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# ISBT 128 STANDARD

## Labeling of Reproductive Tissue and Cell Products

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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 reproductive tissue and cell products.

## 1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001) and defines the labeling requirements for reproductive tissue and cell products.

This Standard specifies the requirements for standardized labels. Where possible, these labels shall be affixed to the product container. If the container is too small to carry a full label, the affixed label shall be unambiguously associated with the full label in the accompanying documentation for that product.

## 1.3 Intended Audience

The intended audience of this document is staff at medically assisted reproduction (MAR) facilities, hospitals that receive reproductive tissue and cell products (managers, information technology, quality, validation, and laboratory), software developers, and label/software vendors.

## 1.4 Normative References

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

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

*ISBT 128 and the Single European Code (SEC)* ([ST-012](#))

## 1.5 Other References

ICCBBA website ([www.isbt128.org](http://www.isbt128.org))

*Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution* ([IG-010](#))

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

*Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]* ([IG-031](#))

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

Ashford P, Rydman K, Sparks A, Tilleman K, Freire M. Standard terminology for reproductive tissue and cell products for use in ART. *Hum Reprod Open* 2019;2019(2). <https://doi.org/10.1093/hropen/hoz005>.

Zegers-Hochschild F, Adamson GD, Dyer S, et al. The International Glossary on Infertility and Fertility Care, 2017. *Hum Reprod* 2017;32(9):1786-1801. <https://doi.org/10.1093/humrep/dex234>.

## 1.6 Background

There is growing recognition at the global level that there is a need to move towards standardization of the coding and labeling used on medical products of human origin (MPHO) in order to improve traceability and enhance patient safety. The World Health Assembly has recognized this need in 2010, and Resolution WHA63.22 urges 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.”

ISBT 128 is a well-established and widely used international coding system for MPHO. It provides globally unique identification and a comprehensive and highly flexible system for describing products and assigning product codes suitable for use in bar codes and other electronic communication.

ICCBBA formed a working group in 2016 to review the initial ISBT 128 terminology for reproductive tissue and cell products. Soon after, in early 2017, the Assisted Reproductive Technology Technical Advisory Group (ARTTAG) was established to continue its development.

The ARTTAG membership comprises Technical Experts in medically assisted reproduction, Liaisons from regulatory authorities, Observers, and Representatives from international professional societies.

In 2019, the ISBT 128 terminology for reproductive tissue and cell products was updated to align with the “The International Glossary on Infertility and Fertility Care, 2017” (Zegers-Hochschild et al. 2017). This major development was announced in the article “Standard terminology for reproductive tissue and cell products for use in ART” (Ashford et al. 2019), published in *Human Reproduction Open*.

In the future, the ARTTAG designation will be changed to MARTAG—Medically Assisted Reproduction Technical Advisory Group—as MAR is a broader term that includes all ART procedures and assisted insemination per its definition in the international glossary.

The adoption of the ISBT 128 Standard can help significantly improve the quality, safety, and traceability of reproductive tissue and cell products by providing:

- globally unique identification,
- internationally standardized product definitions,
- standard data structures for bar coding and electronic interchange, and
- label designs that are consistent worldwide.

The ISBT 128 Standard and terminology are continuously enhanced to accommodate evolving needs and changes in practice. International professional societies are welcome to participate in the committee's work.

## 2 Label Design

### 2.1 General Principles

The following general principles shall 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 little importance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

The following resources are available on the ICCBBA website to assist those designing labels:

- *ISBT 128 Standard Technical Specification (ST-001)* for information on the general requirements and supplementary guidance.
- *ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)* for information on the structure of the terminology and terms definitions.
- ISBT 128 Product Description Code Database (in the password-protected area) for a comprehensive list of the Product Description Codes (PDCs).
- ISBT 128 Product Lookup Web Application (in the password-protected area) to search for existing Product Description Codes (PDCs) and submit new requests.

### 2.2 Full Label Requirements

Whether affixed to the product or in accompanying documentation, an ISBT 128 full label shall carry:

- The electronically-readable Donation Identification Number (DIN)
- The eye-readable Donation Identification Number (DIN) preceded by the text “DIN:”
- Flag characters are optional, but if used, they shall be rotated 90° clockwise
- The boxed manual check character
- The electronically-readable Product Code
- The eye-readable Product Description Code preceded by the text “PDC:”
- The eye-readable Division Code, if non-zero, preceded by the text “DIV:” (leading zeros may be omitted)

