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

Version 2.0.0

November 2005

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Published by:
ICCBBA, Inc
204 St Charles Way, Unit 179E, York, PA 17402, USA
Telephone: +1 (717) 845-4790 Fax: +1 (717) 845-9797
E-mail: iccbba@iccbba.com Website: http://www.iccbba.com

Edited for publication by:

Pat Distler, MS, MT(ASCP)SBB

with the editorial assistance of:

Paul Ashford, CEng, MBCS, SRCS

Suzanne Butch, MA, MT(ASCP)SBB

Jørgen Georgsen, MD

Mario Muon, MD

Mike Stanton, MS, MT(ASCP)SBB

Edwin Steane, PhD

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Definitions for This Document

Attribute Information about the processing or other characteristics of a product beyond Class and Modifier.

Autologous Collection Blood collected from the intended recipient.

Base label The label applied by the manufacturer to: (1) primary and satellite containers for the collection of Whole Blood; (2) apheresis collection containers; and (3) transfer containers.

Collection (as used in Table 3, page 14)

- **Dedicated** A collection arranged by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products).
- **Designated** A unit collected from a donor called by the collecting facility to provide (a) product(s) to be used by a specific recipient in some future therapeutic procedure (for example, HLA-compatible).
- **Directed** A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide (a) product(s) to be used by that person in some future therapeutic procedure.

Class A general description of a product (such as Whole Blood, Red Blood Cells or Fresh Frozen Plasma)

Collection container: Any container that is part of an apheresis collection set intended for a blood product.

Collection label: Any labeling that is attached to an apheresis collection container.

Core conditions The anticoagulant and/or additive, nominal collection volume and storage temperature requirements for a blood component

Data characters The individual ASCII characters that make up the data content

Data content The characters in a data structure that encode the information for which the data structure is named. The data content does not include the data identifiers

Data identifier The first two characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined.

Final label: The label that appears on a blood product ready for release.

Flag character Part of the data content of a data structure used in process control or data transmission checking. Printed in eye-readable format, but distinguished in some manner from the representation of the other data characters.

Modifier A description that relates to the Core Conditions of a blood component and distinguishes it from other members of the same Class (such as Apheresis, Frozen, Frozen Rejuvenated or Washed)

Primary container: The container in which the anticoagulant is placed for Whole Blood collection.

Primary label: Any labeling that is attached to a Whole Blood primary container; *i.e.*, the container in which the anticoagulant is placed.

Satellite container: Any container, often empty, attached by the manufacturer to a primary container as part of a Whole Blood collection set intended to contain Platelets, Plasma, or Cryoprecipitated AHF.

Text (*see* illustration on Page x)

Eye-readable text The representation of the **data characters** in a bar code in letters or numbers (printed left justified immediately below the bar code, unless otherwise specified).

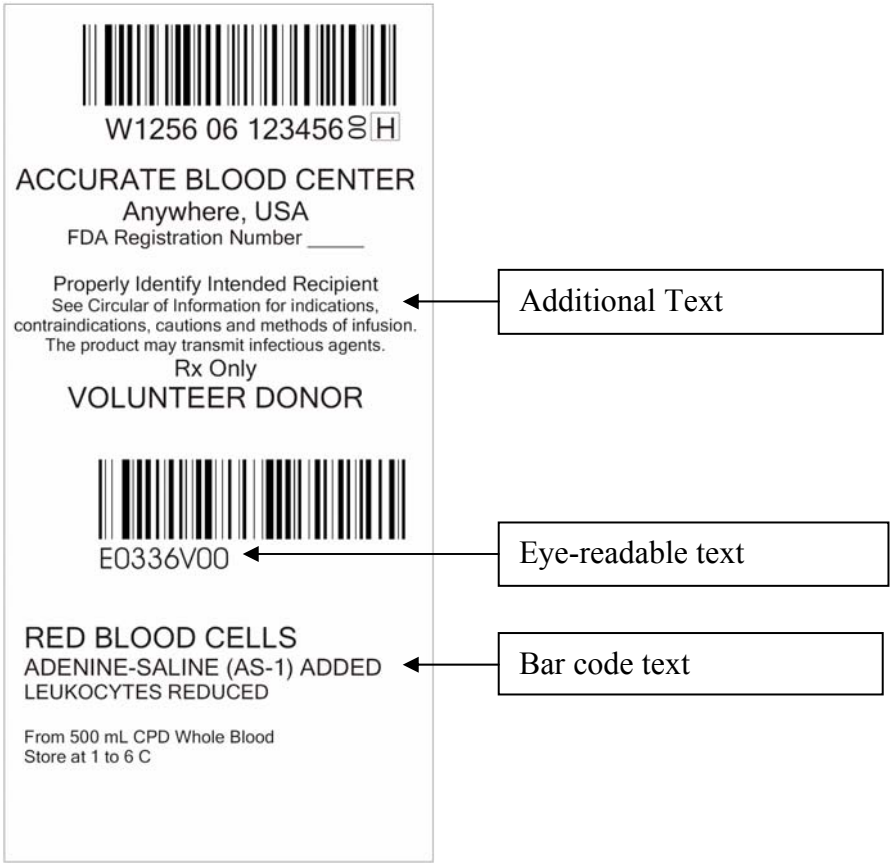
Bar code text The interpretation of the eye-readable text (the data content of the bar code) that generally requires a look-up table.

Additional label text All other information on the label that is not associated with a bar code.

Transfer container: Any container that is not an integral part of a Whole Blood or apheresis collection set intended for a blood product.

Note: No specifications are provided in this document for labeling transfer containers, or for satellite containers that are used for blood products other than Platelets, Plasma and Cryoprecipitated AHF, e.g., those used to contain pediatric doses of blood products. When consensus is reached for standardized labeling of these products, specifications will be included in future versions of this document. Until then, labeling of these containers should conform to the principles of ISBT 128 labeling.

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



Abbreviations and Acronyms

ABC	American Blood Commission
ABC Codabar	Bar code labeling specification based on CODABAR
ANSI	American National Standards Institute
ARC	American Red Cross
ASCII	American Standard Code for Information Exchange
ATAG	Americas Technical Advisory Group
CBER	Center for Biologics Evaluation and Research
CFR	Code of Federal Regulations
DoD	Department of Defense
FDA	United States Food and Drug Administration
ISBT	International Society of Blood Transfusion
ISBT 128	Information technology standard for transfusion medicine and transplantation
ISO	International Organization for Standardization
MEETAG	Middle East and Europe Technical Advisory Group
URL	Universal Resource Locator
US	United States
WPADP	Working Party on Automation and Data Processing
WWW	World Wide Web, Internet

Caution

The illustrations throughout this document are just that, illustrations; they are not "real," that is, accurate representations of *ISBT 128* labels. The illustrations are not necessarily to scale. Therefore, bar codes should be printed and positioned on labels according to the *ISBT 128 Standard: Technical Specification*.

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

1 Preface

Please note that some Proper Names [Component Name (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 United States Food and Drug Administration (FDA) in the hope that it would be considered an acceptable bar code labeling system in the United States. The FDA has made such a determination; however, the Proper Names in the Code of Federal Regulations do not match the *ISBT 128* Component Name (with any appropriate Modifiers and Attributes). Until a change is made in the regulations, all manufacturers of blood products who wish to use the new bar coding system and the new Proper Names (Component Name) [with any appropriate Modifiers and Attributes] should request a variance from the FDA from 21 CFR 606.121 (e)(1)(ii) under the provisions of 21 CFR 640.120., and **licensed** establishments should, in addition, submit copies of their *ISBT 128* labels **for licensed products** to the FDA for approval. Additionally, until these new regulations are finalized, the FDA registration number will continue to be required on the final label.

This document is intended to supersede the 1985 *Guideline for Uniform Labeling of Blood and Blood Components* and its unofficial 1989 revision for those who choose to use it. 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 Description 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, not a complete catalog. For a complete description of *ISBT 128* it is necessary to consult the *ISBT 128 Standard: Technical Specification* and supporting documents.

Other documents detailing specific issues not covered in depth in these documents may be made available from time to time as *Technical Bulletins* and *Technical Notes*, and they should be consulted by anyone implementing the standard.

These documents are produced and distributed by ICCBBA, Inc, and copies of these, and of all extensions and revisions, are made available on its Website to all firms registered with and licensed by ICCBBA, Inc. For single copy prices to individuals, *see* the listing *Currently Available from ICCBBA, Inc* that can be obtained from the ICCBBA, Inc office.

This document delineates the US (United States) specification for the use of *ISBT 128*. It is intended to provide the necessary information to facility managers for use in implementing *ISBT 128*, designing a labeling protocol, training staff and making decisions. It is also intended to be the source document through which vendors and software developers who supply US facilities can be certain their products meet the *ISBT 128* and US specifications.

There are several options outlined in the *ISBT 128 Standard: Technical 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 Americas Technical Advisory Group (ATAG) [ICCBBA, Inc]. Full details regarding the ATAG mandate and membership can be obtained through the ICCBBA, Inc office at the address on the front cover. ICCBBA, Inc 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 ATAG and many other topics: the URL 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, Inc documents and databases will be published through this Website.

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 versions. For registered and licensed facilities, these will be made available on the ICCBBA, Inc Website, where a listing of current versions will be maintained. Those who purchase documents for personal use should consult the ICCBBA, Inc Website at the address in the paragraph above from time to time to ensure that they have the latest revisions.

***ISBT 128* is not in the public domain**. It is copyrighted and otherwise protected by US law. Implementation of *ISBT 128* requires registration with ICCBBA, Inc 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 reading, storing, interpreting, transferring, printing or otherwise manipulating *ISBT 128* data structures. This money is used by ICCBBA, Inc to revise, enhance, extend and maintain the *ISBT 128* standard, including all associated databases. ICCBBA, Inc is a not-for-profit US federally-registered organization incorporated in the Commonwealth of Virginia. Information about ICCBBA, Inc can be obtained through the office at the location or email address listed on the front cover.

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 facilities engaged in transfusion medicine 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 transfusion medicine 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, *e.g.*, 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 primary, collection and satellite container labels;

- 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, fully participated in Working Party meetings. In addition, representatives from the FDA 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 draft 8.1 of 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 proposed by the 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 had 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 (now AdvaMed). 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 its associated databases. In March 1995, the Board of Directors established Bylaws and decided to incorporate ICCBBA as an independent entity.

ICCBBA, Inc previously submitted Version 1.2.0 of this document to the FDA and it was accepted as a satisfactory labeling standard. Machine-readable coding on all blood products was made mandatory by 21 CFR 606.121 (c) (13). FDA's Center for Biologics Evaluation and Research (CBER) took the step of requiring machine readable information, rather than specifically bar codes, to permit the use of new technologies under development that may prove more useful than bar codes in some situations. *ISBT 128*, and the coding described in this document, is designed to work with these new technologies, and specific "rules of use" will be published as soon as there is likely adoption. Version 2.0.0 updates the previously published and FDA-accepted version by incorporating recent additions to the *ISBT 128 Standard*, and by adding modifications, enhancements and additional illustrations requested by the industry and the FDA. It has been submitted to the FDA for approval as the documentation for the use of *ISBT 128* in the US, supplanting Version 1.2.0. The outcome of this submission will be publicized on the ICCBBA, Inc. Website.

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* bar code labeling is based on Code 128. Code 128 was chosen because:

- It is more secure than 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.

- Because 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 "auto discriminate" 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 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 Standard: Technical Application*. That document is the definitive source describing *ISBT 128* and should be consulted when implementing the system. The *ISBT 128 Standard: Technical Specification* can be obtained from ICCBBA, Inc and is provided to facilities that register with ICCBBA, Inc. Updates will be made available to facilities that maintain their registration through payment of an annual license fee. **What this document does is provide specific instructions for the US if there is flexibility or an option in the *ISBT 128 Standard: Technical Specification* and detail the display of those items required by the CFR on blood product container labels.**

These are headed **US Specification** following the general description of the data structure to which they apply, appear in Chapters 3 and 4 under the discussion of quadrant labeling specifics, or are illustrated in Chapter 5.

3.3 Summary of the *ISBT 128 Standard: Technical Specification*

The *ISBT 128 Standard: Technical Specification*:

- describes the layout for a blood product label;
- defines the data identifiers for bar codes used in the transfusion medicine environment;
- defines the data structures that carry information, *i.e.*, 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.”

