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

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ICCBBA
PO Box 11309, San Bernardino, CA 92423 USA

Telephone: +1 (909) 793-6516
E-mail: support@isbt128.org
Fax: +1 (909) 793-6214
Website:www.isbt128.org

Acknowledgement

ICCBBA thanks the members of the US Consensus Standard Subcommittee for their contributions in the development of this consensus standard.

Members of US Consensus Standard Subcommittee

Maria Locher, Chair
Erwin Cabana
Kathleen Hopping
Karen Moniz
Lucinda Olivio
Barbara Peoples
Jessica Poisson
Marsha Senter
Patricia Weddington
Robin Wilkinson

ATAG Representatives

Carrie VanStedum, Veteran’s Administration
Maria Locher, American Red Cross
Jessica Poisson, AABB IS Committee
Nathalie Marin, HémaQuébec
Lucinda Olivio, America's Blood Centers
Wanda Lefresne, Canadian Blood Services
Alan Vaughn, Department of Defense

Liaisons

Francisca Agbanyo, Health Canada
Barbara Peoples, FDA
Patricia Weddington, FDA

Additionally, ICCBBA thanks the many observers who routinely participate in ATAG and provide valuable input.

Editor

Erwin Cabana, BA
Technical Manager, ICCBBA

Standards Committee

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Zbigniew Szczepiorkowski, MD, PhD, FCAP	Technical Expert
Kelly Tilleman, PhD, MSc	ARTTAG Chair
Izabela Uhrynowska-Tyszkiewicz, MD, PhD	ETTAG, ITTAG Chair

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Abbreviations and Acronyms

2-D	Two dimensional
ASCII	American Standard Code for Information Interchange
ATAG	Americas Technical Advisory Group
CBER	Center for Biologics Evaluation and Research
CCD	Charged Coupled Device
CFR	Code of Federal Regulations
CRYO	Cryoprecipitate
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
mnf	Further manufacturing
PF 24	Plasma Frozen Within 24 Hours After Phlebotomy
PF24RT24	Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up to 24 Hours After Phlebotomy
PLT	Platelets
PRT	Pathogen Reduction Technology
RBC	Red Blood Cells
RFID	Radio Frequency Identification
RP	Recovered Plasma
RTTI	Relevant Transfusion Transmitted Infections (21 CFR 630.3(h))
SP	Source Plasma
tx	Transfusion/Transplantation
US	United States
WB	Whole Blood
WBC	White Blood Cells
WBD	Whole Blood Derived

1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance on labeling requirements in the United States (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 contact the FDA/CBER (CBEROBRRBPBInquiries@fda.hhs.gov) 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 Medical Products of Human Origin.

1.3 Intended Audience

The intended audience of this document is blood component manufacturers, 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 Medical Products of Human Origin (ST-002)
ISBT 128 Standard Labeling of Blood Components (ST-005)

AABB
Standards for Blood Banks and Transfusion Services

AABB/ABC/ASBP
Circular of Information for the Use of Human Blood and Blood Components

FDA
21 CFR 601.12(f)
21 CFR 606.121
21 CFR 610.53
21 CFR 610.60
21 CFR 630.10
21 CFR 630.15
21 CFR 630.30

21 CFR Part 640
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.isbt128.org)
AABB Website (www.aabb.org)
FDA Website (https://www.fda.gov/vaccines-blood-biologics)

Note: The following FDA Guidance documents were current at the time this Consensus Standards was published. Guidance may change and be updated by FDA at any time. We suggest that readers consult the FDA website (above) for the most current information.

Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods (Technical Correction January 2001)

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)

Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion (September 2012)

Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture (December 2014)

Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results: (December 2018)

Guidance for Industry: Bacterial Risk Control Strategies for Blood Collection Establishment and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (December 2020)

Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components (March 2022)

Use of Product Code Data Structure [003] – Blood (IG-021)
Use of the Manufacturer's Data File (IG-015)
Blood Bag Identification Using ISBT 128 and GS1 (JP-003)
ISBT 128 Bar Codes Valid and Invalid Examples (IG-013)
Length of the Product Code Bar Code and Concatenation (IG-017)
US Guidance on Printing Text Associated with Red Cell Antigens (IG-025)
Use of Red Cell Antigens with Test History Data Structure [030] (IG-027)
Manufacturer Catalog Number and Lot Number (Items Other Than Containers) (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 4.0.0 of this document is reorganized and expanded from Version 3.0.0. More examples of labels and text are included for products that were not addressed in the previous version 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, this 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 3.0.0 and Version 4.0.0

	Section in Version 3.0.0	Section in Version 4.0.0	Change	Rationale
1.	Throughout	Throughout	Updated the ICCBBA website address to www.isbt128.org.	New ICCBBA website.
2.	Throughout	Throughout	Updated the title of the document Standard Terminology for Medical Products of Human Origin.	The title was revised since the last publication of IG-002.

	Section in Version 3.0.0	Section in Version 4.0.0	Change	Rationale
3.	Throughout	Throughout	Removed references to 21 CFR 640.3 and replaced them with references to 21 CFR 630.10, 630.15, 630.30,and other CFR references.	Updated to reflect current applicable FDA regulations.
4.	Abbreviations and Acronyms	Abbreviations and Acronyms	Added the following abbreviations: CBER, CRYO, mnf, PF24, PF24RT24, PRT, RP, RTTI, SP, tx, WBD.	For completeness.
5.	1.2	1.2	Replaced FDA with CBER, when appropriate.	To be more specific.
6.	1.5	1.5	Expanded the list of guidance documents.	New relevant guidance documents since the last publication of IG-002.
7.	Table 2	Table 2	Expanded the list of ISBT 128 data Structures.	New data structures were created since the last publication of IG-002.
8.	2.6.2		Removed the verbiage regarding the lack of recommendations for the use of 2-D Data Matrix symbols and purchasing of imaging scanners.	2-D labels are now encouraged and imaging scanners are now common.
9.	3.1	3.1	Provided clarification on when facilities need to submit their labels to the FDA for approval.	For clarification.
10.	4.1	4.1	Clarified that the FIN within the DIN designates the organization that assigned the DIN.	For clarification.
11.	4.2.1.2		Removed the verbiage that restricted the use of Directed, Eligible for Crossover.	This is now allowed.
12.	4.2.1.2 Table 6 Table 7 7.8.12	4.3.1.2 Table 6 Table 7 7.8.11	Revised the labeling guidance for Pooled Platelets Bacterial Monitoring	Bacterial monitored Pooled Platelets may be stored for 5 days or 7 days depending on approvals.

	Section in Version 3.0.0	Section in Version 4.0.0	Change	Rationale
13.	4.3		Removed the list of characters that are designated for the various types of product description codes.	To reduce redundancy. This is listed in the ISBT 128 Technical Specification document. Only blood product description codes are applicable to this IG-002 document.
14.	4.3.1.4		Removed the note that the “D” collection type code will be mandatory for directed donations eligible for crossover.	This remains optional.
15.	5.1.3		Removed the note that indicates no specifications for labeling pediatric doses are provided.	Labeling specifications are now provided within IG-002.
16.	Table 5	Table 5	Added several class modifier combinations to the table of proper names.	To provide labeling guidance for new products since the last publication of IG-002.
17.	Table 7	Table 7	Expanded the list of attributes in the table.	To provide labeling guidance for new attributes since the last publication of IG-002.
18.	Table 8	Table 8	For those products containing an additive solution, indicated that the additive should be listed immediately below the class name on the label.	For clarification.
19.	Table 9	Table 9	Revised the descriptions in the Type of Collection field.	For consistency with the ISBT 128 Technical Specification.
20.	7.4	7.4	Removed most of the label examples for the Upper Right Quadrant	Label examples for the upper right quadrant will be provided in an addendum.
21.	7.5	7.5	Removed the label examples for the Lower Left Quadrant.	Label examples for the lower left quadrant will now be provided in an addendum.
22.	7.8.2	7.8.2	Provided additional guidance on the labeling of Reconstituted Red Blood Cells.	For completeness.

	Section in Version 3.0.0	Section in Version 4.0.0	Change	Rationale
23.	7.8.12	7.8.12	Incorporated guidance on labeling bacterially monitored/tested platelets from the TB-015 document.	For completeness.
24.	7.8.13	7.8.12	Incorporated guidance on labeling Apheresis Platelets containers from the TB-003 document.	For completeness.
25.	Appendix	Appendix	Added abbreviations for PRT.	For completeness.

Please note that this table represents the significant changes and corrections introduced in Version 4.0.0. The document must be read in its entirety because of the expansion of some sections.

2 Overview of the ISBT 128 Standard

2.1 Need for an International Standard

A significant amount 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 20, 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 precisely defined in terms of its length and permissible characters (see Table 2, page 20).

Figure 1 Data Structure

$$\underbrace{=<}_{\text{Data Identifier}}\ \underbrace{\text{E1234V00}}_{\text{Data Content}}$$

2.3.1 Data Identifiers

Each data structure begins with 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.

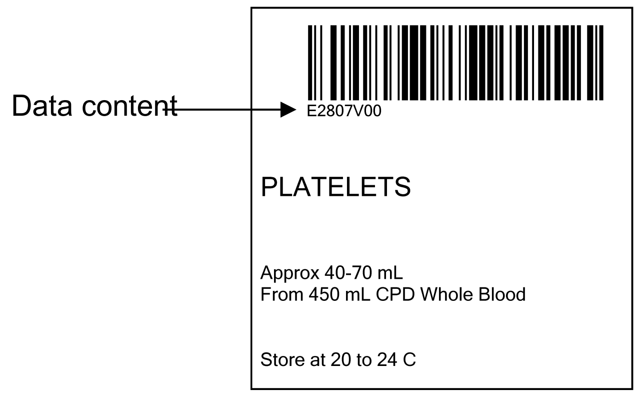
The second character distinguishes the type of ISBT 128 information to be conveyed. For example, the two characters "=%" at the beginning of a data structure indicate that the bar code carries information about the ABO/Rh Blood Groups whereas "=<" means the bar code carries information about the Product Code. Some of the newer data structures will have a third data identifier character. 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 38, 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

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content
			Char-acter	ASCII Value	Char-acter	ASCII Value	Char-acter	ASCII Value	
001	Donation Identification Number	2	=	61	A-N P-Z 1-9	65-78 80-90 49-57	N/A	N/A	αppppyynnnnnnff
002	Blood Groups [ABO and RhD]	2	=	61	%	37	N/A	N/A	ggre
003	Product Code	2	=	61	<	60	N/A	N/A	αooootds
004	Expiration Date	2	=	61	>	62	N/A	N/A	cyyjjj
005	Expiration Date and Time	2	&	38	>	62	N/A	N/A	cyyjjjhhmm
006	Collection Date	2	=	61	*	42	N/A	N/A	cyyjjj
007	Collection Date and Time	2	&	38	*	42	N/A	N/A	cyyjjjhhmm
008	Production Date	2	=	61	}	125	N/A	N/A	cyyjjj
009	Production Date and Time	2	&	38	}	125	N/A	N/A	cyyjjjhhmm

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content
			Char-acter	ASCII Value	Char-acter	ASCII Value	Char-acter	ASCII Value	
010	Special Testing: General	2	&	38	(	40	N/A	N/A	zzzzz
011	Special Testing: Red Blood Cell Antigens **[RETIRED**]	2	=	61	{	123	N/A	N/A	aaaaaaaaaaaaaaaaii
012	Special Testing: Red Blood Cell Antigens – General	2	=	61	\	92	N/A	N/A	aaaaaaaaaaaaaaaaii
013	Special Testing: Red Blood Cell Antigens – Finnish	2	&	38	\	92	N/A	N/A	aaaaaaaaaaaaaaaaii
014	Special Testing: Platelet HLA and Platelet Specific Antigens	2	&	38	{	123	N/A	N/A	AAAABBBBCCCCCCCCDE
015	Special Testing: HLA-A and -B Alleles **[RETIRED]**	2	=	61	[	91	N/A	N/A	EEEEFFFFGGGGHHHHLM
016	Special Testing: HLA-DRB1 Alleles **[RETIRED]**	2	=	61	"	34	N/A	N/A	IIIIJJJJMMMMMMMMM
017	Container Manufacturer and Catalog Number	2	=	61	)	41	N/A	N/A	bqqwwwwwww

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content
			Char-acter	ASCII Value	Char-acter	ASCII Value	Char-acter	ASCII Value	
018	Container Lot Number	2	&	38	)	41	N/A	N/A	xxxxxxxxxx
019	Donor Identification Number	2	=	61	;	59	N/A	N/A	αppppvvvvvvvvvvvvvvvv
020	Staff Member Identification Number	2	=	61	'	39	N/A	N/A	αppppuuuuuu
021	Manufacturer and Catalog Number: Items Other Than Containers	2	=	61	-	45	N/A	N/A	NNOOOOOOOO
022	Lot Number: Items Other Than Containers	2	&	38	-	45	N/A	N/A	PPPPPPPPPP
023	Compound Message	2	=	61	+	43	N/A	N/A	aabbb
024	Patient Date of Birth	2	=	61	#	35	N/A	N/A	aayyyymmdd
025	Patient Identification Number	2	&	38	#	35	N/A	N/A	aallxx…xx
026	Expiration Month and Year	2	=	61	]	93	N/A	N/A	yyyymm
027	Transfusion Transmitted Infection Marker	2	&	38	"	34	N/A	N/A	nnnnnnnnnnnnnnnnnn

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content
			Char-acter	ASCII Value	Char-acter	ASCII Value	Char-acter	ASCII Value	
028	Product Consignment	2	=	61	$	36	N/A	N/A	αppppyynnnnnccdd
029	Dimensions	2	&	38	$	36	N/A	N/A	nnaabbbbcccccdee…aabbbbcccccdee
030	Red Cell Antigens with Test History	2	&	38	%	37	N/A	N/A	nnnpppppprrss…pppppprrss
031	Flexible Date and Time	2	=	61	(	40	N/A	N/A	ZUTTYYYYMMDDhhmm
032	Product Divisions	2	=	61	,	44	N/A	N/A	dddddd
033	Processing Facility Information Code	2	&	38	+	43	N/A	N/A	nnnnnpppppp
034	Processor Product Identification Code	2	=	61	/	47	N/A	N/A	nnnnnppppppqqqqq
035	MPHO Lot Number	3	&	38	,	44	1	49	xxxxxxxxxxxxxxxxxx
036	MPHO Supplemental Identification Number	3	&	38	,	44	2	50	xxxxxxxxxxxxxxxxxx

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content
			Char-acter	ASCII Value	Char-acter	ASCII Value	Char-acter	ASCII Value	
037	Global Registration Identifier for Donors **[RETIRED]**	3	&	38	,	44	3	51	nnnnaaaaaaaaaaaaaaa
038	Single European Code (SEC)	3	&	38	,	44	4	52	xxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxx
039	Global Registration Identifier for Donors	2	&	38	:	58	N/A	N/A	nnnnaaaaaaaaaaaaabb
040	Chain of Identity Identifier	2	&	38	/	47	N/A	N/A	CHαppppyynnnnnn
N/A	Data Structures Not Defined by ICCBBA	2	&	38	a-z	97-122	N/A	N/A	These data identifiers may be assigned by a facility or a regional, national, or supranational authority
N/A	Reserve Data Identifiers for a Nationally Specified Donor Identification Number	2	&	38	;	59	N/A	N/A	Defined nationally
N/A	Confidential Unit Exclusion Status Data Structure	2	&	38	!	33	N/A	N/A	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:

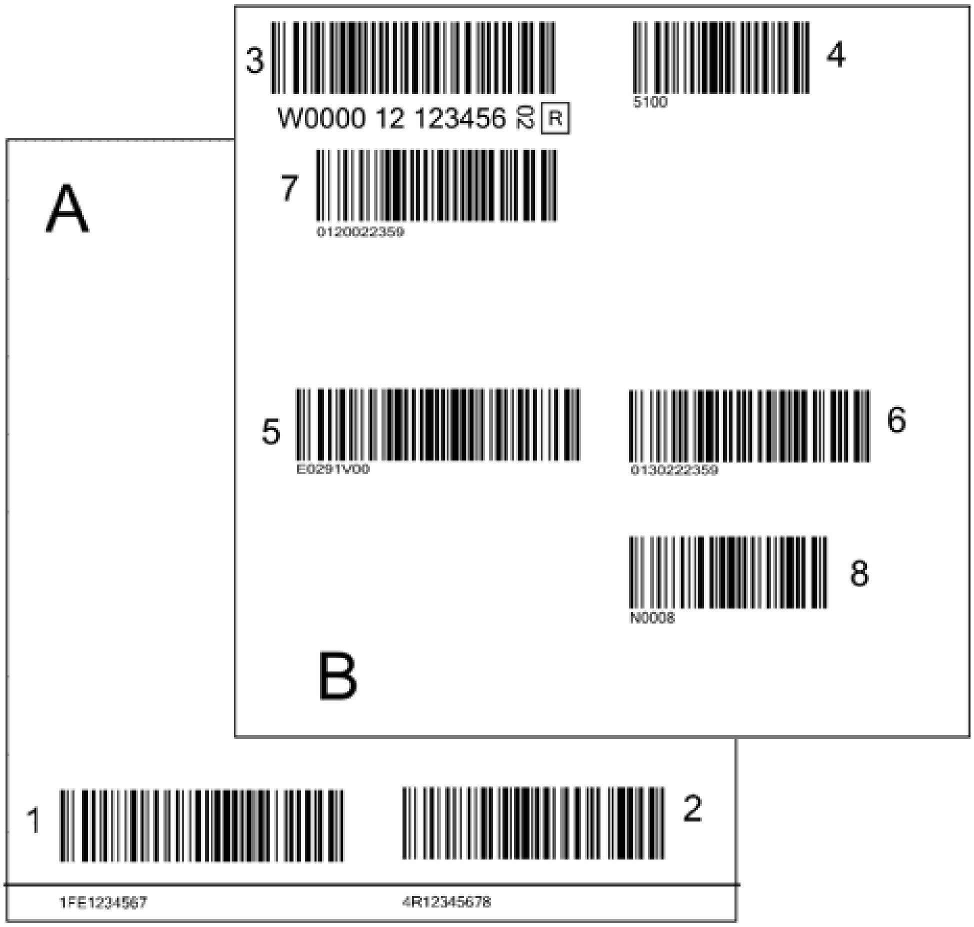
- Container Manufacturer Identity and Catalog Number
- Container Lot Number

Final Label:

- Donation Identification Number
- ABO/Rh Blood Groups [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 71, page 169) 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 71, page 169), 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. 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 can read both 2-D and linear bar codes such as Code 128.

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

W0000 11 123456 02 7

9500

E0310V00

0110312359

N0008

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). In 2014, FDA published *Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels Guidance for Industry.* This Guidance recognized ISBT 128 Version 3.0.0, dated March 2013.

