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

Version 1.2.0

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Abbreviations and Acronyms

ABC	American Blood Commission
<i>ABC Codabar</i>	bar code labeling specification based on Codabar
AABB	American Association of Blood Banks
ANSI	American National Standards Institute
ARC	American Red Cross
ASCII	American Standard Code for Information Exchange
CBER	Center for Biologics Evaluation and Research
CFR	Code of Federal Regulations
Codabar	a bar code symbology
Code 128	a bar code symbology
DoD	Department of Defense
ETAG	ICCBBA European Technical Advisory Group
FDA	United States Food and Drug Administration
ICCBBA	International Council for Commonality in Blood Banking Automation, Inc
ISBT	International Society of Blood Transfusion
<i>ISBT 128</i>	bar code labeling specification based on Code 128
ISO	International Standards Organization
mil	one one-thousandth of an inch
mm	millimeter(s)
NATAG	ICCBBA North American Technical Advisory Group
URL	Universal Resource Location
US	United States
WPADP	Working Party on Automation and Data Processing
WWW	World Wide Web—Internet

Caution

The bar codes used in the illustrations throughout this document are diagrammatic only; they are not “real,” that is, accurate representations of the actual data content of *ISBT 128* bar codes..

For the most part, they reflect the size of the actual bar codes accurately with the one exception of the ABO/Rh bar codes—these are shorter than the proper length. Where length is critical, as in the ABO/Rh labels for blood products designated for a specific recipient, the bar code is shown as an empty box. In these cases the length represented is the actual length of the bar code as required by the *ISBT 128 Application Specification*.

Note also that whenever base labels are discussed these are the labels on standard 450 mL or 500 mL collection containers, or standard containers for collecting apheresis products, and any associated transfer containers. Although labeling for other containers is under discussion, no specifications as to the base labels on these containers is currently available.

1 Preface

Please note that some proper names, with any appropriate modifiers and attributes, listed in this document are not those currently set forth in the Code of Federal Regulations (CFR). *ISBT 128* was developed as an international standard, and presented to the FDA with the hope that it will be considered an acceptable bar code labeling system in the United States. Should the FDA make such a determination, the agency has expressed a willingness to initiate revision of the language in the Code of Federal Regulations to permit use of the proper names, with any appropriate modifiers and attributes, as used in the new system. Until this occurs, all manufacturers of blood products who wish to use the new bar coding system and the new proper names, with any appropriate modifiers and attributes, or print in black instead of color should seek FDA approval for an exception from 21 CFR 606.121(e)(1)(ii) and 21 CFR 606.121(d)(2) under 21 CFR 640.120, and **licensed** establishments should, in addition, submit copies of their *ISBT 128* labels to the FDA for approval.

This document is intended to supersede the 1985 *Guideline for Uniform Labeling of Blood and Blood Components* and its unofficial 1989 revision. It does not, however, constitute the entire documentation for the implementation and use of *ISBT 128* as did the *Guideline for ABC Codabar*. In particular, it provides no details as to Product Codes other than the proper placement of the bar code and its associated eye-readable information. Similarly, this document provides only examples of label formats. For a complete description of *ISBT 128* it is necessary to consult the following additional documents:

ISBT 128: Bar Code Symbolology and Application Specification for Labeling of Whole Blood and Blood Components (ISBT 128 Application Specification);

ISBT 128: Product Code Database—Structure and Definitions;

ISBT 128: Country/Collection Facility Database—Structure and Definitions;

ISBT 128: Accepted United States Labels—A Catalog.

Other documents detailing specific issues not covered in depth in these documents may be made available from time to time as *Technical Bulletins*.

Each of these documents is produced and distributed by the International Council for Commonality in Blood Banking Automation, Inc (ICCBBA), and copies and all extensions and revisions are provided to all firms registered with ICCBBA. For single copy prices to individuals see the listing of *Items Available from ICCBBA, Inc* that can be obtained from the ICCBBA office.

This document delineates the US specifications for the use of *ISBT 128*. It is intended to provide the necessary information to the manager of a blood center or transfusion service for use in implementing *ISBT 128*, designing a labeling protocol, and supplying decision-making and staff training. It is also intended to be the source document through which vendors and software developers who supply US blood centers and transfusion services can be certain their blood products meet the *ISBT 128* and US specifications.

There are several options outlined in the *ISBT 128 Application Specification* that are noted as “nationally determined.” These options are codified for national use by national working groups established for this purpose—unless superseded by regulatory authority. In the US this working group is the North American Technical Advisory Group (NATAG) of the ICCBBA. Full details regarding the NATAG mandate and membership can be obtained through the ICCBBA office at the address on the front cover. ICCBBA maintains an on-line service through the Internet World Wide Web (WWW) that can be consulted for up-to-date information on the current membership of the NATAG and many other topics: the address is <http://www.iccbba.com>. To provide the most rapid dissemination (and to keep costs as low as possible) all additions and changes to ICCBBA documents will eventually be initially published through this Web site.

Unlike *ABC Codabar*, the bar coding methodology in use for so many years, *ISBT 128* will be a “living system.” This document, and other documents important to *ISBT 128*, will be subject to a continual revision process. Users should be sure that they have the most recent version. For most facilities, these will be automatically supplied through the registration and licensing process with ICCBBA. Those who purchase documents for personal use should consult the Website at the address in the paragraph above from time to time to ensure that they have the latest revision.

Since this document is subject to FDA review and approval, any major change, such as a decision to alter the basic philosophy underlying the *ISBT 128* system, will be published for comment and accepted by the FDA before being implemented.

ISBT 128 is not in the public domain. It is copyrighted and otherwise protected by US law. The ICCBBA has expressly authorized the Federal Government to publish this document. Implementation of *ISBT 128* requires registration with the ICCBBA and continued use is permitted by payment of an annual license fee. Implementation is defined as reading, storing, interpreting, transferring, printing or otherwise manipulating *ISBT 128* data structures, or the provision of software or instrumentation that assists in the reading, storing, interpreting, transferring, printing or otherwise manipulating *ISBT 128* data structures. This money is used by the ICCBBA to revise, enhance, extend and maintain the *ISBT 128* system, including all associated databases, and to improve standards for blood banking practice, particularly those related to electronic data interchange. The ICCBBA is a non-profit organization incorporated in the State of Virginia. Information about the ICCBBA can be obtained through the office at the address listed on the front cover or through the Website noted above.

2 Background and History

In the early 1970s, a group known as the Committee for Commonality in Blood Banking Automation was appointed by the American Blood Commission (ABC). Their activities on behalf of the blood banking industry were supported by a federal grant. In 1977 they published a seven-volume report of their meetings and recommendations, the result of which was the gradual adoption by the industry of *ABC Codabar*, a system of bar coding intended to improve and *simplify* the labeling of blood and blood components. In 1985 the FDA published the *Guideline for the Uniform Labeling of Blood and Blood Components*. At that time, the FDA stated that *ABC Codabar* was the only currently approved machine-readable symbol for use in blood component labeling in the United States. Although this system was the first bar coding strategy adopted by the health care industry, and has been immensely successful, it is now showing signs of age. New and better bar code symbologies have been designed, and the complexities of today's blood banking practice were never envisioned by the original designers. Unfortunately, no provision was made to maintain the system, and a revision of the *Guideline*, published in draft form in 1989 through the efforts of the American Red Cross (ARC) and Computype, Inc, was never officially accepted by the FDA. Today, the product code methodology of *ABC Codabar* has almost completely broken down, and it can no longer be expanded in its original format.

The ISBT (International Society of Blood Transfusion) Working Party on Automation and Data Processing (WPADP) supported the adoption of *ABC Codabar* in the early 1980s. Recognizing that *ABC Codabar* had reached the end of its useful life, and the need for and benefits of establishing a truly international system for bar codes on blood products, beginning in 1989 the ISBT WPADP has:

- ! designed a totally new system, named *ISBT 128*, based on the bar code symbology known as Code 128;
- ! encoded critical information, *eg*, donation identification number, ABO/Rh blood groups, blood product description and expiration date (and time), in a uniform manner;
- ! defined an *ISBT 128*-specified label so that the bar codes carrying the data listed above appear in the same relative positions on the final label;
- ! standardized other information to the greatest extent possible to minimize the need for “country-specific” software and the high cost associated with software development and maintenance.

During the development of *ISBT 128*, the American Association of Blood Banks (AABB),

represented by its Information Systems Committee, and the ARC, represented by its Label Issues Task Force, have fully participated in Working Party meetings. In addition, representatives from the FDA have attended almost every AABB, ARC and most ISBT WPADP meetings—both overseas and in the US—providing valuable input.

In July 1994, the Working Party submitted the *ISBT 128 Application Specification* document to the governing body of the Society, the ISBT Council. The Council accepted the *Specification* and approved the resolution of the ISBT WPADP that all bar coded blood products collected after July 4 1998 should be labeled using *ISBT 128*.

In order to provide for an orderly transition to *ISBT 128* in the US, the AABB and the ARC established a five-member Board of Directors and provided funds to start the Council for Commonality in Blood Banking Automation as a national office from which to issue documents, establish and maintain databases and provide for the future. This new enterprise also has the full support of America's Blood Centers (formerly the Council of Community Blood Centers), the US Department of Defense (DoD) and the Health Industry Manufacturers Association. Additional funds were provided through a contract with the DoD and a generous grant from Baxter Healthcare. The Council for Commonality in Blood Banking Automation became the ICCBBA when the ISBT formally joined, provided funding and appointed three additional Board members (for a total of eight). In November 1994, the ICCBBA was given the responsibility by the ISBT for the world wide management and distribution of the *ISBT 128 Application Specification* and the associated databases. In March 1995, the Board of Directors established bylaws and decided to incorporate ICCBBA as an independent entity.

3 Description of the *ISBT 128* Standard

3.1 Need for an International Standard

A great deal of important information is presented on a blood product label. This information varies from country to country according to licensing regulations, language differences and local transfusion practice. In today's world of multinational disaster relief programs and multinational military task force operations, blood collected and processed in one country may be used in another. It is essential that critical information such as ABO and Rh blood groups, 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. Both of these goals are made easier to achieve if there is standardization in blood product labeling.

3.2 Code 128

The symbology selected for implementation of *ISBT 128* is based on Code 128. Code 128 was chosen because:

- ! It is more secure than *ABC Codabar* (the currently used 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.
- ! 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. *ABC Codabar* does not support alphabetic characters.
- ! The double-density coding of numeric characters supported by subset C allows more information to be encoded in a given space than *ABC Codabar*. This is important because of the limited space on blood container and sample tube labels.
- ! Since many bar code readers in current use can interpret both Codabar and Code 128, many users will not have to replace bar code reading equipment to implement *ISBT 128*. Further, most current readers can "autodiscriminate" between Codabar and Code 128. It will be possible for a given hospital to read blood products labeled with *ABC Codabar* from one

supplier and with *ISBT 128* from another during the transition from *ABC Codabar* to *ISBT 128* if the computer software used has been designed to accommodate this.

In designing *ISBT 128* the WPADP has developed data structures that are symbology-independent and can be used with new bar code symbologies or other data capture technologies in the future.

The summary that follows is not intended to replace the document *ISBT 128: Bar Code Symbology and Application Specification for Labeling of Whole Blood and Blood Components (ISBT 128 Application Specification)* for US blood centers and transfusion services. That document is the definitive source describing *ISBT 128* and should be consulted when implementing the system. The *ISBT 128 Application Specification* can be obtained from the ICCBBA and is provided to facilities that register with the ICCBBA. Updates will be sent to facilities that maintain their registration through payment of the annual license fee. **What this section does is to provide specific instructions for the US if there is flexibility or an option in the *ISBT 128 Application Specification*.**

These are headed **US Specification** following the general description of the data structure to which they apply.

3.3 Summary of the *ISBT 128 Application Specification*

The *ISBT 128 Application Specification*:

- ! describes the standard layout for a blood product label;
- ! defines the data identifiers for bar codes used in the blood bank environment;
- ! defines the data structures that carry information, *ie*, how a particular bar code will be recognized by a reader, how many characters there are, and whether the characters are letters, numbers or both;
- ! includes tables that define how complex bar codes should be translated, such as ABO/Rh Blood Groups and Type of Donation or Collection;
- ! defines technical details for the bar code itself, such as the width of the narrowest bars and the minimum height of the bars;
- ! describes the variation made in Code 128 to support specialized “concatenation;”
- ! identifies the authority of the ICCBBA, acting for the ISBT, to define other databases,

particularly the Product Code database;

- ! designates national groups as responsible for the definition of other tables that will have more limited use, such as special testing results.

A description of each of these items follows.

3.4 *ISBT 128*-Specified Label

The standard *ISBT 128* blood product label is divided into four quadrants of equal size (2" [50 mm] wide by 2" [50 mm] long). Regardless of site of collection world wide, the bar codes should be placed in the same relative positions. The *ISBT 128* standard specifies the placement of the following bar codes (*see* Figure 1, Section 3, Page 4):

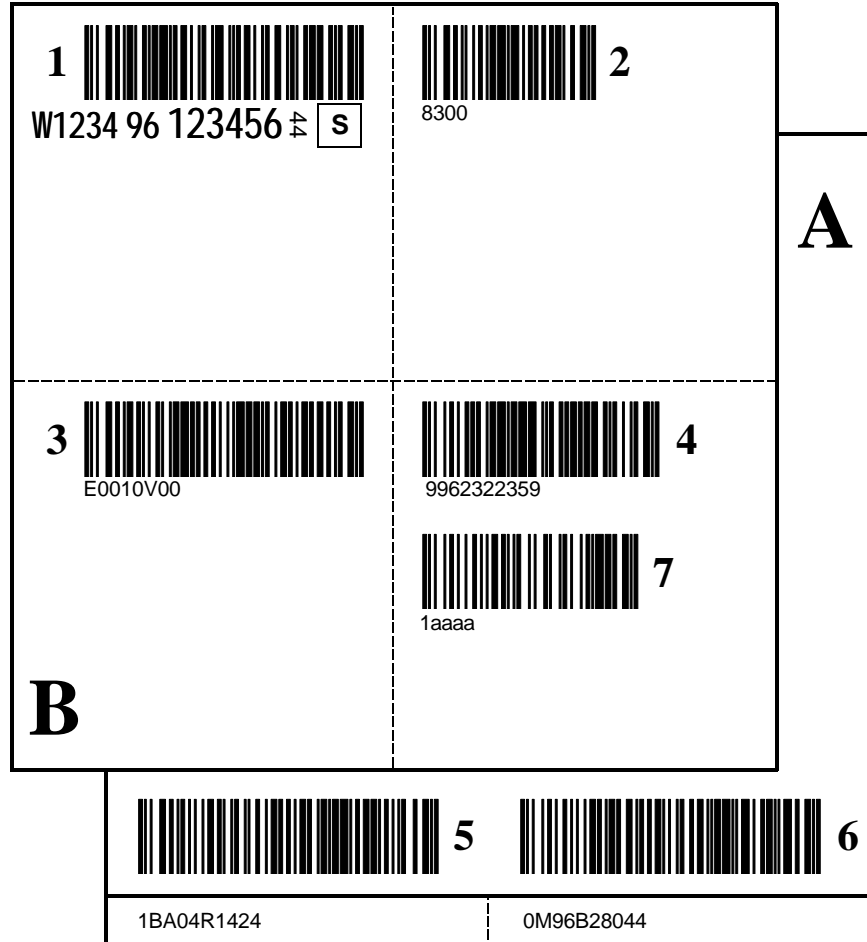
- ! Donation Identification Number (bar code 1);
- ! ABO/Rh Blood Groups [Kell and Rh phenotypes] [Type of Donation or Collection] (bar code 2);
- ! Product Code [Type of Donation or Collection] (bar code 3);
- ! Expiration Date (and Time) (bar code 4);
- ! Container Manufacturer's Identification and Container Description (bar code 5);
- ! Container Manufacturer's Lot Number (bar code 6);
- ! Special Testing (bar code 7).