3.4 *ISBT 128*-Specified Label

The *ISBT 128* blood product label is divided into four quadrants of equal size (2" [51 mm] wide by 2" [51 mm] long). Regardless of site of collection world wide, the bar codes should be placed in the same relative positions. The *ISBT 128 Standard: Technical Specification* defines the placement of the following bar codes (*illustrated here in* Figure 1, Chapter 3, Page 8):

- 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 Identity and Catalog Number (bar code 5);
- Container Lot Number (bar code 6);
- Special Testing (bar code 7).

When referring to Figure 1 (Chapter 3, Page 8), note that bar codes 5 and 6 are part of the original container manufacturer's (base) label (A) and bar codes 1 through 4 and 7 are part of final labeling (B). Bar code 7 is optional 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 covered by final labeling.

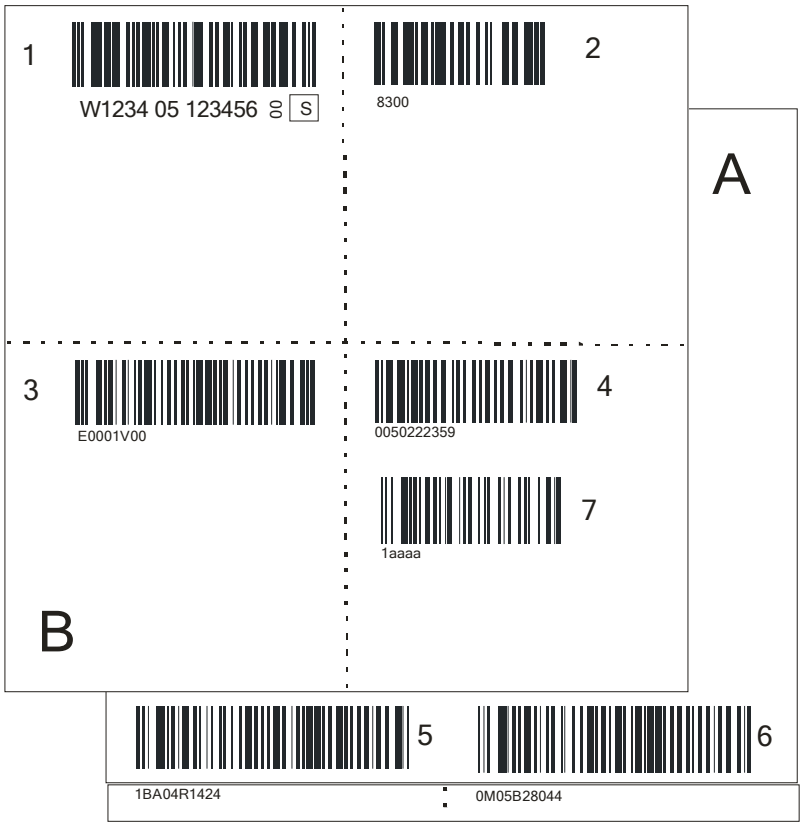
The eye-readable representation of the **interpreted** bar coded information (called bar code text in this document) and any other information on the label (called additional label text in this document) will be defined by each country to meet its own requirements. These are defined for the US in this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

3.5 *ISBT 128* Data Structures

Data structures define the way in which information is presented in *ISBT 128*. Each data structure consists of data identifiers and data content. These data structures can be incorporated into many different information delivery systems including bar codes, electronic messages, reduced space symbology codes and radio frequency ID tags.

Where an *ISBT 128* data structure is presented within a Code 128 bar code the data characters are printed in eye-readable format immediately beneath the bar code. Further details on the presentation of this information are specified in subsequent chapters

Figure 1 *ISBT 128*-Specified Label



A — Base label B — Final container label

Key:

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

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 in 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) and also used with the developing radio frequency (RFID) technology.

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 will always be "=" or "&." By international agreement (*see* the *ISBT 128 Standard: Technical Specification*) these characters are reserved to mean "this bar code specifies an *ISBT 128* data structure."

Data identifiers define the type of information the bar code contains; for example, the second character distinguishes an ABO/Rh bar code from a Product Code bar code (*e.g.*, 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 support process control (*e.g.*, the Donor [not Donation] Identification Number bar code). (*See* the later sections on *Process Control in Labeling, page 32* and *Concatenation, page 33* for more information).

3.5.2 Donation Identification Number

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

α*ppppyynnnnnn*

where:

α*pppp*	designate the collection facility;
yy	designate the year in which the donation or collection was made;
nnnnnn	is a serial number associated with the donation or collection.

An *additional* check character (not the same character integral to every Code 128 bar code) calculated on the entire 13 data characters (αppppyynnnnnn) will be printed, enclosed in a box, to the right of the Donation Identification Number (*see* illustration, Chapter 4, page 27). The ISO modulo 37,2 method will be used to compute this check character. This check character can be used to ensure the accuracy of keyboard data entry when supported by the appropriate computer software.

(For further information, see *ISBT 128* Technical Specification, Appendix A.)

Other characters incorporated into this bar code are "flag" characters. These may be used to assist in process control (such as identifying materials used in the collection process — container 1, container 2, tube 1, tube 2, *etc.* — permitting verification that the correct bar code has been scanned, *i.e.*, the bar code actually attached to container 1, *etc.*.) or to support additional checks for accurate data transmission. The specific meaning associated with flags is defined in Table 3-1 of the *ISBT 128 Standard: Technical Specification*. Flag characters are printed in a way that identifies their special role, either rotated 90 degrees (*i.e.*, vertically rather than horizontally) 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**. Flag characters are to be used in process control; it is not intended that they be recorded as part of the Donation Identification Number.

3.5.2.1 US Specification

3.5.2.1.1 Application

Usually, the Donation Identification Number should be the first label applied to primary and collection containers and all other containers in a collection set intended to contain blood products. 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 05 123456

with "α" being "W" for units collected by US facilities.

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 in that the initial characters may not change in any given calendar year. Other facilities may find the segregation into groups useful for ease of reading.

3.5.2.1.3 Flag Characters

Flag characters may be used in the US as detailed in the *ISBT 128: Technical Specification*. The default or null value, 00, should always be present as part of the Donation Identification Number bar code **if other flags are not used**. On blood containers, the flag characters are printed rotated ninety degrees as shown in the illustration in Chapter 4, Page 27. Graphical icons can be printed 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 interpreted by the host computer software in collecting and/or processing facilities. Outside of the collection and/or processing

facility, the flag characters may not be meaningful.

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 verification of data entry by the additional check character described above.

3.5.2.1.5 Avoiding Label Waste

Preprinted Donation Identification Numbers may be used over a fourteen month period to cut down on waste. For example, labels bearing the year "06" may be used from December 1 2005 through January 31 2007. 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 necessary. Obviously, the collection facility should have an accurate record of the actual date of collection. The rationale behind the 14-month tolerance in the collection year is that the donation year in this data structure exists only to ensure uniqueness of the donation identification number every 100 years. It does not in any way replace the expiration date (or collection date, as appropriate) on the label.

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 Standard: Technical Specification*);
e is reserved for future use.

The ABO and Rh status of a unit of blood (*e.g.*, 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, Chapter 3, Page 13). The information has been expanded, however, to include the type of donation or collection (*e.g.*, autologous, directed) (*see* Table 3, Chapter 3, Page 14).

Special messages, *e.g.*, "FOR LABORATORY RESEARCH USE ONLY," and other information may be encoded instead of ABO and Rh blood groups information if appropriate (*see ISBT 128 Standard: Technical Specification* and Table 2, Chapter 3, Page 13).

3.5.3.1 US Specification

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

Type of donation or collection should be specified in this bar code in the US in accordance with Table 3, page 14.

Except for autologous and directed (dedicated, designated) collections intended solely for a specific recipient, 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 on other than autologous and directed (dedicated, designated) collections intended solely for a specific recipient should be printed in outline form as it was in *ABC Codabar* (*see* illustrations in Chapter 5, Page 47). Autologous and directed (dedicated, designated) units intended solely for a specific recipient, because of the smaller size of the printed interpretation of the bar code, do not use outline fonts for Rh negative products.

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. *(See illustrations in Chapter 5, page 50)*

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 was responsible for the testing unless the product is not suitable for transfusion.

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 (*e.g.*, Autologous or Directed [Dedicated, Designated] Collection) is to be included in the ABO/Rh Blood Groups bar code when the blood product is to be used **solely** for a specific recipient (that is, **it cannot be crossed over**) or used for a special purpose. If the blood product is not intended solely for a specific recipient or is not one of the "special purpose" blood products listed in Table 2 (Chapter 3, Page 13), then the default "*gg*" (n) value for the ABO/Rh blood groups should be used.

The default values of "gg" are shown as an "n" value in Table 1 (Chapter 3, Page 13). 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 3, Chapter 3, Page 14). In the US, these values may be (n–4), (n–3), (n–2), n, (n+2) and (n+3). The values (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" (*see* Table 2, Chapter 3, Page 13), the ABO/Rh label should look very different from the "normal" appearance (*see* illustrations in Chapter 5, pages 48 and 49).

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

ABO/Rh	Value 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

Table 2 Values of "gg" for ABO/Rh Blood Groups Data Structure for Currently Defined "Special Purpose" Blood Groups

Value of "*gg*"	Interpretation
A0	Group A, Pooled Rh [Pooled Products]
B0	Group B, Pooled Rh [Pooled Products]
C0	Group AB, Pooled Rh [Pooled Products]
D0	Group O, Pooled Rh [Pooled Products]
E0	Pooled ABO, Rh Positive [Pooled Products]
F0	Pooled ABO, Rh Negative [Pooled Products]
G0	Pooled ABO, Pooled Rh [Pooled Products]
Md	Discard (to be destroyed)
Mf	For fractionation use only
Mq	Quarantine/hold for further testing or processing
Mr	For research use only
Mx	Not for transfusion based on test results

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

ABO/Rh Blood Groups	Default: Intended Use Not Specified	Directed Only (Dedicated/ Designated/ Donation)	For Emergency Use Only	Directed Only (Dedicated/ Designated/ Donation) Biohazardous	For Autologous Use Only	For Autologous Use Only/ Biohazardous
	n	(n–4)	(n–3)	(n–2)	(n+2)	(n+3)
O Rh(D) negative	95	91	92	93	97	98
O Rh(D) positive	51	47	48	49	53	54
A Rh(D) negative	06	02	03	04	08	09
A Rh(D) positive	62	58	59	60	64	65
B Rh(D) negative	17	13	14	15	19	20
B Rh(D) Positive	73	69	70	71	75	76
AB Rh(D) negative	28	24	25	26	30	31
AB Rh(D) positive	84	80	81	82	86	87
O	55	P2	P3	P4	P8	P9
A	66	A2	A3	A4	A8	A9
B	77	B2	B3	B4	B8	B9
AB	88	C2	C3	C4	C8	C9
para-Bombay, Rh(D) negative	D6	D2	D3	D4	D8	D9
para-Bombay. Rh(D) positive	E6	E2	E3	E4	E8	E9
Bombay, Rh(D) negative	G6	G2	G3	G4	G8	G9
Bombay, Rh(D) positive	H6	H2	H3	H4	H8	H9

If the blood product is for autologous use, values "n+2" (for autologous use only) or "n+3" (For autologous use only/Biohazardous) 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 Chapter 5, page 48. The word **BIOHAZARD** and the international biohazard symbol will be added when "n+3" (For autologous use only/Biohazardous) is used. This labeling is also illustrated in Chapter 5.

If the blood product is a directed, designated or dedicated donation **that is intended solely for a specific recipient,** the "n–4" (Directed Only) and "n-2" (Directed Only/Biohazardous) values may be used and **FOR DESIGNATED RECIPIENT ONLY** should be printed below the ABO/Rh bar code text as shown in the illustration in Chapter 5, page 49. The word **BIOHAZARD** and the international biohazard symbol will be added when "n-2" (Directed Only/Biohazardous) is used. This labeling is also illustrated in Chapter 5.

These values are shown in Table 3 (Chapter 3, Page 14).

3.5.3.1.3 Labeling of Directed Collections That Can Be Crossed Over

These units should be labeled in the upper right quadrant as if they are routine allogeneic donations. During the time that such a unit is reserved for specific recipient, an intended recipient label or tie tag such as the ones illustrated in Chapter 5, page 48, should be attached to the unit providing the appropriate information. When released for routine use, this label or tie tag should be removed.

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.

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:

cyyjjj

and

cyyjjjhhmm

where:

c	designates the century (*e.g.*, 0 for 2000; 1 for 2100);
yy	designates the year of expiration;
jjj	is the Julian date (the number of the day in the year, *e.g.*, 022 is 22 JAN);
hh	specify the hour (00–23);
mm	specify minutes (00–59).

