IMPLEMENTATION GUIDE

Product Coding [Data Structures 003 and 032] Cellular Therapy

Version 1.3.0

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance in the use of the Product Code [Data Structure 003], Product Divisions [Data Structure 032], and the supporting database in the coding of cellular therapy products.

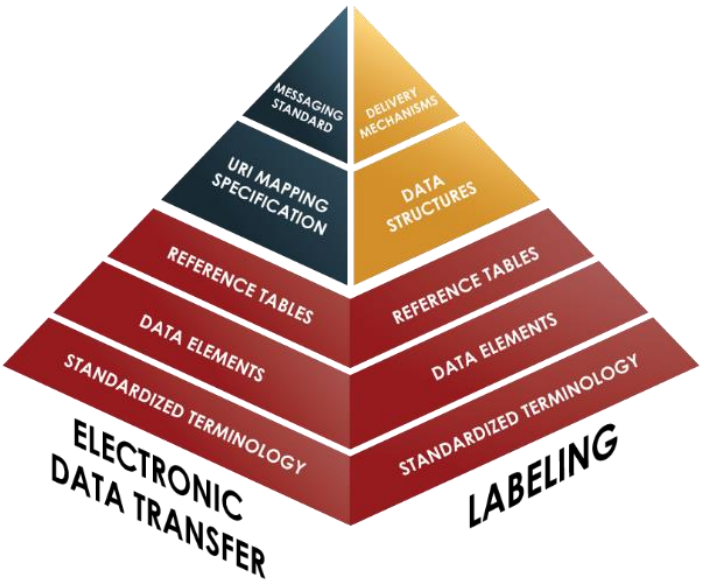
1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides specific guidance for cellular therapy facilities in the use of the Product Code [Data Structure 003], Product Divisions [Data Structure 032], 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 information environment comprises a number of layers (Figure 1) each of which is needed for standardization. This document describes the first layer, "Standardized Terminology" and "Reference Tables" as they pertain to product information. It also discusses the Product Code [Data Structure 003] and Product Divisions [Data Structure 032] from the Data Structures layer.

More information about other data structures, delivery mechanisms, and labeling can be found in the documents listed in Section 1.4.

Figure 1 Information Environment Layers



1.3 Intended Audience

The intended audience of this document is cellular therapy facility staff (management, information technology, quality, validation, and laboratory), software developers, and vendors of equipment and consumables.

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 Cellular Therapy Products (ST-004)
ISBT 128 Standard Product Description Code Database (ST-010)
ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO (ST-017)
ISBT 128 Standard Use of Clinical Trials Product Description Codes (PDCs) (ST-022)

1.5 Other References

ICCBBA Website (www.isbt128.org)

Implementation Guide, Use of Product Divisions [Data Structure 032] (IG-023)

1.6 Background

ISBT 128 Bar Code Symbology and the Application Specification for Labeling of Whole Blood and Blood Components was developed by the International Society of Blood Transfusion Working Party on Automation and Data Processing (WPADP) [now called the Working Party on Information Technology] and published by ICCBBA in 1995. Around the world, implementation in blood establishments began soon after the standard was issued, with a steady increase in adoption since that time. The model originally developed by the WPADP has demonstrated its suitability by accommodating local and regional changes without requiring substantial structural change.

It was quickly recognized that the ISBT 128 Standard would be useful for cellular therapy products, with a small number of facilities beginning use of ISBT 128 for these products in the late 1990s. To expand usage further, greater international standardization in terminology and labeling was needed, and this goal was met through the co-operative endeavor of the following organizations:

- Association for the Advancement of Blood & Biotherapies (AABB)
- American Society for Transplantation and Cellular Therapy (ASTCT)
- American Society for Apheresis (ASFA)
- Asia-Pacific Blood and Marrow Transplantation (APBMT) Group
- European Society for Blood and Marrow Transplantation (EBMT)
- Foundation for the Accreditation of Cellular Therapy (FACT)
- ICCBBA
- International Society of Blood Transfusion (ISBT)
- International Society for Cell and Gene Therapy (ISCT)
- Joint Accreditation Committee ISCT-Europe & EBMT (JACIE)
- Be The Match (operated by the National Marrow Donor Program)
- World Marrow Donor Association (WMDA)

Representatives from these groups, as well as additional technical experts and regulatory liaisons, comprise the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). Through this group, global consensus is reached on the on-going development of terminology and label design for cellular therapy products using the ISBT 128 Standard.

