IMPLEMENTATION GUIDE

Use of the Product Code Data Structure [003] and Supporting Database for Cellular Therapy

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1 Introduction

1.1 Purpose

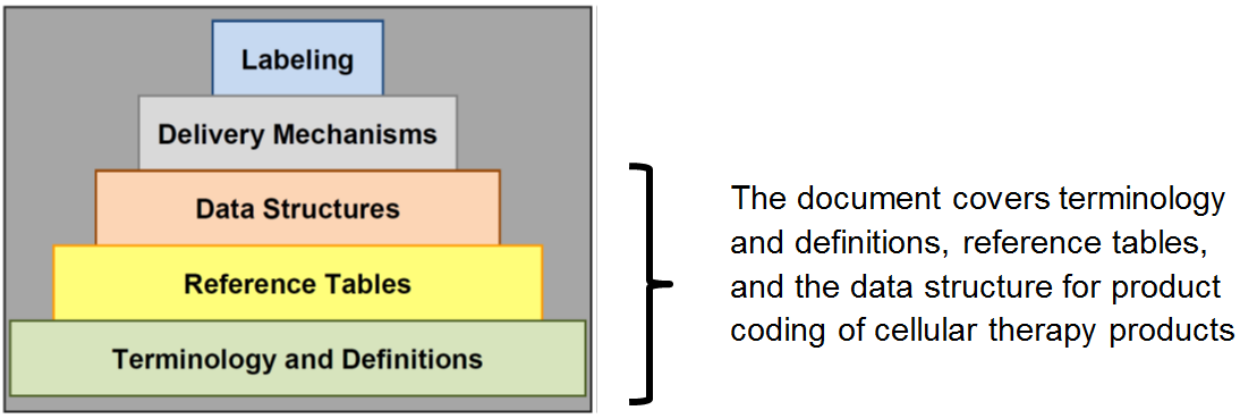
The purpose of this document is to provide guidance in the use of the Product Code Data Structure [003] and its supporting database in the coding of cellular therapy products.

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification*. It provides specific guidance for cellular therapy facilities in the use of the Product Code Data Structure [003] and the Product Description Code database. It assists the user in selecting the correct product description codes and in requesting new product description codes.

The information environment comprises a number of layers each of which needs to be in place to ensure that standardization can be achieved. These are expressed in Figure 1. This document will discuss the first two, Terminology and Definitions and Reference Tables, in depth as they pertain to product information. It will discuss one data structure, The Product Code Data Structure [003], from the third level. More information about other data structures, delivery mechanisms, and labeling can be found in documents listed in 1.4.

Figure 1 Information Environment Layers



1.3 Intended Audience

The intended audience of this document is staff at facilities of cellular therapy facilities (management, information technology, quality, validation, and laboratory), software developers, and vendors of equipment and supplies used by cellular therapy facilities.

1.4 Normative References

ISBT 128 Standard Technical Specification

Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions

ISBT 128 Standard Labeling of Cellular Therapy Products

1.5 Other Reference

ICCBBA Website (www.iccbba.org)

1.6 Background

A Specification, ISBT 128, for labeling blood products 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. Countries around the world began implementing the standard soon after it was issued, and there has been a steady increase in the number of organizations using it. The model originally developed by the WPADP has demonstrated its suitability by accommodating regional changes without substantial structural change.

It was recognized almost immediately that the ISBT 128 Standard would be useful for cellular therapy products as well as blood products. A small number of facilities began using ISBT 128 for these products in the late 1990s. However, greater international standardization in terminology and labeling was needed to allow the use of the Standard to become widespread. This goal was met through the co-operative endeavor of the following organizations: AABB, American Society for Blood and Marrow Transplantation (ASBMT), American Society for Apheresis (ASFA), Asia Pacific Blood and Marrow Transplant (APBMT), European Group for Blood and Marrow Transplantation (EBMT), Foundation for the Accreditation of Cellular Therapy (FACT), ICCBBA, International Society of Blood Transfusion (ISBT), International Society for Cellular Therapy (ISCT), Joint Accreditation Committee of ISCT and EBMT (JACIE), National Marrow Donor Program (NMDP), and the World Marrow Donor Association (WMDA). Representatives from these organizations, 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 used for cellular therapy products using the ISBT 128 Standard.

Standard terminology will help to ensure a common understanding of product definitions. Use of the ISBT 128 Standard will provide unique global identification of cellular therapy

products, an international reference table for product descriptions, and 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.

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.

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 5-character alphanumeric string from the ICCBBA-maintained ISBT 128 Product Description Code Database (discussed in Chapter 3)

S is the first character in the ISBT 128 cellular therapy product codes. E or F is the first character for blood products; T is the first character for tissue products; and X is the first character for derivatives. (See 3.8 for nationally defined product codes.)

The following interpretation of **t** and **ds** applies where **α** is E, F, or S.

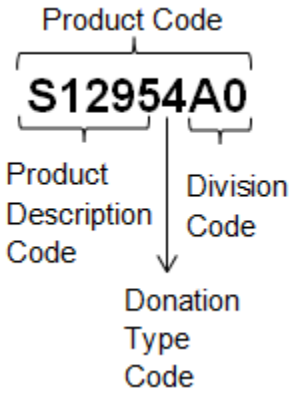
t specifies the type of donation (e.g., autologous or directed) and is encoded and interpreted according to a reference table in the *ISBT 128 Standard Technical Specification* (discussed in Chapter 4)

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 (discussed in Chapter 5)

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

- a five-character product description code
- a one-character donation type code
- a two-character division code

Figure 2 Product Code



The next three sections provide detailed descriptions of each of these three codes.

