ISBT 128 Standard

Labeling of Ocular Tissue

Version 1.1.0

September 2016

Editor
Pat Distler, MS, MT(ASCP)SBB
Technical Expert, ICCBBA

Standards Committee

John Armitage, Prof., BSc, PhD	United Kingdom
Paul Ashford, MSc. CEng. CSci.	ICCBBA
Wayne Bolton, B.App.Sc., M.App.Sc	Australia
Suzanne Butch, MA, MT(ASCP)SBB	United States of America
Erwin Cabana, BA	ICCBBA
Pat Distler, MS, MT(ASCP)SBB	ICCBBA
Jørgen Georgsen, MD	Denmark
Suzy Grabowski, BA, BB(ASCP)SBB	United States of America
Mario Muon, MD	Portugal
Stefan Poniatowski, BSc, MIBMS	Australia
Leigh Sims Poston, BS, MT(ASCP)	United States of America
Ineke Slaper-Cortenbach, PhD	The Netherlands
Zbigniew Szczepiorkowski, MD, PhD	United States of America
Izabela Uhrynowska-Tyszkiewicz, MD, PhD	Poland

Eye Bank Technical Advisory Group (EBTAG)

John Armitage, Chairman	United Kingdom	Representative, European Eye Bank Association
Paul Ashford	United Kingdom	ICCBBA
Samar Basak	India	Eye Bank Association of India
Barbara Crow	USA	Representative, Eye Bank Association of America
Patricia Dahl	USA	Representative, Eye Bank Association of America
Jennifer DeMatteo	USA	Representative, Eye Bank Association of America
Pat Distler	USA	ICCBBA
Monica Freire	USA	ICCBBA
Ken Lotherington	Canada	Technical Expert
Peter Madden	Australia	Technical Expert
Mark Mannis	USA	Representative, Asociacion Pan-Americana de Bancos de Ojos
Michelle McClure	USA	Liaison, US FDA
Louise Moffatt	New Zealand	Representative, Eye Bank Association of Australia and New Zealand
Diego Ponzin	Italy	Representative, European Eye Bank Association
Donald Tan	Singapore	Representative, Asia Cornea Society and the Association of Eye Banks of Asia

Warranty Disclaimer and Limitation of Liability

ICCBBA provides no representation or warranty that the Licensee's use of ISBT 128 is suitable for any particular purpose and the selection, use, efficiency and suitability of ISBT 128 is the sole responsibility of the Licensee.

ICCBBA's liability is limited to that specified in the ICCBBA License Agreement which is available on the ICCBBA website. Under no circumstances shall ICCBBA's liability to licensee or any third party under any theory or cause of action exceed the current annual license fee payable by the licensee to ICCBBA hereunder, and ICCBBA will in no circumstances be liable for any direct or indirect damages whatsoever, including without limitation special, incidental, consequential, or punitive damages or damages for loss of data, business or goodwill or any other consequential losses of any nature arising from the use of ISBT 128 or the marks.

Copyright Notice

Table of Contents

Figures

Table

1   Introduction

1.1   **Purpose**

This document is intended to help facilities and software developers design appropriate ISBT 128 labels for ocular tissue products.

1.2   **Scope**

This document provides guidance in the design of labels for ocular tissue products following the standards described in the *ISBT 128 Standard Technical Specification* (ST-001). Because container size for tissue products may vary, only a sampling of possible label designs is provided.