1.7 Objective of ISBT 128 in Cellular Therapy

The use of the ISBT 128 Standard will provide:

- unique global identification of cellular therapy products
- an international reference table for product descriptions
- label design that is consistent worldwide

The organizations supporting this standard believe that its adoption will significantly improve the quality, safety, and traceability of cellular therapy products and that standard terminology will help to ensure a common understanding of product definitions.

The tables presented in the ISBT 128 Standard can be extended as new products are developed. Proposed additions will be reviewed by CTCLAG to ensure an appropriate level of definition and coding detail is maintained.

1.8 Changes in This Version

The following table indicates the major changes between Version 1.2.0 and Version 1.3.0. 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 Product Coding [Data Structures 003 and 032] – Cellular Therapy Version Control: Version 1.2.0 vs. Version 1.3.0.

	Version 1.2.0 Chapter, Section, Table, or Figure	Version 1.3.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	List of CTCLAG members.	N/A	Removed.	This information is located at https://www.isbt128.org/ctclag.
2.	1.2	1.2	Updated information environment graphic.	To reflect current information.
3.	2.1	2.1	Expanded the description of Data Structure 003.	For consistency with the *ISBT 128 Standard Technical Specification* (ST-001).
4.	2.2	2.2	Relocated the information on the use of Data Structure 032 to Section 5.2.	To consolidate all the information on the use of this data structure in one section.
5.	3.4	3.4	Omitted historical information on the previous database structure.	No longer relevant. The new database structure was implemented several years ago.

	Version 1.2.0 Chapter, Section, Table, or Figure	Version 1.3.0 Chapter, Section, Table, or Figure	Change	Rationale
6.	3.6	3.6	Updated information on how to request new description codes.	To reflect current process.
7.	3.6.1	3.6.1	Removed.	Outdated information.
8.	3.7	3.7	Added the new range for local and national codes.	For consistency with the *ISBT 128 Standard Technical Specification* (ST-001).
9.	Table 1	Table 1	Expanded to include new collection type codes.	For consistency with the *ISBT 128 Standard Technical Specification* (ST-001).
10.	Table 2	Table 2	Updated the definition for “Designated” and added the new terms “Replacement” and “Research.”	For consistency with the *ISBT 128 Standard Technical Specification* (ST-001).
11.	5.2	5.2	Expanded information on the use of Data Structure 032.	For completeness.
12.	6	N/A	Removed.	To minimize repetition since the information from this section is already presented in sections 3.5.1 and 5.2.
13.	Throughout	Throughout	Updated the title of referenced documents and made minor edits to the document’s text and label examples.	To reflect current information and improve clarity.

2 Data Structures

2.1 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 (PDC), a 5-character alphanumeric string that shall be encoded and interpreted by reference to the ISBT 128 Product Description Code Database (discussed in Chapter 3). An exception to this is the clinical trials products, which are coded in a separate database. Refer to the *ISBT 128 Standard Use of Clinical Trials Product Description Codes (PDCs)* (ST-022) for further information.

S is the first character in ISBT 128 cellular therapy Product Description Codes (PDCs). See *ISBT 128 Standard Technical Specification* (ST-001) for the meaning of other alpha characters. See Section 3.7 of this document for nationally defined PDCs.

The following interpretation of **t** and **ds** applies where **α** is **S**.

t shall specify the type of collection and shall be encoded and interpreted according to reference table [RT008] in the *ISBT 128 Standard Technical Specification* (ST-001).

ds shall specify information as to whether the unit has been divided.