When referring to Figure 1 (Section 3, Page 4), note that bar codes 5 and 6 are part of the original container manufacturer's label (A) and bar codes 1–4 and 7 are part of final labeling (B). Bar code 7 is optional at this time and may or may not appear on the final label.

Process control can be enhanced through the use of concatenation (reading of two or more bar codes as if they were a single bar code). For this reason, the Donation Identification Number and ABO/Rh Blood Groups bar codes have been positioned on the label to facilitate a single scanning motion. The Product Code and Expiration Date (and Time) bar codes are similarly aligned.

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 the symbol. One or both of the container manufacturer's information bar codes may be

Figure 1 ISBT 128-Specified Label



A—Base label B—Primary container label

- Key:**
- | | |
|--|-------------------------------------|
| 1 Donation Identification Number | 2 ABO/Rh Blood Groups |
| 3 Product Code | 4 Expiration Date (and Time) |
| 5 Manufacturer's Identity and Container Information | 6 Manufacturer's Lot Number |
| | 7 Special Testing (optional) |

covered by final labeling.

The eye-readable presentation of the interpreted bar coded information (called bar code text in this document) and any other information on the label (called label text in this document) will be defined by each country to meet its own requirements. These are defined for the US in this and subsequent sections.

3.5 ISBT 128 Data Structures

Data structure is the term used to define the organization of information in a bar code (*ie*, what is in the bar code and how it is arranged). Each bar code in *ISBT 128* consists of a data identifier and data characters. A check digit is always added to the bar code and other Code 128 control characters may also be present. Those characters that appear in directly comparable eye-readable format are referred to in *ISBT 128* as data characters; control and other characters (*eg*, flag characters) are not strictly labeling but are involved in bar code reading or process control. To repeat: Data characters appear in a directly corresponding eye-readable format; other characters, including flags, may not. Together they constitute the data structure. This is an important concept and should be clearly understood.

Although the control characters may be symbology-specific, the data identifier and data characters in *ISBT 128* can be translated into any full-ASCII bar code symbology. Therefore, the data structures that are described below are not limited to Code 128; these structures will accommodate improvements in current or new technology without the need to redesign the structures themselves. For example, the *ISBT 128* data structures can be bar coded in CODABLOCK (a stacked linear bar code symbology) and PDF-417 (a two-dimensional bar code symbology).

3.5.1 ISBT 128 Data Identifiers

Each bar code on a blood product will begin with two characters, the data identifier.

The first character (primary data identifier) will always be “=” or “&.” By international agreement (*see the ISBT 128 Application Specification*), these characters are reserved to mean “this bar code specifies a blood product.”

The second character (secondary data identifier), with the exception of the Donation Identification Number bar code, defines what kind of information the bar code contains; for example, the second character distinguishes an ABO/Rh bar code from a Product Code bar code (*eg*, the two characters “=%” at the beginning of a bar code indicate that the bar code carries information about the ABO/Rh Blood Groups whereas “=<” means a Product Code

bar code).

Data identifiers have been assigned to bar codes in addition to those on a blood product label to further support process control (eg, Donor [not donation] Identification Number bar code). (See the later sections on *Process Control in Labeling* and *Concatenation* for more information).

3.5.2 Donation Identification Number

This data structure provides for the unique identification of any donation or collection worldwide for a one hundred year period. It has 13 data characters:

$$\alpha p p p p \ y y \ n n n n n n n$$

where:

$\alpha p p p p$ designate the country and collection facility;
 $y y$ designate the year in which the donation or collection was made;
 $n n n n n n n$ is a serial number associated with the donation or collection.

An *additional* check digit (not the same check digit integral to every Code 128 bar code) calculated on the entire 13 data characters ($\alpha p p p p y n n n n n n n$) will be printed, enclosed in a box, to the right of the Donation Identification Number (see illustration in Section 4, page 6). The ISO modulo 37,2 method will be used to compute this check digit. This check digit can be used to ensure the accuracy of keyboard data entry when supported by the appropriate computer software.

Other characters incorporated into this bar code are the “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) or to support additional checks for accurate data transmission. The specific meaning associated with the flags is defined in Table 2 of the *ISBT 128 Application Specification*. In either case, the flags are printed in such a way that identifies their special role. The information will be printed either rotated 90 degrees (ie, on its side) or in “pictorial” or “iconized” format. Flag characters are the last two characters of the Donation Identification Number data structure. They are **not** part of the Donation Identification Number itself.

3.5.2.1 US Specification

3.5.2.1.1 Application—Usually, this should be the first label applied to the primary container and all other containers in the set. It is applied before whole blood or

apheresis collection and should not afterwards be removed, over-labeled or defaced.

3.5.2.1.2 Data Characters—In the US the data characters should appear as follows:

α1234 95 123456

with “α” being “W” in the US.

The Donation Identification Number is divided into three parts in its eye-readable form for ease in reading. This should facilitate checking and recording identification numbers in institutions that receive their blood products from a single facility.

3.5.2.1.3 Flag Characters—For US collection facilities the only flag characters will be:

- | | |
|-------|--|
| 00 | Flags not used, the null or default values; <i>or</i> |
| 40-59 | Reserved for assignment and <i>local</i> use by each individual collecting facility. |

The default or null values, 00, should always be present as part of the Donation Identification Number bar code if flags 40-59 are not used. Other flag characters listed in the *ISBT 128 Application Specification* will not be used in the US under this system.

On blood containers, the flag characters may be printed. If printed they should be rotated ninety degrees as shown in the illustration in Section 4, Page 6. Graphical icons can be used on other materials used in the collection process (test tubes, donor registration form, *etc*) if desired.

The flag characters will be read by the bar code scanner and correctly interpreted by the host computer software in collecting and/or processing facilities. Transfusion service software should be set, at this time, to read and ignore the flag characters.

3.5.2.1.4 Keyboard Entry Check—Although keyboard entry of the Donation Identification Number 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 Donation Identification Number and to require the entry of and verification by the additional check digit described above.

3.5.2.1.5 Avoiding Label Waste—As permitted by the *ISBT 128 Application Specification*, preprinted Donation Identification Numbers may be used over a

fourteen month period to cut down on waste. That is, labels bearing the year “99” may be used from December 1 1998 through January 31 2000. Obviously, the collection facility should have an accurate record of the actual date of collection. It is expected that collection centers will attempt to be careful in their label orders so that this permissive practice is used to the minimum extent possible.

3.5.3 ABO/Rh Blood Groups

This data structure has four (4) data characters:

ggre

where:

- gg* designate the ABO and Rh blood groups and certain other information (*see below*);
- r* specifies Rh and Kell or GP-Mur (Miltenberger III) phenotype information (*see the ISBT 128 Application Specification*);
- e* is reserved for future use.

The ABO and Rh status of a unit of blood (*eg*, A Rh positive, O Rh positive, O Rh negative) is defined by the first two of the four data characters of this bar code. Because of the critical importance of the ABO and Rh blood groups in transfusion, the codes originally assigned to each of the ABO and Rh blood groups in *ABC Codabar* have been maintained in *ISBT 128* (*see Table 1 [Section 3, Page 9]*). The information has been expanded, however, to include the type of donation or collection (*eg*, autologous, directed).

Special messages, *eg*, “For Research Only,” may be encoded instead of ABO and Rh blood groups information if appropriate.

3.5.3.1 US Specification

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

Rh bar code text is printed black on white for Rh positive units; white on black for Rh negative units. The ABO group on Rh negative units should be printed in outline form as it was in *ABC Codabar* (*see illustrations in Section 5, page 16*).

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

Table 1 Default Values (for Allogeneic Units) of “gg” (“n” Values) for ABO/Rh Blood Groups Data Structure

ABO/Rh	Values of “gg” (“n”)
O Rh Negative	95
O Rh Positive	51
A Rh Negative	06
A Rh Positive	62
B Rh Negative	17
B Rh Positive	73
AB Rh Negative	28
AB Rh Positive	84

3.5.3.1.1 Application—Usually, the ABO/Rh blood groups label should be the last applied after all testing of the donation or collection is complete. Once applied, it should not be removed, over-labeled or defaced by any facility other than the facility that did the testing, or those facilities using “full face” labeling.

3.5.3.1.2 Type of Donation or Collection/Intended Use—In the US, information about the type of donation or collection/intended use (eg, Allogeneic, Autologous Collection or Directed Donation) is to be included in the ABO/Rh Blood Groups bar code when the blood product is to be used for a specific recipient only (that is, it cannot be crossed over) or for a special purpose. If the blood product is not intended for a specific recipient or is not one of the “special purpose” blood products listed in Table 2 (Section 3, Page 11), then the default “gg” value for the ABO/Rh blood groups should be used.

The default values of “gg” are shown as an “n” value in Table 1 above. Note that these are the same values as defined in the 1985 United States *Guideline for the Uniform Labeling of Blood and Blood Components*. These “n” values are used to calculate the appropriate values of “gg” for other units (*see* Table 2, Section 3, Page 11). In the US, these values may be (n-4), (n-2), n, (n+2) and (n+3); *ie*, (n-3), (n-1) and (n+1) are not used.

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 “normal” appearance (*see* illustrations in Section 5).

If the blood product is for autologous use, values “n+2” or “n+3” 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 the illustrations in Section 4 and 5. The word **BIOHAZARD** and the international biohazard symbol will be added when “n+3” is used. This labeling is also illustrated in Section 5.

If the blood product is a directed, designated or dedicated donation that is intended for a specific recipient the (n-4) value may be used and **FOR DESIGNATED RECIPIENT ONLY** printed below the ABO/Rh bar code text as shown in the illustration in Section 5. The word **BIOHAZARD** and the international biohazard symbol will be added when “n-2” is used. This labeling is also illustrated in Section 5.

These values are shown in Table 2 (Section 3, Page 11). This table has been abstracted and extended from Tables 3A and 3B in Version 1.1.0 of the *ISBT 128 Application Specification*. The *Application Specification* will be updated to reflect the extensions.

3.5.3.1.3 Definition of the Terms Directed, Designated and Dedicated—As used in this document, these terms are defined as follows:

Directed—A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide (a) blood product(s) to be used by that person in some future therapeutic procedure.

Designated—A unit collected from a donor called by the collecting facility to provide (a) blood product(s) to be used by a specific recipient in some future therapeutic procedure (for example, compatible with HLA antibodies that the recipient has, CMV antibody negative, etc).

Dedicated—Donations arranged by the collecting facility to support a specific recipient. To ensure limited exposure to allogeneic blood products, these donors may be approved by the Medical Director to donate more frequently than usual.

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

**Table 2 ABO/Rh Blood Groups Data Structure:
Values of “gg”**

ABO/Rh Blood Groups	Directed Donation/ For Designated Recipient Only	Directed Donation/ For Designated Recipient Only/ Biohazardous	Type of Donation or Collection Not Specified	For Autologous Use Only	For Autologous Use Only/ Biohazardous
	(n-4)	(n-2)	(n)	(n+2)	(n+3)
O Rh negative	91	93	95	97	98
O Rh positive	47	49	51	53	54
A Rh negative	02	04	06	08	09
A Rh positive	58	60	62	64	65
B Rh negative	13	15	17	19	20
B Rh Positive	69	71	73	75	76
AB Rh negative	24	26	28	30	31
AB Rh positive	80	82	84	86	87
O	P2	P4	55	P8	P9
A	A2	A4	66	A8	A9
B	B2	B4	77	B8	B9
AB	C2	C4	88	C8	C9
Bombay O _h Rh negative	D2	D4	D6	D8	D9
Bombay O _h Rh positive	E2	E4	E6	E8	E9
Para-Bombay A _h or B _h Rh negative	G2	G4	G6	G8	G9
Para-Bombay A _h or B _h Rh positive	H2	H4	H6	H8	H9

Note: (n-3), (n-1) and (n+1) are not used in the US

3.5.4 Expiration Date (and Time)

There are two data structures that support the expiration date of the blood product. One provides date only; the second additionally incorporates time. These two data structures have essentially the same structure, the first having six (6) data characters and the second ten (10) data characters:

cyjjj and
cyjjjhhmm

where:

c designates the century (*eg*, 9 for 1999; 0 for 2000);
yy designate the year;
jjj is the Julian date (the number of the day in the year, *eg*, 022 is 22 JAN);
hh specify the hour (00–23);
mm specify minutes (00–59).

The WPADP has agreed that all countries should adopt a single format for expressing the expiration date in eye-readable form, *viz*, 21 JUL 1998 (DD MMM YYYY—month in alpha characters, abbreviated), since there are national differences in the order in which day/month/year appear when expressed in a numerical format.

3.5.4.1 US Specification

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

The US will use **only** the second form of this data structure that includes time. When not a time dependent blood product, the time should be encoded as 23:59. When the default 23:59 is used it is **not necessary** to show the time in the bar code text, since a midnight expiration is assumed.

3.5.5 Product Code

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

αoooo t ds

where:

<i>α0000</i>	designate the blood product description;
<i>t</i>	designates the type of donation or collection/intended use;
<i>ds</i>	provide information about divisions of the blood product.

The first five (5) data characters are derived from an ICCBBA-maintained *ISBT 128* database table and provide the *ISBT 128* description of a blood product. They identify the blood component (such as **RED BLOOD CELLS**, **WASHED RED BLOOD CELLS**, **PLATELETS**, **THAWED FRESH FROZEN PLASMA**) and attributes (such as **IRRADIATED**, **RESIDUAL LEUKOCYTE CONTENT**, **LOW VOLUME**) associated with the blood product. A glossary of blood component classes, modifiers and attributes is provided in *ISBT 128: Product Code Database—Structure and Definitions*. A simplified description is provided in *Technical Bulletin 4: ISBT 128 Blood Product Coding*. The following is a short summary.

3.5.5.1 Component Classes and Modifiers

A blood component name consists of a Component Class and may have a Modifier. The Component Class is a cellular or non-cellular blood product characterized by a set of core conditions that includes:

- ! anticoagulant or additive, if present;
- ! nominal volume of original collection; and
- ! relevant storage temperature.

Note: The core conditions do not specify the life of the blood product, since each country determines the permissible period after collection during which a blood product may be used.

Component Classes include **RED BLOOD CELLS**, **FRESH FROZEN PLASMA**, **PLATELETS** and **APHERESIS PLATELETS**. **RED BLOOD CELLS** and **REJUVENATED RED BLOOD CELLS**, for example, are separate classes because they differ in the anticoagulant/additive present. Modifiers relate to the core conditions of a blood component and distinguish it from other members of the same Component Class. **WASHED** and **THAWED** are examples of modifiers.

Appendix 2 provides a listing of the *ISBT 128* blood component classes and modifiers that is current as this document goes to press.

3.5.5.2 Attributes

Attributes provide additional information about a blood component relevant to its intended

use or method of preparation. All components have at least one attribute selected from the Core Conditions group and may have other attributes depending upon the particular blood component. At the time of printing other attributes groups include:

- ! Intended Use;
- ! System Integrity;
- ! Irradiated;
- ! Residual Leukocyte Content;
- ! Altered;
- ! Final Content;
- ! Preparation: Additional Information;
- ! Apheresis: Additional Information;
- ! Quarantine: Additional Information;
- ! Pools: Additional Information;
- ! Method of Treatment.