Recognizing that there are national differences in how dates are printed, the WPADP has agreed that all countries should adopt a single format for expressing the expiration date in eye-readable form, *viz*, **21 JUL 2006** (DD MMM YYYY — month in alpha characters, abbreviated).

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 time should not be shown in the bar code text; a midnight expiration is assumed.

3.5.5 Product Code

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

αooootds

where:

αoooo	designates the blood product description (for blood components α is E or F);
t	designates the type of donation or collection/intended use;
ds	provide information about divisions of the blood product.

The first five (5) data characters are derived from an ICCBBA, Inc-maintained *ISBT 128* database table and provide the *ISBT 128* description of a blood product. They identify the blood component class and modifier(s) (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.

3.5.5.1 Component Name (Component Class and Modifiers)

A blood component name consists of a Component Class and may have one or more Modifiers. The Component Class is a cellular or non-cellular blood product characterized by a set of Core Conditions [codes for Core Conditions begin with the character @] that includes:

- anticoagulant and/or additive;
- nominal volume of original collection; and
- relevant storage temperature.

Note: Core Conditions do not specify the life of the blood product because each country decides the permissible period after collection during which a blood product may be used.

Component Classes include **RED BLOOD CELLS**, **FRESH FROZEN PLASMA** and **PLATELETS**. Modifiers relate to the Core Conditions of a blood component and distinguish it from other members of the same Component Class. **APHERESIS PLATELETS** and **REJUVENATED RED BLOOD CELLS** are examples of Component Names constructed from a Component Class and a Modifier. **WASHED** and **THAWED** are other examples of Modifiers.

Appendix B (beginning on page 64) provides a listing of the *ISBT 128* Component Names (Class and Modifiers) that is current as this document goes to press and indicates how they should be printed on a US label.

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
- Irradiation
- Residual Leukocyte Content
- Altered
- Final Content
- Preparation — Additional Information
- Apheresis and Container — Additional Information
- Quarantine — Additional Information
- Dosage — Additional Information
- Method of Treatment
- Hematocrit
- Platelet Count
- Monitoring

Refer to *ISBT 128 Standard: Product Coding— Bounded Lists 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 Description 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) has been reserved and may be used internally for interim labeling in component processing, but when used in this manner they should not appear on the label of the finished blood product. Similarly, these codes may be used for "local" products, e.g., products under development. These products may be shipped locally, but may not be shipped interstate. See ISBT Standard: Technical Specification for details.

The type of donation or collection/intended use 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" (up to 26 divisions or Z0). Such "divided units" can be further subdivided up to 26 times. 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") up to 26 subunits (or Bz). There is no provision in *ISBT 128* for subdividing a given aliquot more than two times.

Note: "d" and "s" are coding for divisions of a "finished" blood product. When a donation is subdivided during collection (e.g., **APHERESIS RED BLOOD CELLS***) then the subdivision is coded as part of the Product Description Code. A product divided during collection is still coded using "d" and "s" if additional division occurs after final labeling (i.e., the Product Description Code could indicate, for example, Container 2, but there could be an A or B in the seventh position if the contents of the original Collection 2 container were subsequently divided).*

3.5.5.3 US Specification

The *ISBT 128* Product Description Code database contains descriptions for blood products that are not in used 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 Description Code database released by ICCBBA, Inc will be the *ISBT 128* (international) version. The FDA determines which products may be produced in the US.

3.5.5.3.1 Proper Name (Component Name)

In order to simplify label design in a rules-based system, and to promote international harmonization, the Proper Name (Component Name) of a blood product in the US will be as it appears in the *ISBT 128* Product Description Code Database with the following exceptions:

Plasma for manufacture will be either SOURCE PLASMA or RECOVERED PLASMA; Cryoprecipitate will be CRYOPRECIPITATED AHF and platelets with bacterial monitoring following national guidelines will be PLATELETS PHERESIS – 7d to comply with FDA requirements.

3.5.5.3.2 Attributes

Appendix C (beginning on page 70) contains a listing of each Attribute Group used in the US with instructions as to how the information associated with each group is to be presented on the label.

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 3-5 of the *ISBT 128 Standard: Technical Specification.*

In the US, the following usage is **mandatory**:

- V is required for all blood products collected from volunteer donors if one of the optional codes is not used;
- P is required for all blood products collected from paid donors if one of the optional codes is not used
- T is required for therapeutic collections if they are labeled and transfused; it is not required if the collection is promptly discarded or if the facility has been approved by the FDA to label certain therapeutic collections as allogeneic donations.

In the US, the following usage is **optional**:

- R, S, X, D, 1, 2, 3, 4 or 5 may be used in place of V
- r, s or d may be used in place of P

The translation of this information into bar code text is shown in Appendix D (beginning on page 76).

When the type of donation (other than a standard volunteer, allogeneic donor) is encoded in the sixth character of the Product Code bar code, this information should be printed immediately below the bar code to the right of the required eye-readable information as illustrated below. The printing should be the same size and height as the required eye-readable information.

Figure 2 Donation Type Encoded in Product Code

3.5.5.3.4 Divisions

The scheme outlined in the *ISBT 128 Standard: Technical Specification* will be used for identifying divisions. If the seventh and eighth data characters are other than "00," then the term **DIVIDED** should appear on the label in the **first** Attribute line, followed by Attributes such as **IRRADIATED**. If desired, a notation describing the division number may appear in the text below the storage temperature (see example, Chapter 5, page 52).

3.5.5.3.5 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 abbreviations. Currently approved standardized label and other text abbreviations are listed in Appendix E (page 78).

3.5.5.3.6 Examples

Chapter 5, *Illustrations of US Labels*, provides 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, Inc will be glad to assist any currently registered and licensed 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, Inc office. **Remember, the Code of Federal Regulations takes precedence over this and other *ISBT 128* documents for blood product labeling in the US.**

3.5.5.4Obtaining a New Product Description Code

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

A completed Product Description Code Request Form should be submitted to the ICCBBA, Inc office through the designated person. The name of the person and appropriate contact information can be found through the ICCBBA, Inc Website. The form may be completed and submitted on line on the ICCBBA, Inc Website or copies of the form and instructions for its completion are available from ICCBBA, Inc.

3.5.6 Container Manufacturer

3.5.6.1 Container Manufacturer and Catalog Number and Container Lot Number

Two ten (10) data character data structures identify (1) the container manufacturer, and provide a description of the container set by encoding the manufacturer's catalog number, and (2) the container lot number. These bar codes will be placed on base labels applied by the manufacturer to all containers that may contain a blood product. Once the information contained in these bar codes is captured during collection or processing, these bar codes may be over-labeled.

3.5.6.2 US Specification

Now that container manufacturers have reached consensus on the content for the two data structures noted above, the "third bar code" previously designed solely for the US to identify the anticoagulant has been abandoned and discontinued. The US will now adopt internationally standardized labeling (*see* the *ISBT 128 Standard: Technical Specification* for complete details).

3.5.7 Special Testing: General

An optional, *ISBT 128*-specified five (5) data character data structure has been defined to contain the results of special or additional testing (*e.g.*, expanded test results). This coding has now been defined internationally, and the codes appear in the Special Testing: General database maintained on the ICCBBA Inc Website. *See* the *ISBT 128 Standard: Technical Specification* for complete details.

3.5.7.1 US Specification

Examples of US labeling for this bar code are provided in Chapter 5, page 56.

3.5.8 Special Testing: Red Blood Cell Antigens

An optional, *ISBT 128*-specified eighteen (18) data character data structure has been defined to contain the results of additional testing for red blood cell antigens. A description of the coding and the necessary reference tables can be found in the *ISBT 128 Standard: Technical Specification*.

3.5.8.1 US Specification

Examples of US labeling for this bar code are provided in Chapter 5, page 56.

3.5.9 Special Testing: Serologically-Determined Platelet HLA and Platelet-Specific Antigens

An optional, *ISBT 128*-specified eighteen (18) data character data structure has been defined to contain the results of additional testing for serologically-determined platelet HLA and platelet-specific antigens. A description of the coding and the necessary reference tables can be found in the *ISBT 128 Standard: Technical Specification*.

3.5.9.1 US Specification

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

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 derive information about the blood product only from the contents of the label.

- The layout of the bar codes applied to primary, collection, satellite or transfer containers will conform to the quadrant design as outlined in the *ISBT 128 Standard: Technical 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 data content should appear beneath each bar code symbol on the container. It should contain all **data characters** within the symbol, but should not include the data identifier, start/stop characters, special characters (shift C, *etc.*) or the Code 128 modulo 103 check digit. With the exception of the Donation Identification Number, this representation will generally appear left justified with the first bar in the symbol.

- Being able to read the bar codes is of paramount importance. Quiet zones and bar heights must conform to the *ISBT 128 Standard: Technical Specification*. Bar codes 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 US Specification for Bar Code Text and Label Text

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

- 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 text will be left justified. Other bar code and label text may be centered or left justified as appropriate (*see* illustrations in Chapter 5).

- **VOLUNTEER DONOR** should be no less prominent than the Proper Name (Component Name) of the blood product. The maximum height of the letters for **VOLUNTEER DONOR** will be 5/32" [4 mm].

Note: This is a maximum height. Labels printed at a height less than this are acceptable provided that they are easily read and conform to all other requirements.

- 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 E, page 78).

- The *ISBT 128* Product Description Code database design is based on a **Component Class** (**RED BLOOD CELLS**, **WHOLE BLOOD**, **PLASMA**, **PLATELETS**, *etc.*), a **Modifier** (**WASHED**, **FROZEN**, *etc.*), printed above the Component Class and **Attributes** (**IRRADIATED**, **LEUKOCYTES REDUCED,** *etc.*) printed below the Component Class. The Component Name may be printed as large as space allows (not exceeding 5/32" [4 mm] in height) as follows:

Modifier	**WASHED**
Component Name	**RED BLOOD CELLS**
Attribute	**IRRADIATED**

- Modifier(s) and Attribute(s) will be proportionally smaller as shown above (and *see* illustrations in Chapter 5).

- Attributes shall appear in the same order as the Attribute Groups, but with Divided (if applicable) appearing first (*see* Chapter 3.5.5.2, page 17). If the unit is not divided, **IRRADIATED** will be first.

- Except for autologous collections and units designated **only** for a specific recipient, 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 (*i.e.*, as in *ABC Codabar*). Outline text fonts are not used for Rh negative autologous collections or other units designated **only** for a specific recipient.

- The use of color for ABO and Rh labeling is neither prohibited nor encouraged.

4.1.3 Label Design

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

- The base label of primary, collection, and satellite containers will be **at least** 4" [102 mm] wide and 4.25" [108 mm] long;
- The design of the final label will be limited to cover an area 4" [102 mm] wide by 4" [102 mm] long;
- Each 4" [102 mm] wide by 4" [102 mm] long label will be divided into four equal 2" [51 mm] wide by 2" [51 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 Standard: Technical 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 or the Product Code and Expiration Date (and Time) bar codes.

4.1.4 Quadrants and Thirds

A primary container intended for the collection of 450 or 500 mL of Whole Blood, and all apheresis collection containers, will have a base label applied by the container manufacturer that measures 4" [102 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" [51 mm] wide by 2" [51 mm] long areas, as illustrated in Figure 2 (Chapter 4, Page 26). In deciding the relative placement of the bar codes, the WPADP further divided each area into three 2" [51 mm] wide by approximately 5/8" [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.

From this description it becomes obvious that labels are now standardized into a limited number of sizes: 2" [51 mm] wide by 2" [51 mm] long, or 2" [51 mm] wide by about 5/8" [16 mm] long in size, 4" [102 mm] wide by 2" [51 mm] long, 2" [51 mm] wide by 4" [102 mm] long for final ABO/Rh labeling and over-labeling as the blood product and expiration date and/or time changes and 4" [102 mm] wide by 4" [102 mm] long. These were designed to facilitate on-demand printing and limit the sizes of blank stock needed, as discussed later.

