Webinar Q&A Summary

Cracking the Code: An Overview of ISBT 128 Product Description Codes
24 Oct 2023

1. **What is the meaning of the "container" attribute?**
   Container Attribute values and definitions are housed within the Blood Components section of the ISBT 128 Standard Terminology document (ST-002). These values are contained within the Attribute group (Apheresis and Container: Additional Info) and specify additional information related to an apheresis procedure. For example, the 1st container attribute value definition states that it is the first of two or more containers prepared during a single apheresis procedure.
   Keep in mind, that ISBT 128 container attributes are separate from aliquots/ product divisions. Products with container attributes can still be aliquoted and those divisions are indicated within the 7th and 8th positions of the product code.

2. **What is the meaning of the "3rd party component" attribute?**
   The 3rd party component: Yes attribute is housed within the Cellular Therapy section of the ISBT 128 Standard Terminology document (ST-002).
   The attribute group “Blood Component from 3rd Party Donor” for this value specifies that this value describes blood products from other donors used during processing, such as albumin, Fresh Frozen Plasma, AB serum, and Red Blood Cells.

3. **Is there a collection type code to show that a red blood cell product is a directed donation, similar to the code for autologous units?**
   Yes, there are several. Within the product code format for blood components, the 6th position holds information on the collection type. The values presented in this location are referenced from reference table RT008 found within (ST-001). Directed values from this table are presented below:

Character	Type of Collection
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
3	For directed recipient use only, biohazard
B	Directed/Dedicated/Designated Collection Use Only
H	Directed/Dedicated/Designated Collection/Biohazardous
J	Directed/Dedicated/Designated Collection/Eligible for Crossover

   Additionally, for ISBT 128 users within the US please reference section 6.6 of (IG-002) for additional notes on this table.

4. **Can blood suppliers use the "Volunteer homologous (allogeneic) (default)" collection type (V) instead of the "Volunteer directed, eligible for crossover" collection type (D) as the 6th character in the product code?**
   For facilities within the US, the collection type character D “Volunteer directed, eligible for crossover” can optionally be used in the product code and it is up to the labeling facility to determine the most appropriate collection type code to apply in the 6th character of the product code.
   For facilities outside of the US, appropriate national guidance should be referenced to ensure your product is labeled according to those specifications.

5. **How should one determine to use a core condition that reflects the XX volume versus using the 450mL or 500mL collection volume when searching or defining a product code for Washed, Frozen, or Deglycerolized Red Blood Cells?**
   National guidance should be followed when labeling your blood products to determine the most appropriate nominal collection volume to include within the product description code of your product. For facilities within the US, products derived from Whole Blood should encode the product's specified volume (450mL or 500mL), however, If the product is washed, frozen, deglycerolized, or rejuvenated the XX nominal collection volume should be applied. Additionally, for products collected via an apheresis procedure or that have been pooled, the XX nominal collection volume should be applied. This nominal collection volume of XX represents that there is no information about the volume encoded within the product's description. When the nominal collection volume of XX is used within a product description code, additional information regarding the product's volume can be added as additional label text.

6. **Is there a tool for mapping from one product description code to another when modifications are made such as the discontinuation of the washing step of red blood cells?**
   Currently, there is no tool offered that will illustrate the mapping of a product description code (PDC) to another modified PDC. Such a mapping tool may be allowed in one country but not another, and ISBT 128 is an international standard. Rather, the ISBT 128 Product Lookup Program would be the best tool to use for finding the modified PDC. Applicable guidance from our provided technical documents as well as national labeling guidelines that adhere to the ISBT 128 Standard would need to be followed while conducting a search by Product Description using the Lookup Program.

7. **How do I label CAR T Cells with the ISBT 128 Standard?**
   Prior to CAR T Cell production, the originally collected product could be labeled using either the MNC, apheresis or NC, apheresis class (depending on which class best describes your product) and Final car T Cell products are to be labeled using the T CELLS, apheresis class and contain the Genetically Modified:Yes attribute within their product description.