Refer to *ISBT 128: Product Code Database—Structure and Definitions* for a description of each group, the variables within the group and the default values.

Note: There is no provision in the ISBT 128 Product Code database for “in process” blood products. The codes included are intended for “final” labeling. For example, there is no code provided for the first stage of cryoprecipitate preparation. A set of codes (A0000-D9999) have been reserved and may be used internally for interim labeling in component processing, but they should not appear on the label of the finished blood product.

The type of donation or collection/intended use (such as Volunteer, Paid, Autologous) is specified in the sixth data character. Data characters seven and eight are reserved for encoding information about “divisions” of blood products (a practice common in pediatric transfusion services where only a portion of a blood product is given to a patient).

When a blood product is divided into two or more parts (that is, the parts are identical

with the possible exception of volume), the seventh and eighth data characters are changed from “00”, the default values. For example, if a 300 mL unit of **RED BLOOD CELLS** is divided into two subunits, one of 100 mL and one of 200 mL, the last two data characters are changed from “00” to “A0” and “B0”. Such “divided units” can be further subdivided. For example, the “B0” subunit could be further divided into one 100 mL subunit (denoted by “Ba”) and two 50 mL subunits (denoted by “Bb” and “Bc”). There is no provision in *ISBT 128* for more than two divisions.

There may or may not be a change in the first five data characters depending upon whether there is a difference in System Integrity or some other attribute. Refer to the document *ISBT 128: Product Code Database—Structure and Definition* for examples using actual product codes.

3.5.5.3 US Specification

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

The Product Code database released by the ICCBBA will be the *ISBT 128* version. The AABB, as the designated national organization, has determined that the Information Systems Committee will be responsible for specifying those product codes that may not be used in the US under this system. There is a column in the database that is intended to be customized by each country implementing *ISBT 128*. In some countries, two or more customized columns may be needed to provide for multiple languages. In the US, in addition to indicating those product codes that may not be used in this country, this column may also contain proper names that are exceptions to the *ISBT 128* proper name (*see* immediately below).

3.5.5.3.1 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 be as it appears in the *ISBT 128 Product Code Database Table* with the following exceptions:

As noted in Appendix 2, **APHERESIS PLASMA FOR FURTHER MANUFACTURE** will be labeled **SOURCE PLASMA, CRYOPRECIPITATE** will be labeled **CRYOPRECIPITATED AHF**, **THAWED CRYOPRECIPITATE** will be labeled **THAWED CRYOPRECIPITATED AHF** and **POOLED CRYOPRECIPITATE** will be labeled **POOLED CRYOPRECIPITATED AHF** to comply with the Code of Federal Regulations (CFR).

As shown in Appendix 2, the proper name will consist of the Component Class and may have one or more Modifiers.

3.5.5.3.2 Attributes—Appendix 3 contains a listing of each attribute group with instructions as to how the information associated with each group is to be presented on the label.

Note: Consult the ICCBBA Website (<http://www.iccbba.com>) for recent information and updates. The listings in Appendices 2 and 3 are complete as this document goes to press. Registered facilities that have maintained their license to use ISBT 128 will receive notice of all significant changes and regular updates to the database.

3.5.5.3.3 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. The codes are listed in Table 5 of the *ISBT 128 Application Specification*. In the US, the following usage is optional.

If the blood product is intended for transfusion, the sixth data character may be 0 (zero), 1 (one), X, V, D, d, P, 2 (two), L, 3 (three), 4 (four) or 5 (five). If the blood product is not intended for transfusion, the sixth data character may be R, r, S or s. T is required for therapeutic collections if they are labeled and used; it is not required if the collection is promptly discarded. P or d is required if the blood product is from a paid donor. The translation of this information into bar code text is shown in Appendix 4. Note that this coding is not required with the exception of T, P and d. In all cases other than therapeutic collection or blood products from paid donors the default “0” should be used if blood products are not coded as described in Appendix 4.

Transfusion services that drive their billing programs from the Product Code bar code may wish to consider over-labeling the lower left quadrant with a bar code appropriately coded in the sixth position should they wish to capture in their billing system the data that this coding scheme can provide.

3.5.5.3.4 Labeling in the Left Lower Quadrant When Sixth Data Character of the Product Code Is Used—Since the *ISBT 128 Application Specification* makes no provision for indicating the Type of Donation or Collection/Intended Use in the lower left quadrant, the following protocol has been devised to ensure that the information encoded into the sixth data character is conveyed in eye-readable form.

The term AUTOLOGOUS, DIRECTED, DESIGNATED, DEDICATED, RESEARCH OR SOURCE, as appropriate, should be printed immediately below the bar code to the right of the required eye-readable information as illustrated below. The font should be the same

size and height as the required eye-readable information (see Appendix 4) for complete information).



3.5.5.3.5 Divisions—The scheme outlined in the *ISBT 128 Application 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, together with any other attributes such as IRRADIATED as defined below.

3.5.5.3.6 Abbreviations—Abbreviations should only be used when the space available for a bar code text blood product description cannot accommodate the non-abbreviated format. Compressed (condensed) fonts should be used before abbreviating. Currently standardized label and other text abbreviations are listed in Appendix 5.

3.5.5.3.7 Examples—Several illustrations in Section 5, *Illustrations of US Labels*, provide examples of the system in practice. From these illustrations, the logic to be used when designing a blood product description label should become clear. 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 be glad to assist any currently registered facility or their label vendor in designing any needed label should there be difficulty with this. If there are required labels that “will not fit” the logic and rules provided in this document please bring these to the attention of the ICCBBA office. **Remember, the Code of Federal Regulations takes precedence over this and other *ISBT 128* documents for blood product labeling in the US.**

3.5.5.4 Obtaining a New Product Code

Each country that implements *ISBT 128* should have a designated individual or group that makes requests on behalf of the blood centers and transfusion services within that country for new product codes. In the US, the Information Systems Committee of the AABB is the currently delegated group.

A completed New Product Code Request form should be submitted to the ICCBBA office. Copies of the form and instructions for its completion are available from ICCBBA.

3.5.6 Container Manufacturer

3.5.6.1 Manufacturer's Identity and Catalog Number and Manufacturer's Lot Number

Two ten (10) data character data structures intended to identify the container, the container manufacturer (a listing of currently registered container manufacturers and their identification codes is provided in Appendix 6), provide a description of the container set by encoding the manufacturer's catalog number, and the container manufacturer's lot number were proposed by a task force composed mainly of interested container manufacturers. These bar codes will be placed on all container labels applied by the manufacturer. When these bar codes appear on other than the primary container, the bar codes will have no associated eye-readable information, and are placed on satellite containers solely to assist collection facilities in process control. Once the information contained in these bar codes is captured during the collection or processing steps, these bar codes may be over-labeled.

3.5.6.2 Manufacturer's Container Information

In the US, containers will also have a three (3)-data character Container Information bar code (all in subset B) (*see* illustration in Section 5, Page 5) placed on the label applied by the manufacturer. The data identifier is “=@.” This data structure provides information for blood centers regarding the container set, anticoagulant, *etc.* The next few paragraphs summarize the content and interpretation of this data structure.

3.5.6.2.1 Interpretation of the First Data Character—The first data character in this data structure specifies on which container in the set the bar code has been placed. Appendix 7 lists the possible first position data characters and their interpretation.

3.5.6.2.2 Primary Container—When placed on the primary container, the second data character in the Container Information data structure specifies the anticoagulant. The third data character specifies the makeup of the container set. Appendix 7 lists the characters that can appear in the second and third positions and their interpretation.

3.5.6.2.3 Satellite, Transfer and Apheresis Containers—These containers are encoded in the second and third data characters as to the volume capacity of the container and the dating for Red Blood Cells and Plasma according to the plastic film from which the container is made. Appendix 7 provides the necessary details.

3.5.7 Special Testing

An optional, *ISBT 128*-specified five (5) data character data structure has been defined to contain the results of special or additional testing (*eg*, expanded blood grouping test results). At this time, the table to decode the information provided by these five data characters will be nationally-defined to meet the needs of each country.

3.5.7.1 US Specification

Only anti-CMV-negative status will be encoded in the Special Testing bar code at this time. The code used will be 1aaaa; the data identifier is “&” (*see* Section 6.4).

4 Uniform Labeling Using *ISBT 128*

4.1 Concepts

4.1.1 Principles of Label Design

To remain within the “rules-based” system of *ISBT 128* the following principles were adopted and applied:

- ! A change to a new standard implies changes to operating procedures. Wherever possible, procedural changes to accommodate the new label design should also improve the **safety** of the end-product and/or the **efficiency** of the processing/administering facility. When these two conflict, safety takes precedence over efficiency.
- ! Critical information on the blood container will dominate the design *via* position and prominence.
- ! The end user (hospital, clinician) of a blood product can only derive information about the blood product from the contents of the label.
- ! The layout of the bar codes applied to primary or satellite containers will conform to the quadrant design as outlined in the *ISBT 128 Application Specification* as follows:

Upper left: Donation Identification Number;

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 should appear beneath each bar code symbol on the container. It will contain all **data characters** within the symbol, but will not include the data identifier, start/stop characters, special characters (shift C, message append, *etc*) or the Code 128 modulo 103 check digit. With the exception of the Donation Identification Number this interpretation line will appear left justified with the first bar in the symbol.

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

4.1.2 Definitions

- ! **Eye-readable Information** (abbreviated as **eye-readable**): the eye-readable representation of the **data characters** in a bar code (printed left justified below the bar code). For example, the Expiration Date (and Time) bar code will have data characters such as 9960011400 printed beneath the bar code as eye-readable information. Only the donation identification number is printed differently (*see* Section 4, Page 6).
- ! **Bar Coded Label Text** (abbreviated as **bar code text**): the interpretation of text associated with bar coded data characters. For example, the bar code text associated with the Expiration Date (and Time) bar code 9960011400 is **01 JAN 1996 14:00**.
- ! **Additional Label Text** (abbreviated as **label text**): other information on the label that is not associated with a bar code. Properly Identify Intended Recipient and **VOLUNTEER DONOR** are examples of label text.
- ! **Autologous Collection** will be used to refer to blood collected from the intended recipient; **Directed Donation** will be used to refer to blood collected from one donor that is designated for a specific recipient at the time of donation.
- ! **Container** will be used rather than bag.

4.1.3 US Specification for Bar Code Text and Label Text

- ! In general, this document will defer to the *ISBT 128 Application Specification* for typeface or type height of text. This will permit changes to occur in the *ISBT 128 Application Specification* without changing this document.
- ! The term “type size” will not be used; type height, if specified, will be in inches and (millimeters).
- ! Product description and additional information bar coded label text will be left justified. Other bar code and label text may be centered or left justified as appropriate (*see* illustrations in Section 5).
- ! **VOLUNTEER DONOR** should be no less prominent than the proper name of the blood

product. The maximum height of the letters for **VOLUNTEER DONOR** will be 5/32" [4 mm].

- ! Fonts shall be proportionally-spaced *sans serif*. Compressed (condensed) fonts should be used before any text is abbreviated. Only approved label and other text abbreviations should be used (*see* Appendix 5).
- ! The *ISBT 128* Product Code database design is based on a **Component Class** (**RED BLOOD CELLS, WHOLE BLOOD, PLASMA, PLATELETS, CRYOPRECIPITATE, etc**), a **Modifier** (**WASHED, FROZEN, etc**), printed above the Component Class and **Attributes** (**IRRADIATED, DIVIDED, etc**) printed below the Component Class. The proper name (Component Class) may be printed as large as space allows (not exceeding 5/32" [4 mm] in height) as follows:

Modifier	WASHED
Component Class	RED BLOOD CELLS
Attribute	DIVIDED

- ! Modifier(s) and Attribute(s) will be proportionally smaller as shown above (and *see* illustrations in Section 5).
- ! Rh status for the ABO/Rh bar code label text will be printed black on white if Rh positive; white on black if Rh negative. ABO status will be printed black on white if Rh positive, outline black on white if Rh negative (*ie*, as in *ABC Codabar*).
- ! The use of color for ABO and Rh labeling is neither prohibited nor encouraged.

4.1.4 Label Design

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

- ! The base label of the primary container will be at least 4" [100 mm] wide and 4.25" [108 mm] long;
- ! The base label of a satellite container will be at least 4" [100 mm] wide and 4" [100 mm] long;
- ! The design of the additional labels for primary and satellite containers will be limited to cover an area 4" [100 mm] wide by 4" [100 mm] long;
- ! Each 4" [100 mm] wide by 4" [100 mm] long label will be divided into four equal 2" [50 mm] wide by 2" [50 mm] long quadrants;

- ! Each quadrant will be divided “roughly” into thirds;
- ! The placement of the bar codes (Donation Identification Number, ABO/Rh Blood Groups, Product Code, Expiration Date (and Time), and Special Testing) will conform to the *ISBT 128 Application Specification*;
- ! Horizontal lines on base labels and on-demand labels are permitted to facilitate label application and reading. If the labels are applied in sections, there is no need for vertical lines to serve as a visual separation of each section;
- ! Vertical lines are not permitted where they may interfere with the reading of concatenated bar codes. This means there can be no vertical, printed lines between the Donation Identification Number and ABO/Rh Blood Groups nor the Product Code and Expiration Date (and Time) bar codes.

4.1.5 Quadrants and Thirds

A primary container intended for the collection of 450 or 500 mL of whole blood will have a base label applied by the container manufacturer that measures 4" [100 mm] in width by 4.25" [108 mm] in length. To maximize labeling flexibility when using on-demand printing of labels, this area can be conveniently divided into four equal 2" [50 mm] wide by 2" [50 mm] long areas, as illustrated in Figure 2 (Section 4, Page 5). In deciding the relative placement of the bar codes, the WPADP further divided each area into three 2" [50 mm] wide by approximately 0.8" [16 mm] long areas. Indicated in the illustration is the area to be used for the placement of each of the five *ISBT 128* bar codes that appear on the final US label.

Note: The Special Testing bar code is optional.

From this description it becomes obvious that all labels are now standardized as 2" [50 mm] wide by 2" [50 mm] long or 2" [50 mm] wide by about 0.8" [16 mm] long in size. Not so intuitively obvious are the sizes 4" [100 mm] wide by 2" [50 mm] long and 2" [50 mm] wide by 4" [100 mm] long for final ABO/Rh labeling and over-labeling as the blood product and expiration date and/or time changes. These were designed to facilitate on-demand printing and limit the sizes of blank stock needed, as discussed later.

The FDA permits the pre-labeling of the primary container as **RED BLOOD CELLS** and of a specialized satellite container for **PLATELETS**. This allows labeling in two steps for two of the major blood products manufactured by blood centers. First, the Donation Identification Number is applied at collection; second, a 2" [50 mm] wide by 4" [100 mm] long ABO/Rh blood groups label with the Expiration Date (and Time) (and, if this option is chosen, the address and license data for the blood product manufacturer) is applied to complete the

Donation Identification Number	ABO/Rh Blood Groups
Product Code	Expiration Date (and Time)
Container manufacturer's bar code may be visible	Special Testing
Container manufacturer's bar code may be visible	Container manufacturer's bar code may be visible

Figure 2 Primary Label—Four Equally-Sized Labeling Quadrants: Placement of the Bar Codes

labeling of the blood product.