- If the unit has not been divided, **ds** shall be set to the default value of 00 (zero, zero).
- If the Product Divisions [Data Structure 032] is used, **ds** shall be set to **99**. Software shall require that when **99** appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions [Data Structure 032] shall be scanned and recorded. See *Implementation Guide: Use of Product Divisions [Data Structure 032]* (IG-023).
- If divisions are encoded in the Product Code:

  d shall encode the first level division. First level divisions (up to 26) of the primary collection shall be encoded using capital letters.

  s shall encode the second level division. Second level subdivisions (up to 26) shall be encoded using lower-case letters.

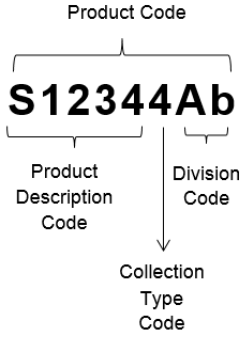
Note: Divisions need not be of equal volume and this nomenclature does not require this.

Note: For cellular therapy products, 26 divisions are not always adequate. Therefore, until the Product Divisions [Data Structure 032] is implemented, d and s may be used to uniquely identify divisions without regard to hierarchal level. Facilities utilizing this option shall ensure that each product is uniquely identified (i.e., multiple products with the same DIN and Product Description Code shall have a unique division code).

Thus, the full Product Code is eight characters long as shown in Figure 2, with:

- a five-character Product Description Code
- a one-character Collection Type Code
- a two-character Division Code

Figure 2 Product Code



As the cellular therapy product description codes (i.e., **S**-codes) reach **S9999**, ICCBBA will move towards using **S-alpha codes** (e.g., SA123) for assigning cellular therapy codes beyond S9999.

The next three chapters provide detailed descriptions of the Product Description Code (PDC), Collection Type Code, and Division Code.

2.2 Product Divisions [Data Structure 032]

Purpose: Data Structure 032 shall convey information about:
- aliquots, or
- one or more individual collections from the donor within the same donation event.

The Product Divisions Code may represent:
- one of the subunits from a single container that has been divided. This can also be referred to as an aliquot or a split.
- one of the containers from a collection, where the volume of product collected required the use of more than one container.
- a single collection into one container.

There are some restrictions to the use of this data structure, see Section 5.2.

Structure: **=,dddddd**

Element	Length	Type
=	1	data identifier, first character
,	1	data identifier, second character
dddddd	6	alphanumeric {A–Z, 0–9}

The 6-character data string **dddddd** shall be encoded and interpreted as follows:

dddddd shall specify the Product Divisions Code.

The Product Divisions Code allows for a high level of flexibility.

- Digits shall be used where a single level of divisions is required (allowing up to 999,999 divisions).
- If it is desirable to show levels of divisions (to allow for divisions of divisions), alpha characters shall be used. In this situation, the six-character field may be split into three pairs, each allowing **AA** through to **ZZ**. This provides up to three levels of division.

When the Product Divisions [Data Structure 032] is used in conjunction with the Product Code [Data Structure 003], **99** shall appear in the 7th and 8th positions of the Product Code.

The Product Divisions [Data Structure 032], when used, is essential for traceability. Software shall require that when **99** appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions [Data Structure 032] shall be scanned and recorded.

If manual records are maintained, the Product Divisions Code shall be recorded along with the DIN and the Product Code for all records required for traceability. Each Product Divisions Code shall be unique for a given Product Code [Data Structure 003] and DIN.

3 Product Description Code (PDC)

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 cellular therapy products, these are the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) and the Regenerative Medicine Technical Advisory Group (RMTAG).

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 and Attributes, a hierarchy of terms which are used as building blocks to describe cellular therapy products.

Classes are broad descriptions of products. Examples are HPC, CORD BLOOD; HPC, MARROW, AND HPC, APHERESIS.