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 a copy of the ISBT 128 container label to CBER in the initial submission for licensing a product as a Prior Approval Supplement in accordance with 21 CFR 601.12(b). The label should be submitted again when any change is made to the label. See 21 CFR 601.12(f) to determine the appropriate submission category for each change.

FDA does not require ISBT 128. However, it does require that at a minimum 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. Please refer to 21 CFR 606.121.

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 [Data Structure 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:

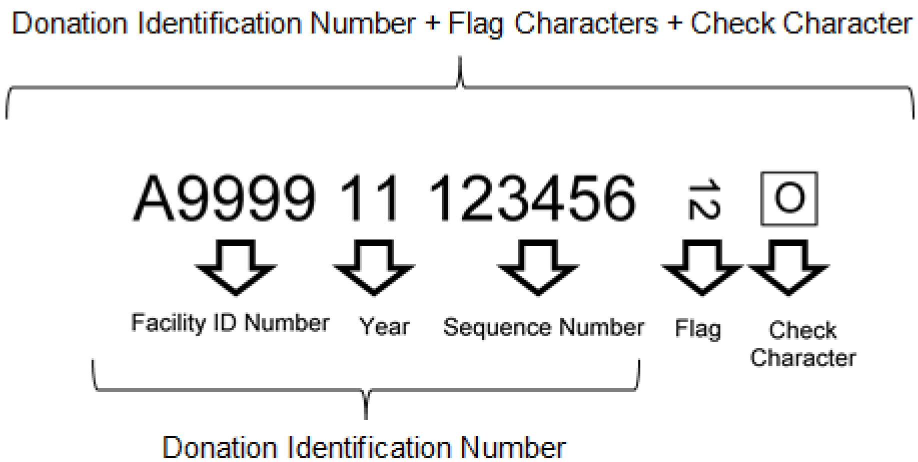
αpppp	designates the organization that assigned the DIN;
yy	designates the year in which the donation or collection was made;
nnnnnn	is a serial number associated with the donation, collection, or pooled product.

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. Refer to ST-001 for how this check character is calculated.

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 02 R

The DIN is divided into three parts (Facility Identification Number, year, and sequence 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 33, 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 33.

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 “22” may be used from December 1, 2021 through January 31, 2023. 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 Blood Groups [ABO and RhD] [Data Structure 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 40).

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 38.

Text should be printed:

	ABO text	Rh text	Example
Rh Positive	Solid black	Black on white	See IG-002 Addendum of Label Examples (www.isbt128.org/IG-002AddendumLabels) for additional ABO/Rh label examples.
Rh Negative	Outline black	White on black	See IG-002 Addendum of Label Examples
Rh not specified	Solid black	Not applicable	See IG-002 Addendum of Label Examples

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 www.isbt128.org/IG-002AddendumLabels and Figure 32, page 106).

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.

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 40, 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 38. 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).

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 www.isbt128.org/IG-002AddendumLabels and Figure 32, page 106).

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 www.isbt128.org/IG-002AddendumLabels. 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 for 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 32, page 106. 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 may 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 68, page 161, 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 45, page 124 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.

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 [Data Structure 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 163). Product Description Codes for blood will begin with E (e.g., E0167, EA123). See the *ISBT 128 Technical Specification* for the assignment of Product Description Codes for the other MPHO categories. **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 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. US 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 96);

ds provides information about divisions of the blood product.

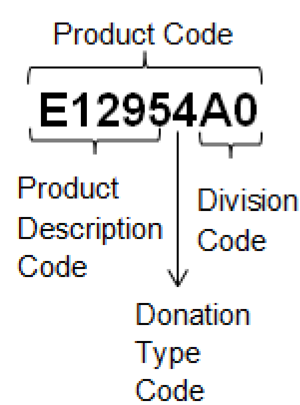
Data characters seven and eight (ds) are reserved for encoding information about divisions of blood products. When a blood product is divided into two or more parts, the seventh and eighth data characters are changed from “00” (zero, zero), the default values. See 7.8.3, page 120, for examples of how 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., smaller or pediatric doses). When a donation is divided into multiple adult doses (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 smaller 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 smaller 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 smaller 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 database and contains descriptions for blood products that are not used in the US. 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 further manufacture is either Source Plasma or Recovered Plasma;
- Cryoprecipitate is Cryoprecipitated AHF;
- Red Cells to which plasma has been added are Reconstituted Red Blood Cells
- Leukocytes for further manufacture (either apheresis or whole blood derived) are Source Leukocytes

Table 5, beginning on page 69, and Table 6, page 76, provide the proper names for products in the US.

4.3.1.3 Attributes

Table 7 (beginning on page 77) 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 96.

In the US, the following usage is mandatory:

Code	Required for
V	Blood products intended for transfusion that are collected from volunteer allogeneic donors if one of the optional codes is not used.
P	Blood products intended for transfusion that are collected from paid donors if one of the optional codes is not used.
T	Collections from donors presenting for therapeutic phlebotomy according to a physician's prescription if they are labeled for transfusion; it is not required if the collection is not intended for transfusion. Facilities may also use “V” rather than “T” if the facility distributes blood products collected from donors who meet all eligibility requirements and undergo phlebotomy for hereditary hemochromatosis or other diagnosed diseases or conditions using procedures that have been found acceptable for this purpose by FDA 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

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 96) 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 37, page 110. 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 96.

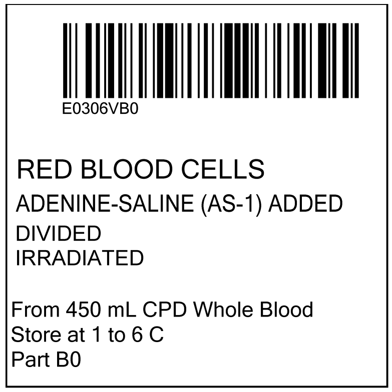
Figure 7 Donation Type Encoded in Product Code

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 46).

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

Examples of labels based on these rules can be found later in this document and in a separate addendum. 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.

4.4 Expiration Date and Time [Data Structure 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.

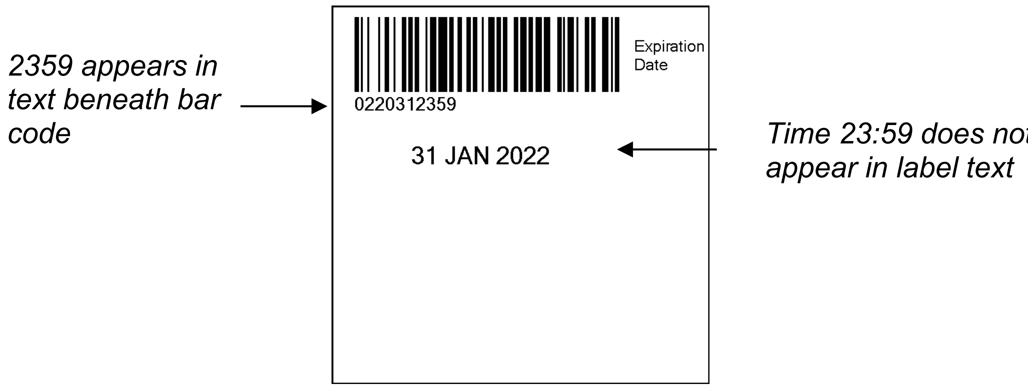
This format is DD MMM YYYY. For example:

21 JUL 2009

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

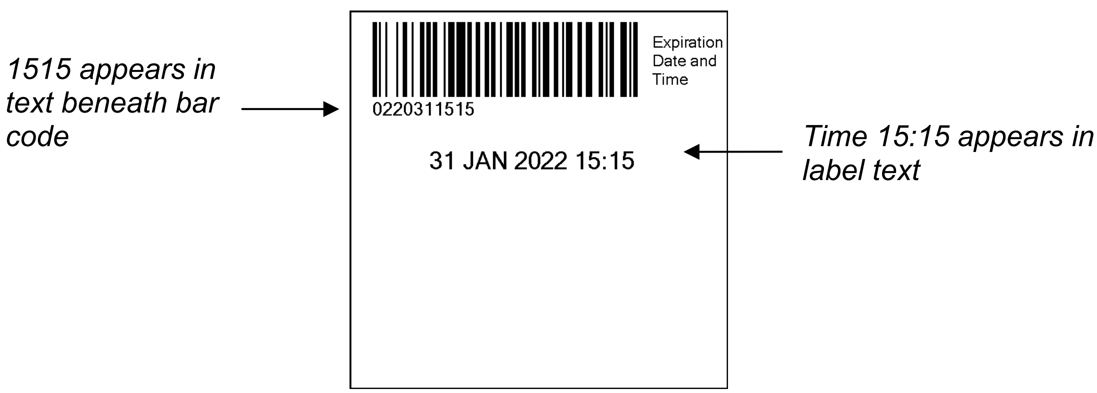
When a product outdates at midnight as a default, the time should be encoded into the bar code as 2359 and be displayed in the text beneath the bar code as 2359, as shown in Figure 9. However, the time should not be shown in the label text; midnight expiration is assumed. (For an explanation of “text” 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 be encoded in the bar code and printed in the bar code label text beneath the bar code In the label 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 [Data Structure 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 included on labels for Source Leukocytes and Recovered Plasma (and may be included on labels for Source Plasma depending on contract requirements) when collection time is not critical. Collection dates may appear on the labels of products intended for transfusion.

Figure 11 Collection Date on Recovered Plasma Label

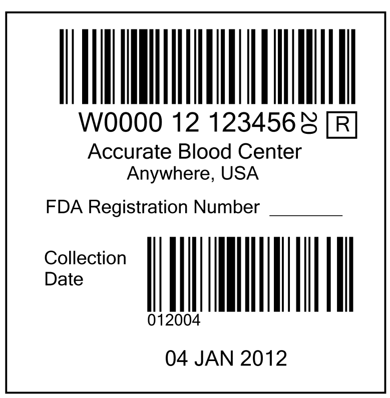
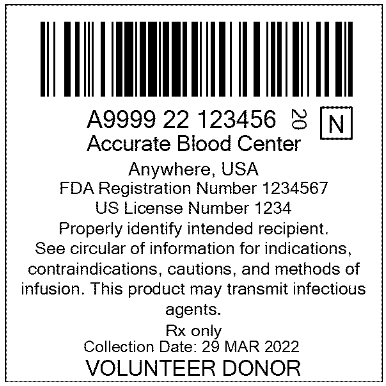


Figure 12 Collection Date on a Product for Transfusion



4.6 Collection Date and Time [Data Structure 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 and shown in Figure 10, regardless of the dating period.

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

4.7 Special Testing: General [Data Structure 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 34, page 108.

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 – General [Data Structure 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 34 and Figure 35, page 108 and Figure 36, page 109.

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

4.9 Special Testing: Platelet HLA and Platelet-Specific Antigens [Data Structure 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 33. 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 165).

Color

- The full 13-character Donation Identification Number must be printed in the same color (see 4.1.1.2, page 33).
- 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 59).
- 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 contact CBER 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 (when only linear bar codes are used)

- 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 56

- 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

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 33.

The text information about the firm that collected (or pooled) the unit shall be printed below the DIN. This should include the full legal name of the firm 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 of the collection or pooling facility, as appropriate, shall be printed in this quadrant as the unique facility identifier.

Generally, the legal 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 57, the US License Number of the facility is shown in one of the two acceptable locations.

- See Figure 17, page 59, for the other acceptable location for the US License Number.
- See Section 7.8.17 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 (21 CFR 606.121(c)(8)(i-iv). This text and suggested order of the statements is:

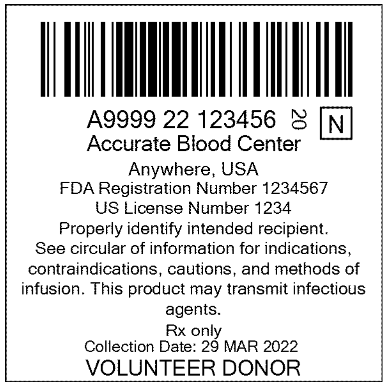
- Properly identify intended recipient.
- See circular of information for indications, contraindications, cautions, and methods of infusion.
- This product may transmit infectious agents.
- Rx only

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 (21 CFR 606.121(c)(8)(v)). If a collection date appears, it should be printed above VOLUNTEER DONOR (or PAID DONOR). See Figure 15, page 58.

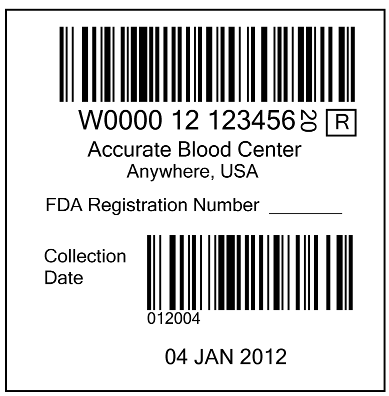
Figure 14 Upper Left Quadrant - Standard

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



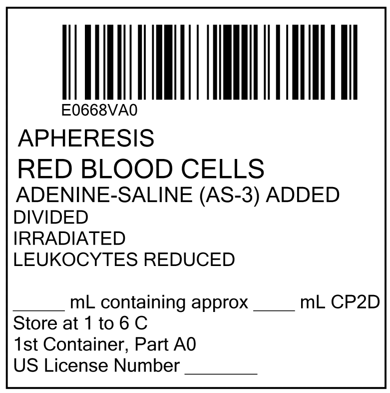
5.1.3.2 Lower Left Quadrant

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 57, for the other acceptable location for the US License Number.
- See Section 7.8.17 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 solely for autologous use, 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 donor who met all eligibility requirements, 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 eligible 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 32, page 106) (see also 5.1.4.1, page 63).

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 biohazardous, the biohazard symbol with the word BIOHAZARD beneath it shall also appear in this quadrant (see Figure 18, page 60). 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 2023 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 48, if the expiration time is coded as the default 23:59, no label 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

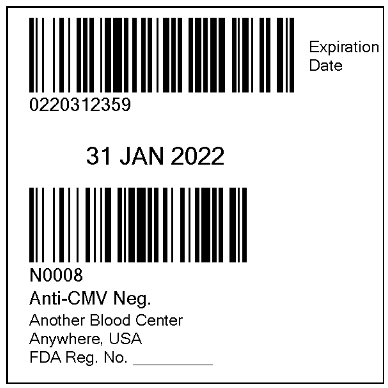
This information does not have to be machine readable.

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.

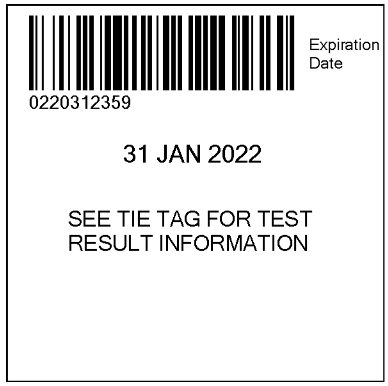
Figure 19 Lower Right Quadrant for Product Leaving the Facility



If allogeneic blood has not been tested for the required relevant transfusion-transmitted infections (RTTI), either (1) the results of tests for RTTI that have been performed and indication of which tests have not been completed shall appear on the affixed label <u>or</u> (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

The labels of products for further manufacturing (Source Plasma, Source Leukocytes) shall include an appropriate statement listing the tests for RTTI that have been performed on the product at the time of release. The statement must include the tests for RTTI that are required by current regulation or recommended in FDA Guidance for the product.

If products for further manufacturing are released prior to the completion of testing, the label must include the statement:

> Caution: Do not use the contents until test results for _____ 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 68, page 161.

Note: Consult the manufacturer's package insert before placing an additional label directly on the plastic container used for platelets. An *additional label may cause decreased gaseous exchange and affect platelet viability.*

5.1.4.2 Emergency Release Labels

When a unit is released before testing is completed, an additional label (either affixed to the container label or on a tie tag) shall indicate which tests for RTTI have and have not been completed. For one possible design of such a tie tag, see Figure 69, page 162.

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 111.

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 67.

- 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.

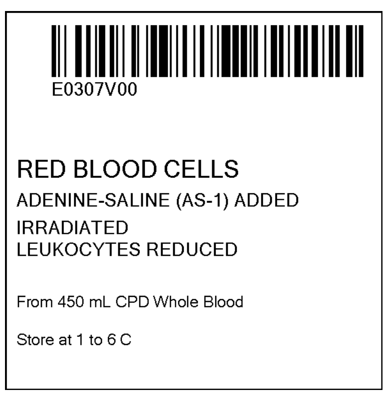
- If the unit is divided, DIVIDED shall appear before Attributes (see 4.3.1.5, page 45).

- 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 Medical Products of Human Origin* (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).

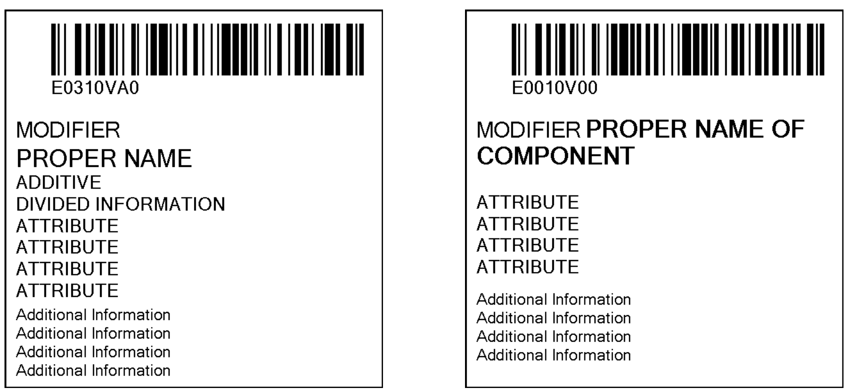
- Container and division texts should appear beneath the storage temperature if space permits.