Although the satellite container is smaller, it is possible to apply labels of the same size as those used on the primary container. Clearly, this means that until the industry adopts two-dimensional or other more sophisticated encoding strategies, much of the additional label text will necessarily be in small print. One may compare this to other drug labeling and package inserts in which the typeface is adjusted to “make it fit” the space available. In specifying the printing to be used in labeling blood products the following “order of importance” was used:

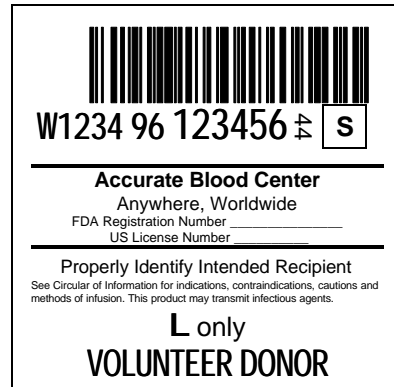
- ! Greatest importance—Donation Identification Number, ABO/Rh Blood Groups;
- ! Intermediate importance—Expiration Date (and Time), Blood Product Identification and Volunteer Donor or Paid Donor statement;

! Least importance—all other bar code and additional label text.

The following general rules for each of the four quadrants were established.

4.1.5.1 Upper Left Quadrant

The Donation Identification Number will be right-justified, and there will be spaces between the Country/Collection Facility Identification Number, the year of collection, the serial number, the rotated flag characters and the boxed check digit. The alignment will be such that the boxed check digit is aligned with the right edge of the bar code, as illustrated to the right.

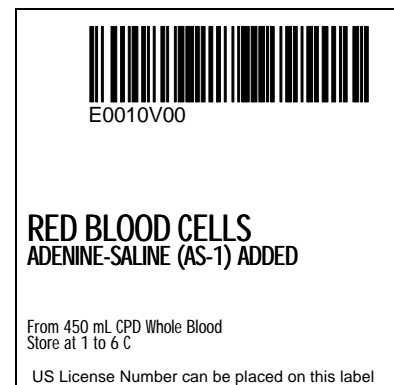


The “Collected/Processed by” information may be printed in one of two places: in the middle third of this quadrant or, alternatively, in the lower third of the lower right quadrant. This flexibility will permit operational issues to be considered (*eg*, use of on-demand label printing *vs* pre-printed label stock). This label, or the lower right quadrant, may also contain information about a secondary processing site. The FDA Registration Number is not bar coded since it can be traced through the Donation Identification Number. In the illustration, one position that the FDA Registration Number and US License Number of the facility can be placed is shown; alternatively it can be placed in the lower left or lower right quadrant. The US License Number, of course, is only applied by licensed facilities to licensed blood products; **a US License Number must not appear on unlicensed blood products.**

The required label text (Properly Identify, *etc*) will be printed in the lower third of this quadrant; **VOLUNTEER DONOR** (or **PAID DONOR**) will be printed at the bottom.

4.1.5.2 Lower Left Quadrant

The base label of the primary container will have the manufacturer’s information bar code in the lower third. On primary container base labels that have a **RED BLOOD CELLS** bar code and label text preprinted, this bar code may remain visible on the finished blood product. The container manufacturer’s bar code may also remain visible on **PLATELETS** and **APHERESIS PLATELETS** containers.



If additional processing is done and the product code changes, or the base label is not preprinted as **RED BLOOD CELLS, PLATELETS** or **APHERESIS PLATELETS** the container manufacturer’s information bar code may be covered. Illustrations are included in Section 5 to show both a pre-printed example (with container manufacturer’s information bar code visible) and the appearance when over-labeled.

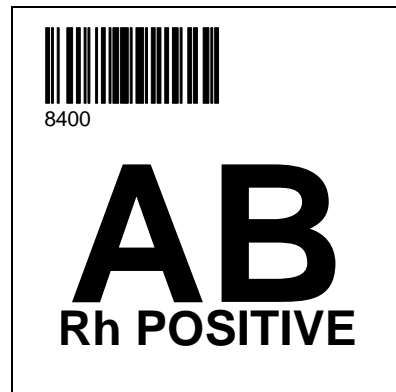
If a blood product is licensed, the US License Number information can be printed on the Product Code label or in the upper left or lower right quadrant. This flexibility provides some options when planning an operational labeling scheme.

4.1.5.3 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, **FOR AUTOLOGOUS USE ONLY** is printed at the bottom of the quadrant (*see* illustrations in Section 5) (*see* also Section 4.1.5.5).

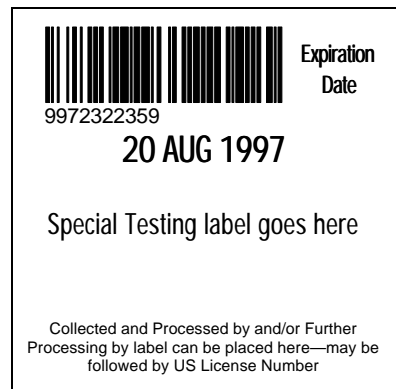
If the unit is designated for a specific recipient, **FOR DESIGNATED RECIPIENT ONLY** is printed at the bottom of the quadrant (*see* illustrations in Section 5) (*see* also Section 4.1.5.5).



In either of these two cases, the ABO/Rh label text should be very different (*see* illustrations in Section 5). If, in either of these latter two cases the unit is biohazardous, the word **BIOHAZARD** and the biohazard symbol should also appear in this quadrant (*see* illustrations in Section 5) (*see* also Section 4.1.5.5). Release of such units should be a very rare occurrence, and they should not carry a US License Number.

4.1.5.4 Lower Right Quadrant

As previously noted, the Expiration Date (and Time) bar code and the bar code text are in the upper third of the quadrant. Label vendors should be advised to make label stock to cover this specific area no larger than 2" [50 mm] wide and 0.9" [23 mm] long if only this portion of the quadrant is being labeled. The label text Expiration Date/(Time) will be printed to the right of the bar code; the bar code text (*eg*, **01 JAN 1997 14:00**) will be printed below the bar code. The standard representation of date



and time for the US will be DD MMM YYYY. The local time (if other than 23:59) will be printed in 24-hour format (with a colon). As previously noted, if the expiration time is coded as 23:59, no bar code text relating to time should appear.

Special Testing information (if this optional bar code is used) will be printed in the middle third of this quadrant. This information may extend into the lower third of the quadrant if the Collected/Processed by or US License Number information is not printed in this space.

4.1.5.5 Autologous Collections and Units Designated for a Specific Recipient: Additional Requirement for an Intended Recipient Label

The identification of the intended recipient of an autologous collection or a unit designated for a specific recipient may appear either on a label on the container or on a tie tag if the container is too small to accommodate a label. A label having the dimensions of no less than 2.5" [64 mm] wide by 1" [25 mm] long should be applied to most blood product containers and should not cover any other labeling. The label should have printed on it **Intended Recipient Information**. The remainder of the label should be arranged so that space is provided for the patient's name, identification (*eg*, medical record) number and birth date, the name of the hospital and other information as shown in the illustration in Section 5, Page 17.

4.1.6 Biohazard Label and "Red" Proper Names

The FDA has permitted the biohazard label to be black on white. This will facilitate the use of on-demand printing for users who wish to print this symbol as part of the ABO/Rh label. This does not preclude the use of the familiar orange biohazard label for those who choose to continue to use it.

As a reminder, the FDA has permitted the proper name of the blood product to be printed in a color other than red. Again, this facilitates the use of on-demand printed labels. [Until such time the wording in 21 CFR 606.121 is changed, approval of a variance should be requested from the FDA by facilities wishing to eliminate the use of red proper names].

Because of the widespread use of on-demand printing, it is preferable that all labels on a blood container be black and white only.

4.2 Process Control in Labeling

The phrase "Process Control" is not used, at least in the blood banking "industry," to mean the

originally accepted concept. Process control meant measurement: the identification of “measurable” critical points in a process and, as the process was improved, re-measurement to determine if the expected improvement did, in fact, occur. As the concept has evolved, the terms process improvement or process re-engineering seem to be becoming the favored phrases.

Process control in blood banking has come to mean the employment of specific checks within each defined process that give some assurance that the process is “in control.” Process control thus becomes another facet of quality assurance. It is to accommodate this diminished concept of process control that *ISBT 128* has been designed.

It is not the expectation of those that have worked so long and hard to produce *ISBT 128* that everyone will implement all the possible quality checks possible in the system. Some may be phased in over time; for example, the flag characters in the Donation Identification Number data structure. If used in a well-designed operating procedure supported by the appropriate software, flag characters can ensure that all numbers in a Donation Number Identification set are used as intended. Once affixed, the numbers can be tracked and used to ensure that each labeled item is properly processed and accounted for.

For example, one idea proposed for flag characters is dynamic assignment. In this scheme, the numbers in a Donation Identification Number set would each have different flag characters. After initial labeling, such as at collection, the numbers are scanned and the flag character associated with a specific labeled entity—primary collection container, satellite container(s), donor registration card, test tubes for collection samples for blood grouping and viral testing, *etc.* Once assigned and associated the numbers can then be tracked throughout the entire manufacturing process to ensure that the appropriate item is being scanned at any given point in the process. It would be possible, for instance, if a “red top” tube is flagged differently from a “purple top” tube, to ensure that those procedures requiring the use of serum rather than plasma use proper samples. Even further, if two sample tubes of the same type are flagged differently, then those operating procedures requiring that confirmatory testing be done on a sample different from the original can be checked to assure that this did, in fact, occur.

Concatenation, discussed in the next section, is another powerful process control tool. In combination with the flag characters, it can make the labeling process practically foolproof, and if supported by well-constructed software, can monitor and report on any discrepancy and the reason it occurred. Using staff identification numbers and controlled access these reports can ensure that any variation from the standard operating procedure occurred with the correct approval, and indicate who sought and who gave that approval.

Keyboard entry, always a source of error, should be controlled using the check digit designed and incorporated into *ISBT 128* specifically for this purpose. Consideration should be given to counting the number of keyboard data entries and the reason keyboard entry was used. This then becomes true process control in that the problems requiring keyboard entry can be researched

and, as far as possible, eliminated. Problems with particular bar code readers, for instance, can be identified quickly using such a systematic approach. ICCBBA will be making available a *Quality Assurance Card* and *Test Tube Labels* that can be used for checking bar code readers periodically. These methods can also assist in training, ensuring that it is hardware and not technique that is the root of the difficulty.

This discussion is not intended to be exhaustive, but illustrative of the potential designed into *ISBT 128*. None of these quality (or process in current terminology) control steps are an integral part of the implementation of *ISBT 128*, but could become “best demonstrated practice” after successful implementation and dissemination.

4.3 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 Application Specification*. There is no US requirement that concatenation be used but, if it is, proper programming of the bar code reader is required to determine which bar codes are to be concatenated and the order of the concatenation.

The value of concatenation is the ability to check that two bar codes are attached to a single unit and are internally consistent. 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 unit. In designing *ISBT 128*, two pairs of bar codes were thought to be the most logical candidates for concatenation and these were placed in horizontal alignment for ease of reading. The first pair, the Donation Identification Number and the ABO/Rh Blood Groups bar codes, make sure 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 internally consistent, particularly as the product code can change in further manufacturing. No specific recommendation as to the use of concatenation in the US is made at this time, but each blood collection facility should seriously consider the use of this powerful tool for additional control of the labeling process.

Although these two pairs of bar codes were specifically designed with concatenation in mind, other pairs *can* be concatenated if desired, such as the Donation Identification Number and the Product Code bar codes. Again, each blood collection facility should consider their labeling SOP and whether concatenation can increase the security of their labeling protocol.

4.4 Labeling Pooled Blood Products

Pooling of blood products, usually **PLATELETS** and **CRYOPRECIPITATED AHF**, should conform to

AABB Standards; that is, they should be given a new Donation Identification Number, not use the Donation Identification Number of one of the units in the pool. If the pooled blood product is to leave the facility in which it is prepared it must be labeled with a Country/Collection Facility Identification Number to conform to the *ISBT 128* Donation Identification Number specification. The Donation Identification Numbers of the units that make up the pool should be in the records kept by the facility that prepares the pool; they are not required on the label: the number of units in the pool should appear, as illustrated in Section 4, Page 12.

4.5 Additional Labeling by the Transfusion Service

There is no specific CFR requirement for the application of labels bearing bar codes. A facility that has no need of such labels does not have to apply them if the blood product is to be used *only within their institution*. This also applies when already bar coded blood products are received from others and modified. Such modification to a blood product should be appropriately documented, and the label on the blood product should reflect the change, but a bar code is not required.

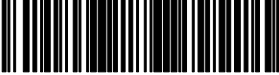
However, those transfusion services supported by sophisticated computer systems may wish to consider the use of bar coded labels for the following reasons.

On-demand label printers are now much cheaper than in the past, and the printing of any given label should become a relatively simple operation given the approach to *ISBT 128* label generation being developed by major vendors. Such on-demand printing systems provide great flexibility in labeling.

If only a few changes are made frequently at a given institution, then preprinted labels that include the necessary bar code might be a rational choice. For example, the pooling of **PLATELETS** and **CRYOPRECIPITATED AHF** are likely candidates. A preprinted label, such as that illustrated at the top of the next page (Section 4, Page 12), would have a blood product description complete with bar code and provide for the expiration date (and time) to be entered by hand. A bar coded expiration date (and time) will obviously require an on-demand printer, since it would be impossible to keep preprinted labels available for this purpose.

A hospital transfusion service that is supported by well-designed software and an on-demand printer can label and capture all modifications that are made to a blood product. This can then drive a billing system and, as computerization throughout the hospital expands, permit the tracking of all blood products, including those changed “in house,” once they leave the laboratory.

A hospital transfusion service that does not collect whole blood or apheresis units is assigned

 E0010V00 POOLED PLATELETS mL Number of units in pool _____ Store at 20 to 24 C	EXPIRATION DATE (AND TIME)
--	-----------------------------------

an identification number similar to the Country/Collection Facility Number for collecting facilities when they register with ICCBBA, and this number can be used for labeling pooled blood products, ensuring a uniquely identified blood product. Such numbers, in small quantities, can either be produced by an on-demand printer or purchased.

With respect to transfusion services that are also collection facilities similar thoughts can be applied with respect to the Donation Identification Number. Although all collections should carry an *ISBT 128*-specified number, the inclusion of the bar code is not necessary, again unless the blood product is to leave the institution.

Since many institutions would probably have such labels prepared in advance through a reliable label vendor, it makes sense for a computer-supported transfusion service to obtain such labels with the bar codes in place to utilize the obvious benefits of bar coding. Those institutions that collect very few units might find it more cost-effective to produce these with an on-demand printer, but would need to be certain that the software driving the printer does not permit the generation of duplicate labels, unless such duplicate labels (*eg*, for applying the donor registrations cards, test tubes, *etc*) is intentional.

