Washed Red Blood Cells, Rejuvenated Red Blood Cells, Deglycerolized Red Blood Cells, and Deglycerolized Rejuvenated Red Blood Cells	____mL Store at 1 to 6 C	*Note: No anticoagulant specified* Additional information line 1 Additional information line 2

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 65)
RBC	Frozen Red Blood Cells and Frozen Rejuvenated Red Blood Cells	____mL Store at -65 C or colder	*Note: No anticoagulant specified* Additional information line 1 Additional information line 2
RBC	Apheresis Red Blood Cells	_____ mL containing approx _____ mL [anticoagulant] Store at 1 to 6 C	Additional information line 1 Additional information line 2 Additional information line 3
RBC	Apheresis Red Blood Cells with Additive	ADENINE-SALINE (AS-1 or AS-3) ADDED _____ mL containing approx _____ mL [anticoagulant] Store at 1 to 6 C	Attribute line 1 Additional information line 1 Additional information line 2 Additional information line 3
RBC	Washed Apheresis Red Blood Cells, Deglycerolized Apheresis Red Blood Cells, Rejuvenated Apheresis Red Blood Cells, and Deglycerolized Rejuvenated Apheresis Red Blood Cells	____ mL Store at 1 to 6 C	Additional information line 1 Additional information line 2
RBC	Frozen Apheresis Red Blood Cells and Frozen Rejuvenated Apheresis Red Blood Cells	____ mL Store at -65 C or colder	Additional information line 1 Additional information line 2
PLASMA	Fresh Frozen Plasma Plasma, Frozen Within 24 Hours After Phlebotomy Plasma	_____mL from [anticoagulant] Whole Blood Store at -18 C or colder	Additional information line 1 Additional information line 2
PLASMA	Thawed Fresh Frozen Plasma, if relabeled; Thawed Plasma, Frozen Within 24 hours After Phlebotomy, if relabeled; Thawed Plasma, if relabeled; Liquid Plasma	_____ mL from [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 65)
PLASMA	Pooled Fresh Frozen Plasma	_____ mL Number of units in pool ____ From [anticoagulant] Whole Blood Store at -18 C or colder	Additional information line 1 Additional information line 2 Additional information line 3 Additional information line 4
PLASMA	Thawed Pooled Fresh Frozen Plasma, Thawed Pooled Plasma, Liquid Pooled Plasma, and Liquid Pooled Recovered Plasma	_____ mL Number of units in pool ____ From [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2 Additional information line 3 Additional information line 4
PLASMA	Apheresis Fresh Frozen Plasma	_____ mL containing approx _____ mL [anticoagulant] Store at -18 C or colder	Additional information line 1 Additional information line 2 Additional information line 3
PLASMA	Thawed Apheresis Fresh Frozen Plasma, Thawed Apheresis Plasma, and Liquid Apheresis Plasma	_____ mL containing approx _____ mL [anticoagulant] Store at 1 to 6 C	Additional information line 1 Additional information line 2 Additional information line 3
PLASMA	Recovered Plasma	____ mL From [anticoagulant] Whole Blood [Storage Temperature]	Additional information line 1 Additional information line 2 Additional information line 3
PLASMA	Pooled Recovered Plasma and Liquid Pooled Recovered Plasma	_____ mL Number of units in pool ____ From [anticoagulant] Whole Blood [Storage temperature]	Additional information line 1 Additional information line 2 Additional information line 3 Additional information line 4
PLASMA	Source Plasma	_____ mL Containing approx ____ mL [anticoagulant] Store at -20 C or colder	Additional information line 1 Additional information line 2 Additional information line 3

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 65)
PLT	Platelets, from 450 mL collection	Approx 40–70 mL From 450 mL [anticoagulant] Whole Blood Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3
PLT	Platelets, from 500 mL collection	Approx 40–70 mL From 500 mL [anticoagulant] Whole Blood Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3
PLT	Washed Platelets	_____ mL Store at 20 to 24 C	Additional information line 1 Additional information line 2
PLT	Pooled Platelets	_____ mL Number of units in pool ___ From [anticoagulant] Whole Blood Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3 Additional information line 4
PLT	Washed Pooled Platelets	_____ mL Number of units in pool____ Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3
PLT	Apheresis Platelets	_____ mL containing approx _____ mL [anticoagulant] Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3
PLT	Apheresis Platelets with Platelet Additive Solution	PAS - X Added (X=PAS solution) _____ mL containing approx _____ mL [anticoagulant] Contains approx __% PAS/___% Plasma Store at 20 to 24 C	Attribute line 1 Additional information line 1 Additional information line 2 Additional information line 3
PLT	Washed Apheresis Platelets	_____ mL Store at 20 to 24 C	Additional information line 1 Additional information line 2

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 65)
CRYO	Cryoprecipitated AHF	Store at -18 C or colder	Additional information line 1
CRYO	Thawed Cryoprecipitated AHF, if relabeled	Store at room temperature	Additional information line 1
CRYO	Pooled Cryoprecipitated AHF	_____ mL Number of units in pool ____ Store at -18 C or colder	Additional information line 1 Additional information line 2 Additional information line 3
CRYO	Thawed Pooled Cryoprecipitated AHF, if relabeled	_____ mL Number of units in pool ____ Store at room temperature	Additional information line 1 Additional information line 2 Additional information line 3
WBC	Granulocytes	____ mL from [volume] [anticoagulant] Whole Blood Store at room temperature	Additional information line 1 Additional information line 2
WBC	Apheresis Granulocytes	____ mL containing approx ____ mL (anticoagulant) in Hydroxyethyl Starch Solution (if HES is present; actual percentage of the HES may be included if desired) Store at room temperature	Additional information line 1 Additional information line 2 Additional information line 3
WBC	Washed Granulocytes	____ mL from [nominal volume] Whole Blood Store at room temperature	Additional information line 1 Additional information line 2

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 65)
WBC	Pooled Granulocytes	____ mL Number of units in pool ____ From [anticoagulant] Whole Blood in ____ mL Hydroxyethyl Starch Solution (if HES is present; actual percentage of the HES may be included if desired) Store at room temperature	Additional information line 1 Additional information line 2 Additional information line 3 Additional information line 4
WBC	Apheresis Granulocytes-Platelets	____ mL containing approx ____ mL (anticoagulant) in Hydroxyethyl Starch Solution (if HES is present; actual percentage of the HES may be included if desired) Store at room temperature	Additional information line 1 Additional information line 2 Additional information line 3
WBC	Leukocytes	____ mL from [volume] [anticoagulant] Whole Blood Store at [temperature]	Additional information line 1 Additional information line 2
WBC	Apheresis Leukocytes	____ mL containing approx ____ mL [anticoagulant] Store at [temperature]	Additional information line 1 Additional information line 2 Additional information line 3

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 65)
WBC	Source Leukocytes	For apheresis products: ____ mL prepared by automated apheresis containing approx ____ mL [anticoagulant] Store at [temperature] For Whole Blood products: ____ mL from [volume] [anticoagulant] Whole Blood Store at [temperature]	 Additional information line 1 Additional information line 2 Additional information line 3 Additional information line 1 Additional information line 2 Additional information line 3

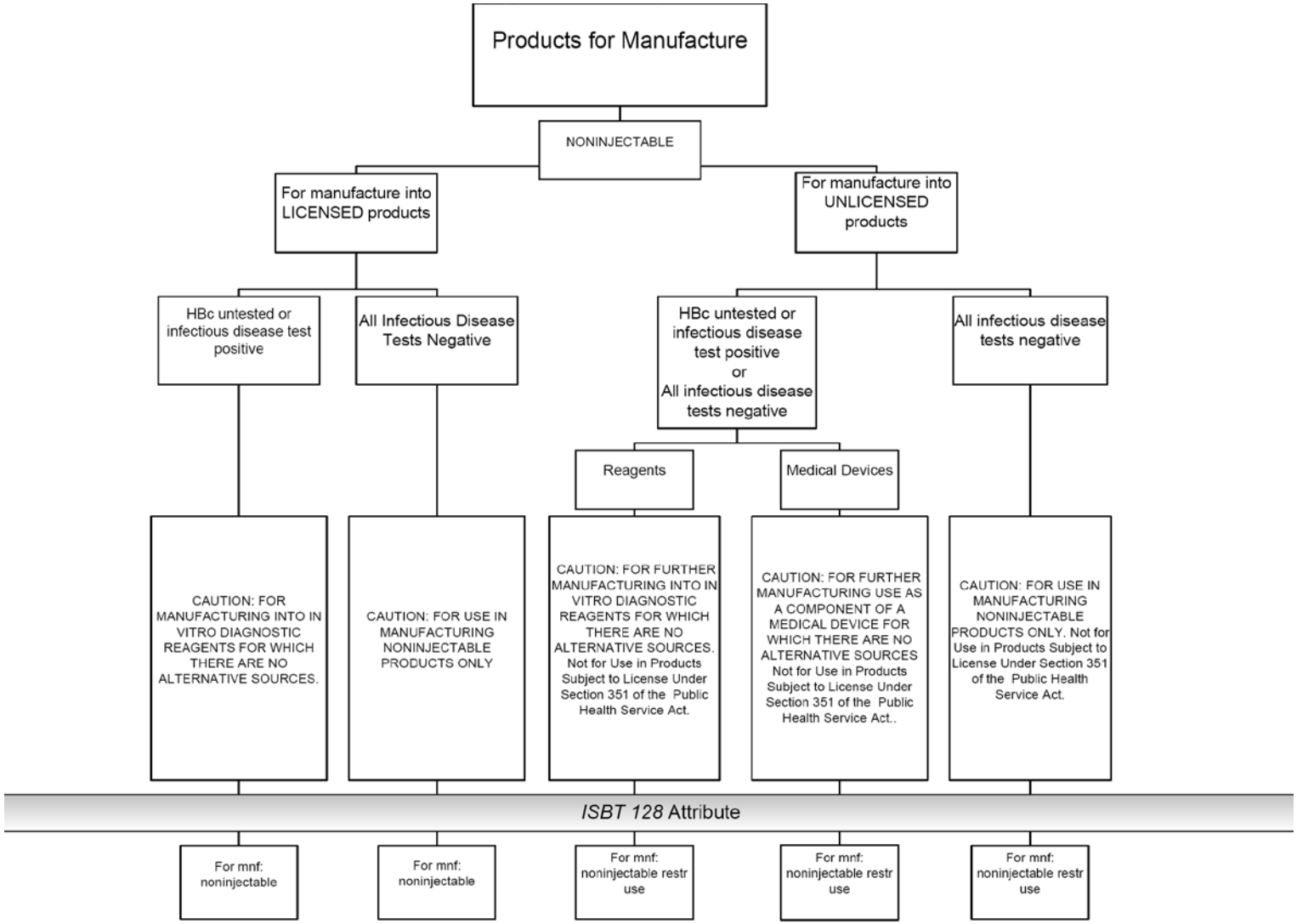
6.5 Coding and Labeling of Products for Further Manufacture

ISBT 128 Attribute Codes on Figure 25 and Figure 26 refer to ISBT 128 Coding as defined in the *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*. While the table is reproduced here, consult this document, available on the ICCBBA website, for the latest information.

Default: For transfusion	**The product is intended for transfusion.**
For mnf: injectable	A product that is intended for injection into humans after further manufacturing (processing)
For mnf: injectable restr use	A product that is intended for injection into humans after further manufacturing (processing). The use of the product is further restricted by national regulation or guidelines
For mnf: noninjectable	A product that is intended for further manufacturing into a product that is not intended for injection into humans
For mnf: noninjectable restr use	A product that is intended for further manufacturing into a product that is not intended for injection into humans. The use of the product is further restricted by national regulation or guidelines
Not for tx or mnf	A product that is not to be used for transfusion/transplantation or further manufacturing into products for human use

Figure 25 Coding & Labeling of Products for Further Manufacture – Research and Injectable

Figure 26 Coding & Labeling of Products for Further Manufacture – Noninjectable



6.6 Donation Type in Product Description Code

Table 9 Donation Type Text (Sixth Position in the Product Code Data Structure)

Sixth Data Character	Type of Donation	Upper Left Quadrant [in no less prominence than Component Class]	Lower Left Quadrant	Upper Right Quadrant
V	Voluntary allogeneic donation	VOLUNTEER DONOR[1]		
0	Not specified[1]			
R	Voluntary research donation	VOLUNTEER DONOR	Data content text beneath bar code: RESEARCH	FOR LABORATORY RESEARCH USE ONLY
S	Voluntary source donation	VOLUNTEER DONOR[1]	Data content text beneath bar code: SOURCE	
T	Voluntary therapeutic collection[2]	VOLUNTEER DONOR	The disease of the patient from which the unit was collected must be specified. [2] Data content text beneath bar code: THERAPEUTIC	THERAPEUTIC COLLECTION
P	Paid allogeneic collection	PAID DONOR		
r	Paid research collection	PAID DONOR	Data content text beneath bar code: RESEARCH	FOR LABORATORY RESEARCH USE ONLY
s	Paid source collection	PAID DONOR[1]	Data content text beneath bar code: SOURCE	
A	Autologous collection, eligible for crossover[3]	VOLUNTEER DONOR	Data content text beneath bar code: AUTOLOGOUS	AUTOLOGOUS DONOR

Sixth Data Character	**Type of Donation**	**Upper Left Quadrant [in no less prominence than Component Class]**	**Lower Left Quadrant**	**Upper Right Quadrant**
X	For autologous use only, biohazard	VOLUNTEER DONOR	Data content text beneath bar code: AUTOLOGOUS	BIOHAZARD FOR AUTOLOGOUS USE ONLY
D	Volunteer directed collection, eligible for crossover	VOLUNTEER DONOR	Data content text beneath bar code: DIRECTED	
d	Paid directed collection, eligible for crossover	PAID DONOR	Data content text beneath bar code: DIRECTED	FOR DESIGNATED RECIPIENT ONLY[4]
1 (one)	For autologous use only	VOLUNTEER DONOR	Data content text beneath bar code: AUTOLOGOUS	FOR AUTOLOGOUS USE ONLY
2	For directed recipient use only	VOLUNTEER DONOR	Data content text beneath bar code: DIRECTED	FOR DESIGNATED RECIPIENT ONLY
3	For directed recipient use only, biohazard	VOLUNTEER DONOR	Data content text beneath bar code: DIRECTED	BIOHAZARD FOR DESIGNATED RECIPIENT ONLY
4	Designated collection	VOLUNTEER DONOR	Data content text beneath bar code: DESIGNATED	FOR DESIGNATED RECIPIENT ONLY[4]
5	Dedicated donation	VOLUNTEER DONOR	Data content text beneath bar code: DEDICATED	FOR DESIGNATED RECIPIENT ONLY[4]

[1] For Source Plasma, printing VOLUNTEER DONOR or PAID DONOR on the label is optional in the US. Donation type may be listed as “Non-specified” since indicating VOLUNTEER DONOR or PAID DONOR is not required.

[2] Facilities may eliminate the donor's disease from the label if the facility has been granted approval from FDA for an alternative procedure to 21 CFR 640.3(d) under the provisions of 21

CFR 640.120 to distribute Whole Blood and blood components collected from individuals with diagnosed hereditary hemochromatosis (HH) without indicating the donor's disorder on the container label. In this situation encoding the "V" rather than "T" in the Donation Type is appropriate.

[3] Shaded line indicates a type of donation (autologous eligible for crossover) that is not commonly used in the US. It is included for the sake of completeness since it is not precluded by federal regulations. Software in the US is unlikely to support this option.

[4] If the donation may be crossed over, "For Designated Recipient Only" need not appear in the upper right quadrant.

7 Illustrations of US Labels

Logos

The *ISBT 128 Standard Technical Specification* makes no provision for logos. Facilities may place a logo in the upper left or lower right quadrant should they choose, provided it does not interfere with any other required item.

