IMPLEMENTATION GUIDE

Use of Product Code [Data Structure 003] Blood

Version 1.2.0

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1   Introduction

1.1   Purpose

The purpose of this document is to provide guidance for the use of the Product Code [Data Structure 003] and its supporting database in the coding of blood components.

1.2   Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides specific guidance for blood facilities in the use of the Product Code [Data Structure 003] and the ISBT 128 Product Description Code Database. It assists the user in selecting the correct Product Description Code (PDC) and in requesting new PDCs.

The diagram in Figure 1 represents the information environment. The information environment model describes how ISBT 128 organizes information to achieve standardization for both labeling and electronic messaging for medical products of human origin. The foundation of the information environment contains standardized terminology, data elements, and reference tables. These layers support the structures, mechanisms, specifications, and standards necessary to print labels and create electronic messages.

This document describes the "Standardized Terminology" and "Reference Tables," as they pertain to product information. It also discusses the Product Code [Data Structure 003] from the "Data Structures." More information about other data structures, delivery mechanisms, and labeling can be found in references listed in Sections 1.4 and 1.5.

Figure 1 Information Environment Layers
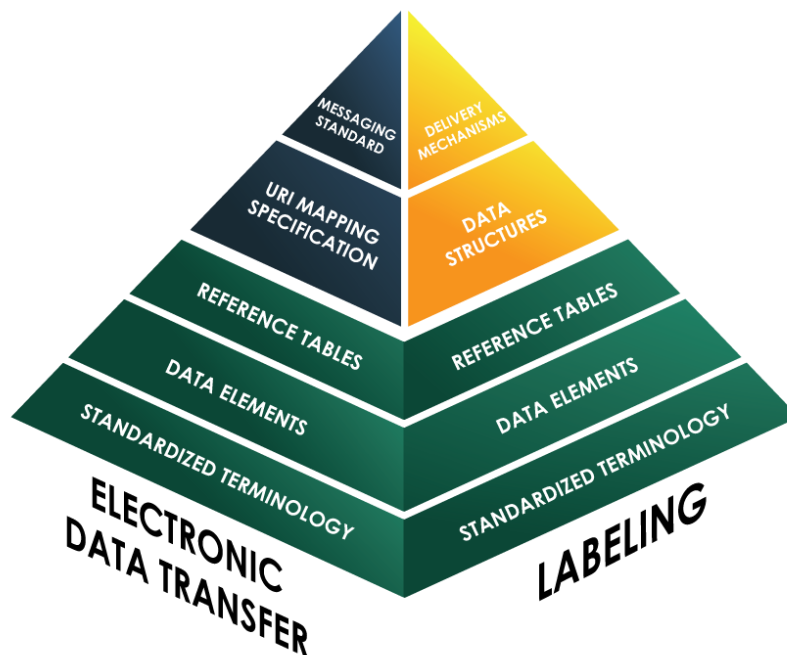
Included in this document are:

- The definition of an ISBT 128 Product Code
- An explanation of the ISBT 128 Product Description Code Database
- Instructions for finding an appropriate Product Description Code (PDC)
- A mechanism to request new PDCs

1.3 Intended Audience

The intended audience of this document is blood collection, blood processing, and transfusion facility staff (management, information technology, quality, validation, and laboratory), software developers, and vendors of equipment and consumables used by these organizations.

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)

1.5 Other References

ICCBBA Website (www.isbt128.org)

1.6 Background

There is wide recognition of the need to standardize the terminology, coding, and labeling of medical products of human origin (MPHO) in order to improve traceability and transparency. The 2010 World Health Assembly Resolution WHA63.22 calls 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 for the use of ISBT 128 for the labeling of blood products was developed by the International Society of Blood Transfusion (ISBT) Working Party on Automation and Data Processing (WPADP) [now called the Working Party on Information Technology] and published by ICCBBA in 1995. Around the world, implementation in blood establishments began soon after the Standard was issued, with a steady increase in adoption since that time. There are now more than 2,000 blood collection facilities and transfusion services licensed to use ISBT 128.

International standardization of 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.