3 Product Description Code

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, this is the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG).

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 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.

Modifiers are the next step in the categorization of the product. Examples are Cryopreserved, Thawed Washed, and Mobilized.

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 and/or additive
- 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 third party donor
- Preparation – Other additives
- Genetically modified

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
- 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.

A list of all Classes, Modifiers, and Attributes is found in the document *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions,* 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 cellular therapy product is "Diluted." This could mean many things. In the ISBT 128 standard it is defined as, "A product to which an additional diluent (e.g. Concurrent Plasma) has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation." By defining each term carefully, ambiguity is avoided.

New terms and definitions are constantly being added to *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.* Users are urged to check the ICCBBA Website to ensure they have the latest version.

3.2 Product Descriptions

Using the nomenclature provided in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions,* 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 a Modifiers may be selected, but is not required. (A modifier may have more than one term, such as Thawed Washed.)
- Next, Core Conditions must be selected.
- Finally, a variable from one or more variable groups may be selected. A selection from groups/variables is not required.

An example cellular therapy product description is:

Class: HPC, Cord Blood
Modifier: Cryopreserved
Attribute, Core Conditions: No anticoagulant or additive specified; nominal collection volume not specified; and stored at less than or equal to -150C
Attribute, Variables: 6% HES + 5% DMSO added, component from a third party donor present

Because variables from only two groups (Cryoprotectant and Blood Component from a Third Party Donor) 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:	No Manipulation
Preparation – Other Additives:	Other additives: No
Genetically Modified:	Genetically modified: No

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, Type of Donation or Collection, and Division Code. The first of these, the Product Description Code, 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 simply assigned sequentially as each new product description is added. For example:

- S1122 is the code for Cryopreserved 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, and preserved in 10% DMSO.
- A more recently assigned product code is S1150, which is Thawed HPC, Marrow, containing citrate and heparin, nominal collection volume not specified in the product code, buffy coat enriched, preserved in 10% DMSO, containing a component from a third party donor.

Product Description Codes and their corresponding product description are listed in a Reference Table called the Product Description Codes Database. This database is available on the ICCBBA website and is available to ICCBBA-licensed facilities.

3.3.2 Product Description Information within the Database

Product descriptions are listed in a very structured way in the Product Description Codes Database. Abbreviations, as described in the *Standard Terminology for Blood, Cellular Therapy and Tissue Product Descriptions*, are used. The order in which the terms appear is consistent: Modifier, 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. For example:

Product Code	Description
S1128	HPC, APHERESIS|Citrate/XX/refg
S1129	HPC, APHERESIS|Citrate/XX/rt

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

Product Code	Description
S1143	Cryopreserved HPC, APHERESIS|Citrate/XX/<=-150C|10% DMSO

Elements of Core Conditions are separated by a "/" (e.g., Citrate/XX/<=-150C). A "|" separates Core Conditions from the Attribute variables that follow. Individual Attributes variables are also separated by the "|" delimiter.

For example:

Product Code	Description
S1150	Cryopreserved HPC, CORD BLOOD|NS/XX/<=-150C|10% DMSO|Other Additives:Yes
S1154	Cryopreserved HPC, APHERESIS|NS/XX/<=-150C|6% HES + 5% DMSO|3rd Party Comp:Yes

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 *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*). For example, if a product includes blood components from a third party donor and an additive, it will be:

Modifier 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

3.4.1 Structure of the Product Description Code Database

ICCBBA maintains the Product Description Code Database and ensures each assigned code is unique and that each product description appears only once in the database. To enable this process, not only are codes assigned to each product description, but also to each Class/Modifier combination, each Core Conditions

combination, and to each Variable. The codes are maintained in reference tables that are part of the Product Description Code Database.

The Product Description Code Database consists of four tables:

- Class (includes the Classes and Modifiers)
- Attribute (Includes Attribute groups and variables);
- Product Description (includes codes and descriptions)
- Version (includes the version number of the database).

The tables are distributed as a Microsoft Access® database and as four comma-delimited text files that can be imported into the database program of choice. The files may be found in the password protected area of the ICCBBA Website. The Access file is called:

Product Description Codes Database – Access 2000

The text files are called:

Text – Attribute
Text – Class
Text – Product Description
Text - Version

The following pages describe the structure of the tables.

Note: The Product Description Codes Database table structures are currently under review and are likely to change in the future. The proposal for change will be reviewed by the Technical Advisory Groups in the normal manner, and efforts will be made to minimize impact on users of these tables.

Table 1 Class Table Structure [RT025]

Field	Field Type	Field Size	Description
NAMECODE	Text	3	Obsolete -- Field is to be depopulated in the near future.
MODIFIER	Text	35	Modifier relates to a set of conditions that distinguishes members of the same component Class, *e.g.*, Washed, Frozen, *etc*.
CLASS	Text	36	The basic naming system adopted for products in ISBT 128
NAME	Text	75	The unique name produced by combining the Modifier and the Class
UNIQUE NAMECODE	Text	4	Unique identifier for the Class/Modifier of product
RETIREDATE	Text	11	Date on which it was recommended that code no longer be used for new products. Code is maintained in the database for backward compatibility. Format is DD MMM YYYY. The field is blank for current codes.