7.1 Introduction

The examples given in this section are illustrations, not copies of actual labels. Together these illustrations demonstrate facets of labeling under ISBT 128 appropriate for the US. They are not meant to be an exhaustive compilation of all possible arrangements nor all possible blood products. From these illustrations, and applying the principles and rules described in Chapters 5 and 6, it should be possible to design any label not illustrated in this chapter.

Typefaces and sizes used in these illustrations are constrained by the software used to produce them. Given this constraint, the illustrations are internally consistent and conform to the rules and logic as written. The actual appearance of any professionally-produced label may be more pleasing to the eye, and the typeface used may provide letters and numbers of a larger height than shown in these illustrations. All facilities should work with their chosen vendor(s) to achieve labeling that meets with FDA approval, is consistent with this document, and presents the required information in the best way possible concomitant with the goal of transfusion recipient safety.

7.2 Container Manufacturer's Base Label

All primary containers used in the US for whole blood and apheresis collections and storage should be labeled with a base label with wording approved by the FDA. The placement of two bar codes on the base label should comply with the *ISBT 128 Standard Technical Specification*. The first of these bar codes represents the identity of the manufacturer, the catalog number, and the identification of the container within the set. The second bar code is the lot number of the container set.

7.2.1 Container Manufacturer and Catalog Number

The interpretation of the container set information, encoded as a catalog number in the last seven data characters of the first bar code, will be provided in literature supplied by the container manufacturer.

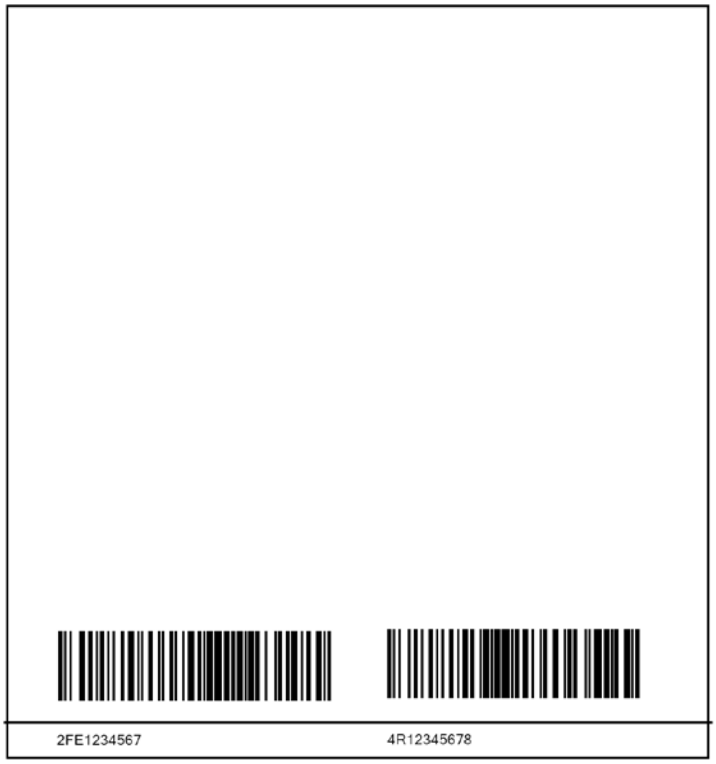
7.2.1.1 Manufacturers Data File

This information may also be linked to a data file that contains a great deal of information about the collection set as well as information about specific containers within the collection set. With appropriate software, the catalog number bar code on a blood container can be scanned during use and linked to the data file to obtain or document a complete description of the set and containers. For example, by scanning the bar code on a whole blood collection set and linking it to the data file, the user can document the set manufacturer, the intended collection volume (e.g., 450 mL), the anticoagulant and its volume, and the number and type of attached containers.

The information in this data file is not intended as a specification of a container or a container set, but solely to provide process control information for use in blood collection management systems. Details of this very powerful tool for process control are found in *the ISBT 128 Standard Technical Specification* and *Implementation Guide: Use of the Manufacturers Data File.*

7.2.2 Base Label Illustrations

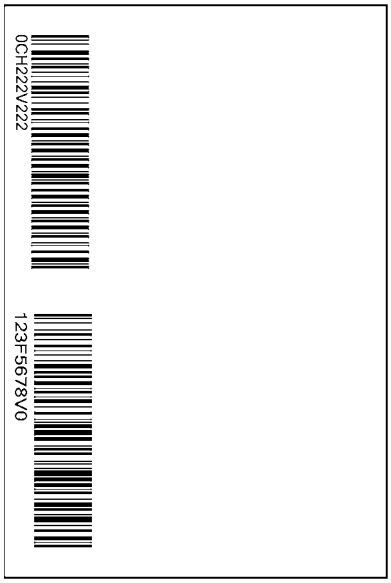
Figure 27 100 mm by 106 mm (4" x 4.25") Base label



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

- 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 28 Base Label for Small Container

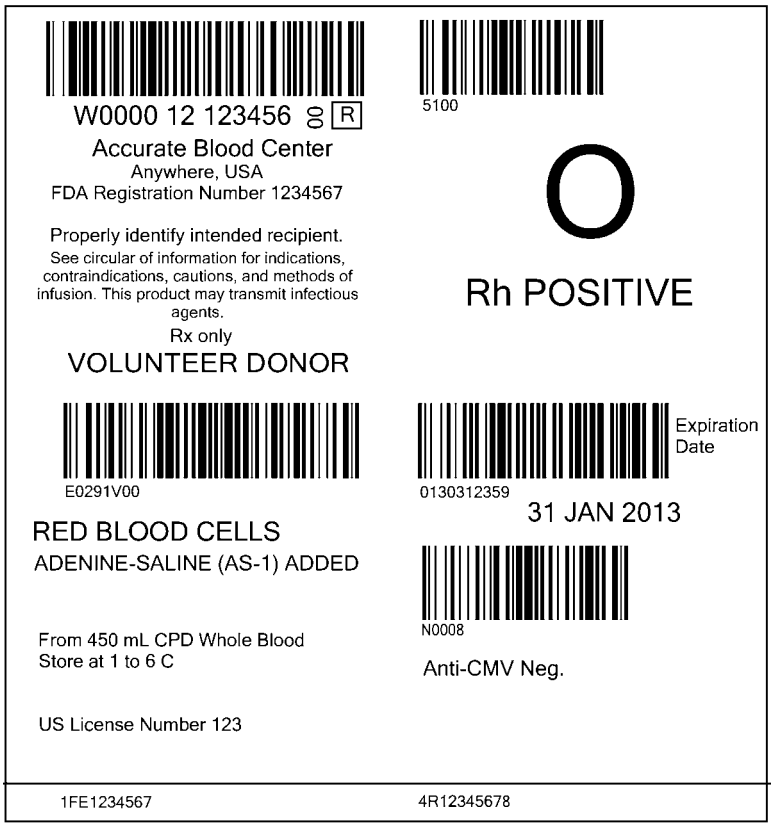


This example represents the minimum amount of ISBT 128 information that must appear on the label. Manufacturers may include additional information such as:

- 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)

7.3 Final Primary Container Label Illustrations

Figure 29 Primary Container—Red Blood Cells



Primary Container—RED BLOOD CELLS—US license number in Lower Left Quadrant

Note: The 6.4 mm [¼"] Section projecting below the 100 mm [4"] wide by 100 mm [4"] long primary container label is the visible portion of the base label applied to the empty container by the manufacturer of the container set.

7.4 Final Satellite Container Label Illustrations

Figure 30 Satellite Container--Platelets

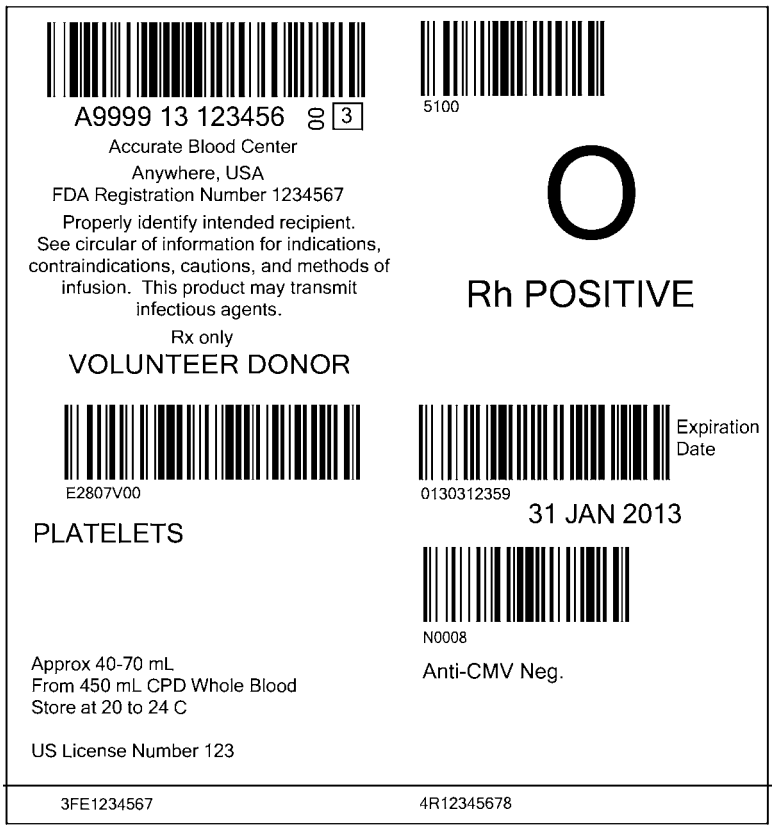
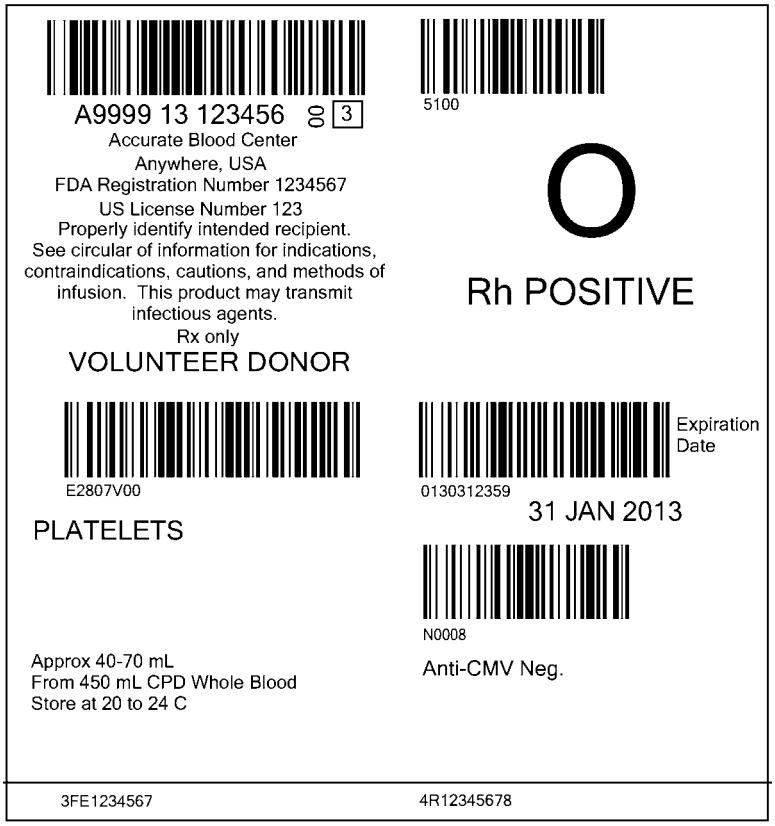


Figure 31 Satellite Container—PLATELETS—US License Number in Upper Left Quadrant



7.5 Upper Right Quadrant

Figure 32 Rh Positive Label

Figure 33 Rh Negative Label

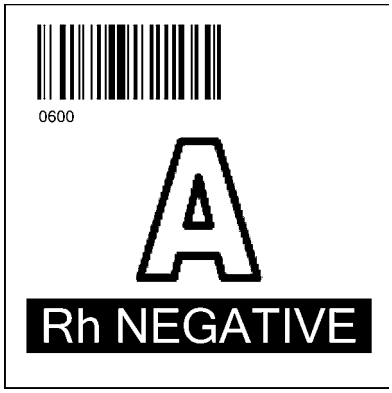


Figure 34 Rh Not Specified Label

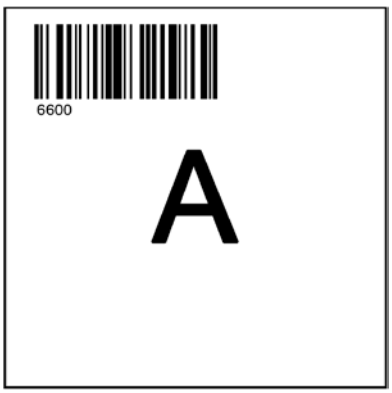


Figure 35 Autologous Products for Upper Right Quadrant

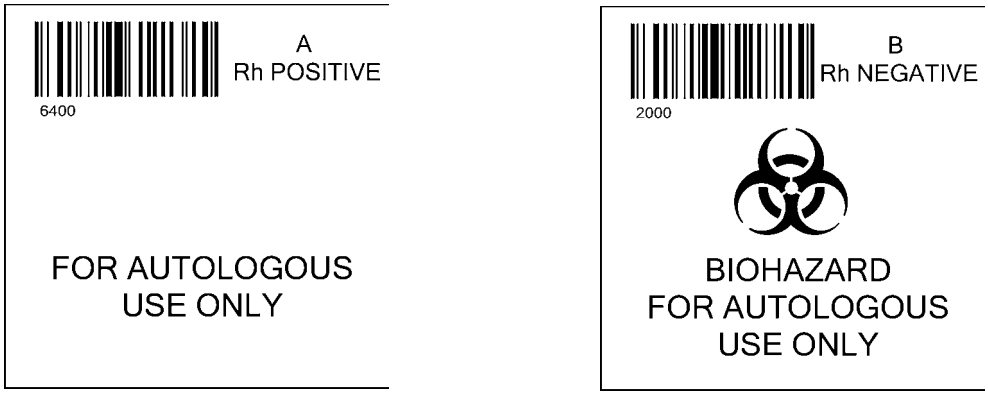
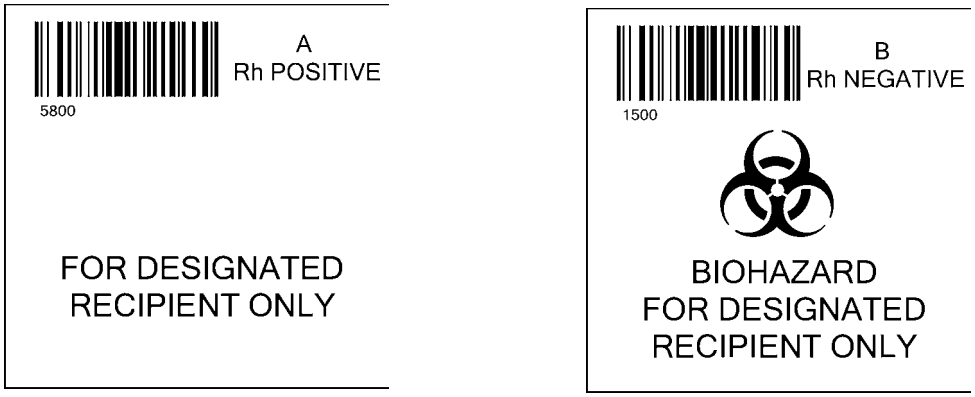


Figure 36 Directed, Designated and Dedicated Labels for Upper Right Quadrant



Note that (n-2) and (n-4) from Table 3, page 37, are used in the ABO/Rh Blood Groups bar code for all directed, designated, and dedicated donations that are intended for a specific recipient only. If the product may be crossed over, the differentiation between directed, designated, and dedicated may be made in the Product Code Data Structure (see 4.3.1.4, page 43).