In designing ISBT 128, the ISBT WPADP developed a coding system for describing blood products that:

- Is based on a set of definitions of component Classes, Modifiers, and Attributes that can be expanded as needed
- Includes the type of collection
- Provides a mechanism to identify divisions of a given product

The tables presented in the ISBT 128 Standard can be extended as new products become developed. Proposed additions to terminology may be reviewed by the Asia Pacific Technical Advisory Group (APTAG), the Americas Technical Advisory Group (ATAG), and the Europe, Middle East, and Africa Technical Advisory Group (EMATAG) to ensure an appropriate level of definition and coding detail is maintained.

1.7   Changes in this Version

The following table indicates the major changes between Version 1.1.0 and Version 1.2.0 of this document. 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. If changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

Implementation Guide: Use of Product Code [Data Structure 003] – Blood Version 1.1.0 vs. Version 1.2.0

	Version 1.1.0 Chapter, Section, Table, or Figure	Version 1.2.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	Throughout	Throughout	Updated title for ST-002.	To reflect the title change for ST-002.
2.	1.2	1.2	The information environment model and corresponding text were updated.	To reflect updates on the information environment model.
3.	2	2	Added information on the transition to E-alpha codes.	To provide information on recent developments.
4.	3.1 and 3.2	3.1 and 3.2	Updated.	To reflect the current terminology in ST-002.
5.	**3.3.1**	**3.3.1**	**Changed references of "numbers" to "alphanumeric characters" for the assignment of a PDC.**	**Per Proposal 16-005, alphanumeric characters are now allowed in positions 2-5 of the PDC.**
6.	3.4.1	3.4	Removed all references to the restructuring of the PDC database.	The database has been restructured, so the information is no longer relevant.
7.	3.5.2	3.5.2	Clarified directions for finding the ISBT 128 Product Lookup Program and added information for the ISBT 128 Product Lookup Web Application. Removed detailed instructions on using the ISBT 128 Product Lookup Program.	To accurately reflect the location of the lookup program on the ICCBBA website and to provide information for the new web application. The detailed instructions for using both formats of the ISBT 128 Product Lookup Program are located and maintained on the ICCBBA website.

	Version 1.1.0 Chapter, Section, Table, or Figure	Version 1.2.0 Chapter, Section, Table, or Figure	Change	Rationale
8.	3.6.1, 3.6.2, and Figures 12 – 15	N/A	Removed sections and figures for completing and submitting the online PDC request form found in the Subject Area on the ICCBBA website.	Requests for new PDCs are now submitted using the ISBT 128 Product Lookup Web Application.
9.	**3.7**	**3.7**	**Updated text for nationally defined and locally/facility-defined codes.**	**To reflect requirements in Section 2.4.3 of ST-001 and Proposal 16-005.**
10.	Table 1	Table 1	Updated.	To be consistent with Table RT008 in ST-001.
11.	Table 2	Table 2	Updated.	To reflect current information in ST-001.

2   Product Code [Data Structure 003]

The ISBT 128 data structure for the Product Code is:

=<αooootds

where:

=<   is the data identifier.

αoooo   is the Product Description Code, a five (5)-character alphanumeric string from the
                 ICCBBA-maintained ISBT 128 Product Description Code Database. **E** or **F** is the
                 first character for blood products. As the blood product description codes (i.e., E-
                 codes) reached E9999, ICCBBA has moved towards using E-alpha codes (e.g.,
                 EA123) for assigning blood codes beyond E9999. The following interpretation of **t**
                 and **ds** applies where **α** is **E** or **F**.

t   specifies the type of collection (e.g., autologous or directed) and is encoded and
                 interpreted according to Table RT008 in the *ISBT 128 Standard Technical
                 Specification* (ST-001).

ds   specifies divisions of a product. If the unit has not been divided, **ds** should be set
                 to the default value of **00**. **d** encodes the first level divisions (up to 26) and is
                 encoded using upper case letters. **s** encodes the second level divisions (up to
                 26) and uses lower case letters.

Thus, the full Product Code is eight characters long, with a five-character Product Description
Code, a one-character Collection Type Code, and a two-character Division Code as shown in
Figure 2. The next three chapters provide detailed descriptions of each of these three codes.

