IMPLEMENTATION GUIDE

Use of ISBT 128 in North American Eye Banks

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance to North American and other eye banks accredited by the Eye Bank Association of America (EBAA) in the implementation of ISBT 128. It is a joint document of the EBAA and ICCBBA.

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001), the *ISBT 128 Standard Labeling of Ocular Tissue* (ST-009), and the *Implementation Guide: Use of Product Code [Data Structure 003] for Ocular Tissue* (IG-032). It provides specific guidance for North American eye banks as they implement ISBT 128 and takes the requirements of the Eye Bank Association of America (EBAA) into consideration. This document also addresses concerns for software developers.

This document will discuss implementation of ISBT 128 following both the EBAA Medical Standards and the ISBT 128 Standard.

1.3 Intended Audience

The intended audience of this document is staff (management, information technology, quality, validation, procurement, laboratory, and processing) at North American eye banks, as well as eye banks accredited by the EBAA in other regions; transplant centers; software developers and label/software vendors that provide products to eye banks and transplant centers.

1.4 Normative References

Eye Bank Association of America Medical Standards (October 2014)

ISO/IEC 16022:2006(E): Information technology—International symbology specification—Data Matrix (and correction ISO/IEC 16022:2006/Cor 1:2008**)**

ISBT 128 Standard Technical Specification (ST-001)

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

ISBT 128 Standard Labeling of Ocular Tissue (ST-009)

1.5 Other Reference

ICCBBA Website (www.iccbba.org)

Implementation Guide: Use of Product Code [Data Structure 003] for Ocular Tissue (IG-032)

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

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

1.6 Background

There is wide recognition of the need to standardize the terminology, coding, and labeling of medical products of human origin (MPHO) in order to improve traceability and transparency. The 2010 World Health Assembly Resolution WHA63.22 called on member states to "encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation." ICCBBA is working with WHO in order to achieve this objective using the ISBT 128 Information Standard. On its website (http://www.who.int/transplantation/tra_isbt/en/), WHO describes ISBT 128 as the sole global standard for the identification and coding of MPHO.

Many countries around the world use ISBT 128 for blood and there is a steady global movement toward implementation of ISBT 128 for cells, tissues, and other MPHO. The use of ISBT 128 for tissues began in the United Kingdom more than a decade ago and has since expanded to a number of other countries in Europe and North America. The Eye Bank for Sight Restoration in New York City was among the first eye banks to implement ISBT 128 in 2014. Since then, many eye banks have implemented ISBT 128, or are in the process of implementing it.

The Eye Bank Association of America has requirements in their standards for the use of ISBT 128. These include:

- Eye banks were required to use ISBT 128 DINs and standardized product codes by January 1, 2016.
- Internationally shipped products must be bar coded using ISBT 128 data structures by January 1, 2017.

1.7 Changes in this Version

The following table indicates the major changes between Version 1.3.0 and Version 1.4.0. 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.

Use of ISBT 128 in North American Eye Banks, Version Control: Version 1.3.0 versus Version 1.4.0

	Version 1.3.0 Chapter, Section, Table, or Figure	Version 1.4.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	1.6	1.6	Updated the information in this section.	This information included dates, some of which have passed.
2.	New Information	3.2	Added Data Structure 002	This was added to support encoding of special messages such as Quarantine/hold for further testing or processing
3.	New Information	3.6.2	Added two new types of time encoded within Flexible Date and Time [Data Structure 031]	Time of Preservation and Time of Donor Death were added at the request of eye banks.
4.	**New Information**	**4.3.2, Table 3**	**Added the Attribute group Ocular Tissue, Non-Clinical**	**This is a new Attribute group.**
5.	4.3.4	4.3.4	Changed the phrase “Additional Text” to “Text not associated with electronically-readable information.”	This expression better describes the text.
6.	New Information	5.3	Added an example of an in-process label using Data Structure 002	This was added to provide clarity.
7.	New information	7.2	Added information about the order in which text should appear for Ocular Tissue, Non-Clinical	This is a new Class and Attribute group.

2 Getting Started: Registration with ICCBBA

2.1 Registration

Facilities wishing to use ISBT 128 must register with ICCBBA. Information about this process and a registration form may be found on the ICCBBA Website (http://www.iccbba.org/registration-licensing).

Once a facility is registered, it will be assigned a Facility Identification Number (FIN) that may be used with Donation Identification Numbers (DINs) and in the Processing Facility Information Code used to uniquely identify products.

There is flexibility in how eye banks with multiple sites may use FINs. Eye banks with multiple locations may opt to have a single FIN and manage the sequence number allocation across all of their locations centrally, or they may request multiple FINs with each facility controlling its own sequence number allocation.

- It is recommended that an organization with a single processing center, but multiple recovery locations, have a single Facility Identification Number (FIN).

- It is recommended that an organization with multiple processing centers request a different FIN for each location. While each location can have a different FIN, registration can be as a single organization or each location can register separately.

2.2 Use of Electronically-Readable Information

The EBAA standards will require that products shipped internationally have electronically-readable information (bar codes). While electronically-readable information is always desirable, it is not required for products that are only distributed within a country. Facilities that do not distribute products internationally may choose to follow only the sections of this guidance document that deal with text.

3 Data Structures Used to Label Ocular Tissue

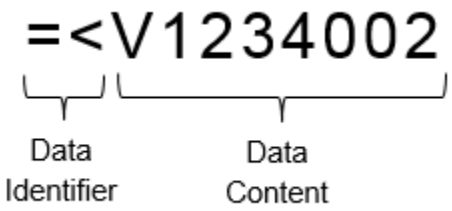
Data structures are the means by which information about ocular tissues is put into computer-friendly codes. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate reference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

Data structures comprise two elements:

- Data identifier: a two- or three-character code that identifies the data structure [described in more detail in the *ISBT 128 Standard Technical Specification* (ST-001)].

- Data content: the data characters that provide the information to be conveyed (e.g., coded information that conveys the product is a cornea).

Figure 1 Data Structure



ISBT 128 data structures are used in bar codes on labels of MPHO for electronic communication.