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

- 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

E5598V00

RECONSTITUTED

RED BLOOD CELLS

ADENINE-SALINE (AS-1) ADDED
OPEN SYSTEM, IRRADIATED
LEUKOCYTES REDUCED
SUPERNATENT
REMOVED/PLASMA ADDED

From 450 mL CPD Whole Blood

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
APHERESIS	PLASMA	APHERESIS 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

Modifier	Component Class	Proper Name
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: LIQUID APHERESIS RECOVERED PLASMA
	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: LIQUID RECOVERED PLASMA
	CONVALESCENT PLASMA	CONVALESCENT PLASMA
APHERESIS	CONVALESCENT PLASMA	APHERESIS CONVALESCENT PLASMA

Modifier	Component Class	Proper Name
LIQUID	CONVALESCENT PLASMA	LIQUID CONVALESCENT PLASMA
LIQUID APHERESIS	CONVALESCENT PLASMA	LIQUID APHERESIS CONVALESCENT PLASMA
THAWED	CONVALESCENT PLASMA	THAWED CONVALESCENT PLASMA
THAWED APHERESIS	CONVALESCENT PLASMA	THAWED APHERESIS CONVALESCENT PLASMA
	POOLED CONVALESCENT PLASMA	POOLED CONVALESCENT PLASMA
APHERESIS	POOLED CONVALESCENT PLASMA	APHERESIS POOLED CONVALESCENT PLASMA
THAWED APHERESIS	POOLED CONVALESCENT PLASMA	THAWED APHERESIS POOLED CONVALESCENT 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
FROZEN APHERESIS	PLATELETS	FROZEN APHERESIS PLATELETS
THAWED APHERESIS	PLATELETS	THAWED APHERESIS PLATELETS
WASHED APHERESIS	PLATELETS	WASHED APHERESIS PLATELETS

Modifier	Component Class	Proper Name
	CRYOPRECIPITATE	CRYOPRECIPITATED AHF
THAWED	CRYOPRECIPITATE	THAWED CRYOPRECIPITATED AHF
APHERESIS	FIBRINOGEN COMPLEX	APHERESIS FIBRINOGEN COMPLEX
THAWED APHERESIS	FIBRINOGEN COMPLEX	THAWED APHERESIS FIBRINOGEN COMPLEX
	POOLED FIBRINOGEN COMPLEX	POOLED FIBRINOGEN COMPLEX
APHERESIS	POOLED FIBRINOGEN COMPLEX	APHERESIS POOLED FIBRINOGEN COMPLEX
THAWED	POOLED FIBRINOGEN COMPLEX	THAWED POOLED FIBRINOGEN COMPLEX
THAWED APHERESIS	POOLED FIBRINOGEN COMPLEX	THAWED APHERESIS POOLED FIBRINOGEN COMPLEX
	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
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 66.

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, required by the CFR, shall be printed in the "Additional Information" Section of the lower left quadrant. 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 RTTI 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<=14d Irradiated<=5d	IRRADIATED shall be printed below the Component Class in the “Attribute” Section. No abbreviation is permitted.
	RBC Irradiated *(Note: Applies only to Reconstituted Red Blood Cells.)*	RBC IRRADIATED shall be in Attribute line.

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 leukocytes 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.)*
	Cryoprecipitated	CRYOPRECIPITATED shall be in Attribute line. *(Note: This Attribute is used for Fibrinogen Complex.)*
	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.
	O2/CO2 reduced	O2/CO2 REDUCED shall be in Attribute line.
	Multiple wash cycles	MULTIPLE WASH CYCLES shall be in Attribute line. *(Note: If used, must be in conjunction with the Washed modifier.)*
	RT<=24h frozen <=24h	FRO ZEN 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.	1^{st} Container (or 1st Container), 2^{nd} Container (or 2nd Container), etc., may be printed beneath the storage temperature in the "Additional Information" section.

Attribute Group	Attribute Variable	US Labeling Instructions
	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	2.0-4.0 E12 plts 3.0-4.7 E11 plts 4.8-5.9 E11 plts <3E11 plts >=6 E11 plts Approx 120 E9 plts Approx 150 E9 plts Approx 180 E9 plts Approx 240 E9 plts Approx 300 E9 plts Approx 360 E9 plts Approx 420 E9 plts Approx 480 E9 plts Approx 540 E9 plts Pediatric dose	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.)*
	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.
Pathogen Reduction	Psoralen-treated	PSORALEN-TREATED shall be in Attribute line.

Attribute Group	Attribute Variable	US Labeling Instructions
Hematocrit	0.4-0.5 0.5-0.6 0.5-0.7 .50-.55 .55-.75 .60-.85 0.7-0.8 .70-.85 >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	For Apheresis Platelets: BACTERIAL MONITORING 7D shall be in Attribute line. For Pooled Platelets: BACTERIAL MONITORING shall be in Attribute line.
	Bacterial monitoring>=24h	BACT MON >=24H RETEST AFTER DAY 3 shall be in Attribute line.
	Bacterial monitoring>=36h	BACTERIAL MONITORING >=36 HOURS shall be in Attribute line.
	Bacterial test	BACTERIAL TEST shall be in Attribute line.
	Bacterial test D4	BACTERIAL TEST DAY 4 shall be in Attribute line.
	Bacterial test D5	BACTERIAL TEST DAY 5 shall be in Attribute line.
	Bacterial test D6	BACTERIAL TEST DAY 6 shall be in Attribute line.
	Bacterial test D7	BACTERIAL TEST DAY 7 shall be in Attribute line.

Attribute Group	Attribute Variable	US Labeling Instructions
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. *(Note: A donor may contribute more than one component to a pool.)*
Antibody Specificity (These attributes only apply to the IMMUNE PLASMA class name)	Anthrax	ANTHRAX ANTIBODY PRESENT shall be in Attribute line.
	CMV	CMV ANTIBODY PRESENT shall be in Attribute line.
	Hepatitis A	HEPATITIS A ANTIBODY PRESENT shall be in Attribute line.
	Hepatitis B	HEPATITIS B ANTIBODY PRESENT shall be in Attribute line.
	Not Specified	UNSPECIFIED ANTIBODY PRESENT shall be in Attribute line.
	RHD	RHD ANTIBODY PRESENT shall be in Attribute line.
	Rabies	RABIES ANTIBODY PRESENT shall be in Attribute line.
	SARS-CoV-2	SARS-COV-2 ANTIBODY PRESENT shall be in Attribute line.
	Tetanus	TETANUS ANTIBODY PRESENT shall be in Attribute line.
	Varicella zoster	VARICELLA ZOSTER ANTIBODY PRESENT shall be in Attribute line.
Infection (These attributes only apply to the CONVALESCENT PLASMA class name)	Covid-19	COVID-19 shall be in Attribute line.
	Covid-19 high titer	HIGH TITER, ANTI-SARS-COV-2 shall be in Attribute line.
	Covid-19 low titer	LOW TITER, ANTI-SARS-COV-2 shall be in Attribute line.
	Ebola	EBOLA shall be in Attribute line.

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 67)
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	Immediately below Class name 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	Immediately below Class name Additional information line 1 Additional information line 2

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 67)
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
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	Immediately below Class name 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

Product Type	Blood Product	Print “what”	Print “where” (all left justified, but see note on Page 67)
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
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

Product Type	Blood Product	Print “what”	Print “where” (all left justified, but see note on Page 67)
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
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

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 67)
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	Immediately below Class name 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
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

Product Type	Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 67)
WBC	Washed Granulocytes	____ mL from [nominal volume] Whole Blood Store at room temperature	Additional information line 1 Additional information line 2
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 67)
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 Medical Products of Human Origin*. 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

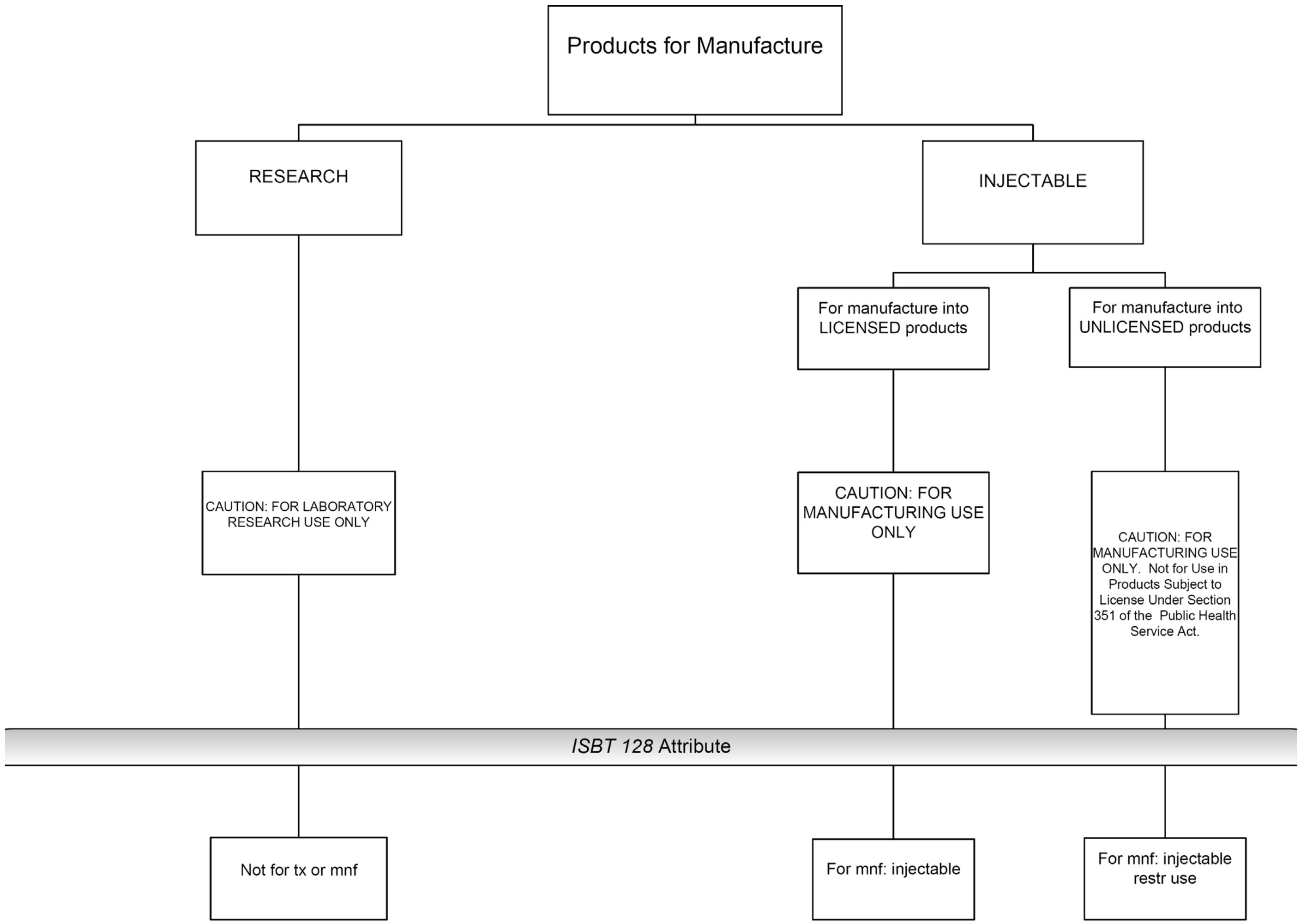
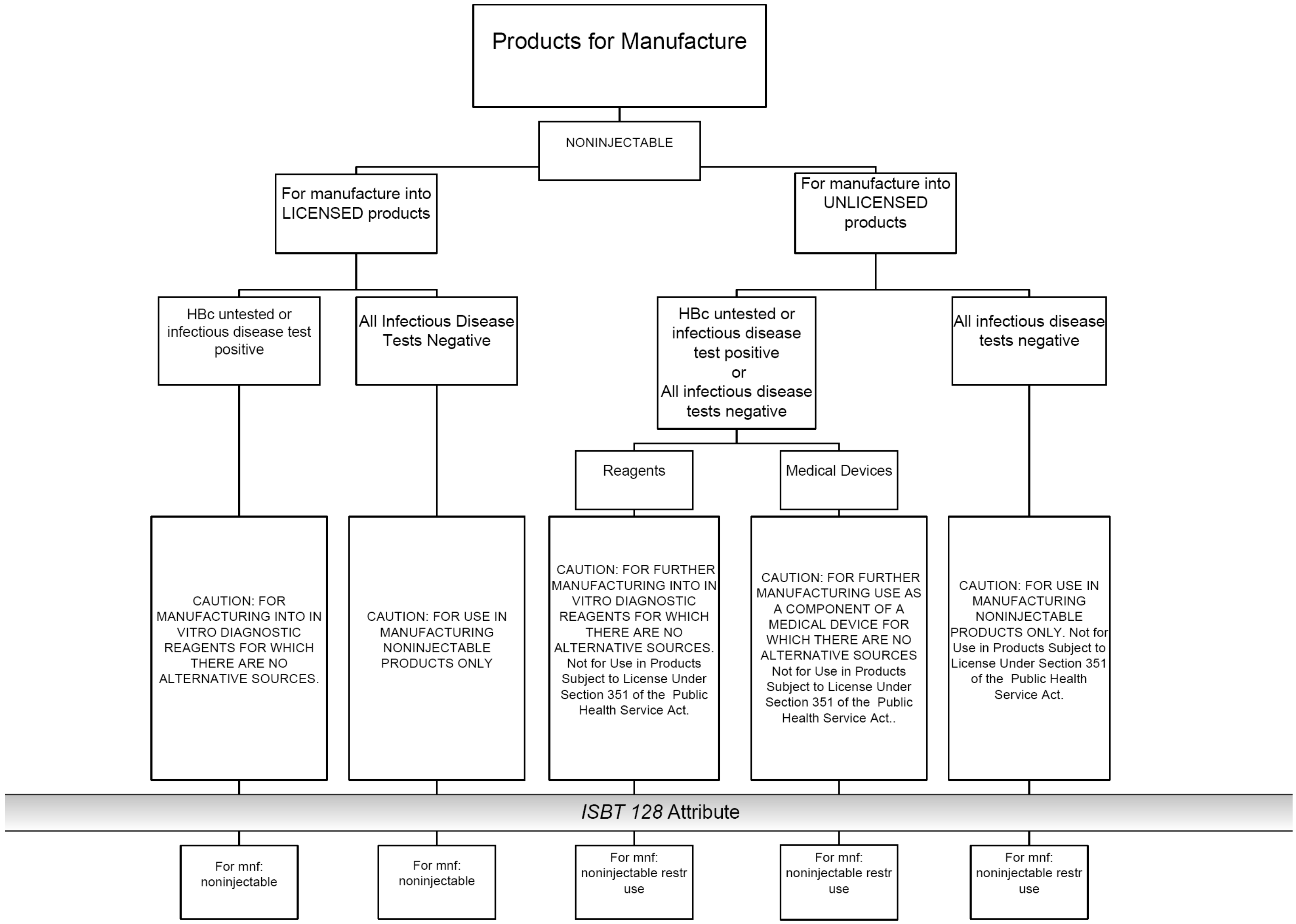


Figure 26 Coding & Labeling of Products for Further Manufacture – Noninjectable



6.6 Collection Type in Product Code

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

Sixth Data Character	**Type of Collection**	**Upper Left Quadrant [in no less prominence than Component Class]**	**Lower Left Quadrant**	**Upper Right Quadrant**
V	Volunteer homologous (allogeneic)	VOLUNTEER DONOR[1]		
0	Not specified[1]			
R	Volunteer research (Product not intended for human application)	VOLUNTEER DONOR	Data content text beneath bar code: RESEARCH	FOR LABORATORY RESEARCH USE ONLY
S	Volunteer source	VOLUNTEER DONOR[1]	Data content text beneath bar code: SOURCE	
T	Volunteer therapeutic	VOLUNTEER DONOR	The disease of the patient from which the unit was collected must be specified. Data content text beneath bar code: THERAPEUTIC	THERAPEUTIC COLLECTION
P	Paid homologous (allogeneic)	PAID DONOR		
r	Paid research (Product not intended for human application)	PAID DONOR	Data content text beneath bar code: RESEARCH	FOR LABORATORY RESEARCH USE ONLY
s	Paid source	PAID DONOR[1]	Data content text beneath bar code: SOURCE	

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

[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: 1) the donor meets all eligibility requirements; 2) the donor undergoes a therapeutic phlebotomy as prescribed by a licensed health care provider; 3) the donor has been diagnosed with hereditary hemochromatosis OR CBER has found the facility's procedures acceptable for the collection of blood from a donor who has another disease or condition that will not be adversely affected by donating and will not adversely affect any products manufactured from the donation; and 5) you perform therapeutic phlebotomies without charge for all individuals with the disease or condition. In this situation, encoding the "V" rather than "T" in the Donation Type is appropriate.

[2] 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.

[3] 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.

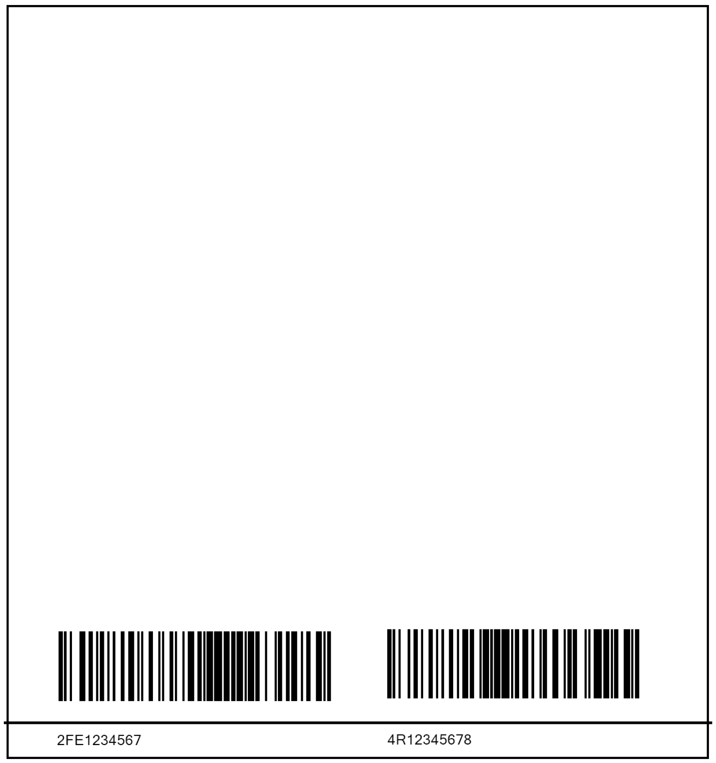
7.2.1.1 Manufacturers Data File

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

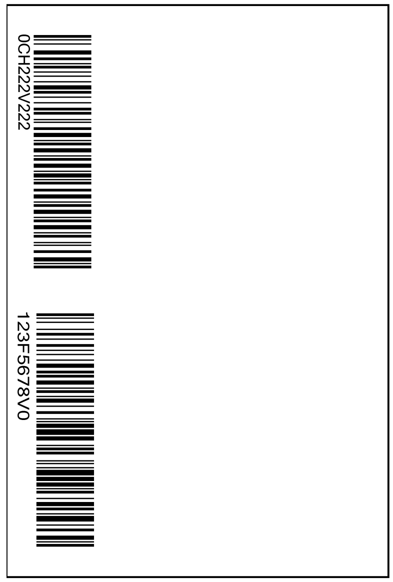
Figure 27 100 mm by 106 mm (4" x 4.25") Base label



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

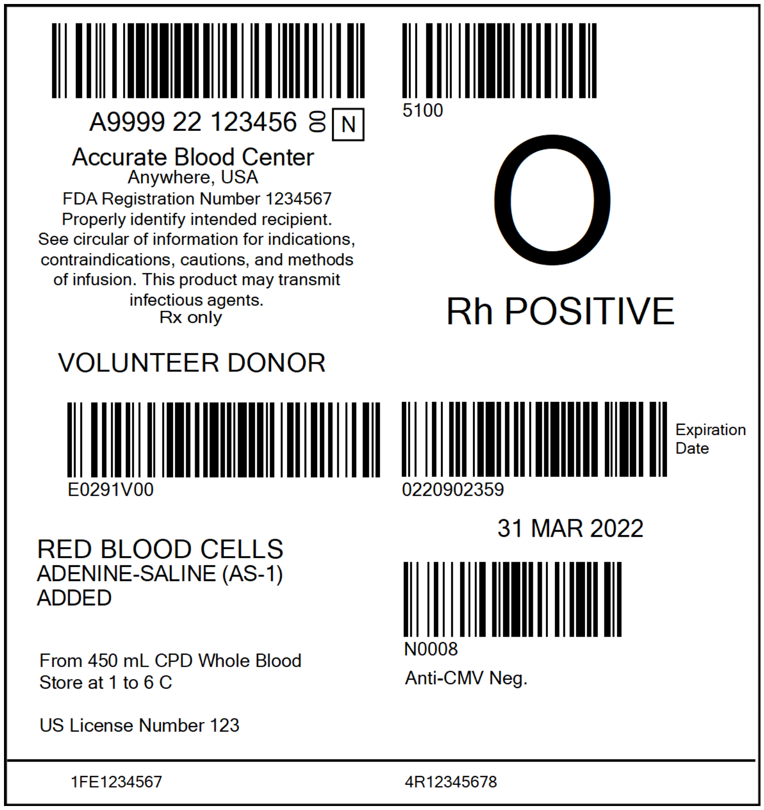


This example represents the minimum amount of ISBT 128 information that must appear on the label. Manufacturers may include additional information such as:

- 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)

7.2.3 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.

