IMPLEMENTATION GUIDE

Use of ISBT 128 in Resource-Limited Countries

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Forward

To meet the vision of the International Council for Commonality in Blood Banking Automation (ICCBBA) of global adoption of ISBT 128 for all medical products of human origin (MPHO), it is necessary to take into consideration the time and costs associated with the implementation of a new coding and labeling system. As these factors are very important in a facility's decision to implement a new system, consideration must be given to facilities located in countries at different levels of development and with limited resources for implementation of such a standard.

Because of these considerations, ICCBBA has created this guidance document to supplement the *ISBT 128 Standard Technical Specification* (ST-001) that limits features within the Standard to those that are required to improve traceability and recipient safety, while reducing time and costs associated with full implementation.

Specifically, this guidance document is targeted to the Blood Transfusion Service (BTS) and Hospital Blood Bank (HBB) staff that are operating in resource-limited countries. Important topics include:

- Traceability (Chapter 2, page 15)
- Interoperability (Section 3.1, page 18)
- The ISBT 128 Standard
    - Standardized Terminology (Chapter 4, page 19)
    - Coding (Chapter 5, page 20)
    - Labeling (Chapter 6, page 34)
- Haemovigilance (Chapter 9, page 67)
- Flexibility (Section 11.1, page 69)
- Options for implementing ISBT 128 (Appendix 2)

To facilitate creation of this guidance document, ICCBBA staff visited a BTS and several HBBs located in a low income country (as classified by the World Bank Group's World Development Indicators (WDI) data. See https://data.worldbank.org/). Valuable information was shared and assessments were made based on the needs and resources of these facilities. This document reflects the results of that visit and provides recommendations for how the ISBT 128 Standard can be adapted to meet users' needs. Of interest is Appendix 2, where different options for implementation are discussed, including relative costs, advantages, and disadvantages for each option.

For more information, contact the ICCBBA office at support@isbt128.org or visit us on the web at www.isbt128.org.

1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance for implementation of the ISBT 128 Standard for blood transfusion in resource-limited countries. It is intended to provide options allowing facilities to promote safety, traceability, and efficiency without needing to implement all features of the ISBT 128 Standard.

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification*. The scope of this document is limited to those features of ISBT 128 that may be used by blood banking facilities with limited resources to improve traceability and recipient safety. It is not intended for use by facilities in countries rated as high or medium in the United Nation's Human Development Index (HDI) . It is also limited to whole blood and blood components.

The first two chapters of this document address two general concepts: Traceability, a requirement for all medical products of human origin (MPHO), and the Information Environment, which is needed for good record keeping to support traceability in the electronic age. Subsequent chapters will discuss ISBT 128 in greater detail. Finally, Chapter 8 returns to a general concept, haemovigilance.

1.3 Intended Audience

The intended audience of this document is Blood Transfusion Service (BTS) and Hospital Blood Bank (HBB) staff (including management, information technology, quality, validation, and laboratory) in resource-limited countries.

1.4 Normative References

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)

ISBT 128 Standard Labeling of Blood Components (ST-005)

ISBT 128 Standard Product Description Code Database (ST-010).

ISO 8601 (2004)(E) Data elements and interchange formats — Information interchange —Representation of dates and times

1.5 Other References

ICCBBA Website (www.isbt128.org)

An Introduction to ISBT 128 (IN-015)

Length of the Product Code Bar Code and Concatenation (IG-017)

Bar Code Scanner Implementation of ISBT 128 Concatenation (IG-008)

Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)

Implementation Guide: Use of Product Code [Data Structure 003] – Blood (IG-021)

Implementation Guide: Choosing an On-Demand Label Printer (IG-029)

Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)

User guide for navigating resources on stepwise implementation of haemovigilance systems. Available from https://www.who.int/publications/i/item/9789240047860 Accessed 14 Sep 2022.

Resolution WHA63.22. Human organ and tissue transplantation. In: *Sixty-third World Health Assembly, Geneva, 17–21 May 2010. Volume 1. Resolutions and decisions*. Geneva: World Health Organization; 2010 (WHA63/2010/REC/1). Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf Accessed 14 Sep 2022.

WHO EB136-32 (third bullet of 'the way forward' applies). Bull World Health Organ 013;91:314–314A WHO Aide-Memoire on Haemovigilance http://apps.who.int/gb/ebwha/pdf_files/EB136/B136_32-en.pdf

A guide to establishing a national haemovigilance system. Available from https://www.who.int/publications/i/item/9789241549844 Accessed 14 Sep 2022.

AfSBT Step-Wise Accreditation Standards, Africa Society for Blood Transfusion (AfSBT), 2013.

Guidance Document, Step-Wise Accreditation Programme, Africa Society for Blood Transfusion (AfSBT), 2013.

1.6 Background

There is growing recognition of the need for standardization of terminology, coding, and labeling of all MPHO in order to improve traceability and transparency. The 2010 World Health Assembly Resolution WHA63.22 called on member states to "encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation."

A Specification, ISBT 128, for labeling blood products was developed by the International Society of Blood Transfusion Working Party on Automation and Data Processing [now called the Working Party on Information Technology] and published by ICCBBA in 1995. Around the world, implementation in blood establishments began soon after the Standard was issued, with a steady increase in adoption since that time. Many countries around the world now use ISBT 128 for blood and there is a steady global movement toward implementation of ISBT 128 for cells, tissues, and other MPHO.

ISBT 128 labeling allows each product to be uniquely identified on a global scale. This supports traceability, which in turn supports vigilance and surveillance. However, ISBT 128 is more than a labeling system. It addresses three related, but distinct, areas: terminology, coding, and labeling.

International standardization of terminology and product coding is a key element of ISBT 128. Standardized product coding allows blood products to be shipped internationally with clear, unambiguous labeling. Language barriers can be overcome through the use of standardized bar codes and a shared ICCBBA-maintained database.

ISBT 128 is managed by ICCBBA, an international non-state actor in official relations with the World Health Organization (WHO)based in the US. It provides a technical help desk (email support@isbt128.org) to answer questions and to help users implement the Standard. Additionally, a great deal of information, including ICCBBA documents and databases, are found on its website (www.isbt128.org).

1.7 Definitions of Terms Referring to Facilities

Throughout this document, the following terms will be used with these definitions:

Blood Transfusion Service (BTS)	An organization, or department within an organization, that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion (excludes Hospital Blood Banks).
Hospital Blood Bank (HBB)	A hospital unit which stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities. It includes hospital-based transfusion activities. An HBB may also be referred to as a hospital transfusion laboratory.

1.8 Changes in this Version

The following table indicates the major changes between Version 1.0.0 and Version 1.0.2. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

Implementation Guide: Use of ISBT 128 in Resource-Limited Countries Version Control: Version 1.0.0 vs. Version 1.0.2

	Version 1.0.0 Chapter, Section, Table or Figure	Version 1.0.2 Chapter, Section, Table or Figure	Change	Rationale
1.	Throughout	Throughout	Updated reference titles as needed.	To reflect current titles.
2.	Throughout	Throughout	Changed “ABO/Rh” to “Blood Groups [ABO and RhD]” when referring to DS 002 and as applicable.	To be consistent with current usage across the Standard.
3.	Throughout	Throughout	Removed/changed references to “bar code text” as applicable.	To be consistent with ST-001.
4.	Throughout	Throughout	Replaced all instances of “2-D bar code” with “2-D symbol”; “bar code” replaced with “linear bar code” where applicable.	To be consistent with current usage across the Standard.
5.	Throughout	Throughout	Updated previous descriptions and links for HDI to the newer World Development Indicators (WDI) data (by World Bank Group) at data.worldbank.org.	To keep the publication up-to-date.
6.	Throughout	Throughout	Updated the links to the WHO Haemovigilance documents.	To provide a working link.
7.	Throughout	Throughout	Changed “donation type” to “Collection Type”.	To be consistent with ST-001.
8.	Throughout	Throughout	Updated ICCBBA’s website links to www.isbt128.org	To reflect the address of the new website.
9.	Throughout	Throughout	Updated ICCBBA’s help desk e-mail address to support@isbt128.org.	To reflect the new e-mail address.
10.	2.2.1	2.2.1	Updated wording about the DIN.	To be consistent with ST-001.

	Version 1.0.0 Chapter, Section, Table or Figure	Version 1.0.2 Chapter, Section, Table or Figure	Change	Rationale
11.	Figure 3	Figure 3	Provided a new diagram of the Information Environment.	To reflect the revised diagram.
12.	5.1.1	5.1.1	Updated wording about the DIN.	For consistency with ST-001.
13.	5.1.3	5.1.3	Included the collection type element and division code element of the Product Code.	For clarification.
14.	Table 2	Table 2	Added code “Ma”.	Missing code that is part of reference table RT006.
15.	5.2.2	5.2.2	Minor changes to wording.	For internal consistency.
16.	Table 4	Table 4	Updated text for V, 1, and P entries.	For consistency with reference table RT008.
17.	Table 5	Table 5	Updated text for V entry.	For consistency with reference table RT008.
18.	6.3.1.1	6.3.1.1	Removed references to “data content text” and reworded section to describe “Text Associated with Data Content.”	For consistency with ST-001.
19.	6.3.1.2	6.3.1.2	Removed references to “bar code text” and reworded section to describe “Text Associated with Electronically Readable Information.”	For consistency with ST-001.
20.	6.3.1.3	6.3.1.3	Updated and reworded section on “Additional Text” to describe “Text Not Associated with Electronically Readable Information.”	For consistency with ST-001.
21.	6.3.4	6.3.4	Removed reference to “bar code text”.	For consistency with ST-001.
22.	7.2.2	7.2.2	Updated wording about the product lookup tool, which is now primarily used online, and kept the reference to the downloadable version of the tool in parentheses.	To reflect the most up-to-date information regarding the Product Lookup Web Application.

	Version 1.0.0 Chapter, Section, Table or Figure	Version 1.0.2 Chapter, Section, Table or Figure	Change	Rationale
23.	8	8	Added text for “Standard Operating Procedures” as SOPs hadn’t been defined.	For clarification.
24.	10	10	Updated previous descriptions and links for HDI to the newer World Development Indicators (WDI) data (by World Bank Group) at data.worldbank.org.	To reflect the use of the World Bank’s development indicators.
25.	11.2	11.2	Updated reference to GMT to the currently accepted UTC (Coordinated Universal Time).	For consistency with ST-001.
26.	Acronyms	Acronyms	Removed HDI and added WDI.	To reflect the use of the World Bank’s development indicators.
27.	Glossary	Glossary	Updated 2-D bar code definition to reflect current use of 2-D symbol. Changed descriptions of “data content text”, “bar code text” and “additional text”.	For consistency with ST-001.

2 Traceability

2.1 Concepts

Traceability in blood banking involves the ability to track a blood product from donor to recipient and from recipient to donor, and to track from any blood product to all the other blood products derived from the same donation. The concept of traceability is central to the management of all medical products of human origin (MPHO), which include blood, tissues, organs, cellular therapy products, and human milk. Requirements for traceability are frequently embedded in regulations as well as in standards formulated by professional societies. While the principles of traceability apply to all MPHO, this document will focus on blood and blood components.

Two requirements must be met to ensure traceability:

- Unique Identifiers: Each unit of blood or blood component must be uniquely identified in order to create an unambiguous path between donor and recipient.

- Good record keeping: Because an adverse event can occur soon after transfusion or it may be recognized years later, reliable systems must exist to accurately record and store information about the source and disposition of the blood component, as well as the path the product takes between donor and recipient, for many years.

Together, these requirements mean that facilities must assign identifiers to products that are unique for a long period of time and develop mechanisms to ensure these identifiers are transcribed and recorded accurately at each point in the transfusion chain. The actual length of time for which an identifier must remain unique will vary by national regulations.

2.2 ISBT 128 and Traceability

Implementation of the ISBT 128 Standard facilitates traceability by providing the mechanism for uniquely identifying each product for a period of 100 years and by supporting automation of information capture and record keeping by making key traceability information electronically readable (bar coded). Chapters 3 and 5 will discuss how information is encoded for use in bar codes.

To uniquely identify each blood product, ISBT 128 requires two elements: the Donation Identification Number and the Product Code.

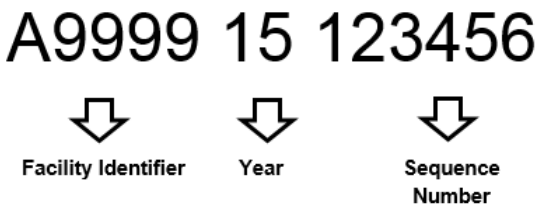
2.2.1 Donation Identification Number (DIN)

An ISBT 128 DIN uniquely identifies a donation event and links the unit to the donor in the facility records. (*Note: A DIN may also be used to identify a product pool. This is discussed in 7.2.2 in the section on Pooled Products*.) It comprises three elements:

- A five (5)-character Facility Identification Number that is assigned by ICCBBA to ensure global uniqueness.
- A two (2)-character year code that represents the year the DIN was assigned and ensures uniqueness for a 100-year period.

- A six (6)-character sequence number assigned by the facility to ensure uniqueness during the year indicated.

Figure 1 Donation Identification Number (DIN)



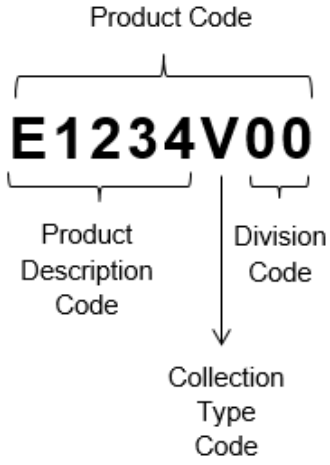
For more information about coding the DIN into an electronically readable format, see Section 5.1.1. For text presentation of the DIN on the product label, see 6.3.2.

2.2.2 Product Code

A Product Code uniquely identifies different products from the same donation (e.g., Red Cells, Plasma, and Platelets from the same donation). The eight (8)-character Product Code comprises three elements:

- A five (5)-character Product Description Code (PDC) that indicates the type of product (red cells, plasma, platelets, etc., and may include details such as storage temperature and anticoagulant)
- A one (1)-character Collection Type Code (allogeneic, autologous, directed, replacement, etc.)
- A two (2)-character Division Code (to uniquely identify multiple aliquots from the same donation and with the same Product Description Code)

Figure 2 Product Code



For more information about coding the product information into an electronically readable format, see Section 5.1.3. For printing product information as text, see Section 6.3.4.

Each blood component is assigned a DIN and a Product Code that work in a hierarchical manner:

- The DIN uniquely identifies a collection event and appears on all products from that collection. Once assigned to products, the DIN should never change. It is the link to the donor. (*Note: A DIN may also be used to identify a product pool. This is discussed in 7.2.2 in the section on Pooled Products*.)
- The Product Code uniquely identifies each product that results from the collection. The Product Code will change if the product is modified or divided.

3 Information Environment

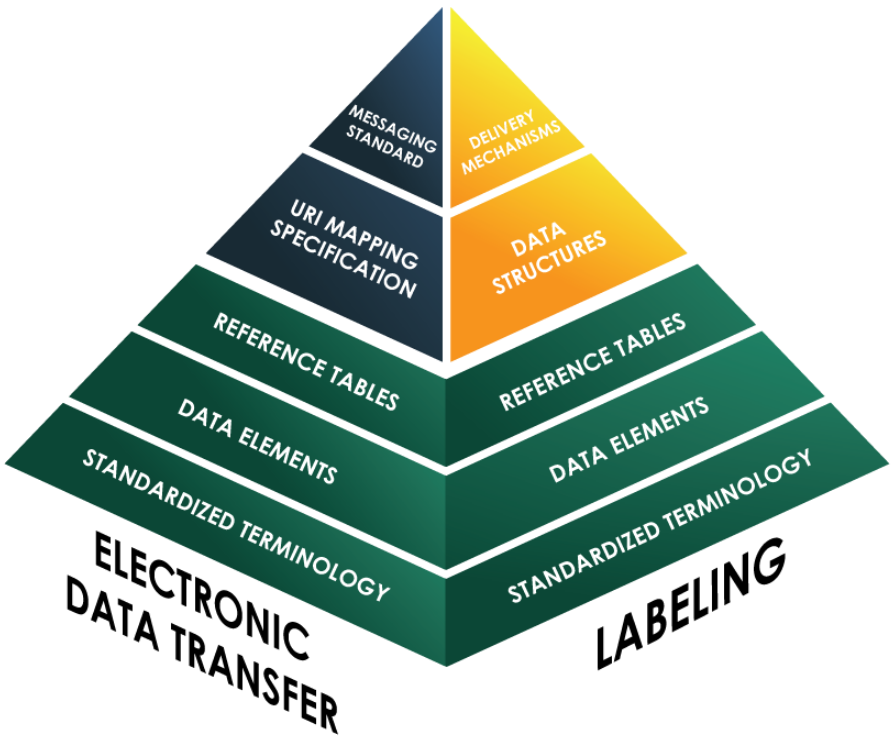
3.1 Interoperability

Interoperability is the property of a system that allows it to be used across disparate computer systems. This is an important feature of a blood bank coding system because (1) it supports sharing of blood resources and (2) it means blood bank software does not need to be customized for each organization. ISBT 128 provides interoperability for over 5000 facilities licensed for its use worldwide.