There are many ISBT 128 data structures and not all will be used in the labeling of ocular tissue. Data structures that are required for **traceability** include:

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

If the facility that assigns the Product Code is not the same as the facility that assigned the DIN, then an additional data structure is required for traceability:

- Processing Facility Information Code [Data Structure 033]

Because EBAA requires 2-D symbols (Data Matrix), eye bank computer systems must also be able to support:

- Compound Message [Data Structure 023]

Other data structures that may be useful to eye banks, but that are not essential to traceability, include:

- Blood Groups [ABO and RhD] [Data Structure 002] (for special messages that can be encoded in this data structure)
- Expiration Date and Time [Data Structure 005]

- Collection/Recovery Date and Time [Data Structure 007]
- Production Date and Time [Data Structure 009] (This data structure may be used to record the date and time of preservation.)
- Dimensions [Data Structure 029]
- Flexible Date and Time [Data Structure 031] (This data structure may be used to encode the date and time of preservation and/or the date and time of death.)

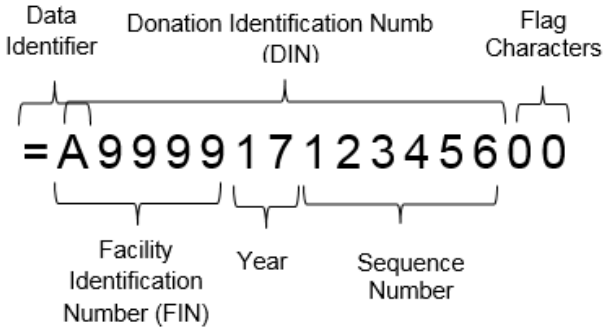
This chapter will include a high level description of the required data structures as well as other data structures that users may find useful in the labeling of ocular tissue. Specific details of coding are found in the *ISBT 128 Standard Technical Specification* (ST-001)] Guidance on how and when to use these data structures appears later in this document and/or in one of the documents referenced in Section 1.5.

3.1 Donation Identification Number [Data Structure 001]

Data Structure 001 specifies a Donation Identification Number (DIN) that is a unique identification of a donation/recovery event from anywhere in the world over a one hundred year period.

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

Figure 2 Donation Identification Number Data Structure



3.1.1 DIN

The DIN contains three elements.

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

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

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

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

3.1.2 Flag Characters

Flag characters, used for process control, are also a part of this data structure although not a part of the DIN itself. These characters allow a facility to indicate where a bar coded DIN appeared (e.g., on the product, a sample test tube, or a donor record) and can be used to facilitate automated process control. These flag characters are optional and, if not needed, the flag value of “00” should be used. Systems receiving ISBT 128 labeled products should accept any valid final product flag characters. In the text presentation, flag characters are rotated clockwise by 90 degrees (see Figure 8 on page 25).

3.1.3 Check Character

Although not a part of the data structure (or the bar coded information), a check character is added to the end of the DIN to support verification of correct keyboard entry. This check character is calculated following MOD 37-2 within ISO/IEC 7064:2003(E). Whenever ISBT 128 DINs are printed in eye-readable format on a product label, the manual entry check character should appear to the right of the DIN and flag characters and enclosed in a box (see Figure, page 25). The check character may be any one of the thirty seven characters in the set (0-9, A-Z, asterisk). Care should therefore be taken to use a font which clearly distinguishes between similar characters (0 and O, I and 1 etc.). Where computer systems accept manual entry of a DIN, the check character should always be a required part of the entry and software should verify the character is correct.

See Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033) for further information.

3.1.4 Options for Eye Banks

The DIN is assigned for each recovery event. Therefore, if cornea from both the right and left eyes are recovered, they will have the same DIN. Product Codes will be used to differentiate multiple products from the same recovery event.

3.1.4.1 When to Assign a DIN

As this guidance is focused on the use of ISBT 128 on final products, it does not directly address the point at which the ISBT 128 donation numbering is introduced. Two possible situations are identified for informational purposes, but no recommendation is made, as the most suitable option will vary according to the needs of the eye bank.

Assignment at Time of Recovery

Some eye banks may wish to assign the ISBT 128 DIN at the point of recovery. This could be done either by the eye bank allocating a DIN from their own range or by a recovery organization having its own FIN and DINs.

In all cases the assigned DIN should remain with the ocular tissue and appear on all final labeled products from that donation. If the facility that assigned the Product Code is different from the one that assigned the DIN, the identification of the processing facility [called the FIN(P) in 3.4)] shall be on the label.

It is a long term goal that DINs would be assigned at the time of recovery and be used from recovery to processing and transplant.

Assignment at Time of Processing

If existing numbering systems are used for the earlier part of the donation pathway, then the eye bank will assign the ISBT 128 DIN some time during processing before final labeling of the product. The eye bank is responsible for ensuring traceability between the ISBT 128 DIN and other identifiers.

3.1.4.2 Use of Existing Identifiers within a DIN

If a facility has an identifier that is numeric and has six or fewer characters, that identifier may be incorporated into the sequence number portion of the DIN for easier mapping between the two identifiers. Leading zeroes may be used for numbers with fewer than 6 characters. For example,

The FIN is A9999 and the existing identifier is 0238, then the DIN could be W9999 17 000238
or
if the FIN is A9999 and the existing identifier is 123456, then the DIN could be A9999 17 123456.

If the existing identifier includes other information such as year and a product code, it is not necessary to carry this information into the DIN since this information is present elsewhere in ISBT 128. For example, an existing identifier is 17-0003-200 where the 17 is the year of recovery, the 0003 is the sequence number assigned to the donor, and 200 is the code for a cornea, anterior and posterior layers, right. The year (17) is already captured in the DIN and the code for the product is captured in an ISBT 128 Product Description Code.

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

While ocular tissue is not labeled with ABO and RhD, this data structure provides a means of encoding special messages such as quarantine status. For ocular tissue, Data Structure 002 shall convey special messages such as the status of a collection, restrictions on use, or processing instructions.

gg shall, for ocular tissue, specify a range of special messages as shown in Table 1

r shall be set to 0 (zero) indicating the data structure does not contain information about these red cell phenotypes

e shall be reserved for future use. The value of e shall always be set to 0 (zero)

Figure 3 Data Structure 002

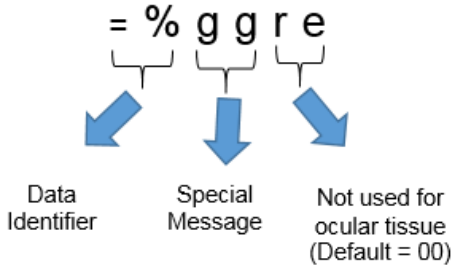


Table 1 Special Messages for Data Structure 002 (Excerpt of RT06)

gg	Interpretation
Mb	Biohazardous
Md	Discard (to be destroyed)
Mq	Quarantine/hold for further testing or processing
Mr	For research use only