Figure 2   Product Code
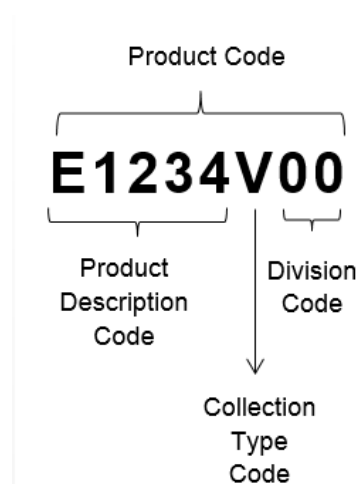
3   Product Description Codes

3.1   Terminology and Definitions

The foundation of ISBT 128 product coding is standardized terminology. The process begins by having international groups of experts on Technical Advisory Groups (TAGs) select and define terms for different types of biological products through consensus processes. For blood products, these groups are the Asia Pacific Technical Advisory Group (APTAG); the Americas Technical Advisory Group (ATAG); and the Europe, Middle East, and Africa Technical Advisory Group (EMATAG).

It is critical that the words used to identify and define each product are precise and unambiguous. Terminology is based on the concepts of Classes, Modifiers, and Attributes, a hierarchy of terms that are used as building blocks to describe blood products.

Classes are broad descriptions of products. Examples are RED BLOOD CELLS, PLATELETS, and FRESH FROZEN PLASMA.

Modifiers are applied to Classes in order to provide the next step in the categorization of the product. Examples are Thawed, Washed, and Apheresis.

Attributes provide the means to define the product in detail. For blood products, there are two kinds of attributes:

- Core Conditions
- Groups and Variables

Core Conditions are very basic characteristics that apply to all blood products and are therefore mandatory for each product description. Default values do not exist for Core Conditions, and therefore values must be selected for each product description. Core Conditions convey three types of information regarding the collected unit:

- Anticoagulant/additive/cryoprotectant solution
- Nominal collection volume
- Storage temperature

Groups and Variables describe characteristics that apply to some, but not all, blood products. These characteristics are first organized into groups of like terms. The Attribute groups for blood product descriptions are:

Group Name:
- Intended Use
- System Integrity
- Irradiation
- Residual Leukocyte Content
- Altered
- Final Content
- Preparation: Additional Information
- Apheresis and Container: Additional Information

- Quarantine: Additional Information
- Dosage: Additional Information
- Pathogen Reduction
- Hematocrit
- Monitoring
- Donor Exposure: Additional Information
- Antibody Specificity
- Infection

Within each group are variables, or options, for describing blood products. For example, in the Intended Use group, the variables are:

- Default: For transfusion
- For manufacture: injectable
- For manufacture: injectable - source
- For manufacture: injectable restricted use
- For manufacture: noninjectable
- For manufacture: noninjectable – source
- For manufacture: noninjectable -- converted
- For manufacture: noninjectable restricted use
- Not for transfusion or manufacture

Within each group there is a default value ("For transfusion" in the example above). The default variable applies automatically if no other variable from the group is selected. The variables within each group are mutually exclusive. This means that while a variable from any or all of the groups may be selected to describe a given blood product, only one variable from each group may be selected.

A list of all Classes, Modifiers, and Attributes is found in the document *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002), which can be found in the public access section of the ICCBBA Website. This document also includes the definition of each term, which is critical to achieve common understanding. For example, an Attribute variable for a blood product is "Bacterial monitoring." This could mean many things. In the ISBT 128 Standard, it is defined as "A product subjected to on-going bacterial monitoring meeting national specifications for extension of the expiry date." By defining each term carefully, ambiguity is avoided.

New terms and definitions are constantly being added to the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002). Users are urged to check the ICCBBA website to ensure they have the latest version.

3.2　Product Descriptions

Using the nomenclature provided in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002), blood products may be described in detail. The terms may be used as building blocks by selecting those terms that best describe a product. The terms are then strung together to form the description of a given blood product.

- First, a Class must be selected.
- Then, a Modifier may be selected but is not required. A modifier may have more than one term, such as Deglycerolized Rejuvenated.
- Next, Core Conditions must be selected.
- Finally, a variable from one or more attribute groups may be selected. A selection from groups/variables is not required.