3.2 ISBT 128 Environment

The information environment comprises a number of layers each of which needs to be in place to ensure that standardization can be achieved. ISBT 128 is a terminology, coding, and labeling system. This can be broken further into the elements shown in Figure 3. The next three chapters will look at the elements associated with labeling in more detail.

Figure 3 Information Environment



4 Terminology

Standardized product terminology is the foundation of the ISBT 128 coding system. For bar codes to have a standardized meaning, users must first agree upon what to call a product. This is not as easy as it may seem, given the diversity of the use of ISBT 128 both geographically and across different MPHO. ICCBBA, the organization that manages the ISBT 128 Standard, organizes experts from various fields (blood, cells, tissues, human milk, etc.) into Technical Advisory Groups (TAGs). These experts work together to propose terms and definitions which are then released for public comment. When consensus is reached, terminology is published in the document *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) and used to describe products within the ISBT 128 system.

For a complete list of terms and definitions, see the ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002).

This agreed upon terminology is used to describe blood products in terms of Classes, Modifiers, and Attributes.

For a detailed description of how the system works, see Implementation Guide: Use of Product Code [Data Structure 003] – Blood (IG-021).

5 Coding

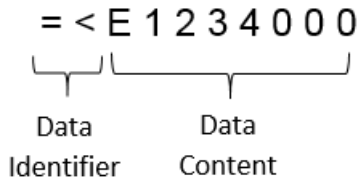
5.1 Data Structures

Data structures are the means by which information about blood components is put into computer-friendly codes. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate reference tables for conversion of codes into meaningful information.

Data structures comprise two elements:

- Data identifier: a two (2)- or three (3)-character code that identifies the data structure [described in more detail in the *ISBT 128 Standard Technical Specification* (ST-001)].
- Data content: the data characters that provide the information to be conveyed (e.g., coded information that conveys that the product is Red Blood Cells).

Figure 4 Data Structure



ISBT 128 data structures may be used in bar codes on labels of blood components for electronic communication or may be used for electronic messaging between computers.

There are many ISBT 128 data structures not all of which will be used in the labeling of blood. A description of all ISBT 128 data structures is found in the *ISBT 128 Standard Technical Specification* (ST-001). Each data structure is identified with a number in brackets after the name of the data structure. Data structures that are required for **traceability** are:

- Donation Identification Number [Data Structure 001]
- Product Code [Data Structure 003]

Other data structures that are needed for blood banks, but that are not essential to traceability, include:

- Blood Groups [ABO and RhD] [Data Structure 002]
- Expiration Date and Time [Data Structure 005]
- Collection Date [Data Structure 006] or Collection Date and Time [Data Structure 007]

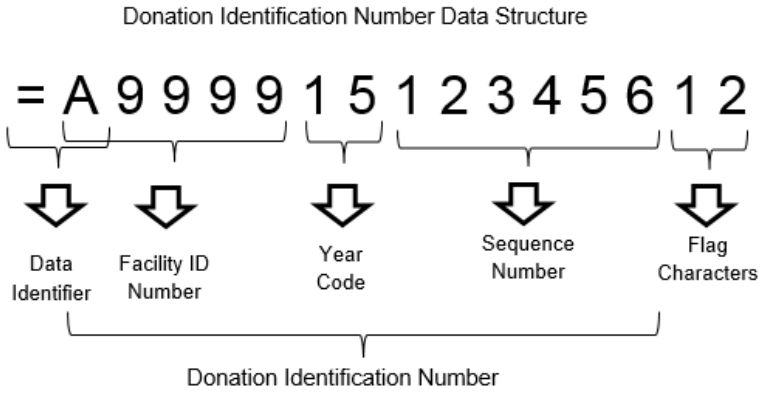
This chapter will include a high level description of these data structures. Specific details of coding are found in the *ISBT 128 Standard Technical Specification* (ST-001). Guidance on how and when to use these data structures appears later in this document and/or in one of the documents referenced in Sections 1.4 or 1.5.

5.1.1 Donation Identification Number [Data Structure 001]

Data Structure 001 specifies a Donation Identification Number (DIN) that is a unique identification of a donation event or product pool from anywhere in the world over a 100-year period.

This data structure is unique in that the second character of the data identifier also serves as the first character of the data content.

Figure 5 Donation Identification Number Data Structure



The DIN contains three elements:

- The first element, the Facility Identification Number (FIN), is assigned to a facility by ICCBBA and supports global uniqueness. In order to obtain a FIN, blood banks will need to register with ICCBBA. ICCBBA maintains a database of code assignments and this table is available to licensed users of the ISBT 128 system. It is called “Registered Facilities” and is found in a password-protected area of the ICCBBA website (www.isbt128.org). The FIN within the DIN identifies the organization that assigned the DIN.

- The second element is a two (2)-digit year and supports uniqueness for a 100-year period. This is a nominal year identifier and should not be used as an alternative to other date data structures (such as Collection Date, Expiration Date and Time, etc.). Its purpose is solely to support the requirement for 100-year uniqueness. *Note: In practice, this is the “nominal” year. To cut down on wastage, DIN labels may be used for up to one month in the year before, and one month in the year after, the year shown on the label.*

- The third element is a sequence number assigned by the facility. The facility is responsible for ensuring the sequence number is unique to each collection/recovery event or product pool for a given year and FIN.

Together, the three elements create global uniqueness for the DIN.

5.1.1.1 Sequence Number

A facility can determine how a sequence number is assigned. For example, it can start at 000001 at the beginning of each year. That is, it can start at 000001 when it first starts to use 22 as the year code, number sequentially through the year, and then start again at 000001 when it begins to use DINs with a year code of 23. However, this is not essential.

Scenario 1: If the BTS prints its own DINs, it can assign the next sequential number when a new year code is used. For example, if the BTS ends 2022 with the sequence number 019598, which appears as:

A9997 22 019598

It could start 2023 using the next sequential number for the sequence number which would be:

A9997 23 019599

Scenario 2: If a BTS has its labels printed by a commercial company, and it collects fewer than 100,000 units of blood each year, it could vary the first character of the sequence number each year.

Following this plan, if the facility began using ISBT 128 in 2022, the first sequence number would be:

A9997 22 000001

And thereafter, the DINs would be assigned in sequential order.

It could then start 2023 with the sequence number 100001 which would then appear as:

A9997 23 100001

2024 would start with the sequence number 200001 which would appear as:

A9997 24 200001

For more information on how the sequence number can be used to support facility operations, contact the ICCBBA help desk at support@isbt128.org.

5.1.1.2 Flag Characters

It is not recommended that flag characters be adopted during the initial implementation of ISBT 128 in resource-limited countries. However, this decision is left to each facility. Flag characters, used for process control, are a part of the DIN data structure, but are

not a part of the 13-character DIN itself. These characters allow a facility to indicate where a bar coded DIN appeared (e.g., on the product label, a sample test tube, or a donor record) and can be used to facilitate automated process control. These flag characters are optional and, if not needed, the flag value of "00" should be used. Systems receiving ISBT 128 labeled products should accept any valid final product flag characters.

The meaning of some of the values have been standardized while the meaning of others may be assigned by the facility.

For more information on flag characters, see the ISBT 128 Standard Technical Specification (ST-001).

5.1.1.3 Check Character

Although not a part of the data structure (nor the bar coded information), a check character is added to the end of the DIN to support verification of correct keyboard entry. This check character is calculated following MOD 37-2 within ISO/IEC 7064:2003(E).

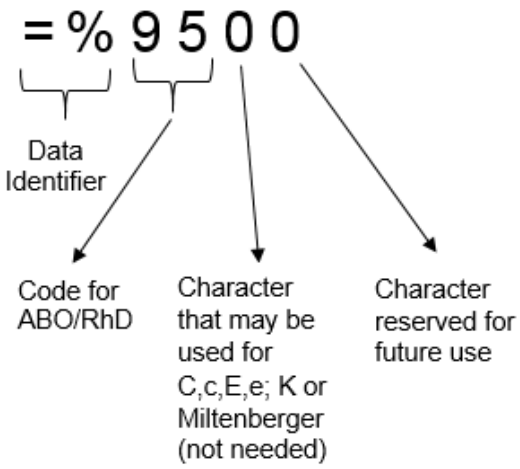
The check character may be any one of the thirty seven characters in the set (0-9, A-Z, asterisk). Where computer systems accept manual entry of a DIN, the check character should always be a required part of the entry and software should verify the character is correct.

For more information about the check character, see Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033).

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

Blood Groups are encoded using the first two data content characters of the Blood Groups [ABO and RhD] data structure. The third character of this data structure is sometimes used to encode other blood group antigens (C, c, E, e; K; or Miltenberger antigens), but it is not recommended that this coding be adopted on initial implementation of ISBT 128 in resource-limited countries. This third character should be set to the default, 0. The fourth character of the data structure has been set aside for future use and should always be set to 0.

Figure 6 Blood Groups [ABO and RhD] Data Structure



This data structure can also be used to encode special messages when encoding the ABO/RhD is not needed. For example, one such message is: "Discard (to be destroyed)" and another is "Quarantine/hold for further testing or processing." This is discussed further in Section 6.3.3 on page 42.

5.1.3 Product Code [Data Structure 003]

Data Structure 003 uniquely identifies a product intended for human use, encodes information about the type of collection, and encodes whether or not the product has been divided. The Product Code contains three elements:

- A five (5)-character Product Description Code (PDC) is assigned by ICCBBA to each product description. Products are described using terminology created by expert advisory groups such as the Europe, Middle East, and Africa Technical Advisory Group (EMATAG). These groups utilize a scheme of Classes (broad descriptions of product such as Red Blood Cells or Platelets), Modifiers (the next level of detail such as Apheresis or Frozen), and Attributes (the next level of detail such as irradiation or dosage) to describe products. Each product is described minimally with a Class and may also have a Modifier or one or more Attributes.
  - A database, called the ISBT 128 Product Description Code Database, lists all assigned codes and the corresponding product descriptions. The database is found in a password-protected area of the ICCBBA website (www.isbt128.org) and is accessible by licensed users.

Detailed information on creating PDCs may be found in Implementation Guide: Use of Product Code [Data Structure 003] – Blood (IG-021).

- A one (1)-character Collection Type Code that allows facilities to encode the type of collection (e.g., autologous or allogeneic).

A two (2)-character Division Code that allows each product with the same DIN and PDC to be uniquely identified. For example, if a unit of Red Blood Cells is divided, both portions will have the same DIN and PDC. To be able to trace each product separately, they must be uniquely identified by giving each a different Division Code. See

- Figure 8. More information is found in Section 5.2.2.3.

Figure 7 Product Code Data Structure for a Blood Product

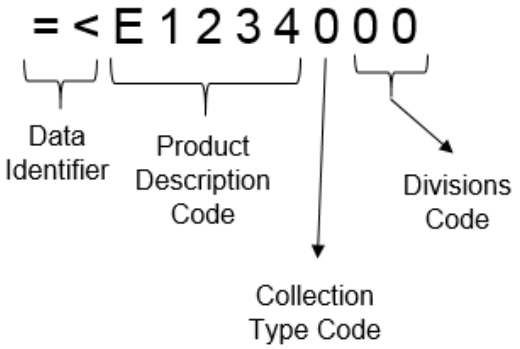
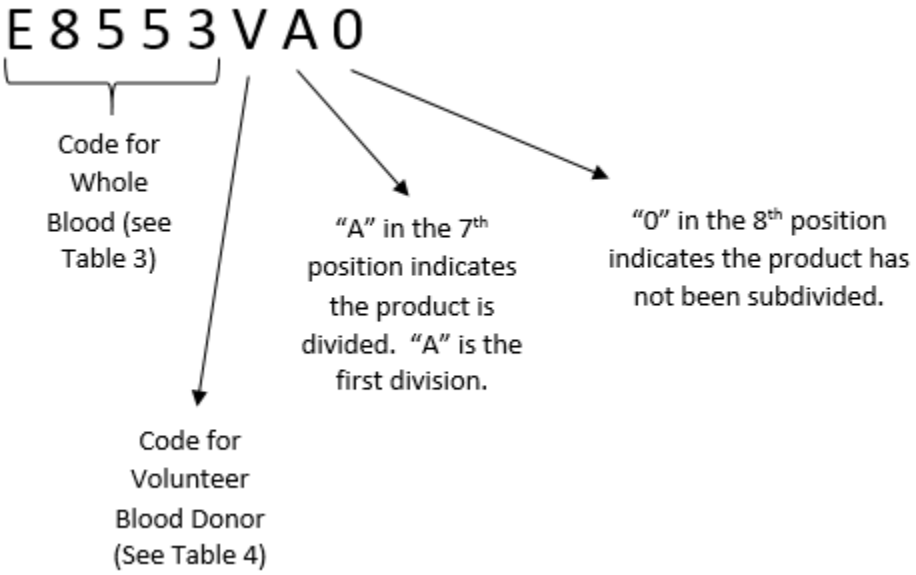


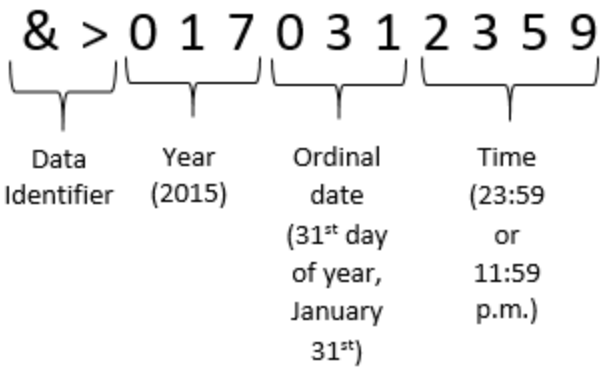
Figure 8 Product Code of a Divided Product



5.1.4 Expiration Date and Time [Data Structure 005]

While having an electronically readable expiry date is not required, it can enhance safety and accuracy. This data structure uses the last three numbers of the year (e.g., 2017 becomes 017 in the code); the ordinal number of the calendar year (or Julian date) where the days of the year are numbered sequentially beginning with 001 on January 1; and the time based on a 24-hour clock. If the product expires at midnight, 2359 (23:59 or 11:59 p.m.) is encoded. See Figure 9.

Figure 9 Expiration Date and Time



5.1.5 Collection Date [Data Structure 006]

The collection date is not required in all countries. If it is required as text, there are no additional ISBT 128 requirements to bar code this information. If desired, however, it can be bar coded. This data structure uses the last three numbers of the year (e.g., 2017 becomes 017 in the code); the ordinal number of the calendar year (or Julian date) where the days of the year are numbered sequentially beginning with 001 on January 1. Data Structure 006 encodes the collection date (see Figure 10). If the collection date and time are needed, Data Structure 007 should be used (see Figure 11).

Figure 10 Collection Date [Data Structure 006]

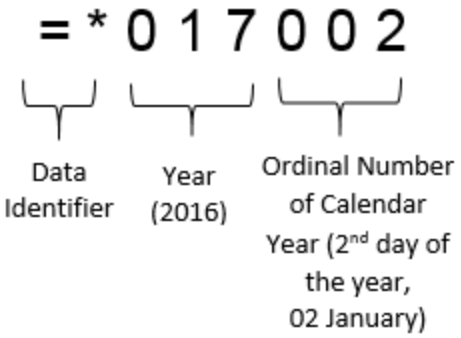
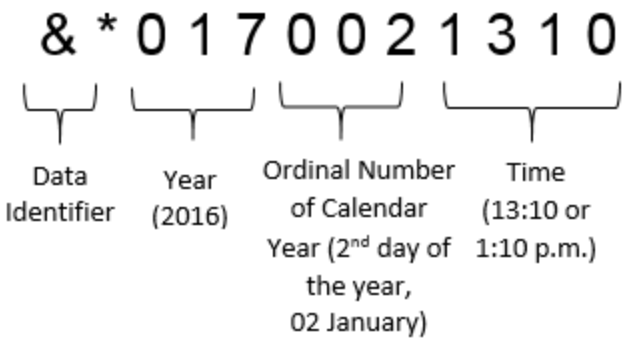


Figure 11 Collection Date and Time [Data Structure 007]



5.2 Reference Tables

Reference tables provide the link between the codes found in data structures and meaningful information. For the DIN, the link between the assigned code (the DIN) and the donor, whose blood is labeled with the DIN, is in the facility's records.

5.2.1 Blood Groups [ABO and RhD]

For Blood Groups [ABO and RhD], there are two reference tables, one for when the first two data content characters that encode the ABO and RhD, and one for when these two characters encode a special message.