8. **Is ICCBBA planning to adjust the ISBT 128 labeling requirements to account for partial label elements that are required by FACT at the time of distribution?**
   There are no plans to adjust the ISBT 128 labeling requirements outlined by FACT. The ISBT 128 minimum label requirements are designed to ensure product traceability by labeling products using globally unique identifiers that are both electronically- and eye-readable. These identifiers are the Donation Identification Number (DIN) and the Product Code data structure. In addition to these outlined ISBT 128 minimum labeling requirements, applicable regulations, and standards should be consulted for other minimum requirements for partial labels.

9. **For a cellular therapy label is it required to list the volume and name of the anticoagulant on the label even though the product code already defines the anticoagulant?**
   Listing the volume and name of the anticoagulant on the label is not an ISBT 128 minimum labeling requirement for cellular therapy products. Rather, specifications such as label text requirements are nationally specified, thus applicable regulations and standards should be consulted for other labeling requirements for cellular therapy products.
   Minimum ISBT 128 labeling requirements can be found within section 3.2 of the ISBT 128 Standard Labeling of Cellular Therapy Products document (ST-004).

10. **Do you foresee in the future going down to the granularity of the type of genetically modified antigen of the CAR-T cell? For example, CD19 or CD45?**
    This topic is something that would have to be discussed with the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) to determine the best approach for addressing this level of granularity.

11. **Are there ISBT 128 product description codes for interim products requiring further manufacturing?**
    ICCBBA does not assign product description codes to interim products. If there is an existing ISBT 128 product description code that fits the facility's needs for an interim product description, that code may be applied. Another suggestion would be to utilize ISBT 128 Local Codes.
    Local codes are defined and maintained by the facility—ICCBBA does not maintain or keep track of these codes or their assigned product descriptions.
    As specified within section 2.4.3 of the ISBT 128 Standard Technical document (ST-001), codes A0000 through D9999 that are not reserved for national use may be used for local codes. Codes beginning with D, and having alpha characters within positions 2-5 (e.g., DAX12), are also reserved as locally defined codes.

12. **How can universal allogeneic cellular therapy products be distinguished where the same donor donates for multiple patients but at different timelines?**
    Donation events are assigned unique Donation Identification Numbers (DINs). Therefore, if a donor donates multiple times, each event will have its own unique DIN assigned to the collected product distinguishing the donation events. It is the responsibility of the labeling facility to ensure the uniqueness of the assigned DINs.

13. **If we are already a registered facility using ISBT 128, is there an additional fee for using clinical trials product description codes?**
    The issuing of clinical trials PDCs is a separate service offered by ICCBBA not included within annual license fees or registration fees. Currently, the fee for requesting clinical trials PDCs is $204.92 for a batch of ten. This fee may change in the future. To view the most up-to-date fees for batches of clinical trials PDCs, you can navigate to the Steps to Obtain Clinical Trials PDCs heading on the following page: https://www.isbt128.org/request-a-code.**Note: You will need to be logged in to your Website Member Account in order to access this page.*

14. **If there's a standardized ISBT 128 code that fits a Clinical Trial Product description, should the facility use the standardized ISBT 128 PDC or is it recommended to use a Clinical Trial Product Description Code?**
    If there is a standardized ISBT 128 Product Description Code available that accurately describes the clinical trial product, then that standardized ISBT 128 Product Description Code may be used. It is up to the labeling facility to determine the best practice that fits their needs.

15. **Who should request/own the clinical trials product description codes? Should it be the study protocol personnel or the collection/processing center?**
    Clinical Trials Product Description Codes can be requested by the study sponsor, the clinical trial conducting facility, or any other organizations that wish to use these Clinical Trials PDCs.
    The organization that requests and is allocated a batch (or batches) of Clinical Trials PDCs by ICCBBA becomes responsible for defining and maintaining the record of the product description associated with each Clinical Trials PDC allocated to them, as well as defining the associated label text for that PDC. Also, it is the requesting organization’s responsibility to share and make accessible those clinical trials PDCs.