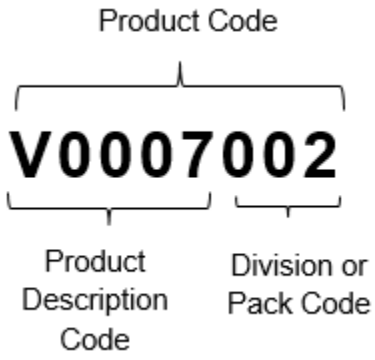
3.3 Product Code [Data Structure 003]

Data Structure 003 uniquely identifies a product intended for human use. The Product Code contains two elements:

- A 5-character Product Description Code (PDC) is assigned by ICCBBA to each product description. Products are described using terminology created by expert advisory groups such as EBTAG. These groups utilize a scheme of Classes (broad descriptions of product such as Cornea or Sclera) and Attributes (more detailed information such as storage solutions or pathogen reduction methods) to describe products. Each product is described minimally with a Class and may also have one or more Attributes. Detailed information on creating PDCs may be found in *Implementation Guide: Use of Product Code [Data Structure 003] – Ocular Tissues* (IG-032). A database, called the ISBT 128 Product Description Codes Database, lists all assigned codes and the corresponding product descriptions. The database is found in a password-protected area of the ICCBBA Website (www.iccbba.org) and is accessible by licensed users.

- For ocular tissues (PDCs beginning with the letter “V”), a 3-character Division (or Pack) Code allows each product with the same DIN and PDC to be uniquely identified. For example, if there are two products from the Sclera, both described as Right, Hypothermic storage, Part, not specified with the code V0007, from the same donor (A9999 15 123456), each will be uniquely identified using the Division (Pack) code (001 and 002). If there are not multiple packs with the same DIN and PDC, this code is set to 000. See Figure 4.

Figure 4 Product Code Data Structure for Ocular Tissue



A-D National or Local Codes

The block of PDCs A0000-D9999 has been reserved for use as nationally- or facility-defined PDCs. There shall be no international interpretation associated with these values.

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

National agencies may reserve a range of these values for national assignment. **In the US, B7000 through B9999 have been reserved for national use. There are no nationally reserved codes for Canada at this time.**

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, the facility shall ensure that definitions are provided for use within their service region, and that products bearing such codes are not transferred outside their normal distribution network. Care shall be taken in interpreting the product description from a local code as this will be specific to the supplier.

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

3.4 Processing Facility Information Code [Data Structure 033]

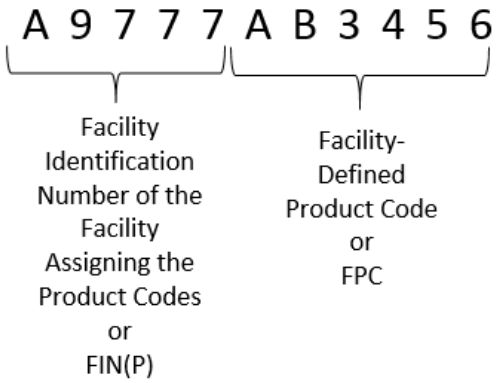
Data Structure 033 identifies the facility that assigned the Product Code (usually a processing facility). It is used when the facility that assigned the Product Code is not the same facility that assigned the DIN.

The Processing Facility Information Code contains two elements:

- A 5-character Facility Identification Code. While this is the same code as used within the first element of the DIN, it is abbreviated as FIN(P) to indicate it identifies the facility that assigned the Product Code. Information about obtaining a FIN(P), and the reference table for its interpretation, are the same as a FIN and are described in 3.1.1.

- A 6-character Facility-Defined Product Code. This code may be used to specify a catalog or other number that identifies the product within its system. The FPC shall not be used to create uniqueness for the product. The processing or labeling facility may choose to publish reference tables for use by the organizations receiving the product. If a value is not required, the default value 000000 (zeroes) shall be used.

Figure 5 Example of Data Content for Data Structure 033



3.5 Compound Message [Data Structure 023]

The compound message data structure allows multiple data structures to be combined into a single data string to be used in 2-D symbols and other newer technology delivery systems. Because EBAA has chosen to use 2-D symbols on the labels of ocular tissue shipped internationally, eye bank software must be able to code and decode information in this data structure.

Structure: =+aabbb

Element	Length	Type
=	1	data identifier, first character
+	1	data identifier, second character
aa	2	numeric {0–9}
bbb	3	numeric {0–9}

The five-character data content string **aabbb** shall be encoded and interpreted as follows:

aa shall specify the number of ISBT 128 data structures that follow;

bbb shall be either:

- all zeroes – indicating this is an undefined message, i.e. only the number of data structures is identified, but not what each one is

- a three-digit number referencing an entry in an ICCBBA maintained table that specifies the sequence of the data structures within a compound message. See Table W2, [RT017] ICCBBA-Specified Compound Messages described in the *ISBT 128 Standard Technical Specification* (ST-001). The reference table is found on the ICCBBA Website.

Rules for constructing compound messages:

1. A compound message shall comprise a string of ISBT 128 data structures (excluding nationally-defined structures), beginning with the Compound Message [Data Structure 023].

2. Data structures shall be combined with no intervening characters and each data structure shall begin with its data identifier characters.

3. The string shall only contain ISBT 128 data structures (excluding nationally defined structures).

4. The number of data structures following the Compound Message Data Structure shall be indicated in element aa of the Compound Message Data Structure.

5. If the sequence of the message is unspecified, the Compound Message Data Structure shall have elements bbb set to zeroes and element aa shall be set as specified in Rule 4.

6. If an ICCBBA-specified sequence is used, the reference number of the selected message from Table RT017 shall be included in element bbb of the Compound Message Data Structure. The order of the data structures shall be that shown on Table RT017 for the reference number selected.

Reading software should be able to interpret both unspecified sequence and specified sequence compound messages. The software should always verify the integrity of the data string, including checking that the correct number of data structures appears and, when specified sequence messages are used, that the sequence of data structures is correct. Data should only be interpreted if the integrity of the relevant data structures has been confirmed.