Table 1 Excerpt of Blood Groups [ABO and RhD] Reference Table for Data Structure 002

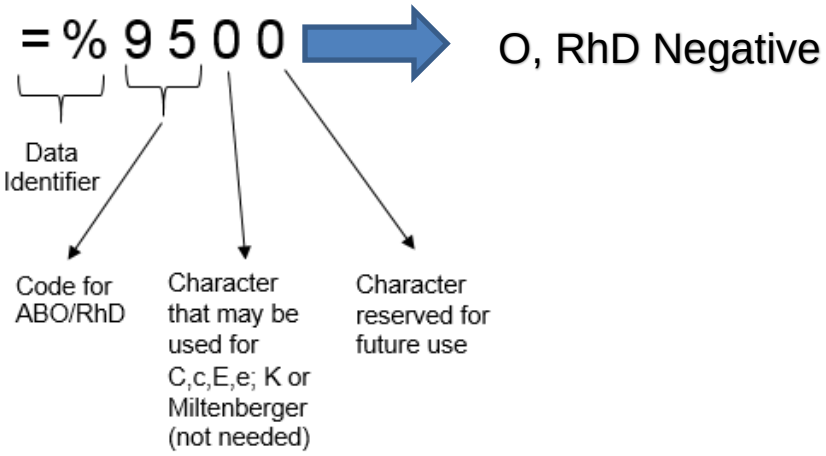
ABO and RhD Blood Groups	Code*
O RhD negative	95
O RhD positive	51
A RhD negative	06
A RhD positive	62
B RhD negative	17
B RhD positive	73
AB RhD negative	28
AB RhD positive	84
O	55
A	66
B	77
AB	88

- This code is used when a special collection type (e.g., autologous, designated, emergency release) is not encoded within the ABO and

RhD. See the *ISBT 128 Standard Technical Specification* (ST-001) for other codes.

Looking back at the example used previously, the “95” in Figure 6, page 244, would be interpreted as Group O, RhD Negative according to the first line in Table 1.

Figure 12 Blood Groups [ABO and RhD] Data Structure

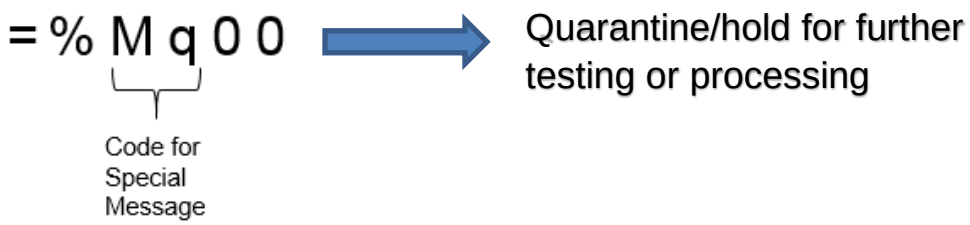


If a special message is desired, values found in Table 2 may be used. For example, if “Quarantine/hold for further testing or processing” were to be used instead of an ABO/RhD type, the encoded information would be as shown in Figure 13, based on the 5th line in Table 2.

Table 2 Special Messages Used in Data Structure 002

Code	Interpretation
00	No ABO or Rh information is available
Ma	Autologous collection
Mb	Biohazardous
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

Figure 13 Encoding a Special Message



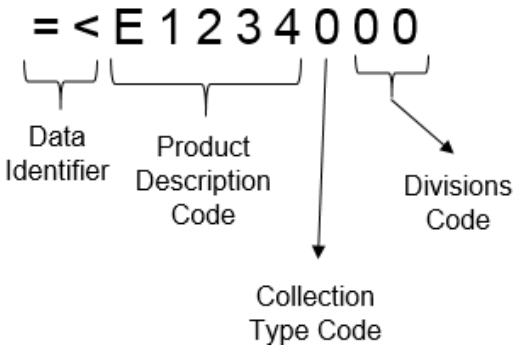
Both of these reference tables have more options for coding, including pooled products and rare ABO groups such as Bombay and paraBombay. There are also options for encoding the type of collection or release (e.g., for emergency release).

For complete tables, see the ISBT 128 Standard Technical Specification (ST-001).

5.2.2 Product Codes

As explained in Section 5.1.3, the Product Code comprises three elements: the Product Description Code, the Collection Type Code, and the Divisions Code.

Figure 14 Product Code Data Structure



5.2.2.1 Product Description Code

For the Product Code [Data Structure 003], there is a very long and complex reference table called the ISBT 128 Product Description Code Database that is found in the password protected area of the ICCBBA website.

The Product Description Code Database is described in detail in ISBT 128 Standard Product Description Code Database (ST-010).

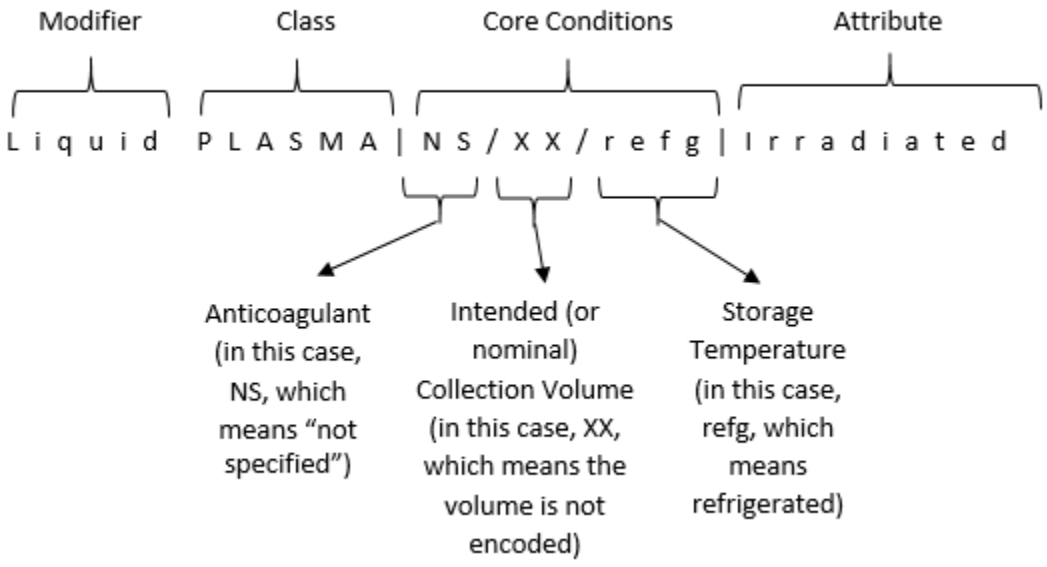
Over 8,500 Product Description Codes for blood are listed in this reference table. These thousands of codes support the many practices of users of ISBT 128 around the world. Not only are practices different, but so are regulations. For example, regulations in some countries require encoding the anticoagulant, while others do not. In reality, even the most complex of facilities typically only use a small portion (perhaps 100 or 150) of these 8,500 codes.

Within the ISBT 128 Product Description Code Database, each product is described by:

- Class (broad descriptions such as Red Blood Cells and Whole Blood) (required)
- Modifiers (providing the next level of detail such as Frozen or Thawed) (optional)
- "Core Conditions" which are Anticoagulant (which can be unspecified or a specific anticoagulant), Intended Collection Volume (which can be unspecified or volumes such as 450 or 500 mL), and Storage Temperature (required)
- Additional information, called Attributes (e.g., Leukocyte Reduced or Irradiated) (optional)

These characteristics are listed in the database in a specific order and separated by specific characters. Modifiers (if present) are listed first, followed by Class, Core Conditions, and finally Attributes. The different characteristics are separated by specific characters, either a "|" or, between characteristics in the Core Conditions, by a "/". For example, a product description in the database is shown in Figure 15.

Figure 15 Example Product Description



For more detailed information about Product Description Coding, see Implementation Guide, Use of Product Code [Data Structure 003] – Blood (IG-021).

One of the most important features of ISBT 128 product coding is that facilities can chose the level of complexity needed by their own operations and those of their customers. Thus, some facilities may find that fewer than 15 of the more than 8,500 codes are needed.

ICCBBA recommends that facilities in resource-limited countries identify and use only those codes that are needed to differentiate its products. For example, if only one anticoagulant or anticoagulant/additive system is used within a facility, and only a few products are produced, perhaps the list of codes in Table 3 is sufficient. As an organization grows, and its product mix becomes more complex, additional codes may be added.

Table 3 Product Description Codes Reference Table

Product Description Code	Product
E8553	WHOLE BLOOD|NS/XX/refg
E8285	RED BLOOD CELLS|NS/XX/refg
E8554	PLASMA|NS/XX/Frozen
E8555	Liquid PLASMA|NS/XX/refg
E8556	PLATELETS|NS/XX/rt

Should more codes be needed, there are two references the user should consult:

1. *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002)
2. *Implementation Guide: Use of Product Code [Data Structure 003] – Blood* (IG-021)

The latter document also describes a lookup tool that may be found on the ICCBBA website that assists the user in selecting the appropriate code from the thousands found in the database.

Facilities are encouraged to contact the ICCBBA help desk (support@isbt128.org) for assistance with the selection of Product Description Codes.

5.2.2.2 Collection Type

As with other data structures, the reference table for Collection Type reflects a wide variety of practices around the world. An excerpt of this table is shown as Table 4. There is no requirement to encode the Collection Type and the code “0” may be used when Collection Type is not needed, as shown in Figure 14.

Table 4 Collection Type

Character	Type of Collection
0 (zero)	Not specified (null value)
V	Volunteer homologous (allogeneic) (default)
1 (one)	For autologous use only
P	Paid homologous (allogeneic)
C	Replacement

The full reference table for Collection Type is found in the ISBT 128 Standard Technical Specification (ST-001).

5.2.2.3 Division Codes

There is no reference table for Division Codes. Assignment of Division Codes follows a standardized scheme.

- If the unit has not been divided, the Division Code is the default value of 00 (zero, zero).
- If the unit has been divided, these divisions are encoded in the Product Code:

  The 7th character of the Product Code will encode the first level division. First level divisions (up to 26) of the primary collection shall be encoded using capital letters.

  The 8th character of the Product Code will encode the second level division (a division of an already-divided product). Second level subdivisions (up to 26) shall be encoded using lowercase letters. See Figure 16 and Figure 17.

Figure 16 Example of Division Code

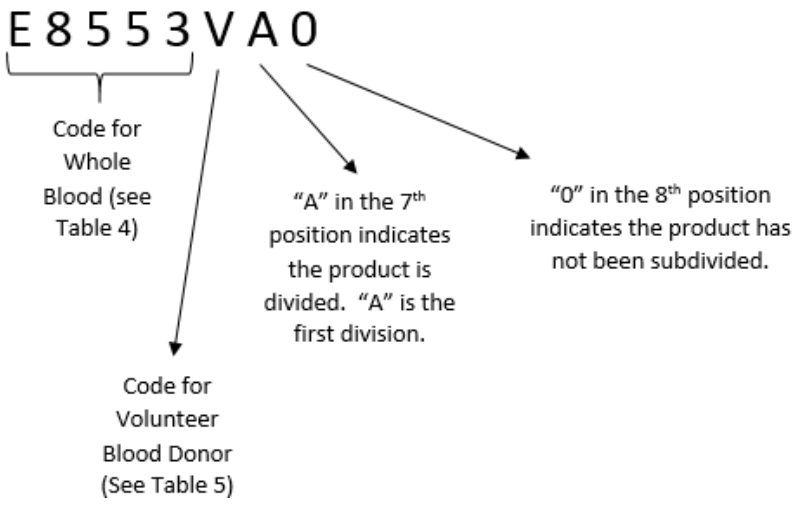
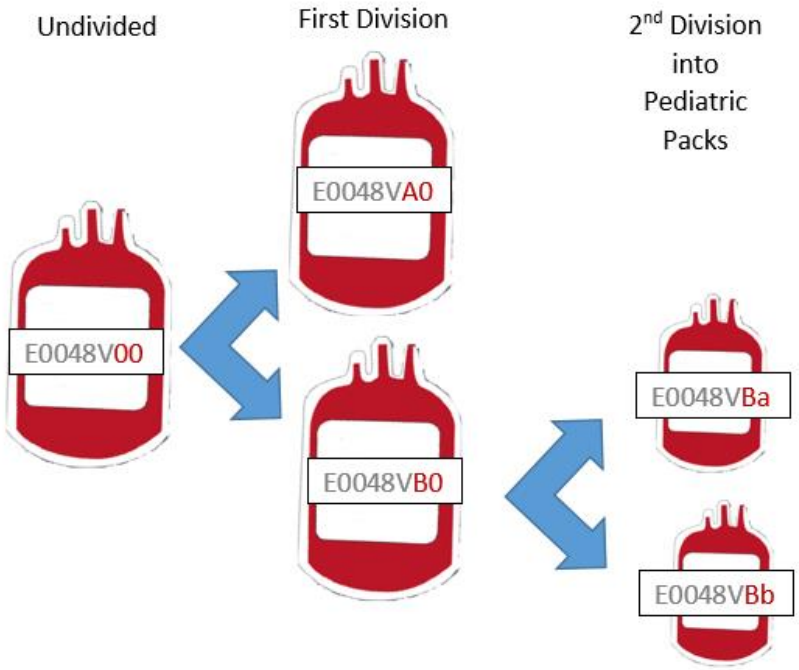


Figure 17 Use of Division Codes for Two Division Levels



For more detailed information about coding of aliquots, see Implementation Guide: Use of Product Code [Data Structure 003] – Blood (IG-021).

6 Labeling

6.1 Electronically Readable Information

6.1.1 Delivery Mechanisms

The delivery mechanism is the means of delivering the electronic information. Higher capacity delivery systems are available using 2-dimensional (2-D) or reduced space symbology bar codes. These codes can carry much more information in each symbol. More recently the use of radio frequency identification (RFID) chips that can carry encoded information is being developed for medical products of human origin.

It is important to recognize that a range of delivery systems can sit at this level of the hierarchy. The definitions, reference tables, and data structures of the ISBT 128 Information Standard can be delivered as easily in a linear bar code as they can in an RFID tag. The Standard is adaptable in order to make best use of new delivery mechanisms as they are developed.

6.1.1.1 Linear Bar Codes

Probably the most well-known delivery mechanism is the linear bar code that has been used in blood transfusion practice for many years. There are in fact several types of linear bar codes including the Codabar system that was only capable of encoding numeric information, and Code 128, a bar code standard widely used in coding standards such as GS1 and ISBT 128.

6.1.1.2 2-D Symbols

Higher capacity delivery systems are available using 2-dimensional (2-D) symbols. For use on blood labels, the Data Matrix symbology is required. 2-D symbols can carry much more information in each symbol and are much more efficient in practice since a single scan can include all the information normally found in multiple linear bar codes.

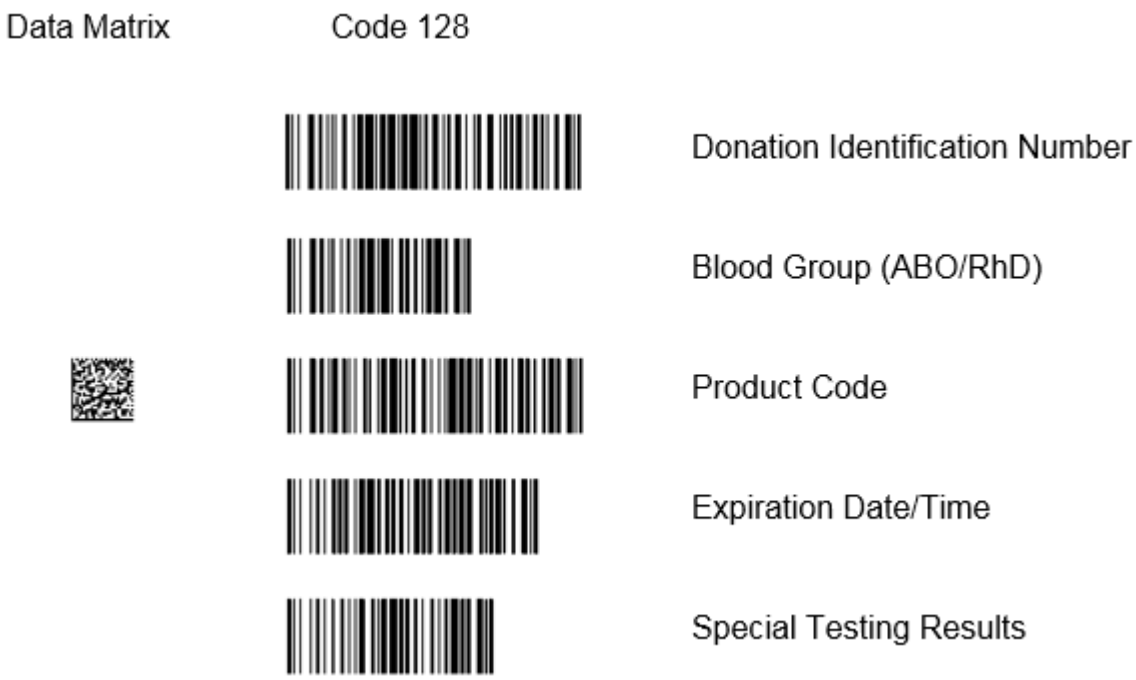
Use of a 2-D symbol requires the use of the Compound Message [Data Structure 023].