5 Illustrations of US Labels

Because of the importance of the opening statement in the Preface (Section 1) it is repeated here:

*Please note that some proper names, with any appropriate modifiers and attributes, listed in this document are not those currently set forth in the Code of Federal Regulations (CFR). ISBT 128 was developed as an international standard, and presented to the FDA with the hope that it will be considered an acceptable bar code labeling system in the United States. Should the FDA make such a determination, the agency has expressed a willingness to initiate revision of the language in the Code of Federal Regulations to permit use of the proper names, with any appropriate modifiers and attributes, as used in the new system. Until this occurs, all manufacturers of blood products who wish to use the new bar coding system and the new proper names, with any appropriate modifiers and attributes, or print in black instead of color should seek FDA approval for an exception from 21 CFR 606.121(e)(1)(ii) and 21 CFR 606.121(d)(2) under 21 CFR 640.120, and **licensed establishments** should, in addition, submit copies of their ISBT 128 labels to the FDA for approval.*

NOTICE

Logos

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

5.1 Introduction

The examples given in this section are illustrations, **not** copies of actual labels. For examples of actual labels consult *ISBT 128: Accepted United States Labels — A Catalog*. Illustrations in this section are presented one to a page in Subsections 5.3, 5.4 and 5.5. In Subsection 5.6 there are often several examples of blood product description labels on each page. Together these illustrations demonstrate all facets of labeling under *ISBT 128* appropriate to the US. They are **not** meant to be an exhaustive compilation of all possible arrangements nor all possible blood

products. From these illustrations, using the US column in the *ISBT 128* Product Code database, and applying the principles and rules enunciated in Section 4, it should be possible to design any label not illustrated in this section.

Typefaces and sizes used in these illustrations are constrained by the word processor used to produce this document. 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, that is consistent with this document and that presents the required information in the best way possible concomitant with the goal of transfusion recipient safety.

5.2 Printing *ISBT 128* Product Code Label Text

Illustrations in this document are intended to demonstrate the following in this “rules-based system” (in addition to those in Section 4) for printing product code label text, that is, the description of the blood product. In the US, these system rules reflect certain requirements imposed by the FDA and are intended to present the needed information with as little abbreviation as possible given the constraints imposed by the increased height of the bar code and decreased available white space compared to labeling under *ABC Codabar*. There are some examples of these rules in practice later in this Section and in Appendices 1 through 3.

The rules are:

- ! The size of modifiers and attributes should be proportionally smaller than the proper name of the blood product **unless** otherwise specified in the CFR.
- ! Modifiers are to be printed on the line above the proper name **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.
- ! Attributes should be printed on the lines below the proper name, but again may be printed beginning immediately after the proper name if space considerations dictate. Size difference should be maintained. Whenever the volume is shown (____ mL) it must appear on the first attribute line.
- ! In general, modifiers and attributes should be applied in reverse of the order of the procedures

used. For example, units of **RED BLOOD CELLS** are rejuvenated before they are frozen, so the correct order for the modifiers is **FROZEN REJUVENATED**.

- ! Exceptions to these general rules are as follows:
 - ! intended use will always be the last attribute listed, be printed at the same size as other attributes but always begin on a new line to distinguish it clearly from other attributes;
 - ! additive solutions will be listed on the line immediately after the proper name;
 - ! of the other attributes, **IRRADIATED** will always be listed first and **DIVIDED** will always be last.

- ! Provided that small fonts are used, there is usually sufficient space that there need be no 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 Appendix 5. If there is no appropriate abbreviation in Appendix 5 for the particular blood product for which a label is being designed, 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 Appendix 5 and publish the revised Appendix.

5.2.1 Pooled Blood Products

Pooled blood products should be labeled using a unique Donation Identification Number. That is, they should not use the number associated with one of the blood products in the pool. The host computer software should associate the assigned number with each of the numbers belonging to the components in the pool. This practice is consistent with the design of *ISBT 128* that all blood products should be uniquely identified.

5.3 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. In addition to this labeling there are to be three bar codes placed as specified in the *ISBT 128 Application Specification and this document*. Two of these bar codes will identify the container manufacturer, the container catalog number—that specifies the container set (single, double, triple, *etc*)—and the lot number. The placing of these bar codes and the associated eye-readable information is extremely important. After capture of the bar coded information by the collecting and processing facility, these bar codes may be over-labeled. The third bar code that appears in the upper right quadrant specifies the information shown in Section 3 and Appendix 7 and is always over-labeled before a unit is released for transfusion.

Container manufacturers will work with the ICCBBA to ensure that these labels are properly

encoded and placed. Both bar codes are ten data characters long but may be padded or filled with zeros. 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. It is the user's responsibility to ensure that the computer software employed can interpret this information. The lot number, the second bar code, should be captured exactly as encoded. Only the interpretation of the second and third data characters of the first bar code, the identity of the container manufacturer, will be provided by the ICCBBA in the Container Manufacturer Identification Code listing (*see* Appendix 6).

Each blood product manufacturing facility should use software that can maintain the information provided by these three bar codes and design a protocol to ensure that it is captured at an appropriate stage of collection or processing. This information should be tied to the Donation Identification Number in the host computer database such that it can be archived and retrieved whenever a recall or other need to trace the information is initiated. Accurate encoding and placing of the information is the responsibility of the container manufacturer. Ability to be able to provide this information associated to a particular donation is the responsibility of the blood product manufacturer. Collection facilities that are not computerized (*eg*, small hospitals providing autologous collection services) should maintain this information in some other suitable format.

5.3.1 Listing of Illustrations

Page 5-5 Base Label:
Primary Container—
RED BLOOD CELLS
—not preprinted

Page 5-6 Base Label:
Primary Container—
RED BLOOD CELLS
—preprinted

Page 5-7 Base Label:
Satellite Container—
PLATELETS
—not preprinted

Page 5-8 Base Label:
Satellite Container—
PLATELETS
—preprinted







Base Label
Primary Container
RED BLOOD CELLS
—not preprinted

Notes:

The base label is the label applied to the empty container (prior to whole blood or apheresis collection) by the manufacturer.

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number—ABO/Rh Blood Groups and Product Code—Expiration Date (and Time) bar code pairs as they could interfere with concatenation.

Manufacturer may add horizontal lines to divide portions of the label if they wish (see Section 4, Page 6 for an illustration of their use in the upper left quadrant).

<p style="text-align: center;">PLACE DONATION IDENTIFICATION NUMBER HERE</p> <hr/> <p style="text-align: center;">Accurate Blood Center Anywhere, Worldwide</p> <p>FDA Registration Number _____ US License Number _____</p> <p style="text-align: center;">Properly Identify Intended Recipient <small>See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.</small></p> <p style="text-align: center;">L only VOLUNTEER DONOR</p>	<p style="text-align: center;">DO NOT TRANSFUSE UNLESS ABO LABEL APPLIED HERE</p> <p>ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION, USP</p>  <p style="text-align: center;">P53</p> <p><small>63 mL Anticoagulant Citrate Phosphate Dextrose Solution, USP for collection of 450 mL Whole Blood. Each 63 mL of anticoagulant contains 1.66 g Sodium Citrate (dihydrate) USP, 1.61 g Dextrose (monohydrate) USP, 1.88 mg Citric Acid (anhydrous) USP and 140 mg Monobasic Sodium Phosphate USP. pH may have been adjusted with Sodium Hydroxide</small></p> <p style="text-align: center;">CAUTION: Refer to instructions for use</p>
 <p style="text-align: center;">9972322359</p> <p>RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED</p> <p><small>From 450 mL CPD Whole Blood Store at 1 to 6 C</small></p> 	<p style="text-align: center;">Container Makers, Inc Somewhere, USA</p> 
1BA04R1424	0M96B28044

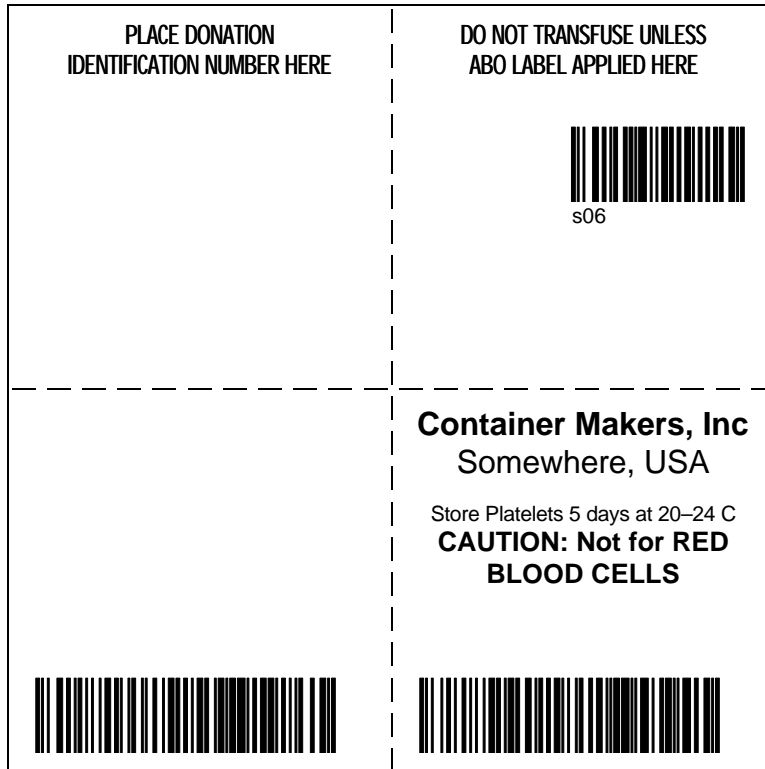
Base Label:
Primary Container—
RED BLOOD CELLS
—preprinted

Notes:

The base label is the label applied to the empty container (prior to whole blood or apheresis collection) by the manufacturer.

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number—ABO/Rh Blood Groups and Product Code—Expiration Date (and Time) bar code pairs as they could interfere with concatenation.

Manufacturer may add horizontal lines to divide portions of the label if they wish (see Section 4, Page 6 for an illustration of their use in the upper left quadrant).



Base Label
 Satellite Container—
PLATELETS
 —not preprinted


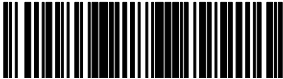


Notes:

The base label is the label applied to the empty container (prior to whole blood or apheresis collection) by the manufacturer.

Note that the left and right lower quadrant bar codes have no associated eye-readable information. These bar codes are for use by the collection and/or processing facility only, and may be over-labeled.

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number—ABO/Rh Blood Groups and Product Code—Expiration Date (and Time) bar code pairs as they could interfere with concatenation.

Manufacturer may add horizontal lines to divide portions of the label if they wish (see Section 4, Page 6 for an illustration of their use in the upper left quadrant).

<p style="text-align: center;">PLACE DONATION IDENTIFICATION NUMBER HERE</p> <hr/> <p style="text-align: center;">Accurate Blood Center Anywhere, Worldwide FDA Registration Number _____ US License Number _____</p> <p style="text-align: center;">Properly Identify Intended Recipient <small>See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.</small></p> <p style="text-align: center;">L only VOLUNTEER DONOR</p>	<p style="text-align: center;">DO NOT TRANSFUSE UNLESS ABO LABEL APPLIED HERE</p> <div style="text-align: center;">  s06 </div>
<div style="text-align: center;">  9972322359 </div> <p style="text-align: center;">PLATELETS</p> <p><small>Approx 45-65 mL From 450 mL CPD Whole Blood Store at 20 to 24 C</small></p> <div style="text-align: center;">  </div>	<p style="text-align: center;">Container Makers, Inc Somewhere, USA</p> <p style="text-align: center;">Store Platelets 5 days at 20–24 C CAUTION: Not for RED BLOOD CELLS</p> <div style="text-align: center;">  </div>

Base Label
Satellite Container—
PLATELETS
—preprinted

Notes:

The base label is the label applied to the empty container (prior to whole blood or apheresis collection) by the manufacturer.

Note that the left and right lower quadrant bar codes have no associated eye-readable information. These bar codes are for use by the collection and/or processing facility only, and may be over-labeled.

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number—ABO/Rh Blood Groups and Product Code—Expiration Date (and Time) bar code pairs as they could interfere with concatenation.





Manufacturer may add horizontal lines to divide portions of the label if they wish (see Section 4, Page 6 for an illustration of their use in the upper left quadrant).

5.4 Primary Container Labels

5.4.1 Listing of Illustrations

Page 5-10 Primary Container—
RED BLOOD CELLS
—not preprinted

Page 5-11 Primary Container—
RED BLOOD CELLS
—preprinted

 W1234 96 123456 $\frac{1}{4}$ S <hr/> Accurate Blood Center Anywhere, Worldwide FDA Registration Number _____ US License Number _____ <hr/> Properly Identify Intended Recipient <small>See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.</small> L only VOLUNTEER DONOR	 8400 <h1>AB</h1> Rh POSITIVE
 9972322359 RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED From 450 mL CPD Whole Blood Store at 1 to 6 C US License Number _____	 9972322359 Expiration Date 20 AUG 1997 Special Testing label goes here Collected and Processed by and/or Further Processing by label can be placed here—may be followed by US License Number
1BA04R1424	0M96B28044

Primary Container—
RED BLOOD CELLS
 —not preprinted







Notes:

This illustration represents a unit ready for release (statements indicating options, for example, “Collected and Processed” would obviously not be present). One alternative placement of the license number is illustrated.

The ¼” [6.4 mm] section projecting below the 4” [100 mm] wide by 4” [100 mm] long primary container label is the visible portion of the base label applied to the empty container (prior to whole blood or apheresis collection) by the manufacturer.

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number—ABO/Rh Blood Groups and Product Code—Expiration Date (and Time) bar code pairs as they could interfere with concatenation.

US License Number may appear in one of three positions as noted. It should only appear in one of these alternative positions.

 W1234 96 123456 $\frac{1}{4}$ S <hr/> Accurate Blood Center Anywhere, Worldwide FDA Registration Number _____ US License Number _____ <hr/> Properly Identify Intended Recipient <small>See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.</small> L only VOLUNTEER DONOR	 8400 <h1>AB</h1> Rh POSITIVE
 9972322359 RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED From 450 mL CPD Whole Blood Store at 1 to 6 C 	 Expiration Date 9972322359 20 AUG 1997 Special Testing label goes here 
1BA04R1424	0M96B28044

Primary Container—
RED BLOOD CELLS
 —preprinted

Notes:

This illustration represents a unit ready for release (statements indicating options, for example, “Collected and Processed ...,” would obviously not be present). One alternative placement of the license number is illustrated.

The 1/4” [6.4 mm] section projecting below the 4” [100 mm] wide by 4” [100 mm] long primary container label is the visible portion of the base label applied to the empty container (prior to whole blood or apheresis collection) by the manufacturer.

Manufacturer’s bar codes remain visible after final labeling when using preprinted base labels.



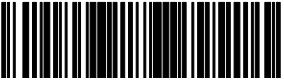

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number—ABO/Rh Blood Groups and Product Code—Expiration Date (and Time) bar code pairs as they could interfere with concatenation.