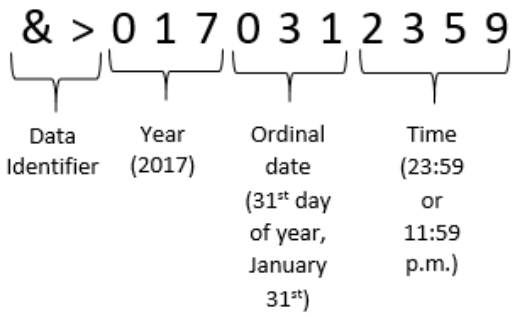
A full list of specified sequence compound messages is found in Table W2, [RT017] ICCBBA-Specified Compound Messages on the ICCBBA Website. Requests for additional entries should be submitted to the ICCBBA office (tech.manager@iccbba.org).

3.6 Date and Time Data Structures

3.6.1 Expiration, Recovery, and Production Dates and Times

There are a number of data structures designed to encode specific types of time (expiration, recovery, and production). All use the last three numbers of the year (e.g., 2017 becomes 017 in the code); the ordinal number within the calendar year (or Julian date), where the days of the year are numbered sequentially beginning with 001 on January 1; and, for some, the time based on a 24-hour clock. If the product expires at midnight, 2359 (23:59 or 11:59 p.m.) is encoded. See Figure 6.

Figure 6 Expiration Date and Time Data Structure



The types of time data structures are differentiated using the data identifier (see beginning of Section 3) as shown in Table 2. Some of the data structures include only the date while others include both date and time. Where options exist, facilities may select whatever data structure works best for them.

Table 2 Data Identifiers for Date and Time Data Structures.

Type of Time	Data Identifier
Expiration Date and Time [Data Structure 005]	& >
Collection/Recovery Date [Data Structure 006]	= *
Collection/Recovery Date and Time [Data Structure 007]	& *
Production/Processing Date and Time [Data Structure 009] (may be used for Date and Time of Preservation)	& }

3.6.2 Flexible Date and Time

As the use of ISBT 128 spread from blood to other MPHO, it became clear that many more types of time (e.g., cross-clamp time, date/time of preservation, date/time of death) might be needed. Rather than create a different data structure for each type of time, a new data structure was created that supported not only multiple types of time, but also supported encoding Coordinated Universal Time (UTC).

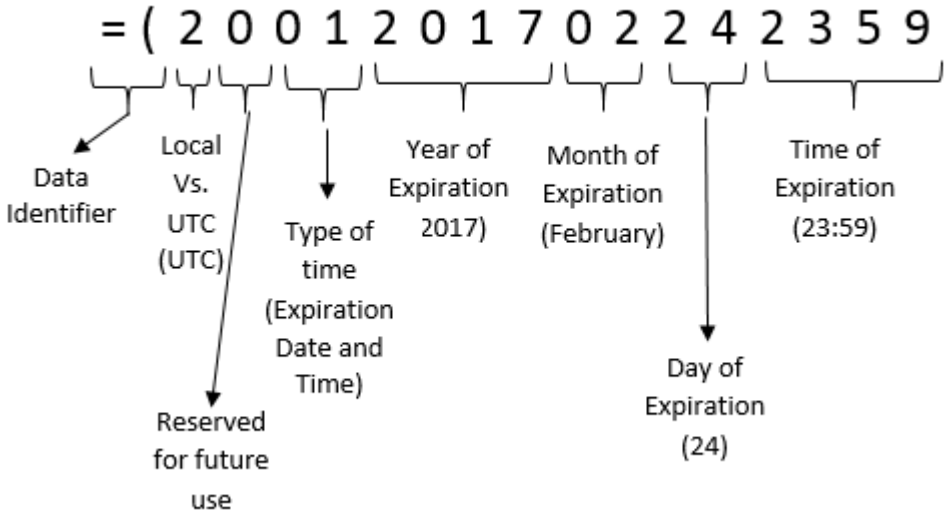
The first character of the data content indicates if the time is local (encoded as a 1) or UTC (encoded as a 2). The second character is reserved for future use. The third and fourth characters indicate the type of date and time (Expiration is 01, Collection/Recovery is 02, Production/Processing is 03, Cross Clamp is 04, Preservation is 05, and Death of Donor is 06). Additional types of time may be added for use with this data structure as they are needed.

See Figure 7.

Guidance for the use of this data structure is described within *Implementation Guide: Use of Flexible Date and Time [Data Structure 031]* (IG-024).

This data structure may be used in place of other date and time data structures or may be used when a specific type of date and time data structure does not exist (e.g., time of death).

Figure 7 Example of Flexible Date and Time [Data Structure 031]



4 Label Design

The following description applies to information required by the EBAA and the ISBT 128 Standard. It does not include all of the regulatory requirements for labeling. It is the responsibility of the eye bank to ensure regulatory and other standards requirements are met. Regulatory requirements take precedence over any guidance provided in this document.

The EBAA has decided to use 2-D symbols rather than linear bar codes. This section will therefore discuss only the use of 2-D symbols.

4.1 Information Requirements

4.1.1 ISBT 128 Label Requirements

The ISBT 128 label area must have a white background.

The minimum information content to ensure traceability shall be:

1. The electronically-readable DIN and Product Code [Product Description Code and Division Code (Pack) Code]
2. The eye-readable DIN, flag characters (rotated 90° clockwise) and the boxed manual entry check character
3. The text “Product Code:” and the eye-readable Product Code [Product Description Code and Division Code (Pack) Code]
4. The eye-readable description of the product (Class, and as space permits, Attributes)
5. The electronically- and eye-readable Facility Identification Number of the processing facility [the FIN(P)], if the facility that assigned the Product Code is different from the one that assigned the DIN.

Eye Banks that do not distribute tissue internationally are not required to use electronically-readable information on their labels. In this situation, item 1 and the requirement for electronically-readable information in item 5 (above) do not apply.

4.1.2 Additional EBAA Label Requirements

All ocular tissue distributed for surgical use shall be in a container which is clearly and indelibly labeled to include at least the information below.

<u>All tissues:</u>

1. Name of the source eye bank
2. ISBT 128 tissue identifier. The ISBT 128 tissue identifier includes the Donation Identification Number (DIN), Product Code, and Processing Facility Information Code (if applicable).
3. Type of tissue (e.g., cornea, whole eye, sclera)
4. If cornea has had additional processing (e.g., lamellar, laser shaped), clearly indicate this on the label.

