



ISBT 128 Standard

Labeling of Ocular Tissue

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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 References

ISBT 128 Standard Technical Specification ([ST-001](#))

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

1.5 Other References

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

Implementation Guide: Use of Flexible Date and Time [Data Structure 031] ([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](#))

Implementation Guide: A Validation Tool for ISBT 128 Data Structures ([IG-043](#))

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 was 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 confirmed their support for the international use of ISBT 128 in the First Joint Statement by Eye Bank Societies on Terminology, Coding, and Labeling of Ocular Tissue. 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.

At present, the Eye Bank Association of America (EBAA) requires ISBT 128 on all products distributed interstate and internationally. However, EBAA does not require eye banks to include a 2-D symbol on labels unless the graft will be distributed internationally.

The activities of EBTAG are summarized at <https://www.isbt128.org/ebtag>. Information about ocular tissue is found in the Ocular area at <https://www.isbt128.org/technical-documents>.

1.7 Changes in this Version

The following table summarizes the major changes between Version 1.1.0 and Version 1.2.0 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 1.1.0 vs. Version 1.2.0.

	Version 1.1.0 Chapter, Section, Table, or Figure	Version 1.2.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	Page 3	N/A	The list of members of the “Eye Bank Technical Advisory Group” was removed.	The list of members is posted on the ISBT 128 website (https://www.isbt128.org/ehtag).
2.	1.6	1.6	The “Joint Statement by Eye Bank Societies” was removed.	The joint statement will be published as a joint publication (stand-alone document).
3.	1.6	1.6	Information on the EBAA was updated.	To reflect the current EBAA policy.
4.	2	2	Removed reference to Table RT006 for Data Structure 005.	Table RT006 does not contain information for Data Structure 005.
5.	6.3.3	6.3.3	Removed the reference to Bar Code Text.	This terminology is no longer used in ST-001.
6.	6.3.3	6.3.3	Added that abbreviations for month shall comply with relevant national standards where applicable.	To reflect current information on ST-001.
7.	6.3.4	6.3.4	Removed the reference to Additional Text.	This terminology is no longer used in ST-001.
8.	Throughout	Throughout	Minor updates on the text and label examples.	To reflect current information.

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

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

Additional data structures may also be useful. These are:

Data Structure	Purpose	Reference Document
Blood Groups [ABO and RhD] [Data Structure 002]	To encode EITHER blood groups or special messages such as "Quarantine/hold for further testing or processing"	See <i>ISBT 128 Standard Technical Specification</i> (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	<i>Implementation Guide: Use of Flexible Date and Time [Data Structure 032]</i> (IG-024)
Dimensions [Data Structure 029]	To encode specific tissue measurements (e.g., exact length, width, depth, etc.)	<i>Implementation Guide: Dimensions (Data Structure 029)</i> (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)	<i>Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031)</i>

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 1. 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 1 Comparison of 2-D and Linear Bar Codes



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 (IG-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.