Table 2 Excerpt from Class Table

Class					
NAMECODE	**MODIFIER**	**CLASS**	**NAME**	**UNIQUE NAMECODE**	**RETIREDATE**
001		HPC, MARROW	HPC, MARROW	S001	
002	Cryopreserved	HPC, MARROW	Cryopreserved HPC, MARROW	S002	
003	Thawed	HPC, MARROW	Thawed HPC, MARROW	S003	
004	Heparinized	HPC, MARROW	Heparinized HPC, MARROW	S004	01 MAR 2008

Table 3 Attribute Table Structure [RT026]

Field	Field Type	Field Size	Description
ATTRGRP	Text	1	Identifier for Attribute group.
ATTRVAR	Text	2	Identifier for Attribute variable within a group.
ATTRNAME	Text	50	Description of the Attribute group and variable (note: the group description is in the row with a variable value of zero).
ATTRFORM	Text	3	Obsolete -- Field is depopulated
UNIQUE ATTRFORM	Text	4	Unique identifier for the Attribute value combining the product type, Attribute group, and variable.
RETIREDATE	Text	11	Date on which it was recommended that code no longer be used for new products. Code is maintained in the database for backward compatibility. Format is DD MMM YYYY. The field is blank for current codes.

Table 4 Excerpt from Attribute Table

Attribute					
ATTRGRP	**ATTRVAR**	**ATTRNAME**	**ATTRFORM**	**UNIQUE ATTRFORM**	**RETIREDATE**
@	26	CPD+Heparin/XX/refg		S@26	01 MAR 2008
@	27	ACD-A+PBS+alb/XX/rt		S@27	01 MAR 2008
@	28	Heparin/XX/refg		S@28	
@	29	NS/XX/<=-150C		S@29	
@	30	Citrate/XX/rt		S@30	

Table 5 Product Description Table Structure [RT027]

Field	Field Type	Field Size	Description
PRODDESCRIPCODE	Text	5	The unique product description code for the product
NAMECODE	Text	3	Obsolete -- Field will be depopulated in the near future
COMBATTRFORM	Text	60	Obsolete -- Field is depopulated.
PRODDESCRIP0	Text	254	The description of the product in structured format
CODEDATE	Text	11	The date the code was assigned. Format is DD MMM YYYY.
PRODDESCRIP1	Text	254	Field available for national descriptions, not populated by ICCBBA
PRODCODEFORM	Text	50	Obsolete -- Field is depopulated.
PRODDESCRIPCODEFORM	Text	65	Unique formula for the product comprising the Class description (corresponds to UNIQUE NAMECODE in the Class Table) and the combined Attribute codes (corresponds to UNIQUE ATTRFORM in the Attribute Table)
RETIREDATE	Text	11	Date on which it was recommended that code no longer be used for new products. Code is maintained in the database for backward compatibility. Format is DD MMM YYYY. The field is blank for current codes.

Table 6 Excerpt from Product Description Table

Product Description								
PRODDESCRIPCODE	**NAMECODE**	**COMBATTRFORM**	**PRODDESCRIP0**	**CODEDATE**	**PRODDESCRIP1**	**PRODCODEFORM**	**PRODDESCRIPCODEFORM**	**RETIREDATE**
S1120	001		HPC, MARROW|Heparin/XX/refg|Open|RBC reduced	05 DEC 2005			S001S@28SB2SEC	01 MAR 2008
S1121	001		HPC, MARROW|Heparin/XX/refg|Open|Donor Erythrocytes added|RBC reduced	05 DEC 2005			S001S@28SB2SC9SEC	01 MAR 2008
S1122	002		Cryopreserved HPC, MARROW|NS/XX/<=-150C|10% DMSO	17 JUL 2007			S002S@29SG3	
S1123	006		Cryopreserved HPC, APHERESIS|NS/XX/<=-150C|10% DMSO	17 JUL 2007			S006S@29SG3	

Table 7 Version Table Structure [RT028}

Field	Field Type	Field Size	Description
Version Number	Text	50	The version number of the product database
Date	Date/Time	11	The date issued (DD MMM YYYY)

Table 8 Example Version Table

Version	
Version Number	**Date**
3.46.0	10 FEB 2011

3.4.2 Obsolete Fields

Each of the tables, except Version, includes some obsolete fields—fields that have become unnecessary over time. While sometimes unpopulated, these fields are retained for backwards compatibility with existing software. They are identified as obsolete in Table 1, Table 3, and Table 5.

3.4.3 Code and Formula Fields

As previously described, each Modifier/Class combination, each Core Conditions combination, and each Attribute is given a code. The codes are found in the appropriate reference tables and fields as follows:

Term	Table	Field
Modifier/Class	Class	UNIQUE NAMECODE
Core Conditions	Attributes	UNIQUE ATTRFORM
Variables	Attributes	UNIQUE ATTRFORM

Codes for Core Conditions and Variables are found on the same table and field because they are both Attributes.

For examples of codes, see Table 9, an excerpt from the Class table. The second to the last column (UNIQUE NAMECODE) shows the code S002 for Cryopreserved HPC MARROW.