7.3 Final Satellite Container Label Illustrations

Figure 30 Satellite Container - Platelets

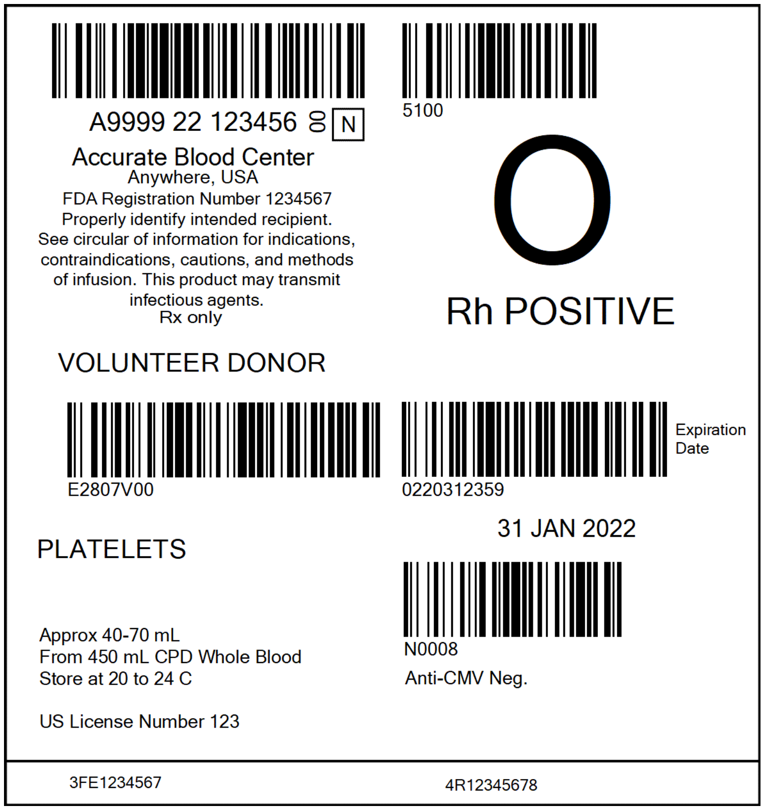
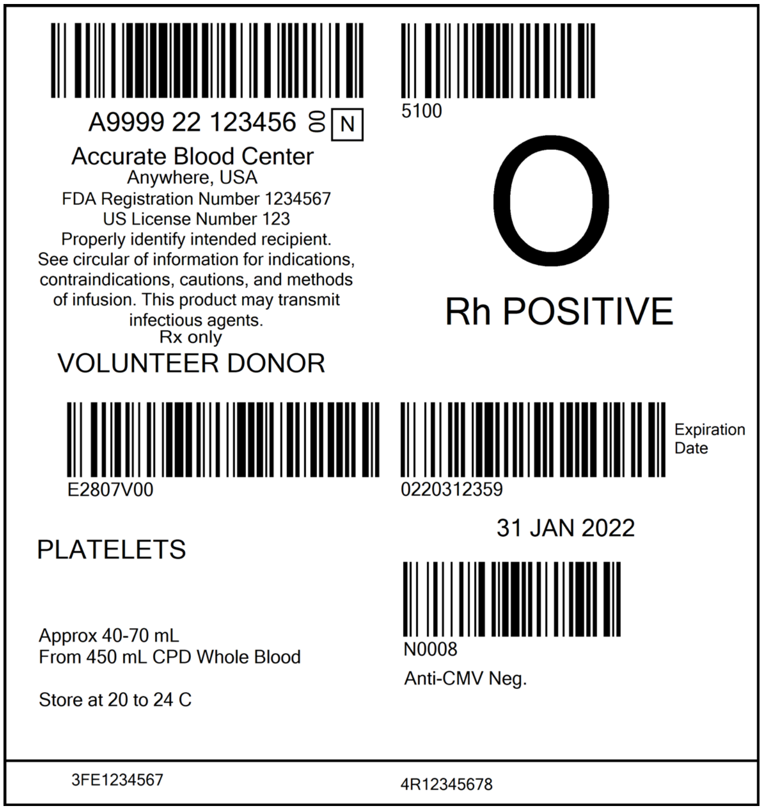


Figure 31 Satellite Container - PLATELETS - US License Number in Upper Left Quadrant



7.4 Upper Right Quadrant

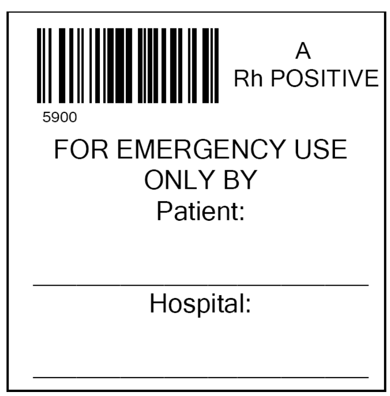
See IG-002 Addendum of Label Examples (www.isbt128.org/IG-002AddendumLabels) for additional ABO/Rh label examples.

Figure 32 Directed, Designated and Dedicated Labels for Upper Right Quadrant

Note that (n-2) and (n-4) from Table 3, page 38, 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 33 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.

7.5 Lower Left Quadrant Labels

See IG-002 Addendum of Label Examples (www.isbt128.org/IG-002AddendumLabels).

7.6 Special Testing Labels

Figure 34 Special Testing General and Red Cell Antigen Labels

N0008

Negative for antibodies to CMV

67999999999999996 2

k-;C+c-E-e+;K+
Hgb S Neg.

9799999999999924799 N

k-;C+c-E-e+;K+
Anti-CMV Neg.

973559957589924796 G

k-;C+c-E-e+;M-N+S-s+;Le(a-b+);
K+;Fy(a+b-);Jk(a-b+);Do(a+b+);Cw-
Anti-CMV Neg.; Hgb S Neg.

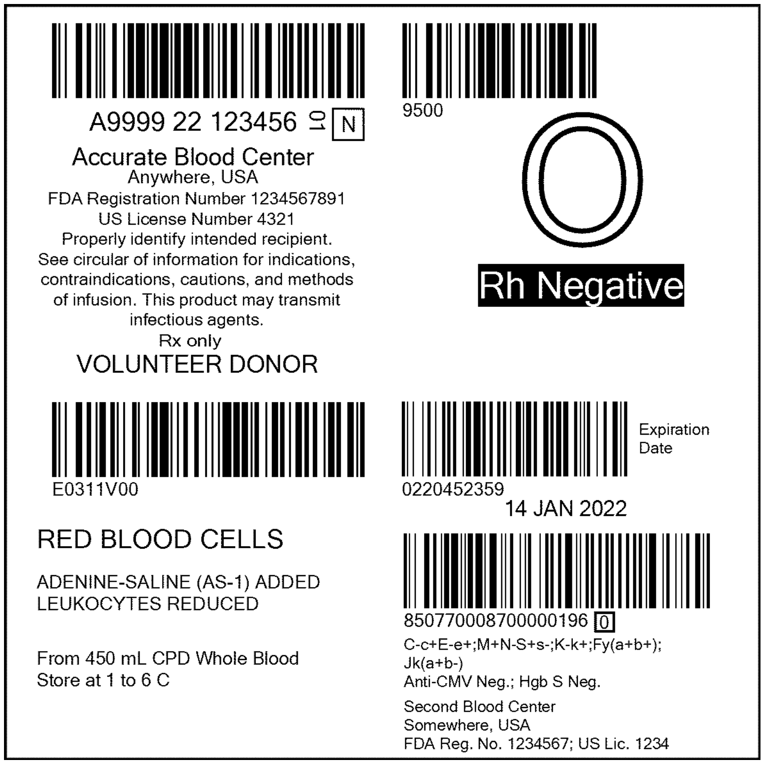
To save space, it is permissible to print only negative antigens and omit punctuation between red cell antigens. Abbreviations such as Anti-CMV Neg. and Hgb S Neg. are acceptable, as are more complete phrases such as Negative for Antibodies to CMV or Hemoglobin S Negative.

Figure 35 Red Cell Antigen Label - Negative Antigens Only

973559957589924796 0

k-c-E-M-S-Le(a-)Fy(b-)Jk(a-)Cw-
Anti-CMV Neg.; Hgb S Neg.

Figure 36 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 36. 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 36.

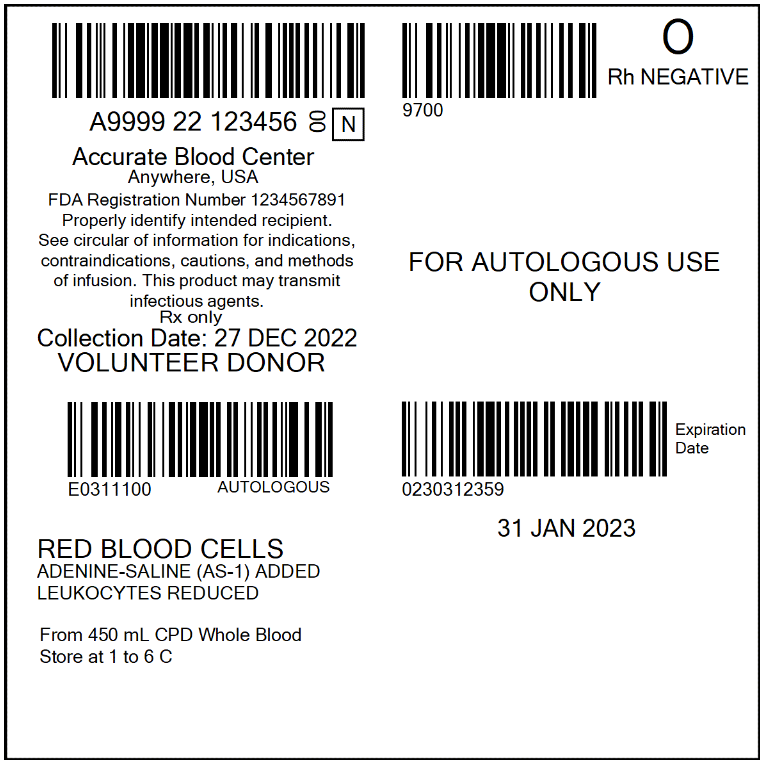
Refer to IG-025 US Guidance on Printing Text Associated with Red Cell Antigens for the order and format in which antigens will appear in text on the label.

Refer to IG-027 Use of Red Cell Antigens with Test History Data Structure [030] for encoding historical antigen test results.

Refer to Guidance for Industry : Labeling of Red Blood Cell Units with Historical Antigen Typing Results: Guidance for Industry (December 2018) for FDA recommendations for labeling with historical antigen test results.

7.7 Autologous Label

Figure 37 For Autologous Use Only Label



7.8 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 65.

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.

7.8.1 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 38 through Figure 41, page 113.

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 41, page 113. Platelet pools with mixed anticoagulants should have 4 hour dating.

Figure 38 Pooled Platelets, Mixed Anticoagulant

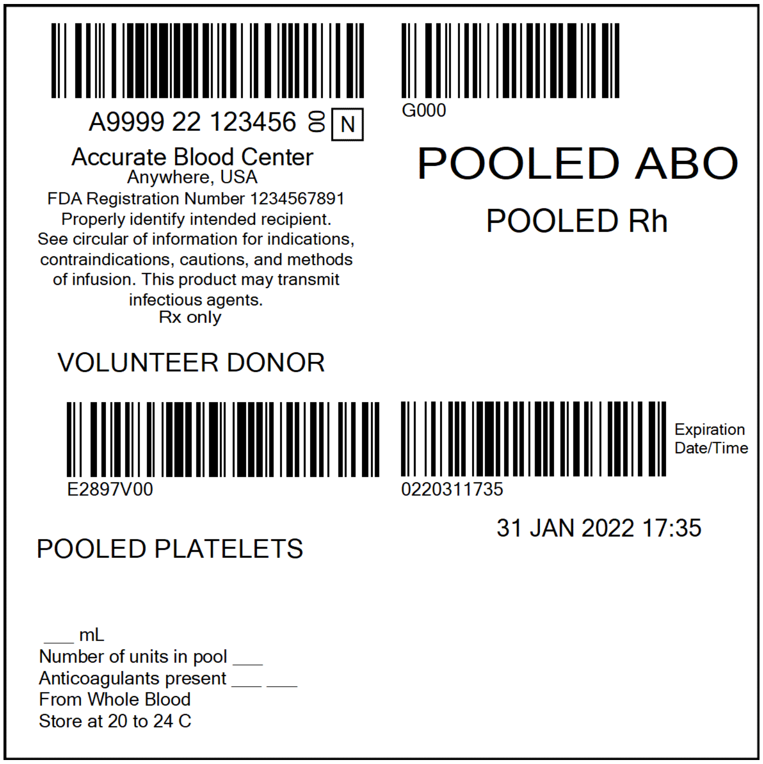


Figure 39 Thawed Pooled Cryoprecipitated AHF, Rh Not Specified

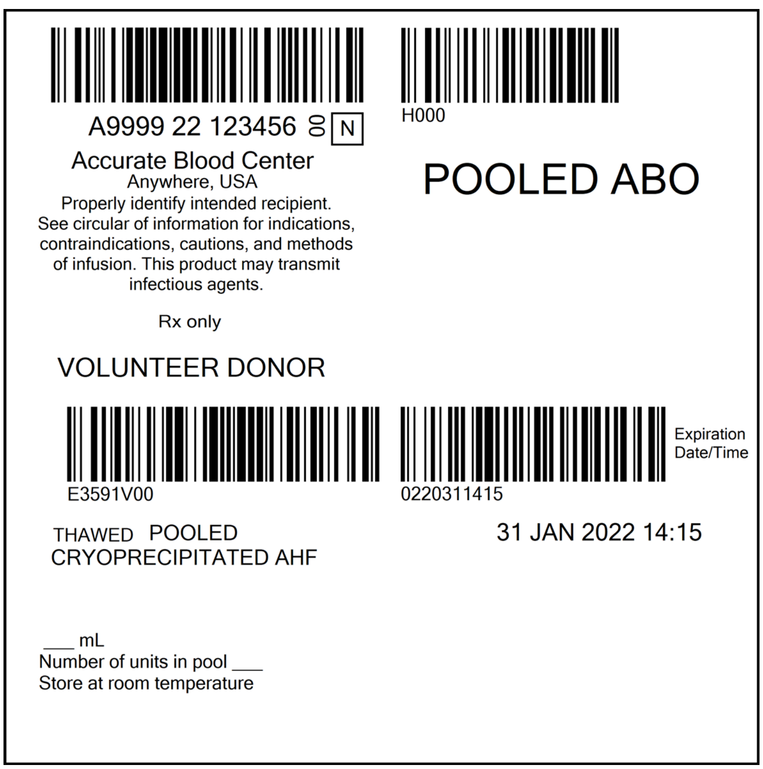


Figure 40 Thawed Pooled Cryoprecipitated AHF, Group A, Rh Pooled

A9999 22 123456 00 N

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

Rx only

A000

A

POOLED Rh

VOLUNTEER DONOR

E3591V00

0220451415

Expiration Date/Time

THAWED POOLED
CRYOPRECIPITATED AHF

14 FEB 2022 14:15

___ mL
Number of units in pool ___
Store at room temperature

Figure 41 Pooled Platelets

A9999 22 123456 00 N

Accurate Blood Center
Anywhere, USA
FDA Registration Number 1234567891
Properly identify intended recipient.
See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents.
Rx only

E000

POOLED ABO

Rh POSITIVE

VOLUNTEER DONOR

E2902V00

0220311735

Expiration Date/Time

31 JAN 2022 17:35

POOLED PLATELETS
OPEN SYSTEM

___ mL
Number of units in pool ___

Anticoagulants Present ___ ___
From Whole Blood
Store at 20 to 24 C

7.8.2 Reconstituted Red Blood Cells

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

7.8.2.1 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"

7.8.2.2 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. See Figure 42 and Figure 43.

If a Red Blood Cell is divided and a reconstituted Red Blood Cell is prepared from one of the divisions, the original division code assigned to the Red Blood Cells shall be maintained on the container label of the Reconstituted Red Blood Cell if the original DIN is retained (for example, if the Red Blood Cell is Wxxxx-xx-123456, Part A0, the reconstituted Red Blood Cell is Wxxxx-xx-123456, Part A0). If a plasma unit is divided and one of the divisions is used to prepare a Reconstituted Red Blood Cell, the division code assigned to the plasma shall be included in the manufacturing records for the product, but does not need to appear on the container label.

If a new DIN is assigned by the pooling facility, division codes assigned to either the Red Blood Cell or the plasma unit shall be included in the manufacturing records for the product but do not need to appear on the container label.