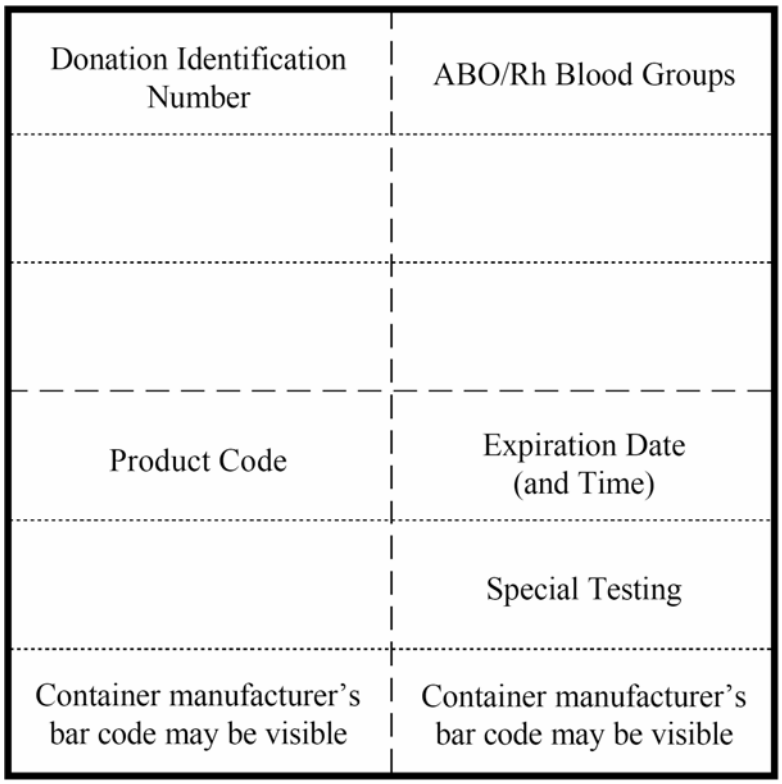
Although the satellite container is usually smaller, it is possible to apply labels of the same size as

those used on the primary and collection containers. In specifying the print height and position of information to be used in labeling blood products, the following order of importance was used:

- Greatest importance: Donation Identification Number; 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.

Note: No specifications are provided in this document for labeling transfer containers, or for satellite containers that are used for blood products other than Platelets, Plasma and Cryoprecipitated AHF, e.g., those used to contain pediatric doses of blood products. When consensus is reached for standardized labeling of these products, specifications will be included in future versions of this document. Until then, labeling of these containers should conform to the principles of ISBT 128 labeling.

Figure 3 Final Label--Four Equally-Sized Labeling Quadrants: Placement of the Bar Codes



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

4.1.4.1 Upper Left Quadrant

The Donation Identification Number will be right-justified, and there will be spaces between the Country/Collection Facility Identification Number (the unique facility identifier), the year of collection, and the serial number. The alignment will be such that the boxed check digit is aligned with the right edge of the bar code, as illustrated below.

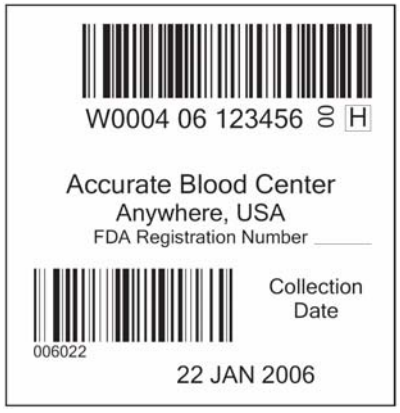
The information about the facility that collected and processed the unit should be printed in the middle third of this quadrant [the lower third of the lower right quadrant should be used for the name and address of a secondary processing site]. The FDA registration number is currently included in this quadrant. In the illustration, the US License Number of the facility is shown in one of the two acceptable locations. The other possible location is in the lower left quadrant (*see* below). The US license number may appear in either place, but must NOT appear in both places. A US License Number is only applied by licensed facilities to blood products they are licensed to produce; **a US License Number must not appear on unlicensed blood products**.

The required label text (Properly Identify, *etc.*) will be printed in the lower third of this quadrant on blood components intended for transfusion. Recovered Plasma labels do not require the same required label text as components for transfusion. These labels do, however, require the Collection Date. This date should appear in the lower one third of this quadrant (see illustration on page 28) in place of the required label test.

VOLUNTEER DONOR (or **PAID DONOR**) will be printed at the bottom of the quadrant.

Figure 4 Upper Left Quadrant--Standard

Figure 5 Upper Left Quadrant--Recovered Plasma



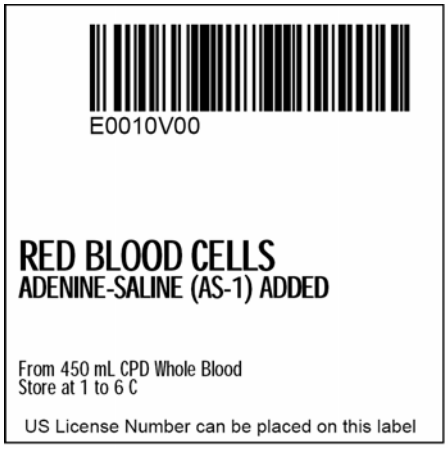
4.1.4.2 Lower Left Quadrant

The base label of the primary and collection containers 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.

The US License Number is shown in the other acceptable location in the illustration below. Applying the US license number in this location will allow the US license number to be easily over-labeled if the product is modified to a non-licensed product. The US license number may appear in either place, but must NOT appear in both places.

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 Chapter 5 to show both a preprinted example (with container manufacturer's information bar code visible) and the appearance when over-labeled.

Figure 6 Lower Left Quadrant



4.1.4.3 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 Chapter 5, page 48) (*see* also 4.1.4.5, page 31).

If the unit is designated solely for a specific recipient, **FOR DESIGNATED RECIPIENT ONLY** is printed at the bottom of the quadrant (*see* illustrations in Chapter 5, page 49) (*see* also 4.1.4.5, page 31).

In either of these two cases, the ABO/Rh label text should be very different as shown in the illustrations. 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 Chapter 5, page 48 and 49) (*see* also 4.1.4.5, page 31). Release of such units to a non-autologous recipient should be a very rare occurrence, and they should not carry a US License Number.

Figure 7 Upper Right Quadrant

4.1.4.4 Lower Right Quadrant

Expiration Date (and Time) bar code and the bar code text appear in the upper third of this quadrant. Label vendors should be advised to make label stock to cover this specific area no larger than 2" [51 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 (*e.g.*, **01 JAN 2005 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.

Identification of the facility that further processed or modified a product will be in the bottom one third of this quadrant.

Special Testing information (if any of these optional bar codes are used) will be printed in the middle third of this quadrant. This information may extend into the lower third of the quadrant if the "Further Processed by" is not printed in this space.

Figure 8 Lower Right Quadrant

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

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. A label having the dimensions of no less than 2.5" [64 mm] by 1" [25 mm] long should be used, and if used as a label on the container, should not cover any other labeling. The label should have **Intended Recipient Information** printed on it. The remainder of the label should be arranged so that

space is provided for the patient's name, identification (*e.g.*, medical record) number and birth date, the name of the hospital and other information as shown in the illustrations in Chapter 5, Page 48.

4.1.5 Biohazard Label

OSHA has permitted the biohazard label to be black on white when produced by an on-demand printer 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, and it is still required for preprinted labels.

Note: Because of the widespread use of on-demand printing, it is preferable that all labels on a blood container be black and white only. The FDA has permitted the Proper Name (Component Name) of the blood product to be printed in a color other than red. This facilitates the use of on-demand printed labels.

4.2 Process Control in Labeling

Process control in transfusion medicine 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 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.

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 and collection containers, satellite container(s), donor registration card, test tubes for collection samples for blood grouping and viral testing, *etc.*, are assigned. 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, Inc has made available bar codes that can be used for checking bar code readers periodically. These methods can also assist in staff training, and ensuring that it is hardware and not technique that is the root of any 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 Standard: Technical 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.

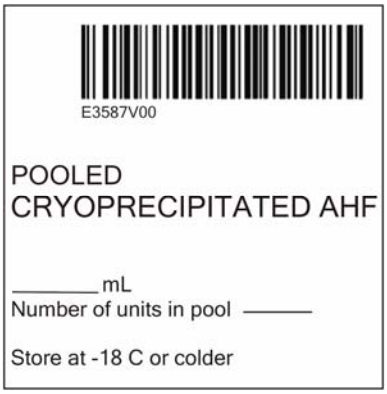
The value of concatenation is the ability to check that two bar codes are attached to a single unit and are internally consistent. This is accomplished by requiring that the second bar code be read within a time period too short to permit reading a bar code not on the unit. In designing *ISBT 128*, two 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, ensures that the ABO/Rh label applied is correct according to the data in the host computer for the particular unit. The second pair, the Product Code and the Expiration Date (and Time) bar codes, should also be 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

Donation Identification Numbers (DIN) may be used to create a product identification numbers for pooled blood products, usually **PLATELETS** and **CRYOPRECIPITATED AHF.** These products should be given a unique product identification number and 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 Collection Facility Identification Number to conform to the *ISBT 128* Donation Identification Number specifications. 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 to be on the label: the number of units in the pool should appear, as illustrated below.

Figure 9 Pooled Cryoprecipitate



4.5 Additional Labeling by a Facility Modifying a Blood Product

There is now a specific CFR requirement for the application of labels bearing machine readable information. Information that must be machine readable includes: unique facility identifier, ABO/Rh, product name and donation identification number. This 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. Often, preprinted labels will serve for this purpose. If only a few changes are made frequently at a given institution, then preprinted labels that include the necessary bar code are a rational choice. For example, the pooling of **PLATELETS** and **CRYOPRECIPITATED AHF** are likely candidates. A preprinted label, such as that illustrated above, but extended to 4" by 2" would have a blood product description complete with bar code and a blank 2" by 2" space to the right for the expiration date (and time) to be entered by hand. A bar coded expiration date (and time) obviously requires an on-demand printer; it would be impossible to keep preprinted labels available for this purpose.

End-user facilities supported by sophisticated computer systems may wish to consider the following:

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

- Any facility that modifies blood products and 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 facility that modifies blood products but that does not collect Whole Blood or apheresis units is assigned an identification number similar to the Country/Collection Facility Number for collecting facilities when they register with ICCBBA, Inc, and this number can be used, *e.g.*, 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.

Similar facilities that are also collection facilities should consider their requirements with respect to Donation Identification Numbers. Because many institutions would probably have such labels prepared in advance through a reliable label vendor, it makes sense for a computer-supported facility 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 using 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 (*e.g.*, 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 (Chapter 1) it is repeated here:

Please note that some Proper Names [Component Name (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 United States Food and Drug Administration (FDA) in the hope that it would be considered an acceptable bar code labeling system in the United States. The FDA has made such a determination; however, the Proper Names in the Code of Federal Regulations do not match the *ISBT 128* Component Name (with any appropriate Modifiers and Attributes). Until a change is made in the regulations, all manufacturers of blood products who wish to use the new bar coding system and the new Proper Names (Component Name) [with any appropriate Modifiers and Attributes] should request a variance from the FDA from 21 CFR 606.121 (e)(1)(ii) under the provisions of 21 CFR 640.120., and **licensed** establishments should, in addition, submit copies of their *ISBT 128* labels **for licensed products** to the FDA for approval. Additionally, until these new regulations are finalized, the FDA registration number will continue to be required on the final label.

NOTICE

Logos

The *ISBT 128 Standard: Technical Specification* makes no provision for logos. Facilities may place a logo in the upper left or lower right quadrant should they 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. 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, and applying the principles and rules enunciated in Chapter 4, it should be possible to design any label not illustrated in this chapter.

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 Chapter 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 chapter and in Appendices A through C.

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.

- Class, modifier and attributes should be printed in all upper case letters.

- 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. They shall appear in the same order as the Attribute Groups. Whenever the volume is shown (____ mL) it must appear on the first line below the attributes (the first "Addition information" line).

- In general, modifiers 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 information (in the form of a cautionary statement such as "CAUTION: FOR USE IN MANUFACTURING NON-INJECTABLE PRODUCTS ONLY") will be printed at the same size as the proper name and on the lines immediately following the proper

name;
- additive solutions will be listed on the line immediately after the proper name (and before the intended use cautionary statement, if applicable);
- if a product is divided, **DIVIDED** will always be listed first, on the first line of the attribute section; **IRRADIATED,** if applicable, will appear next.

- 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 E. If there is no appropriate abbreviation in Appendix E 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 E and publish the revised Appendix.