An example blood product description is:

Class:	Red Blood Cells
Modifier:	Apheresis
Attribute, Core Conditions:	Anticoagulant is ACD-A; nominal collection volume is not specified; and storage temperature is refrigerated (actual temperature range is nationally defined)
Attribute, Variables:	Irradiated, Residual Leukocyte Count <1 x 10^6, 1st container

Because variables from only three groups (Irradiation, Residual Leukocyte Content, and Apheresis and Container: Additional Information) were selected, the default values from all other Attribute groups apply to this product. This means the following additional information applies:

Attribute Group	Default Value
Intended Use	For transfusion
System Integrity	Closed
Altered	Not altered
Final Content	Usual nominal volume
Preparation: Additional Information	No additional information
Quarantine: Additional Information	No additional information
Dosage: Additional Information	No additional information
Pathogen Reduction	No treatment
Hematocrit	Not specified
Monitoring	Not specified
Donor Exposure: Additional Information	No information is provided
Antibody Specificity	Not applicable
Infection	Not applicable

3.3   Coding of Product Description Information

3.3.1 Assignment of a Code

Once terminology is established and products are described, the product descriptions must be coded for use in electronic communication. This means short, computer-friendly codes for every product description must be assigned.

Chapter 2 described a Product Code as having three parts: Product Description Code (PDC), Collection Type Code, and Division Code. The first of these, the PDC, is the code that is assigned to each blood product described. It comprises a letter (E or F for blood products) followed by four alphanumeric characters. The alphanumeric characters are simply assigned sequentially as each new product description is added. For example:

- E0195 is the PDC for Red Blood Cells with CPDA-1 anticoagulant, a nominal collection volume of 450 mL, and stored at refrigerated temperatures.
- E7039 is the PDC for Apheresis Platelets, stored in PAS-E at 20-24 C, leukocyte reduced, supernatant reduced, first container, and riboflavin treated.

PDCs and their corresponding product descriptions are listed in a reference table called the ISBT 128 Product Description Code Database. This database is available on the ICCBBA website for ICCBBA-licensed facilities.

3.3.2 Product Description Information within the Database

Product descriptions are listed in a very structured way in the ISBT 128 Product Description Code Database. Abbreviations, as described in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002), are used. The order in which the terms appear is consistent: Modifier, Class, Attribute Core Conditions, and Attribute Variables.

The delimiters that separate each of these terms are also consistent. The Class and Attribute Core Conditions are separated by the "|" delimiter. For example:

Product Description Code	Description
E0262	RED BLOOD CELLS|CP2D/500mL/refg
E0167	RED BLOOD CELLS|CPD/500mL/refg

If a Modifier applies, it is included with the Class. For example, "Washed" is a Modifier in the example below:

Product Description Code	Description
E5140	Washed RED BLOOD CELLS|None/350mL/refg|Open

Attributes may be used to further describe the product. Only one variable from each Attribute group may be used. Other Attributes are also separated by the "|" delimiter.

Modifier CLASS|Core Conditions|Other Attribute|Other Attribute

For example:

Product Description Code	Description
E5141	Washed RED BLOOD CELLS|None/350mL/refg|Open|Irradiated
E5169	Washed RED BLOOD CELLS|None/XX/refg|Open|ResLeu:<5E6

Attribute variables, when present, will always be listed in the product description in the order of the group names listed in the database and the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002). If a product was irradiated and leukoreduced, it would appear as:

Modifier CLASS|Core Conditions|Irradiation|Residual Leukocyte Content

In the database, information is consistently formatted. Information about intended use will always precede information about system integrity and that will always precede information about alterations and so forth.

When new Attribute groups are added, they will be added to the end of the list. The list of Attribute groups is maintained in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002).

The order in which text appears in the description column does not specify the order in which Attributes will appear as label text. The placement of label text can be country-specific; national guidelines should be consulted when available.

3.4   ISBT 128 Product Description Code Database

All ISBT 128 database tables shall be published in the password-protected area of the ICCBBA website. This file is a Microsoft Access® file and is listed on the website as:

ISBT 128 Product Description Code Database

3.5   Selecting Appropriate PDCs

The codes are listed in alphabetical order in the full database so blood component codes (those beginning with an E or F) are found at the beginning of the full database tables.

To appropriately select product descriptions, it is important to understand the definitions of each term. These definitions are found in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002). This document must be consulted in order to select the appropriate descriptions and codes for blood products.

3.5.1 Retired Codes

Over time, codes may become inappropriate, redundant, or errors may be discovered. As a result, a mechanism must exist to discontinue future use of these codes. However, because products may exist in inventories across the world, the codes must be retained in the database for backward compatibility.