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

- Core Conditions
- Groups and Variables

Core Conditions are very basic characteristics that apply to all cellular therapy 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:

- Anticoagulant
- Nominal collection volume
- Storage temperature

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

- Intended Use
- Manipulation
- Cryoprotectant
- Blood Component from 3rd Party Donor
- Other Additives
- Genetically Modified
- Irradiation
- Modification
- Mobilization
- Pooled Single Donor
- Cultured
- Enrichment
- Reduction

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

- For administration (default)
- For further processing
- For further processing: donor's cell product
- Not for administration

Within each group there is a default value ("For administration" 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 cellular therapy product, only one variable from each group may be selected.

Attributes should be selected based on pertinence. If an Attribute is not of value for differentiating the product for purposes of inventory, biovigilance, providing essential information to the person administering the product, or meeting other regulatory or standards requirements, it should not be included. For example, "non-mobilized" is not usually pertinent to a marrow collection so the default value of "not specified" is appropriate. Attributes should also not be used to provide a history of the product. For example, once a product has been washed, very little of the original citrate anticoagulant remains. Therefore, it is no longer essential to include citrate in the core conditions. (Anticoagulant is important if it is added after washing to prevent clumping of cells.) This philosophy can become important when the label is printed since all attributes (except the default value) must be printed on the label. Space can become an issue when non-pertinent attributes are included.

The list of all Classes and Attributes is found in the document *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) at https://www.isbt128.org/standard-terminology. This document also includes the definition of each term, which is critical to achieving a common understanding. By defining each term carefully, multiple interpretations are avoided.

New terms and definitions are constantly added to the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002). Therefore, users are urged to check this document 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), cellular therapy 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.

- First a Class must be selected.
- Then, 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 cellular therapy product description is:

Class:	HPC CORD BLOOD
Attribute Core Conditions:	Anticoagulant not specified in coding
	Volume not specified in coding
	Stored at less than or equal to -150 degrees Celsius
Attribute Variables:	6% HES + 5% DMSO added
	Third party blood component added
	Cryopreserved

Because attribute variables from only three groups (Cryoprotectant, Blood Component from 3rd Party Donor, and Modification) were selected, the default values from all other Attribute groups apply to this product. This means the following additional information applies:

Intended Use:	For administration
Manipulation:	Not specified
Other Additives:	Other additives:No
Genetically Modified:	Genetically modified:No
Irradiation:	Irradiation:No
Mobilization:	Not specified
Pooled Single Donor:	Not specified
Cultured:	Cultured:No
Enrichment:	Not specified
Reduction:	Not specified

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), Type of Collection, and Division Code. The first of these, the PDC, is the code that is assigned to each cellular therapy product described. It comprises a letter (**S** for cellular therapy products) followed by a four-digit number. The numbers are assigned sequentially as each new product description is added. For example:

A product is HPC, MARROW with no anticoagulant or additive specified, nominal collection volume not specified in the Product Code, stored at less

than or equal to -150C, preserved in 10% DMSO, and cryopreserved. The PDC for this is S1122.

Another product is HPC, MARROW, containing citrate and heparin, nominal collection volume not specified in the Product Code, stored at refrigerator temperatures, preserved in 10% DMSO, containing a component from a third-party donor, thawed, and buffy coat enriched. The PDC for this is S1550.

PDCs and their corresponding product descriptions are listed in a Reference Table called the ISBT 128 Product Description Code Database. This database is available at https://www.isbt128.org/m-databases-ref-tables and is accessible to 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: Class, Attribute Core Conditions, and Attribute Variables. The characters that separate each of these terms are also consistent.

The Class and Core Conditions are separated by the "|" delimiter.

Product Code	Description ⬇
S1128	HPC, APHERESIS|Citrate/XX/refg|Mobilized

Elements of Core Conditions are separated by a "/" delimiter.

Product Code	Description ⬇
S1128	HPC, APHERESIS|Citrate/XX/refg|Mobilized

A "|" separates Core Conditions from the Attribute variables that follow.