Table 9 Class

Class					
NAMECODE	**MODIFIER**	**CLASS**	**NAME**	**UNIQUE NAMECODE**	**RETIREDATE**
		HPC, MARROW	HPC, MARROW	S001	
	Cryopreserved	HPC, MARROW	Cryopreserved HPC, MARROW	S002	
	Thawed	HPC, MARROW	Thawed HPC, MARROW	S003	
	Heparinized	HPC, MARROW	Heparinized HPC, MARROW	S004	01 MAR 2008

Table 10 is an excerpt from the Attribute table, and NS/XX/<=-150C has the code S@29 in the second to the last column (UNIQUE ATTRFORM).

Table 10 Attribute – Core Conditions

Attribute					
ATTRGRP	**ATTRVAR**	**ATTRNAME**	**ATTRFORM**	**UNIQUE ATTRFORM**	**RETIREDATE**
@	28	Heparin/XX/refg		S@28	
@	29	NS/XX/<=-150C		S@29	
@	30	Citrate/XX/rt		S@30	
@	31	Citrate+Heparin/XX/rt		S@31	
@	28	Heparin/XX/refg		S@28	

Further down on the Attribute table are variable codes for the Attribute variables. These may be quickly differentiated from Core condition codes because they do not have "@" within the code. For example, in Table 11, SG3 is the code in the second to the last column (UNIQUE ATTRFORM) for 10% DMSO.

Table 11 Attribute - Variables

Attribute					
ATTRGRP	**ATTRVAR**	**ATTRNAME**	**ATTRFORM**	**UNIQUE ATTRFORM**	**RETIREDATE**
G	1	Default: No cryoprotectant has been added		SG1	
G	2	6% HES + 5% DMSO		SG2	
G	3	10% DMSO		SG3	
G	4	5% DMSO		SG4	

Just as ISBT 128 product descriptions are created by stringing together Classes, Modifiers, and Attributes, the codes can be strung together to create a unique Product Description Code formula.

From the above examples:

Cryopreserved HPC, APHERESIS = S002
NS/XX/<=-150C = S@29
10% DMSO = SG3

These codes are strung together without spaces or punctuation to create the Product Description Code Formula: S002S@29SG3 (see the second to the last column, PRODDESCRIPCODEFORM, in the Table 12).

Table 12 Product Description

Product Description								
PRODDESCRIPCODE	**NAMECODE**	**COMBATTRFORM**	**PRODDESCRIP0**	**CODEDATE**	**PRODDESCRIP1**	**PRODCODEFORM**	**PRODDESCRIPCODEFORM**	**RETIREDATE**
S1120	001		HPC, MARROW|Heparin/XX/refg| Open|RBC reduced	05 DEC 2005			S001S@28SB2SEC	01 MAR 2008
S1121	001		HPC, MARROW|Heparin/XX/refg| Open|Donor Erythrocytes added|RBC reduced	05 DEC 2005			S001S@28SB2SC9SEC	01 MAR 2008
S1122	002		Cryopreserved HPC, MARROW|NS/XX/<=-150C|10% DMSO	17 JUL 2007			S002S@29SG3	
S1123	006		Cryopreserved HPC, APHERESIS|NS/XX/<=-150C|10% DMSO	17 JUL 2007			S006S@29SG3	

3.4.4 "Retired" Code Fields

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, since products may exist in inventories across the world, the codes must be retained in the database for backward compatibility.

To accomplish this goal, a field exists in the ICCBBA database tables to indicate such codes. This "Retired Date" column indicates the date on which ICCBBA recommended the code 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.

3.4.5 Queries

There are a number of queries that are available for the Product Description Codes in the Microsoft Access® database that can assist the user by focusing on only the information needed. These queries are:

- Attribute (Blood Component)
- Attribute (HPCs)
- Attribute (Tissues)
- Class (Blood Components)
- Class (HPCs)
- Class (Tissue)
- Product Description (Blood Components Active and Retired)
- Product Description (Blood Components Active)
- Product Description (HPC Active and Retired)
- Product Description (HPC Active)
- Product Description (Tissues Active and Retired)
- Product Description (Tissues Active)

By utilizing the Product Description (HPC Active), the user can, for example, filter out blood, tissue, and retired product description codes and quickly view only those product description codes that are relevant.

3.5 Selecting Appropriate Product Description Codes

Cellular therapy codes begin with 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. For convenience, users may find the databases for blood, cellular therapy, and tissues listed separately in the Queries section of the Product Description Code database.

To appropriately select product descriptions, it is important to understand the definitions of each term. These definitions are found in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*. This document must be consulted in order to select the appropriate descriptions and codes for cellular therapy products.

3.5.1 "Retired" Codes

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

3.5.2 Using Formulas to Select Product Description Codes

Searching for the correct product code can be simplified by the use of the formulas discussed in 3.4.3. As noted in this section, if the product code being sought is for Cryopreserved HPC, APHERESIS stored at <=-150C in 10% DMSO, its formula is created by stringing together the codes without spaces:

Cryopreserved HPC, APHERESIS = S002
NS/XX/<=-150C = S@29
10% DMSO = SG3

The Product Description Code Formula is thus S002S@29SG3.

This formula can be used in the Microsoft Access® database to search for the needed product code by typing the formula (S002S@29SG3) into the search field on the Product Description table.