5. If the Product Code and Donation Identification Number are not assigned by the same entity, then the label must include the Processing Facility Identification Code [FIN(P)].
6. Expiration date of tissue, in the international format (YYYY-MM-DD).
7. A statement that the tissue is intended for single patient application only
8. A statement that the tissue is not to be considered sterile unless the tissue has been subjected to a validated process to ensure sterility.
9. Type of storage solution
10. ISBT 128 data structures within Data Matrix 2-D symbols on ocular tissue products distributed internationally effective January 2, 2017

Short and intermediate term preserved tissues:

- Date and time of donor's death (YYYY-MM-DD HH:MM)
- Date and time of initial corneal/scleral preservation (YYYY-MM-DD HH:MM)

4.2 Electronically-Readable Information

Data Matrix 2-D symbols should be used. Symbol specifications shall follow ISO/IEC 16022:2006(E) and additional requirements found in the *ISBT 128 Standard Technical Specification* (ST-001). Information shall be encoded within an ISBT 128 Compound Message data structure. See *Use of Data Matrix Symbols with ISBT 128* (IG-014) for more information about the encoding of information within a Data Matrix symbol.

4.3 Eye-Readable Information

Minimum font sizes are determined by the printer used and readability. Typically, font sizes below 6 cannot be used because distinguishing between an "o" and an "e" becomes difficult.

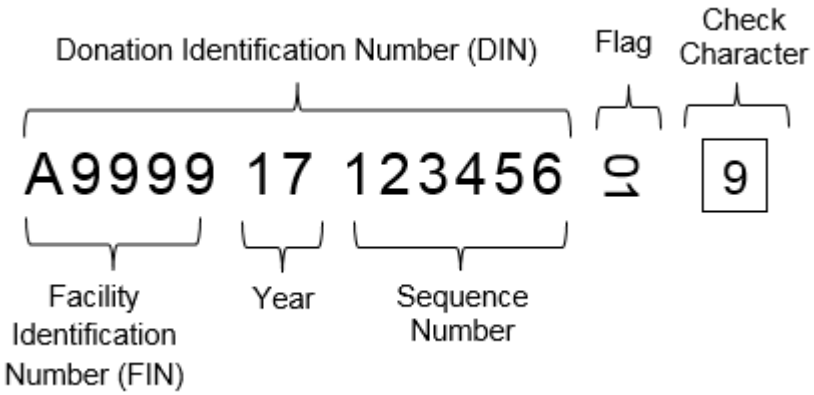
4.3.1 Donation Identification Number [001]

The DIN shall be printed using a sans serif typeface. A national authority should determine how it should be displayed. In the US and Canada, the DIN is printed by having spaces before and after the year code to facilitate ease of reading:

A9999 17 499999

The text presentation of the DIN does not include the first character of the data identifier. It includes the second character of the data identifier because it is also a part of the data content. See Figure 8.

Figure 8 Text Presentation of DIN



The flag characters may be used to convey specific information other than the unique identification of the product and shall be distinguished from the Donation Identification Number [see *ISBT 128 Standard Technical Specification* (ST-001)].

There are three types of flag characters (Types 1, 2, and 3). See *ISBT 128 Standard Technical Specification (ST-001)* for more information. Only two (Types 1 and 2) are used in the US. When Type 1 or Type 2 flag characters are used they shall be printed as either:

- Numeric Presentation: The two-digit values of flags “ff” shall be printed rotated 90° clockwise to make them visually different from the Donation Identification Number.

- Non-numeric Presentation: A graphical icon or other representation of the value of “ff”, e.g., for flag “07” printing an icon showing a small test tube.

4.3.2 Product Descriptions [Data Structure 003]

Class name shall be printed on the label. The Class name shall be printed as it appears in the *Standard Terminology for Medical Products of Human Origin* (ST-002).

Where space permits, Attributes text shall be printed on the label (except default Attributes). The text for Attributes shall appear as in Table 3. If an Attribute does not appear in Table 3, please contact the ICCBBA help desk (email iccbba@iccbba.org) for guidance on appropriate text. Information that cannot be printed on the label shall appear in accompanying documentation.

Product description bar code text should be printed with the Class name in larger print than Attribute(s).

Table 3 Text Associated with Attributes

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
Corneal Graft	Default: Not applicable or not specified	No text corresponding to the default appears on the label.	
	Anterior and posterior layers	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Anterior and Posterior Layers
	Anterior layer	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Anterior Layer
	Bowman Layer	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Bowman Layer
	Corneal button	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Corneal Button
	Corneal ring	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Corneal Ring
	Corneoscleral disc	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Corneoscleral Disc
Corneal Graft	Laser shaped	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Laser Shaped

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
	Posterior layer	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Posterior Layer
	Split cornea	Print the text shown in the next column immediately beneath the Class name “CORNEA”.	Split Cornea
Anatomical Position	Default: Not specified	No text corresponding to the default appears on the label.	
	Left		Left
	Right		Right
Storage State	Default: No information provided	No text corresponding to the default appears on the label.	
	Ambient storage	Print the storage temperature range on the affixed label or in the accompanying documentation.	Example text: Room Temperature
	Cryopreserved	Print the storage temperature range on the affixed label or in the accompanying documentation.	Example text: ≤-120 C
Storage Stage	Freeze dried		Freeze Dried
	Frozen	Print the storage temperature range on the affixed label or in the accompanying documentation.	Example text: ≤-25 C

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
	Hypothermic storage	Print the storage temperature range on the affixed label or in the accompanying documentation.	Example text: 2 C – 8 C
	Moist chamber		Moist Chamber
	Organ culture	(This term is not used in North America.)	
Storage Solution	Default: Not specified	Print the brand name of the storage solution after the Class name. Note: For the Storage Solution Attribute group, select the Default (Not Specified).	Example text: CORNEA in OPTISOL-GS
	Albumin	Print “In Albumin” after the Class name.	Example text: CORNEA in Albumin
	Antimicrobial solution	Print the name of the antimicrobial solution on the affixed label after the Class name.	Example text: CORNEA in Polytrimethoprim or in Ciprofloxacin
Storage Solution	Cryoprotectant medium	(This term is not used in North America.)	