To accomplish this goal, a column exists in the ICCBBA database to indicate such codes. This "Retired Date" column indicates the date on which ICCBBA recommended the codes no longer be used for new products. Software should be written to recognize these codes but not assign them to newly created products. It is understood that facilities must be given time to retire codes after ICCBBA has made its recommendation.

3.5.2 ISBT 128 Product Lookup Program

Searching for the correct PDC can be simplified by the use of the ISBT 128 Product Lookup Program. This program allows users with password access to the ICCBBA website to look up a product description for a given PDC or look up a PDC based on a product description.

The program—in both a web application and downloadable file—and instructions on how to use it are accessible on the ICCBBA website (https://www.isbt128.org/find-product-info). Alternatively, on the home page, select "Find Product Information" in the "Lookup Tools" drop-down menu at the top of the page.

- The ISBT 128 Product Lookup Web Application can be used without the need to download any programs and can also be used to submit requests for new Product Description Codes.

- The downloadable ISBT 128 Product Lookup Program is a Microsoft Excel file that can be downloaded onto your computer. It is compatible with Microsoft Excel 2007-2013. It has not been validated, and should not be used, with earlier versions of Microsoft Excel. It is updated with each new version of the ISBT 128 Product Description Code Database. Therefore, users must download the file frequently to ensure the most recent PDCs are available. New PDC requests cannot be submitted using this option.

3.6 Requesting New PDCs

Facilities may need to describe a product that is not currently in the database. New PDC requests can be submitted using the ISBT 128 Product Lookup Web Application. The web application and detailed instructions on how to use it are accessible on the ICCBBA website (https://www.isbt128.org/find-product-info).

New PDC descriptions must be compatible with the existing system. Codes that represent new combinations of existing Classes, Modifiers, or Attributes will be added without delay. If a new Class or Modifier, a new Attribute group, or a new variable within an existing Attribute group is included in the product description, the request must be

accompanied by appropriate definitions. If there is a question of consistency, the request may be referred to an ICCBBA Advisory Group.

Updates to the PDC Database will be regularly posted in the password-protected area of the ICCBBA Website and made apparent by a change in the version number of the ISBT 128 Product Description Code Database. Version control sheets describing the changes are published with each update and are available in the same section of the Website as the ISBT 128 Product Description Code Database.

3.7 PDCs Designated for National or Local/Facility Use

The block of PDCs beginning with alpha characters A-D (A0000-D9999 and AAAAA-DZZZZ) shall be reserved for use as nationally defined or facility-defined Product Description Codes. There shall be no international interpretation associated with these values.

These codes should ONLY be used where there is not an appropriate international code and there is good reason why an international code should not be allocated. For example, local codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty whether the code assigned to a product should be international or local/regional/national, the user should contact the ICCBBA office (support@isbt128.org).

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

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

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

Care should be taken within a country to carefully coordinate use of these codes since the same range of codes may be used for blood, cellular therapy, and tissue products.

4 Collection Type Code (Intended Use)

Collection, processing, and transfusion services often find it useful to be able to distinguish collection types, such as autologous and directed, through the Product Code. In ISBT 128 blood product codes, the collection type is encoded in the 6th character of the Product Code. The value of "0" (zero) may be used if the collection type is not specified. The other characters and their definitions are given in the current version of *ISBT 128 Standard Technical Specification* (ST-001), Table RT008. For convenience, the table is reproduced in this document, but the *ISBT 128 Standard Technical Specification* (ST-001) must be consulted for the latest version.

Table 1 Data Structure 003: Type of Collection in 6th Position of Product Code [RT008]

Character	Type of Collection
0 (zero)	Not specified (null value)
V	Volunteer homologous (allogeneic) (default)
R	Volunteer research (Product not intended for human application)
S	Volunteer source
T	Volunteer therapeutic
P	Paid homologous (allogeneic)
r	Paid research (Product not intended for human application)
s	Paid source
A	Autologous, eligible for crossover
1 (one)	For autologous use only
X	For autologous use only, biohazard
D	Volunteer directed, eligible for crossover
d	Paid directed, eligible for crossover
2	For directed recipient use only
L	For directed recipient use only, limited exposure
E	Medical exception, for specified recipient only (allogeneic)
Q	See (i.e., read [scan]) Special Testing bar code
3	For directed recipient use only, biohazard
4	Designated
5	Dedicated
6	Designated, biohazard

F	Family reserved
C	Replacement
7	For allogeneic use.
8	For autologous use. Contains allogeneic material.
B	Directed/Dedicated/Designated Collection Use Only
H	Directed/Dedicated/Designated Collection/Biohazardous
J	Directed/Dedicated/Designated Collection/Eligible for Crossover
G	For Emergency Use Only

In selecting the appropriate collection type, definitions provided in Table 2 should be used.