5.3 Container Manufacturer's Base Label

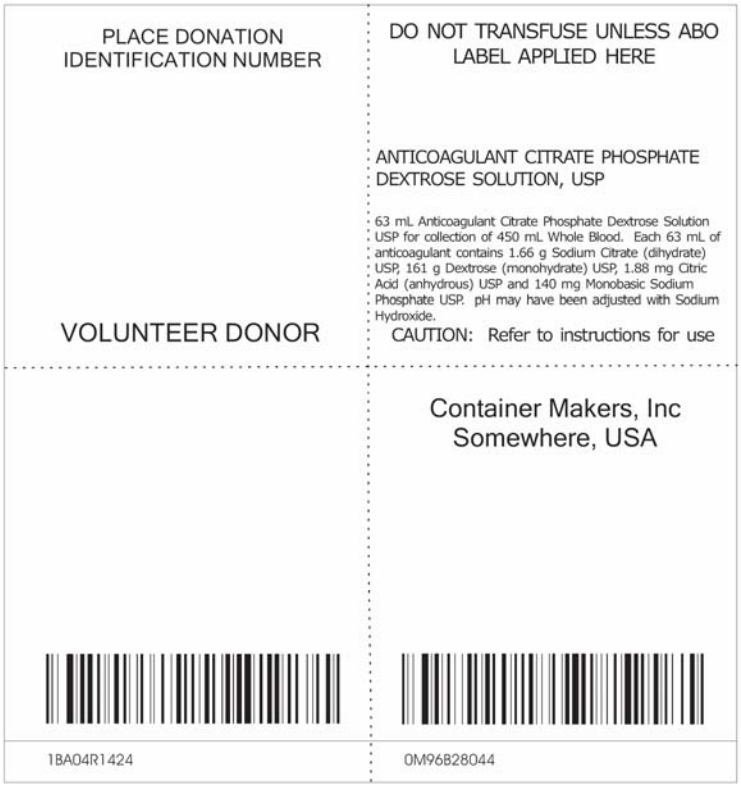
All primary containers used in the US for whole blood and apheresis collections and storage should be labeled with a base label with wording approved by the FDA. Other labeling should comply with the *ISBT 128 Standard: Technical Specification*.

Container manufacturers will work with the ICCBBA to ensure that these labels are properly encoded and placed. 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.

Each blood product manufacturing facility should use software that can maintain the information provided by these 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 (*e.g.*, small hospitals providing autologous collection services) should maintain this information in some other suitable format.

5.3.1 Base Label Illustrations

Figure 10 Base Label Primary Container: RED BLOOD CELLS—Not preprinted



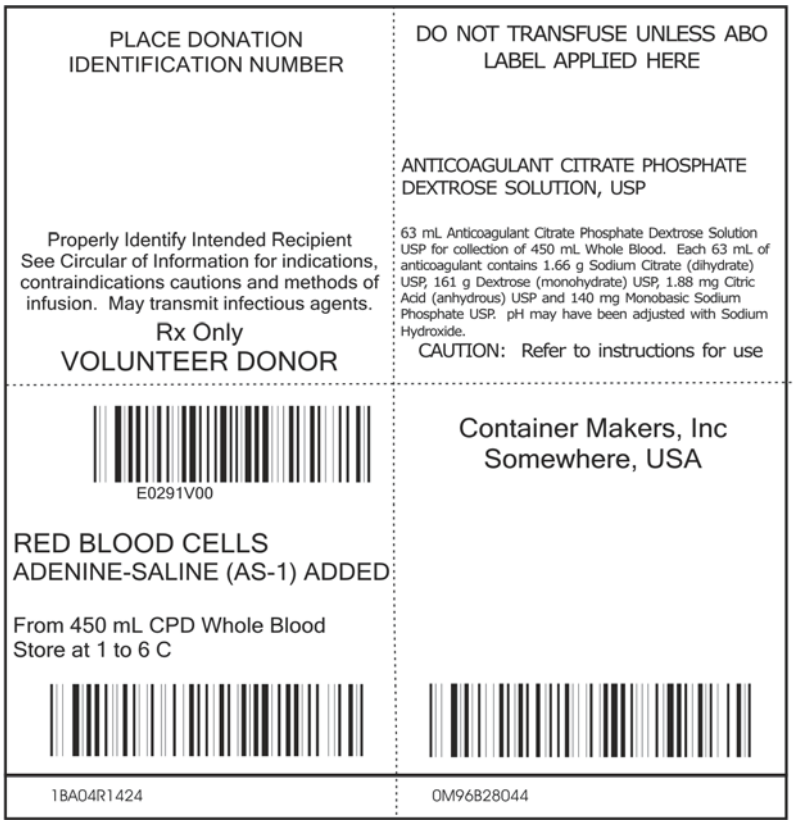
Notes:

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.

Figure 11 Base Label Primary Container: RED BLOOD CELLS—Preprinted with product label



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.

Figure 12 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.

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.

Figure 13 Base Label Satellite Container--PLATELETS—Preprinted with product label

Notes:

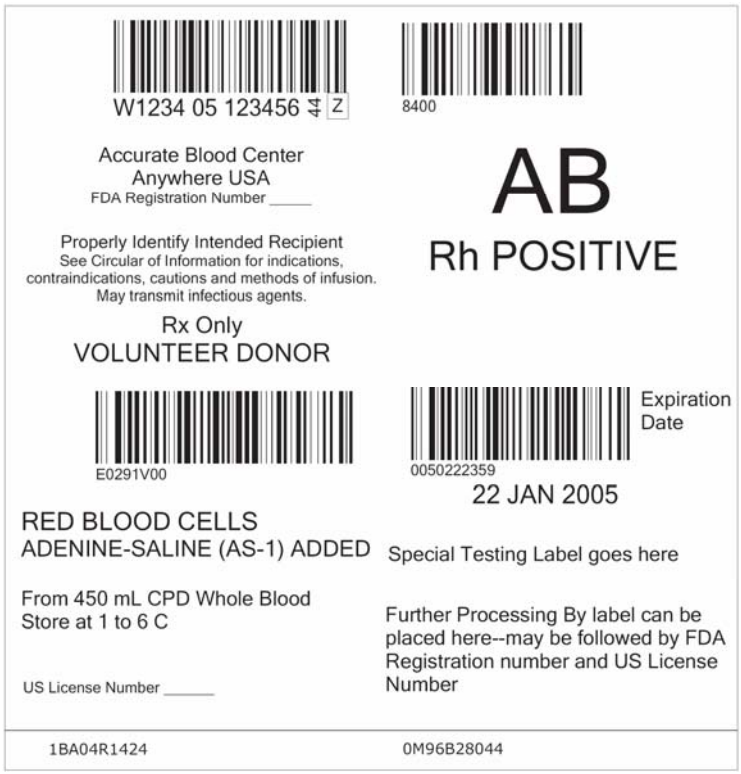
The base label is the label applied to the empty container (prior to whole blood or apheresis collection) by the manufacturer.

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.

5.4 Primary Container Label Illustrations

Figure 14 Primary Container--RED BLOOD CELLS

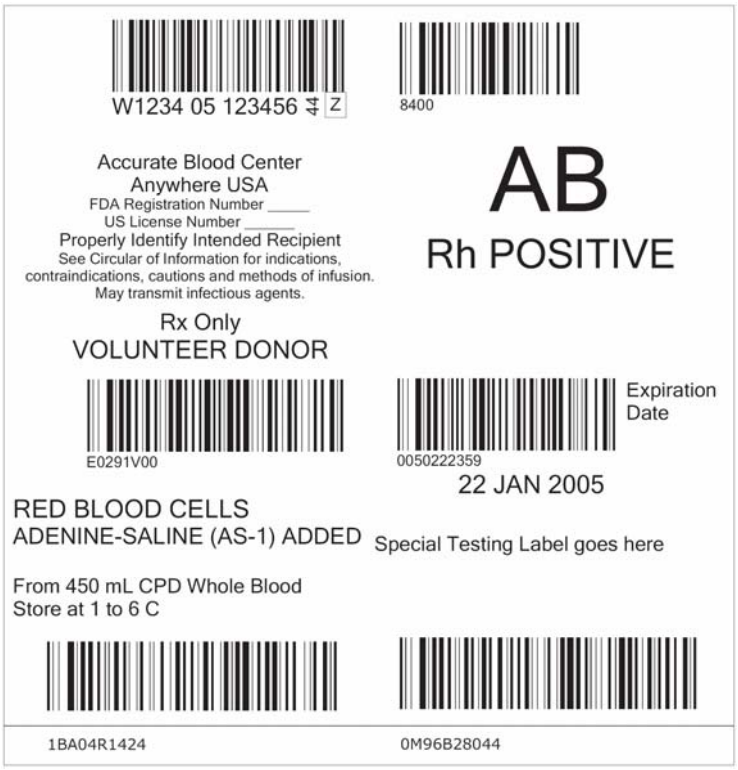


Notes:

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

The ¼" [6.4 mm] Section projecting below the 4" [102 mm] wide by 4" [102 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.

Figure 15 Primary Container— RED BLOOD CELLS—Preprinted product label and alternate location of US license number



Notes:

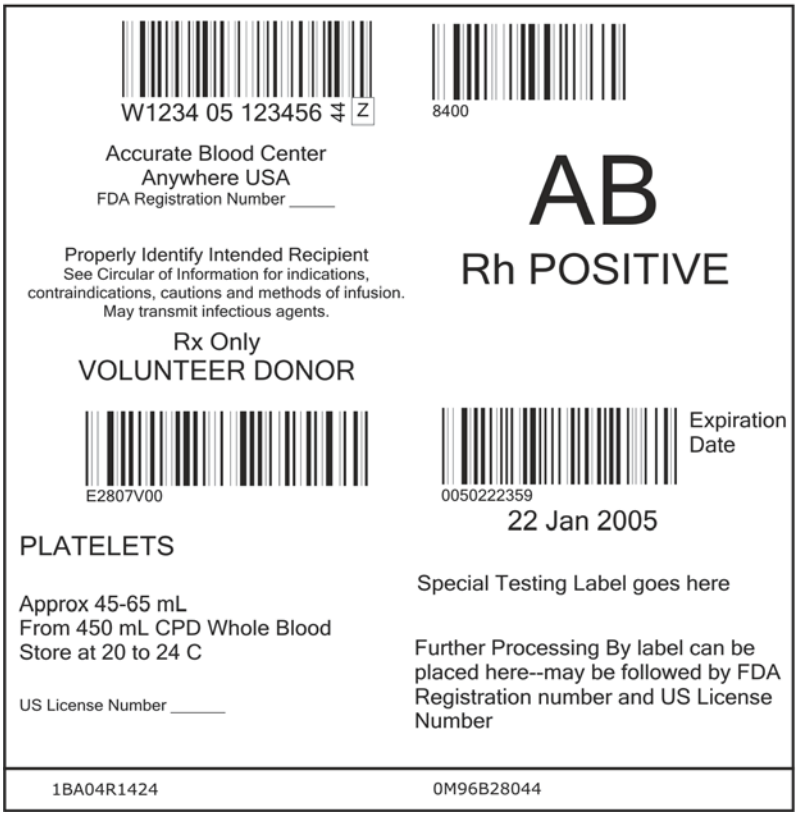
This illustration represents a unit ready for release (statements indicating options, for example, “Special Testing label goes here” would obviously not be present). One alternative placement of the license number is illustrated.

The ¼" [6.4 mm] Section projecting below the 4" [102 mm] wide by 4" [102 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.

5.5 Satellite Container Label Illustrations

Figure 16 Satellite Container--PLATELETS

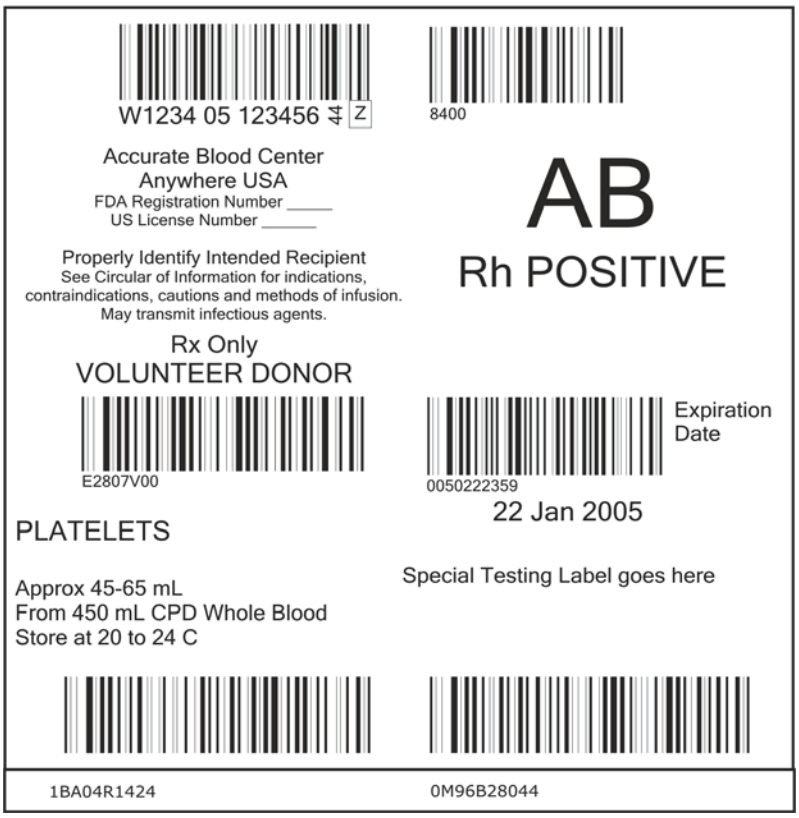


Notes:

This illustration represents a unit ready for release (statements indicating options, for example, “Special testing label goes here” would obviously not be present).