Figure 42 Reconstituted Red Cells, Pool Number Assigned

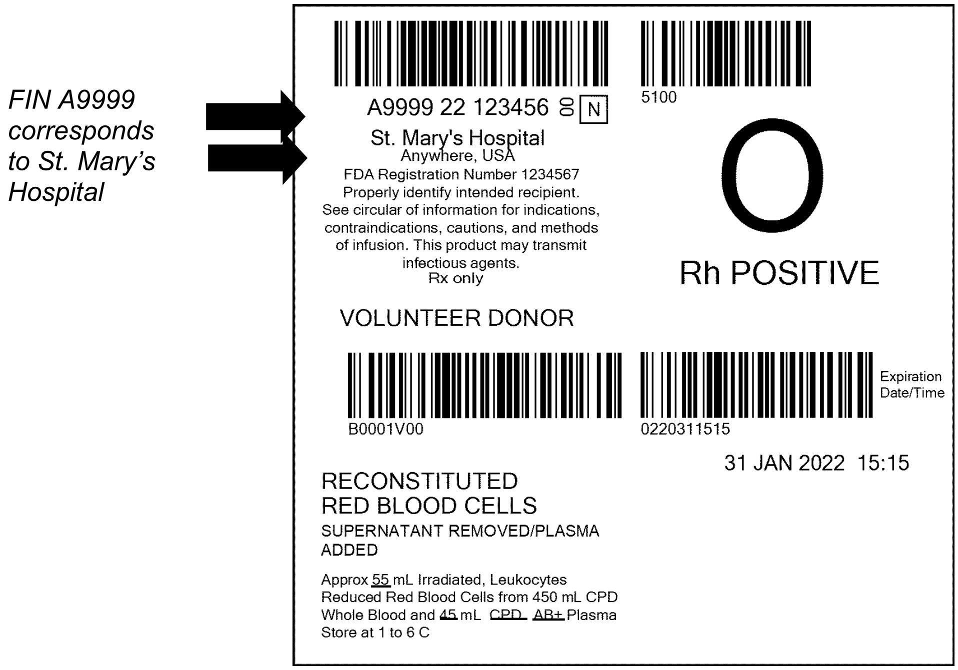
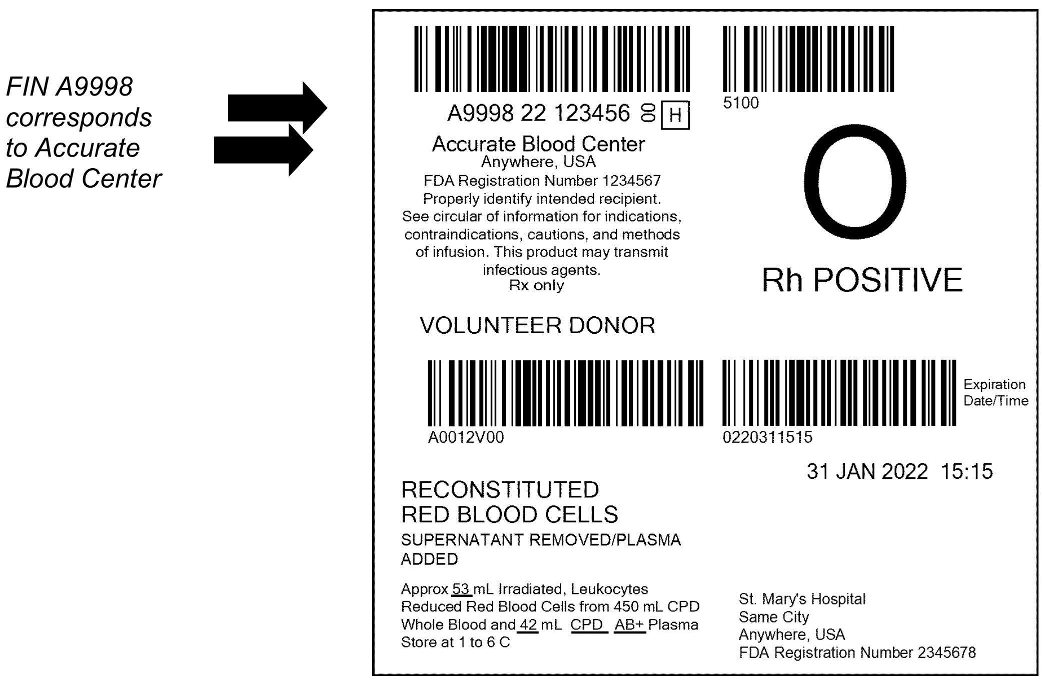


Figure 43 Reconstituted Red Blood Cells, Original RBC DIN Retained



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

7.8.2.3 ABO/Rh, anticoagulant and volume

The ABO/Rh, anticoagulant, and volume of both the red blood cells and the plasma shall be on the label. This information appears in the lower left quadrant, other than the ABO/Rh of the red blood cell, which remains in the upper right quadrant.

7.8.2.4 Number of donors

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

7.8.2.5 Hematocrit

Hematocrit may optionally appear on the label.

7.8.2.6 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.

7.8.2.7 CMV

Label Reconstituted Red Blood Cells with appropriate CMV status as described in the table below.

IF	THEN Text in Lower Right Quadrant	THEN Bar Coded Information
Both the Red Blood Cells and the Plasma have been screened and found negative for antibodies to CMV	Negative for antibodies to CMV	N0008 or other Special Testing Code indicating product is CMV negative *(Note: Bar coding of this information is optional.)*
Red Blood Cells CMV negative; Plasma NOT tested for CMV	Red Blood Cells Negative for antibodies to CMV; Plasma not tested for antibodies to CMV	No code for this—use text only

7.8.2.8 Hemoglobin S

Labeling of Reconstituted Red Blood Cells for Hemoglobin S should be based on the test results of the red blood cells. If the red blood cells have been found to be Hemoglobin S negative, it is acceptable to label the combined product as Hemoglobin S negative. N0106 (or other Special Testing Code indicating the product is Hemoglobin S negative) could be used if the facility chooses to bar code this information.

7.8.2.9 Leukocyte Reduction

Label Reconstituted Red Blood Cells with appropriate Leukocytes Reduced attribute as described in the table below.

IF	THEN Text in Lower Left Quadrant	THEN Bar Coded Information
Both the Red Blood Cells and the Plasma are leukocytes reduced (or the combined product is leukocytes reduced)	"LEUKOCYTES REDUCED" in Attribute line	Select a Product Description Code with the Attribute "ResLeu:<5E6"
Red Blood Cells leukocytes reduced; Plasma NOT leukocytes reduced (or production method has not been validated to ensure that the residual leukocyte count of the plasma is below the requisite level)	"Leukocytes Reduced" shall NOT appear as Attribute text. It shall appear as additional text. For example "Approx ___ mL Leukocytes Reduced Red Blood Cells from 450 mL CPD Whole Blood"	Select a Product Description Code with the Attribute "ResLeu:NS" ("NS" in this context means: Residual Leukocyte Content Not Specified: a procedure has been used to reduce the leukocyte count of the product but the target count is not specified.)

7.8.2.11 Irradiation

Label Reconstituted Red Blood Cells with appropriate Irradiated attribute as described in the table below.

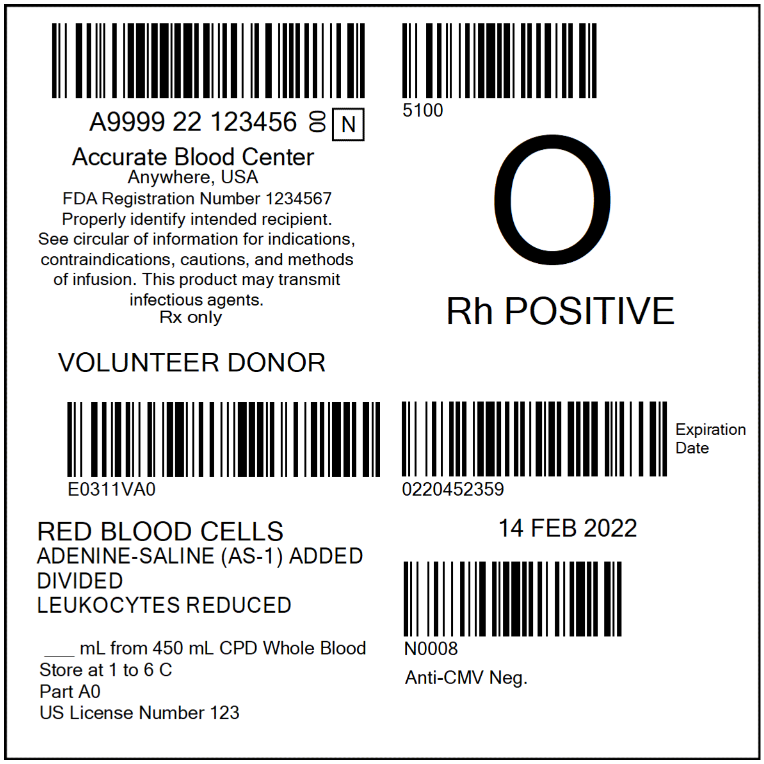
IF	THEN Text in Lower Left Quadrant	THEN Bar Coded Information
Both the Red Blood Cells and the Plasma are irradiated (or the combined product is)	"IRRADIATED" in Attribute line	Select a Product Description Code with the Attribute "Irradiated"

IF	THEN Text in Lower Left Quadrant	THEN Bar Coded Information
Red Blood Cells irradiated; Plasma NOT irradiated	“RBC IRRADIATED” in Attribute line OR “Irradiated” shall NOT appear as Attribute text. It shall appear as additional text. For example “Approx ___ mL Irradiated Red Blood Cells from 450 mL CPD Whole Blood”	Select a Product Description Code with the Attribute “RBC irradiated” OR Use a local Product Description Code.

7.8.3 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 (for example, Part A0) should appear in the text below the storage temperature.

Figure 44 Divided Product



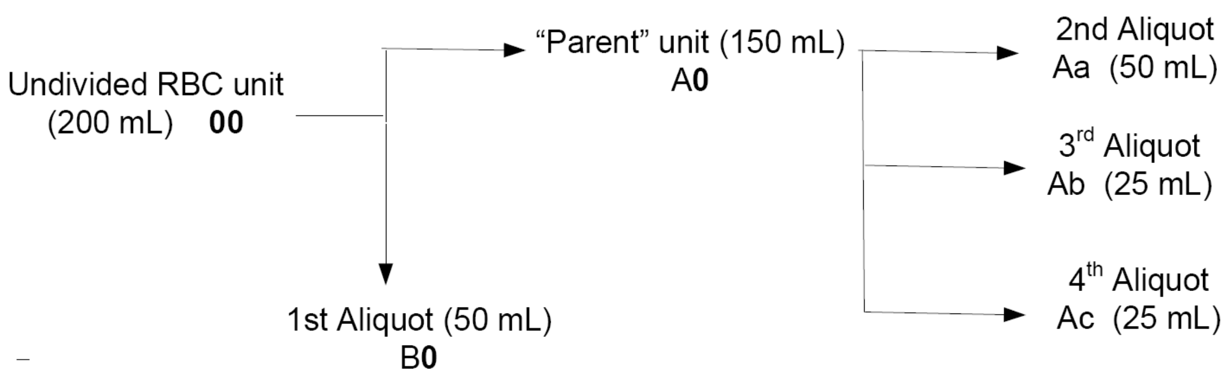
Examples of Use of Division Codes for Pediatric Aliquots

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.

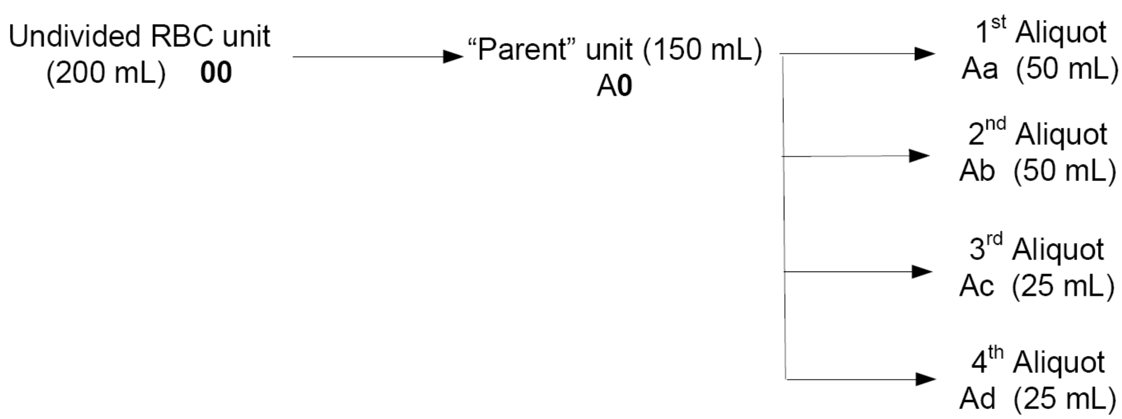
It would be good practice for a facility to determine how it will label its aliquots (i.e., whether the “parent” unit is A0 or B0) and be consistent about this approach.

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).

7.8.4 Frozen, Deglycerolized, Washed, or Rejuvenated 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.

The labels for Frozen, Deglycerolized, Washed and Rejuvenated Red Blood Cells do not need to include the original anticoagulant, nominal collection volume, type of additive solution used for the original product or presence of unexpected red blood cell antibodies. The actual volume shall appear on the label of these products.

7.8.5 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 receiving 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 60, if the blood has not been completely tested as required in 21 CFR 610.40(a): <u>either</u>:

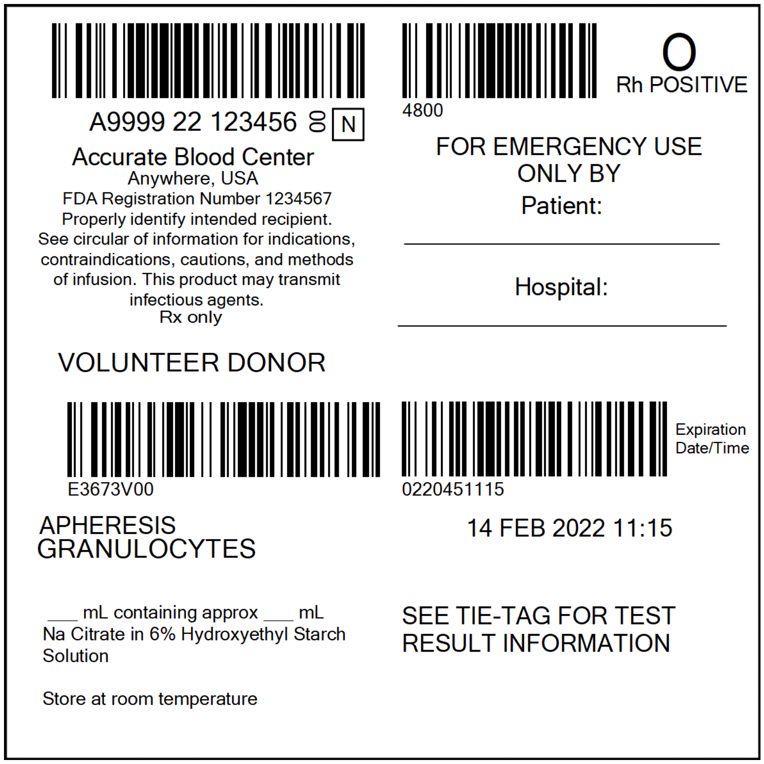
(1) the results of tests for RTTI that have been performed and indication of which tests have not been completed shall appear on the affixed label in the lower right quadrant <u>or</u>

(2) this information shall appear on a tie tag and a phrase such as SEE TIE TAG FOR TEST RESULT INFORMATION shall appear in this quadrant. (See Figure 69, Page 162 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 45 Granulocytes



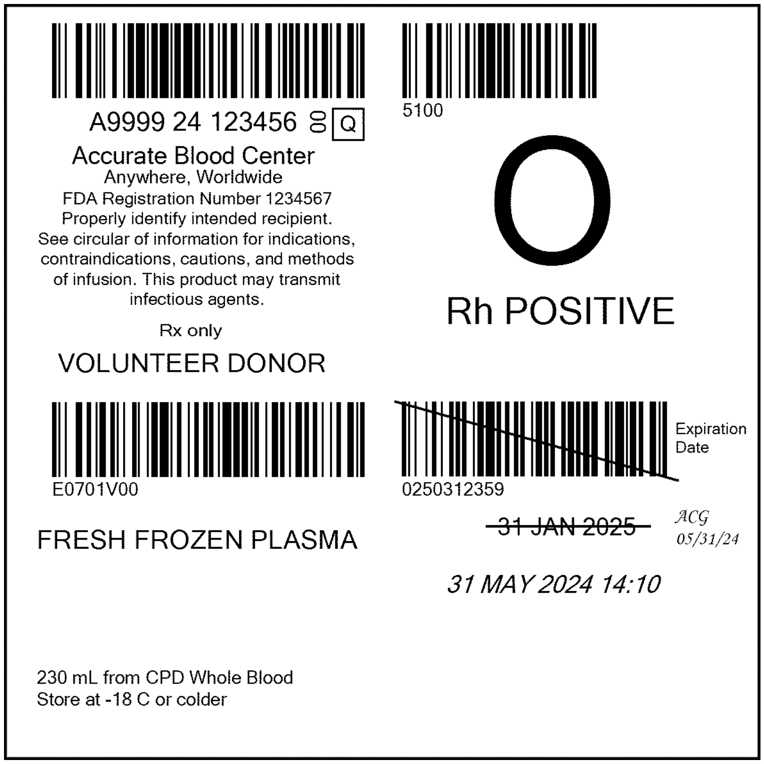
7.8.6 Plasma Products

The nominal Whole Blood collection volume does not need to appear on the label. The actual volume shall appear on the labels of plasma units obtained from Whole Blood collections or by apheresis.

7.8.7 Thawed Plasma Products or Cryoprecipitated AHF

Thawed Plasma products and thawed Cryoprecipitated AHF (used within their designated dating period) may retain their original Product Description Codes (“frozen code”) or be changed to a Product Description Code indicating they have been thawed. For example, 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 on the container label and this information does not have to be bar coded.

Figure 46 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 24 -hour period following thawing, they shall be relabeled as Thawed Plasma, if they are retained for transfusion purposes. Thawed Plasma units may be used for up to four additional days (total of 5 days from the date the units were thawed). A new product label that is both machine and eye-readable shall be applied. Thawed Plasma is not a licensable product, and the US License Number shall not appear.

Figure 47 Thawed Plasma

7.8.8 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 48 and Figure 49 or division codes (7th and 8th character designations) as shown in Figure 50.