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
	Ethanol	In addition to printing “in Ethanol” after the Class name on the affixed label, print the concentration (%) of ethanol on the affixed label or in the accompanying documentation. Note: The word “Ethanol” does not have to be printed twice if the concentration is printed on the label,	CORNEA in Ethanol Example text: 100% Ethanol
	Glycerol (high conc)	Print “in Glycerol” after the Class name.	Example text: CORNEA in Glycerol
	No storage solution		No Storage Solution
	Nutrient medium	(This term is not used in North America.)	
	Recombinant albumin	Print the name of the solution on the affixed label after the Class name.	Example text: CORNEA in 20% rHSA
	Saline	Print “in Saline” after the Class name.	Example text: CORNEA in Saline
Endothelial Cell Density	Default: No information provided	No text corresponding to the default appears on the label.	
Endothelial Cell Density	Information provided	(No information needs to be printed. The endothelial density should be provided in accompanying documents.)	

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
Pathogen Reduction	Default: No information	No text corresponding to the default appears on the label.	
	No pathogen reduction		Not Sterile
	Pathogen reduced: method NS		Pathogen reduced
	Radiation sterilization		Radiation sterilization
Transport Solution	Default: Not specified	No text corresponding to the default appears on the label.	
	Dextran		Dextran
Portion	Default: Not specified	No text corresponding to the default appears on the label.	
	Eighth	Print text shown in the next column immediately below the Lamellar Preparation Attribute, if present. If the Lamellar Preparation attribute is not present, it should appear immediately below the Class “Sclera” or the Corneal graft attribute.	Eighth
Portion	Half	Print text shown in the next column immediately below the Lamellar Preparation Attribute, if present. If the Lamellar Preparation attribute is not present, it should appear immediately below the Class “Sclera” or the Corneal graft attribute.	Half

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
	Part, NS	Print text shown in the next column immediately below the Lamellar Preparation Attribute, if present. If the Lamellar Preparation attribute is not present, it should appear immediately below the Class “Sclera” or the Corneal graft attribute.	Partial
	Quarter	Print text shown in the next column immediately below the Lamellar Preparation Attribute, if present. If the Lamellar Preparation attribute is not present, it should appear immediately below the Class “Sclera” or the Corneal graft attribute.	Quarter
Portion	Sixth	Print text shown in the next column immediately below the Lamellar Preparation Attribute, if present. If the Lamellar Preparation attribute is not present, it should appear immediately below the Class “Sclera” or the Corneal graft attribute.	Sixth
	Third	Print text shown in the next column immediately below the Lamellar Preparation Attribute, if present. If the Lamellar Preparation attribute is not present, it should appear immediately below the Class “Sclera” or the Corneal graft attribute.	Third

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
	Whole	Print text shown in the next column immediately below the Lamellar Preparation Attribute, if present. If the Lamellar Preparation attribute is not present, it should appear immediately below the Class “Sclera” or the Corneal graft attribute.	Whole
Whole Eye Type	Default: Not applicable or not specified.	No text corresponding to the default appears on the label. Default: No information provided	
	Content Removed	Print text shown in the next column immediately below the Class “Whole Eye”.	Content Removed
Lamellar Layer Preparation	Default: Not applicable or not specified	No text corresponding to the default appears on the label.	
	Laser	Print text shown in the next column immediately below the Corneal Graft Type Attribute.	Laser
Lamellar Layer Preparation	Manual Dissection	Print text shown in the next column immediately below the Corneal Graft Type Attribute.	Manual Dissection
	Microkeratome	Print text shown in the next column immediately below the Corneal Graft Type Attribute.	Microkeratome

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
Ocular Tissue, Non-Clinical	Default: Does not apply because tissue is for clinical use or, if for non-clinical use, type of non-clinical tissue is not encoded.	No text corresponding to the default appears on the label.	
	Aqueous Humor	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Aqueous Humor
	Cornea	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Cornea
	Iris	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Iris
	Lens	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Lens
	Optic nerve	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Optic nerve
Ocular Tissue, Non-Clinical	Posterior part	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Posterior part
	Retina	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Retina

Attribute Group	Attribute Variable	Instructions for Printing Text	Text (or example text when indicated) to Print on Product Label
	Vitreous Humor	Print text shown in the next column immediately below the Class name “OCULAR TISSUE, NON-CLINICAL”	Vitreous Humor

4.3.3 Dates [Data Structures 004, 005, 006, 007, 008, 009, 031]

Dates shall be printed in compliance with ISO 8601-2004 extended format.

Expiration Date:

2017-03-17

Times shall be printed based on a twenty-four hour clock with a colon placed between the hours and minutes.

The UTC, if desired, shall be printed beneath the local time in parenthesis with the designation “UTC”. Italics may also be used to clearly differentiate UTC from local time. For example:

Expiration Date/Time:

2017-01-15 15:15 EST
(2017-01-15 20:15 UTC)

4.3.4 Text Not Associated with Electronically-Readable Information

Text not associated with electronically-readable information includes such things as warnings (e.g., “Single patient use only” and “Not sterile”) and information not included within the ISBT 128 Product Description Code (e.g., the specific type of commercial storage solution). This text may appear on the label as space permits.

5 Label Examples

5.1 Examples of labels when the facility that assigned the DIN is the same as the facility that assigned the Product Code.