1.3   **Intended Audience**

The intended audience of this document is:

- staff at eye banks and hospitals that receive ocular tissue products (management, information technology, quality, validation, and laboratory)
- software developers
- label vendors
- regulatory authorities in countries where ISBT 128 is used to label ocular tissue products

1.4   **Normative Reference**

ISBT 128 Standard Technical Specification (ST-001)
Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions (ST-002)

1.5   **Other Reference**

Technical Bulletin 10: Valid and Invalid Bar Codes for Use in ISBT 128 Validations (IG-013)
Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)
Implementation Guide: Use of Flexible Date and Time [Data Structure 032] (IG-024)
Implementation Guide: Use of Dimensions [Data Structure 029] (IG-026)
Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031)
Implementation Guide: Use of Product Code [Data Structure 003] - Ocular Tissue (IG-032)
Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)
Implementation Guide: Use of ISBT 128 in North American Eye Banks (IG-040)

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 [subsequently renamed the Working Party on Information Technology (WPIT)] and published by ICCBBA in 1995. Originally developed as a coding and labeling standard for blood, ISBT 128 has demonstrated its suitability for use by cell and tissue facilities.

The United Kingdom Blood Transfusion Services/National Institute for Biological Standards and Controls Standing Advisory Committee on Information Technology was the first to consider using a structure based upon the ISBT 128 Product Code model for tissue. Intended initially as a national code, the proposal was taken forward by ICCBBA as an international standard. Facilities in other countries have since implemented ISBT 128 for tissues.

In 2010, an eye bank professional in Australia first expressed interest in using ISBT 128 to code and label ocular tissue. To expand ISBT 128 for ocular tissue, an advisory group, the Eye Bank Technical Advisory Group (EBTAG) was formed with representatives from global eye bank societies, as well as technical and regulatory experts. The societies represented were:

- Association of Eye Banks of Asia
- Eye Bank Association of Australia and New Zealand
- Eye Bank Association of America
- Eye Bank Association of India
- European Eye Bank Association
- Pan-American Association of Eye Banks

EBTAG devised terminology and released it for public comment in 2011. Comments were received and the terminology updated in response to the comments. In August 2012 the terminology was finalized and the Boards of the societies listed above approved the terminology and encouraged their members to utilize ISBT 128 (see Figure 1). That same month, the first ISBT 128 Product Description Codes for ocular tissue were issued at the request of a Canadian facility. Terminology has been added and modified as additional needs were identified.

Since this time, the Eye Bank Association of America has mandated the use of ISBT 128 for products shipped internationally in its accredited eye banks. Implementation is to occur in phases over a period of time. Therefore, many eye banks in the US have either implemented ISBT 128 or are in the process of doing so. Eye banks in Croatia and Canada have also implemented the Standard.

The activities of EBTAG is summarized on the ICCBBA Website. Information about ocular tissue is found in the Eye Bank Subject Area.

Figure 1 Joint Statement by Eye Bank Societies

International Eye Banking Technical Advisory Group on Terminology, Coding and Labeling of Ocular Tissue

The Boards of the Association of Eye Banks of Asia, Eye Bank Association of Australia and New Zealand, Eye Bank Association of America, Eye Bank Association of India, European Eye Bank Association, Pan-American Association of Eye Banks, and ICCBBA:

- taking into account World Health Assembly Resolution WHA63.22 which calls for the implementation of globally consistent coding systems for human cells tissues and organs;

- recognizing the significant benefits of international standardization of nomenclature, coding and labeling in clinical practice;

- recognizing the need for globally unique identification of grafts to support international traceability and biovigilance;

- acknowledging the widespread use of the international information standard *ISBT 128* in the fields of transfusion and transplantation;

- recognizing the need for international management and technical co-operation for the successful maintenance and development of such standards,

have established an international advisory group for nomenclature, coding and labeling of ocular tissue to:

a) develop a standard terminology to describe ocular tissue grafts;
b) provide guidance on standard labeling of ocular tissue grafts;
c) promote the adoption of the ISBT 128 standard in Eye Bank facilities around the world;
d) provide advice and support to facilities introducing the standard;
e) advise on the ongoing development of the ISBT 128 standard to support new developments in eye banking.

An agreed nomenclature has now been developed, and the Boards of the above organizations confirm their support for the international use of ISBT 128 in the coding of ocular tissue and encourage Eye Banks to:

- Adopt this standard terminology for use in communications and in the labeling of ocular tissue grafts;

- Implement ISBT 128 globally unique donation identification for ocular tissue grafts;

- Move towards full implementation of ISBT 128 nomenclature, coding and labeling in accordance with guidance published by the eye bank technical advisory group.