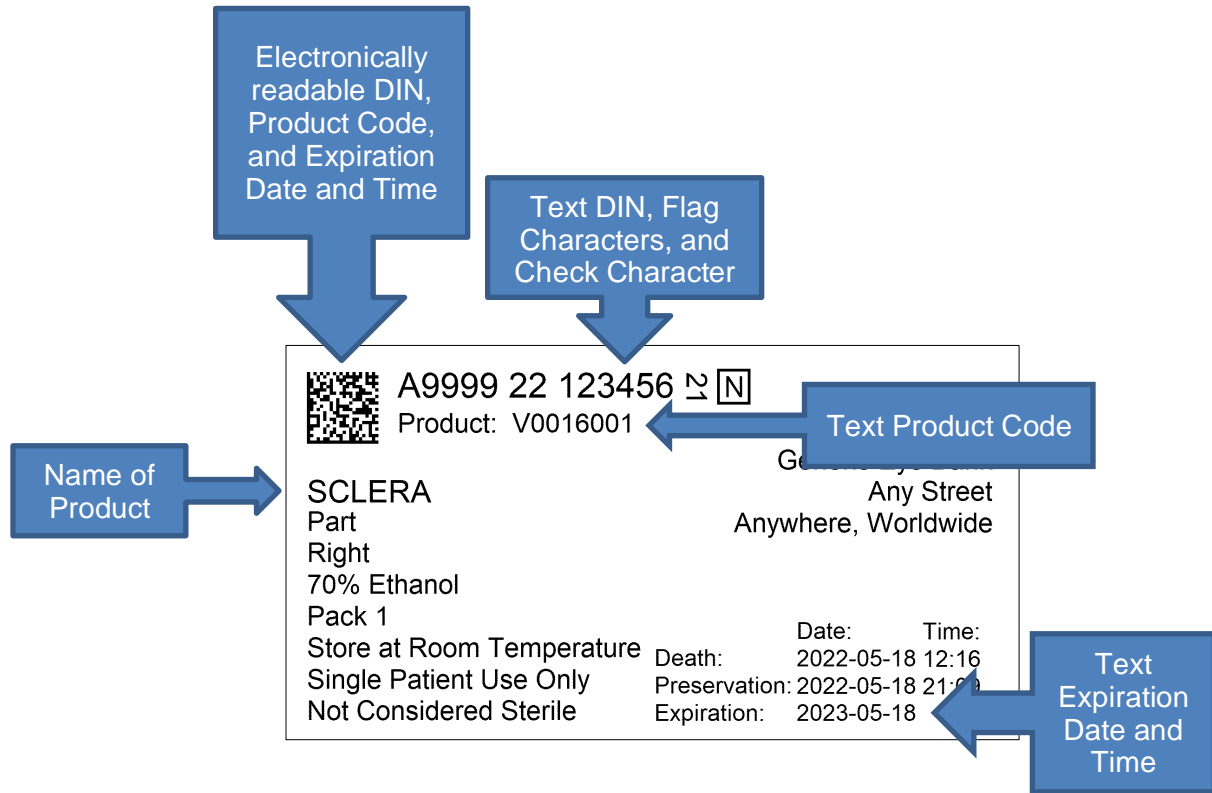
In addition to meeting the requirements of regulatory agencies and applicable standard setting organizations, the minimum information content of the ISBT 128 area of the label shall be:

- 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 2.

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

Figure 2 Minimum Information Content



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 [Data Structure 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:

A9999 22 123456

V004322 499999

7004 222 123 456

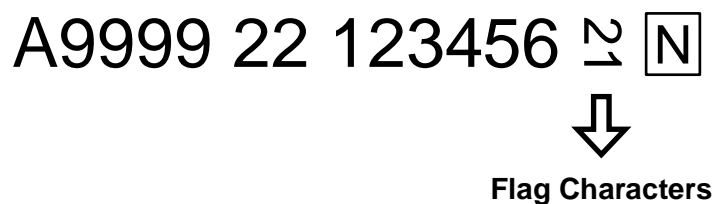
All 13 data characters in the DIN shall be printed.

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 (ST-001)* for more details.

When Type 1 or Type 2 flag characters are used they shall be printed as either:

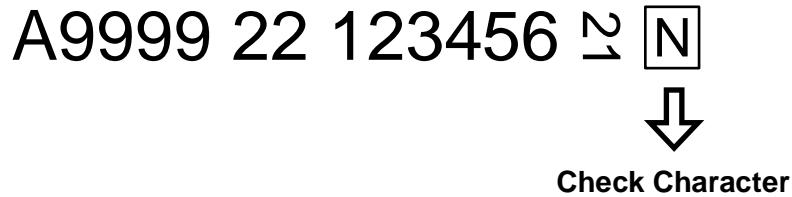
- **Numeric Presentation:** The two-digit values of flags “ff” shall be printed rotated 90° clockwise to make them visually different from the Donation Identification Number.
- **Non-numeric Presentation:** A graphical icon or other representation of the value of “ff”, e.g., for flag “07” printing an icon showing a small test tube.

Figure 3 Representation of 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 4.

Figure 4 Representation of the Keyboard Entry Check Character

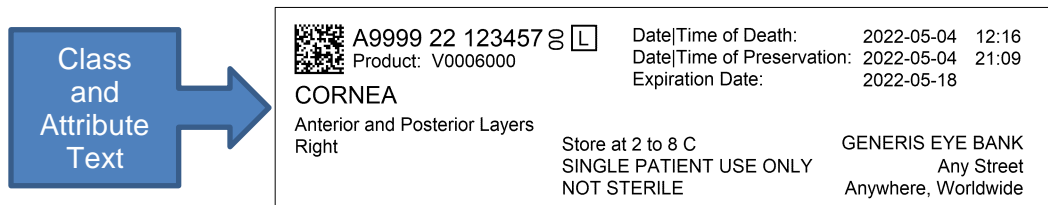


6.3.2 Product Codes and Descriptions

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 5.