3.5.3 Using the Look-up Tool to Find Product Description Codes

A tool that may be used to find a Product Description code is available on the ICCBBA Website under the home page tab called Lookup Tools, then "Find Product Information." (You must be logged in to see this option.) The tool is called:

Product Description Code Lookup Program

When the program is downloaded along with text files (Text - Attribute, Text - Class, and Text - Product Description) product codes may be identified by entering product characteristics into a table with dropdown menus. After selection of characteristics from the drop-down menus, the appropriate code (or codes) will be

provided by the program. There are two options for code selection: Search Exact and Search Inclusive (see Figure 3, page 26).

- If Search Exact is selected, the program will return the Product Description Code that exactly matches the characteristics entered.
- If Search Inclusive is selected, the program will return all Product Descriptions that include the characteristics selected.

Alternatively, a product description code maybe entered and the program will return the product description that applies to the code (see Figure 4, page 27).

Figure 3 Product Description Code Lookup

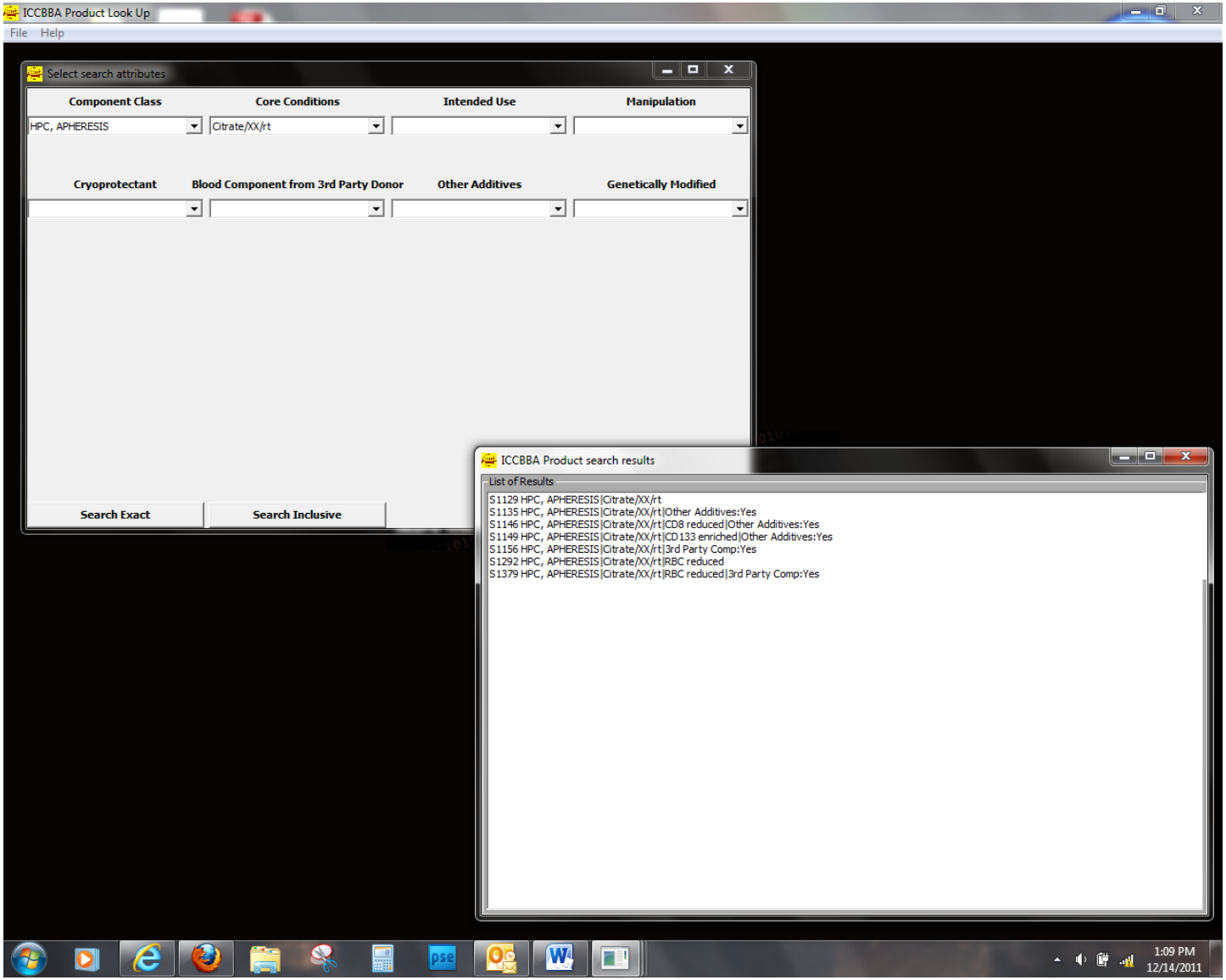
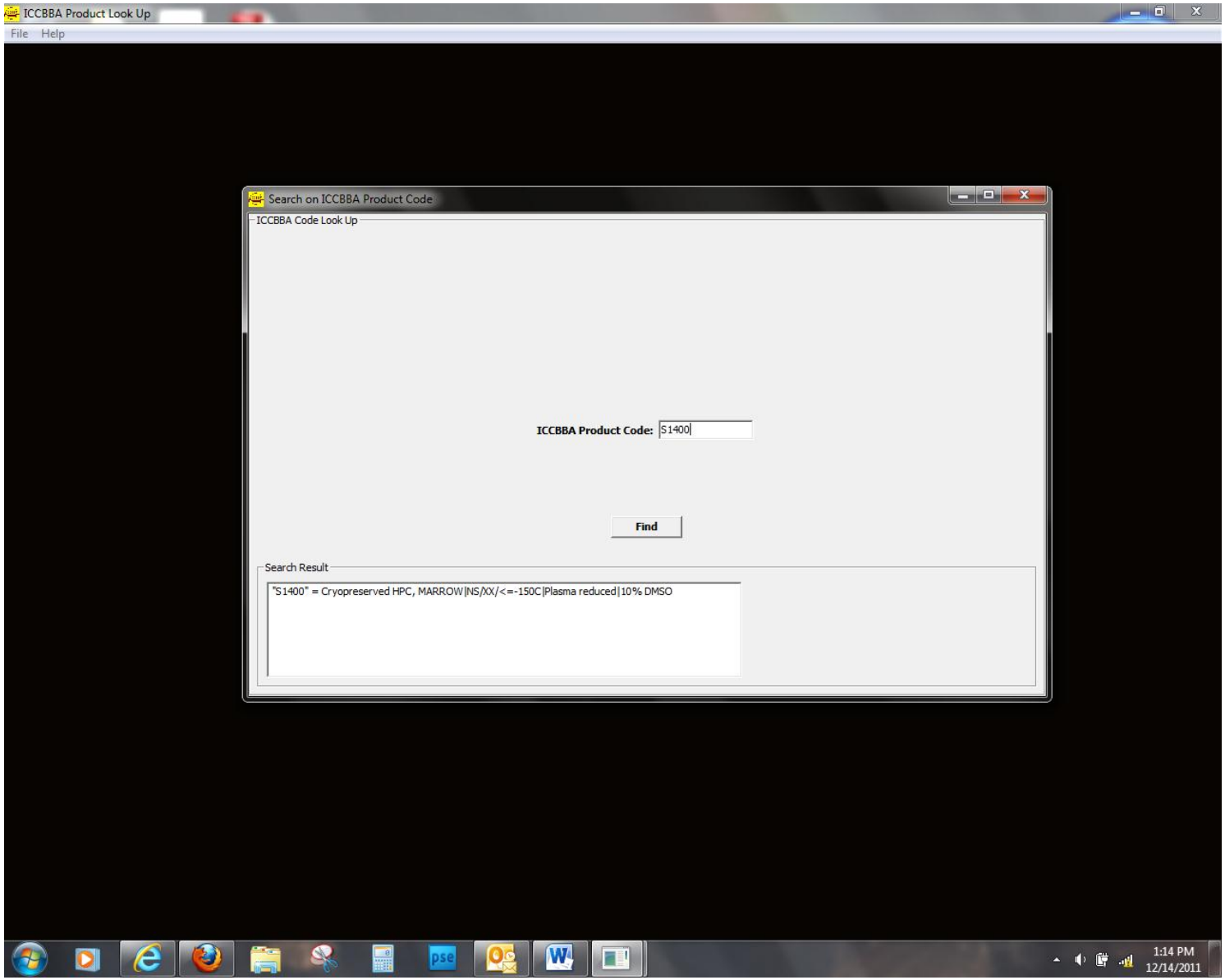