For further information on this initiative see http://www.iccbba.org/subject-area/eye-bank

1.7 **Changes in this Version**

The following table summarizes the major changes between Version 1.0.0 and Version 1.1.0 of this document. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

ISBT 128 Standard, Labeling of Ocular Tissue (ST-009) Version 1.0.0 vs. Version 1.1.0

	Version 1.0.0 Chapter, Section, Table, or Figure	Version 1.1.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	New information	1.5	Added references.	These documents are new since the last version of this document.
2.	New information	1.6	Updated information about the implementation of ISBT 128 in eye banks.	This is an update.
3.	2	2	Expanded section on which data structures would be used in labeling of ocular tissue.	New data structures have been added that may be useful for ocular tissue.
4.	6 and 7	6	Reorganized to combine chapters 6 and 7 into one chapter. Listed requirements first. Updated text terminology.	This was done to improve the flow.
5.	6.2 and 6.21	Removed	Requirement for sans serif font was removed.	Stating that the font selected must clearly differentiate similar characters addresses the key issue.
6.	7.1	6.1	Indicated the name of the product (e.g., Class name) shall appear on the label.	While space constraints may preclude the full product description, the Class name (or equivalent) is necessary information.

www.iccbba.org

	Version 1.0.0 Chapter, Section, Table, or Figure	Version 1.1.0 Chapter, Section, Table, or Figure	Change	Rationale
7.	**New information**	**6.3.2**	**Indicated the order that Attributes should appear on the label.**	**This follows recent decisions by EBTAG.**

2 Data Structures

The data structures that will commonly be used to label ocular tissue products include:

Data Structure	Purpose	Reference Document
Donation Identification Number [Data Structure 001]	To uniquely identify a recovery event	*Implementation Guide: Use of the Donation Identification Number [Data Structure 001]* (IG-033)
Product Code [Data Structure 003]	To uniquely identify a product from a recovery event	*Implementation Guide: Use of the Product Code Data Structure [003], Ocular Tissue* (IG-032)
Expiration Date and Time [Data Structure 005]*	To provide the expiration date of the product	See *ISBT 128 Standard Technical Specification* (ST-001) (Table RT006 provides specific messages that may be encoded.)
If Data Matrix (2-D symbols) are used, **Compound Message** [Data Structure 023]	To encode multiple data structures into a single 2-D symbol. See Chapter 5	*Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014)

*Flexible Date and Time [Data Structure 031] may be used in place of Data Structure 005

Additional bar codes may also be useful. These are:

Data Structure	Purpose	Reference Document
Blood Groups [ABO and RhD]	To encode EITHER blood groups or special messages such as "Quarantine/hold for further testing or processing"	See *ISBT 128 Standard Technical Specification* (ST-001) (Table RT006 provides specific messages that may be encoded.)
Flexible Date and Time [Data Structure 031]	To encode additional dates such as time of death and time of preservation	*Implementation Guide: Use of Flexible Date and Time [Data Structure 032]* (IG-024)
Dimensions [Data Structure 029]	To encode specific tissue measurements (e.g., exact length, width, depth, etc.).	*Implementation Guide: Dimensions (Data Structure 029)* (IG-026)

Data Structure	Purpose	Reference Document
Processing Facility Information Code [Data Structure 033]	To identify the processing facility when different from the facility that assigned the Donation Identification Number (DIN).	*Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]* (IG-031)

3 Label Size

The size of an ISBT 128 label for ocular tissue will vary depending upon a range of factors, such as the size of the container, the amount of information that a facility wants to encode using ISBT 128 data structures, the symbology (linear versus 2-D symbols) chosen to convey electronically readable information, the number of languages that may be required for text, and the requirements for other information on the label. The ISBT 128 standard therefore does not specify a particular size of label.