For more information about encoding information into a 2-D symbol, see Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014).

The 2-D symbols may be used in conjunction with linear bar codes during a time when not all facilities are able to code and decode information in a Compound Message data structure. Currently there is a proposal under consideration to utilize only a 2-D symbol on a blood label. The design of this label is very different

from the design of a traditional ISBT 128 blood label. Facilities interested in use of 2-D symbols on blood product labels should contact the ICCBBA office for more information (support@isbt128.org).

Figure 18 Comparison of 2-D (Data Matrix) and Linear (Code 128)



In Figure 18, the Data Matrix symbol on the left contains the same information as the 5 linear bar codes on the right.

6.1.2 Concatenation

Concatenation within the ISBT 128 context is the reading of two bar codes as if they were a single bar code. The ISBT 128 blood component label was designed to allow two pairs of bar codes to be concatenated:

- The DIN and the Blood Groups [ABO and RhD]
- The Product Code and the Expiration Date and Time

Other pairs of bar codes may be concatenated.

Parameters of scanners have to be appropriately configured to allow concatenation and software has to support placing the information into the proper fields. However, once set up concatenation of bar codes can add to efficiency by allowing a single scan for two bar codes and promote safety by ensuring the information (e.g., the DIN and Blood Groups [ABO and RhD]) was scanned from the same container of blood.

For more information about concatenation, see:

- *ISBT 128 Standard Technical Specification (ST-001);*
- *Length of the Product Code Bar Code and Concatenation (IG-017); and*
- *Bar Code Scanner Implementation of ISBT 128 Concatenation (IG-008).*

It is also possible to concatenate a linear bar code (e.g., a DIN) with a 2-D symbol to ensure the latter has been applied to the correct unit.

6.1.3 Coding of Information within Electronically Readable Symbols

The information within an ISBT 128 electronically readable symbol is strictly standardized to allow interoperability between all facilities that use ISBT 128 globally. Information must be encoded as described in Chapter 5 and in the *ISBT 128 Standard Technical Specification* (ST-001).

6.2 Label Design

6.2.1 Role of Regulations and Other Standards

Within many countries, governments regulate the collection, processing, and testing of blood. There may, therefore, be nationally specified regulations governing the labeling of blood. Such regulations take precedence over requirements and recommendations found in this guidance document.

Similarly, accrediting organizations such as the African Society of Blood Transfusion and the AABB have standards that indicate what information must appear on blood labels. Organizations wishing to be accredited by such organizations must follow the appropriate standards.

6.2.2 Principles

Primary considerations in label design shall include improving the safety of the product and the efficiency of processing/administering. If these two considerations conflict, safety shall take precedence over efficiency.

Critical information on the container shall dominate the label via position and prominence and shall take precedence over information that is of little importance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

Examples of labels are shown in Appendix 3.

A library of example labels from different countries is posted on the ICCBBA website to assist facilities in designing their labels.

6.2.3 Quadrant Design

The ISBT 128 label was designed in four quadrants, each 50 mm by 50 mm. See Figure 19**.**

The location of each of the 4 major linear bar codes (DIN, Blood Groups [ABO and RhD], Product Code, and Expiration Date and Time) are rigidly defined to ensure the bar codes may be concatenated. The Collection Date (or Collection Date and Time) is in the upper left quadrant, but its exact location is not rigidly defined. See Figure 20.

The specification for the location of linear bar codes on the label may be found in ISBT 128 Standard Labeling of Blood Components (ST-005).

Figure 19 Quadrant Design of Blood Label

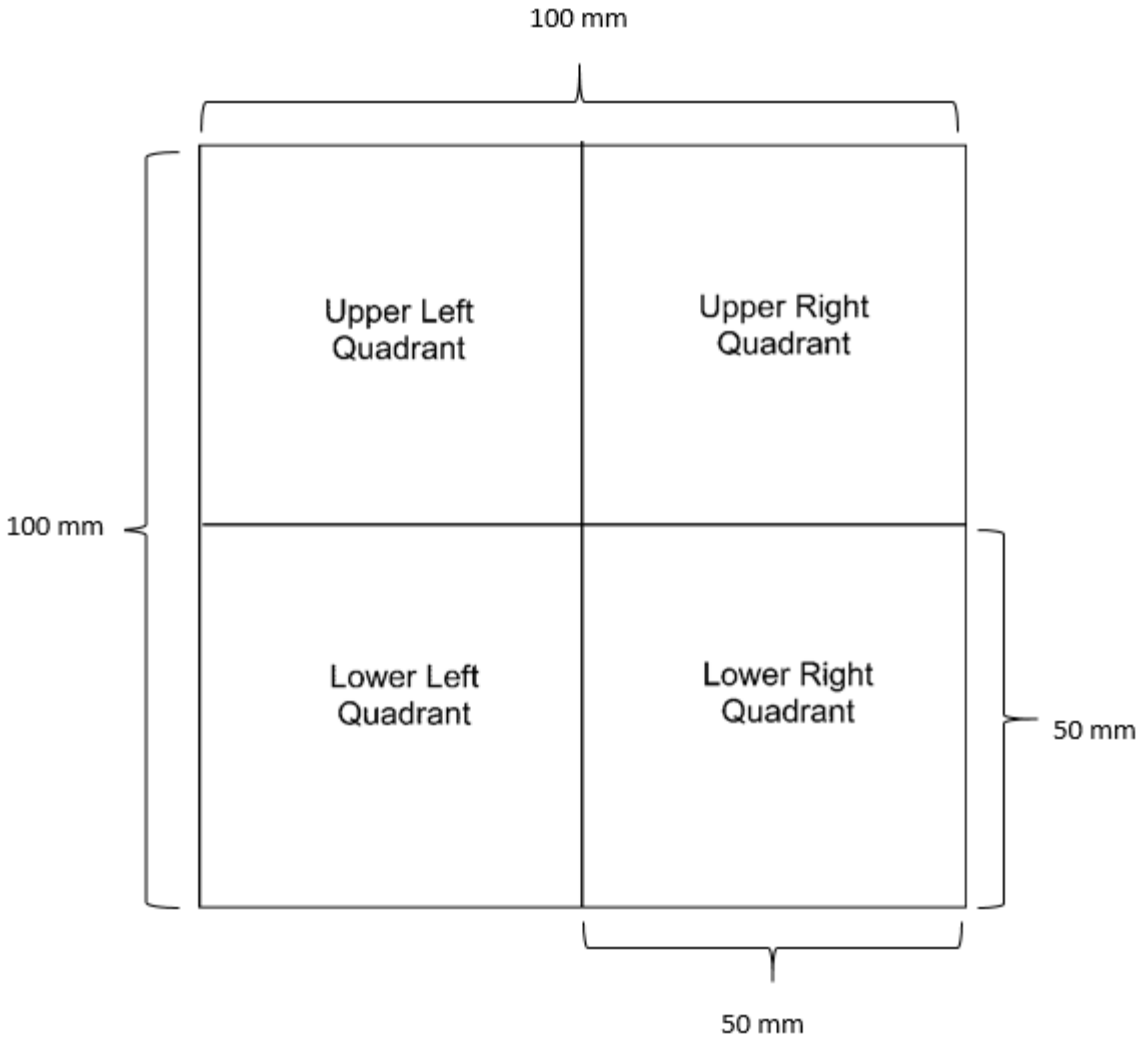
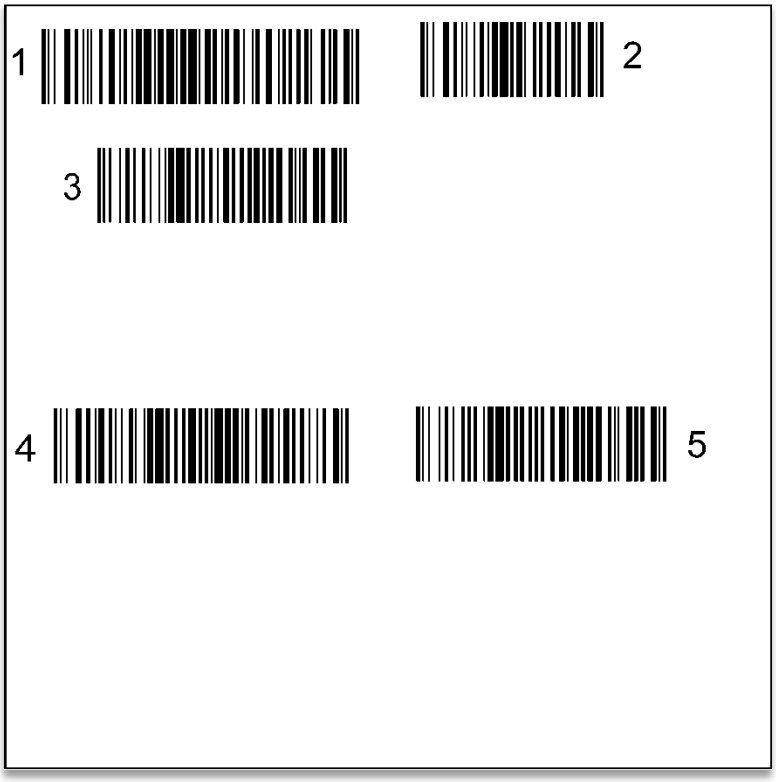
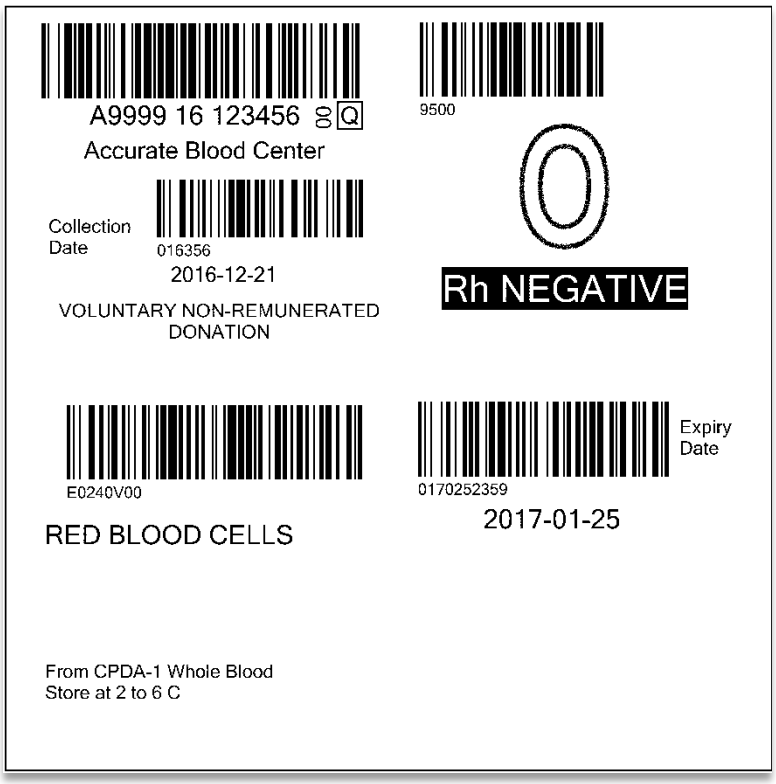


Figure 20 Location of Bar Codes



1. Donation Identification Number
2. Blood Groups [ABO and RhD]
3. Collection Date or Collection Date and Time
4. Product Code
5. Expiration Date and Time

Figure 21 ISBT 128 Final Blood Label



For detailed information about label design, see ISBT 128 Standard Labeling of Blood Components (ST-005).

6.3 Text

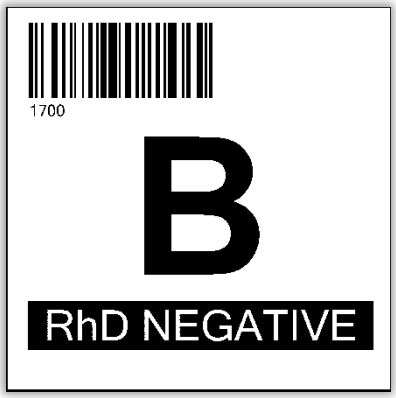
6.3.1 Eye-Readable Text

Human-readable text corresponding to the information encoded within the bar codes must appear on the affixed label of the blood product. There are three types of text on an ISBT 128 label.

6.3.1.1 Text Associated with Data Content

The text associated with data content corresponds to the exact characters within a bar code, with the exception of the data identifiers. Except for the DIN, this text appears in small letters left-justified immediately beneath the bar code. For example, in the blood group label example in Figure 22, this is the “1700” immediately beneath the bar code.

Figure 22 Blood Group Label



6.3.1.2 Text Associated with Electronically Readable Information

This type of text is the interpretation of the message within the bar code into meaningful information. In Figure 22, the “B RhD Negative” is the text associated with electronically readable information. As explained in Section 5.2, this information typically comes from looking up the code in one or more reference tables.

While the ISBT 128 Standard is very specific about what information may be encoded into a bar code and how it is encoded, its associated text may be specified by national authorities. Appropriate standards and regulations should be consulted. Additionally, the information printed within this associated text is not rigidly defined and should be in words that make sense to the users within a given country, provided the meaning of the words is consistent with the meaning of the code in the reference table. It should also be in a language(s) of the country. For example, Table 5 shows an excerpt from the Type of Collection reference table.

Table 5 Excerpt from Type of Collection Reference Table [RT008]

Character	Type of Collection
V	Volunteer homologous (allogeneic) (default)
C	Replacement

In Africa, where the Africa Society for Blood Transfusion Step-Wise Accreditation Standards define a Voluntary Non-Remunerated Donor, facilities may wish to print “Voluntary Non-Remunerated Donation” or a similar phrase when the code “V” is used within the Product Code. When “C” is selected, they may wish to print “Replacement Donation” on the label.

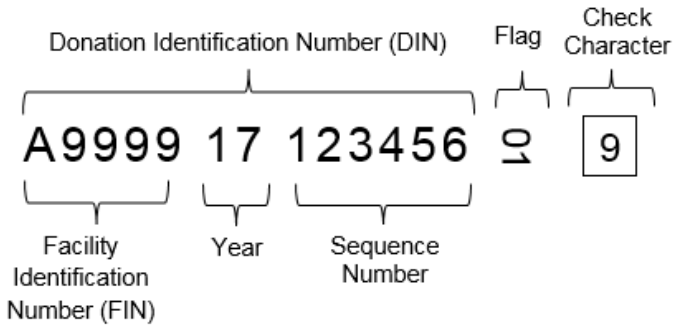
6.3.1.3 Text Not Associated with Electronically Readable Information

Some information on a blood label is not encoded into a bar code and appears only as text. Warning messages such as “Properly identify intended recipient” and the address of the blood collection facility are examples of this additional information. This text should follow national regulations and requirements of other standards setting organizations.

6.3.2 DIN

Text corresponding to the DIN shall be printed as follows: (1) flag characters are rotated clockwise by 90 degrees and (2) the manual entry check character shall appear to the right of the DIN and flag characters and be enclosed in a box (see Figure 23). Care should be taken to use a font which clearly distinguishes between similar characters (0 and O, I and 1 etc.).

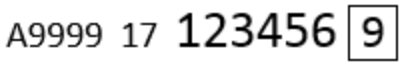
Figure 23 Text Presentation of DIN



Spaces have been inserted in the example in Figure 23 to make the 13-character DIN more easily read by humans. While the example shows a space between the FIN and the year, and between the year and the sequence number, this arrangement is not required. National authorities may decide how the DIN text is displayed. For example, as shown in Figure 24, the FIN and year may be printed in a smaller font to emphasize the sequence

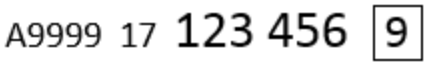
number and, if the default of 00 is used for flag characters, these characters do not need to be printed. This design would be appropriate if (1) a single FIN is used by a BTS, and its customers only receive blood products labeled with this single FIN and (2) the facility does not start over each year with a sequence number of 000001 (see 5.1.1.1).

Figure 24 Emphasis of Sequence Number in DIN



It is also acceptable to add a space within the sequence number. For example:

Figure 25 Adding Spaces in Sequence Number



Regardless of the text presentation of the DIN, it is always encoded the same way within the bar code.

6.3.3 Blood Groups [ABO and RhD] and Special Message Text

The ABO blood group should be printed as large as space allows. The RhD type should be printed beneath the ABO group in smaller print. National regulations and guidelines should be followed.