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

Figure 17 Satellite Container--PLATELETS—Preprinted product label and alternate location of US license number



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**.

5.6 Other Label Illustrations

Figure 18 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.

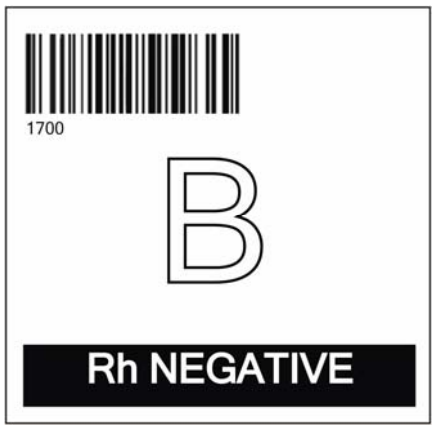


Figure 19 Upper Right Quadrant for Autologous Products

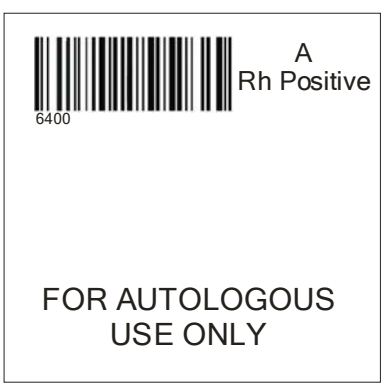
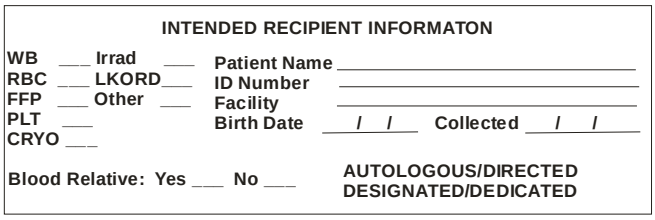
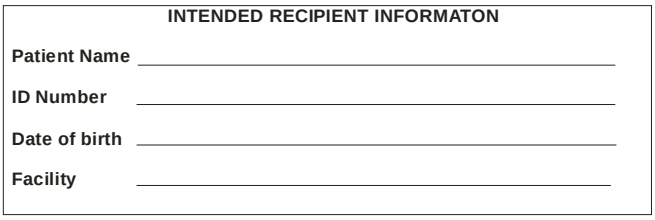


Figure 20 Intended Recipient Information Label





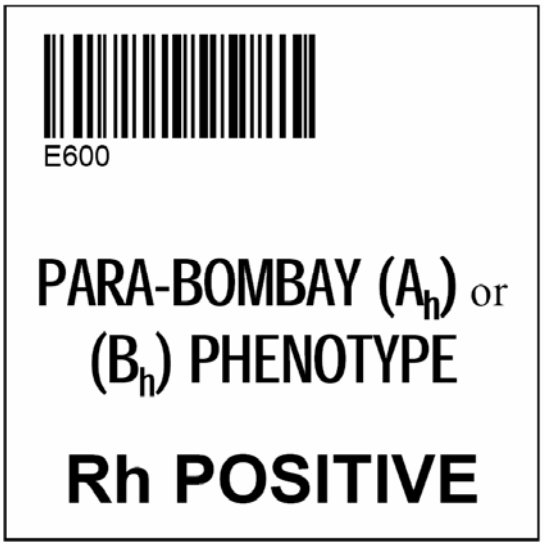
The Intended Recipient Information Label should be placed on the front of the container, immediately above the Donation Information Number and ABO/Rh Blood Groups bar codes or on a tie tag. Either of these label examples (or other designs with similar information) could be used.

Figure 21 Directed, Designated and Dedicated Labels: Common Labels

Note that (n-2) and (n-4) from Table 2 (Chapter 3) are used in the ABO/Rh Blood Groups bar code for all directed, designated and dedicated donations that are intended for a specific recipient only: the differentiation between directed, designated and dedicated is made in the Product Code bar code (*see ISBT 128 Standard Technical Specification*).

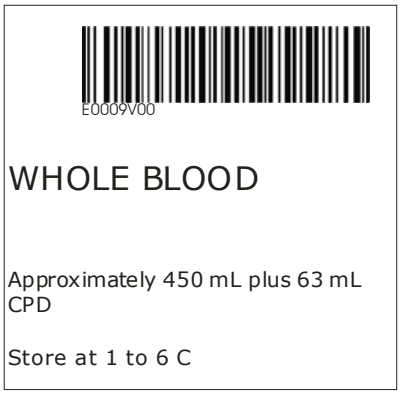
Containers labeled as above should also bear an Intended Recipient Information label.

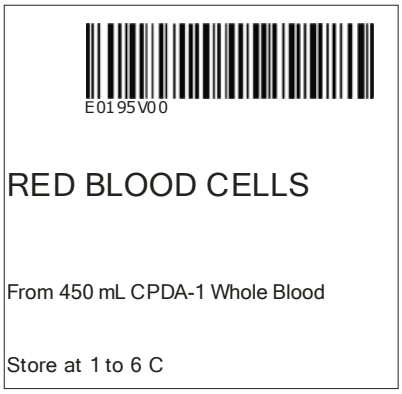
Figure 22 Bombay and Para-Bombay Phenotypes

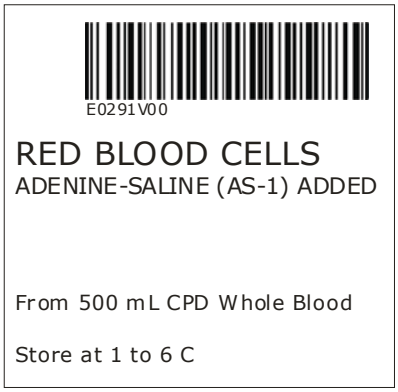


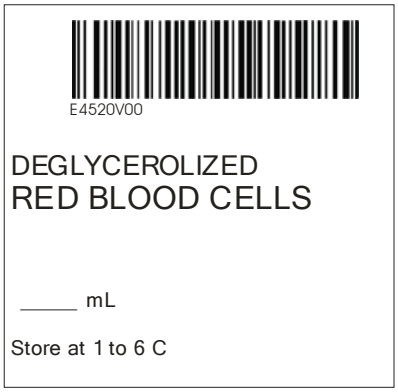
Note that the values E6 and G6 come from Table 3, page 14.

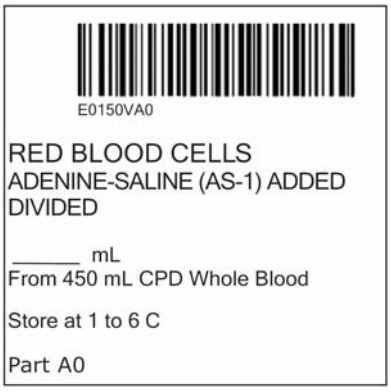
Figure 23 Product Description Labels

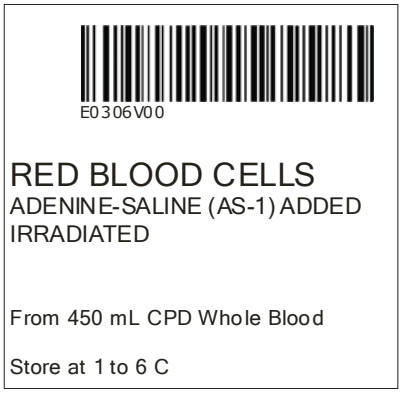












Product Description Labels (continued)


E0307V00

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

From 450 mL CPD Whole Blood

Store at 1 to 6 C


E0668VA0

APHERESIS
RED BLOOD CELLS
ADENINE-SALINE (AS-3) ADDED
DIVIDED
IRRADIATED
LEUKOCYTES REDUCED

_____ mL in approx_____ mL CP2D anticoagulant

Store at 1 to 6 C

1st Container, Part A0


E4154V00

WHOLE BLOOD
LOW VOLUME

Approx____mL plus____mL CPDA-1

Store at 1 to 6 C


E5017V00

RED BLOOD CELLS
LOW VOLUME

Approx _____ mL from CPD Whole Blood

Store at 1 to 6 C


E2807V00

PLATELETS

Approx 45-65 mL
From 450 mL CPD Whole Blood

Store at 20 to 24 C


E0000V00

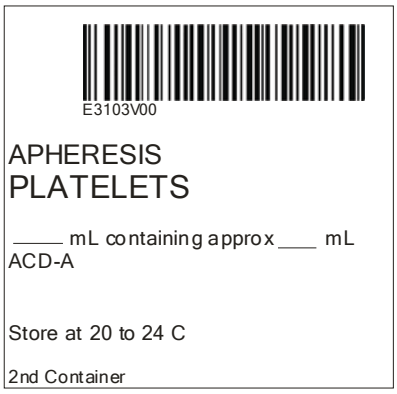
POOLED PLATELETS

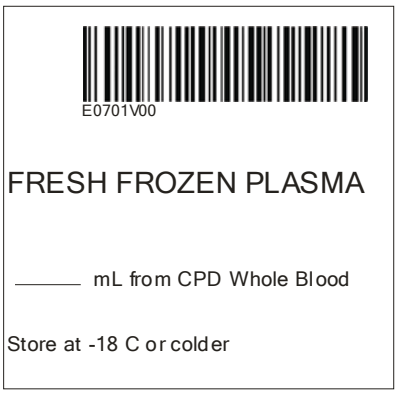
_____ mL

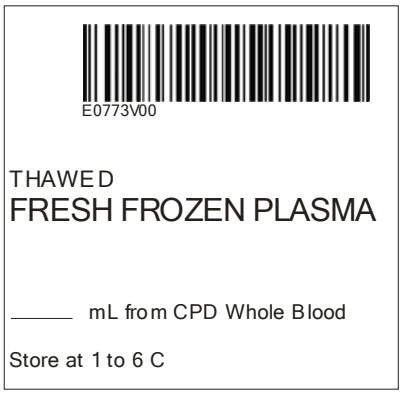
Number of units in pool _____
From CPD Whole Blood

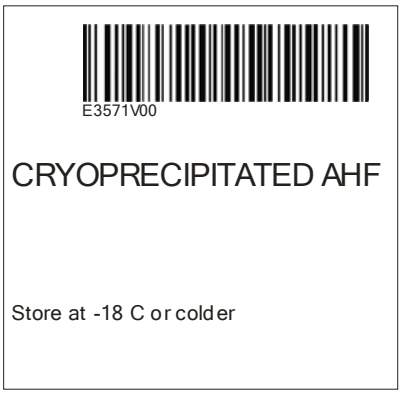
Store at 20 to 24 C

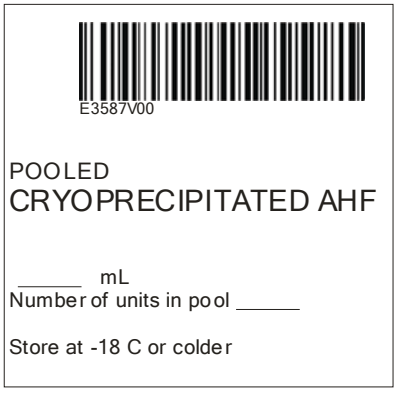
Product Description Labels (continued)