4 Label Access

The ISBT 128 label should be available at the time of transplantation so that information can be directly scanned into patient records. This is essential to eliminate the risk of manual transcription errors at this critical point of information transfer. However, for tracking purposes, the label will need to be scanned at various other points in the production and supply chain. To ensure this visibility of the label throughout the pathway from product release to transplantation, it may be necessary to have multiple copies of the label on different levels of packaging or to make use of outer packaging through which the underlying label can be scanned.

5   Electronically Readable Symbols

While two-dimensional (2-D) symbols are strongly recommended for labeling ocular tissue, either linear bar codes (Code 128) or 2-D symbols (Data Matrix), or both, may be used. 2-D symbols have the advantage of allowing a great deal of information to be encoded into a very small amount of space. See Figure 2. A more modern type of scanner, an imaging scanner, must be used to read them.

Specifications (quality, dimensions, etc.) for the printing of electronically readable symbols may be found in the *ISBT 128 Standard Technical Specification* (ST-001) Information on the rationale for the selection of Data Matrix, as well as implementation guidance, is found in *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014).

Figure 2 Comparison of 2-D and Linear Bar Codes

A9999 17 123456 Ζ 9

V0310V00

0170312359

All of the information contained in the three linear bar codes on the right is contained within the 2-D symbol on the left.

6 Label Design

Since ocular tissues are packaged in a variety of containers of different sizes and shapes, the Standard allows flexibility in designing labels. This document describes label designs that meet the ISBT 128 requirements, but does not preclude other designs that meet the requirements.

National agencies may publish guidelines for labeling that adhere to the ISBT 128 Standard and which take local language and regulatory requirements into consideration. An example document, *Implementation Guide: Use of ISBT 128 in North American Eye Banks* (ST-040), is available to countries wishing to create such a guideline.

The following general principles apply to label design:

- Primary considerations in label design shall include improving the safety of the product and the efficiency of processing/administering. If these two considerations conflict, safety shall take precedence over efficiency.

- Critical information on the container shall dominate the label via position and prominence and shall take precedence over information that is of lesser significance to the end-user (surgeon, nurse, and other hospital personnel).

6.1 Requirements for ISBT 128 Labels

The ISBT 128 label area shall have a white background.

In addition to meeting the requirements of regulatory agencies and applicable standard setting organizations, the minimum information content of the ISBT 128 area of the label shall be:

- Electronically-readable Donation Identification Number (DIN), Product Code, and Expiration Date and Time
- A text Donation Identification Number, flag characters when required (rotated 90° clockwise), and the boxed manual check character
- The text "Product" or "Product Code" (or equivalent text) and the Product Code (Product Description Code and Division Code)
- The text expiration date.
- The product name (e.g., Class name)

Text will usually be in the local language, but for exported tissue, may be in the language of the recipient country. See Figure 3.

Regulatory authorities and other standard setting organizations will have other minimum requirements which must also be met.

Figure 3 Minimum Information Content

Electronically readable DIN, Product Code, and Expiration Date and Time

Text DIN, Flag Characters, and Check Character

Text Product Code

Name of Product

A9999 17 123456 21 9
Product: V0016001

Generis Eye Bank
Any Street
Anywhere, Worldwide

SCLERA
Part
Right
70% Ethanol
Pack 1
Store at Room Temperature
Single Patient Use Only
Not Considered Sterile

	Date:	Time:
Death:	2017-05-18	12:16
Preservation:	2017-05-18	21: 9
Expiration:	2018-05-18	

Text Expiration Date and Time

6.2   **Small Label Design**

If the size of the label does not support the information content required by this standard, appropriate regulations and requirements of standard setting organizations should be consulted. Some required information may need to appear on secondary packaging.

6.3 **Label Text**

When printing text, the font selected must allow differentiation between similar characters (e.g., 0/O and 1/I). Particular font sizes and types are not specified, but designers shall ensure clarity of all text and use larger fonts to emphasize critical information.