Figure 9 Cornea Label

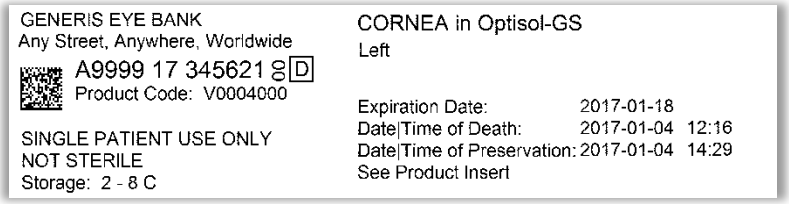


Figure 10 Cornea, Anterior and Posterior Layers

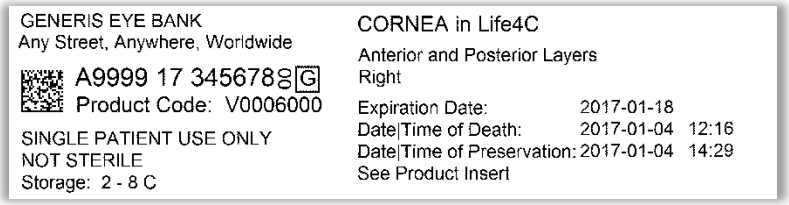


Figure 11 Partial Sclera

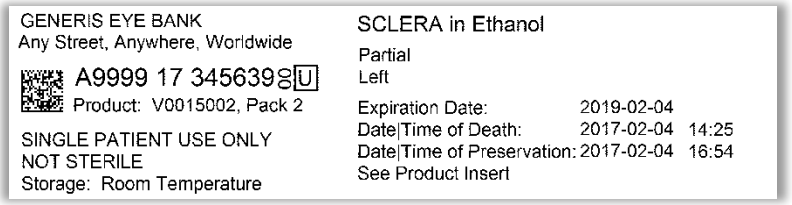
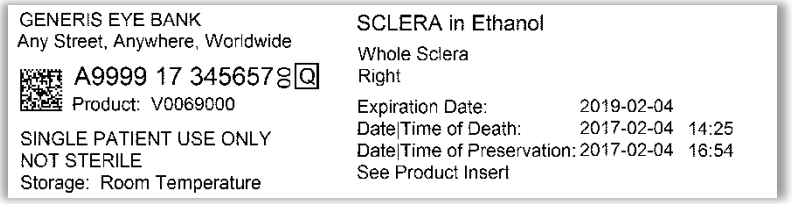


Figure 12 Whole Sclera



5.2 Examples of labels when the facility that assigned the DIN is not the same as the facility that assigned the Product Code.

The FIN(P) appears beneath the Product Code on the left side of the label. The full name of the processor may appear on the label as shown in Figure 14 (see lower right portion of the label), but this is not required and may not be possible given the size of the label.

Figure 13 Cornea Label with FIN(P)

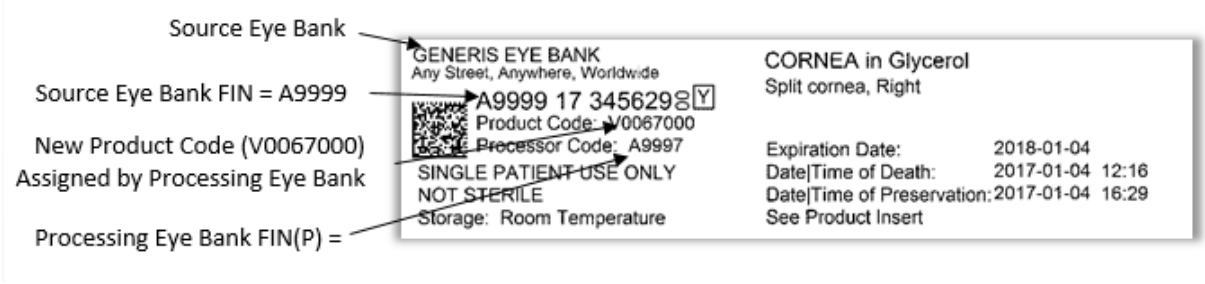
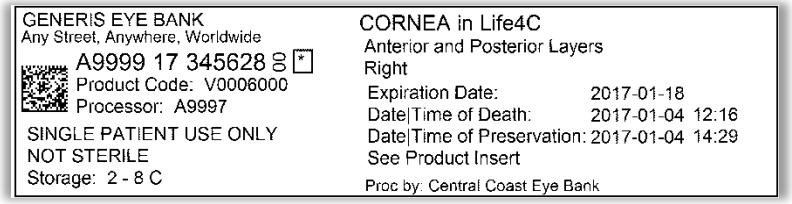
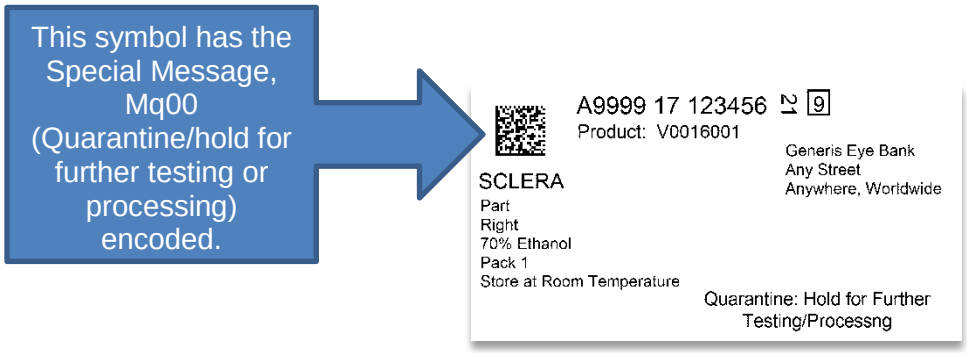


Figure 14 Cornea, Anterior and Posterior Layers with FIN(P)



5.3 Example of In-Process Label

Figure 15 In-Process Label Example



6 Re-Labeling

Facilities may receive and re-label products from other organizations. If products are re-labeled then:

- The DIN [Data Structure 001] should not be changed.
- The Product Code [Data Structure 003] shall be changed when the product is modified into a product that has a different Product Description Code or is divided such that a different Division (Pack) Code is needed.
- If a new Product Code is assigned, a Processing Facility Information Code [Data Structure 033] shall be changed or added. It shall correspond to the facility that assigned the Product Code that is on the label.

Facilities that re-label shall ensure that all products are labeled uniquely. This requires the use of the Processing Facility Information Code if an eye bank receives tissue from a recovery organization that supplies tissues to multiple eye banks. This is important to ensure each tissue is uniquely identified. For example, a recovery organization assigned the DIN A9997 17 345639 to a donation. It then sent scleral tissue to two eye banks, A and B.