Table 2 Definitions Associated with Type of Collection

| Collection Type	Definition
Autologous	A product collected from an individual for his or her own use.
Dedicated	A product collected through an arrangement by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products) when the collections occur more frequently than would normally be allowed.
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.
Family reserved	A product collected from an individual that is reserved for use in the treatment of that individual or a member of his/her family with the consent of that individual or his/her representative. Crossover is not precluded if allowed by pertinent regulations, provided all necessary regulatory and consent requirements are satisfied.
Medical exception	A product collected from an individual who did not meet the usual eligibility criteria. Because of the special value of the product to a specified recipient (e.g., HLA type), a medical director or other authorizer has approved the collection for the specified recipient. An example would be a donor whose travel history would normally preclude him from donating. This category should not be used for biohazard collections.
Replacement	Replacement collection is defined by national authorities rather than by ICCBBA since the definition may vary by country.
Research	Product not intended for human application. Note: A future version will specify that this collection type should not be applied to product intended for clinical use. The term "research" has not been intended in the past for clinical use and in the future it will be explicitly defined as not intended for clinical use. After the new definition is in place, time will be given for backward compatibility.

5   Division Code

Units made by the division of a single container of a product into two or more parts that are identical (at the time of division) except for volume are called "divided units." Such units have the same Donation Identification Number and may have the same first six data characters of the eight-character Product Code. The purpose of data characters seven and eight is to provide a mechanism to distinguish each part (division) uniquely for tracking purposes.

The (undivided) primary collection will be encoded with "**00**" (two zeros); this is the default value.

First level divisions are encoded by the first of the two alphanumeric characters "**ds**". The system provides for 26 first level divisions of the primary collection using capital letters followed by a zero that is, "**A0**," "**B0**," "**C0**," "**D0**," "**E0**," "**F0**," etc.

Second level divisions (up to 26) will be encoded using the letter of the first level division followed by a lowercase letter indicating the subdivision , for example: "**A0**" would be subdivided as "**Aa**," "**Ab**," "**Ac**," etc. "**B0**" would be subdivided as "**Ba**," "**Bb**," "**Bc**," etc. See Figure 3.

Figure 3 Example of First and Second Level Divisions
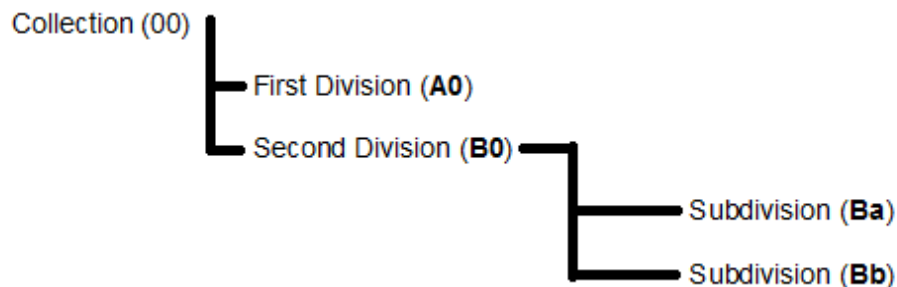
For example:

Red Blood Cells from a volunteer donor have the Product Code E0164V**00**. If you perform a single first level division, the resulting aliquots will be E0164V**A0** and E0164V**B0**. If you further divide product E0164V**B0** into three syringe aliquots (an open system), the resulting second level subdivisions will be: E0158V**Ba**, E0158V**Bb**, and E0158V**Bc**. Notice that the PDC changed from E0164 to E0158 because the "Open System" Attribute was added. See Figure 4.