Product Code	Description ⬇
S1128	HPC, APHERESIS|Citrate/XX/refg|Mobilized

Individual Attribute variables are also separated by the "|" delimiter.

Product Code	Description ⬇
S1122	HPC, MARROW|NS/XX/<=-150C|10% DMSO|Cryopreserved

Attribute variables, when present, will always be listed in the product description in the order of the groups as they appear in the database, which is the same order that they appear in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002). For example, if a product includes blood components from a third-party donor and an additive, it will be:

CLASS|Core Conditions|3rd Party Comp:Yes|Other Additives:Yes.

When new Attribute groups are added, they will be added to the end of the list.

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

3.4 Product Description Code Database

The ISBT 128 Product Description Code Database structure was extensively updated in 2015 to support the expanding scope of ISBT 128. The revised structure of the database may not affect all existing ISBT 128 software. Existing software that only utilizes the ISBT 128 Product Description code should not be affected. The Product Description codes themselves have not been redefined or restructured.

For details on the current database structure, refer to the document *ISBT 128 Standard Product Description Code Database* (ST-010).

The ISBT 128 Product Description Code Database is protected by copyright. These files are available at https://www.isbt128.org/m-databases-ref-tables to currently licensed facilities. The database is a Microsoft Access file that is downloaded as a ZIP file from the website.

3.5 Selecting Appropriate PDCs

Cellular therapy codes begin with the letter “S”. The codes are listed in alphabetical order in the full database so cellular therapy codes are found in the middle 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).

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.

Codes with a date in the “Retired” field should not be selected for labeling of new products.

3.5.2 Using the Lookup Tool to Find PDCs

Searching for the correct PDC can be simplified by using the ISBT 128 Product Lookup Web Application accessible to ICCBBA-licensed facilities at https://www.isbt128.org/find-product-info.

This web application allows users to look up a description for a given PDC or a PDC based on a description. Furthermore, it can be used to submit requests for new PDCs.

The lookup tool webpage contains instructions on how to use it along with a demonstration on:

- How to navigate to the ISBT 128 Product Lookup Web Application
- How to use the "Search by Product Description Code" function
- How to use the "Search by Product Description" function
- How to export search results from the ISBT 128 Product Lookup Web Application
- How to submit a new product description code request

Note: The previously downloadable ISBT 128 Product Lookup Program (Microsoft Excel) is still available on the lookup tool webpage.

3.6 Additions to the ISBT 128 Product Description Code Database

Instructions on how to submit a request for a new Product Description Code (PDC) are provided at https://www.isbt128.org/find-product-info.

The request(s) will undergo internal review, and a member of the ICCBBA technical staff will contact users within 5 business days to verify the product description(s) requested. Requestors can expect a turnaround time of 4-7 weeks for routine requests. Requests that require new terminology or in-depth review may take longer to process.

A product request that requires a new Class or a new Attribute Group or variable should be submitted by email to the ICCBBA Technical Manager. A definition compatible with the format of those in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) document must accompany such a request. If there is a question regarding the consistency of terms/definitions, the request will be referred to CTCLAG for review.

Updates to the database are regularly posted at https://www.isbt128.org/m-databases-ref-tables (accessible to ICCBBA-licensed facilities) and made apparent by a change in the Version Number. In addition, version control sheets describing the changes are published with each update.

3.7 PDCs Designated for Local or National Use

The block of PDCs indicated below has been reserved for use as nationally or facility defined PDCs. There will be no international interpretation associated with these values.

- **National Codes** = A-alphanumeric to C-alphanumeric [e.g., AE134, BT123, CRA12]
- **Local/Facility Codes** = D (alphanumeric) [e.g., DAX12]
- **Both/Either** = A0000 to D9999 [e.g., A1234, B1234, C1234, D1234]

These codes should be used when there is not an appropriate international code and there is a 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 or when a product is not intended for infusion and will be discarded. 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.