5.5 Satellite Container Labels

5.5.1 Listing of Illustrations

Page 5-13 Satellite Container—
PLATELETS
—not preprinted

Page 5-14 Satellite Container—
PLATELETS
—preprinted

 W1234 96 123456 $\frac{1}{4}$ S <hr/> Accurate Blood Center Anywhere, Worldwide FDA Registration Number _____ US License Number _____ <hr/> Properly Identify Intended Recipient <small>See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.</small> L only VOLUNTEER DONOR	 8400 <h1>AB</h1> Rh POSITIVE
 9972322359 PLATELETS Approx 45-65 mL From 450 mL CPD Whole Blood Store at 20 to 24 C US License Number _____	 9972322359 Expiration Date 20 AUG 1997 Special Testing label goes here Collected and Processed by and/or Further Processing by label can be placed here—may be followed by US License Number

Satellite Container—
PLATELETS
 —not preprinted

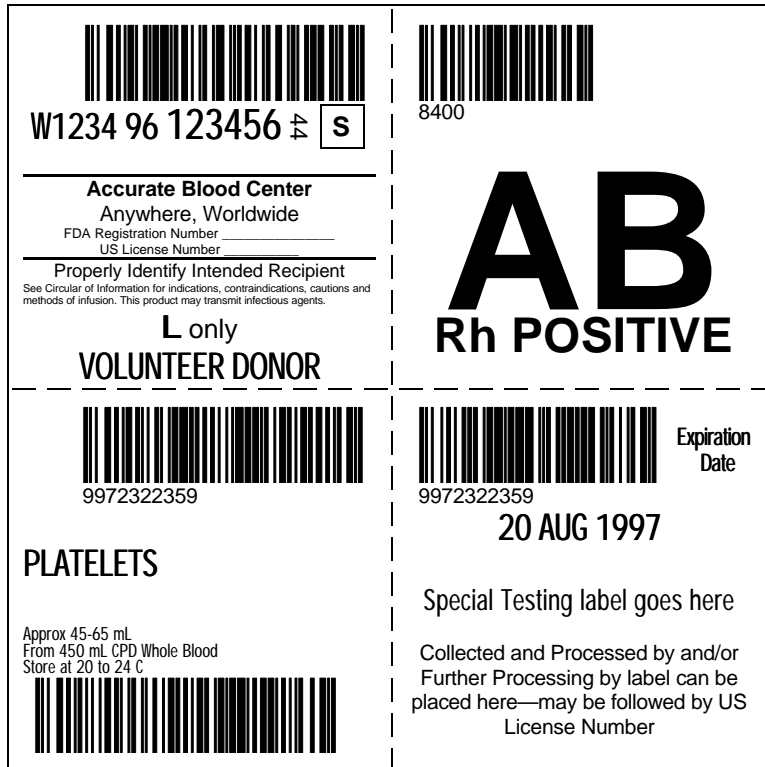
Notes:

This illustration represents a unit ready for release (statements indicating options, for example, “License information ...,” would obviously not be present).

Except for the lower left quadrant the label is the same as for a unit of **RED BLOOD CELLS**.

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number—ABO/Rh Blood Groups and Product Code—Expiration Date (and Time) bar code pairs as they could interfere with concatenation.

US License Number may appear in one of three positions as noted. It should only appear in one of these alternative positions.



Satellite Container—
PLATELETS
 —preprinted

Notes:

This illustration represents a unit ready for release.

Except for the lower left quadrant the label is the same as for a unit of **RED BLOOD CELLS**.

Note that the left lower quadrant bar code has no eye-readable information. As noted earlier, this bar code is for use by the collection and/or processing facility only. The manufacturer’s bar code in the right lower quadrant will usually be over-labeled; therefore, it does not appear in this illustration.

Dashed lines in these illustrations are for reference only. Manufacturer may add dashed lines to assist in label placement. No vertical lines should appear between Donation Identification Number/ABO Blood Groups and Product Code/Expiration Date(and Time) bar code pairs as they could interfere with concatenation.

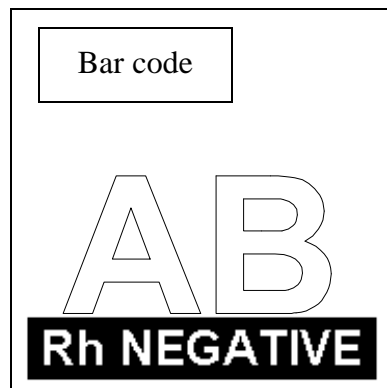
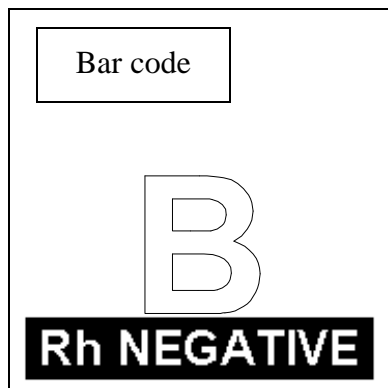
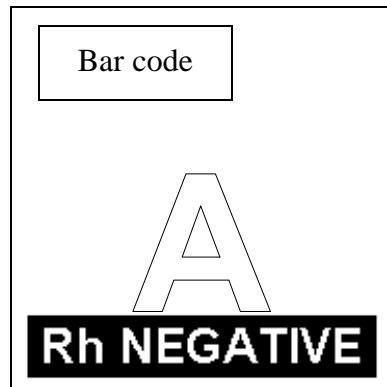
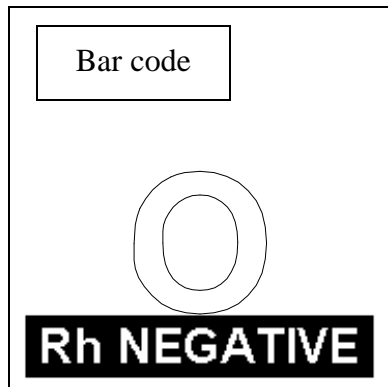
5.6 Other Labels

5.6.1 Listing of Illustrations

Page 5-16	Printing Rh Negative Labels
Page 5-17	Autologous Collection Labels
Page 5-17	Intended Recipient Information Label
Page 5-18	Directed, Designated and Dedicated: a Common Label
Page 5-19	Bombay and Para-Bombay Phenotypes
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	Whole Blood—CPD
	Red Blood Cells—CPDA-1
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	Washed Red Blood Cells
	Red Blood Cells—AS-1—Divided
	Red Blood Cells—AS-1—Irradiated
Page 5-21	Product Description Labels (continued)
	Red Blood Cells—AS-1—Irradiated, Leukocytes Reduced
	Red Blood Cells—AS-1—Irradiated, Leukocytes Reduced, Divided
	Red Blood Cells—AS-1—Low Volume (anticoagulant reduced)
	Red Blood Cells—AS-1—Low Volume (anticoagulant not reduced)
	Platelets
	Pooled Platelets
Page 5-22	Product Description Labels (continued)
	Apheresis Platelets
	Fresh Frozen Plasma
	Thawed Fresh Frozen Plasma
	Cryoprecipitated AHF
	Pooled Cryoprecipitated AHF
	Thawed Pooled Cryoprecipitated AHF—Irradiated
Page 5-23	Product Description Labels (continued)
	Deglycerolized Red Blood Cells—Irradiated, Plasma Added
	Red Blood Cells—Plasma Added after Supernatant Removed
	Recovered Plasma—Frozen Within 24 Hours after Phlebotomy—Caution: For Further Manufacturing Use Only
Page 5-24	Therapeutic Collection Labels
Page 5-25	Examples of Source Plasma Labels

Printing Rh Negative Labels


Rh negative labels should be printed as they were in *ABC Codabar*, that is, reversed from their Rh positive counterparts. Examples are presented below.



Autologous Collection Labels

<div style="border: 1px solid black; padding: 2px; text-align: center;">Bar code</div>	A Rh Positive
6400	
FOR AUTOLOGOUS USE ONLY	

For Autologous Use Only

<div style="border: 1px solid black; padding: 2px; text-align: center;">Bar code</div>	AB Rh Positive
8700	
 BIOHAZARD FOR AUTOLOGOUS USE ONLY	

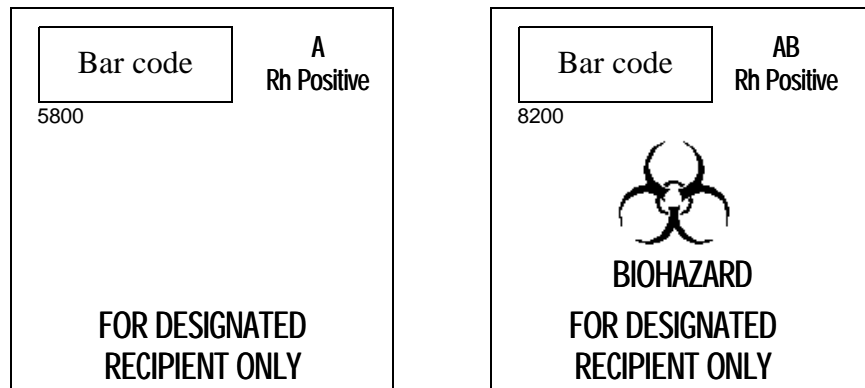
**For Autologous Use Only/
Biohazardous**

Intended Recipient Information Label

INTENDED RECIPIENT INFORMATION	
Patient _____	
WB ___ Irrad ___ ID Number _____	
RBC ___ LKORED ___ Hospital _____	
FFP ___ Other ___ Birth date ___/___/___ Collected ___/___/___	
PLT _____	AUTOLOGOUS/DIRECTED
CRYO ___ Blood relative : Yes ___ No ___	DESIGNATE/DEDICATED

The Intended Recipient Information Label should be placed on the front of the container, immediately above the Donation Information Number and ABO/Rh Blood Groups bar codes.

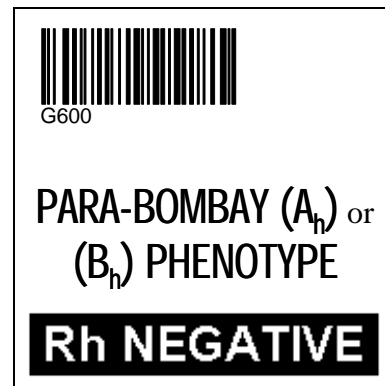
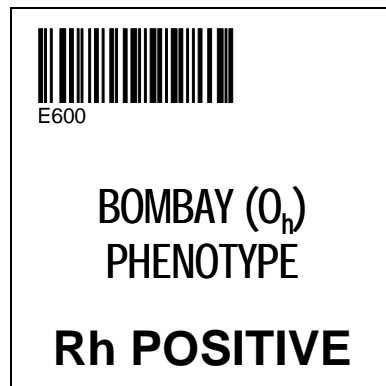
Directed, Designated and Dedicated: A Common Label



Note that (n-2) and (n-4) from Table 2 (Section 3, Page 11) are used in the ABO/Rh Blood Groups bar code for all directed, designated and dedicated donations that are intended for a specific recipient: the differentiation between directed, designated and dedicated is made in the Product Code bar code (*see* Section 3, Page 18).


Containers labeled as above should also bear an Intended Recipient Information label (*see* Section 5, Page 17).

Bombay and Para-Bombay Phenotypes



Note that the values E6 and H6 come from Table 2 (Section 3, Page 11).


Product Description Labels



E0010V00

WHOLE BLOOD

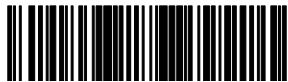
Approx 450 mL plus 63 mL CPD
Store at 1 to 6 C



E0010V00

RED BLOOD CELLS


From 450 mL CPDA-1 Whole Blood
Store at 1 to 6 C



E0010V00

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

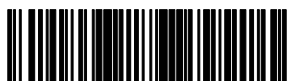
From 450 mL CPD Whole Blood
Store at 1 to 6 C



E0010V00

**WASHED
RED BLOOD CELLS**


From 450 mL Whole Blood
Store at 1 to 6 C



E0010V00

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

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




E0010V00

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


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

Product Description Labels (continued)


E0010V00

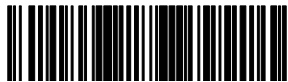
**RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED
IRRADIATED
LEUKOCYTES REDUCED**

From 450 mL CPD Whole Blood
Store at 1 to 6 C
Residual Leukocyte Content <math>< 5 \times 10^6</math>


E0010V00


**RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED
IRRADIATED
LEUKOCYTES REDUCED
DIVIDED**

_____ mL
From 450 mL CPD Whole Blood
Store at 1 to 6 C
Residual Leukocyte Content <math>< 5 \times 10^6</math>


E0010V00

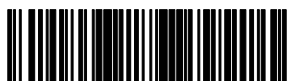
**RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED
LOW VOLUME**

Approx _____ mL plus _____ mL CPD plus
_____ mL Adenine-Saline (AS-1) Solution
Store at 1 to 6 C


E0010V00


**RED BLOOD CELLS
LOW VOLUME**

Approx _____ mL plus 63 mL CPD
Store at 1 to 6 C


E0010V00

PLATELETS

Approx 45-65 mL
From 450 mL CPD Whole Blood
Store at 20 to 24 C



E0010V00

POOLED PLATELETS

_____ mL
Number of units in pool _____
From CPD Whole Blood
Store at 20 to 24 C


Not a licensed product

Product Description Labels (continued)


E0010V00

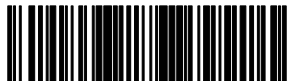
APHERESIS PLATELETS

_____ mL containing approx _____ mL ACD-A
Store at 20 to 24 C


E0010V00


FRESH FROZEN PLASMA

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


E0010V00

**THAWED
FRESH FROZEN PLASMA**

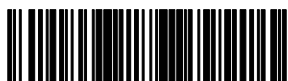
_____ mL from CPD Whole Blood
Store at 1 to 6 C


E0010V00

CRYOPRECIPITATED AHF


Store at -18 C or colder

Not a licensed product


E0010V00

**POOLED
CRYOPRECIPITATED AHF**

_____ mL
Number of units in pool _____
Store at -18 C or colder


E0010V00

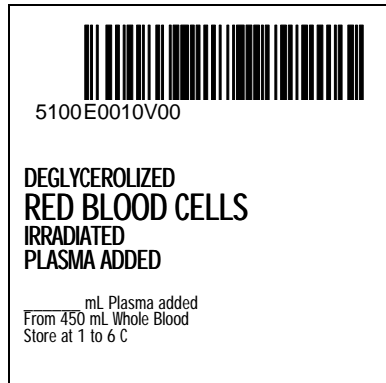
**THAWED POOLED
CRYOPRECIPITATED AHF
IRRADIATED**

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

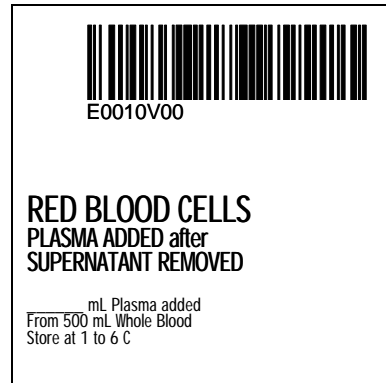
Not a licensed product

Not a licensed product

Product Description Labels (continued)



Not a licensed product

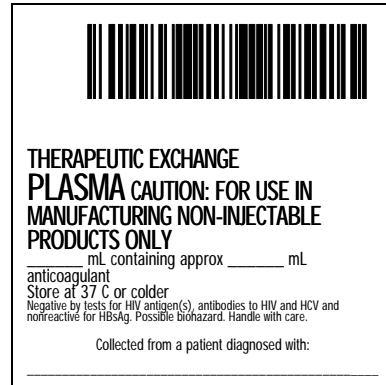


Not a licensed product

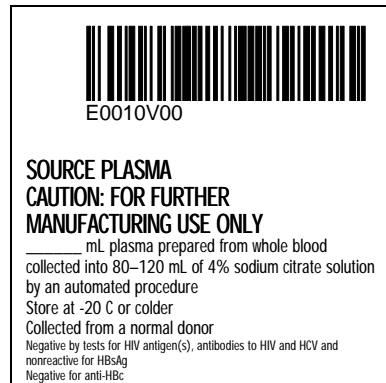
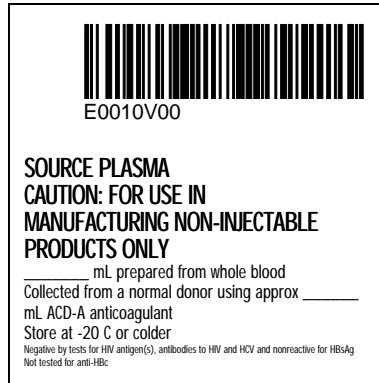


Not a licensed product

Therapeutic Collection Labels



Examples of Source Plasma Labels



Obviously, requirements for extensive information to be placed on these labels causes the *ISBT 128* labeling scheme to break down. These examples illustrate practical approaches to this problem.