There are a number of options for RhD negative units that include:

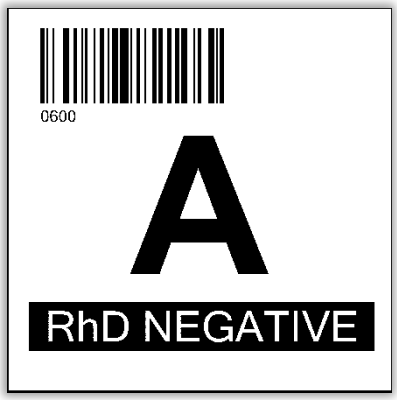
- The ABO blood group may be printed as a solid character or as an outline.
- RhD negative can be printed black on white or white on black.

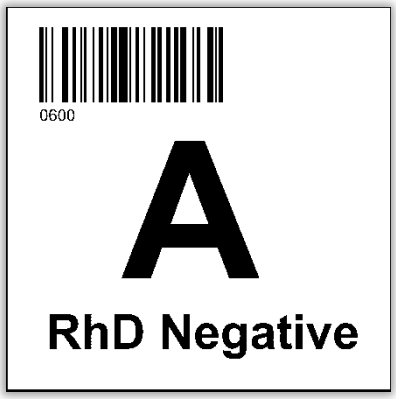
Color coding of ABO blood group is acceptable and is neither encouraged nor discouraged.

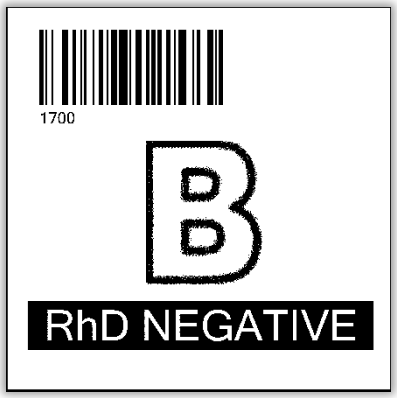
Other formats that follow national guidelines or regulations are also acceptable. Whatever design is selected, it should be used consistently.

Figure 26 Group O, RhD Positive Label

Figure 27 Some Options for RhD Negative Labels

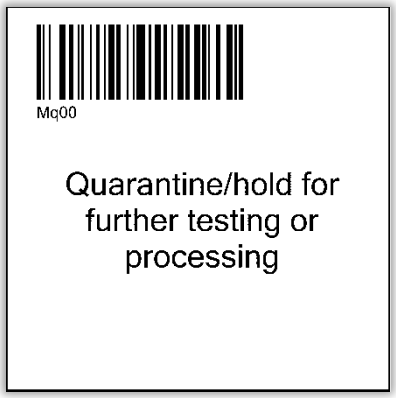






Special messages appear in the upper right quadrant in place of the ABO/RhD. For example:

Figure 28 Example Special Message Label



6.3.4 Product Information Text

The wording of product information shall be consistent with the information encoded within the electronically readable information, shall follow national requirements, and shall be in a language that is appropriate for the users. For example, one country may print “Red Blood Cells” while another country might print “Erythrocytes.” In general, the Class name should be more prominent than Modifiers or Attributes.

MODIFIER
CLASS
Attribute
Attribute

For example, text for the product information may appear as:

WASHED
RED BLOOD CELLS
Leukocytes Reduced
SAG-M Added

Store at 2 to 6 C

However, it is again important to note that text is not rigidly prescribed in ISBT 128 beyond being consistent with the information encoded in the bar code. Therefore, a different order of the text (e.g., listing the Modifier after the Class name) and other fonts are acceptable.

6.3.5 Expiry Date and Time Text

The expiry date shall appear in one of two formats:

- Following the ISO 8601 (2004)(E) format (Year, Month, Day separated by hyphens): 2015-06-24
- Day, Month (using a 3-letter abbreviation), year format: 24 JUN 2017.

Expiry time, if relevant, shall be printed based on a 24-hour clock with the hour and minutes separated by a colon. For example:

2017-06-24 15:15

If the product expires at a default of midnight (for example, the product expires at midnight on the 35th day), it is not required that the time be printed, even though it is encoded in the bar code. In this situation, only the expiry date is printed.

6.4 Label Options

Labels may be purchased from a commercial printer, may be printed in-house using appropriate software and hardware, or be a combination of the two. Which of these methods works best depends on the operations of the facility, including how many units per year it collects. The more blood that is collected, or the greater variety of components produced, the more likely in-house printing will be best. Additionally, if bar coding of expiry and/or collection date is desired, then in-house printing of labels is essential.

Labels should have tamper evidence to reduce the chance of a label being removed and reapplied, i.e., any tampering with a label should deface the label making it unusable.

Labeling of frozen products may require special label stock capable of adhering to a frozen product with an irregular surface. Freezing on a flat surface may minimize irregularities in shape.

6.4.1 Purchasing Preprinted Labels

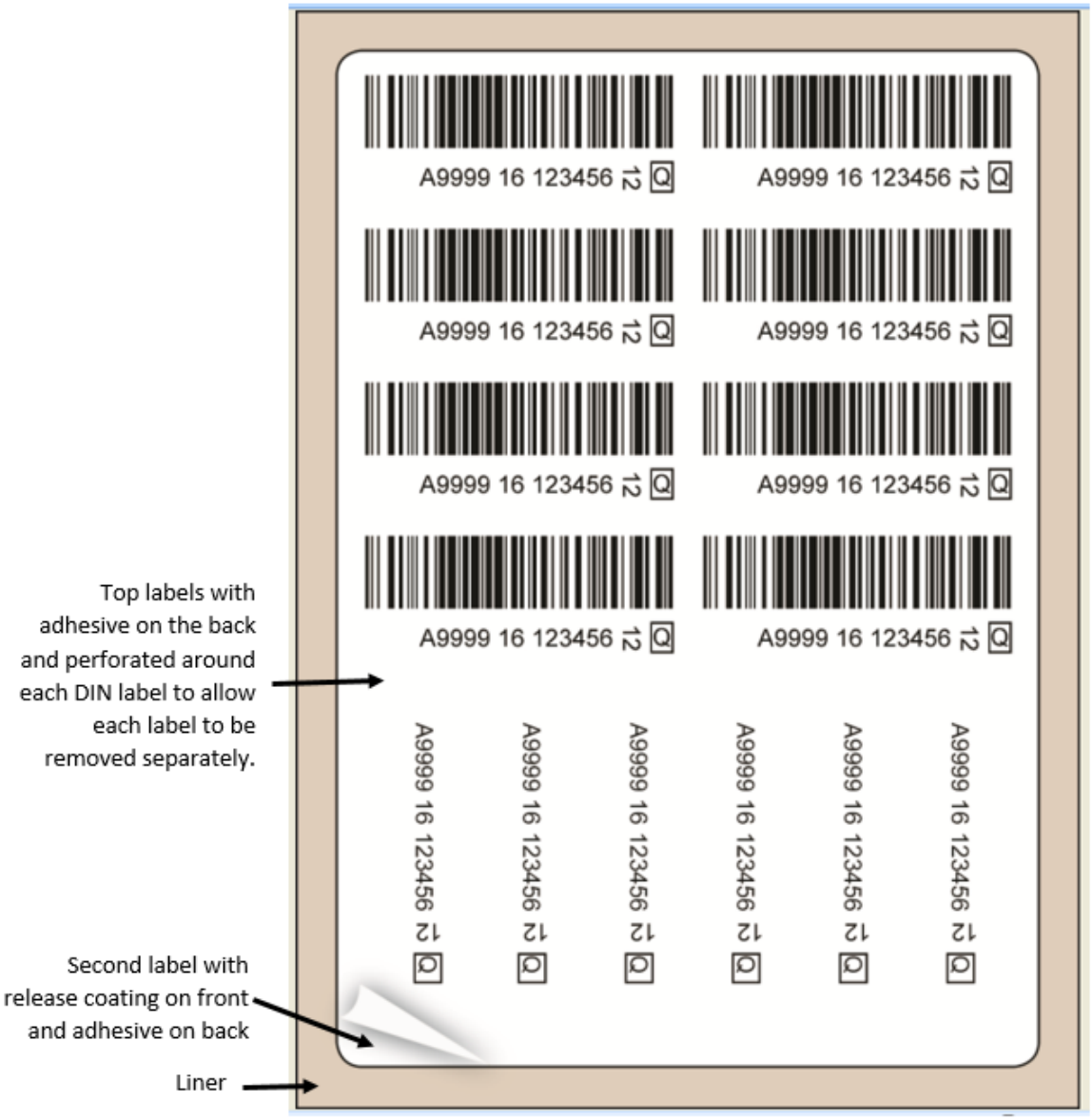
Many commercial companies offer preprinted ISBT 128 labels. A list of such companies may be found on the ICCBBA website. Go to https://isbt128.org/licensed-vendors. The website lists vendors alphabetically and by product categories. Follow the links to the blood label companies of interest.

6.4.1.1 Preprinted DIN Sets

DINs are typically purchased or printed in sets with multiple copies of the DIN so that a copy of the DIN label may be affixed to each bag within the collection set, on the donor history questionnaire form, on sample tubes, etc. Facilities should assess their processes and ensure their DIN label sets include an appropriate number of copies of the DIN label.

Piggyback Labels: Another consideration would be the purchase of piggyback DIN sets. See Figure 29. Piggyback labels have two label layers and one liner. (1) The top layer has the DIN on the front and adhesive on the back. (2) The second layer has a release coating on the front (to which the top layer is attached) and adhesive on the back. The adhesive attaches the second label layer to the liner. (3) The liner holds the two label layers and provides the support so the label set can be manufactured into rolls or tablets. When ready to use, the label set (both layers) is pulled off the liner and attached to the back of the blood bag. The top label (with a DIN) can be pulled off when needed. This allows extra DIN labels to be attached to the blood bag and used either by the BTS or the HBB later in the process.

Figure 29 Piggyback DIN Labels



6.4.1.2 Tear-Off Labels

Tear-Off Labels: Tear-off labels are another option. See Figure 30. The tear-off portion has a backing that is removed to reveal the adhesive. The adhesive on the tear-off portion is used to apply the label to a recipient record.

Figure 30 Tear-Off Label

This portion of the label may be torn off and placed in the blood recipient's medical record.

It may be possible to order preprinted sets of DINs. There are several considerations if this method is chosen.

(1) How many DINs are needed within a set? Each product from a collection (e.g., red cells and plasma) will need a DIN label, as will each sample tube and the donor history document. Therefore a facility will need to determine how many DINs it will need for each collection. Ordering unnecessary DINs increases costs and increases likelihood that DIN label may be used on an inappropriate item. Ordering too few DINs may

result in handwritten information where a more legible printed version would be more desirable.

(2) Because the year of collection is encoded in the DIN, facilities must estimate how many collections will occur in a given year. While there is a one-month tolerance (that is, “17” may be used from 1 December 2016 through 31 January 2018), the facility must approximate how many DINs will be needed each year.

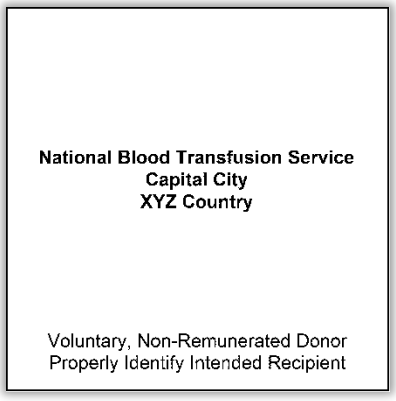
(3) A DIN must be unique. A system must exist to ensure the same DIN is never ordered and used twice.

A facility can determine the sequence number. It may make sense for one facility to start at 000001 each year, but for another facility it may make sense to number continuously from 000001 to 999999 over several years. See Section 5.1.1.1.

6.4.1.3 Upper Left Quadrant

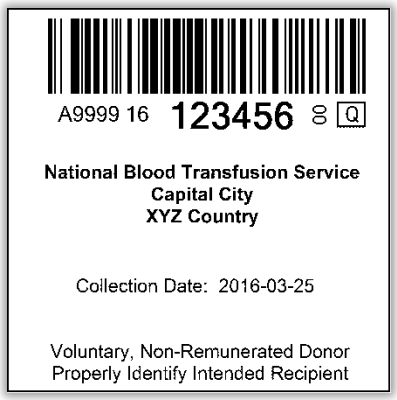
The DIN is usually ordered as a separate label and the rest of the upper left quadrant may be ordered as a preprinted 50 mm by 50 mm label. The content of this label will depend on national requirements, but will likely include the name and the address of the facility and may contain various informational or warning messages (e.g., “Voluntary, Non-Remunerated Donor” or “Properly identify intended recipient”). See Figure 31.

Figure 31 Preprinted Upper Left Quadrant



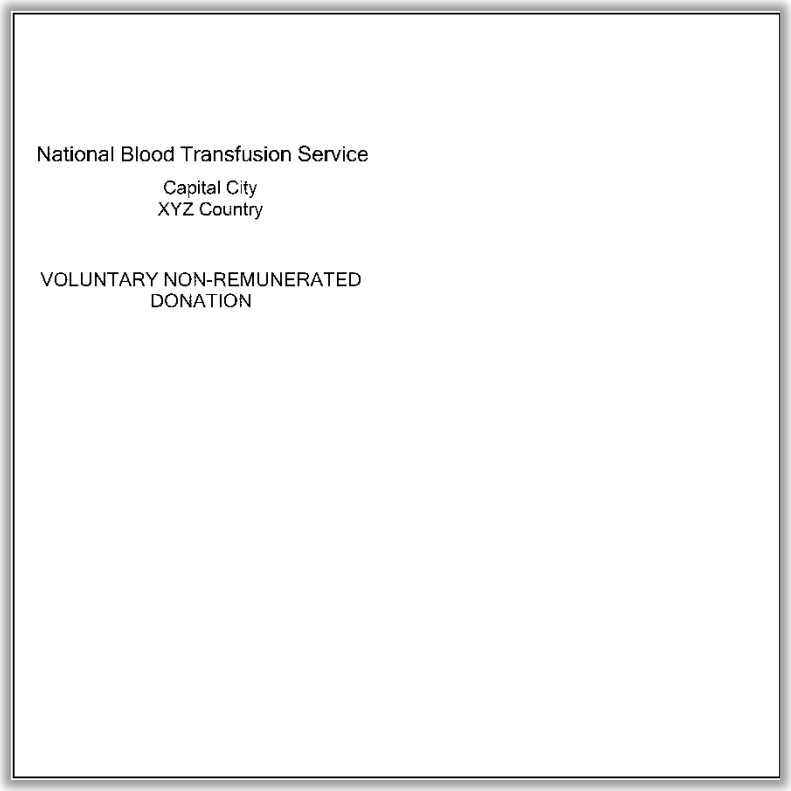
This label may be placed on the bag as soon as it is removed from its packaging. Prior to collection of blood, the DIN should be added to this label. The collection date, if desired, could be added at any time before or during final labeling. See Figure 32.

Figure 32 Upper Left Quadrant after Addition of DIN and Collection Date



Alternatively, the full 100 mm by 100 mm label may be ordered with only the information shown in Figure 33. This provides a base onto which the DIN and the other 50 mm by 50 mm quadrant labels can be affixed.

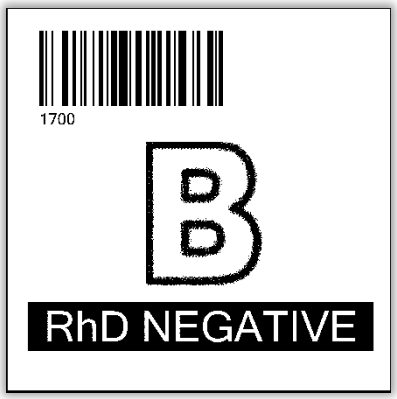
Figure 33 100 mm by 100 mm Initial Label



6.4.1.4 Upper Right (ABO/RhD) Quadrant

Blood Groups [ABO and RhD] and special message labels may be ordered preprinted. See Figure 34. If preprinted labels are used, consideration can be given to color coding different ABO groups.

Figure 34 Preprinted Upper Right Quadrant Label



6.4.1.5 Lower Left (Product) Quadrant

Ordering preprinted labels for the lower left quadrant (see Figure 35) works best when relatively few products are being produced. One means to reduce the number of different types of labels to order is to use Product Description Codes that utilize more generic descriptions such as “not specified” for anticoagulant. The actual anticoagulant may not be needed on the label, or, if required, it may be handwritten in a blank space provided. Likewise, a Product Description Code with the nominal collection volume encoded as “not specified” may be used and the actual nominal collection volume (e.g., 250, 350, 450 or 500 mL) may not be necessary or may be handwritten on the label. See Figure 35 and Figure 36.