6.3.1 **Donation Identification Number [001]**

Consult the *ISBT 128 Standard Technical Specification* (ST-001) for details about the Donation Identification Number (DIN). A national authority should determine how it should be displayed including if and where spaces should appear. For example:

<div align="center">

A9999 02 123456

V004399 499999

7004 203 123 456

</div>

All 13 data characters in the DIN shall be printed.

The flag characters "ff" 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* for more details).

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.

Figure 4 Representation of Flag Characters
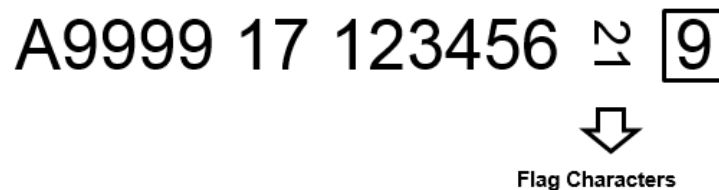
Flag Characters

The keyboard entry check character shall be printed in a manner that clearly distinguishes it from the DIN. When printed in association with the eye-readable text of a code, a box shall be drawn around the keyboard entry check character as shown in Figure 5.
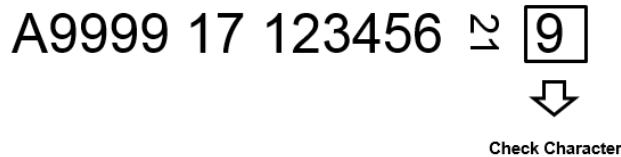
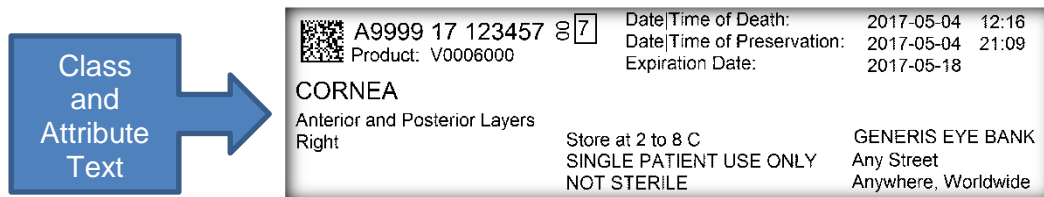**Figure 5 Representation of the Keyboard Entry Check Character**

A9999 17 123456 21 9

Check Character

6.3.2   **Product Codes and Descriptions**

The Product Code shall be printed on the label, as shown in 6.1. This can be printed with or without a space between the Product Description Code and the Division Code (e.g., V0016 001 or V0016001).

The product description Class and Attributes (except default Attributes) text shall be printed on the label, unless space does not permit. See Figure 6.

Figure 6 Example of Relative Text Sizes of Class and Attributes

Class and Attribute Text →

A9999 17 123457 8 7
Product: V0006000

CORNEA
Anterior and Posterior Layers
Right

Date|Time of Death: 2017-05-04   12:16
Date|Time of Preservation: 2017-05-04   21:09
Expiration Date: 2017-05-18

Store at 2 to 8 C
SINGLE PATIENT USE ONLY
NOT STERILE

GENERIS EYE BANK
Any Street
Anywhere, Worldwide

The order and size of text relating to the Product Description should be based on the importance of the information to the end user. In general, Class name will be in larger print than Attributes. However, this may not always be the case. (See *Implementation Guide: Use of Product Code Data Structure [003] Ocular Tissue* for information about Class and Attributes in Product Description Codes.)

If an Attribute variable (other than the default value) from one of the Attribute groups shown in Table 1 is used, text for this variable should appear in the order shown in the table. Other Attributes should appear in a nationally-defined order following Attributes from the groups listed in Table 1, or, if there is not a nationally-defined order, in the order determined by the facility.