Figure 4 Product Code Lookup



3.7 Additions to the Product Description Codes Database

Facilities may need to describe a product that is not currently in the database. To do this, they should complete one on-line request form for each new product code desired following the instructions in Section 3.7.1.

New Product Description Codes 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 Product Description Codes will be regularly posted in the password-protected section of the ICCBBA Website (under the tabs “Tech Library” and “Databases and Reference Tables”) and made apparent by a change in the Version Number of the Product Description Code Database. Version control sheets describing the changes are published with each update.

3.7.1 Completing the Request Form

The on-line form for requesting new product codes is found in the password-protected area of the ICCBBA Website in the Cellular Therapy Subject Area. It is found on the Request a Code page (see Figure 5) and is called Cellular Therapy Product Description Code Request Form (see Figure 6).

One completed form is required for each new Product Description Code requested.

- Complete header information (Facility Identification Number, contact name, and contact e-mail address)

Minimally, the request must include a Class and Core Conditions.

- Select one Class from the dropdown list.
- If needed, select one Modifier from the dropdown list.
- Select Core Conditions (Anticoagulant-Additive, Volume, and Storage Temperature) from the drop down lists.
- Select Attributes from each Attribute group where needed (only one per Attribute group) from the dropdown lists.

If a new Class, Modifier, Attribute group, or variable within an Attribute group is needed, please contact the ICCBBA Technical Director (tech.director@iccbba.org). A definition compatible with the format of those in the Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions must accompany such a request.