Containers labeled as above should also bear an Intended Recipient Information label either affixed to the product or as a tie tag.

Figure 37 ABO/Rh for Emergency Release

Note: When blood is released from the collection facility before testing is completed, another label or tie tag should indicate which tests have and have not been performed.

Figure 38 Bombay and Para-Bombay Phenotypes

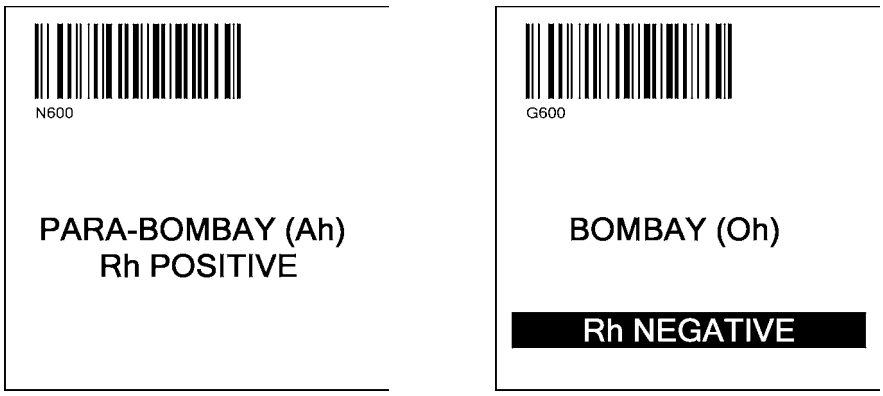


Figure 39 Therapeutic Collection Upper Right Quadrant

7.6 Lower Left Quadrant Labels

Figure 40 Whole Blood

Figure 41 Whole Blood, Low Volume

Figure 42 Red Blood Cells

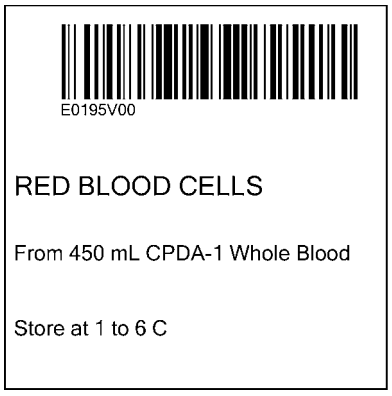


Figure 43 Red Blood Cells with Additive

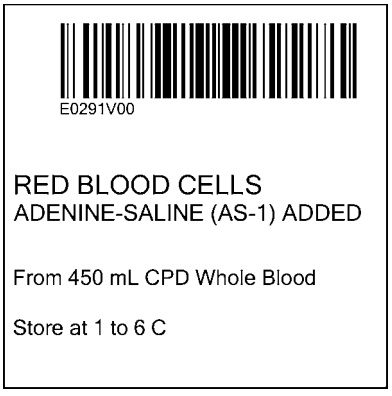


Figure 44 Divided RBCs

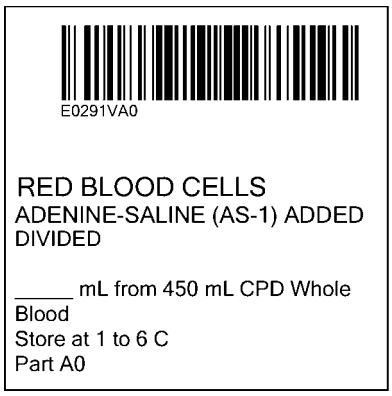
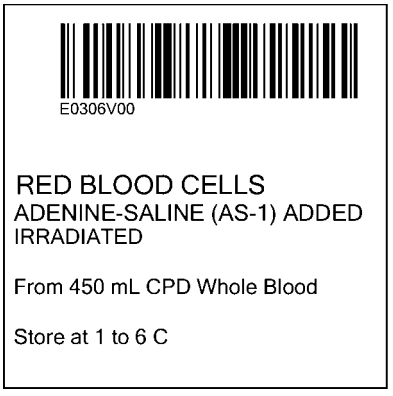


Figure 45 Irradiated RBCs



Lower Left Quadrant Labels (continued)

Figure 46 Leukocytes Reduced RBCs

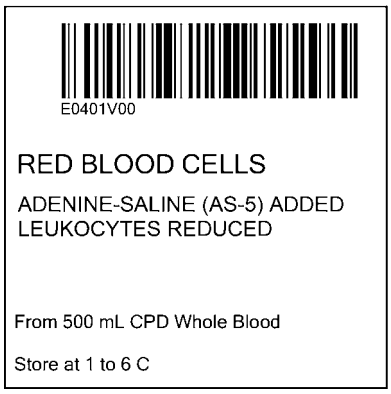


Figure 47 Washed, Leukocytes Reduced RBCs

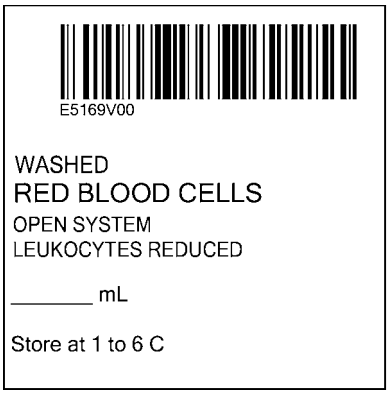


Figure 48 Irradiated, Leukocytes Reduced RBCs

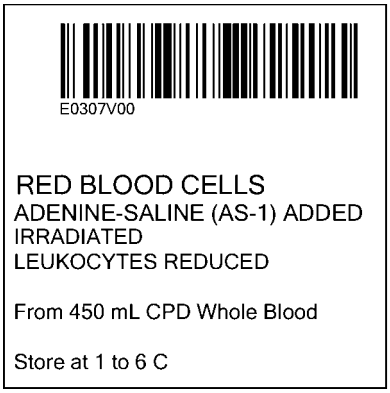


Figure 49 Deglycerolized RBCs

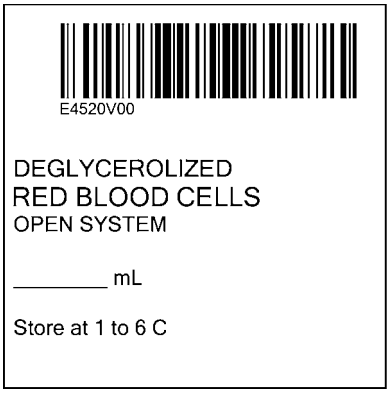


Figure 50 Divided, Irradiated, Leukocytes Reduced Apheresis RBCs

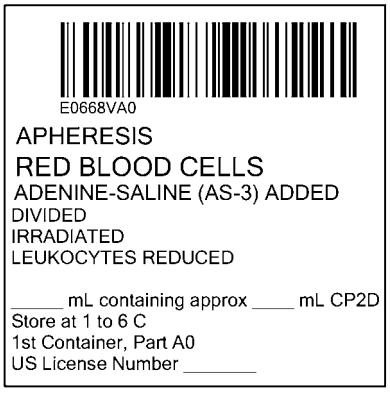
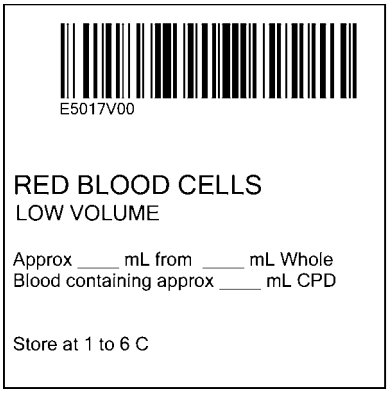


Figure 51 Red Blood Cells, Low Volume



Lower Left Quadrant Labels (continued)

Figure 52 Platelets

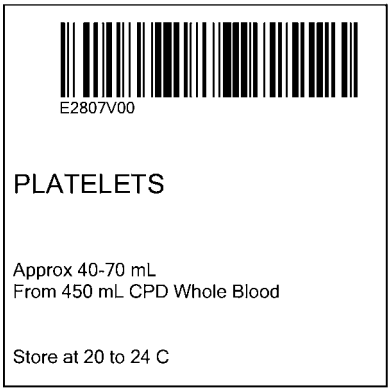


Figure 53 Pooled Platelets

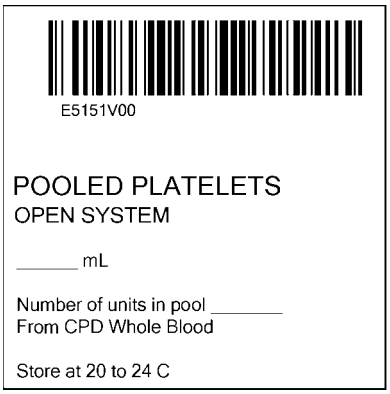


Figure 54 Pooled Platelets -5d

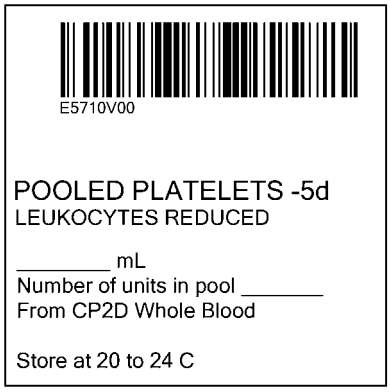


Figure 55 Apheresis Platelets

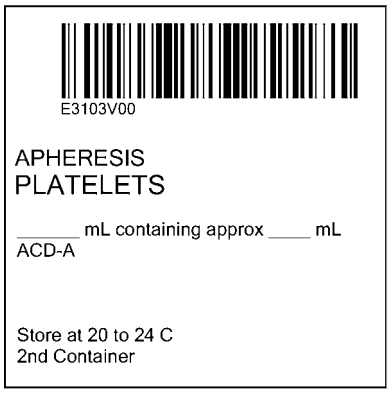


Figure 56 Low Yield Apheresis Platelets

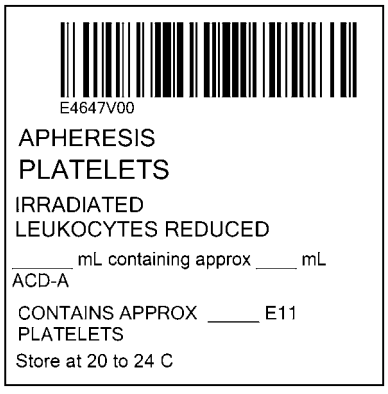
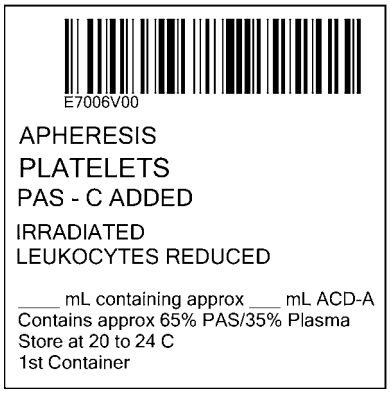


Figure 57 Apheresis Platelets with PAS



Lower Left Quadrant Labels (continued)

Figure 58 Apheresis Plasma with 24 Hour Room Temperature Hold

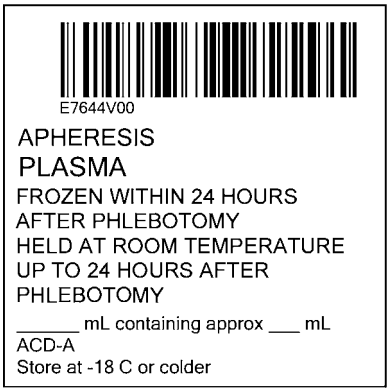


Figure 59 Apheresis FFP

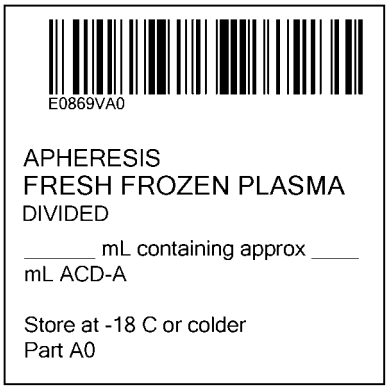


Figure 60 Plasma Frozen <24 Hours after Phlebotomy

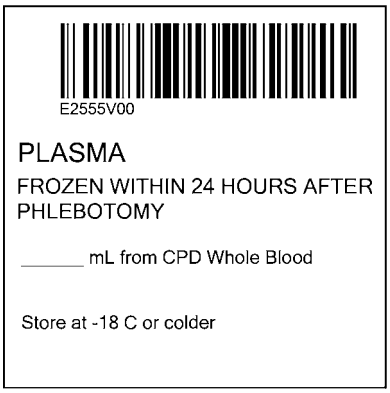


Figure 61 Fresh Frozen Plasma

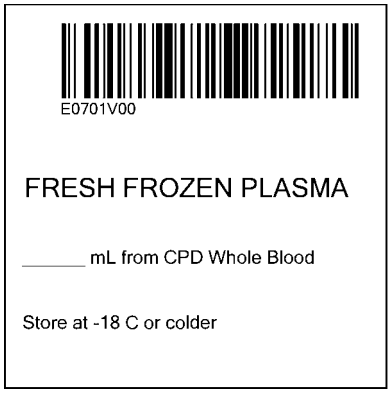
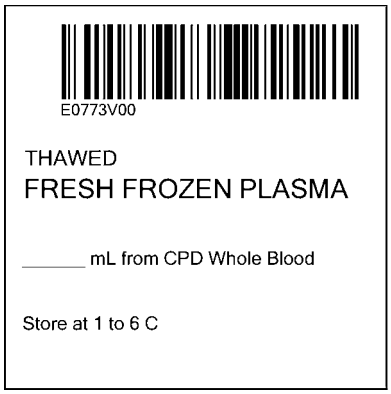


Figure 62 Thawed Fresh Frozen Plasma



Lower Left Quadrant Labels (continued)

Figure 63 Cryoprecipitated AHF

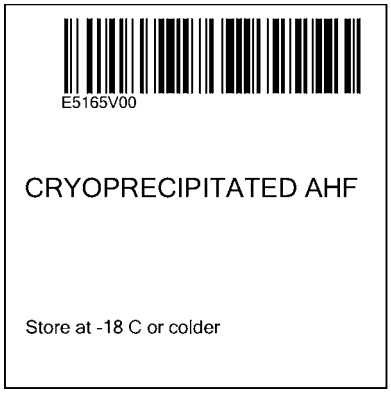


Figure 64 Pooled Cryoprecipitated AHF

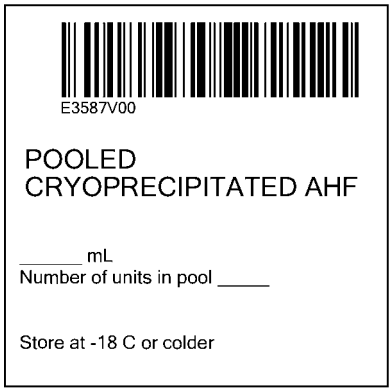
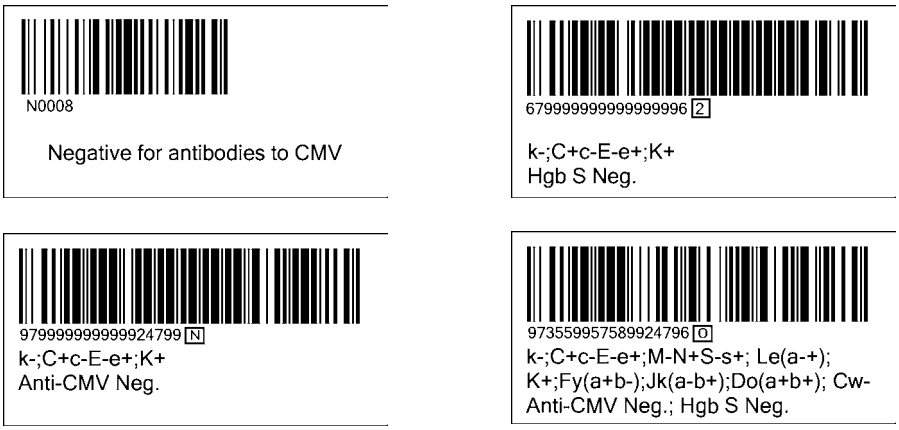


Figure 65 Thawed Pooled Cryoprecipitated AHF

7.7 Special Testing Labels

Figure 66 Special Testing General and Red Cell Antigen Labels



To save space, it is permissible to print only negative antigens and omit punctuation between red cell antigens. Abbreviations such as Anti-CMV Neg. and Hgb S Neg. are acceptable, as are more complete phrases such as Negative for Antibodies to CMV or Hemoglobin S Negative.