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

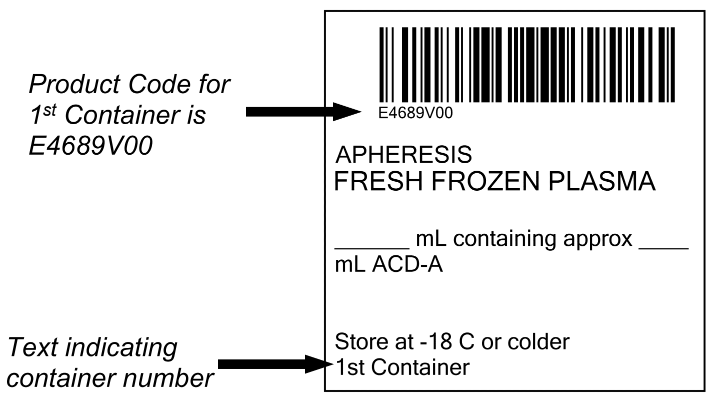


Figure 49 Apheresis FFP with 2nd Container Designation (Product Code E4693V00)

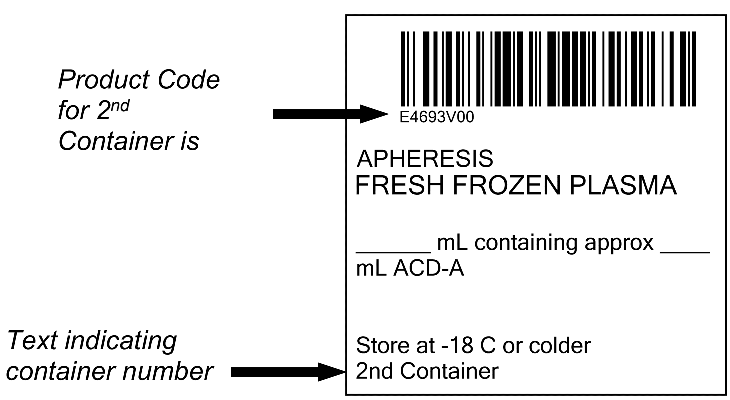
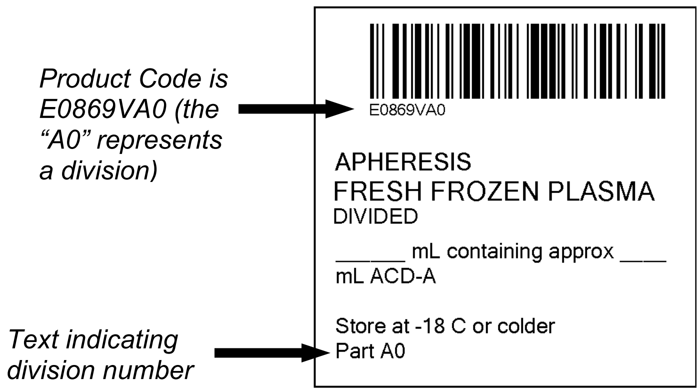


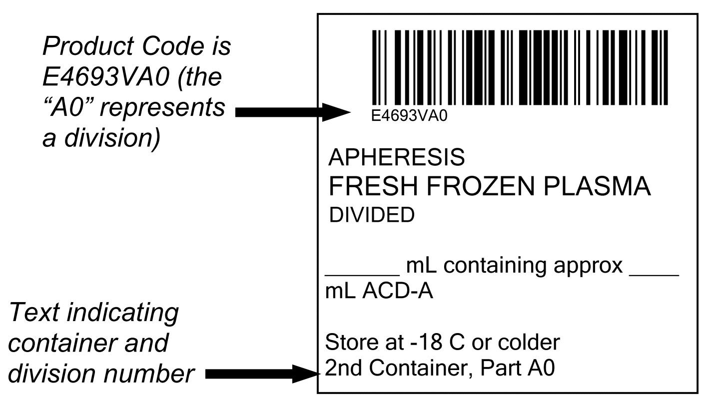
Figure 50 Apheresis FFP with Division Code



Further Divisions

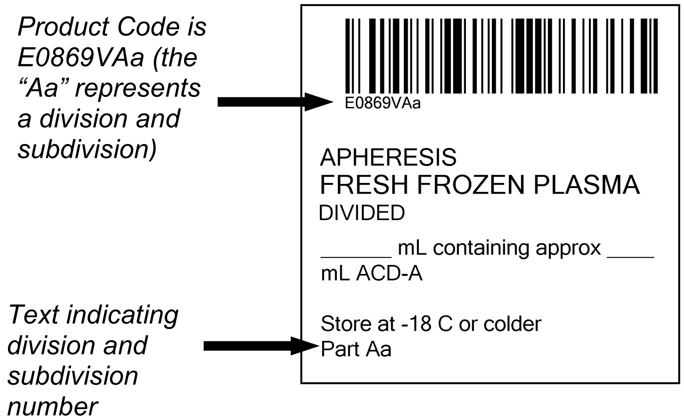
It is possible that these products could be further divided for pediatric use. Should products using the Container codes be further divided, the Division Codes (Position 7 and 8 of the Product Code) would be used. That is, Divisions of E4693V00 from the above example would become E4693VA0 and E4693VB0, etc. See Figure 51.

Figure 51 Product with Container Number Further Divided



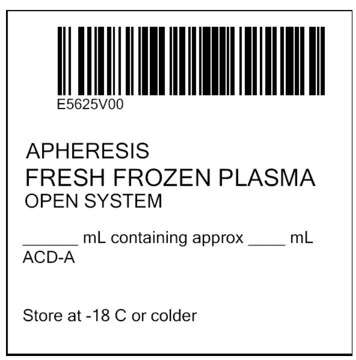
If products using the division codes are further divided, the 8th position of the Product Code is used. That is, from the above example, divisions of E0869VA0 become E0869VAa, E0869VAb, etc. See Figure 52.

Figure 52 Divided Product Further Divided



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

Figure 53 Apheresis Fresh Frozen Plasma, Open System



7.8.9 Thawed Apheresis Fresh Frozen Plasma

A thawed Apheresis Fresh Frozen Plasma product (used within its 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 24-hour period following thawing, and it was made in a closed system, it may be relabeled as Thawed Apheresis Plasma and used for transfusion for an additional 4 days (total of 5 days from the date on which the unit was originally thawed). A new product label that is both machine and eye-readable shall be applied. This is not an FDA licensable product and an FDA License Number shall not appear on the label.

7.8.10 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.

The Container designation (1st Container) should be printed below the storage temperature.

7.8.11 Platelets with Bacterial Monitoring or Bacterial Test

A. Strategies for Apheresis Platelets and/or Pre-Storage Pools of Whole Blood Derived (WBD) Platelets

Note: These strategies for controlling bacterial contamination in platelet components are taken from FDA's Guidance for Industry: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (December 2020), which is referenced in the paragraphs below as "the Guidance." Please refer to the Guidance for additional information.

Single-Step Strategies

a. Large volume, delayed sampling (LVDS) no sooner than 36 hours (5-day expiry)

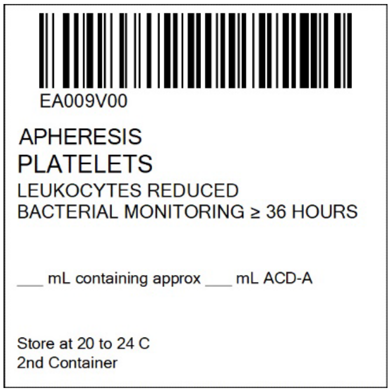
Note: LVDS conducted no sooner than 36 hours may also constitute Step 1 of a 2-Step strategy to extend storage beyond 5 days. Refer to Primary culture LVDS no sooner than 36 hours (5-day expiry).

Labeling requirements: Product Description Codes that include the Attribute "Bacterial monitoring >=36h" are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 36 hours after collection. The "Bacterial monitoring ≥36h" attribute shall appear in all caps in the Attribute section of the lower left quadrant of the label. The user's system assigns the expiration date.

Note: The "Bacterial monitoring >=36h" attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

EA009



b. LVDS no sooner than 48 hours (7-day expiry)

Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring” are available for use. Per the definition, this attribute indicates that the product meets national specifications for extension of the expiry date. In the U.S. this attribute is applied to units subjected to on-going bacterial monitoring from a sample taken at least 48 hours after collection. The “Bacterial monitoring” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. “7D” shall be appended to the attribute name (i.e., BACTERIAL MONITORING 7D). The user’s system assigns the expiration date and must ensure the date does NOT exceed 7 days from the collection of the platelet product.

The storage container must be FDA approved for 7-day storage.

Note: The “Bacterial monitoring” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

E5030 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial monitoring

E5030V00

APHERESIS
PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

___ mL containing approx ___ mL ACD-A

Store at 20 to 24 C

c. Pathogen Reduction (5-day expiry)

Note: Currently, this strategy only applies to apheresis platelets; however, the strategy could apply to other platelet products in the future if the pathogen reduction methodology is FDA cleared/approved for other products.

Labeling requirements: Pathogen reduced components should be labeled with expiration dates consistent with the operator's manual for the device used for pathogen reduction and instructions for use of the processing set.

Label Example:

E8340

E8340V00

APHERESIS
PLATELETS
PAS-C ADDED
LEUKOCYTES REDUCED
PSORALEN-TREATED

___ mL containing approx ___ mL ACD-A
Contains approx 65% PAS/35% Plasma

Store at 20 to 24 C

Two-Step Strategies

a. Primary culture performed no sooner than 24 hours (5-day expiry, but requires secondary testing >/= day 3)

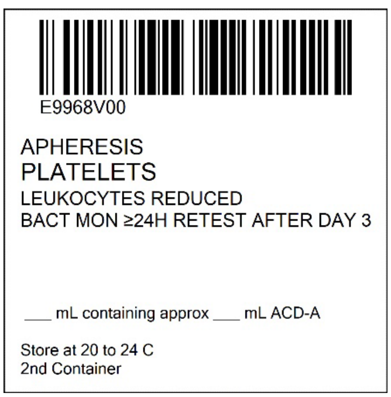
Per the Guidance, “Following primary culture performed no sooner than 24 hours, apheresis and pre-storage pooled platelet components should not be transfused after day 3 unless appropriate secondary testing (culture or rapid testing) has been performed to assure that the risk of bacterial contamination has been adequately controlled.”

Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring >=24h” are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 24 hours after collection. BACT MON ≥24H RETEST AFTER DAY 3 shall be printed below the Component Class in the “Attribute” Section. The user’s system assigns the expiration date.

Note: The “Bacterial monitoring >=24h” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

E9968



i. Secondary culture performed no sooner than Day 3 (5-day expiry)

Note: Per the Guidance, “During the incubation period of the secondary culture, products remain in-date through their labeled storage period, and removal of products from inventory is not required during any portion of the labeled storage, provided you have developed procedures to 1) identify when secondary testing has been completed, and 2) maintain product control during the incubation period.”

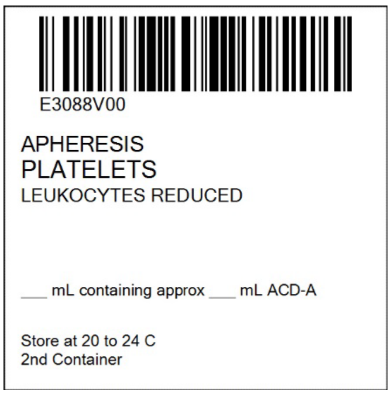
Labeling requirements: For this scenario, the component was originally labeled with a Product Description Code that included the attribute “Bacterial monitoring >=24h”. This attribute prints the statement BACT MON ≥24H RETEST AFTER DAY 3. Following secondary culture performed no sooner than Day 3, the unit may be relabeled to omit the attribute “Bacterial monitoring >=24h” (Default: Not specified) or the retest statement may be crossed-out. The originally assigned 5-

day expiration date remains valid. If the unit is relabeled, the user's system must ensure the expiration date does NOT exceed 5 days from the collection of the platelet product.

Note: The "Default: Not specified" attribute does NOT specify monitoring. Such information would be included in the accompanying documentation.

Label Example:

E3088



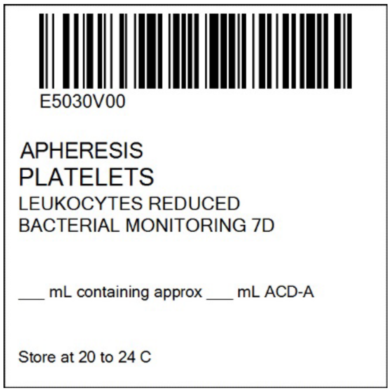
ii. Secondary culture performed no sooner than Day 4 (up to 7-day expiry)

Note: Per the Guidance, "During the incubation period of the secondary culture, products remain in-date through their storage period, and do not necessitate removal from inventory during any portion of the storage period, provided you have developed procedures to identify when secondary testing has been completed, and maintain product control during the recommended incubation period." The storage container must be FDA approved/cleared for 7-day storage.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attribute "Bacterial monitoring" are available for use. This attribute indicates that a unit is subjected to on-going bacterial monitoring for extension of the expiration date. The "Bacterial monitoring" attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. "7D" shall be appended to the attribute name (i.e., BACTERIAL MONITORING 7D). The user's system assigns the expiration date and must ensure the date does NOT exceed 7 days from the collection of the platelet product.

Note: The "Bacterial monitoring" attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example: Secondary bacterial monitoring (7-day expiry)
E5030



iii. Secondary rapid testing (up to 7-day expiry)

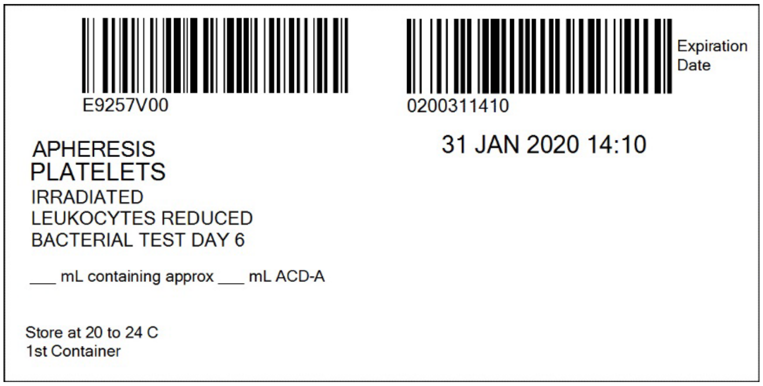
Note: Secondary rapid testing should be performed according to the bacterial testing device instructions for use. Currently, for available FDA cleared/approved devices labeled as a "safety measure", platelets should be transfused within 24 hours of the most recent non-reactive test. The storage container must be FDA approved/cleared for 7-day storage.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attributes “Bacterial test D4,” “Bacterial test D5,” “Bacterial test D6,” “Bacterial test D7” are available for use. These attributes indicate that a unit was bacterially tested on a sample taken X days after collection. For example, if a platelet product was sampled on the fourth day for bacterial testing, the “Bacterial test D4” attribute would apply. The “Bacterial Test Day [X]” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. The user’s system assigns the appropriate expiration date and time.

Note: The “Bacterial Test Day [X]” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

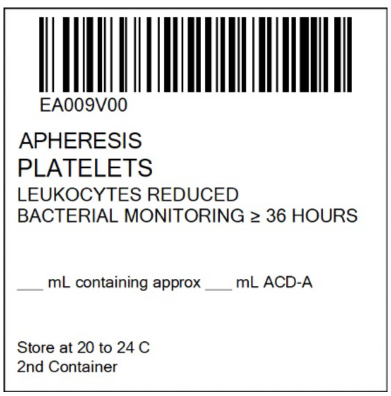
Label Example: Secondary rapid testing (up to 7-day expiry)

E9257



b. Primary culture LVDS no sooner than 36 hours (5-day expiry)

The storage of platelets tested by LVDS no sooner than 36 hours may be extended up to 7 days by secondary testing methods. See also Large volume, delayed sampling (LVDS) no sooner than 36 hours (5-day expiry).



i. Secondary culture performed no sooner than Day 4 (up to 7-day expiry)

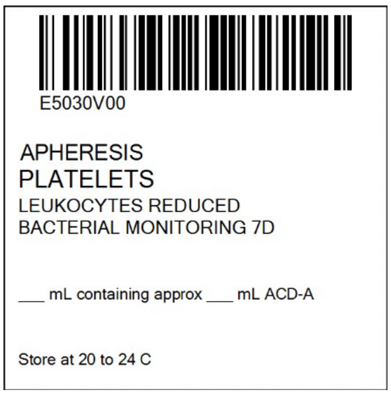
Note: Per the Guidance, "During the incubation period of the secondary culture, products remain in-date through their storage period, and do not necessitate removal from inventory during any portion of the storage period, provided you have developed procedures to identify when secondary testing has been completed, and maintain product control during the recommended incubation period." The storage container must be FDA approved/cleared for 7-day storage.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attribute “Bacterial monitoring” are available for use. This attribute indicates that a unit is subjected to on-going bacterial monitoring for extension of the expiration date. The “Bacterial monitoring” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. “7D” shall be appended to the attribute name (i.e., BACTERIAL MONITORING 7D). The user’s system assigns the expiration date and must ensure the date does NOT exceed 7 days from the collection of the platelet product.

Note: The "Bacterial monitoring" attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

E5030



ii. Secondary rapid testing (up to 7-day expiry)

Note: Secondary rapid testing should be performed according to the bacterial testing device instructions for use. Currently, for available cleared/approved devices labeled as a "safety measure", platelets should be transfused within 24 hours of the most recent non-reactive test. The storage container must be FDA approved/cleared for 7-days storage.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attributes "Bacterial test D4," "Bacterial test D5," "Bacterial test D6," "Bacterial test D7" are available for use. These attributes indicate that a unit was bacterially tested on a sample taken X days after collection. For example, if a platelet product was sampled on the fourth day for bacterial testing, the "Bacterial test D4" attribute would apply. The "Bacterial Test Day [X]" attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. The user's system assigns the appropriate expiration date and time.

Note: The "Bacterial Test Day [X]" attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example: Secondary rapid testing (up to 7-day expiry)

E9257

E9257V00 0200311410 Expiration Date

APHERESIS
PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL TEST DAY 6

31 JAN 2020 14:10

___ mL containing approx ___ mL ACD-A

Store at 20 to 24 C
1st Container

B. Strategies for Single Units and Post-storage Pools of WBD Platelets

The recommended strategies for single units of WBD platelets and post-storage Pools of WBD platelets are single step.

a. Single Units of WBD Platelets

i. Rapid bacterial testing (5-day expiry)

Note: Testing should be performed according to the bacterial testing device instructions for use. The device must be FDA approved/cleared and be labeled as a "safety measure."

Labeling requirements: Product Description Codes that include the default attribute “Default: Not specified” are available for use. This attribute indicates that no monitoring is specified. Products must be labeled with no more than a 5-day expiration.

Note: The “Default: Not specified” attribute does NOT specify monitoring. Such information would be included in the accompanying documentation.