Figure 4 Division Codes
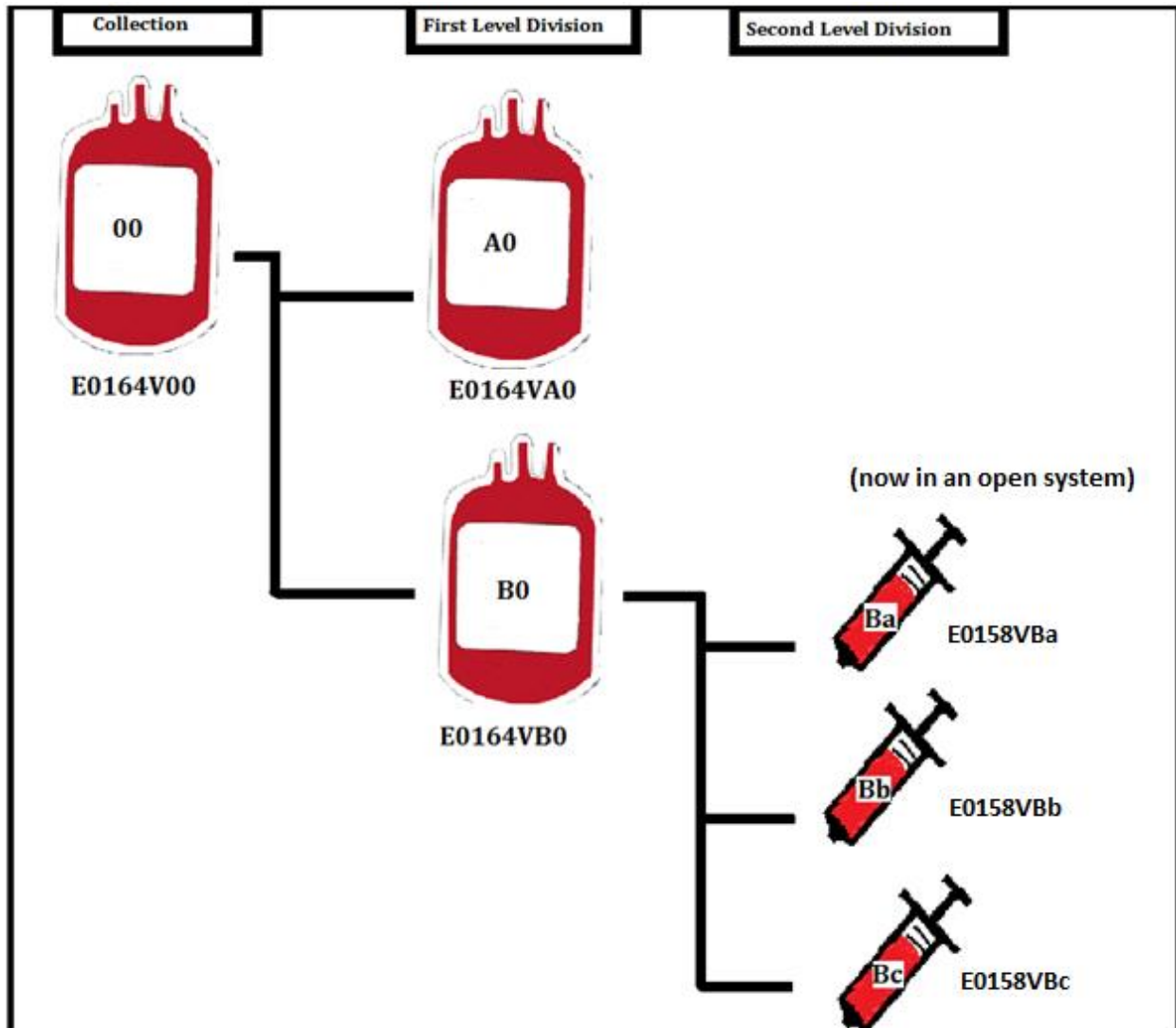
PDCs used in Figure 4**:**

- E0164 = RED BLOOD CELLS|CPD/450mL/refg|ResLeu:<5E6
- E0158 = RED BLOOD CELLS|CPD/450mL/refg|Open|ResLeu:<5E6

As another example, if you further divide product E0164V**B0** into three aliquots in a closed system, the resulting second level subdivisions will be: E0164V**Ba**, E0164V**Bb**, and E0164V**Bc**. See Figure 5.