Figure 67 Red Cell Antigen Label – Negative Antigens Only

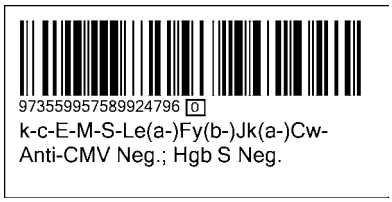
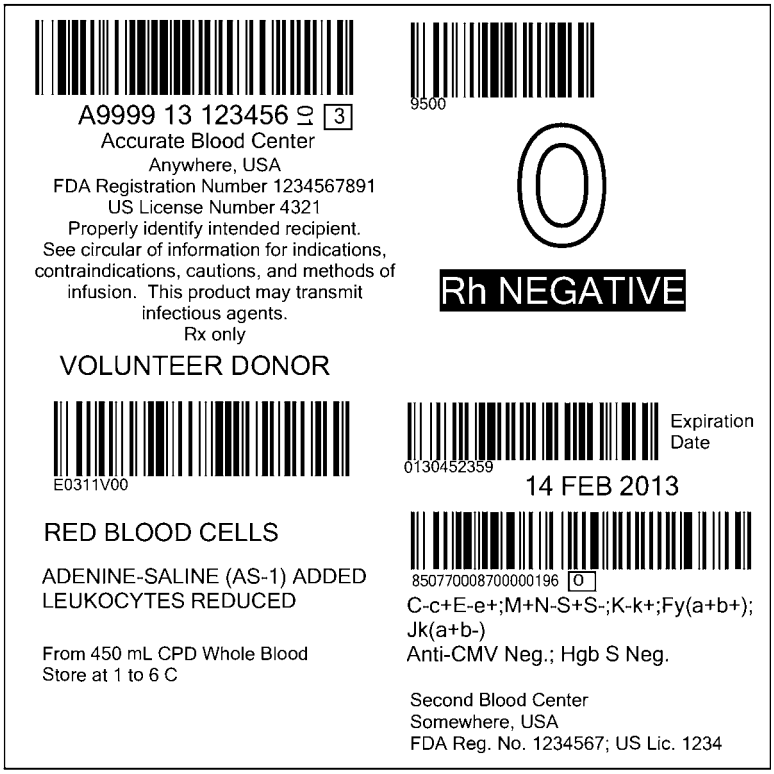


Figure 68 Full Label with Red Cell Phenotype



Notes:

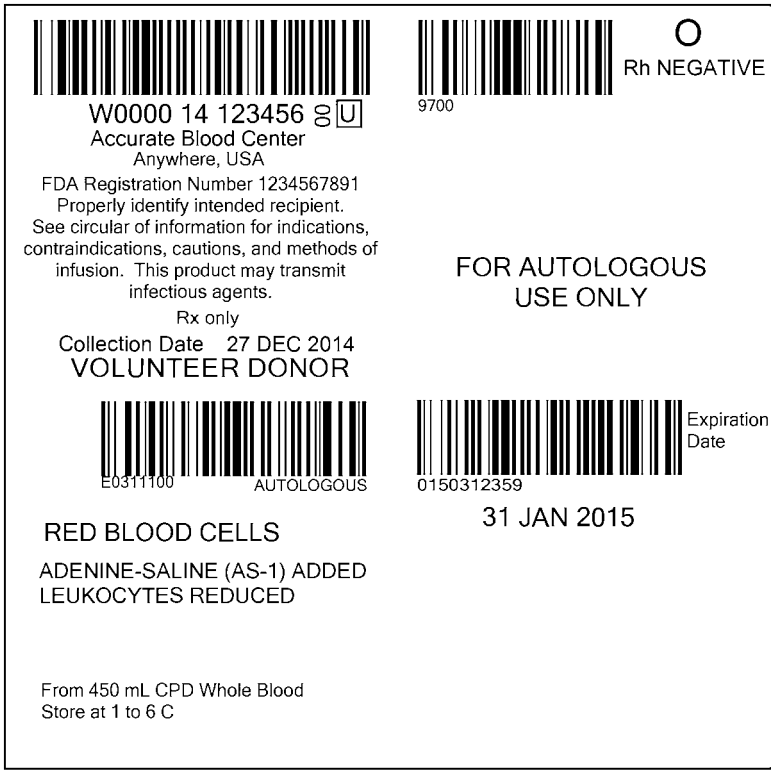
If more than one bar code appears in the lower right quadrant, the height of the bar code may need to be reduced as shown in Figure 68. The height should be at least 15% of the length of the bar code.

When a full phenotype is printed, it is acceptable to abbreviate information about the CMV and Hemoglobin S status, as well as "FDA Registration Number" and "US License" text, as shown in Figure 68.

A subcommittee of the Americas Technical Advisory Group is working on consensus for the order and format in which antigens will appear in text on the label.

7.8 Autologous Label

Figure 69 For Autologous Use Only Label



7.9 Labeling Specific Products

There may be multiple ways to encode a given product which vary by the amount of detail provided. For example, frozen cells may be encoded with the concentration of glycerol or without it. In the interest of standardization, a working group of the Americas Technical Advisory Group (ATAG) determined the preferred coding for the US. Their decisions are captured in this chapter.

In some cases, products are included in this section because they do not follow the General Rules outlined in 6.1, beginning on page 63.

The following sections provide guidance on selection of Product Description Codes and labeling of specific products within the US. As noted in the Preface, bar code text is the prerogative of a country, and the instructions that follow are US-specific.

7.9.1 Pooled Blood Products

These products shall be given a new Donation Identification Number (DIN) and not use a DIN from one of the units in the pool. The new DIN shall have the Facility Identification Number of the pooling facility.

The DINs and the ABO/Rh of the units that make up the pool shall be in the records kept by the facility that prepares the pool; they are not required to be on the label but may appear on a tie tag. The actual volume and the number of units in the pool shall appear on the affixed label, as illustrated in Figure 70 and Figure 73, page 114.

The use of an Attribute which defines the number of units in the pool is acceptable, but not required. This may be used when the facility routinely varies the number of units within a pool. If a facility routinely uses the same number of units (e.g., has a standardized pool of 5 units for platelets), then encoding the information might not be helpful and Product Description Codes without Attributes for the number of donors may be used.

If Pooled Platelets contain a mixture of Rh positive and Rh negative products, they may either be labeled Pooled Rh or Rh positive.

The label of Pooled Cryoprecipitated AHF does not need to indicate Rh.

If pooled platelets contain mixed anticoagulants, the product should be coded as POOLED PLATELETS|NS/XX/20-24 C, (see *Use of Product Code Data Structure [003] – Blood* for explanation on coding). The NS in the first position of the core conditions indicates that the anticoagulant is not specified in the machine readable information, but it shall appear in text on the label. The XX indicates the nominal collection volume is not encoded. Actual volume shall appear on the label. See

Figure 73, page 114. Platelet pools with mixed anticoagulants should have 4 hour dating.

Figure 70 Pooled Platelets, Mixed Anticoagulant

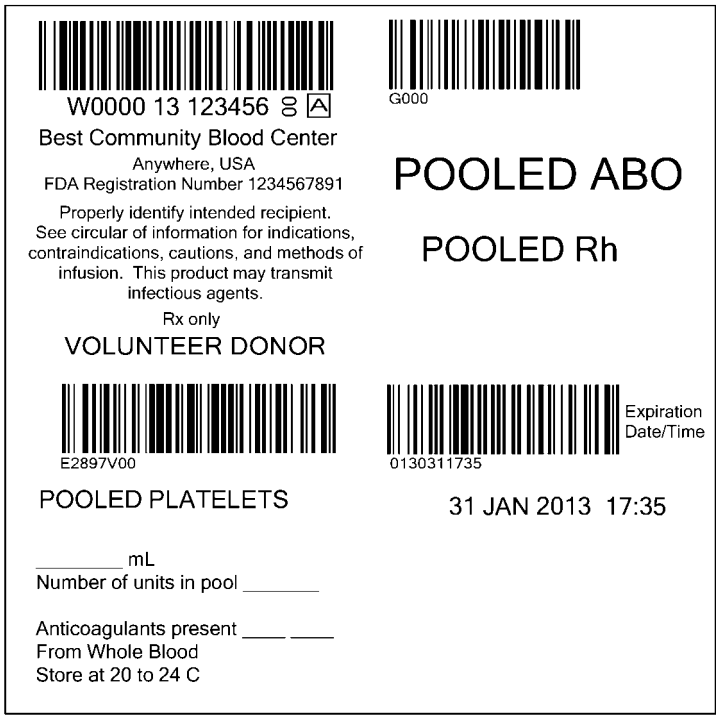


Figure 71 Thawed Pooled Cryoprecipitated AHF, Rh Not Specified

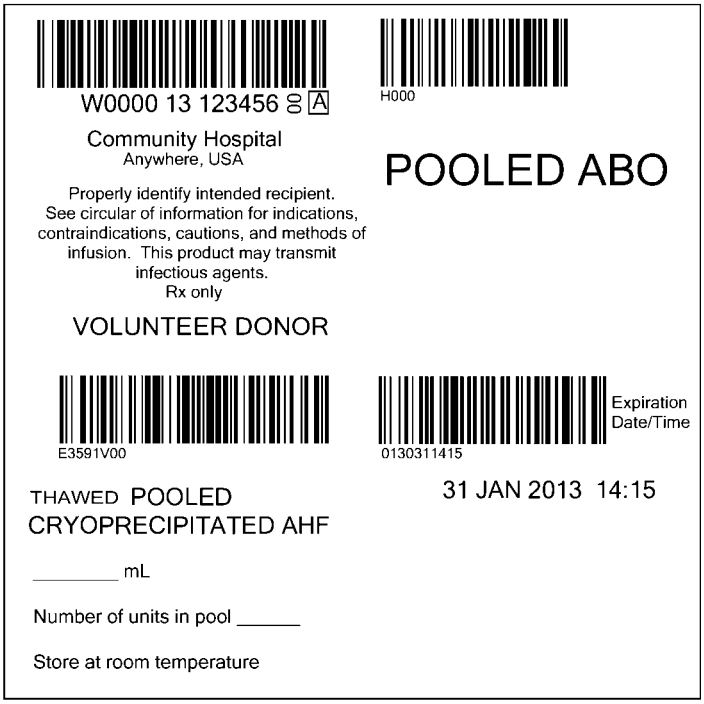


Figure 72 Thawed Pooled Cryoprecipitated AHF, Group A, Rh Pooled

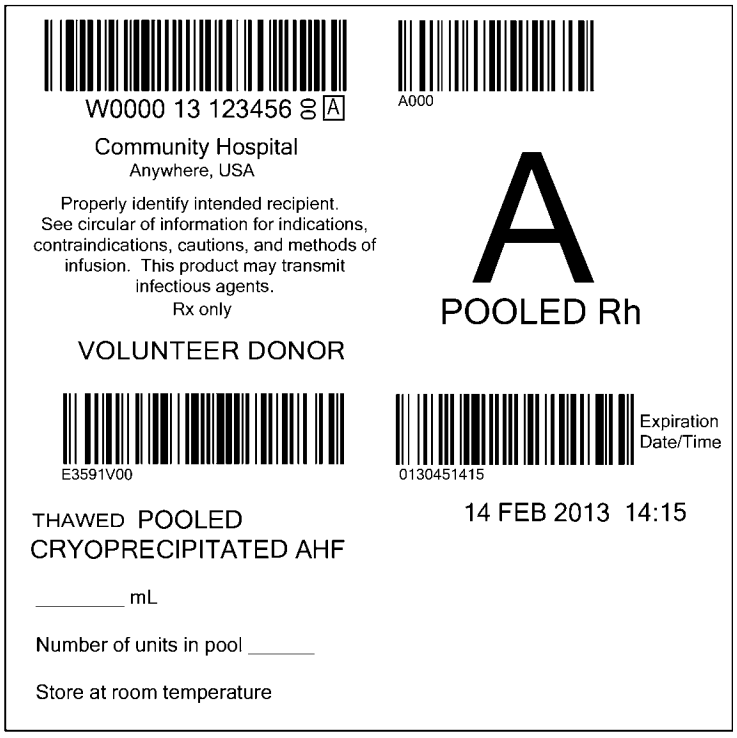
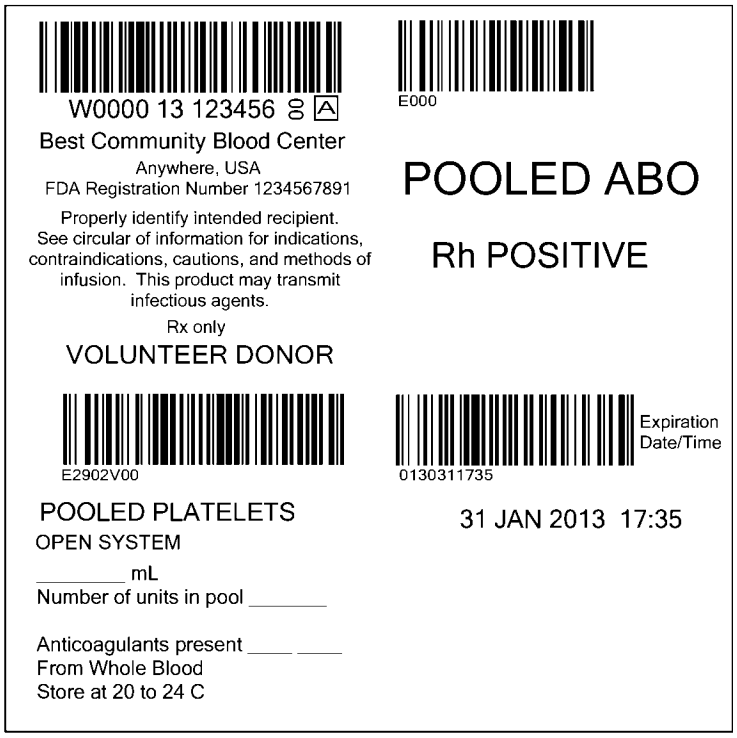


Figure 73 Pooled Platelets



7.9.2 Reconstituted Red Blood Cells

Reconstituted Red Blood Cells refer to red cells to which plasma is added, often to a specific hematocrit.

7.9.2.1 Selecting a Product Description Code

Depending on the way in which they are made, they are encoded as follows:

IF	THEN
The product is made by adding blood group-compatible plasma to red blood cells	Product is encoded as Red Blood Cells with the Attribute “Plasma Added”
The product is made by first removing additive from the red blood cells and then adding blood group-compatible plasma	Product is encoded as Red Blood Cells with the Attribute “Supernatant removed/Plasma added”
The product is made by removing some of the plasma from red blood cells and then adding blood group-compatible plasma	Product is encoded as Red Blood Cells with the Attribute “Plasma reduced/Plasma added”

7.9.2.2 Donation Identification Number

Some computer systems treat reconstituted red cells as a pooled product; others do not. The Donation Identification Number (DIN) can either be a newly assigned Pool Number (for those systems that treat the product as a pooled product) or that of the red blood cells (for those systems that do not treat it as a pooled product). The text name and location of the facility that appears beneath the DIN shall correspond to the Facility Identification Number within the DIN. That means, if the original DIN of the red blood cells is used, the name beneath the DIN shall correspond to the collection facility. If a new pool number is assigned to the product, the DIN shall have the Facility Identification Number of the pooling facility, and the name beneath the DIN shall be that of the pooling facility. Regardless of which method is chosen, traceability of both the red blood cells and the plasma shall be assured. The DIN of the plasma must be associated with the DIN of the final product in the facility records. See Figure 74 and Figure 75.