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 authority to ensure that definitions are provided for use within the country and that products bearing such codes are not transferred outside the country.

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.

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

Collection, processing, and administration services often find it useful to be able to distinguish collection types such as autologous and directed through the Product Code [Data Structure 003]. In ISBT 128 this information can be encoded in the 6th character of this data structure. If the character is "0" the collection type is not specified. The other characters and their definitions are given in the current version of *ISBT 128 Standard Technical Specificatio*n (ST-001), Table RT008. For convenience, the table is reproduced in this document as Table 1, but ST-001 should be consulted for the latest version.

Table 1 Type of Collection in 6th Position of the Product Code

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. For cellular therapy collections, the “Designated” collection type is a common occurrence.

Table 2 Definitions of Collection Types

Type of Collection	**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 of the *ISBT 128 Standard Technical Specification* (ST-001) 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

5.1 Divisions encoded in Product 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 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 “00” (two zeros). This is the default value.

The first of the two alphanumeric characters “ds” encode the first division. 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 lower-case letter indicating the subdivision, for example: “A0” would be subdivided as “Aa,” “Ab,” “Ac,” etc. “B0” would be subdivided as “Ba,” “Bb,” “Bc,” etc.

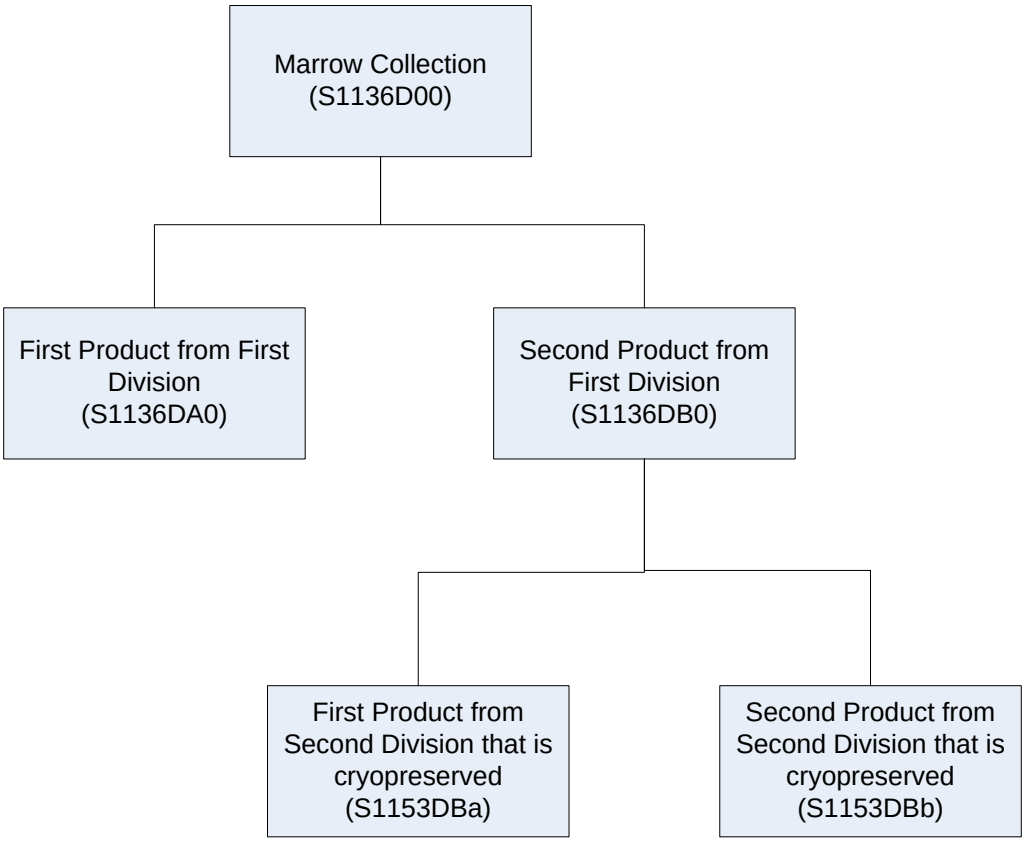
For example:

An apheresis-derived Hematopoietic Progenitor Cell product (HPC, APHERESIS) from a volunteer donor yields two products. The PDC for the original product is S1128. The Product Codes for the two products that result following division become S1128VA0 and S1128VB0. The V indicates the product is from a volunteer donor, the A0 and B0 indicate divisions. As soon as the first aliquot is removed from the “parent” product (00), that product (S1128V00) no longer exists because it is no longer a “full” product (labeling must indicate it is now only a “partial” product since an aliquot has been removed). It must bear a division code (A0, B0, C0, etc.).

If one of the products (S1128VA0) is further divided into two products, the eighth character of the code changes and the Product Codes for these “daughter” products become S1128VAa and S1128VAb. The Donation Identification Number (DIN) for the products would not change. This new “parent” portion (S1128VA0) may be used up by production of the Aa and Ab (in which case it ceases to exist) or it may still contain some product, in which case it may remain labeled S1128VA0. Because the A0 designation already indicates it is a divided product, it is not necessary to re-label it. Laboratory records must indicate what has happened to division A0 (whether it was used up or continues to exist) when it was subdivided.

As a specific example of this scheme in practice, consider a bone marrow harvest as diagrammed in Figure 3. When collected and undivided, the 7th and 8th characters of the Product Code are 00 (zero, zero). The product is initially divided into two parts, one for further processing into the desired population of cells [this becomes A0 (A, zero)] and the other is for backup or rescue [this becomes B0 (B, zero)]. The B0 portion is divided again later that day for freezing in separate aliquots, which become Ba and Bb. Again, the “parent” portion (“B0”) may continue to exist or it may be used up and no longer exist. Laboratory records must indicate what has happened to division B0 (whether it was used up or continues to exist) when it was subdivided.