Label Example:

E2807

E2807V00

PLATELETS

Approx 40-70 mL
From 450 mL CPD Whole Blood

Store at 20 to 24 C

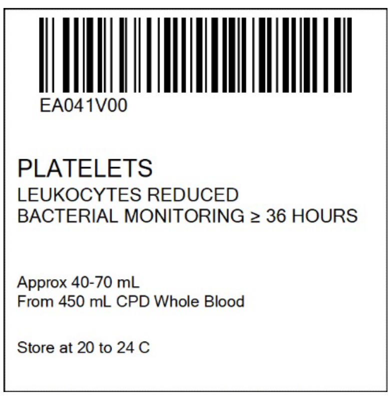
ii. Single culture with sampling performed no sooner than 36 hours after collection (5-day expiry)

Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring >=36h” are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 36 hours after collection. The “Bacterial monitoring >=36h” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. The user’s system assigns the expiration date.

Note: The “Bacterial monitoring >=36h” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

EA041



iii. Single culture with sampling performed no sooner than 24 hours after collection (5-day expiry, but consider secondary testing >/= day 3)

Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring >=24h” are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 24 hours after collection. BACT MON ≥24H RETEST AFTER DAY 3 shall be printed below the Component Class in the “Attribute” Section. Products must be labeled with no more than a 5-day expiration. If the unit is transfused after day 3 of storage, secondary rapid testing should be considered.

Note: The “Bacterial monitoring >=24h” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

EA000

EA000V00

PLATELETS
LEUKOCYTES REDUCED
BACT MON ≥24H RETEST AFTER DAY 3

Approx 40-70 mL
From 450 mL CPD Whole Blood

Store at 20 to 24 C

2. Post-storage Pools of previously untested WBD Platelets

i. Rapid bacterial testing (Expiry 4 hours after pooling)

Note: Testing should be performed according to the bacterial testing device instructions for use. The device must be FDA approved/cleared and labeled as a "safety measure."

Labeling requirements: Products expire 4 hours after pooling.

Label Example:

E5151

E5151V00

POOLED PLATELETS
OPEN SYSTEM

_____ mL

Number of units in pool _____
From CPD Whole Blood

Store at 20 to 24 C

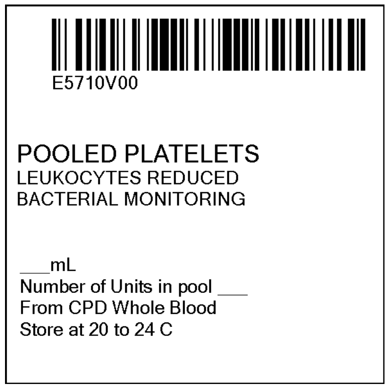
Pre-Storage Pooled Platelets Bacterial Monitoring and Testing (Closed System)

Pre-storage 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. 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 Medical Products of Human Origin*).

Further modification (e.g., washing, reducing the plasma volume, irradiation) of Pre-Storage Pooled Platelets may reduce the expiration date/time. Firms should consult the Circular of Information for the Use of Human Blood and Blood Components in order to determine the appropriate dating period that applies.

Figure 54 Pre-Storage Pooled Platelets with Bacterial Monitoring or Bacterial Test

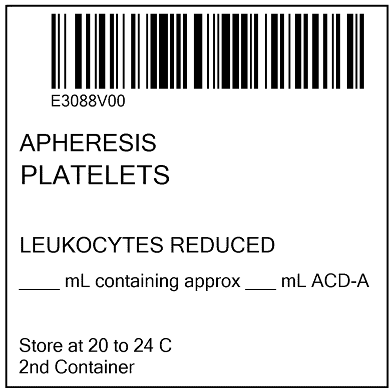


7.8.12 Apheresis Platelets

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

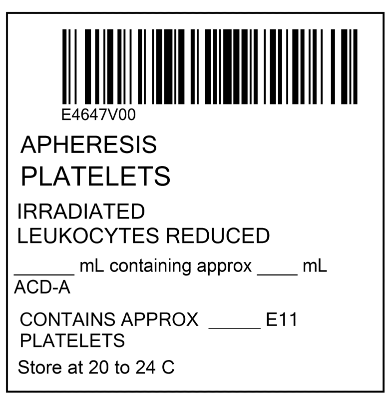
Container Designation or Division Code Text: Below the storage temperature, the Container designation shall be printed. The Division code may also be printed in this space. See Figure 55 for an example of Container Code designation.

Figure 55 "Container" Code on Apheresis Platelets



Single Collection and Divided Products with $<3 \times 10^{11}$ Platelets: Single collections and divided products with platelet yields $<3 \times 10^{11}$ are considered "low yield". Product description codes for these platelets should include the Attribute "<3E11 plts" from the Dosage — Additional Information attribute group. Alternatively, if the product is intended for pediatric use, the Attribute "Pediatric dose" may be used. In both instances, the actual platelet yield shall appear on the label. See Figure 56.

Figure 56 Example Statement on Low Yield Collection



Single, Double or Triple Collections and Divided Products with ≥3 x 10^{11} Platelets: A facility may elect to include the platelet yield on a product with ≥3 x 10^{11} platelets. See Figure 57. A Product Description Code with the default "Dosage: No additional Information" from the Dosage — Additional Information attribute group should be selected.

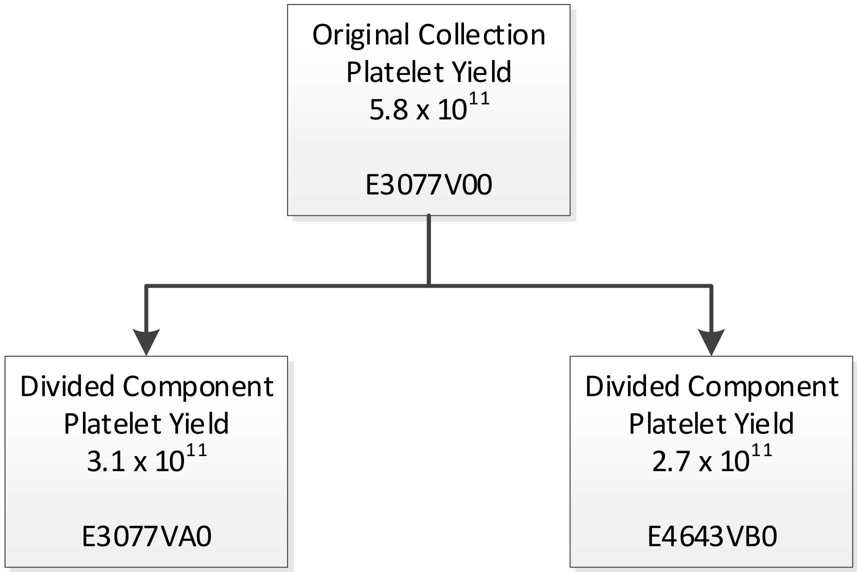
Figure 57 Example of Optional Platelet Yield Statement

Single Collection: If a collection results in only one product with a yield of ≥3 x 10^{11}, Product Description Codes without container Attributes (e.g., E3077 Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6) should be used.

If the single product is divided, the products should be labeled as divided components. That is, the character in the 7th position of the Product Code must change from a 0 (zero) to an upper case 'A' for one product and an upper case 'B' for the other.

If a division results in one product with ≥3 x 10^{11} and one < 3.0 x 10^{11}, 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.

Example: An apheresis platelet collection with a platelet count of 5.8 x 10^{11} is divided into two products. One has a count of 3.1 x 10^{11} and the other has a count of 2.7 x 10^{11}.



- Original Collection = E3077V00 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6, not divided)
- Divided product with 3.1 x 10^{11} platelets = E3077VA0 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6, divided)
- Divided product with 2.7 x 10^{11} platelets = E4643VB0 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|<3E11 plts, divided

Double or Triple Apheresis Collections

Multiple products prepared by splitting an apheresis platelet collection into approximately equal volumes must each have a yield of ≥3 x 10^{11}. Each of these products with yields of ≥3 x 10^{11} shall have a Product Description Code with a container Attribute. For example:

E3087 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container
E3088 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container
E3089 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container

If one of these products is subsequently divided, Division Codes (7th and 8th position of the Product Codes) shall be used. Further, if a divided product has a yield of <3 x 10^{11} a Product Description Code with the Attribute “<3E11 plts” from the "Dosage — Additional Information" Attribute Group shall be used. Alternatively, if the product is intended for pediatric use, the Attribute “Pediatric dose” may be used. In both instances the actual platelet count shall appear on the label.

For example:
The Product Description Code for this product would be:

E4646 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts

The full Product Code for this divided product would then be: E4646VA0

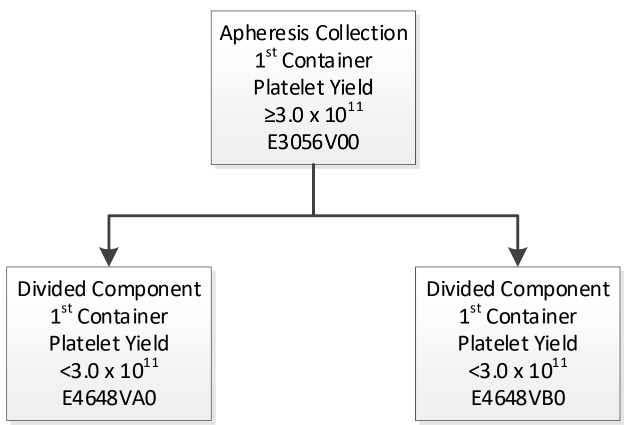
OR

The Product Description Code for this product would be:
E7966 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Pediatric dose

The full Product Code for this divided product would be: E7966VA0.

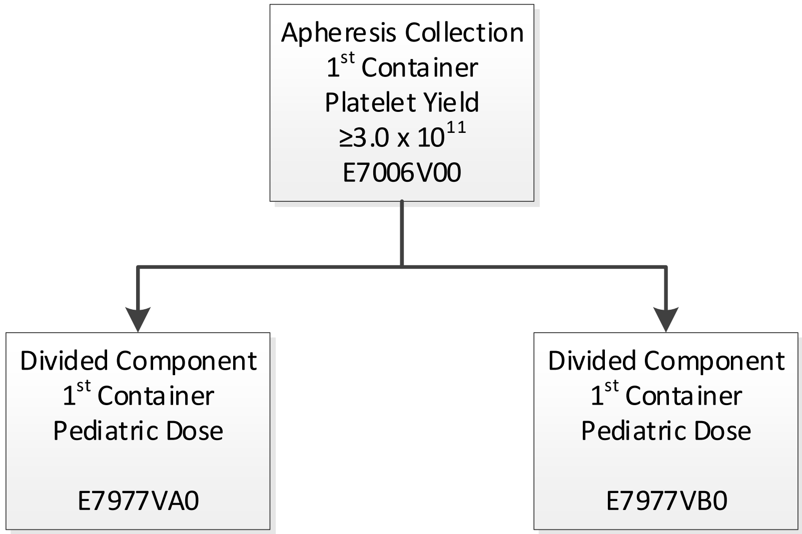
Example Scenario:
If a component with a yield of $\geq 3 \times 10^{11}$ labeled with a container Attribute is further divided for pediatric use, the unit will retain the container Attribute and be assigned a Division Code. In this situation, there are two labeling options: (1) use the low volume Attribute "<3E11 plts" or (2) use the Attribute "Pediatric dose." In both instances, the actual platelet count shall appear on the label.

Example for Option 1 – Use of <3E11 plts Attribute



- E3056 = Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container
- E4648 = Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|<3E11 plts

Example for Option 2 - Use of "Pediatric dose" Attribute



- E7006 = Apheresis PLATELETS|ACD-A>PAS-C/XX/20-24C|Irradiated|ResLeu:<5E6|1st container
- E7977 = Apheresis PLATELETS|ACD-A>PAS-C/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Pediatric dose

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 55.

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 58, Figure *59*, 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 7^{th} and 8^{th} position of the Product Code) should be used. See Figure *59* 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 58).

- Product with 3.1 X 10^{11} platelets: E3077VA0 (Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6), divided (See Figure 59).

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.

Figure 58 Divided Low Yield Product

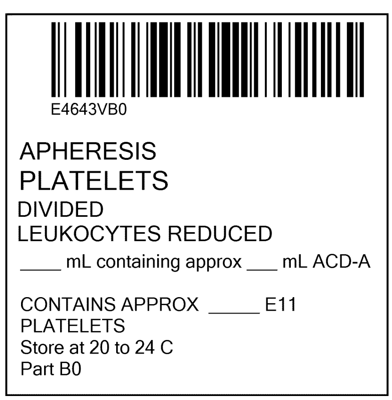


Figure 59 Divided Product (Yield ≥3 x 10^{11})

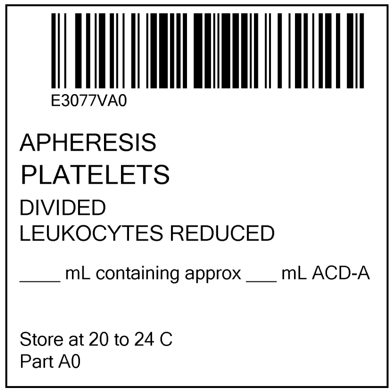
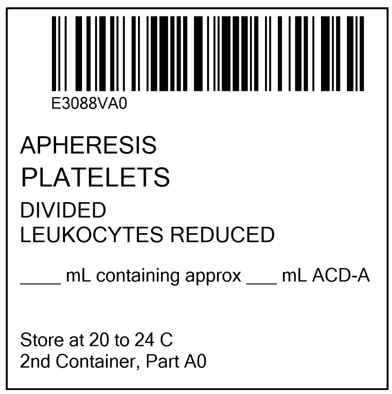


Figure 60 Divided Product from 2nd Container



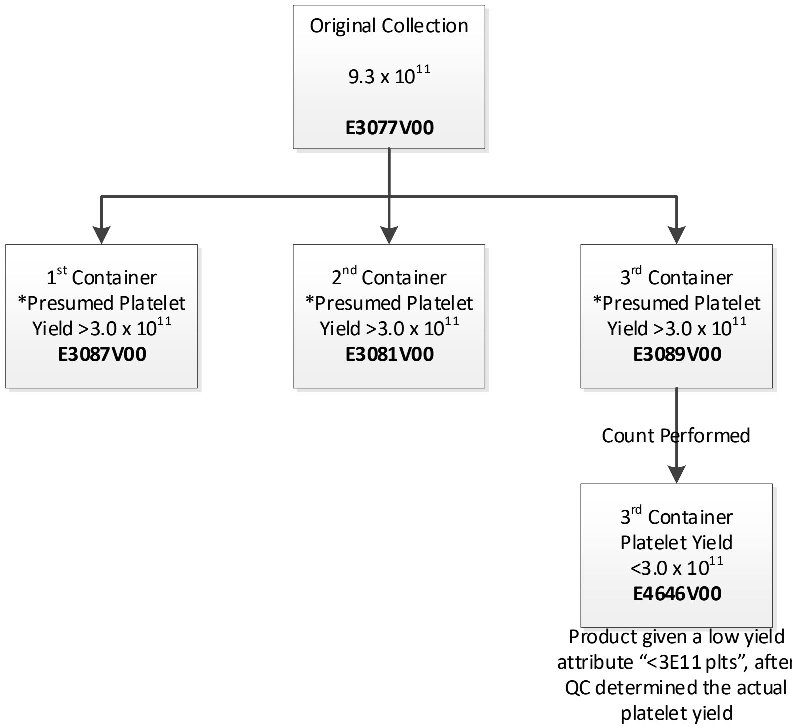
Exception to General Labeling Conditions

Relabeling Platelet Units after Quality Control Testing

A double or triple collection that results in more than one transfusable component believed to contain ≥3.0x10^{11} platelets will be labeled with Product Description Codes that have container Attributes. If Quality Control is subsequently performed (near the time of outdating or distribution) and it is determined that one container has a yield of <3.0 x 10^{11} platelets, this unit shall be relabeled and given a low yield Attribute but does not need a Division Code.

Example Scenario:
An apheresis platelet collection that results in three containers all believed to have yields of ≥3 x 10^{11} is later tested for quality assurance. One unit reveals an actual yield of 2.9 x 10^{11} platelets. The other two products have already been distributed. The low yield product shall be relabeled and assigned a new Product Code indicating the low yield (either <3E11 or, if intended for pediatric use, “Pediatric dose”). In this scenario the product would retain the container Attribute

even though the product does not contain a full adult dose. Since this product is low yield, the actual platelet count must appear on the label.



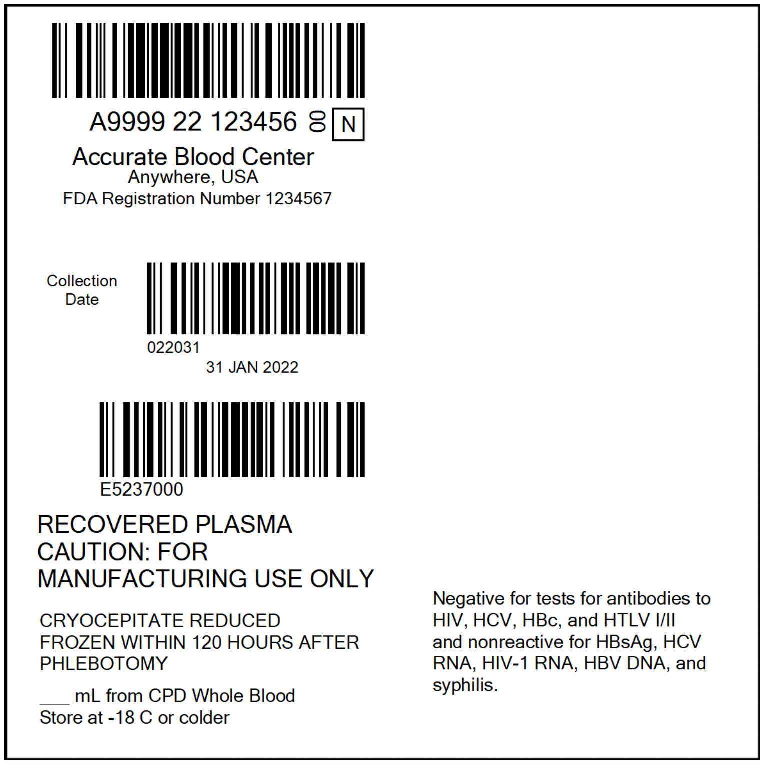
Original Collection is E3077 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6

- E3087 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container
- E3081 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Plasma reduced|2nd container
- E3089 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container
- E4646 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|<3E11 plts

7.8.13 Recovered Plasma

Recovered Plasma shall be coded as Plasma with an Intended Use Attribute indicating it is intended for further manufacturing. 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 61 Recovered Plasma



Specific text associated with Recovered Plasma may be found on Figure 25, page 94 and Figure 26, page 95. 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 62 Additional Recovered Plasma Label Examples Showing Lower Quadrants

E2487000

LIQUID

RECOVERED PLASMA
CAUTION: FOR
MANUFACTURING USE
ONLY

____ mL from CPD Whole Blood
Store at 37 C or colder

Negative for tests for antibodies to
HIV, HCV, HBc, and HTLV-I/II and
nonreactive for HBsAg, HCV RNA, HIV-1
RNA, HBV DNA, and syphilis

E5268000

RECOVERED PLASMA
CAUTION: FOR FURTHER
MANUFACTURING INTO IN VITRO
DIAGNOSTIC REAGENTS FOR
WHICH THERE ARE NO
ALTERNATIVE SOURCES

Not for Use in Products Subject to License
Under Section 351 of the Public Health Service
Act.
_____ mL from CPDA-1 Whole Blood
Store at -18 C or colder

Reactive by an FDA licensed test for
anti-HBc

Negative for tests for antibodies to
HIV, HCV, and HTLV-I/II and
nonreactive for HBsAg, HCV RNA,
HIV-1 RNA, HBV DNA, and syphilis

E2539000

RECOVERED PLASMA
CAUTION: FOR USE IN
MANUFACTURING
NONINJECTABLE
PRODUCTS ONLY

____ mL from CPD Whole Blood
Store at -18 C or colder

Negative for tests for antibodies to
HIV, HCV, HBc, and HTLV-I/II and
nonreactive for HBsAg, HCV RNA, HIV-1
RNA, HBV DNA, and syphilis

Note: These examples show only the lower half of the label. The upper portion of the label should appear as shown in Figure 61.