Figure 74 Reconstituted Red Cells, Pool Number Assigned

FIN A9999 corresponds to St. Mary's Hospital

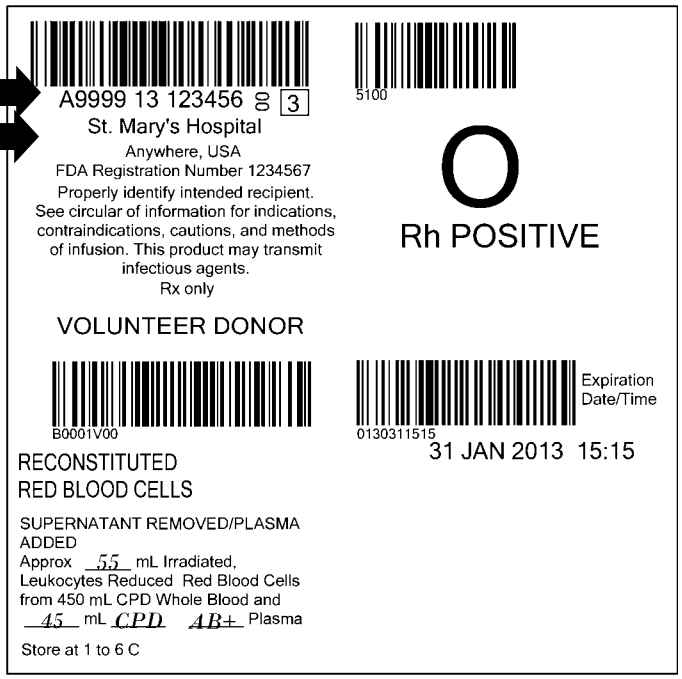
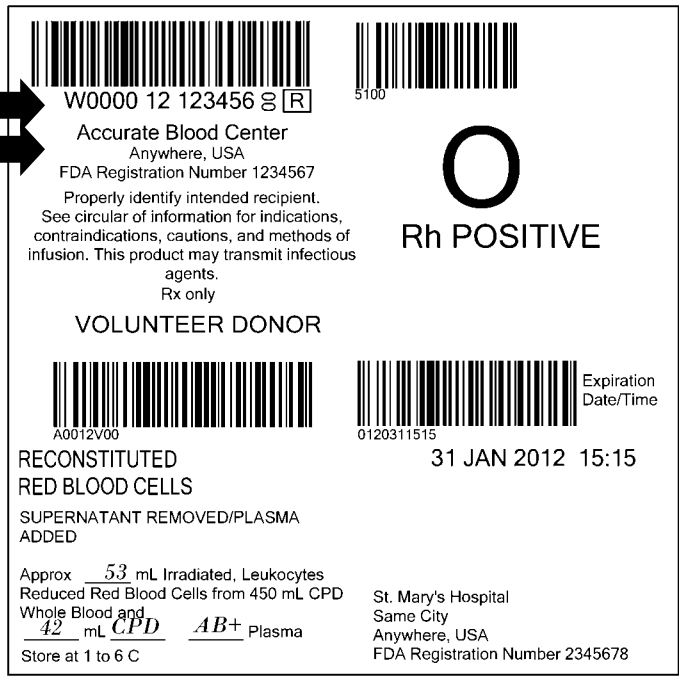


Figure 75 Reconstituted Red Blood Cells, Original RBC DIN Retained

FIN W0000 corresponds to Accurate Blood Center



Note: The name of the modifying facility in the lower right quadrant is required ONLY if the product leaves the modifying facility.

7.9.2.3 ABO/Rh, anticoagulant and volume

The ABO/Rh, anticoagulant, and volume of both the red blood cells and the plasma must be on the label.

7.9.2.4 Number of donors

The US has chosen not to use an Attribute indicating the number of donors in this product.

7.9.2.5 Hematocrit

Hematocrit may optionally appear on the label.

7.9.2.6 Modifiers

The proper name of this product is Reconstituted Red Blood Cells. If Modifiers apply, they should be printed before Reconstituted Red Blood Cells. That is, if the red blood cells were washed, the name of the product becomes Washed Reconstituted Red Blood Cells.

7.9.2.7 Additional processing

If the red cell, but not the plasma, component is irradiated and/or leukocyte reduced, labeling and Product Description Code selection becomes more complicated.

Please see the US Frequently Asked Questions on the ICCBBA Website or contact the ICCBBA office (iccbba@iccbba.org) for current thinking on how these products should be labeled.

7.9.2.8 CMV

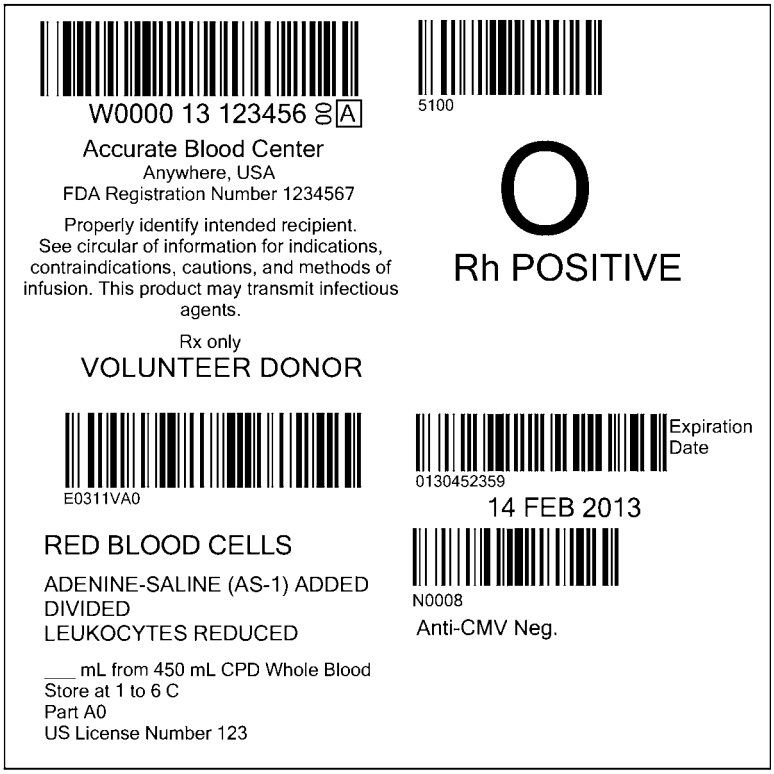
If the red cell, but not the plasma, component is tested and found negative for antibodies to CMV, labeling becomes more complicated.

Please see the US Frequently Asked Questions on the ICCBBA Website or contact the ICCBBA office (iccbba@iccbba.org) for current thinking on how these products should be labeled.

7.9.3 Divided Products

If the seventh and eighth data characters are other than “00,” then the term DIVIDED shall appear on the label in the first Attribute line, followed by Attributes such as LEUKOCYTES REDUCED. A notation describing the division number may appear in the text below the storage temperature, but this is not required.

Figure 76 Divided Product



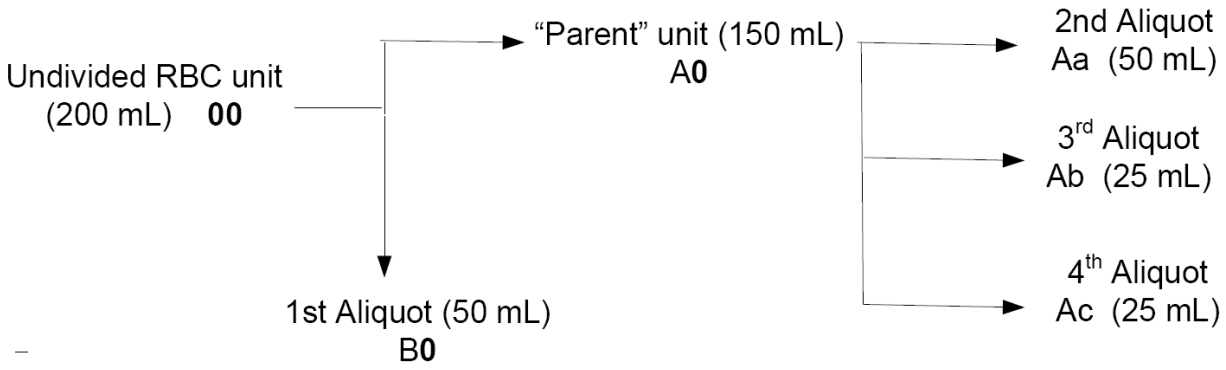
Examples of Use of Division Codes for Pediatric Aliquots

Section 4.3.1.5 discussed how divisions of blood products are labeled. To further clarify this for pediatric divisions, the following two examples are provided.

Example 1: Pediatric Aliquots

An undivided 200-mL unit of AS-1 Red Blood Cells is the starting product.

- A 50-mL aliquot is removed from this unit. In fact, this can be viewed as dividing the unit into two subunits that are denoted as A0 and B0.
- One of these subunits (A0) has 150 mL and becomes a "parent" unit and is returned to storage. It is important that this "parent" unit be labeled A0 to indicate it is no longer a full unit. The other (B0) aliquot has 50 mL and is transfused.
- Later, a 50-mL aliquot is removed from A0. This aliquot is labeled Aa. The "parent unit," A0, remains labeled A0.
- A few hours later, a 25-mL aliquot is removed from A0. This aliquot is labeled Ab. A0 remains A0.
- Later yet, another 25-mL aliquot is removed from A0. This aliquot is labeled Ac. A0 remains A0.
- A0 eventually expires and is discarded.



In the original division, it does not matter which part (A0 or B0) becomes the parent unit. However, traceability must be maintained. Therefore, any aliquots taken from A0 must be labeled Aa, Ab, Ac, etc. Any aliquots taken from B0 must be labeled Ba, Bb, Bc, etc.

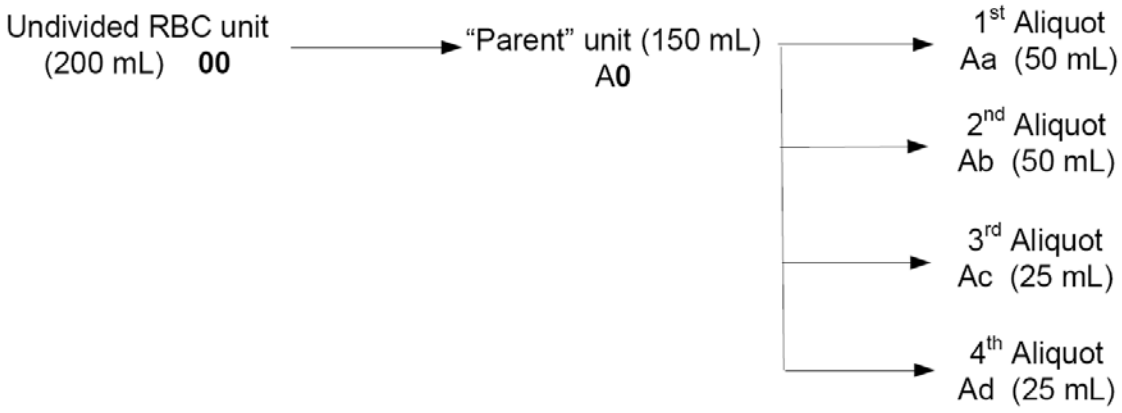
It would be good practice for a facility to determine how it will label its aliquots (i.e., whether the "parent" unit is A0 or B0) and be consistent about this approach.

Example 2: Pediatric Aliquots

An alternative to Example 1 is labeling all aliquots as “children” of the parent unit.

The starting product is a 200-mL unit of red cells.

- A 50-mL aliquot is removed from a 200-mL unit. Immediately, the label on the primary pack is changed to A0 division indicating it is no longer a full unit. The first aliquot is labeled Aa.
- Later a 50-mL aliquot is removed from A0. It is labeled Ab. The parent unit remains A0.
- Later a 25-mL aliquot is removed and it is labeled Ac. The parent unit remains A0.
- Later another 25-mL aliquot is removed and it is labeled Ad. The parent unit remains A0.
- A0 eventually expires and is discarded.



The ISBT 128 system is flexible to allow users to adapt a system that suits them as long as each aliquot is traceable (i.e., there must never be two aliquots labeled Aa).

7.9.4 Frozen Red Blood Cells

The ISBT 128 Standard allows encoding of Frozen Red Blood Cells to include the glycerol concentration or not. The US has chosen not to encode the glycerol concentration since it is not required.

Neither the anticoagulant nor the nominal collection volume needs to appear on the label. The actual volume shall appear on the label.

7.9.5 Washed, Deglycerolized, or Rejuvenated Red Blood Cells

Neither the anticoagulant nor the nominal collection volume needs to appear on the label. The actual volume shall appear on the label.

7.9.6 Granulocytes - Untested

Granulocyte products may be released from the collection center prior to completion of testing because of their short shelf life. The upper right quadrant in this case should indicate the product is being released for emergency use only and include the name of the patient. The name of the hospital on the affixed label is optional, but should be included in the labeling of the product (e.g., tie tag). As described in 5.1.3.4, page 59, if the blood has not been tested for the required infectious disease markers either:

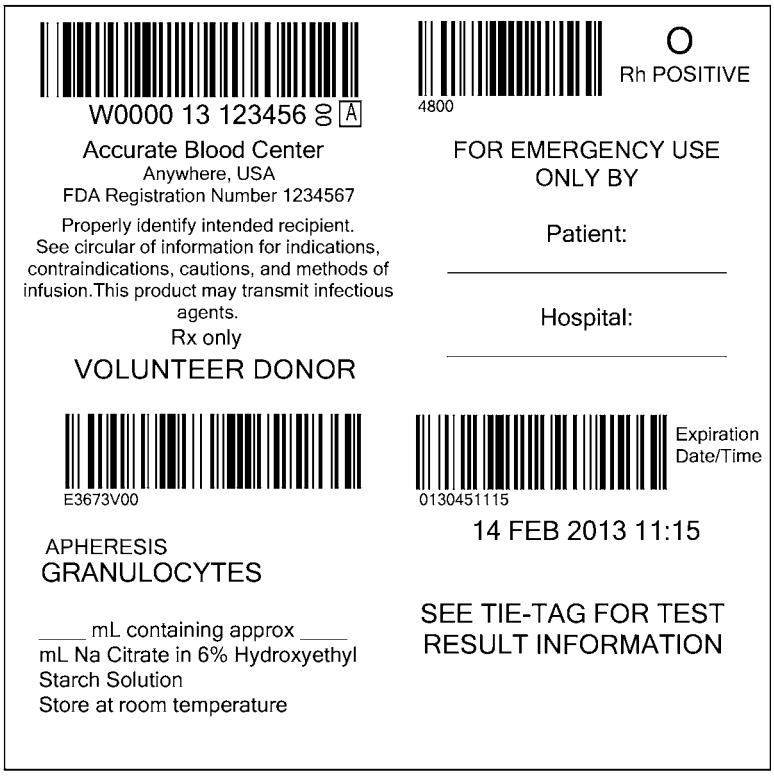
(1) the results of tests for infectious disease markers that have been performed and indication of which tests have not been completed shall appear on the affixed label in the lower right quadrant or

(2) this information shall appear on a tie tag and a phrase such as SEE TIE TAG FOR TEST RESULT INFORMATION should appear in this quadrant. (See Figure 101, Page 144 for an example tie tag.)