Figure 5 Example of Relative Text Sizes of Class and Attributes



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 (IG-032)* 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.

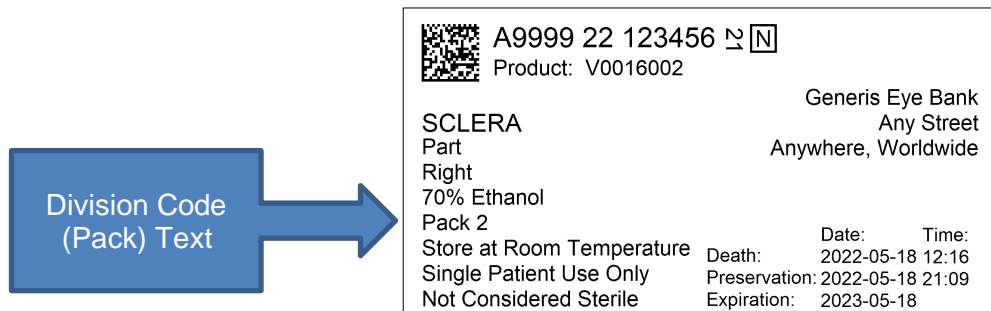
Table 1 Order of Attribute Text on Labels

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	<p>For Cornea:</p> <ul style="list-style-type: none"> • Immediately below the Lamellar Layer Preparation Attribute, if present. • If the Lamellar Layer Preparation attribute is not present, immediately below the Corneal graft attribute. <p>For Sclera: Immediately below the Class name "SCLERA".</p>
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 6.

Figure 6 Example of Division Code Text



6.3.3 Dates

Dates shall be printed in compliance with ISO 8601-2004 extended numeric format [YYYY]-[MM]-[DD] or in the format [DD] [MMM] [YYYY]. If the latter, the day shall be numerical, the month alphabetical, using a three-letter abbreviation, and 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.

2022-06-25 15:15

or

25 JUN 2022 15:15

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

2022-06-25

or

25 JUN 2022

Note: Abbreviations for month shall comply with relevant national standards where applicable.

6.3.4 Text Not Associated with Electronically Readable Information

Text not associated with electronically readable information 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

Category	Description
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)

6.3.5 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 *Implementation Guide: A Validation Tool for ISBT 128 Data Structures (IG-043)* that may be obtained on the ICCBBA website (www.isbt128.org).

Figure 7 Ocular Tissue Label Examples of Different Sizes

65 mm x 34 mm

	A9999 22 123456 	
	Product: V0016001	
SCLERA		Generis Eye Bank
Part		Any Street
Right		Anywhere, Worldwide
70% Ethanol		
Pack 1		
Store at Room Temperature	Date:	Time:
Single Patient Use Only	Death: 2022-05-18	12:16
Not Considered Sterile	Preservation: 2022-05-18	21:09
	Expiration: 2023-05-18	

100 mm x 25 mm

	A9999 22 123457 	Date Time of Death:	2022-05-04	12:16
	Product: V0006000	Date Time of Preservation:	2022-05-04	21:09
		Expiration Date:	2022-05-18	
CORNEA				
Anterior and Posterior Layers				
Right	Store at 2 to 8 C		GENERIS EYE BANK	
	SINGLE PATIENT USE ONLY		Any Street	
	NOT STERILE		Anywhere, Worldwide	

150 mm x 20 mm



	A9999 22 123459 	Date Time of Death:	2022-05-04	12:16	Generis Eye Bank
	Product: V0005000	Date Time of Preservation:	2022-05-04	21:09	Any Street
		Expiration Date:	2022-05-18		Anywhere, Worldwide
CORNEA					
Anterior and Posterior Layers					
Left	Store at 2 to 8 C				
	SINGLE PATIENT USE ONLY				
	NOT STERILE				