7.8.14 Source Plasma

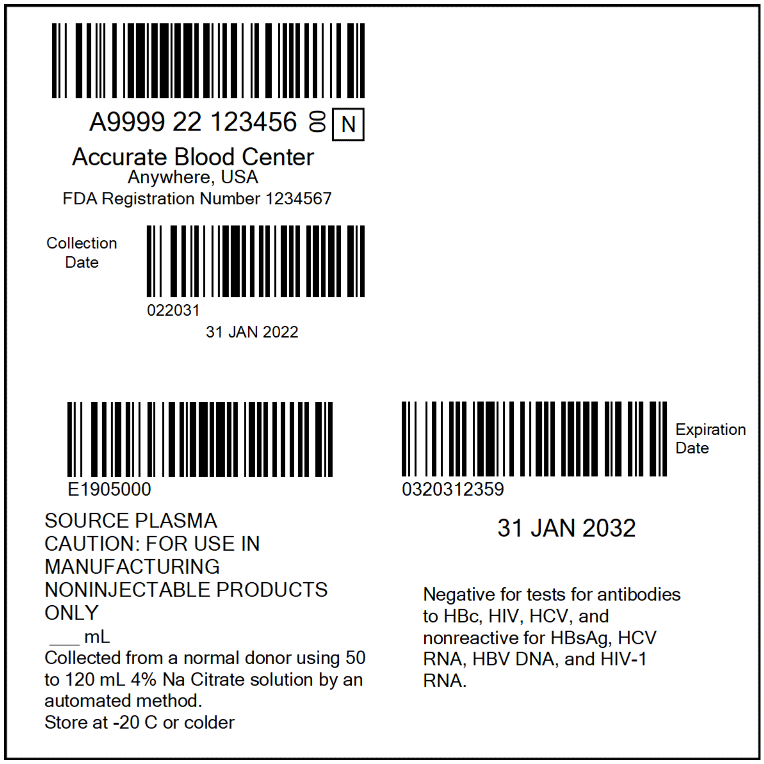
Source Plasma is to be coded as Apheresis Plasma with an Intended Use Attribute indicating it is intended for further manufacturing. The storage temperature, the total volume or weight of plasma, the total quantity and type of anticoagulant used, and the expiration date must appear on the label. In some 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 63 Source Plasma



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

7.8.15 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 64 Source Leukocytes from Whole Blood

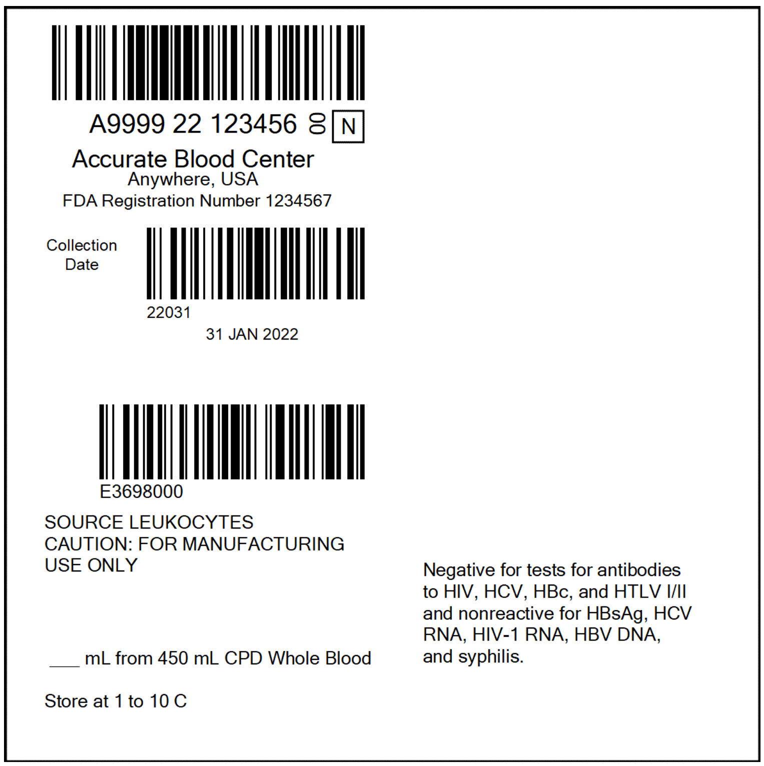


Figure 65 Source Leukocytes Collected by Apheresis

A9999 22 123456 00 N

Accurate Blood Center
Anywhere, USA
FDA Registration Number 1234567

Collection Date

22031

31 JAN 2022

E3758000

SOURCE LEUKOCYTES
CAUTION: FOR MANUFACTURING USE ONLY

___ mL prepared by automated apheresis containing approx ___ mL ACD-A

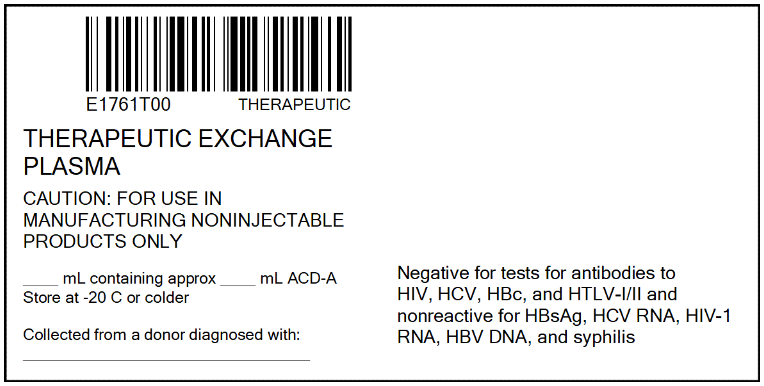
Store at 1 to 10 C

Negative for tests for antibodies to HIV, HCV, HBc, HTLV I/II, and nonreactive for HBsAg, HCV RNA, HIV-1 RNA, HBV DNA, and syphilis.

7.8.16 Therapeutic Plasma for Manufacture

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

Figure 66 Therapeutic Plasma for Manufacture into Noninjectable Products (Lower Quadrants)



7.8.17 Red Blood Cells Collected by Therapeutic Phlebotomy

The container label of Red Blood Cells collected from a donor who undergoes therapeutic phlebotomy in accordance with a licensed health care provider's prescription shall conspicuously state the donor's disease or condition that necessitated phlebotomy, unless certain conditions defined in 21 CFR 630.15(a)(2) are met (see below). The donor's disease or condition shall be printed in the lower right quadrant of the label.

The donor's disease does not need to be included on the container label of Red Blood Cells collected by therapeutic phlebotomy as prescribed by a licensed health care provider if:

1) the donor meets all eligibility requirements;
2) the donor has been diagnosed with hereditary hemochromatosis OR CBER has found the firm's procedure acceptable to collect Red Blood Cells from a donor who has been diagnosed with another disease or condition that will not be adversely affected by donating and the donor's disease or condition will not adversely affect products manufactured from the donation; and
3) you perform therapeutic phlebotomies without charge for all individuals with the disease or condition.

7.8.18 Additional Labeling by a Facility Modifying a Blood Product

21 CFR 606.121 (c) (13) (iii) requires that certain information on the container labels be machine readable including: unique facility identifier, lot number relating to the donor (called Donation Identification Number in this document), ABO/Rh of the donor, and Product Code. These requirements apply to the facility that originally collected and labeled the blood products and also to facilities modifying blood products collected at other facilities. The product description label on the blood product shall reflect the modification (with the exception of when frozen plasma or Cryoprecipitated AHF products are thawed and used within their designated expiration time.

Donation Identification Number (DIN): The DIN should remain that of the collection facility unless the product is pooled (see 7.8.2, page 114 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 (either the collection or pooling facility).

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 <u>if the product leaves the facility</u>, 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.

7.8.18.1 FDA License Number

A US License Number must appear on the container label, if the manufacturer is licensed to manufacture the blood product.

If two manufacturers operating under separate US Licenses each performs part of the manufacturing process and both are approved/licensed to perform their respective part, the names and FDA license numbers of both the collection and modifying facilities should appear on the final product label. Please refer to this FDA's Guidance for Industry: Cooperative Manufacturing Arrangements (2008) for more detailed information about joint or contract manufacturing arrangements.

If the original blood product is licensed, but the product is modified by the same facility or by another facility, including a contractor, that is not approved/licensed to perform the manufacturing step, the final product is not licensed. No FDA license numbers should appear on the final product label. (i.e., the license number of the original collecting facility should be crossed out). The licensure status of the component, and appropriate labeling, can be determined from Table 11 and Table 12.

Table 11 Licensure Status of Component

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

Table 12 Appropriate Labeling of Licensed Products that are Modified

Scenarios	Should both manufacturers be on the label if the product is modified by a second facility?	Additional information
Final modified product used in-house (where modified) only	No, not required	Records should indicate when and where product modification occurred
Final product modified by a separate manufacturer and distributed to another facility (both in-state and out-of-state)	Yes, the label should show both manufacturers (that collected the product and modified the product)	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
Final product modified by an FDA approved contractor of the original collecting facility 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

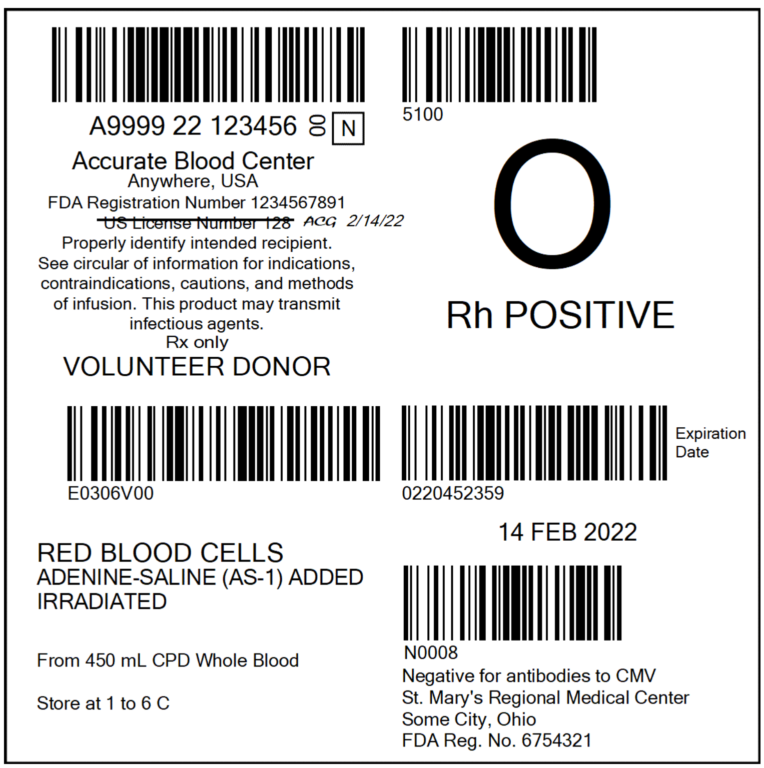
7.8.18.2 Over-labeling:

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, 21 CFR 606.121(b) does not allow the original label applied by the collecting or processing facility to be removed, altered or obscured, except that the label may be altered to indicate the proper name of the product, with any appropriate modifiers and attributes and other information required to identify accurately the contents of the container after the final blood component has been prepared. 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 67, page 159, 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 collecting/processing facility may remain on the label, but this is not required.

Figure 67 Product Modified by a Facility other than the Collection Facility



Notes:
The identification 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.

If the original collecting facility and the modifying facility both operate under the same US License Number, the identification of the modifying facility location does not need to be added to the label.

7.9 Intended Recipient Information Label

Figure 68 Intended Recipient Information Label Examples

INTENDED RECIPIENT INFORMATION LABEL

WB ___ Irrad ___
RBC ___ Leukrd___
FFP ___ Other ___
PLT ___
CRYO ___

Patient Name ______________
ID Number ______________
Facility ______________
Birth Date ___/___/___ Collected ___/___/___

Blood Relative: Yes ____ No ____

AUTOLOGOUS/DIRECTED/
DESIGNATED/DEDICATED

INTENDED RECIPIENT INFORMATION LABEL

Patient Name ____

ID Number ____

Birth Date ____

Facility ____

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 not be acceptable to place a label directly on the plastic container (not on the base label) because it reduces gaseous exchange and could result in decreased platelet viability. Please consult the package insert provided by 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.

7.10 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 at the time the product is released. 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. The list of tests should be updated to reflect tests for RTTI currently required by regulation or recommended by FDA in Guidance.

Figure 69 Emergency Release Test Results Tie Tag or Label

For Emergency Use Only

Donation Identification Number:

Test	Result	Test	Result
ABO/Rh	________	HCV RNA	________
Antibody Screen	________	HIV-1/2 antibody	________
Syphilis	________	HIV-1 RNA	________
HBsAg	________	HBV DNA	________
Anti-HBc	________	HTLV I/II antibody	________
HCV antibody	________	WNV	________
ZIKA	________	Chagas	________

7.11 Unexpected Antibodies

If unexpected antibodies are present in the unit, “contains (name of antibody)” shall appear in eye-readable form on the labels for Whole Blood, Red Blood Cells (except Frozen, Deglycerolized, or Washed) and Plasma intended for transfusion (21 CFR 606.121(e)). The antibody information may appear as additional text in the lower right quadrant of the label or on a tie tag attached to the unit.

Figure 70 Labeling for Unexpected Antibodies

979999999999924799 N
k-;C+c-E-e+;K+
Anti-CMV Neg.
Contains anti-c and anti-E

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 [RT065] – 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 and location as it appears on the FDA annual registration document

A look-up tool is available on the ICCBBA Website for identifying the facility and city/state 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 Code Database

A comma-delimited text file (Product Description Codes Table [RT064] – Text File) is also provided.

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

A comma-delimited text file of the table in the Special Testing: General database (Special Testing General Codes table [RT068] – Text File) 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, [RT016] - Manufacturer Identifier Codes

8.5 ICCBBA-Specified Compound Messages

This table lists standardized compound messages which may be used with Data Structure 023. 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, [RT017] – ICCBBA-Specified Compound Messages

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 Virus
HgbS	Hemoglobin S
HLA	Human Leukocyte Antigen
HTLV	Human T-cell Lymphotropic Virus
mg	milligram(s)
mL	milliliter(s)
Na	sodium
Neg.	negative
PAS	Platelet Additive Solution
PRT	Pathogen Reduction Technology
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

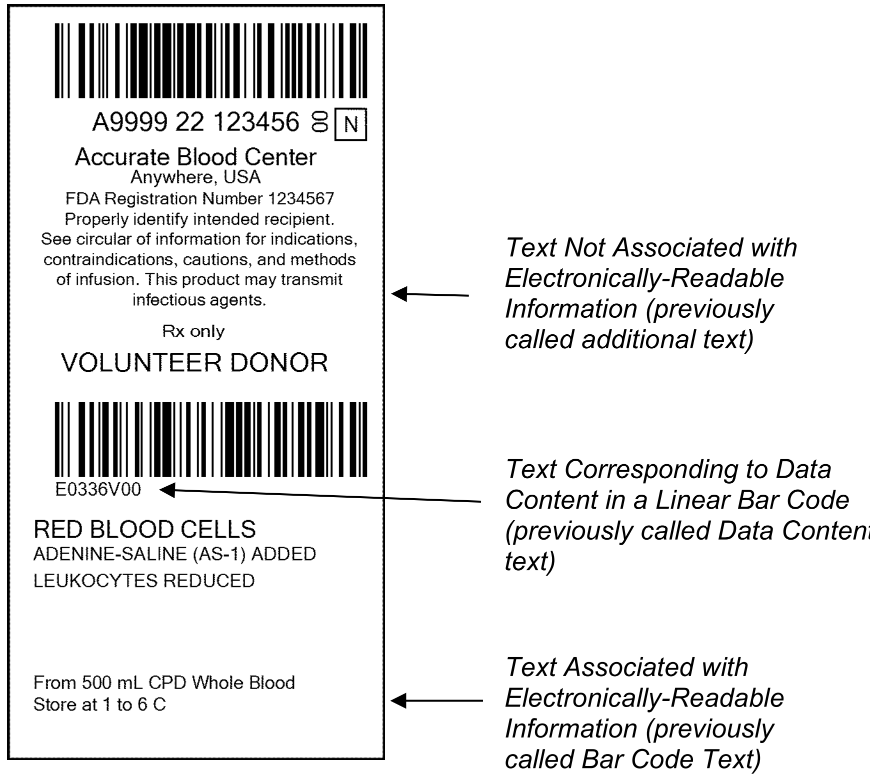
Glossary

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 container 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 $\geq 3 \times 10^{11}$ or $<3 \times 10^{11}$(low yield).
Double Platelet Apheresis Collection	A type of collection that results in two equal transfusable apheresis platelets components, each with platelet yields of $\geq 3 \times 10^{11}$ (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 $\geq 3 \times 10^{11}$ 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 $\geq 3 \times 10^{11}$ or $<3 \times 10^{11}$ (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 71, page 169.
Text Corresponding to Data Content	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).
Text Associated with Electronically-Readable Information	The interpretation of the data content text (the data content of the bar code) that generally requires a look-up table.
Text Not Associated with Electronically-Readable Information	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 71 Text Terminology in ISBT 128 Documents



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