Similarly, the message DONOR TESTED WITHIN THE LAST 30 DAYS should appear in this quadrant, when appropriate.

The percentage of HES on the label (e.g., “6% Hydroxyethyl Starch Solution”) is optional. The label may simply state, “____ mL Hydroxyethyl Starch Solution”.

Figure 77 Granulocytes



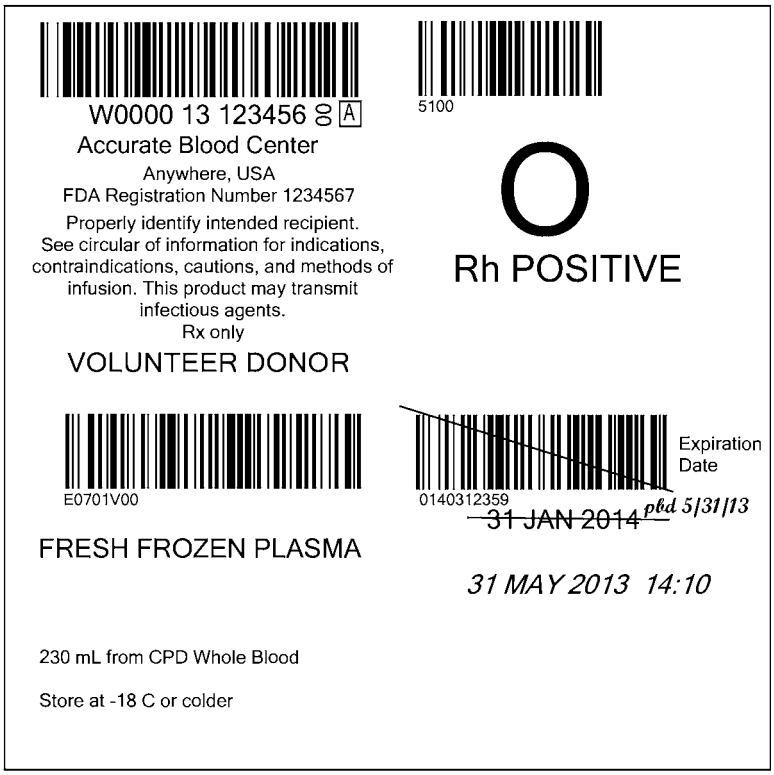
7.9.7 Plasma Products

The nominal collection volume does not need to appear on the label. The actual volume shall appear on the label.

7.9.8 Thawed Plasma Products or Cryoprecipitated AHF

Thawed Plasma products (used within their 6-24 hour dating period) and Thawed Cryoprecipitated AHF (used within its 6 hour dating period for a single unit) may retain their original Product Description Codes (“frozen code”) or be changed to a Product Description Code indicating they have been thawed. That is, either a code for Fresh Frozen Plasma or a code for Thawed Fresh Frozen Plasma may be used. Only the expiration date/time must be changed and this information does not have to be bar coded.

Figure 78 Thawed Plasma with Manually Changed Expiration



If Fresh Frozen Plasma and Plasma that has been frozen within 24 hours after phlebotomy (made in a closed system) are not used within the allowable 6- or 24-hour periods following thawing, they shall be relabeled as Thawed Plasma. This requires applying a new product label that is both machine and eye-readable. This product is not a licensable product and the US License Number shall not appear.

Figure 79 Thawed Plasma

7.9.9 Apheresis Fresh Frozen Plasma

In the US Apheresis Fresh Frozen Plasma (FFP) that is collected into a single bag and subsequently divided into smaller ADULT aliquots (e.g., 600 mL is collected and divided into three 200-mL aliquots) may be given **either** container designations (different Product Description Codes) as shown in Figure 80 and Figure 81 or division codes (7th and 8th character designations) as shown in Figure 82.

If the plasma is divided into aliquots smaller than a standard adult dose (as defined by the facility), it must be given division codes (7th and 8th character designations).

Figure 80 Apheresis FFP with 1st Container Designation (Product Code E4689V00)

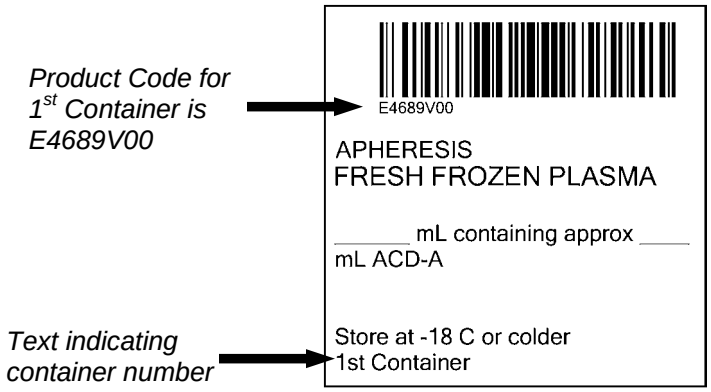


Figure 81 Apheresis FFP with 2nd Container Designation (Product Code E4693V00)

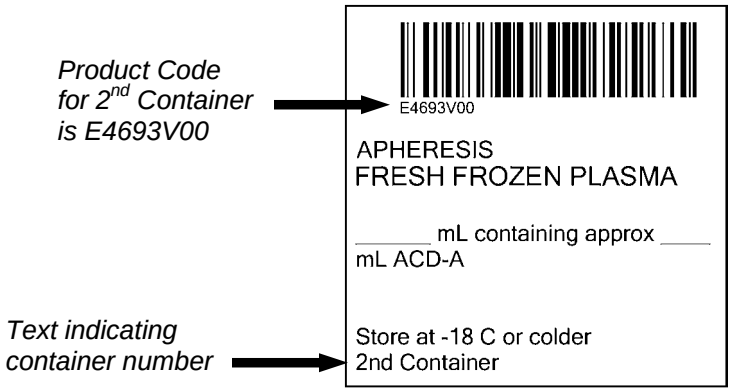
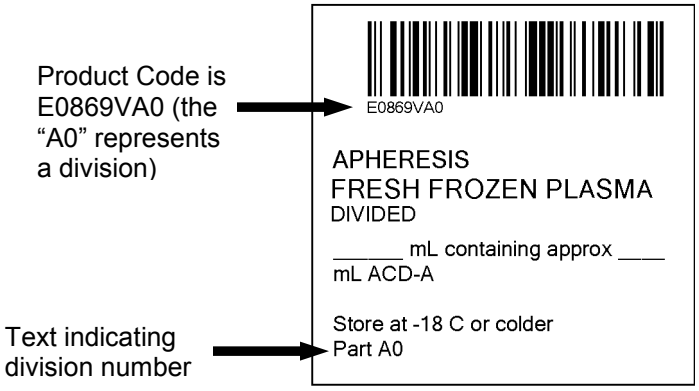


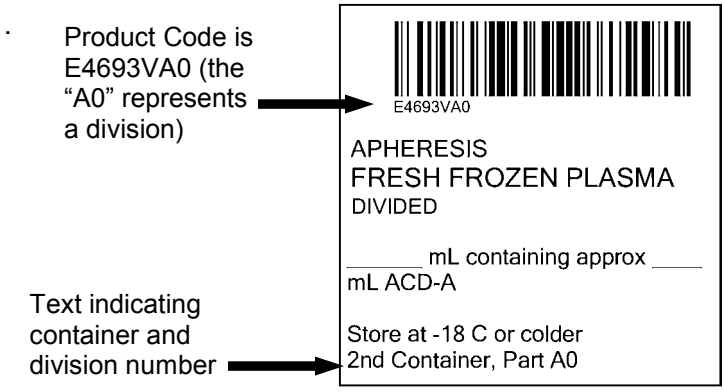
Figure 82 Apheresis FFP with Division Code



Further Divisions

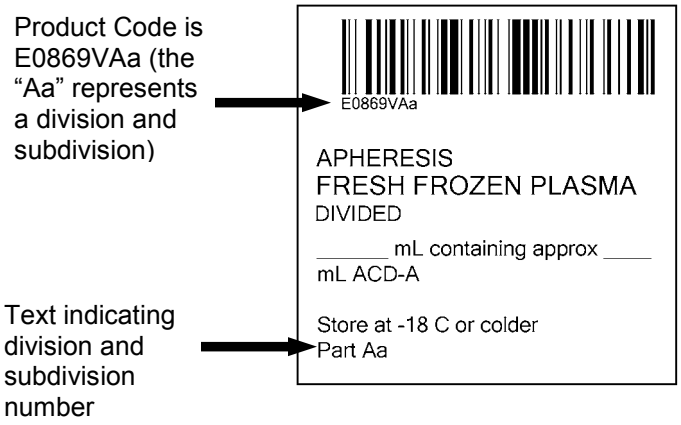
It is possible that these products could be further divided for pediatric use. Should products using the Container codes be further divided, the Division Codes (Position 7 and 8 of the Product Code) would be used. That is, Divisions of E4693V00 from the above example would become E4693VA0 and E4693VB0, etc. See Figure 83.

Figure 83 Product with Container Number Further Divided



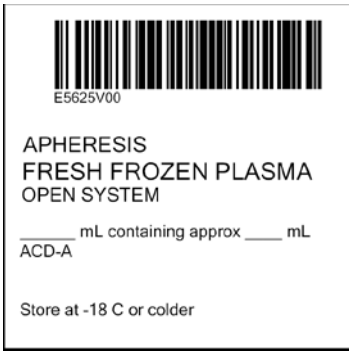
If products using the division codes are further divided, the 8th position of the Product Code is used. That is, from the above example, divisions of E0869VA0 become E0869VAa, E0869VAb, etc. See Figure 84.

Figure 84 Divided Product Further Divided



Apheresis Fresh Frozen Plasma (FFP) may be made in either an open system or a closed system. If it is made in an open system, the dating on the thawed plasma may not be extended beyond the original 6- or 24-hour period. The label text must indicate the plasma was made in an open system.

Figure 85 Apheresis Fresh Frozen Plasma, Open System



7.9.10 Thawed Apheresis Fresh Frozen Plasma

A thawed Apheresis Fresh Frozen Plasma product (used within its 6-24 hour dating period) may retain its original Product Description Code ("frozen code") or be changed to a Product Description Code indicating it has been thawed. That is, either a code for Apheresis Fresh Frozen Plasma or for Thawed Apheresis Fresh Frozen Plasma may be used. Only the expiration date/time must be changed and this information does not have to be bar coded.

If Thawed Apheresis Fresh Frozen Plasma is not used within the allowable 6- or 24-hour periods following thawing, and it was made in a closed system, it may be relabeled as Thawed Apheresis Plasma. This requires applying a new product label that is both machine and eye-readable. This is not an FDA licensable product and an FDA License Number shall not appear on the label.

7.9.11 Apheresis Red Blood Cells

When multiple adult doses of Apheresis Red Blood Cells are collected, Product Description Codes with container Attributes (e.g., 1st container or 2nd container) shall be selected. If only one red cell product is collected, a Product Description Code with no container Attributes should be selected.

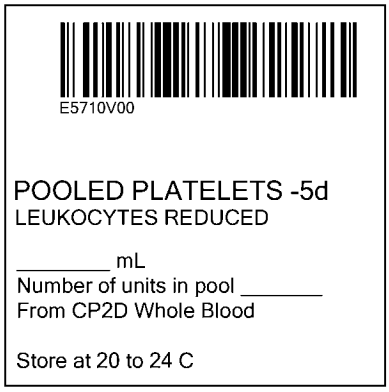
Below the storage temperature, the Container designation may be printed, but this is not required.

7.9.12 Pooled Platelets with Bacterial Monitoring or Bacterial Test

Pooled platelets which have had bacterial testing or monitoring AND meet the criteria in the US for extension of dating should be labeled as Pooled Platelets -5d. Only platelet products that have their expiration extended because of bacterial testing may use the Attributes Bacterial Monitoring or Bacterial Test. (See definitions of these Attributes in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*).

Further modification (e.g., washing or reducing the plasma volume) of this product such that the dating is no longer extended causes the product to lose the bacterial monitoring or bacterial test Attribute.

Figure 86 Pooled Platelets with Bacterial Monitoring or Bacterial Test

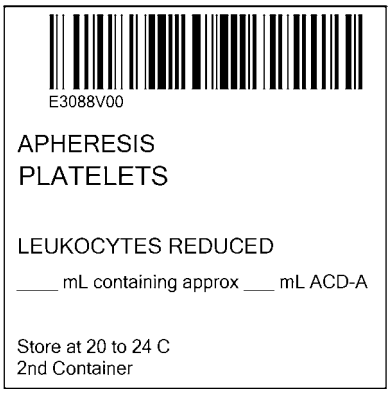


7.9.13 Apheresis Platelets

Users must understand the terms and definitions in the Glossary under "Apheresis Platelet Terminology" to understand this section.

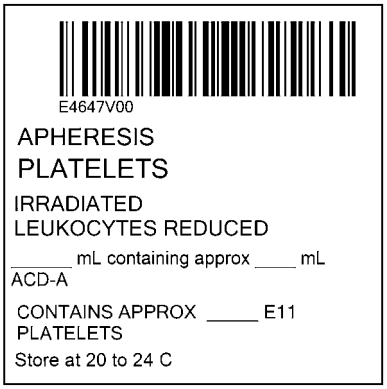
Container Designation or Division Code Text: Below the storage temperature, the Container designation shall be printed. The Division code may also be printed in this space. See Figure 87 for an example of Container Code designation.

Figure 87 "Container" Code on Apheresis Platelets



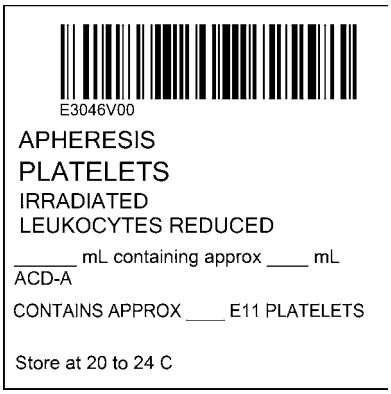
Single Collection and Divided Products with <3 x 10^{11} Platelets: Single collections and divided products with platelet yields <3 x 10^{11} are considered "low yield". Product description codes for these platelets should include the Attribute "<3E11 plts" from the Dosage — Additional Information attribute group. The actual platelet yield on these units shall appear on the label. See Figure 88.

Figure 88 Example Statement on Low Yield Collection



Single, Double or Triple Collections and Divided Products with ≥3 x 10^{11} Platelets: Optionally, a facility may elect to include the platelet yield on a product with ≥3 x 10^{11} platelets. See Figure 89. A Product Description Code with the default "Dosage: No additional Information" from the Dosage — Additional Information attribute group should be selected.

Figure 89 Example of Optional Platelet Yield Statement



Selection of Product Description Codes:
Users are reminded to review terms and definitions for Apheresis Platelet Terminology in the Glossary to interpret this chart.

IF	Then
Single Collection	Product Description Codes without container Attributes should be selected (e.g., E3077 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6)
Low Yield Single Collection	Product Description Codes without container Attributes and with Attribute "<3E11 plts" should be selected (e.g., E4643 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts)
Products from a Double or Triple Collection	Product Description Codes with container Attributes should be selected (e.g., codes with 1st container or 2nd container such as E3087 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container). See Figure 87.
Divided Product	Division codes (codes such as A0 and B0 in the 7th and 8th position of the Product Code) should be used. See Figure 90, Figure 91, and Example of Product Description Code Selection in text box below.
Low Yield Divided Product	Product Description Codes with Attribute "<3E11 plts" should be selected. Division codes (codes such as A0 and B0 in the 7th and 8th position of the Product Code) should be used. See Figure 91 and Example of Product Description Code Selection in text box below.
Single Platelet Collection with Red Cells or Plasma Co-components	Product Description Codes without container Attributes should be selected (e.g., E3077 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6)

Example of Product Description Code Selection:

- Beginning product (Single Collection, platelet yield = 5.8 x 10^{11}): E3077V00 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6), undivided

This product is divided into two portions, one of which has a platelet yield of 2.7 x 10^{11} platelets and the other has a platelet yield of 3.1 X 10^{11} platelets. These products should be labeled as:

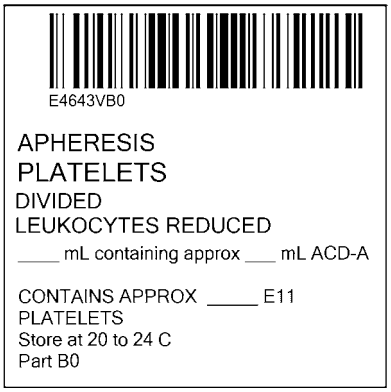
- Product with 2.7 x 10^{11} platelets: E4643VB0 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts), divided (See Figure 90).