Figure 8 Example Label with Additional Consent Text



	A9999 22 123459 	Date Time of Death:	2022-05-04	12:16	Generis Eye Bank
	Product: V0005000	Date Time of Preservation:	2022-05-04	21:09	Any Street
		Expiration Date:	2022-05-18		Anywhere, Worldwide
CORNEA					
Anterior and Posterior Layers					
Left	Store at 2 to 8 C				
	SINGLE PATIENT USE ONLY				
	NOT STERILE				
					Additional consent has been obtained for research and educational use (includes surgical training) of this product

Figure 9 Label Example with Time of Preservation and Death Encoded

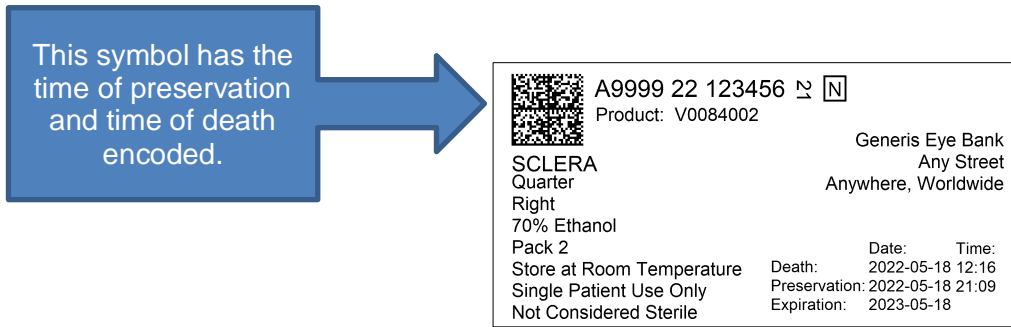
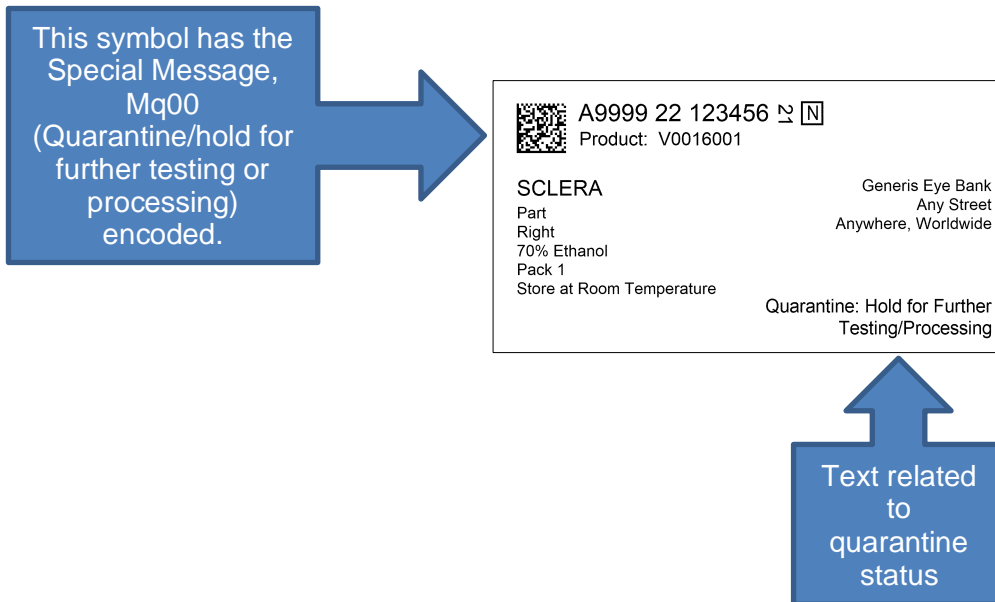


Figure 10 In-Process Label Example



END OF PUBLICATION

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

[ST-001 ISBT 128 Standard Technical Specification](#)

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

[IG-014 Use of Data Matrix Symbols with ISBT 128](#)

[IG-024 Use of Flexible Date and Time \[Data Structure 031\]](#)

[IG-026 Use of Dimensions \[Data Structure 029\]](#)

[IG-031 Use of the Processing Facility Information Code \[Data Structure 033\]](#)

[IG-032 Use of Product Code \[Data Structure 003\] - Ocular Tissue](#)

[IG-033 Use of the Donation Identification Number \[Data Structure 001\]](#)

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