Figure 5 ICCBBA Website Home Page

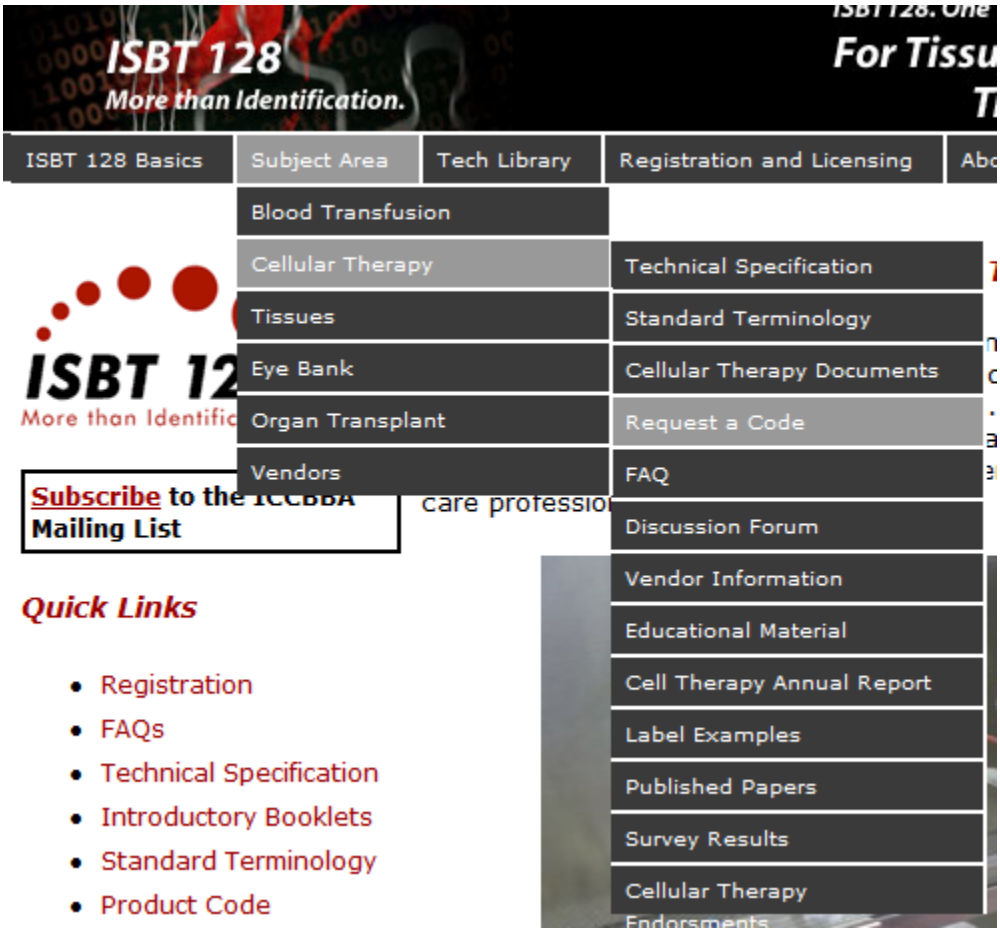
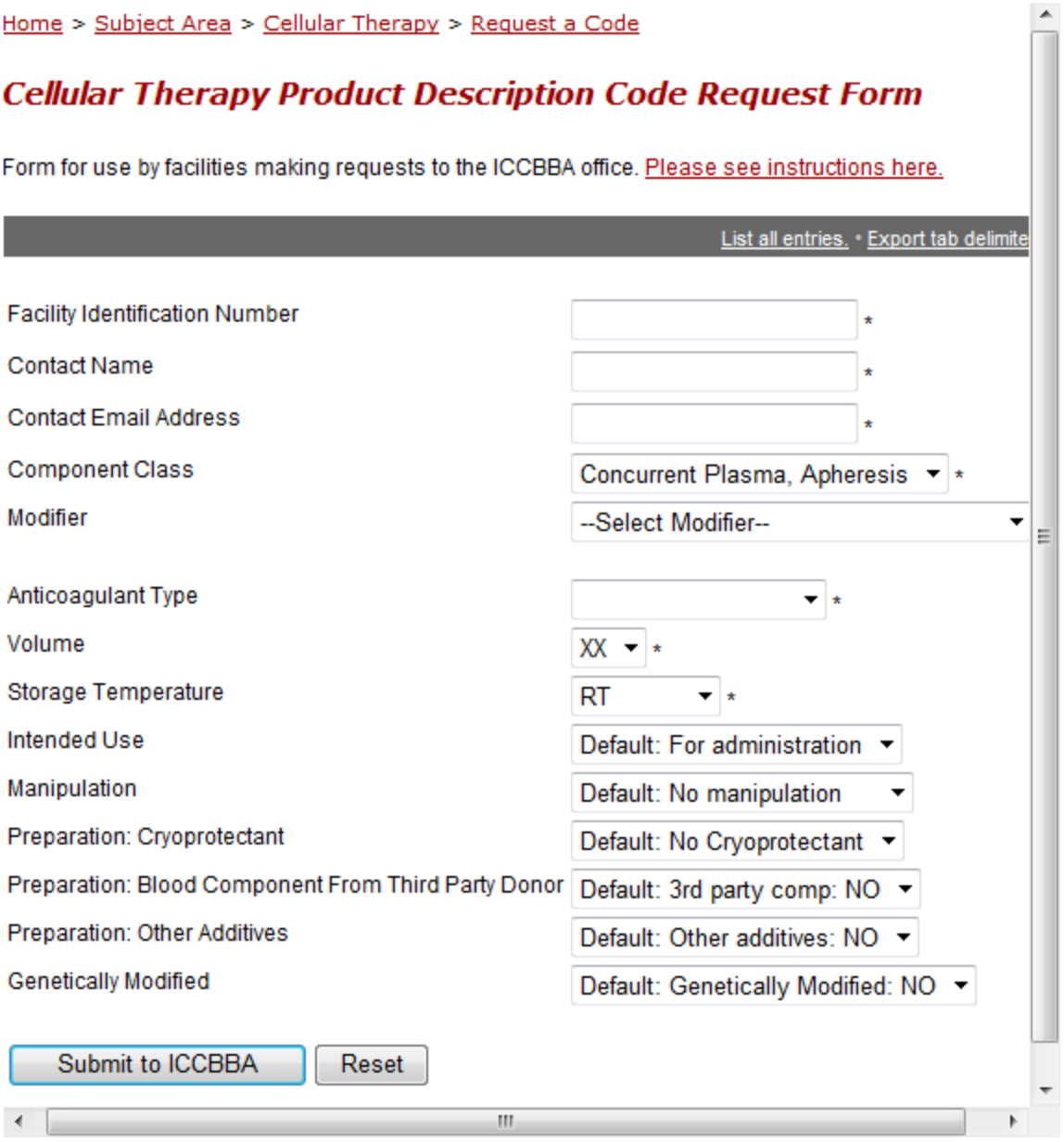