Note that, at present, there are no label printing “rules” for **SOURCE PLASMA**, since each product has traditionally been labeled according to the intended use as determined by further manufacturing. This may change when the *Industry Consensus Standard for the Labeling of Source Plasma Using ISBT 128* is published.

6 ICCBBA Databases

6.1 Country/Collection Facility Identification Code

This database lists all collection facilities registered with ICCBBA. The US codes begin with “W.” Each four (4)-digit code then provides an index to the name and address of the collection facility, the responsible person, and telephone and facsimile numbers. Using this database, every registered collection facility world wide can be identified. These data provide ready access to pertinent information should there be a need to contact the supplier of a blood product.

6.2 Product Code

As noted in the Preface, the major description of the *ISBT 128* Product Code database can be found in the document *ISBT 128: Product Code Database—Structure and Definitions*. In Section 4 and Appendices 2 and 4 there is some expansion of the description given earlier of the Product Code data structure (Section 3, Page 13 *et seq*), including a general depiction of the rules-based system applied to the naming conventions and code assignments for *ISBT 128* product codes, and some examples of the system in practice. As noted in the *ISBT 128 Application Specification*, the official language used in defining *ISBT 128* is English, but even in countries in which English is the major language the naming of blood products is often specific to that country. In deriving names for each blood product coded in the *ISBT 128* Product Code database, the Working Party has endorsed a system that specifies core conditions, modifiers and attributes that is internally consistent. Each country may apply its desired names to all blood products, and in some countries (eg, Canada, Switzerland) two or more names are needed (English/French and French/German/Italian, respectively). It is the intent of the WPADP that a given blood product, described by the core conditions with any added modifiers and attributes should have the **same** product code regardless of the name or names applied by any particular country.

6.3 Container Manufacturer Identification Code

The Container Manufacturer Identification Code is a two (2)-character alphabetic code. Codes assigned when this document went to press are given in Appendix 6. Although the *ISBT 128 Specification* has a provisional listing of assignments for container manufacturers, **this** document lists manufacturers that have **registered** with ICCBBA and are authorized to use *ISBT 128*. ICCBBA will post additions to its Website and include them in periodic mailings to currently

registered facilities.

6.4 Special Testing Code

At the present time, a single code is recognized. “1” in the first position of this bar code signifies the unit has been tested and found CMV-antibody negative. There is no default at this time since the Special Testing bar code should not appear except when it is desired to label a unit as CMV-antibody negative. Whatever is in the remaining four data character positions has no current meaning and these characters should be ignored.

When this bar code is more fully developed, ICCBBA will release the database table(s) or other information that is necessary to interpret it. It is hoped that this bar code can eventually carry very complex information such as a complete red blood cell or HLA phenotype. The ICCBBA Technical Advisory Groups are currently working on these and other possibilities.

7 Other Publications to Consult

7.1 Published by ICCBBA, Inc

ISBT 128: Bar Code Symbology and Application Specification for Labeling of Whole Blood and Blood Components, Version 1.2.0, September 1998.

ISBT 128: Product Code Database—Structure and Definitions, Version 1.1.0, May 1999.

ISBT 128: Country/Collection Facility Database—Structure and Definitions, Version 1.0.0 (in press).

ISBT 128: Approved United States Labels—A Catalog, Version 1.0.0 (in press).

Note: All ICCBBA publications are sent to registered software developers, manufacturers and collection facilities upon publication; there is no need to request them unless you need additional copies. Registered hospital transfusion services are given the option of receiving technical documents, since these are often of little benefit, but these facilities will also receive all other ICCBBA publications.

An Introduction to ISBT 128—A non-technical booklet useful for teaching.

An Introduction to Bar Coding—A non-technical booklet useful for teaching.

Technical Bulletin 1: Why Code 128? The Rationale Behind ISBT 128. March 1997.

Technical Bulletin 2: Secure On-Demand ISBT 128 Blood Container Label Printing. March 1997.

Technical Bulletin 3: On-Demand and Preprinted Labels: A Discussion and Bar Code Quality and Label Verification. April 1997.

Technical Bulletin 4: ISBT 128 Blood Product Coding, April 1998 (currently being revised).

Technical Bulletin 5: Bar Code Scanner Implementation of ISBT 128 Concatenation (in press).

7.2 Published by Others

American National Standard for Information Systems—Bar Code Print Quality—Guideline (ANSI X3.182-1990). American National Standards Institute, 1430 Broadway, New York, NY 10018.

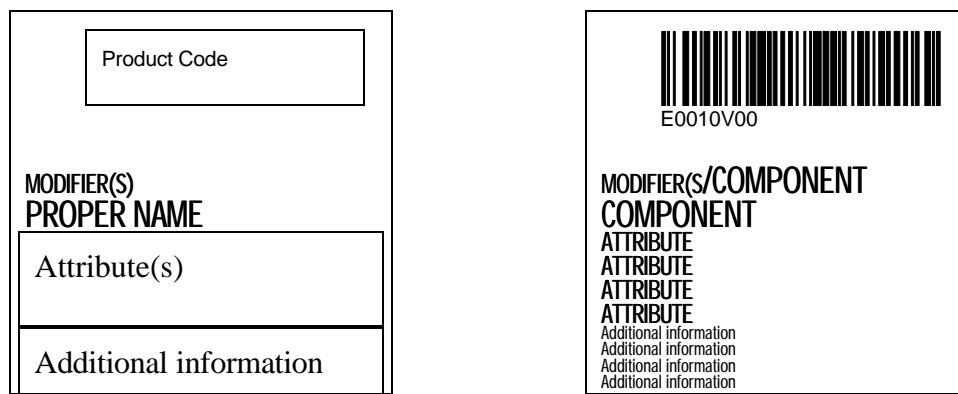
Guideline for the Uniform Labeling of Blood and Blood Components. Published by the Food and Drug Administration, Center for Drugs and Biologics, Office of Biologics Research and Review, in cooperation with the American Blood Commission, August 1985.

Guidelines for the Uniform Labeling of Blood and Blood Components (Draft: August, 1989). Prepared by American Association of Blood Banks, American Red Cross & Council of Community Blood Centers in cooperation with American Blood Commission & Food and Drug Administration Center for Biologics Evaluation and Research. Printed by Computype, Inc., St. Paul, Minnesota.

Appendix 1 Printing *ISBT 128* Blood Product Description Labels

This appendix provides generalized instructions for printing *ISBT 128* blood product description labels for the most common blood products. Appendices 2 and 3 give US labeling instructions for blood product proper names (Component Classes), modifiers and attributes. Appendix 4 provides instructions for labeling when the sixth position in the product code is used to indicate type of donation or collection/intended use. Appendix 5 lists acceptable abbreviations for label text. All other information for printing blood product description labels is provided below.

In general, the position of the bar code, the eye-readable representation of the data characters in the bar code and the proper name are fixed. Modifiers, attributes and additional information are placed in their proper relationship to the proper name.



As can be seen from the two illustrations above, this standard placing permits a maximum of four (4) lines for attributes, and four (4) lines for additional information. It is recommended that the fourth attribute and additional information lines only be used if absolutely necessary, using the placement illustrated in the diagram to the left, above, to provide an uncluttered appearance. All illustrations in Section 5 conform to this placement scheme. Note that if the US License Number is placed in the quadrant, as permitted and illustrated in Section 5, it will use one of the lines in the available for attributes or additional information.

The bar code is right justified, and placed approximately 0.1 inch [2.5 mm] from the top edge and 0.15 inch [3.8 mm] from the right edge of the label as shown. The eye-readable data are printed below the bar code, left-justified and aligned with the left edge of the bar code. The font should be *sans serif* and not less than 0.08" [2 mm].

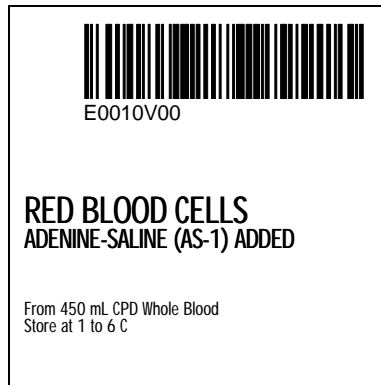
The proper name should be placed somewhat above the middle of the label, as shown, and left justified. The size of the proper name should be as large as possible (maximum height 5/32" [4 mm]), remembering that some label information in other quadrants must be no less prominent than the proper name. A 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.

The only exception to this standard positioning scheme, *viz*:

MODIFIER(S)
PROPER NAME (COMPONENT CLASS)
 ATTRIBUTE(S)

is for **RED BLOOD CELLS** containing an additive. In this case the standard format is modified as follows:

MODIFIER(S)
PROPER NAME (COMPONENT CLASS)
 ADDITIVE SOLUTION
 ATTRIBUTE(S)



If the anticoagulant has been essentially removed from the product (**WASHED, SUPERNATANT REMOVED**) then any reference to the anticoagulant should be eliminated when indicating that the product was prepared from a Whole Blood collection.

Note that label manufacturers that are able to print statements in the additional information section of the label “right justified” may do so, thus combining two statements on a single line and saving considerable space, *provided* that the reading of the statements is not compromised and that the general order of the statements is not changed.

Other information to be included on Product Code Description labels that is not covered in Appendices 2 through 5 is presented in the table beginning on Page 4 of this Appendix.

This general labeling scheme is modified slightly to accommodate the manufacturer's bar code that appears in the left lower quadrant on preprinted base labels. The additional information section should be moved up in this particular case, leaving the remainder of the items in the same position . Since this is only for preprinted base labels it does not affect labels applied by blood centers or transfusion services, whether preprinted or produced on-demand. Base labels are illustrated in Section 5.

SOURCE PLASMA labels are a special case. They often need to be modified because of the large amount of information they must contain. Some *example* labels are shown in Section 5, but it is expected that a standard specifically devoted to Source Plasma will be available soon.

Blood Product	Print “what”	Print “where” (all left justified, but see note on Page 2)
Whole Blood, 450 mL collection	Approx 450 mL plus 63 mL [anticoagulant] Store at 1 to 6 C	On the first line of the “additional information” section On the second line of the “additional information” section
Whole Blood, 500 mL collection	Approx 500 mL plus 70 mL [anticoagulant] Store at 1 to 6 C	On the first line of the “additional information” section On the second line of the “additional information” section
Red Blood Cells, 450 mL collection	From 450 mL [anticoagulant] Whole Blood Store at 1 to 6 C	On the first line of the “additional information” section On the first line of the “additional information” section
Red Blood Cells, 500 mL collection	From 500 mL [anticoagulant] Whole Blood Store at 1 to 6 C	On the first line of the “additional information” section On the first line of the “additional information” section
Red Blood Cells with AS-1 additive, 450 mL collection	ADENINE-SALINE (AS-1) ADDED From 450 mL CPD Whole Blood Store at 1 to 6 C	Immediately below proper name On the first line of the “additional information” section On the second line of the “additional information” section
Red Blood Cells with AS-3 additive, 450 mL collection	ADENINE-SALINE (AS-3) ADDED From 450 mL CP2D Whole Blood Store at 1 to 6 C	Immediately below proper name On the first line of the “additional information” section On the second line of the “additional information” section
Red Blood Cells with AS-5 additive, 450 mL collection	ADENINE-SALINE (AS-5) ADDED From 450 mL CPD Whole Blood Store at 1 to 6 C	Immediately below proper name On the first line of the “additional information” section, left On the second line of the “additional information” section

Blood Product	Print “what”	Print “where” (all left justified, but see note on Page 2)
Red Blood Cells with AS-1 additive, 500 mL collection	ADENINE-SALINE (AS-1) ADDED From 500 mL CPD Whole Blood Store at 1 to 6 C	Immediately below proper name On the first line of the “additional information” section On the second line of the “additional information” section
Red Blood Cells with AS-3 additive, 500 mL collection	ADENINE-SALINE (AS-3) ADDED From 500 mL CP2D Whole Blood Store at 1 to 6 C	Immediately below proper name On the first line of the “additional information” section On the second line of the “additional information” section
Red Blood Cells with AS-5 additive, 500 mL collection	ADENINE-SALINE (AS-5) ADDED From 500 mL CPD Whole Blood Store at 1 to 6 C	Immediately below proper name On the first line of the “additional information” section On the second line of the “additional information” section
Washed, Frozen, Rejuvenated and Deglycerolized Red Blood Cells, 450 mL and 500 mL collections	From [mL] Whole Bloo Store at 1 to 6 C or -65 C or colder	On the first line of the “additional information” section; <i>note: no anticoagulant specified</i> On the second line of the “additional information” section
Fresh Frozen Plasma	____ mL from [anticoagulant] Whole Blood Store at -18 C or colde	On the first line of the “additional information” section On the second line of the “additional information” section
Fresh Frozen Plasma	____ mL from [anticoagulant] Whole Blood Store at -65 C or colder	On the first line of the “additional information” section On the second line of the “additional information” section
Thawed Fresh Frozen Plasma, if relabeled	____ mL from [anticoagulant] Whole Blood Store at 1 to 6 C	On the first line of the “additional information” section On the second line of the “additional information” section

Blood Product	Print “what”	Print “where” (all left justified, but see note on Page 2)
Thawed Fresh Frozen Plasma, if relabeled	____ mL from [anticoagulant] Whole Blood Store at 1 to 6 C	On the first line of the “additional information” section On the second line of the “additional information” section
Cryoprecipitated AHF	Store at -18 C or colder	On the first line of the “additional information” section
Thawed Cryoprecipitated AHF, if relabeled	Store at room temperature	On the first line of the “additional information” section
Pooled Cryoprecipitated AHF, if frozen	____ mL Number of units in pool ____ Store at -18 C or colder	On the first line of the “additional information” section On the second line of the “additional information” section On the third line of the “additional information” section
Pooled Cryoprecipitated AHF, if thawed	____ mL Number of units in pool ____ Store at room temperature	On the first line of the “additional information” section On the second line of the “additional information” section On the third line of the “additional information” section
Platelets, 450 mL collection	Approx 45–65 mL From 450 mL [anticoagulant] Whole Blood Store at 20 to 24 C	On the first line of the “additional information” section On the second line of the “additional information” section On the third line of the “additional information” section
Platelets, 500 mL collection	Approx 45–65 mL From 500 mL [anticoagulant] Whole Blood Store at 20 to 24 C	On the first line of the “additional information” section On the second line of the “additional information” section On the third line of the “additional information” section

Blood Product	Print “what”	Print “where” (all left justified, but see note on Page 2)
Pooled Platelets	_____ mL Number of units in pool _____ From [anticoagulant] Whole Blood Store at 20 to 24 C	On the first line of the “additional information” section, left On the second line of the “additional information” section On the third line of the “additional information” section On the fourth line of the “additional information” section
Apheresis Red Blood Cells	_____ mL containing approx _____ mL [anticoagulant] Store at 1 to 6 C	On the first line of the “additional information” section On the second line of the “additional information” section
Apheresis Platelets	_____ mL containing approx _____ mL [anticoagulant] Store at 20 to 24 C	On the first line of the “additional information” section On the second line of the “additional information” section
Apheresis Fresh Frozen Plasma	_____ mL containing approx _____ mL [anticoagulant] Store at -18 C or colder	On the first line of the “additional information” section On the second line of the “additional information” section
Apheresis Cryoprecipitated AHF*	Prepared from _____ mL Plasma Store at -65 C or colder	On the first line of the “additional information” section On the second line of the “additional information” section

* Currently, the FDA has not cleared any equipment for manufacturing this product in the US

For thawed apheresis products, if relabeled, use statements similar to those given for products made from Whole Blood.