16. **We are in the middle of a clinical trial using a local ISBT 128 product description code. Is it appropriate to switch over to using ISBT 128 clinical trial codes, providing that the deviation is documented?**
    Clinical Trials Product Description codes may be requested at any time during the clinical trial. Provided that the deviation is documented, this would be an appropriate labeling approach to guarantee global uniqueness in the Product Description Code identifier used to identify your Clinical Trial product. However, it should be mentioned that relabeling may not be feasible or appropriate in some cases (i.e., such as with cryopreserved products).
    Following the allocation of the Clinical Trials PDCs by ICCBBA to your facility, to maintain product traceability and global uniqueness of ISBT 128 Clinical Trials PDCs, once an ISBT 128 Clinical Trials PDC has been defined it shall not be redefined.

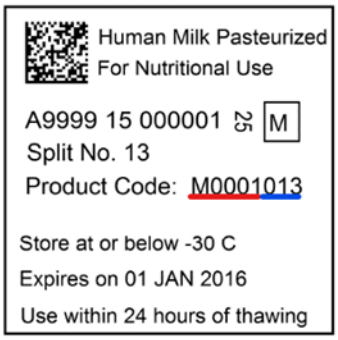
17. **How long would it take a new user to fully implement ISBT 128? Are there tips for implementation?**
    Each facility's implementation process varies on a multitude of factors therefore we cannot provide a timeline on when a newly registered facility could have completed its implementation process. Tips for implementing would be to review the ISBT 128 Implementation ToolBox.
    The purpose of this document is to provide a toolbox of commonly used items essential for implementing ISBT 128. It also provides guidance and recommended steps for consideration when planning out one's ISBT 128 implementation. Members that have questions about the labeling standards or tools like the ISBT 128 PDC Database or Lookup Program please contact the ICCBBA support team at support@isbt128.org.

18. **Is ISBT 128 the only international MPHO labeling standard?**
    ISBT 128 is the only international MPHO standard that offers globally unique identifiers.

19. **Are there any regulations or guidelines that recommend or require the use of the ISBT 128 Standard?**
    Recommendations and requirements for the use of ISBT 128 vary by country/region.
    Some countries require ISBT 128 for certain MPHO fields. There are some accrediting bodies that require ISBT 128 implementation for accreditation.

20. **Is there an ISBT 128 Product Code for Human Milk?**
    Human Milk Product Codes follow a similar 8-character format as Tissue Product Codes within the ISBT 128 Standard. Specifically, this consists of a 5-character ISBT 128 Product Description Code and a 3-character Division Code of the product.
    The modified Figure 3 from our document ISBT 128 Standard Labeling of Human Milk Banking Products (ST-013) illustrates the 5-character PDC (underlined red) and the 3-character division code (underlined blue) below this Product Code structure in use for a Human Milk product label:

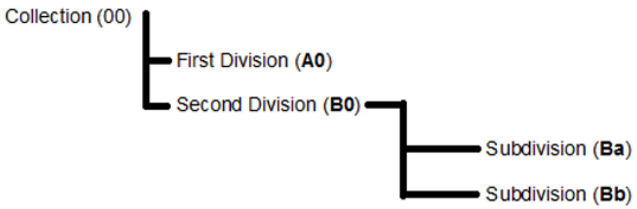
Figure 3 Example Label 4.5cm x 4.5cm



With this, ISBT 128 Human Milk Product Codes are encoded using a Product Description Code that begins with the characters, “M0” (such as the PDC in the example above). You can find the currently defined list of ISBT 128 Human Milk Product Description Codes using the ISBT 128 Online Product Lookup Tool. You can filter for these specific PDCs by selecting the Category “Other Therapies”, selecting the Subcategory “Other Therapies”, and finally selecting the class “Human Milk”.

21. **When a product is divided, does the original product receive a new code afterward? For example, an aliquot is made from E0336V00. If the aliquot is labeled as E0336VA0, does the original product remain as E0336V00 or would it become E0336VB0?**
Once the product is divided the original product code would not continue to hold values zero, zero (00) within the 7th and 8th positions.
It would be the facility’s responsibility to appropriately identify whether the original product or the aliquot would receive the division code A0 or B0.
Facilities should have internal standards set in place to remain consistent when labeling divided products.
Please see the example image - Figure 3 from IG-021.