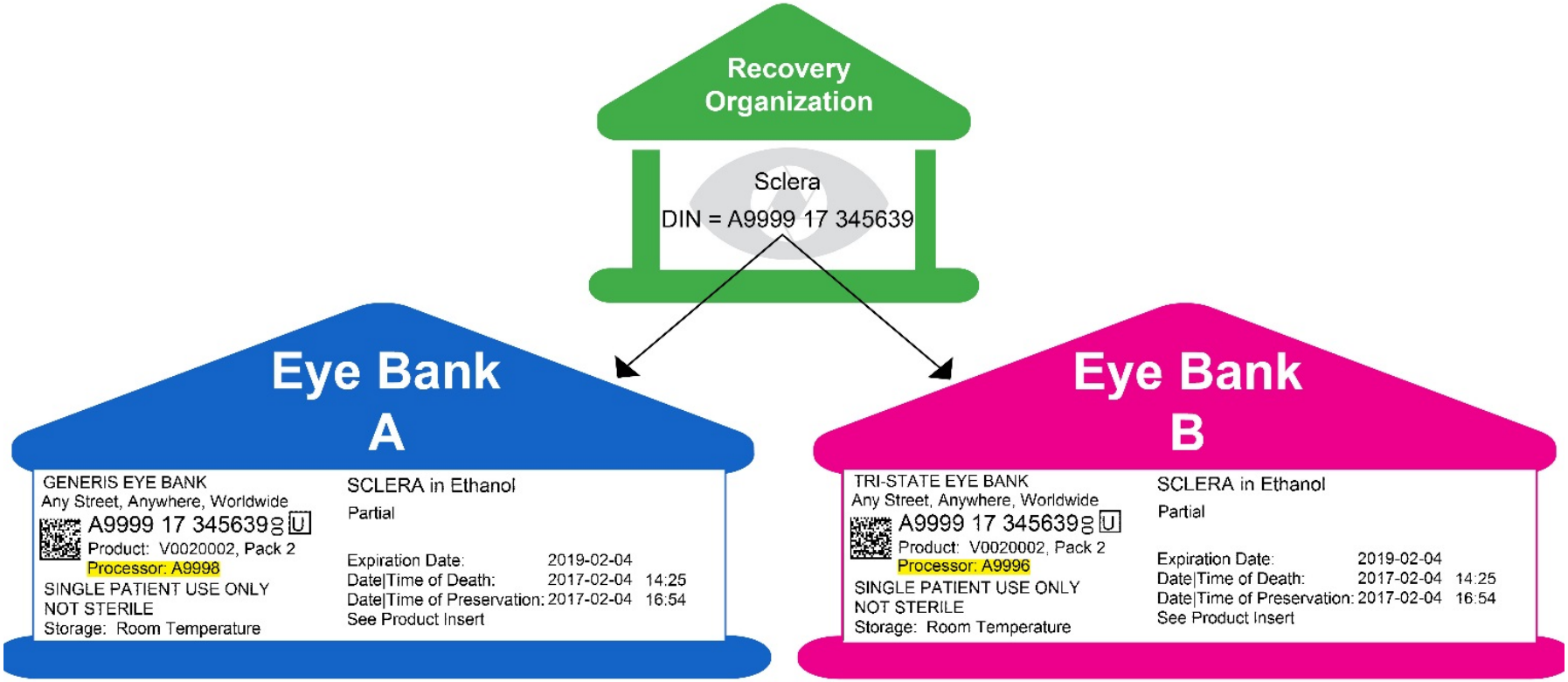
Bank A created:
DIN: A9997 17 345639
Product Code: V0020002 (SCLERA|Ambient storage|Ethanol|Part, NS)
Processing Facility Information Code: A9998000000

Bank B created:
DIN: A9997 17 345639
Product Code: V0020002 (SCLERA|Ambient storage|Ethanol|Part, NS)
Processing Facility Information Code: A9996000000

The DIN and Product Codes are identical (A9997 17 345639 and V0020002). The codes only vary by the 5th character in the Processing Facility Information Code. Thus this code is essential to support traceability of the tissue.

See Figure 16.

Figure 16 Use of Processing Facility Information Code to Create Uniqueness



7 Software Developers Information

7.1 Data Structures

Software must support all essential ISBT 128 data structures needed for tissue traceability or are required by other Standards and Regulations. These are:

- Data Structure 001 (Donation Identification Number)
- Data Structure 003 (Product Code)
- Data Structure 005 (Expiration Date and Time)
- Data Structure 033 (Processing Facility Information Code)

Additionally, since EBAA has chosen to use Data Matrix, software must also support Data Structure 023 (Compound Message).

Other data structures that may also be useful for eye banks are:

- Data Structure 002 [Blood Groups (ABO and Rh)] – used for special messages
- Data Structure 007 [Collection (or Recovery) Date and Time]
- Data Structure 009 (Production Date and Time) which may be used to convey the date/time of preservation.
- Data Structure 031(Flexible Date and Time) which may be used to convey any date and time, including the date/time of death
- Data Structure 029 (Dimensions) which at some point may be used to convey endothelial cell density

See the *ISBT 128 Standard Technical Specification* (ST-001) for more information about data structures.

7.2 Order of Product Description Attributes on the Label

While often Attributes are printed in the order the Attribute group appears in the ISBT 128 Product Description Code Database, this is not appropriate for ocular tissues. Attributes shown in **Table 4** are printed in the order shown.

Table 4 Order of Attributes

Attribute Group	Location on Label
Corneal Graft	Immediately beneath the Class name “CORNEA”.
Whole Eye Type	Immediately below the Class “WHOLE EYE”.
Lamellar Layer Preparation	Immediately below the Corneal Graft Type Attribute.

Attribute Group	Location on Label
Portion	For CORNEA: • Immediately below the Lamellar Preparation Attribute, if present. • If the Lamellar Preparation attribute is not present, immediately below the Corneal graft attribute. For SCLERA: Immediately below the Class name "SCLERA".
Type of Non-Clinical Tissue	Immediately beneath the Class name "OCULAR TISSUE, NON-CLINICAL".

7.3 Facility Identifiers

Facility identifiers within an ISBT 128 code [e.g., the FIN within Data Structure 001 and the FIN(P) within Data Structure 033] serve to uniquely identify products. They shall not be used to determine which organization played a particular role in producing a tissue. For example, the FIN within the DIN identifies the organization that assigned the DIN. No further interpretation of the role of that organization (e.g., recovery organization, source bank, or processor) shall be made. If a particular role of an organization is to be captured in facility records, a separate field shall exist. That means, for example, if the facility wants to capture the source eye bank as part of its records, that information should be captured in a separate field from the DIN.

The organization that supplied the tissue shall be recorded in the receiving facility's records. This information might not be on the label (either in electronically- or eye-readable format), but would be available from documents shipped with the tissue.

8 Abbreviations

DIN	Donation Identification Number
EBAA	Eye Bank Association of America
EBTAG	Eye Bank Technical Advisory Group
FDA	Food and Drug Administration
FIN	Facility Identification Number
FIN(P)	Facility Identification Number of the Processing Facility
FPC	Facility Defined Product Code
ICCBBA	International Council for Commonality in Blood Banking Automation
MPHO	Medical Products of Human Origin
PDC	Product Description Code
UTC	Coordinated Universal Time
WHO	World Health Organization