Table 1 Order of Attribute Text on Labels

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.
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".

The use of upper and lower case text is a decision that may be made at a national level.

Text corresponding to the Division Code may appear in user-friendly text following the word "Pack" (or equivalent term). Only significant digits need appear (i.e., if the Division Code is 002, "Pack 2" is acceptable). See Figure 7.

Figure 7 Example of Division Code Text
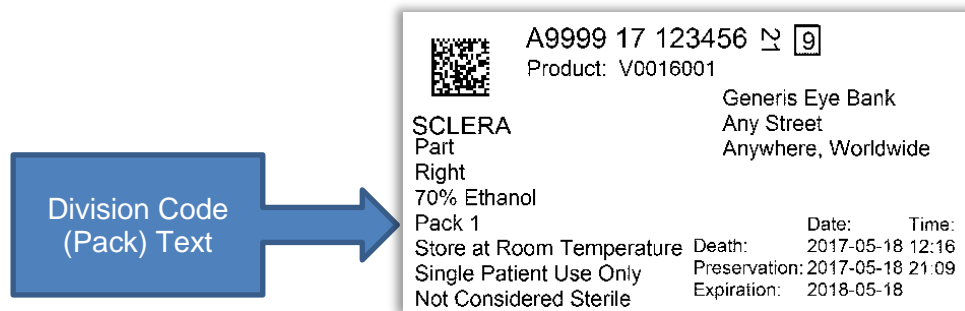
6.3.3 **Dates**

Dates shall be printed in compliance with ISO 8601-2004 extended format (2010-03-17) or in the format day — month — year. If the latter, the day shall be numerical, the month alphabetical, using a three-letter abbreviation. The year shall be a four-digit numerical representation.

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

2017-06-25 15:15

or

25 JUN 2017 15:15

When the default time of 23:59 is encoded, the time does not have to appear as bar code text.

2017-06-25

or

25 JUN 2017

6.3.4 **Additional Text**

Additional text is defined as text not associated with a bar code. Examples of additional text includes warnings (e.g., Single Patient Use Only) or the information shown in Table 2.

In designing labels, facilities may add additional text to the label where space permits. The placement of this information is not standardized.

Labeled products are assumed to have been consented for clinical use. (It is acknowledged that some countries have presumed consent where specific consent to procure and use tissue is not required.) However, when known, it is beneficial to provide information on additional consent and it is recommended that the additional consent categories shown on Table 2 be used. With the exception of "No additional consent" category, this terminology (or similar terminology in the appropriate language) should appear when needed on the affixed label or accompanying documentation.

Table 2 Additional Consent Categories

No additional consent	Consent for surgical use but no additional consent has been obtained.
Research consent	Additional consent has been obtained for research use
Educational use consent	Additional consent has been obtained for educational use (includes surgical training)
Consent for research or educational use	Additional consent has been obtained for research and educational use (includes surgical training)

Other Information

When appropriate the following information should be included in text on the affixed label or accompanying documentation:
- Corneal thickness
- Corneal disc diameter
- Corneal opacity
- Donor HLA type
- Donor ABO group
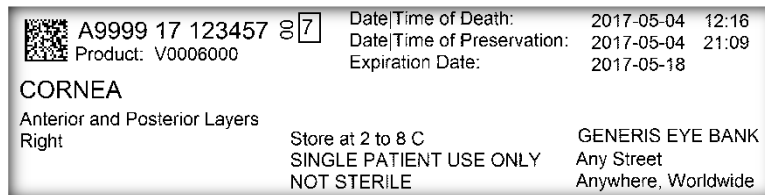
7 Label Examples

The following examples demonstrate how labels may be designed, but do not preclude other designs. Additional labels that may be used for validation purposes are found in the document Technical Bulletin 10: Valid and Invalid Bar Codes for Use in ISBT 128 Validations that may be obtained on the ICCBBA website (www.iccbba.org).