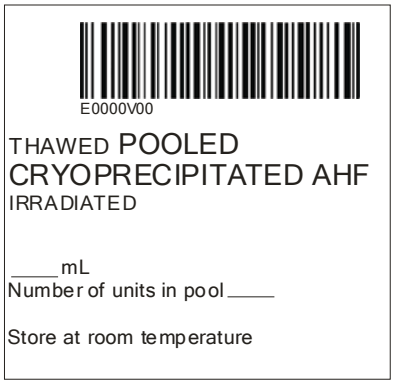










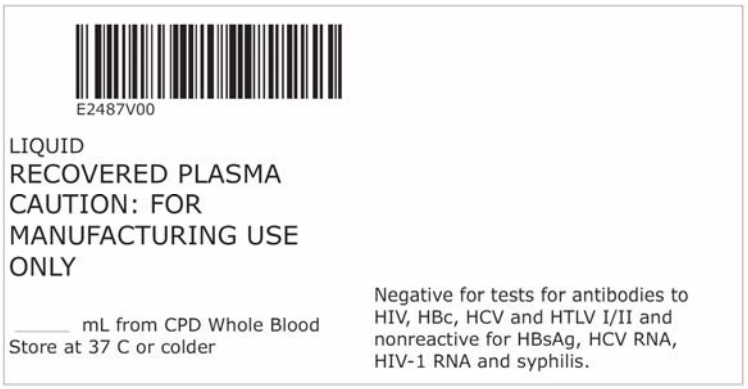


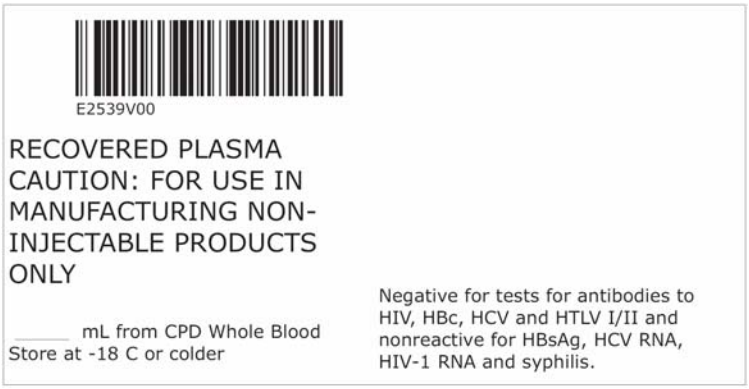
Note: Use of the "thawed" product code label is not required by the FDA. Only the expiration date/time must be changed under these circumstances.

Figure 24 Product Description Labels--Recovered and Source Plasma

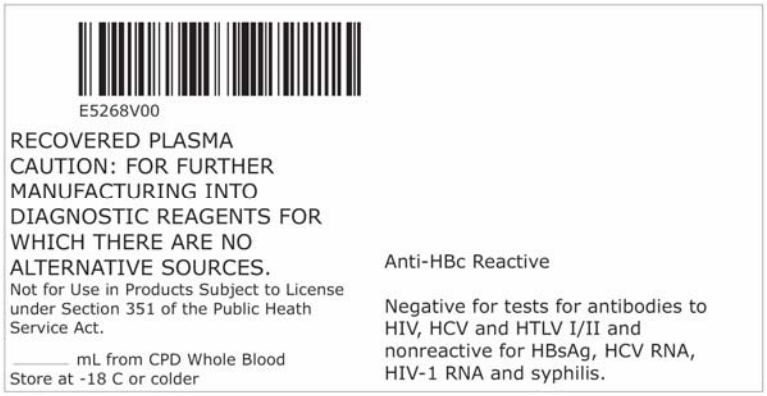
Obviously, requirements for extensive information to be placed on these labels causes the *ISBT 128* labeling scheme to break down. These examples illustrate practical approaches to this problem.

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.





Product Description Labels: Recovered and Source Plasma (continued)



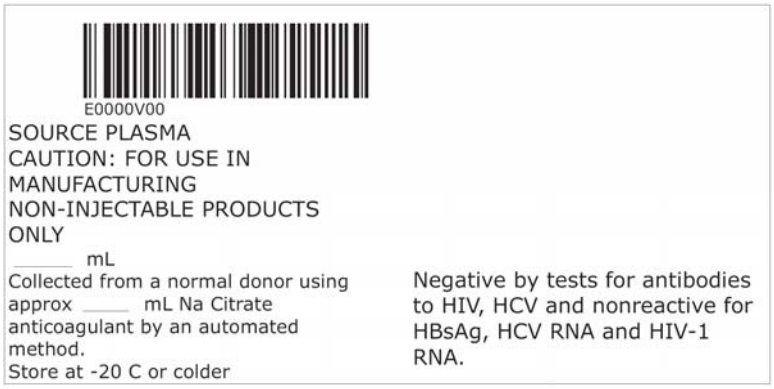
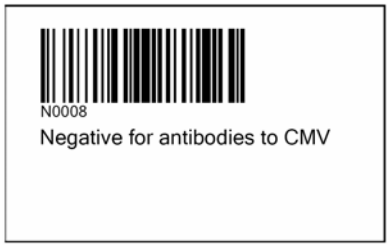
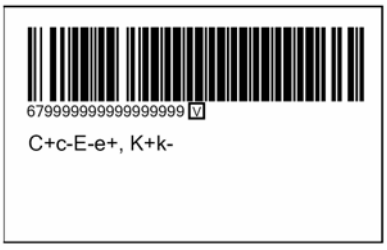
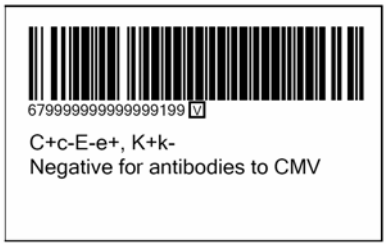


Figure 25 Therapeutic Collection Labels

Figure 26 Special Testing and Red Cell Antigen Labels







6 ICCBBA, Inc Databases

6.1 Facility Identification Number/Manufacturer Identification Code

This database lists all facilities and manufacturers registered with ICCBBA, Inc. US facility codes begin with "W." Each four-digit code then provides an index to the name and address of the facility. Manufacturers are given a two-character code. Using this database, every registered facility and manufacturer 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, or other product used during collection or processing.

6.2 Product Description Code

As noted in the Preface, the major description of the *ISBT 128* Product Description Code database can be found in the document *ISBT 128 Standard: Technical Specification* and supporting documents. In Chapter 4 and Appendices B and C there is some expansion of the description given earlier of the Product Code data structure (3.5.5, page 16), including a general depiction of the rules-based system applied to the naming conventions and code assignments for *ISBT 128* product description codes, and some examples of the system in practice. As noted in the *ISBT 128 Standard: Technical 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 Description 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 (*e.g.*, Canada, Switzerland) two or more names are needed (English/French and French/German/Italian, respectively). It was 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 Description Code regardless of the name or names applied by any particular country.

6.3 Special Testing Code: General

This is the name given to the database that is used to encode and decode general information about a blood product other than antigenic testing. A specific data identifier distinguishes this data structure from the others, and these are encoded and decoded by reference to special tables. *See* the *ISBT 128: Technical Specification* for complete details.

7 Other Publications to Consult

7.1 Published by ICCBBA, Inc

ISBT 128 Standard: Technical Specification, Version 2.1.0, August 2004.

ISBT 128: *Product Code Database (Blood Components) — Structure and Definitions, Version 1.3.0, June 2001*.

ISBT 128 Standard: Product Coding: Bounded Lists and Definitions, Version 2.8, October 2005.

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, May 2004.

Technical Bulletin 5: Bar Code Scanner Implementation of ISBT 128 Concatenation, May 2001.

Technical Bulletin 6: EDI: Electronic Data Interchange, May 2001.

Technical Bulletin 7:Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution, March 2005.

Technical Note 1: Case Conversion, May 2001.

Technical Note 2: Length of the Product Code Bar Code and Concatenation, June 2001.

Technical Note 3: ISBT 128 and Compound Message, May 2005.

Technical Note 4: Manufacturer's Catalog Number and Lot Number (NOT Containers).

Note: All ICCBBA, Inc publications are made available upon publication to registered and licensed facilities, software developers and manufacturers through the ICCBBA, Inc Website.

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.

Uniform Symbology Specification: Code 128. AIM USA, 634 Alpha Drive, Pittsburgh, PA 15238.

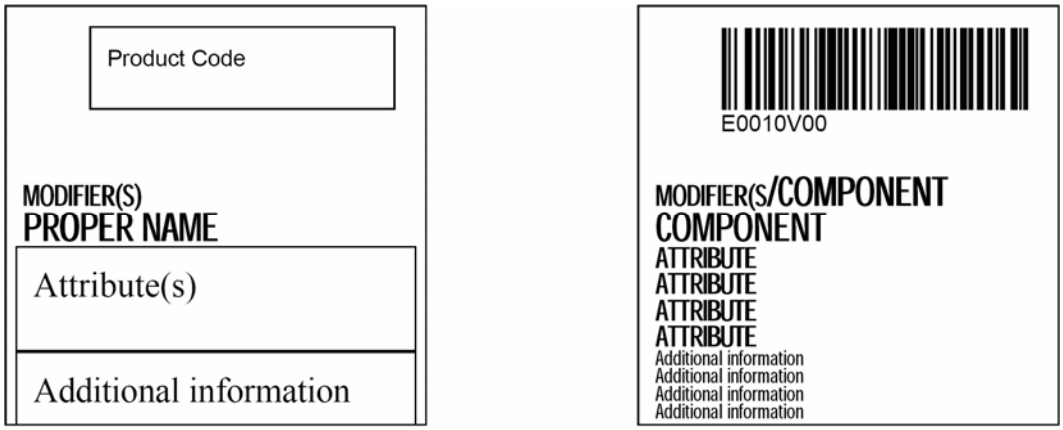
Guideline for the Uniform Labeling of Blood and Blood Components. Published by the Food and Drug Administration, Center for Drugs and Biologics, Office of Biologics Research and Review, in cooperation with the American Blood Commission, August 1985.

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 A 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 B and C give US labeling instructions for blood product Proper Names [Component Name (with any appropriate Modifiers and Attributes)] and for Attributes that are not part of the Proper Name. Appendix D provides instructions for labeling when the sixth position in the product code is used to indicate type of donation or collection/intended use. Appendix E lists acceptable abbreviations for label text.

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 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. To provide an uncluttered appearance, it is recommended that the fourth Attribute and Additional Information lines only be used if absolutely necessary. All illustrations in Chapter 5 conform to this placement scheme. Note that when the US License Number is placed in this quadrant, it will use one of the lines available for Attributes or Additional Information.

The bar code is right justified, and placed 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 (Component Name) should be placed somewhat above the middle of the label, as shown, and left justified. The size of the Proper Name (Component Name) should be as large as possible (maximum height 5/32" [4 mm]), remembering that some label information in other quadrants must be

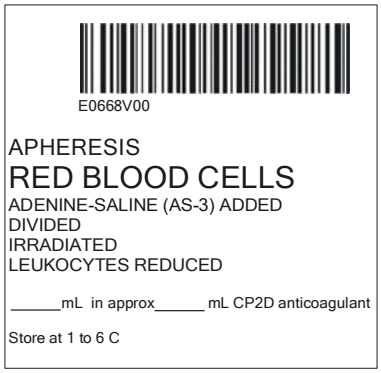
no less prominent than the Proper Name (Component Name). A compressed font that permits the height of the font to remain as large as possible is preferable to using a font that necessitates decreasing the height of the font.

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

MODIFIER
PROPER NAME
ATTRIBUTE(S)

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

MODIFIER
PROPER NAME
ADDITIVE SOLUTION
ATTRIBUTE(S)



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

Note: 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 to 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 Description labels that is not covered in Appendices B through E is presented in the table beginning on Page 62 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 Chapter 5.

SOURCE PLASMA labels are a special case. They often need to be modified because of the large amount of information they must contain. Labeling of these products is covered in Chapter 5.