- Product with 3.1 X 10^{11} platelets: E3077VA0 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6), divided (See Figure 91).

It does not matter which product becomes A0 and which becomes B0. However, it is recommended that facilities develop a policy for which division code is assigned to the "standard" product and which is assigned to the low yield product, and then be consistent in following their policy.

Additional examples may be found in the FAQ section of the ICCBBA website. There are a few exceptions to the above rules. Users are advised to consult their FDA Consumer Safety Officer for more details.

Figure 90 Divided Low Yield Product



.

Figure 91 Divided Product (Yield ≥3 x 10^{11})

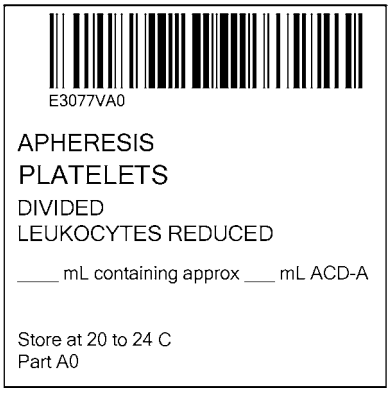
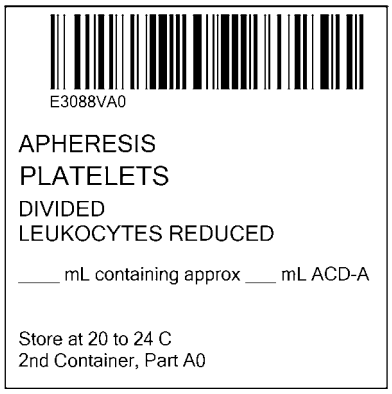


Figure 92 Divided Product from Second Container



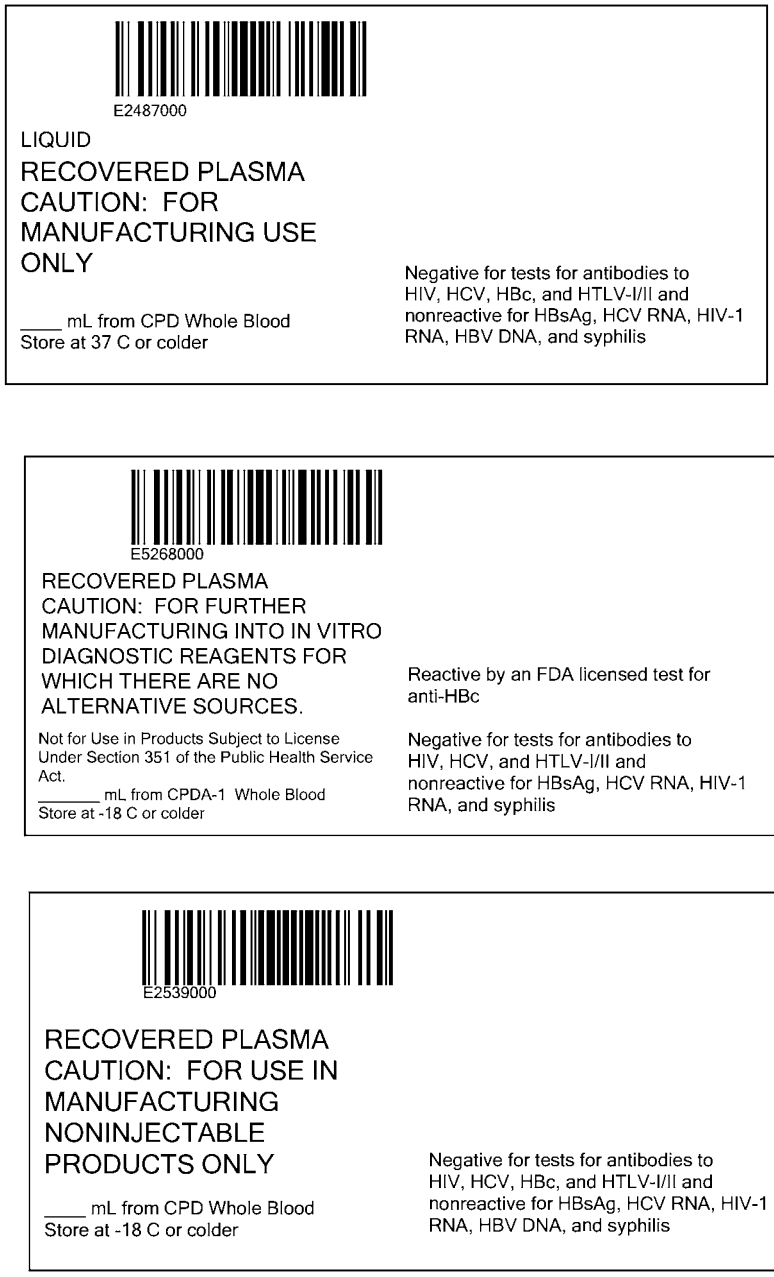
7.9.14 Recovered Plasma

Recovered Plasma shall be coded as Plasma with an Intended Use Attribute indicating it is intended for manufacture. A collection date shall appear on the label. Donation type may be 0 (zero) (indicating the donation type is not specified) or V (if donor was a volunteer donor). Test results should display in the lower right quadrant.

Figure 93 Recovered Plasma

Specific text associated with Recovered Plasma may be found on Figure 25, page 89 and Figure 26, page 90. At the bottom of the chart are the ISBT 128 Product Description Code Attributes associated with each type of Recovered Plasma. Attributes with the phrase “restr use” (restricted use) shall be used for Recovered Plasma that is to be manufactured into a product that is not FDA licensed.

Figure 94 Additional Recovered Plasma Label Examples Showing Lower Quadrants



Note: These examples show only the lower half of the label. The upper portion of the label should appear as shown in Figure 93.

7.9.15 Source Plasma

Source Plasma is to be coded as Apheresis Plasma with an Intended Use Attribute indicating it is intended for manufacture. The expiration date must appear on the label. In some cases, a collection date should also appear (depending on the agreement with the purchaser of the plasma). Donation type may be 0 (zero), (indicating the donation type is not specified); a V (if donor was a volunteer donor); an S (volunteer source donor); or s (paid source donor). Test results should display in the lower right quadrant. The printing of VOLUNTEER DONOR or PAID DONOR in the upper left quadrant is optional in the US.

The type of donor must be clearly described on the label. The specific wording is not standardized, but the table below lists acceptable phrases.

Table 10 Source Donor Type Text

Type of Donor	Examples of Phrases
Normal Donor	• Plasma collected from a normal donor • Collected from a normal donor • Normal donor
Donor with Pre-Existing Antibodies	• Pre-existing antibody _____ • Collected from a donor with pre-existing antibody/ies to _____ • Collected from a donor with pre-existing _____ antibody/ies • From donor with pre-existing _____ antibody/ies
Immunized Donors (includes vaccine and RBCs)	• From donor immunized with _____ • Immunizing antigen used _____ • Plasma collected from immunized donor. Immunizing antigen _____ • Collected from donor immunized with _____
Disease State Donors	• Collected from donor with known Factor _____ Deficiency • Collected from donor with pre-existing _____ antibody/ies • Collected from donor with _____ • Plasma collected from donor with _____ • Collected from a donor on _____
High Risk Donors	• Collected from donor who is _____ reactive/positive • Collected from donor who is reactive/positive for _____ • Collected from donor with _____ antibody/antigen/DNA/RNA • Collected from donor known to be reactive/positive for _____ *Note – test statement on label must also be amended to include the correct test results for the specific donor.*

Figure 95 Source Plasma

Note: The presence of the collection date on the label is dependent on the agreement with the purchaser.

7.9.16 Source Leukocytes

Source leukocytes may be produced from whole blood or by apheresis. The name of the product is the same regardless of how it was collected.

The storage temperature of Source Leukocytes varies, depending on the agreement with the purchaser. If the product is to be stored at 1 to 6 C or 1 to 10 C, it is coded as “refg” in the core conditions; the label text, however, must indicate the actual range for appropriate storage temperature.

Figure 96 Source Leukocytes from Whole Blood

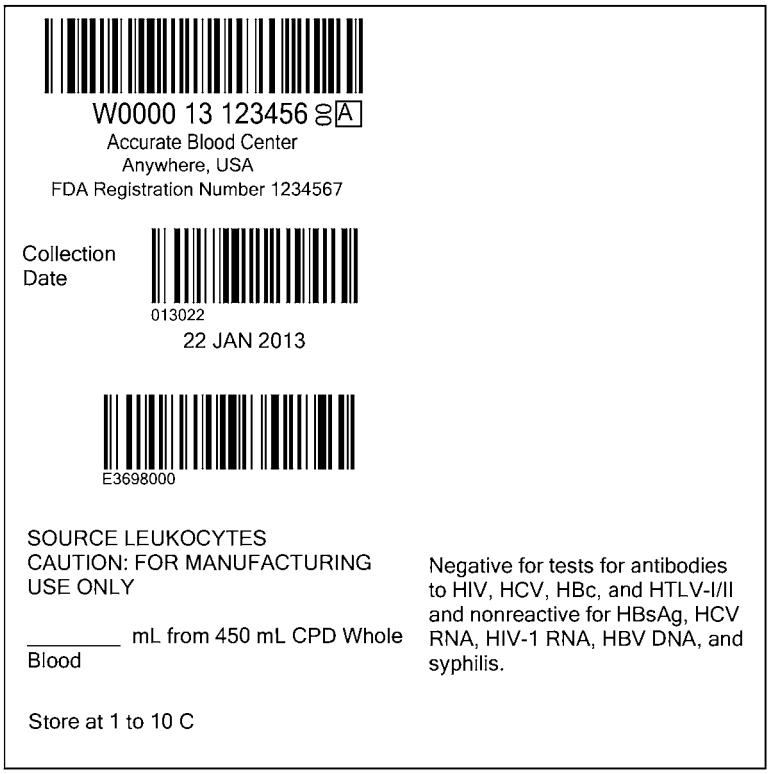


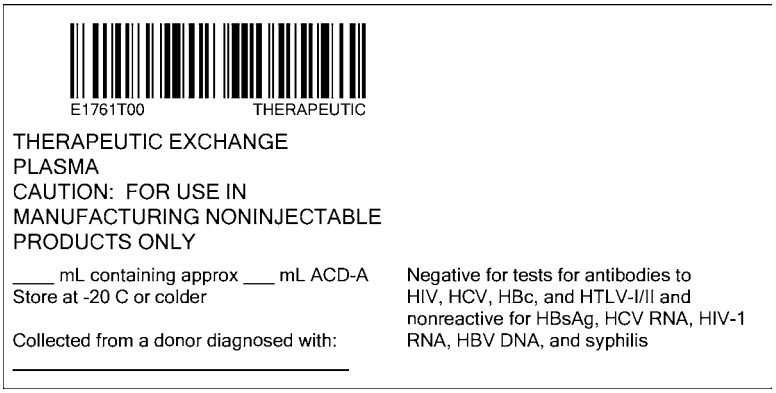
Figure 97 Source Leukocytes Collected by Apheresis

7.9.17 Therapeutic Plasma for Manufacture

This label is similar to other labels for plasma for manufacture, but shall include the diagnosis of the patient in the lower left quadrant.

Facilities may eliminate the donor's disease from the label if the facility has been granted approval from FDA for an alternative procedure to 21 CFR 640.3(d) under the provisions of 21 CFR 640.120 to distribute Whole Blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor’s disorder on the container label.

Figure 98 Therapeutic Plasma for Manufacture into Noninjectable Products (Lower Quadrants)



7.9.18 Additional Labeling by a Facility Modifying a Blood Product

21 CFR 606.121 (c) (13) (iii) requires that certain information be machine readable. This includes: unique facility identifier, lot number relating to the donor (called Donation Identification Number in this document), ABO/Rh of the donor, and Product Code. This applies to facilities modifying units collected at other facilities. The product description label on the blood product shall reflect the modification (with the exception of when frozen plasma is thawed and used within its 6-24 hour time frame or cryoprecipitated AHF products are thawed and used within their 4 or 6 hour time frame).

Donation Identification Number (DIN): The DIN should remain that of the collection facility unless the product is pooled (see 7.8.2, page 115 on Reconstituted Red Cells for another exception). If the product is pooled, a unique pool number (in the same format as the DIN) shall be assigned by the pooling facility. The name beneath the DIN in text must correspond to the Facility Identification Number within the DIN.

If the DIN of the original collection facility is used on the product, the name and location of the modifying facility must appear in the lower right quadrant if the product leaves the facility, per AABB Standards. Only one facility identification has to be machine readable, and this is the one reflected in the DIN. Therefore a machine readable version of the modifying facility identification is not required in the lower right quadrant.

The name and location of the modifying facility is optional on the label if the unit will not leave the facility in which it was modified.

Whenever the name and location of a collection or modifying facility appear, the FDA registration number (or a unique facility identifier) should also appear.

7.9.18.1 FDA License Number

The Guidance for Industry Cooperative Manufacturing Arrangements for Licensed Biologicals (2008) requires the names and FDA license numbers of both the collection and modifying facility on a product if both are licensed to perform their part of the manufacturing. Please refer to this FDA guidance document for detailed information.

If the final product is not licensed, no FDA license numbers should appear on the label (i.e., the license number of the collecting facility should be crossed out). Licensure status of the component, and appropriate labeling based on this, can be determined from Table 11 and Table 12.