Figure 8 Ocular Tissue Label Examples of Different Sizes
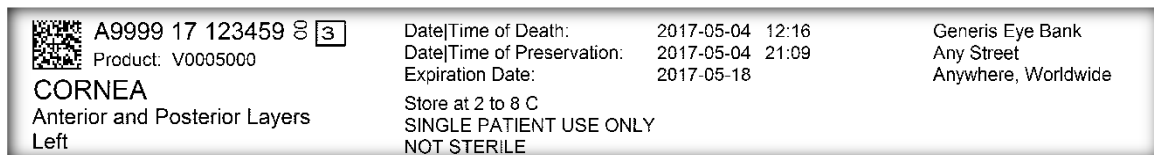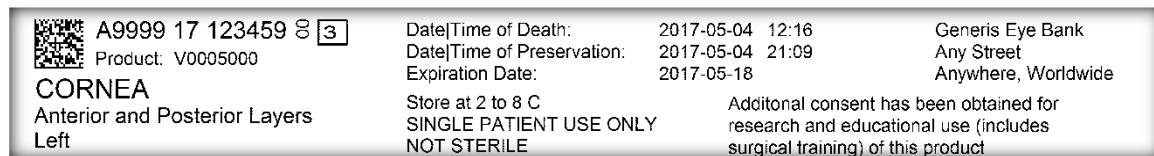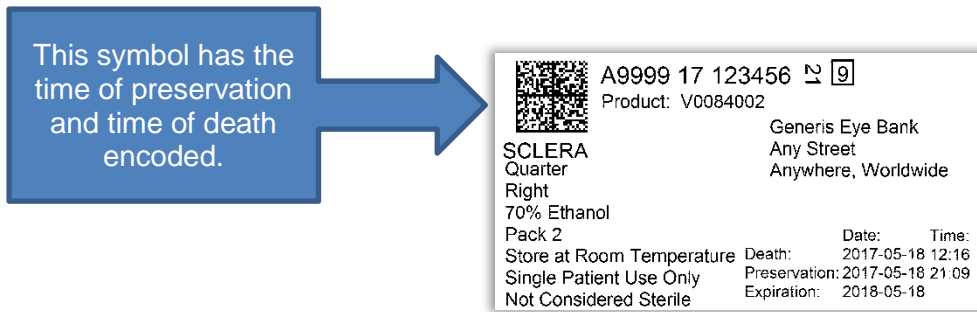
65 mm x 34 mm
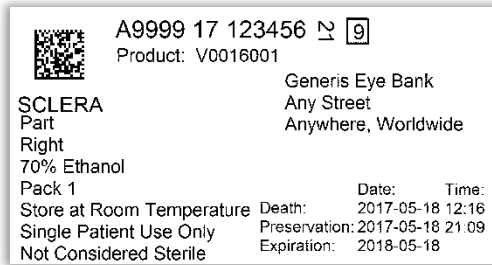
100 mm x 25 mm

150 mm x 20 mm

Figure 9 Example Label with Additional Consent Text

Figure 10 Label Example with Time of Preservation and Death Encoded

This symbol has the time of preservation and time of death encoded.

A9999 17 123456 21 9
Product: V0084002

SCLERA
Quarter
Right
70% Ethanol
Pack 2
Store at Room Temperature
Single Patient Use Only
Not Considered Sterile

Generis Eye Bank
Any Street
Anywhere, Worldwide

                          Date: Time:
Death: 2017-05-18 12:16
Preservation: 2017-05-18 21:09
Expiration: 2018-05-18

Figure 11 In-Process Label Example

This symbol has the Special Message, Mq00 (Quarantine/hold for further testing or processing) encoded.

A9999 17 123456 21 9
Product: V0016001

SCLERA
Part
Right
70% Ethanol
Pack 1
Store at Room Temperature

Generis Eye Bank
Any Street
Anywhere, Worldwide

Quarantine: Hold for Further
Testing/Processng

Text related to quarantine status