For additional Autologous Collection and Directed, Designated and Dedicated Donation labeling *see* Section 5.

For Source Plasma labeling *see* Section 5.

For other, less common blood products *see* Section 5 or “*ISBT 128: Accepted United States Labels—A Catalog.*”

For additions and updates *see* the ICCBBA Website (<http://www.iccbba.com>).

Appendix 2 *ISBT 128* Component Classes and Modifiers

The proper name of the blood product on the label will be printed as follows:

MODIFIER
COMPONENT CLASS
 unless exceptions are noted.

<i>ISBT 128</i> Modifier(s)	<i>ISBT 128</i> Component Class	US Labeling—Standardized Printing of 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
	FRESH FROZEN PLASMA	FRESH FROZEN PLASMA If the product is to be used for further manufacturing, it will be named: RECOVERED PLASMA

ISBT 128 Modifier(s)	ISBT 128 Component Class	US Labeling—Standardized Printing of Proper Name
THAWED	FRESH FROZEN PLASMA	THAWED FRESH FROZEN PLASMA If the product is to be used for further manufacturing, it will be named: RECOVERED PLASMA
	APHERESIS FRESH FROZEN PLASMA	APHERESIS FRESH FROZEN PLASMA If the product is to be used for further manufacturing, it will be named: SOURCE PLASMA
THAWED	APHERESIS FRESH FROZEN PLASMA	THAWED APHERESIS FRESH FROZEN PLASMA If the product is to be used for further manufacturing, it will be named: RECOVERED PLASMA
	APHERESIS PLASMA	APHERESIS PLASMA If the product is to be used for further manufacturing, it will be named: SOURCE PLASMA
THAWED	APHERESIS PLASMA	THAWED APHERESIS PLASMA If the product is to be used for further manufacturing, it will be named: RECOVERED PLASMA
LIQUID	APHERESIS PLASMA	LIQUID APHERESIS PLASMA
	PLASMA	PLASMA
THAWED	PLASMA	THAWED PLASMA

ISBT 128 Modifier(s)	ISBT 128 Component Class	US Labeling—Standardized Printing of Proper Name
LIQUID	PLASMA	LIQUID PLASMA
	PLATELET RICH PLASMA	PLATELET RICH 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
	CRYOPRECIPITATE	CRYOPRECIPITATED AHF
THAWED	CRYOPRECIPITATE	THAWED CRYOPRECIPITATED AHF
THAWED	CRYOPRECIPITATE	THAWED CRYOPRECIPITATED AHF
	POOLED CRYOPRECIPITATE	POOLED CRYOPRECIPITATED AHF
THAWED	POOLED CRYOPRECIPITATE	THAWED POOLED CRYOPRECIPITATED AHF
	APHERESIS CRYOPRECIPITATE	APHERESIS CRYOPRECIPITATED AHF
THAWED	APHERESIS CRYOPRECIPITATE	THAWED APHERESIS CRYOPRECIPITATED AHF
	GRANULOCYTES	GRANULOCYTES
	APHERESIS GRANULOCYTES	APHERESIS GRANULOCYTES

<i>ISBT 128</i> Modifier(s)	<i>ISBT 128</i> Component Class	US Labeling—Standardized Printing of Proper Name
	POOLED GRANULOCYTES	POOLED GRANULOCYTES
	APHERESIS GRANULOCYTES/PLATELETS	APHR GRANULOCYTES/ PLATELETS
	LEUKOCYTES	LEUKOCYTES
	APHERESIS LEUKOCYTES	APHERESIS LEUKOCYTES
	POOLED PLASMA	POOLED PLASMA

The following Component Classes, defined in the *ISBT 128* Product Code Database, are currently not used in the US: **PLATELET-RICH BUFFY COAT, APHERESIS LYMPHOCYTES, APHERESIS MONOCYTES, SERUM, POOLED SERUM** and **FROZEN POOLED SERUM**.

Appendix 3 *ISBT 128* Attribute Groups

Note: There are default values 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.

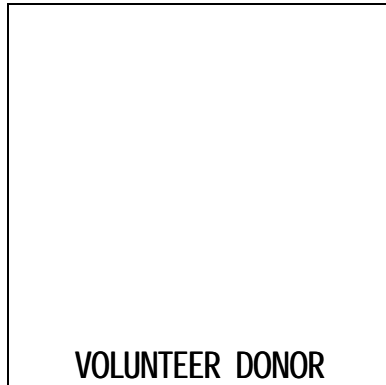
Attribute Group	<i>ISBT 128</i>	US Labeling Instructions
Core Conditions	Anticoagulant, additive if present Nominal volume of original collection Recommended storage temperature	Information associated with these variables will be printed in the “additional information” section of the lower left quadrant as required by the CFR Exceptions: ADENINE-SALINE (AS-1) ADDED or ADENINE-SALINE (AS-3) ADDED or ADENINE-SALINE (AS-5) ADDED will be printed in the “attribute” section (on the line following the proper name)
	For further manufacture—injectable	CAUTION: FOR FURTHER MANUFACTURING USE ONLY
	For further manufacture—non-injectable	CAUTION: FOR USE IN MANUFACTURING NON-INJECTABLE PRODUCTS ONLY
Intended Use	For further manufacture—non-injectable	CAUTION: FOR FURTHER MANUFACTURING INTO IN-VITRO DIAGNOSTIC REAGENTS FOR WHICH THERE ARE NO ALTERNATIVE SOURCES
	Not for transfusion or further manufacture	CAUTION: NOT FOR TRANSFUSION OR FURTHER MANUFACTURE
	For research	CAUTION: FOR LABORATORY RESEARCH ONLY
System Integrity		This information is reflected in the Expiration Date (and Time) of the product
Irradiated		IRRADIATED will be printed below the proper name in the “attribute” section No abbreviation is permitted

Attribute Group	ISBT 128	US Labeling Instructions
Residual Leukocyte Content	Residual Leukocyte Content $<5 \times 10^6$ For PLATELETS prepared from WHOLE BLOOD Residual Leukocyte Content $<8.3 \times 10^6$	<p>LEUKOCYTES REDUCED will be printed below the proper name in the “attribute” section</p> <p>The residual leukocyte content may be printed in the “additional information” section as Residual Leukocyte Content $<5 \times 10^6$</p> <p>The residual leukocyte content may be printed in the “additional information” section as Residual Leukocyte Content $<8.3 \times 10^6$</p>
Altered	Albumin Added Cryoprecipitate Reduced Plasma Added Plasma Reduced Platelets Reduced Supernatant Removed Supernatant Removed/Plasma Added Platelets/Cryoprecipitate Reduced Supernatant Reduced	<p>Print below the proper name in the “attribute” section:</p> <p>ALBUMIN ADDED</p> <p>CRYOPRECIPITATE REDUCED</p> <p>PLASMA ADDED</p> <p>PLASMA REDUCED</p> <p>PLATELETS REDUCED</p> <p>SUPERNATANT REMOVED</p> <p>PLASMA ADDED after SUPERNATANT REMOVED</p> <p>PLATELETS and CRYOPRECIPITATE REDUCED</p> <p>SUPERNATANT REDUCED</p>

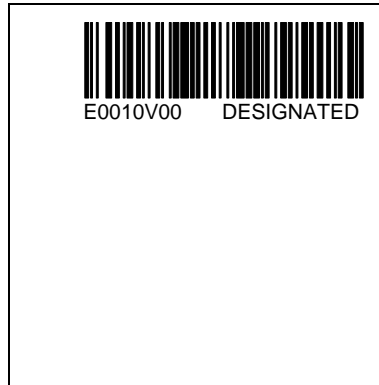
Attribute Group	<i>ISBT 128</i>	US Labeling Instructions
Final Content	<p>Low Volume</p> <p>Final Content <200 mL</p> <p>Final Content ≥200 mL <400 mL</p> <p>Final Content ≥400 mL <600 mL</p> <p>Final Content ≥600 mL</p>	<p>LOW VOLUME will be printed below the proper name in the “attribute” section</p> <p>Note that there are two possibilities for low volume units, “anticoagulant adjusted” and “anticoagulant not adjusted.” Approx ____ mL plus ____ mL [anticoagulant] should appear on the first line of the “additional information” section providing volumes as appropriate</p> <p>Actual volume is to be printed as ____ mL in the “Additional information” section</p>
Preparation: Additional Information	<p>Plasma Frozen ≤15 hours</p> <p>Plasma Frozen ≤24 hours</p> <p>Plasma Frozen >24 hours</p> <p>Granulocytes prepared using HES</p>	<p>Print below the proper name in the “attribute” section</p> <p>FROZEN WITHIN 15 HOURS AFTER PHLEBOTOMY</p> <p>FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY</p> <p>FROZEN MORE THAN 24 HOURS AFTER PHLEBOTOMY</p> <p>Information is to be included in the “addition information” section together with any anticoagulant present</p>

Attribute Group	<i>ISBT 128</i>	US Labeling Instructions
Apheresis: Additional Information	1st Container, 2nd Container, <i>etc</i> Apheresis not automated	No additional information on the label These products are “Single Product Equivalent” Prepared by a manual procedure will be printed in the “additional information” section
Quarantine: Additional Information		Not used in the US at this time
Pools: Additional Information		Not used in the US at this time
Method of Treatment		Not used in the US at this time

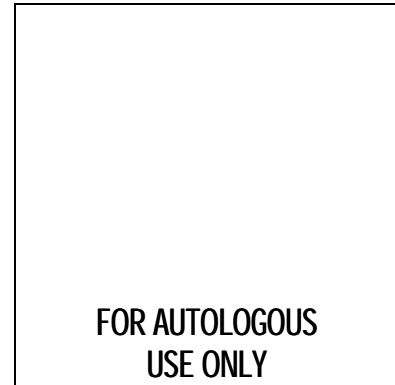
Appendix 4 Labeling Instructions for Donation Type (Sixth Position in the Product Code Bar Code)



Upper Left Quadrant



Lower Left Quadrant



Upper Right Quadrant

The diagrams above are intended to assist in visualizing the labeling instructions given in the table that follows. Additional illustrations can be found in Section 5.

Sixth Data Character	Type of Donation	Upper Left Quadrant [in no less prominence than product name]	Lower Left Quadrant	Upper Right Quadrant [in no less prominence than product name]
0 (zero) [default]	Not specified in product code	VOLUNTEER DONOR		
1(one)	Autologous collection—for autologous use only	VOLUNTEER DONOR	AUTOLOGOUS	FOR AUTOLOGOUS USE ONLY (see Section 4 for additional requirements)
X	Autologous collection —for autologous use only—biohazardous	VOLUNTEER DONOR	AUTOLOGOUS	FOR AUTOLOGOUS USE ONLY BIOHAZARD and a biohazard symbol
V	Voluntary allogeneic	VOLUNTEER DONOR		
D	Directed voluntary allogeneic—eligible for crossover	VOLUNTEER DONOR	DIRECTED	
d	Directed paid allogeneic— eligible for crossover	PAID DONOR	DIRECTED	
P	Paid allogeneic	PAID DONOR		
2 (two)	Directed voluntary allogeneic—for directed donor use only	VOLUNTEER DONOR	DIRECTED	FOR DESIGNATED RECIPIENT ONLY
L	Directed voluntary allogeneic—for directed donor use only—limited exposure	VOLUNTEER DONOR	DIRECTED	FOR DESIGNATED RECIPIENT ONLY

Sixth Data Character	Type of Donation	Upper Left Quadrant [in no less prominence than product name]	Lower Left Quadrant	Upper Right Quadrant [in no less prominence than product name]
3 (three)	Directed voluntary allogeneic—for directed donor use only—biohazardous	VOLUNTEER DONOR	DESIGNATED	FOR DESIGNATED RECIPIENT ONLY
4 (four)	Designated voluntary allogeneic	VOLUNTEER DONOR	DESIGNATED	FOR DESIGNATED RECIPIENT ONLY
5 (five)	Dedicated voluntary allogeneic	VOLUNTEER DONOR	DEDICATED	FOR DESIGNATED RECIPIENT ONLY
R	Voluntary research donor	VOLUNTEER DONOR	RESEARCH	
r	Paid research donor	PAID DONOR	RESEARCH	
S	Voluntary source donor	VOLUNTEER DONOR	SOURCE	
T	Voluntary therapeutic collection	VOLUNTEER DONOR	The disease of the patient from which the unit was collected must be specified	THERAPEUTIC COLLECTION

Appendix 5 Acceptable Abbreviations for Label Text

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)
CPD	Citrate Phosphate Dextrose
CPDA-1	Citrate Phosphate Dextrose Adenine Formula 1
CP2D	Citrate Phosphate Double Dextrose
g	gram(s)
h	hour(s)
mg	milligram(s)
mL	milliliter(s)
room temperature	room temp

Appendix 6 Container Manufacturer Identification Code

BA	Baxter—Fenwal Division
CO	Cobe BCT
FR	Fresenius
HA	Haemonetics
PA	Pall (Medsep)

Note: Only manufacturers that are registered with ICCBBA and licensed to use *ISBT 128* are listed.

Appendix 7 Container Information Data Structure

Interpretation of the First Data Character

Container in Set On Which Bar Code Is Placed	Character in First Position
Primary	P
Satellite	s
Transfer	t
Apheresis	A

Primary Container: Second Data Character—Anticoagulant

Anticoagulant	Character in Second Position
No anticoagulant (empty primary container)	0
Heparin	1
Acid Citrate Dextrose Formula A (ACD-A)	2
Acid Citrate Dextrose Formula B (ACD-B)	3
Reserved	4
Citrate Phosphate Dextrose (CPD)	5
Citrate Phosphate Dextrose Adenine Formula 1 (CPDA-1)	6
Not used	7
Citrate Phosphate Double Dextrose (CP2D)	8
Sodium Citrate	9

Primary Container: Third Data Character— Configuration of Container Set

Container Set	Character in Third Position
Reserved	0
Single plastic collection container	1
Double plastic collection set	2
Triple plastic collection set	3
Quadruple plastic collection set	4
Quintuple plastic collection set	5
Single 800 mL plastic collection container	6
Reserved	7-9

Satellite, Transfer and Apheresis Containers: Interpretation of the Second and Third Data Characters

Storage Restrictions for Red Blood Cells and Plasma Components	Container Capacity	Platelets (Days)	Characters in Second and Third Positions
Red Blood Cells limited dating Plasma maximum dating	300–400 mL	†	00
Red Blood Cells and Plasma maximum dating	300 mL	3	01
Red Blood Cells and Plasma maximum dating	400 mL	3	02
Red Blood Cells and Plasma maximum dating	Other than 300–400 mL	3	03
Red Blood Cells limited dating Plasma maximum dating	300–400 mL	5	04
Red Blood Cells prohibited Plasma maximum dating	300–400 mL	5	05
Red Blood Cells and Plasma maximum dating	300–400 mL	5	06
	Plasma Pooling Bottle		09
Red Blood Cells limited dating Plasma maximum dating	Other than 300–400 mL	5	10
Red Blood Cells prohibited Plasma maximum dating	Other than 300–400 mL	5	11
Red Blood Cells and Plasma maximum dating	Other than 300–400 mL	5	12
Red Blood Cells prohibited Plasma maximum dating	300–400 mL	†	17

† Storage of Platelets not permitted in this container