Figure 35 Preprinted Lower Left Quadrant

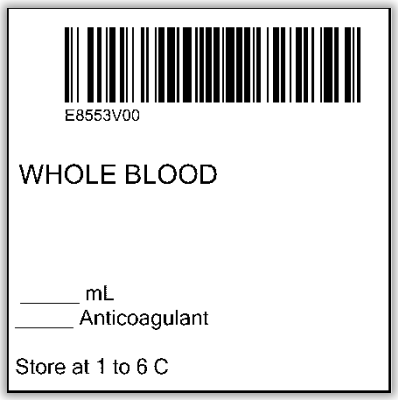
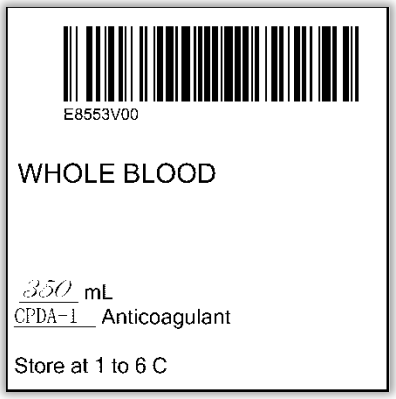


Figure 36 Lower Left Quadrant with Handwritten Information



6.4.1.6 Lower Right Quadrant (Expiration Date and Time; Special Testing)

The lower right quadrant comprises two significant types of information: the expiry date and time and the results of special testing such as CMV and Hemoglobin S. See Figure 37.

It is not practical to order bar coded expiry date or date/time labels so if preprinted labels are used, handwritten or rubber-stamped expiry dates and times could be used. If rubber-stamped, small label stock could be used. The inks used should be validated to ensure that the ink is indelible and does not smear.

It may be possible to order preprinted labels for CMV negative or Hemoglobin S negative labels, if these are needed.

Figure 37 Lower Right Quadrant

Figure 38 Use of Preprinted Labels

Preprinted labels can be purchased and assembled to create a final label. Below, a 100 mm by 100 mm base label is purchased and applied to the unit prior to collection. This label contains the text identification of the collection center, the statement “VOLUNTARY NON-REMUNERATED DONATION, and the text for collection date and expiration date. At the time of collection, the DIN label is added. This will likely come from a set, as shown in Figure 29, page 46. Then, a product code label is applied. If the product is whole blood, this can be applied at the time of collection. If the product is packed red blood cells, plasma, or platelets, it can be affixed when the component is made. Expiration dates are rubber-stamped onto blank label stock. The Blood Groups [ABO and RhD] may be applied when all testing is completed, as the final labeling step. See Figure 39, page 52. When completed, the label will appear as in Figure 40, page 53.

Figure 39 Assembly of Preprinted Labels

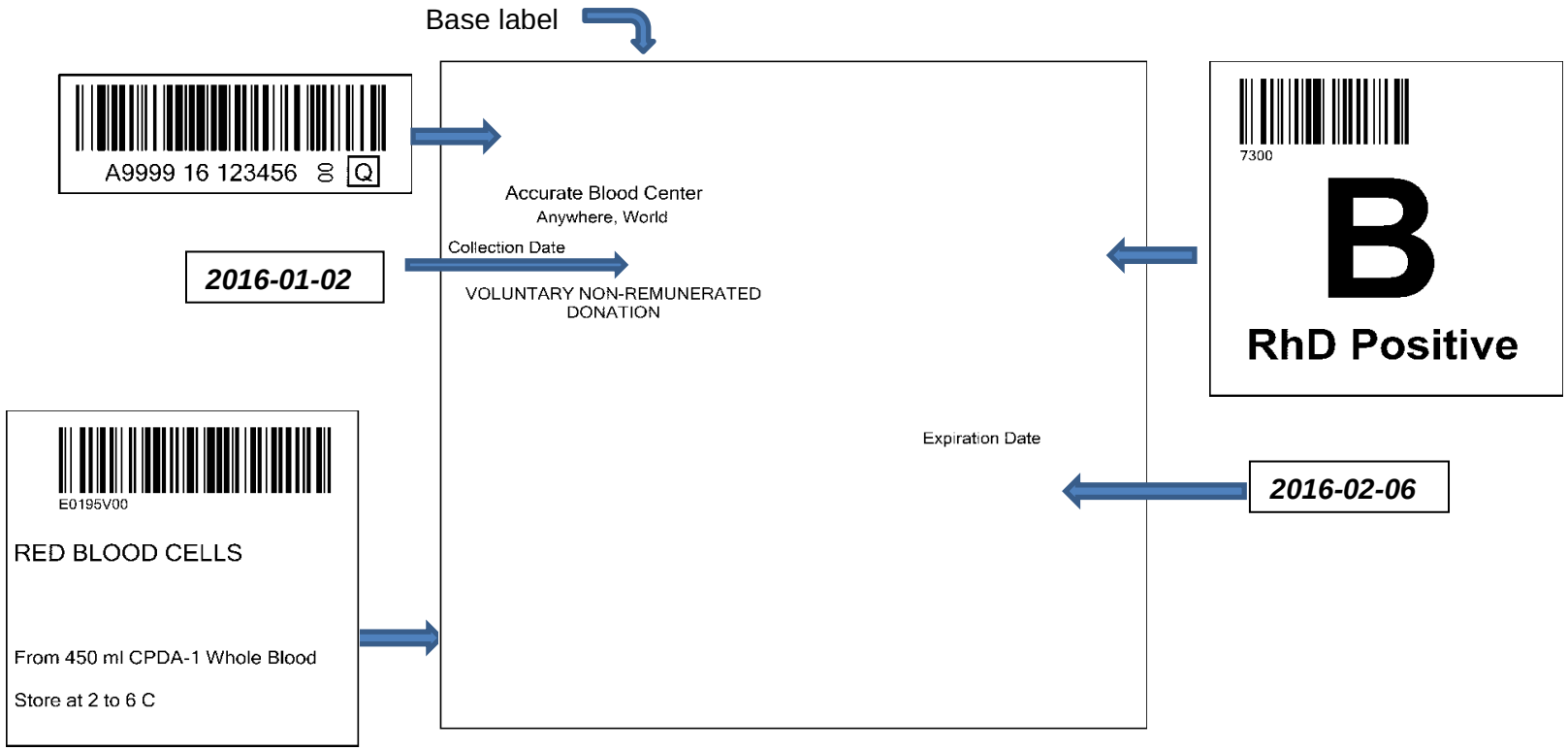
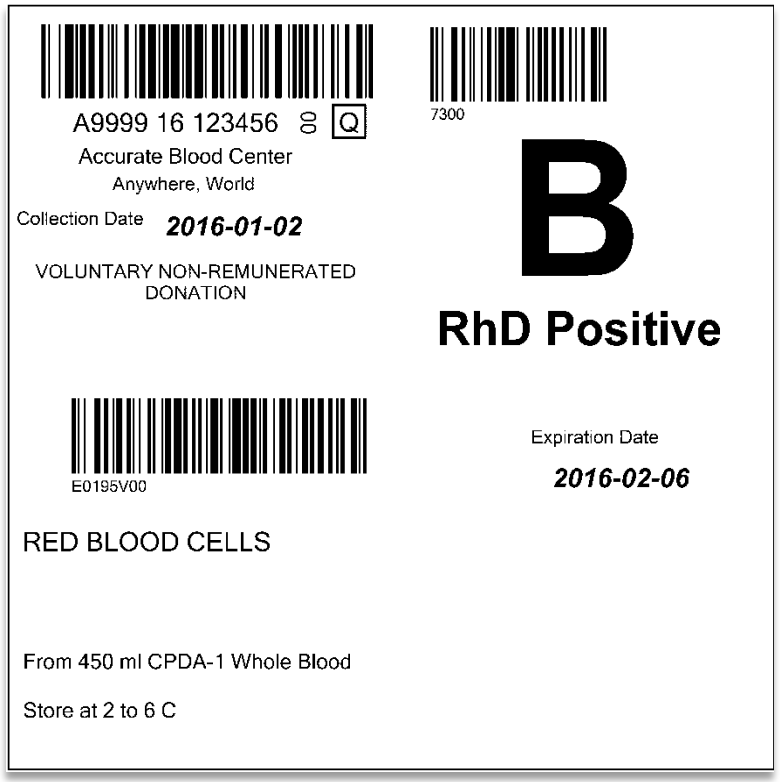


Figure 40 Label Created Using Preprinted Quadrant Labels



6.4.1.7 Control of Labels

It is important to properly control preprinted labels. New labels should be examined upon receipt to ensure they are correct and meet the needs of the facility. When a label design is changed, old labels with the former design must be discarded so they are no longer available for inadvertent use.

As noted above, DIN labels must be carefully controlled to ensure the same DIN is never used on different collections.

Additionally, consideration should be given to physically controlling labels to ensure they are not available for inappropriate use. For example, DIN sets available in a donor room should be only those appropriate for assignment to donors whose blood is collected in that location. If personnel working in a components laboratory should never change a DIN, making DIN sets unavailable in the components laboratory would enforce the policy.

6.4.2 On-Demand Labels

On-demand labels are those that are printed as needed within the facility. This requires appropriate printers, software, and supplies such as label stock.

Many commercial companies offer software programs that produce ISBT 128 labels. A list of such companies may be found on the ICCBBA website. Go to https://isbt128.org/licensed-vendors. The website lists vendors alphabetically and by product categories.

Excellent sources of information about selecting printers and evaluating the quality of bar codes can be found in two references:

- *Implementation Guide: Choosing an On-Demand Label Printer (IG-029)*
- *An Introduction to ISBT 128 (IN-015)*

6.4.2.1 Use of On-Demand Labels

Software can be part of an integrated system that manages donor information, component production, laboratory testing, and distribution/traceability information or it may be a stand-alone system that simply produces labels based on user input. Which of these options is best must be determined by each facility. The decision depends on such things as the volume of collections, the budgetary resources available, and the degree of automation desirable.

Integrated systems allow the user to print labels based on information within the Laboratory Information System. A Product Code label (usually preprinted) would need to be added at the time of component preparation. Thereafter, integrated systems allow users to simply scan the DIN and Product Code and the system will print an appropriate label.

Stand-alone systems may have general label software or may be specific to ISBT 128. Options 2 and 3 on the chart in Appendix 2 describe these two options. For the general label software, users may need to select from pre-established templates and these templates may not include the option for printing highly variable data, such as expiry dates. For ISBT 128-specific software, users must enter the appropriate data for each unit in order to print a correct label.

DINs may be printed as described in Section 6.4.1.1 on appropriate label stock, although piggyback and tear-off stock may not be available in all locations. DINs are often printed in advance of need.

Labeling Process: With on-demand labels, a 100 mm by 100 mm label is typically printed that has everything except the DIN. The blank label stock may have a dye-cut (or cutout) in the upper left corner to allow the DIN to be visible after the printed label is applied. See Figure 41. If such a cutout is not present, strong controls must be in place to ensure the correct label is applied.

Figure 41 Labeling Using 100 mm by 100 mm "Over-Lay" Label

The label on the left (beneath the label with the Blood Groups [ABO and RhD]) is the base label after the DIN has been applied. On the right is a 100 mm by 100 mm over-lay label. There is a "cutout" in the upper left corner so that the DIN will not be over-labeled. The over-lay label could be created using general label software or ISBT 128-specific software and affixed over the base label.

6.4.2.2 Control of Software/Validation

Label software, whether stand-alone or integrated, needs to be validated to ensure it will consistently produce an outcome meeting its predetermined specifications and quality attributes. If used in more than one location, validated software should be verified to ensure it works in the additional location(s). When software is updated, revalidation/reverification should be performed.

7 ISBT 128 in the Hospital Blood Bank

7.1 Essential Records

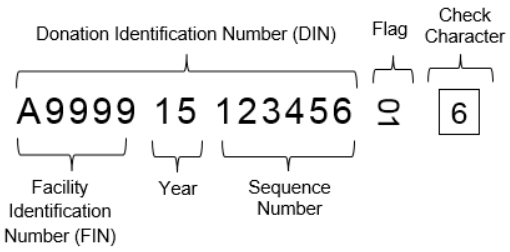
Enough information from the product label must be recorded in facility records to ensure traceability and safety. One of the advantages of ISBT 128 is that the location of critical information is very consistent across all suppliers and blood products.

7.1.1 DIN

The full DIN is 13-characters, comprising the Facility Identification Number, a year code, and a sequence number. At the end of the DIN, within a box, will be a check character. Between the DIN and the check character, there may also be “flag characters” printed at a 90 degree angle from the DIN. See Figure 42.

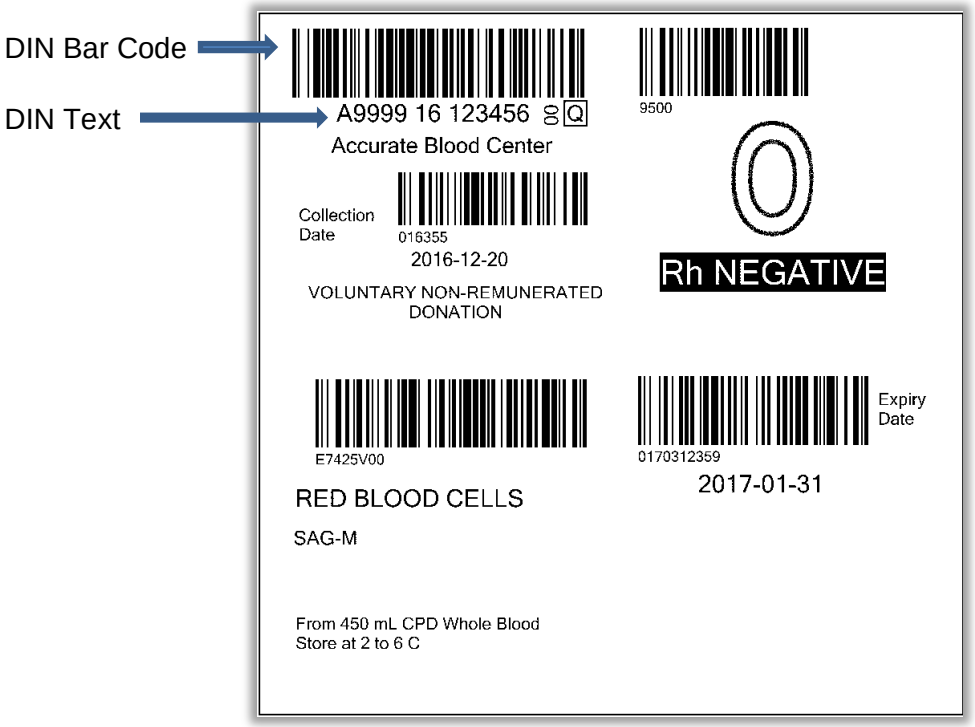
.

Figure 42 Donation Identification Number



On the label, the DIN appears in the upper left portion of the label.

Figure 43 Location of DIN on ISBT 128 Label

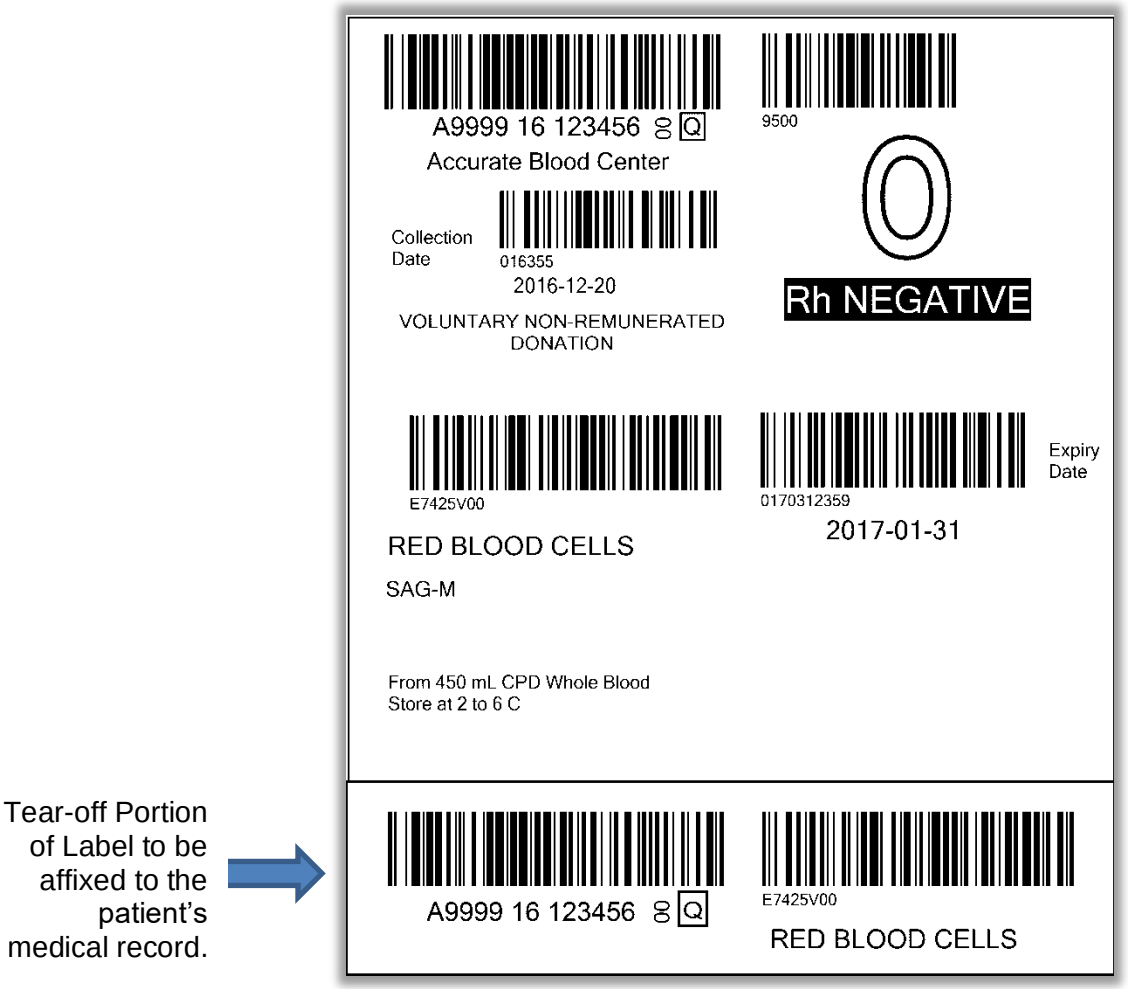


7.1.1.1 DIN Labels

Some blood suppliers may provide copies of DIN labels on the back of the blood bag, as shown in Figure 29, page 46. In this situation, a label may be peeled from the bag and placed into facility records.