Table 11 Licensure Status of Component

Beginning Product Status	Status of firm performing product modification	Final status of product
Licensed product	Licensed firm approved for a specific manufacturing step	Licensed product (see Table 12 for labeling instructions)
Licensed product	Unlicensed firm/Licensed firm not approved for a specific manufacturing step	Unlicensed product
Unlicensed product	Licensed firm/Unlicensed firm	Unlicensed product

Table 12 Appropriate Labeling of Licensed Products

Scenarios	Should the FDA license number of both manufacturers be on the label?	Additional information
Final product used in-house only	No, not required	Records should indicate when and where product modification occurred
Final product distributed out of facility (both in-state and out-of-state)	Yes, the label should show both who collected the product and who performed the product modification	Name, location, FDA registration number (and FDA license number if applicable) of the facility performing the product modification should be in the lower right quadrant
Product modification performed by a contractor and product is used either in-house or distributed out of the facility	No, contractor's information does not need to be on the label	Records should indicate when and where product modification occurred

7.9.18.2 Over-labeling:

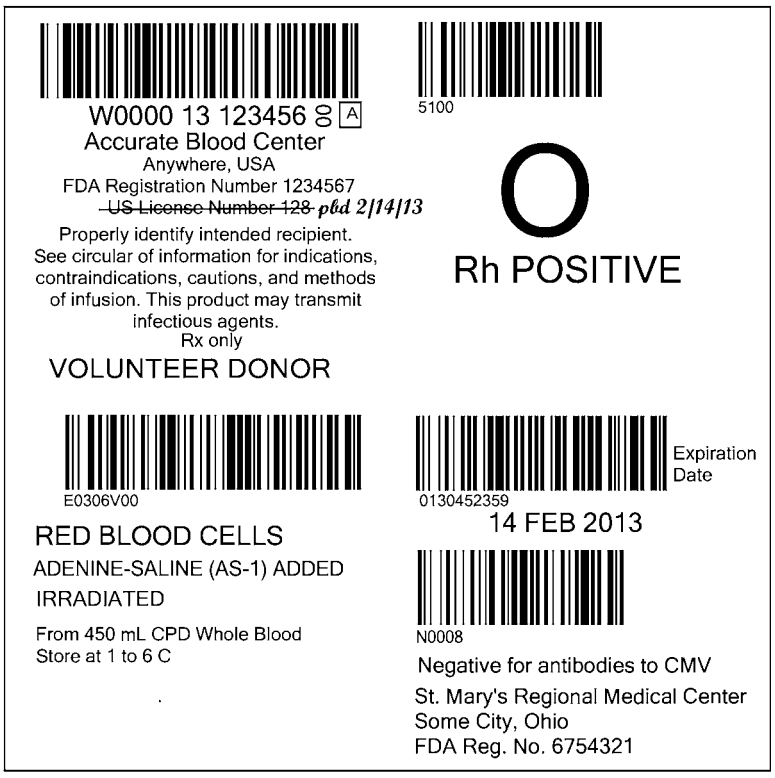
ISBT 128 labels were designed to be applied as 50 mm x 50 mm (2" x 2") quadrant labels, 50 mm x 100 mm (2" x 4") two-quadrant labels (either vertically or horizontally), or as a full 100 mm x 100 mm (4" x 4") label. These options apply to over-labeling when modifying products. However, AABB Standards preclude obscuring, altering, or removing the DIN by

facilities that subsequently handle the unit so a full 100 mm x 100 mm label will need a cut-out to prevent over-labeling the DIN.

Figure 99, page 142, gives an example of a product that was collected by one facility and modified (irradiated) by a second facility when the resulting product is not FDA licensed. Phrases such as “Further processed by” or “Irradiated by” are not required above the name of the modifying facility.

When the only modification of the product is to divide it, as done for pediatric aliquots, the FDA license number of the collection/processing center may remain on the label, but this is not required.

Figure 99 Product Modified by a Facility other than the Collection Facility

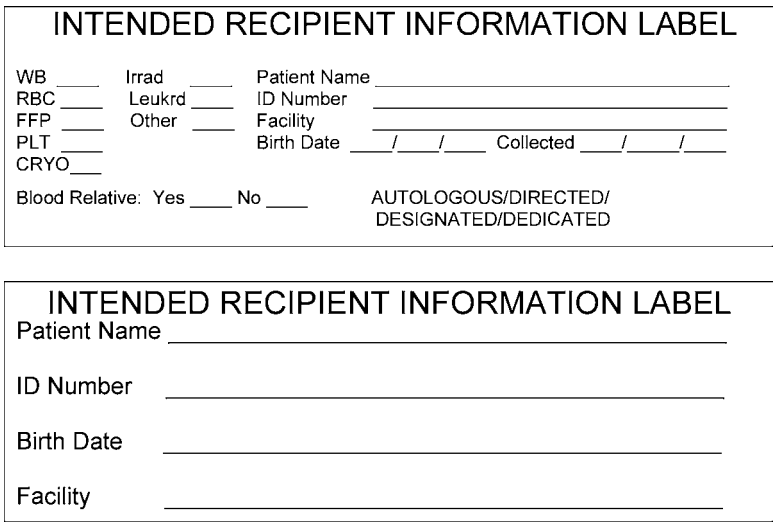


Notes:
The name of the modifying facility in the lower right quadrant is required ONLY if the product leaves the modifying facility.

The US license number is crossed-out when the product has been modified from the original licensed product and the resulting product is not FDA licensed.

7.10 Intended Recipient Information Label

Figure 100 Intended Recipient Information Label Examples

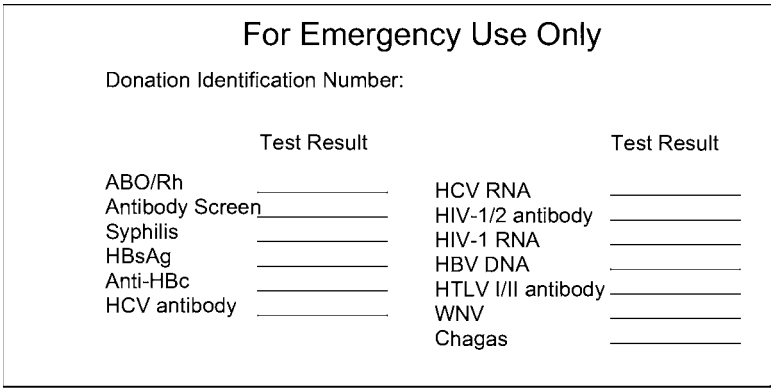


The Intended Recipient Information Label should be placed on the front of the container, immediately above the Donation Identification Number and ABO/Rh Blood Groups bar codes (unless it is a platelet bag) or on a tie tag. (*Note: On a platelet storage bag it may be inappropriate to place a label in the area above the base label because it reduces the breathable area for platelet storage and could result in decreased platelet viability. Please consult the manufacturer of the bag for guidance.)* Either of these label examples (or other designs with similar information) could be used. The minimum information on the tag is defined by the collection facility based on requirements of accrediting organizations.

7.11 Additional Emergency Release Label

In addition to the label in the upper right quadrant indicating a product is being released under emergency conditions, a tie tag should indicate which tests have and have not been performed. Below is an example of such a tie tag; however, the label does not have to follow this format and any format with this information would be acceptable. This information may also be placed in the lower right quadrant of the affixed label.

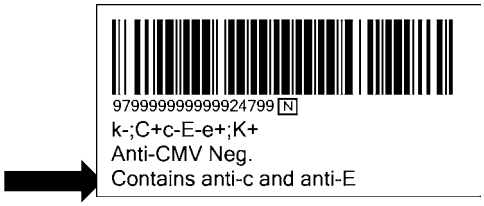
Figure 101 Emergency Release Test Results Tie Tag or Label



7.12 Unexpected Antibodies

While the presence of unexpected antibodies in the unit is not bar coded on the label, it may appear as additional text in the lower right quadrant of the label. This information may also appear on a tie tag attached to the unit.

Figure 102 Labeling for Unexpected Antibodies



8 ICCBBA Databases

ICCBBA maintains the ISBT 128 database tables using Microsoft Access® or Microsoft Excel®.

8.1 Facility Identification Number

This database contains the names and locations of all ICCBBA-registered facilities worldwide. Each facility is assigned a five-character Facility Identification Number (FIN) that for US facilities begins with "W." This database is found on the ICCBBA Website (you must be from an ICCBBA-licensed facility to access this database) and is called:

Registered Facilities – xls

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

When a US facility registers with ICCBBA, it is important that it provides ICCBBA with its full legal name. For an FDA licensed facility, this should be the name and location as it appears on the FDA license. For a facility that is FDA registered but not licensed, it should be the legal name and location as it appears on the FDA registration.

A look-up tool is available on the ICCBBA Website for identifying the facility associated with a given FIN.

8.2 Product Description Code

This database provides a list of all Product Description Codes and their descriptions. A detailed description of the ISBT 128 Product Description Code database can be found in the document *Use of Product Code Data Structure [003] – Blood.* The database is found on the ICCBBA Website (you must be from an ICCBBA-licensed facility to access this database) and is called:

Product Description Codes Database - Access 2000

Comma-delimited text files of each of the tables in the Product Description Code Database (Attribute Text File, Class Text File, Product Description Codes Database Text File, and Version Text File) are also provided to permit end-users to incorporate these tables into any preferred database application.

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

8.3 Special Testing: General

This database contains the test names and codes for data conveyed in the Special Testing Data Structure (Data Structure 010) such as CMV and Hemoglobin S. The database is found on the ICCBBA Website (you must be from an ICCBBA-licensed facility to access this database) and is called:

Special Testing General - Access 2000

A comma-delimited text file of the table in the Special Testing: General database (Special Testing General Text) is also provided to permit end-users to incorporate this table into any preferred database application.

8.4 Manufacturer Identification Codes

The table contains the identification codes assigned to manufacturers for use in the Container Manufacturer and Catalog Number (Data structure 017) and the Manufacturer and Catalog Number - Items other than Containers (Data structure 021). Some of the entries may not be in current use but are retained for use in look back situations. Licensed vendors who wish to have a code assigned for use in these data structures should contact ICCBBA. This database is published on the ICCBBA Website. This table is named:

Table W1 Manufacturer ID Codes [RT016]

8.5 Structured Compound Messages

The table contains the reference numbers and structures for structured ISBT 128 compound messages. When using these messages, the data identifier is incorporated into the compound message structure. Requests for additions to this table should be submitted through the ICCBBA office. This database is published on the ICCBBA Website. This table is named:

Table W2 Structured Compound Messages [RT017]

9 Appendix Acceptable Abbreviations for Blood Label Text

Ab	antibody(ies)
ACD	Acid Citrate Dextrose
ACD-A	Acid Citrate Dextrose Formula A
ACD-B	Acid Citrate Dextrose Formula B
Approx	approximately
C	degree(s) Celsius (Centigrade)
CMV	Cytomegalovirus
CPD	Citrate Phosphate Dextrose
CPDA-1	Citrate Phosphate Dextrose Adenine Formula 1
CP2D	Citrate Phosphate Double Dextrose
DNA	Deoxyribonucleic Acid
E11 (for any exponents)	$X10^{11}$
g	gram(s)
h	hour(s)
HBc	Hepatitis B Core
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Viruses
HgbS	Hemoglobin S
HLA	Human Leukocyte Antigen
HTLV	Human T-cell Lymphotropic Viruses
mg	milligram(s)
mL	milliliter(s)
Na	sodium
Neg.	negative
PAS	Platelet Additive Solution
RNA	Ribonucleic Acid
room temp	room temperature
STS	serological test for syphilis
FDA Reg. No.	FDA Registration Number
US Lic.	US License Number
WNV	West Nile virus

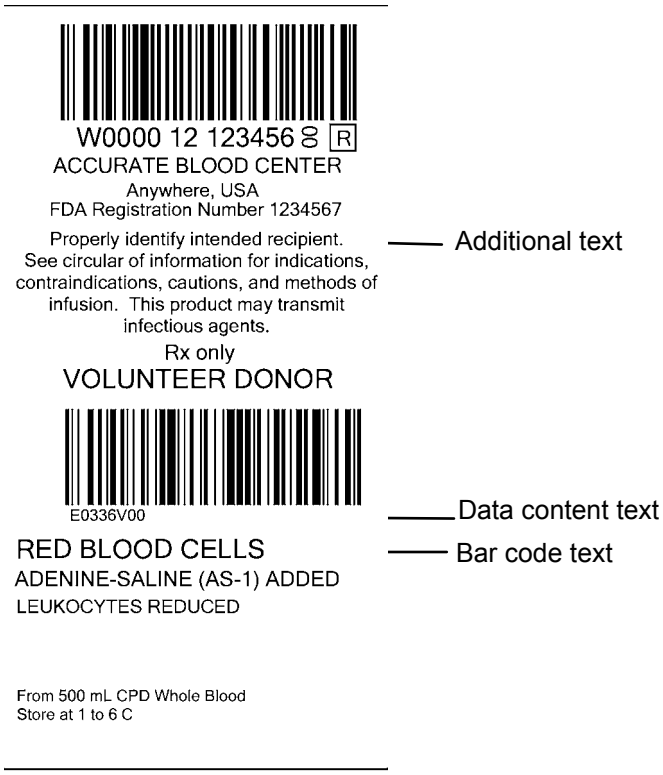
Glossary

Attribute	Information about the processing or other characteristics of a blood component beyond Class and Modifier.
Autologous collection	Blood collected from the intended recipient.
Base label	The label applied by the manufacturer to: (1) primary and satellite containers for the collection of Whole Blood; (2) apheresis collection containers; and (3) transfer containers.
Class	A general description of a product (such as Whole Blood, Red Blood Cells, or Fresh Frozen Plasma).
Concatenation	A method by which the information held in two bar codes is combined in the scanner into a single string of data before being sent to the host computer. ISBT 128 places specific rules on the operation of concatenation which ensures that the two codes are adjacent to one another, hence allowing this feature to be used in label process control.
Core conditions	The anticoagulant and/or additive, nominal collection volume, and storage temperature requirements for a blood component.
Data characters	The individual ASCII characters that make up the data content.
Data content	The characters in a data structure that encode the information for which the data structure is named. The data content does not include the data identifiers.
Data identifier	The first two characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined.
Dedicated collection	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). This term may be used when donors are authorized by a medical director to give blood more frequently than the routine interval between donations in order to support a particular patient. An example would be when a parent is donating low volume units to support an infant.
Designated collection	A unit collected from a donor called by the collecting facility to provide (a) product(s) to be used by a specific recipient in some future therapeutic procedure. An example would be when an HLA-compatible donor is recruited to meet the specific needs a patient with antibodies to HLA antigens.
Directed collection	A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide (a) product(s) to be used by that person in some future therapeutic procedure.
Final label	The label that appears on a blood product ready for release.

Flag character	Part of the data content of a data structure used in process control or data transmission checking. For ISBT 128, flag characters are used with the Donation Identification Number. They are printed in eye-readable format, but distinguished in some manner from the representation of the other data characters.
Modifier	A description that relates to the Core Conditions of a blood component and distinguishes it from other members of the same Class (such as Apheresis, Frozen, Frozen Rejuvenated, or Washed).
Platelet apheresis terminology	*Note: The following terminology is specific to US apheresis manufacturing and may not represent use of these words in other contexts (including other ISBT 128 contexts).* Reference: Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (December 2007)
Single Platelet Apheresis Collection	A type of collection that results in one transfusable apheresis platelets component with a platelet yield of either ≥3 x 10^{11} or <3 x 10^{11}(low yield).
Double Platelet Apheresis Collection	A type of collection that results in two equal transfusable apheresis platelets components, each with platelet yields of ≥3 x 10^{11} (1st and 2nd Containers). The two components may have either been collected during the apheresis process or produced by the post-collection separation (splitting) of the single parent container.
Triple Platelet Apheresis Collection	A type of collection that results in three equal transfusable apheresis platelets components, each with platelet yields of ≥3 x 10^{11} produced by the post-collection separation (splitting) of the single parent container (1st, 2nd and 3rd Containers).
Divided Platelet Apheresis Component	A component that results from the separation (division) of a transfusable apheresis platelets component obtained from a single, double or triple collection into components with lower volumes and yields. The resulting components are designated with alpha characters in position 7 of the ISBT 128 Product Code (e.g., A0 or B0). If a divided component is again divided, position 8 of the ISBT 128 Product Code would be changed to the appropriate lower case letter (e.g., Aa or Ab). Divided components may have platelet yields that are either ≥3 x 10^{11} or <3 x 10^{11} (low yield). *(Note: This definition applies only to divided apheresis platelets. The term "divided" may be used with other components for which this definition does not apply.)*
Primary container	The container in which the anticoagulant is placed for whole blood collection.
Satellite container	Any container, often empty, attached by the manufacturer to a primary container as part of a Whole Blood collection set intended to contain Platelets, Plasma, or Cryoprecipitated AHF.

Text	See Figure 103, page 151.
Data content text	The representation of the data characters in a bar code in letters or numbers (printed left justified immediately below the bar code, unless otherwise specified).
Bar code text	The interpretation of the data content text (the data content of the bar code) that generally requires a look-up table.
Additional text	All other information on the label that is not associated with a bar code.
Transfer container	Any container that is not an integral part of a Whole Blood or apheresis collection set intended for a blood product.

Figure 103 Text Terminology in ISBT 128 Documents



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