Figure 3 Example of First and Second Level Divisions



22. **At my ocular tissue facility, I understand there is the 5-character code, but I regularly see a 5-character code followed by "000" making it 8 characters. Why do I see 8-character codes sometimes? What does it mean when there is "000" at the end of the product code?**
The ISBT 128 Product Code Data Structure is 8 characters long. The first 5 positions will be the ISBT 128 PDC. For tissue products, the 6th, 7th, and 8th positions of the product code hold information on the product divisions. Product divisions with these types of products will captured by numerical values from right to left (001, 002,…010, etc.). The value “000” means this product has not been divided.

23. **Is there a lookup tool for the product codes or only for the product description codes?**
There is only one lookup tool for ISBT 128 PDCs. For clarification, the Product Code refers to the 8 characters within the ISBT 128 Product Code Data Structure. For MPHO groups like Blood and Cellular

Therapy, the first 5 characters will be the ISBT 128 PDC while the 6th character will be the collection type, and the 7th and 8th will be information on product divisions.
ICCBBA updates and manages the ISBT 128 PDC Database which houses all ISBT 128 PDCs (first 5 characters of the product code). We do have an existing ISBT 128 Product Lookup Tool where users can search for existing ISBT 128 PDCs within the database.
However, ICCBBA does not manage, maintain, or assign collection type or product division information on the product as this would be the responsibility of the facility. Therefore, we cannot build a lookup tool that searches product codes.

24. **Are product codes that have been retired identified as such in the ISBT 128 Product Lookup Tool?**
    Yes. PDCs that are retired are identified as such when searched in both the Online and the Downloadable ISBT 128 Product Lookup Programs.

25. **How do we request a new attribute group for reproductive tissues? We want to have a new "Unit of Issue" attribute group to account for multiple pieces of ovarian tissue in one vial or several oocytes in one straw. Can this be requested via the online ISBT 128 Product Lookup Tool?**
    Requests that require new terminology to be developed should be sent via e-mail to support@isbt128.org. An ICCBBA staff member will respond by requesting additional details.

26. **As a software developer, I have a problem uploading modified product descriptions (e.g., if the product name is Thawed Plasma), how can I upload this exactly?**
    Software developers can update their systems with new or modified product descriptions by downloading the text file published alongside the latest version of the PDC Database. This semi-colon delimited text file contains all ISBT 128 PDCs found within the associated version's database.

    Alternatively, new, or modified product descriptions can be extracted from the Product Description Codes table of the PDC Database.

27. **Can ICCBBA recommend an ISBT 128-compliant labeling software? Does ICCBBA offer software that contains all ISBT 128 Product Description Codes?**
    ICCBBA's purpose is to maintain and manage the ISBT 128 Standard but does not provide any labeling or software products. Regarding recommendations for ISBT 128-compliant software, we have several Licensed Vendors who could meet this need. You can find a list of all of our ISBT 128 Licensed Vendors by using our ISBT 128 Vendor Lookup Tool. With this tool, you can filter through potential ISBT 128 Compliant Vendors by searching by their organization's name, applying the "Category" filter, or applying the "Region" filter to display ISBT 128 -compliant vendors that fall within the scope of your organization's needs.

28. **For entities that acquire ISBT 128 labeled products, are there certain software requirements to recognize the data identifiers upon receipt to ensure data is scanned to the appropriate fields, or is that a programming issue that is required for product attribute recognition?**
    It is the software vendor's responsibility to configure the system to recognize the ISBT 128 Data Identifiers to then interpret the data to the appropriate fields. It is the end user's responsibility to validate that software and verify that it meets their needs.

29. **Is ISBT 128 available to purchase as a font? For example, for use in lab-developed packing slips.**

ISBT 128 is not a font, it is a labeling Standard that provides specifications for identifying medical products of human origin.