Alternatively, DIN labels may be provided as tear-off portions of the label on the front of the bag. The backing on the tear-off portion has a backing that is removed to reveal the adhesive.

Figure 44 Label with Tear-Off Portion for Patient Record



7.1.2 Product Information

Because more than one product may be made from each collection, it is important to keep a record of which component was received and transfused. Thus, in addition to the DIN, records must include product information which is found in the lower left portion of the label. In a HBB that has scanners and a computer system that reads, interprets, and records ISBT 128 data structures, this is done by scanning the Product Code.

Figure 45 Location of Product Information on ISBT 128 Label

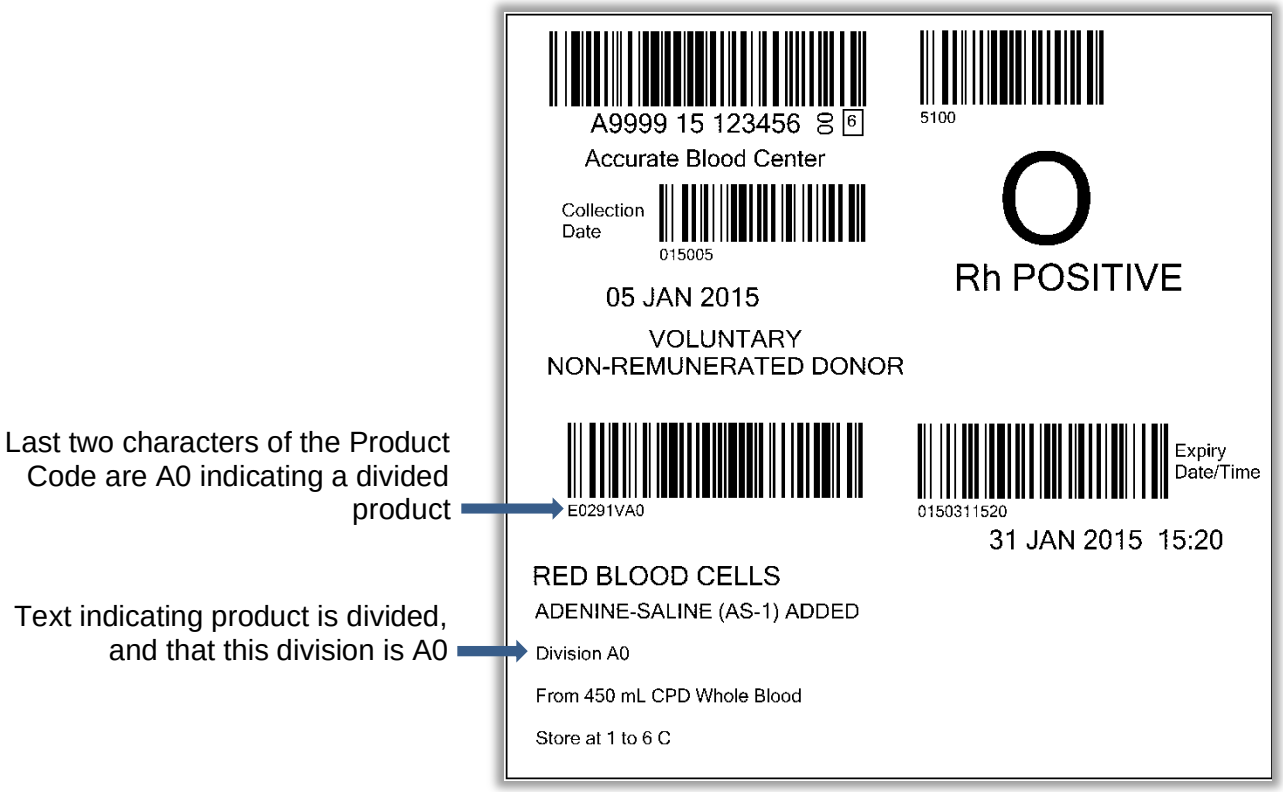
If a HBB maintains manual records, it must record enough information to ensure each component may be traced. An HBB should discuss with their blood supplier how much information must be recorded. It is quite possible only the Class of the product (e.g., Red Blood Cells, Plasma, or Platelets) needs to be recorded. This will depend on the complexity of the supplier's operations. For example, if the blood supplier provides multiple products of a given Class (e.g., multiple plasma units) from a given collection, more information must be recorded.

If pediatric aliquots are made, the Division Code of the aliquot must be recorded in facility records. Within ISBT 128 this will appear as the last two characters of the Product Code (found immediately below the Product Code bar code) as well as within product description text. This will usually appear as a combination of numbers and letters. When a product is not divided, the last two characters of the Product Code will be 00 (zero, zero). If the product has been divided (for example, for use with pediatric patients), the first of these two zeroes will change to an uppercase letter. That is, the code will

change from 00 to A0, B0, C0, etc., numbering each product successively. Should one of the divisions be further divided, the second zero will change to a lowercase letter. That is, the code will change from A0 to Aa and Ab or from B0 to Ba and Bb.

While the precise position of the division code text or the exact words may vary, text identifying product divisions should appear in the lower left quadrant of the label as shown in Figure 46.

Figure 46 Location of Product Division Information on ISBT 128 Label



7.1.3 Blood Groups [ABO and RhD]

While not needed for traceability, the ABO and RhD type of the unit should be recorded in facility records. This information is found in the upper right portion of the ISBT 128 label. See Figure 46.

7.1.4 Expiry date

It is also recommended that the expiry date (and time, if an expiry time is included on the label) be recorded. This information is found in the lower right portion of the label. See Figure 47.

Figure 47 Placement of ABO/RhD and Expiry Date

7.1.5 Linking Product Information to Recipient Information

Facility records should also link the DIN and product information with the name and identification number of the patient who received the product. This is generally done in two places: a log created as units are received (chronological record) and in a patient record.

7.2 Modification of Products

HBBs may modify products; thawing frozen products, pooling platelets, and dividing products for pediatric patients are probably the most common. It is not required that ISBT 128 be used to re-label such modified products, but a facility (especially one with a sophisticated computer system) may choose to do so. Facilities that apply ISBT 128 bar codes should be registered with ICCBBA and pay an annual licensing fee.

For information about registration and licensing with ICCBBA, see Chapter 10 and the Registration and Licensing section of the ICCBBA website (www.isbt128.org). You may also email the help desk at support@isbt128.org.

7.2.1 Expiry Dates

If the expiry date changes because of a modification, the expiry date on the label must be changed to reflect the new expiry date (or expiry date and time). This can be a handwritten correction following appropriate procedures or a new label may be applied over the old label.

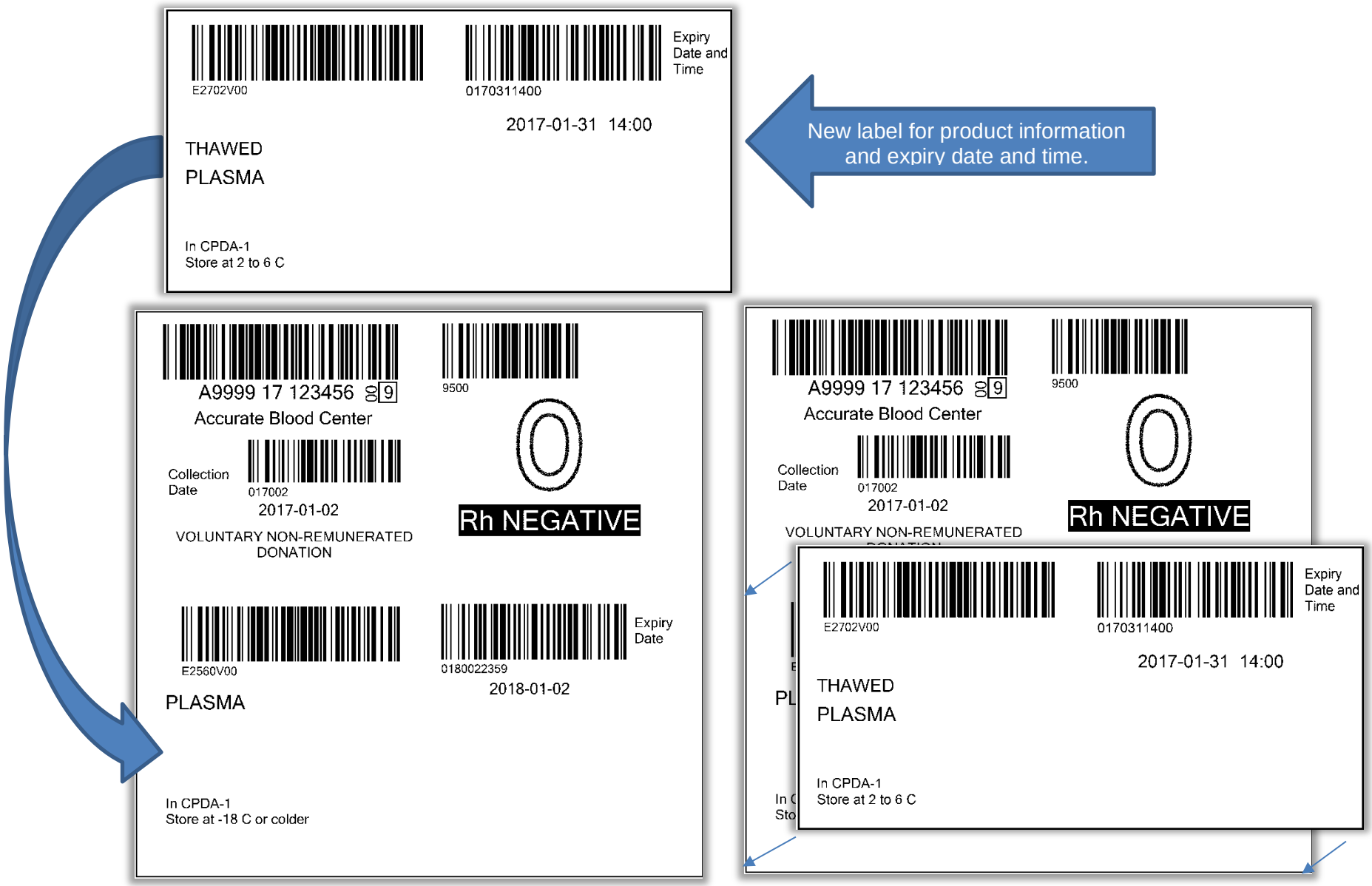
7.2.2 Product Code

Thawed Plasma: Changing the product code/description on a unit of thawed plasma is not required. Simply changing the expiration date is adequate.

If an HBB wishes to re-label with ISBT 128, it may change the lower half of the label to reflect both a thawed plasma Product Code and the new expiry date and time. This may be done by over-labeling with a preprinted lower left quadrant label (Product Code) and handwritten correction to the lower right quadrant.

If the facility is able to print labels, a label stock that is 100 mm by 50 mm that can overlay the bottom half of the plasma label may be used. See Figure 46, page 61.

Figure 48 Replacing Lower Half of the Label for Thawed Plasma



ISBT 128 has many Product Codes for modified products. The ICCBBA website provides an online lookup tool for Product Description Codes (as well as a version that may be downloaded onto a local computer). This is found at www.isbt128.org under the “Lookup Tools” tab, then “Find Product Information.”

Pooled Products: HBBs are not required to use ISBT 128 labeling on pooled products such as Pooled Platelets. They may simply pool all selected products and label the bag with non-ISBT 128 labels. Records should indicate which products (DIN plus product) are in the pooled product.

If an HBB choses to re-label with ISBT 128, a unique DIN (pool number) should be assigned to the pool and a pooled Product Description Code should be selected. For example, E2897 is Pooled Platelets stored at 20 to 24 C. Neither the anticoagulant nor the nominal collection volume are specified for this Product Description Code.

Divided Products: If the facility chooses to label with ISBT 128, as noted in 5.2.2.3, the Division Code is the last two characters of the eight (8)-character Product Code. The 7th character denotes a first level division; the 8th character a division of an already divided product.

Details on dividing products may be found in Chapter 5 of Implementation Guide: Use of Product Code [Data Structure 003] – Blood (IG-021)

8 Backup Systems

A backup labeling system must be planned to ensure continued operation in the event of a power failure, equipment failure, or other interruption. There must be Standard Operating Procedures (SOPs), training, and regular tests of the backup system to ensure it will work when needed.

For DINs, an inventory of an adequate number of labels for anticipated downtime should be available. If the facility prints its own labels, this generally means routinely having a dynamic inventory that continually runs a few days in advance of need.

Options include:

- Maintain an inventory of preprinted labels to be used in the manner described in 6.4.1.
- If using on-demand labels, retain an adequate stock of preprinted labels to be used in the event of downtime.
- Collection and expiration time labels cannot be created in advance, so a backup system for including this information is needed. The backup system may not allow for bar coding this information.

Having more than one scanner and printer will eliminate some downtime.

9 Haemovigilance

Haemovigilance is the monitoring of blood transfusions and their complications with the aim of improving the quality and safety of transfusion. It involves continuous data collection and analysis of transfusion-related adverse events and reactions, as well as investigation of causes and outcomes, to prevent occurrence or recurrence.

In November of 2012, the WHO, the International Haemovigilance Network, and the International Society of Blood Transfusion held a Global Consultation on Haemovigilance. At the conclusion of the conference, the group published recommendations for the different levels within a transfusion medicine chain: the Hospital/Institution, National, and International. Among these recommendations were two that specifically addressed traceability:

For the Hospital/Institution Level:

“Define quality indications as measures of clinical practice and traceability including confirmation of transfusion; and collect and analyse the indicators data on regular basis for quality improvement.”

For the National Level (Blood Transfusion Services):

“Secure traceability (bidirectional tracking from donor to transfused patient and vice versa (vein to vein, using appropriate IT and communication tools).”

ISBT 128 supports haemovigilance in a number of ways:

- By providing electronically readable critical information on blood labels, record keeping becomes more accurate and efficient.
- Standardized terminology supports comparing data from multiple organizations.
- Product Description Codes (PDCs) provide a wealth of information useful for analysis of data. Software may be developed to help haemovigilance organizations mine the data available from PDCs.

10 Registration and Licensing with ICCBBA

Facilities wishing to use ISBT 128 by applying ISBT 128 bar codes must register with ICCBBA. Information about this process and a registration form may be found on the ICCBBA website (https://www.isbt128.org/registration-licensing). The cost of registration and licensing is reduced for facilities that are located in countries with a lower middle or low income according to the World Bank's World Development Indicators (WDI) data. For facilities in Low WDI countries, the fees are 33% of the normal amounts indicated on the ICCBBA Website. Information about WDI may be found at https://data.worldbank.org/.

Fees support ICCBBA's management of the ISBT 128 Standard—databases, documents, help desk, educational activities, etc. ICCBBA does not provide software or hardware used with the ISBT 128 Standard. ICCBBA-licensed vendors provide software that utilizes ISBT 128. A list of such vendors can be found on the ICCBBA website.

Once a facility is registered, it will be assigned a Facility Identification Number (FIN) that may be used within the DIN to uniquely identify products.