Figure 5 Division Codes Continued
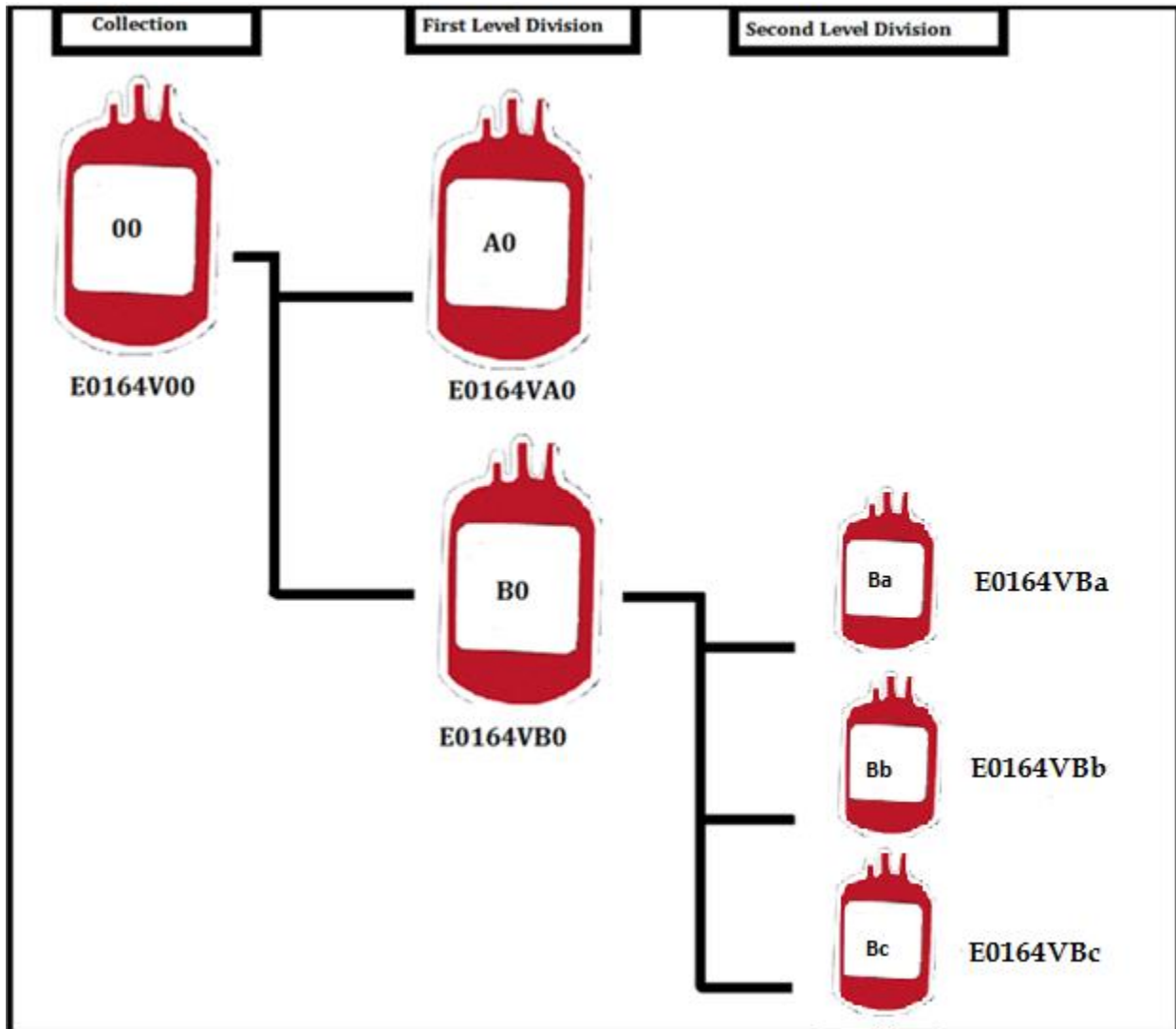
PDC used in Figure 5:

- E0164 = RED BLOOD CELLS|CPD/450mL/refg|ResLeu:<5E6

6 Questions?

If you have additional questions about product coding, or the selection of the appropriate PDC for your products, please contact the ICCBBA office (support@isbt128.org).