Figure 3 Product Division Coding

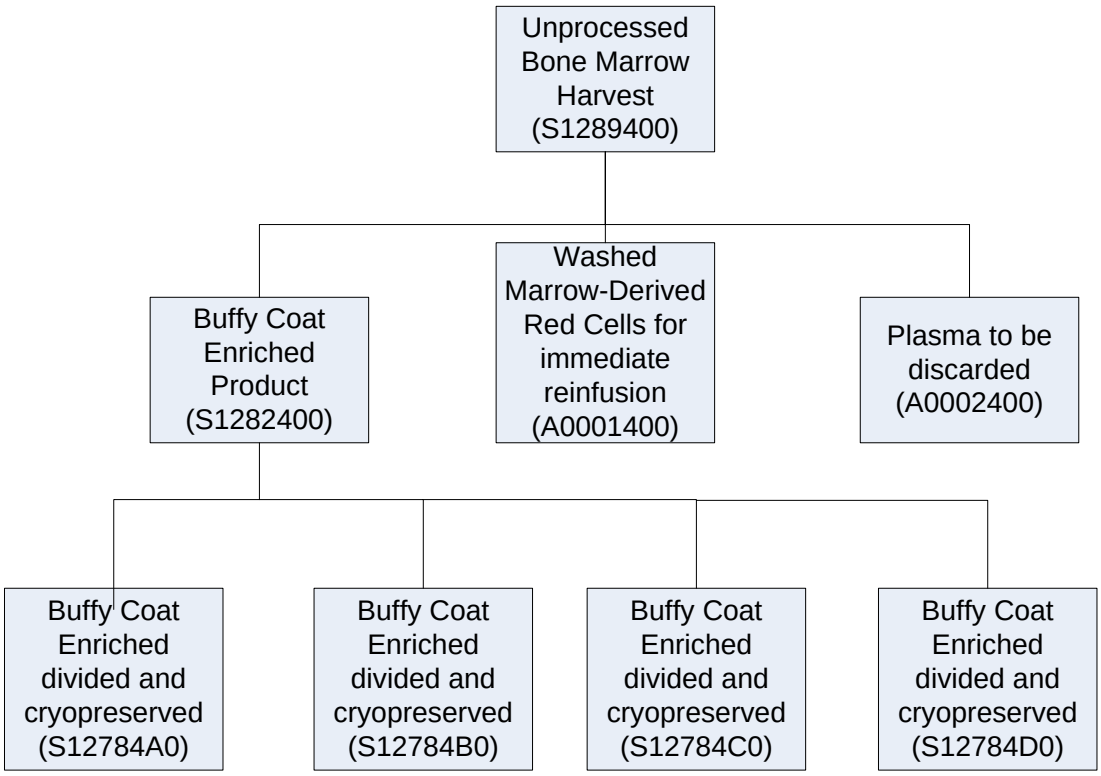


PDCs used in example:
S1136 = HPC, MARROW|Citrate/XX/refg
S1153 = HPC, MARROW|NS/XX/<=-150C|6% HES + 5% DMSO|Cryopreserved

Figure 4, shows an example where a bone marrow product is collected. The red cells from the collection are separated and immediately returned to the donor. The plasma from the collection is discarded. Because neither of these products will leave the collection facility, they have been assigned local codes (see Section 3.7). The other product is a buffy coat enriched product. Because each of the three products resulting from the initial collection (red cells, plasma, and buffy coat enriched product) has a different PDC, they are not treated as divisions. Divisions are aliquots of a product that are the same except for volume.

The buffy coat enriched product is subsequently divided into four products and cryopreserved. Note that the cryopreserved portions carry the division codes A0, B0, C0, and D0.

Figure 4 Multiple Products from Single Collection



PDCs Used in Example:
S1289 = HPC, MARROW|Heparin/XX/rt|Other Additives:Yes
S1282 = HPC, MARROW|Heparin/XX/rt|Buffy coat enriched
S1278 = HPC, MARROW|Heparin/XX/<=-120C|10% DMSO|Other Additives:Yes|Cryopreserved|Buffy coat enriched

Local Codes: Two local codes, A0001 and A0002, were used in this example for products that would not leave facility in which they were collected. *See Section 3.7.*

5.2 Use of Product Divisions [Data Structure 032]

There are situations in which 26 first level or second level divisions are not enough. The Product Divisions [Data Structure 032] was created to address this issue.

At the present time, use of the Product Divisions data structure with Data Structure 003 is restricted to Cellular Therapy and Regenerated Tissue Product Codes (where α is S and P, respectively) and for products identified using Data Structure 034. However, in the future the use of the Product Divisions data structure may be extended to blood products (where α is E or F).

Date of implementation depends on the data structure with which it will be used.

That is:

When used in conjunction with Data Structure 003: Because this data structure becomes part of the unique identification of a product, implementation of the data structure must be coordinated so that computer systems of facilities receiving the product are able to scan and interpret the codes.

This data structure may be used for Cellular Therapy if:

- a product will remain within the facility that labeled it with this data structure,

  OR

- there is an agreement between the supplier and the receiver of a product to utilize this data structure sooner.

For use of this data structure in conjunction with the Product Code [Data Structure 003] see *Implementation Guide, Use of Product Divisions [Data Structure 032]* (IG-023).

When used in conjunction with Data Structure 034: This data structure may be used at any time.

For use of this data structure in conjunction with the Processor Product Identification Code [Data Structure 034], see *ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO* (ST-017).

END OF PUBLICATION

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These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification
ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin
ST-004 ISBT 128 Standard Labeling of Cellular Therapy Products
ST-010 ISBT 128 Standard Product Description Code Database
ST-017 ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO
ST-022 ISBT 128 Standard Use of Clinical Trials Product Description Codes (PDCs)
IG-023 Use of Product Divisions [Data Structure 032]