There is flexibility in how facilities owned and operated by the same organization with multiple sites may use FINs. Facilities with multiple locations may opt to have a single FIN and manage the sequence number allocation across all of their locations centrally, or they may request multiple FINs with each facility controlling its own sequence number allocation.

- It is recommended that an organization with a single processing center, but multiple collection locations, have a single Facility Identification Number (FIN).
- It is recommended that an organization with multiple processing centers request a different FIN for each location. While each location can have a different FIN, registration can be as a single organization or each location can register separately.

Please contact the ICCBBA help desk (support@isbt128.org) for more information.

11 Conclusion

11.1 Flexibility

ISBT 128 is a highly flexible system. It can be kept simple by using only a few basic Product Description Codes and preprinted labels. As the complexity of a facility grows, additional features of ISBT 128 can be implemented and greater automation of the labeling system can be introduced.

Appendix 1 provides a basic implementation plan. Step 4 of this plan requires a facility to identify its automation needs. Appendix 2 goes into detail of the options available to complete Step 4.

11.2 More Information and Technical Support

A great deal of information may be found on the ICCBBA website (www.isbt128.org). Information on registration, as well as technical information, is available.

ICCBBA provides technical and registration support for those considering or implementing ISBT 128. This support is available through the ICCBBA help desk (email support@isbt128.org). The staff are based near Los Angeles, California, USA, and are therefore in the Pacific Time Zone (UTC -8:00).

Acronyms

2-D	Two-dimensional
AfSBT	Africa Society for Blood Transfusion
BTS	Blood Transfusion Service
DIN	Donation Identification Number
FIN	Facility Identification Number
EMATAG	Europe, Middle East, and Africa Technical Advisory Group
HBB	Hospital Blood Bank
IEC	International Electrotechnical Commission
ICCBBA	International Council for Commonality in Blood Banking Automation
ISO	International Standards Organization
MPHO	Medical Products of Human Origin
PDC	Product Description Code
RFID	Radio Frequency Identification
WDI	World Development Indicators
WHO	World Health Organization

Glossary

Bar Code	A symbolic representation of a data structure that also includes the symbology-specific start and stop codes.	
	Linear Bar Code	Single row of bars and spaces. In this document the unqualified use of linear bar code implies the use of Code 128 symbology with its associated modulo 103 check character.
	2-D Symbol	Two-dimensional (2-D) pattern of data cells. In this document the unqualified use of 2-D symbol implies the use of Data Matrix (ECC 200).
Blood Transfusion Service (BTS)	An organization, or department within an organization, that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended processing, storage, and distribution when intended for transfusion (excludes Hospital Blood Banks).	
Check Character	A character used to ensure the accuracy of data. The value is calculated based on an algorithm applied to the data. Examples are the modulo 103 check character internal to Code 128 and the ISO/IEC 7064 modulo 37-2 check character appended to text that verifies accurate keyboard entry.	
Concatenation	A method by which the information held in two bar codes is combined in the scanner into a single string of data before being sent to the host computer. ISBT 128 places specific rules on the operation of concatenation which ensures that the two codes are adjacent to one another, hence allowing this feature to be used in label process control. (Note: ISBT 128 concatenation is a specific enhancement to the Code 128 Specification. See Section 6.1.2, page 35.)	
Data Character	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 identifier. (The Donation Identification Number is an exception to this rule. See Section 5.1.1, page 21.)	
Data Identifier	The first two or three characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined. (The Donation Identification Number is an exception to this rule. The second character of the data identifier can never be dropped because it is also part of the data content. See Section 5.1.1, page 21.)	

Data Structure	Information content comprising the data identifier and data content. When a data structure is represented as a bar code, the term data structure does not include the symbology-specific and always-present start and stop codes, the modulo 103 check character, or any specified control characters.	
Division Code	A code assigned to blood products that has the same Donation Identification Number (DIN) and Product Code to provide unique identification.	
Donation Identification Number (DIN)	A globally unique identifier that is assigned to each collection and to each pooled product. When used on a collection, the DIN is used to link the collected product to the donor.	
Europe, Middle East, and Africa Technical Advisory Group (EMATAG)	A group of experts from countries within Europe, the Middle East, and Africa that advise ICCBBA on labeling, coding and terminology needs of blood facilities in countries within these regions.	
Collection Type	A designation indicating why a product was collected.	
	Autologous	A product collected from an individual for his or her own use.
	Designated	A special product (for example, HLA-compatible) collected through an arrangement by the collecting facility to be used by a specific recipient (or for Cellular Therapy products, possibly a small group of recipients).
	Directed	A product collected from an individual who presents to the collecting facility at the request of another person intending his/her product to be used by that person.
Facility	An organization that is responsible for the collection/recovery, processing, and/or distribution of ISBT 128-encoded products.	
Facility Identification Number (FIN)	A five (5)-character alphanumeric code assigned by ICCBBA to licensed facilities. It can be used in a variety of ways to ensure uniqueness of an identification number.	
Flag Character	Part of the data content of a data structure used in process control or data transmission checking. For ISBT 128, flag characters are used with the Donation Identification Number. The characters are printed in eye-readable format and distinguished in some manner from the representation of the other data characters.	
Haemovigilance	A set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence.	

Hospital Blood Bank (HBB)	A hospital unit which stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities. It includes hospital-based transfusion activities. An HBB may also be referred to as a Hospital Transfusion Laboratory.	
Interoperability	A characteristic of systems (including coding systems such as ISBT 128) that allows them to work with other products or systems without restrictions.	
ISBT 128	An international standard for the transfer of information associated with medical products of human origin. It provides for a globally unique donation numbering system, internationally standardized product definitions, and standard data structures for bar coding and electronic data interchange.	
Julian Date	See Ordinal Number.	
Label	An independent entity that may carry one or more bar codes and also provides eye-readable information about the product.	
	Affixed Label	A label that adheres in physical contact with the product container.
	Base Label	The label placed on a container by a manufacturer. It carries the manufacturer's identity, the catalog number of the container (or container set), and the lot number of the container (or container set) encoded as ISBT 128 data structures OR an initial label applied by the facility to which additional labels will be applied.
	Final Label	Labeling as it appears on a product ready for release to another entity or for administration to a recipient.
Medical Products of Human Origin (MPHO)	Products derived from a human source that are intended for therapeutic use in a human. They include blood, organs, bone marrow, cord blood, ocular tissue, tissues, reproductive cells, and milk.	
Ordinal Number	A number within the calendar year used in a system for maintaining dates that numbers the first day of the year (January 1) as 1 and the last (December 31) as 365 or 366 (in a leap year). Also known as Julian Date.	
Product Coding	The following terms are used in describing products within ISBT 128.	
	Attribute	An level of terminology that provides the most detailed information about a product (e.g., irradiation or plasma reduced).

	Class	A broad description of a product (e.g., Red Blood Cells or Platelets).
	Modifier	An intermediate level of terminology that provides information primarily about the physical state of a product (e.g., Frozen, Deglycerolized, Thawed).
	Product Description Code (PDC)	A code assigned to products. Each product comprises a unique combination of Class, Modifier, and Attributes within the ISBT 128 system.
Radio Frequency Identification (RFID)	The use of electromagnetic fields to automatically identify and track tags attached to objects.	
Surveillance	In the context of transfusion and transplantation, the close and continuous monitoring of outcomes.	
Text	The following terms are used within ISBT 128 to describe label text.	
	Text Associated with Data Content (previously called data content text)	The eye-readable representation of the data characters in a bar code (printed left justified immediately below the linear bar code, unless otherwise specified).
	Text Associated with Electronically Readable Information	The interpretation into meaningful information of the data content of the bar code.
	Text Not Associated with Electronically Readable Information	All other information on the label that is not associated with a bar code.
Traceability	The ability to verify the history, location, or application of an item by means of documented recorded identification.	
Vigilance	A comprehensive and integrated patient safety program to collect, analyze, and report on the outcome of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues, and organs.	

Appendix 1: Example Implementation Plan

The following example plan was meant to be comprehensive, and not all steps may be needed by all facilities. Therefore, facilities should use it as a guide (or checklist) of things to consider rather than attempting to follow it precisely.

Step	Activity
1.	Form team a. Identify leader b. Identify team members (IT, Quality, Laboratory, Processing, Recovery/Collections, Product Management)
2.	Register with ICCBBA a. Obtain FIN b. Obtain password to access to all documents and databases c. Subscribe to update notification service
3.	Become familiar with resources and identify changes that are needed. a. Explore ICCBBA website (www.isbt128.org) b. Assemble and review documents and implementation tools c. Utilize ICCBBA help desk (support@isbt128.org)
4.	Identify equipment/software needs a. Determine specifications b. Assess current software and equipment against needs c. Determine if organization will need to upgrade or replace software and equipment d. If new software or equipment is needed, analyze alternatives
5.	Obtain funding a. Determine resources needed and their cost b. Create budget plan c. Request funding
6.	Upgrade or purchase equipment/software, if needed
7.	Develop and approve plans a. Project/implementation/change control plan(s) b. Transition plan i. Determine how dual-labeled inventory will be managed ii. Determine how conversion will be coordinated with testing laboratory and facilities that will receive products c. Validation plan

Step	Activity
8.	Perform IT-related operational steps a. Plan product coding i. Map products from current coding to ISBT 128 ii. Request new codes where appropriate codes are not available b. Populate computer tables c. Validate software, equipment, processes, and labels
9.	Update/create/approve documentation a. Label design b. Standard Operating Procedures (SOPs) and work instructions c. Quality plan d. Training materials for staff e. Educational materials for those who will receive products
10.	Communicate a. Notify testing laboratories and other affected suppliers of the changes to sample and product identification b. Train staff c. Provide educational sessions for those who will receive products d. Notify competent authorities, if required
11.	Implement ISBT 128
12.	Assess results and opportunities for improvement

Appendix 2: Options for Implementing ISBT 128

The following table is for informational use only. It is not intended to recommend a specific course of action. Reference to any particular vendor is not an endorsement of that vendor's products and other suitable vendors may also be available.

Options	Advantages	Disadvantages	Comments	Costs*
1. Preprinted Label	• No equipment maintenance • Low cost for start-up • Short start-up time • Once approved by facility's Quality Department (and verified by ICCBBA, if desired), the labels can be used by trained staff	• May not be available from a local supplier, making reliably receiving supplies a problem • Cannot bar code the expiry or collection dates	Facility would probably need to find a supplier within their region that could produce these labels.	• Variable, depending on volume • Scanners • Relative cost: **$**
2. General labeling, Stand-alone software program for general labeling	• Lower cost for software • Can produce a large variety of different labels • Templates can be created so that a label may be designed in advance by Quality or IT staff • Different vendors, and editions from a given vendor, are available to increase flexibility of the system • There is global technical support available from some suppliers. This would be limited to the use of the software, and	• Requires high level of knowledge of the ISBT 128 Standard. The software does not have the logic to create ISBT 128 bar codes from user-friendly input (i.e., you cannot enter 25 June 2017 and have the system encode it properly) • Time-consuming to set up label templates • Some such software is not scalable for multiple centers with	• Because use of this software requires someone with a high level of knowledge about ISBT 128, it may not be practical across the entire system unless versions with greater flexibility are chosen • A template for each product, and each ABO/RhD type, could be developed. Users would have to select the right template (e.g., Platelets that are A, RhD positive) • Bar coding the expiry and collection dates would be difficult with some versions of this software. These dates could not be encoded within the	Example costs: • Printer(s) • Blank label stock • Ribbons for printer • Licenses may be based on the number of computer stations or the number of printers • Scanner(s) • Relative cost: **$$**

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	would not cover ISBT 128 label-specific support	central control. Software that is scalable may be more expensive	template because the information would change each day and with each type of product. The date encoded in the bar code is the last 3 characters of the year (e.g., 2017 is encoded 017) and the ordinal number/Julian date. Thus, it is in a different format from the eye-readable date which is either DD MMM YYYY (08 JAN 2017) or YYYY-MM-DD (2017-01-08). This could create a source of error if the bar coded date does not match the eye-readable date. Eye-readable-only dates might be necessary. A printed date that could be added to the label, or a rubber-stamp dating, might work best • Facilities would need to ensure software allows "locking" of the template so users cannot change the template inadvertently	
3. Stand-alone software, with specific ISBT 128 functionality	• Vendor takes responsibility for compliance with ISBT 128 Standard	• May be "overkill" for the number of different products produced	• Some systems are stand-alone and some may be interfaced to a laboratory system	Example costs: • Printer(s) • Blank label stock • Ribbons for

The following table is for informational use only. It is not intended to recommend a specific course of action. Reference to any particular vendor is not an endorsement of that vendor's products and other suitable vendors may also be available.

	• Users select product label data from drop-down menus. For example, they select the Product Description Code and the blood group/type from drop-down menus to create the label. The software then encodes the information and prints a correct ISBT 128 label • Users enter the correct date in user-friendly manner and the software creates the correct bar code as well as the correct text. This allows expiry date to be bar coded • Scalable for additional locations. Once set up, the equipment should be easy for anyone to use	• There are not a large number of companies providing this software. Technical support may not be available near the facility and may only be by telephone/email		printer • Annual license/support: • Scanner cost • Relative cost: **$$$**
4. Integrated software package	• Greatest benefits and safety improvement • ISBT 128 is just one piece of a complex program to support computer control of critical steps in a blood	• Long start-up time • Greatest cost • Often requires many months of learning, validation, training, etc. • High maintenance		• Printer(s) • Blank label stock • Ribbons for printer • Scanner(s) • Annual license/support

The following table is for informational use only. It is not intended to recommend a specific course of action. Reference to any particular vendor is not an endorsement of that vendor's products and other suitable vendors may also be available.

	banking system	(backups, emergency power, controlled shut down, etc.) • May need additional labeling software with ISBT 128 functionality • There may be annual maintenance costs		• Relative cost: **$$$$**

*Costs are very approximate and based on quotes obtained in the US. The cost in other countries may vary and would need to be investigated. If not purchasing locally, shipping costs would need to be evaluated.

Appendix 3: Example Labels

Figure 49 Full Label

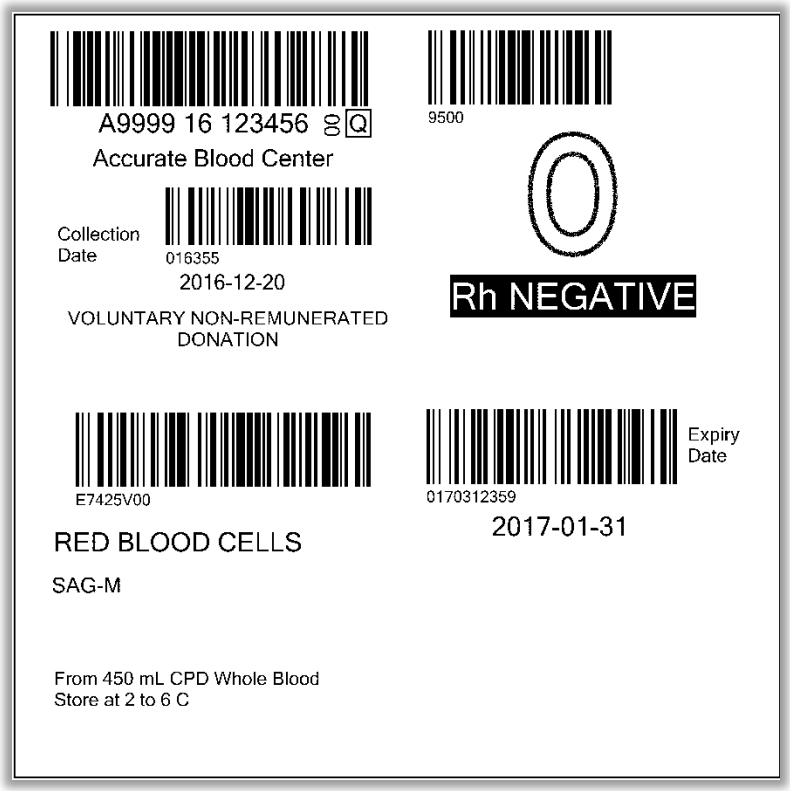
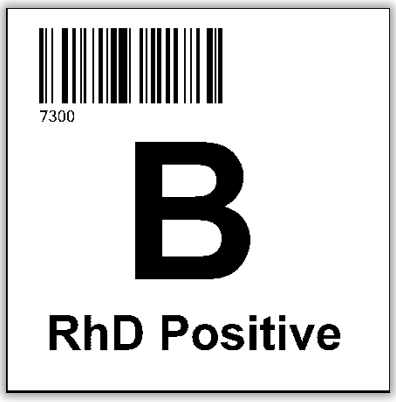


Figure 50 Examples of Upper Right Quadrant



Examples of RhD Negative labels are shown in Figure 27 on page 43.

Figure 51 Examples of Lower Left Quadrant Labels

Figure 52 Examples of Lower Right Quadrant Labels