Table 4 Additional Product Label Information

Blood Product	Print "what"	Print "where" (all left justified, but see note on Page 61)
Whole Blood, 450 mL	Approx 450 mL plus 63 mL [anticoagulant] Store at 1 to 6 C	Additional information line 1 Additional information line 2
Whole Blood, 500 mL	Approx 500 mL plus 70 mL [anticoagulant] Store at 1 to 6 C	Additional information line 1 Additional information line 2
Red Blood Cells, 450 mL	From 450 mL [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2
Red Blood Cells, 500 mL	From 500 mL [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2
Red Blood Cells with AS-1 additive, 450 mL	**ADENINE-SALINE (AS-1) ADDED** From 450 mL CPD Whole Blood Store at 1 to 6 C	**Attribute line 1** Additional information line 1 Additional information line 2
Red Blood Cells with AS-3 additive, 450 mL	**ADENINE-SALINE (AS-3) ADDED** From 450 mL CP2D Whole Blood Store at 1 to 6 C	**Attribute line 1** Additional information line 1 Additional information line 2
Red Blood Cells with AS-5 additive, 450 mL	**ADENINE-SALINE (AS-5) ADDED** From 450 mL CPD Whole Blood Store at 1 to 6 C	**Attribute line 1** Additional information line 1 Additional information line 2
Red Blood Cells with AS-1 additive, 500 mL	**ADENINE-SALINE (AS-1) ADDED** From 500 mL CPD Whole Blood Store at 1 to 6 C	**Attribute line 1** Additional information line 1 Additional information line 2
Red Blood Cells with AS-3 additive, 500 mL	**ADENINE-SALINE (AS-3) ADDED** From 500 mL CP2D Whole Blood Store at 1 to 6 C	**Attribute line 1** Additional information line 1 Additional information line 2
Red Blood Cells with AS-5 additive, 500 mL	**ADENINE-SALINE (AS-5) ADDED** From 500 mL CPD Whole Blood Store at 1 to 6 C	**Attribute line 1** Additional information line 1 Additional information line 2

Washed, Frozen, Rejuvenated and Deglycerolized Red Blood Cells	___mL Store at 1 to 6 C *or* -65 C or colder	*Note: No anticoagulant specified* Additional information line 1 Additional information line 2
Fresh Frozen Plasma	_____ mL from [anticoagulant] Whole Blood Store at -18 C or colder	Additional information line 1 Additional information line 2
Thawed Fresh Frozen Plasma, if relabeled	____ mL from [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2
Thawed Plasma, if relabeled	_____ mL from [anticoagulant] Whole Blood Store at 1 to 6 C	Additional information line 1 Additional information line 2
Cryoprecipitated AHF	Store at -18 C or colder	Additional information line 1
Thawed Cryopreciptated AHF, if relabeled	Store at room temperature	Additional information line 1
Pooled Cryoprecipitated AHF	_____ mL Number of units in pool _____ Store at -18 C or colder	Additional information line 1 Additional information line 2 Additional information line 3
Thawed Pooled Cryoprecipitated AHF, if relabeled	_____ mL Number of units in pool _____ Store at room temperature	Additional information line 1 Additional information line 2 Additional information line 3
Platelets, from 450 mL collection	Approx 45–65 mL From 450 mL [anticoagulant] Whole Blood Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3
Platelets, from 500 mL collection	Approx 45–65 mL From 500 mL [anticoagulant] Whole Blood Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3
Pooled Platelets	_____ mL Number of units in pool _____ From [anticoagulant] Whole Blood Store at 20 to 24 C	Additional information line 1 Additional information line 2 Additional information line 3 Additional information line 4
Apheresis Red Blood Cells	_____ mL containing approx _____ mL [anticoagulant] Store at 1 to 6 C	Additional information line 1 Additional information line 2
Apheresis Platelets	_____ mL containing approx _____ mL [anticoagulant] Store at 20 to 24 C	Additional information line 1 Additional information line 2
Apheresis Fresh Frozen Plasma	_____ mL containing approx _____ mL [anticoagulant] Store at -18 C or colder	Additional information line 1 Additional information line 2
Apheresis Cryoprecipitated AHF*	Prepared from _____ mL Plasma Store at -18 C or colder	Additional information line 1 Additional information line 2

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

Appendix B Proper Names for Products

Table 5 US Labeling — Standardized Printing of ISBT 128 Proper Name (Component Name [Component Class and Modifier])

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

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

Modifier	Component Class	Proper Name
	PLASMA	**PLASMA** If the product is to be used for further manufacturing, it will be labeled: **RECOVERED PLASMA**
THAWED	PLASMA	**THAWED PLASMA**
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**

Modifier	Component Class	Proper Name
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**
	POOLED GRANULOCYTES	**POOLED GRANULOCYTES**
APHERESIS	GRANULOCYTES/ PLATELETS	**APHRERESIS GRANULOCYTES/ PLATELETS**
	LEUKOCYTES	**LEUKOCYTES**

Modifier	Component Class	Proper Name
APHERESIS	LEUKOCYTES	**APHERESIS LEUKOCYTES** If the product is to be used for further manufacturing, it will be labeled: **SOURCE LEUKOCYTES**
	POOLED PLASMA	**POOLED PLASMA**
LIQUID APHERESIS	PLASMA	**LIQUID APHERESIS PLASMA**
WASHED APHERESIS	RED BLOOD CELLS	**WASHED APHERESIS RED BLOOD CELLS**
FROZEN APHERESIS	RED BLOOD CELLS	**FROZEN APHERESIS RED BLOOD CELLS**
DEGLYCEROLIZED APHERESIS	RED BLOOD CELLS	**DEGLYCEROLIZED APHERESIS RED BLOOD CELLS**
REJUVENATED APHERESIS	RED BLOOD CELLS	**REJUVENATED APHERESIS RED BLOOD CELLS**
FROZEN REJUVENATED APHERESIS	RED BLOOD CELLS	**FROZEN REJUVENATED APHERESIS RED BLOOD CELLS**
DEGLYCEROLIZED REJUVENATED APHERESIS	RED BLOOD CELLS	**DEGLYCEROLIZED REJUVENATED APHERESIS RED BLOOD CELLS**

Note: The following Component Classes, defined in the ISBT 128 Product Description 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 C Attributes

Table 6 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 on the label.

Attribute Group	*ISBT 128*	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
Intended Use	For further manufacture — injectable	**CAUTION: FOR MANUFACTURING USE ONLY** will be printed in the "Attribute" Section on the lines following the Proper Name

Attribute Group	*ISBT 128*	US Labeling Instructions
	For further manufacture — non-injectable	**CAUTION: FOR USE IN MANUFACTURING NON-INJECTABLE PRODUCTS ONLY** will be printed in the "Attribute" Section on the lines following the Proper Name *or* **CAUTION: FOR FURTHER MANUFACTURING INTO IN VITRO DIAGNOSTIC REAGENTS FOR WHICH THERE ARE NO ALTERNATIVE SOURCES** will be printed in the "Attribute" Section on the lines following the Proper Name if the unit has a reactive test for an infectious disease or if anti-HBc was not performed..

Attribute Group	*ISBT 128*	US Labeling Instructions
	For further manufacture—non-injectable restricted use	**CAUTION: FOR USE IN MANUFACTURING NON-INJECTABLE PRODUCTS ONLY** will be printed in the "Attribute" Section on the lines following the Proper Name *or* **CAUTION: FOR FURTHER MANUFACTURING INTO IN VITRO DIAGNOSTIC REAGENTS FOR WHICH THERE ARE NO ALTERNATIVE SOURCES** will be printed in the "Attribute" Section on the lines following the Proper Name if the unit has a reactive test for an infectious disease or if anti-HBc was not performed. *and* "**Not for Use in Products Subject to License Under Section 351 of the Public Health Service Act"** must also be on the label.
	Not for transfusion or further manufacture	**CAUTION: FOR LABORATORY RESEARCH USE ONLY** will be printed in the "Attribute" Section on the lines following the Proper Name
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 x 10^6	**LEUKOCYTES REDUCED** will be printed below the Proper Name in the "Attribute" Section *Note: Printing the actual count is optional and is not recommended. If it is printed, it should appear beneath the storage temperature of the product.*
	For **PLATELETS** prepared from **WHOLE BLOOD** Residual Leukocyte Content <8.3 x 10^5	**LEUKOCYTES REDUCED** will be printed below the Proper Name in the "Attribute" Section *Note: Printing the actual count is optional and is not recommended. If it is printed, it should appear beneath the storage temperature of the product.*
Altered	Albumin Added	**ALBUMIN ADDED**
	Cryoprecipitate Reduced	**CRYOPRECIPITATE REDUCED**
	Plasma Added	**PLASMA ADDED**
	Plasma Reduced	**PLASMA REDUCED**
	Platelets Reduced	**PLATELETS REDUCED**
	Supernatant Reduced	**SUPERNATANT REDUCED**

Attribute Group	*ISBT 128*	US Labeling Instructions
	Supernatant Removed/Plasma Added	**PLASMA ADDED after SUPERNATANT REMOVED**
	Platelets/Cryoprecipitate Reduced	**PLATELETS and CRYOPRECIPITATE REDUCED**
Final Content	Low Volume	**LOW VOLUME** will be printed below the proper name in the "Attribute" Section Note that there are two possibilities for low volume units, "anticoagulant adjusted" and "anticoagulant not adjusted." For **WHOLE BLOOD**: _____ mL plus _____ mL [anticoagulant] should appear on the first line of the "Additional Information" Section providing volumes as appropriate. For **RED CELLS:** Approx _____ mL from _____mL [anticoagulant] Whole Blood (if anticoagulant was not adjusted) OR ____ mL from ___ mL Whole Blood containing approx. ___ mL (anticoagulant) (if anticoagulant was adjusted) should appear on the first line of the "Additional Information" Section providing the volume as appropriate.
	Final Content <200 mL Final Content ≥200 mL <400 mL Final Content ≥400 mL <600 mL Final Content ≥600 mL	Actual volume is to be printed as ____ mL in the "Additional Information" Section
Preparation: Additional Information	Plasma Frozen ≤15 hours	Print below the proper name in the "Attribute" Section **FROZEN WITHIN 15 HOURS AFTER PHLEBOTOMY**
	Plasma Frozen ≤24 hours	**FROZEN WITHIN 24 HOURS AFTER PHLEBOTOMY**

Attribute Group	*ISBT 128*	US Labeling Instructions
	Plasma Frozen >24 hours	**FROZEN MORE THAN 24 HOURS AFTER PHLEBOTOMY**
	Granulocytes prepared using HES	Information is to be included in the "addition information" Section together with any anticoagulant present
Apheresis and container: Additional Information	1st Container, 2nd Container, etc.	1st Container, 2nd Container, etc.. may be printed beneath the storage temperature in the "additional information" section.
	Apheresis not automated	Prepared by a manual procedure will be printed in the "Additional Information" Section
Quarantine: Additional Information		Not used in the US at this time
Dosage: Additional Information	<3 X10log11	Label with actual platelet count
Method of Treatment		Not used in the US at this time
Platelet Count		Not used in the US at this time
Monitoring	Bacterial monitoring	7 d will be printed as part of proper name

Appendix D Donation Type

Table 7 Labeling Instructions for Donation Type (Sixth Position in the Product Code Bar Code)

Sixth Data Character	**Type of Donation**	**Upper Left Quadrant** [in no less prominence than Proper Name]	**Lower Left Quadrant**	**Upper Right Quadrant** [in no less prominence than Proper Name]
V	Voluntary allogeneic donation	**VOLUNTEER DONOR**		
R	Voluntary research donation	**VOLUNTEER DONOR**		FOR LABORATORY RESEARCH USE ONLY
S	Voluntary source donation	**VOLUNTEER DONOR**		
T	Voluntary therapeutic collection*	**VOLUNTEER DONOR**	The disease of the patient from which the unit was collected must be specified	**THERAPEUTIC COLLECTION**
P	Paid allogeneic collection	**PAID DONOR**		
r	Paid research collection	**PAID DONOR**		FOR LABORATORY RESEARCH USE ONLY
s	Paid source collection	**PAID DONOR**		

X	For autologous use only, biohazardous	**VOLUNTEER DONOR**		**FOR AUTOLOGOUS USE ONLY, BIOHAZARDOUS**
D	Volunteer directed collection, eligible for crossover	**VOLUNTEER DONOR**		
d	Paid directed collection	**PAID DONOR**		**FOR DESIGNATED RECIPIENT ONLY****
1 (one)	For autologous use only	**VOLUNTEER DONOR**		**FOR AUTOLOGOUS USE ONLY**
2	For directed recipient use only	**VOLUNTEER DONOR**		**FOR DESIGNATED RECIPIENT USE ONLY**
3	For directed recipient use only, biohazardous	**VOLUNTEER DONOR**		**FOR DESIGNATED RECIPIENT USE ONLY, BIOHAZARDOUS**
4	Designated collection	**VOLUNTEER DONOR**		**FOR DESIGNATED RECIPIENT ONLY****
5	Dedicated collection	**VOLUNTEER DONOR**		**FOR DESIGNATED RECIPIENT ONLY****

** With the necessary variance from the FDA, therapeutic collections may be labeled as voluntary allogeneic donations.*
***If the donation may be crossed over, "For Designated Recipient Only" need not appear in the upper right quadrant.*

Appendix E 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 temp	room temperature