Figure 6 On-Line Product Description Code Request Form



3.7.2 Submitting the Request

Clicking on the “Submit to ICCBBA” button will result in the form being submitted to the appropriate individual. You will receive an automated acknowledgement of the submission. Questions should be submitted to the ICCBBA Technical Director at tech.director@iccbba.org.

3.8 Product Description Codes Designated for Local or National Use

A block of product description codes, A0000-D9999, has been reserved for use as nationally or facility defined Product Description Codes. There will be no international interpretation associated with these values.

These codes should 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.

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 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.

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 reused.

4 Donation Type Code

Collection, processing, and administration services often find it useful to be able to distinguish donations types such as autologous and directed donations through the product code. In ISBT 128 this information can be encoded in the 6th character of the product code. If the character is "0," the donation type is not specified. The other characters and their definitions are given in the current version of *ISBT 128 Standard Technical Specificatio*n, Table RT 008. For convenience, the table is reproduced in this document as Table 13, but the *ISBT 128 Standard Technical Specification* should be consulted for the latest version.

Table 13 Type of Donation or Collection in 6th Position of Product Code

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

In selecting the appropriate donation type, definitions provided in Table 14 should be used. For cellular therapy donations, the Designated donation type is a common occurrence.

Table 14 Definitions of Dedicated, Designated, and Directed Donations

Dedicated donation	A collection arranged by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products).
Designated donation	A unit collected from a donor called by the collecting facility to provide product (for example, HLA-compatible) to be used by a specific recipient (or for cellular therapy products, possibly a small group of recipients).
Directed donation	A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide product to be used by that person.

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 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 left-most 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*.

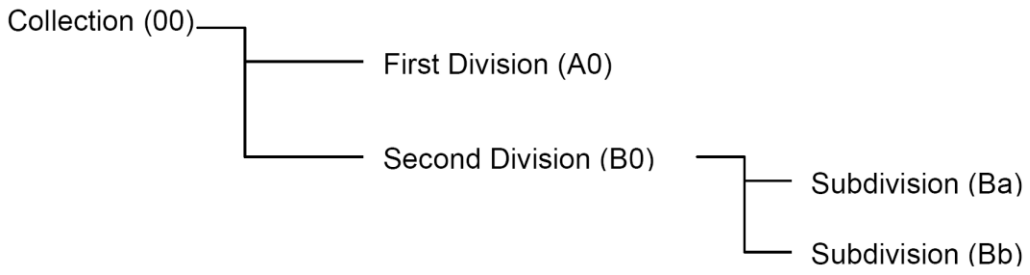
For example:

An apheresis-derived Hematopoietic Progenitor Cell product (HPC, Apheresis) from a volunteer donor yields two products. The product description code 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.).

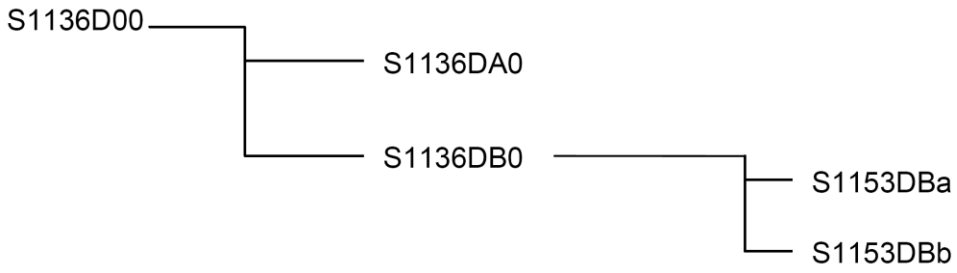
If one of the products (S1128VA0) is further divided into two products, the eighth character of the code changes and the product codes for these "daughter" products become **S1128VAa** and **S1128VAb**. The Donation Identification Number (DIN) for the products would not change. This new "parent" portion (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 S2238VA0. 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 7, page 35.. 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. As with division A0 described above, laboratory records must indicate what has happened to division B0 (whether it was used up or continues to exist) when it was subdivided.

Figure 7 Product Division Coding



Or, using the product description codes for a designated product:



S1136 = HPC, Marrow|Citrate/XX/refg

S1153 = Cryopreserved HPC, Marrow|NS/XX/<=-150C|6%HES+5% DMSO

6 Questions?

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