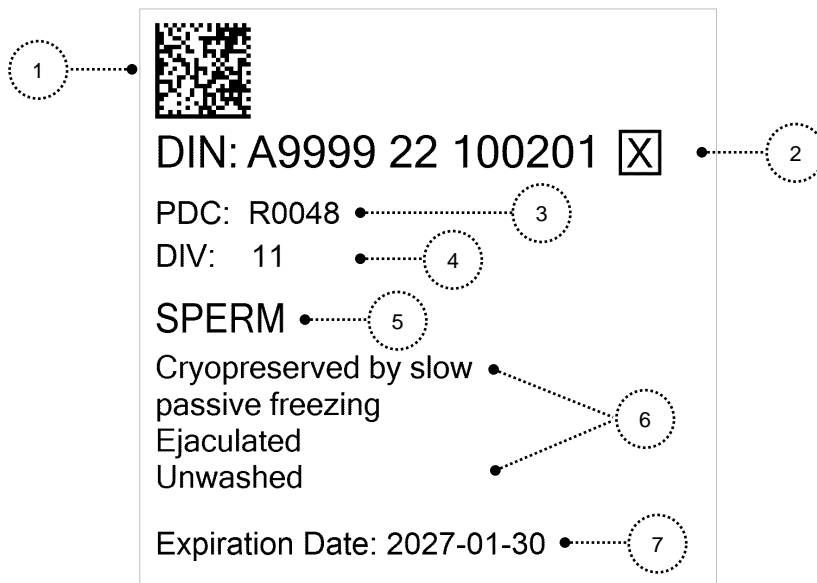


- The Class Name
- The product Attributes (except default Attributes). Note: The level of detail in product descriptions is up to the facility and regulatory/accreditation authorities. To request new terminology, refer to the instructions at <https://www.isbt128.org/find-product-info>.
- The electronically-readable expiration date (if the product has an expiration date)
- The eye-readable expiration date (if the product has an expiration date)

If the Single European Code (SEC) is required, it shall either be printed on one line with a single space between the Donation Identification Sequence and Product Identification Sequence or on two lines. The SEC should be positioned towards the bottom of the label. For guidance, refer to *ISBT 128 and the Single European Code (SEC)* (ST-012).

Figure 1 shows a label example with the required information.

Figure 1 Labeling Requirements



1. Electronically-readable Donation Identification Number (DIN), Product Code, and Expiration Date (2-D symbol)
2. Eye-readable Donation Identification Number (DIN): A9999 22 100201 preceded by the text “DIN:” and Boxed Check Character:
3. Eye-readable Product Description Code “R0048” preceded by the text “PDC:”
4. Eye-readable Division Code “11” preceded by the text “DIV:”
5. Class Name
6. Attributes (except default Attributes)
7. Eye-readable Expiration Date (if the product has an expiration date)

## 2.3 Small Label Requirements - Mapping of Information

As the majority of reproductive product containers are too small to accommodate a full label, the label affixed on a small container shall be unambiguously associated with the full label in the accompanying documentation for that product.

To ensure unambiguous association, the product shall carry an affixed label that is either:

- A reduced ISBT 128 label that can be linked via a minimum of the eye-readable Donation Identification Number (DIN), Product Description Code (PDC), and Division Code (DIV) to the full label in the accompanying documentation. This is the minimum information required for traceability. See the illustration in Figure 2.

Or

- A product identifier—assigned by the labeling organization—that is carried on the affixed label and the ISBT 128 full label in the accompanying documentation. See the illustrations in Figure 3.

Figure 2 Affixed Reduced ISBT 128 Label and Full Label in Accompanying Documentation

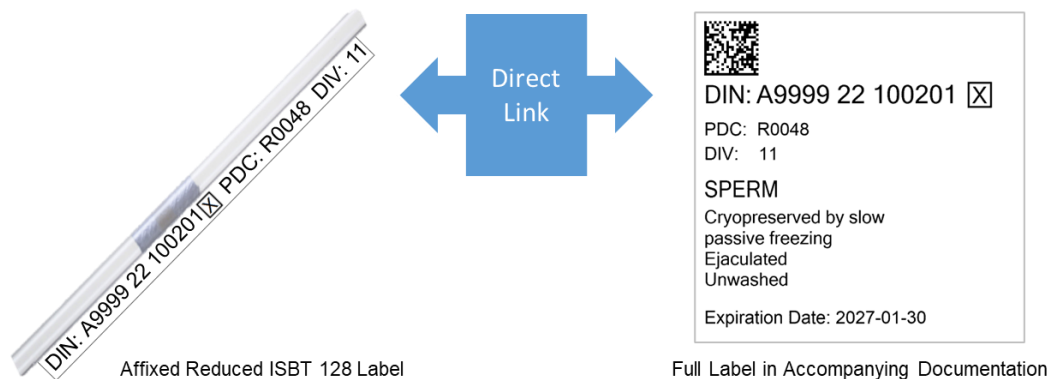


Figure 3 Affixed Product Identifier and Full Label in Accompanying Documentation



### 3 Data Structures

The data structures that will commonly be used to label reproductive tissue and cell products include:

Data Structure	Purpose	Reference Document
Donation Identification Number [Data Structure 001]	To uniquely identify a collection event or a zygote/embryo formed through ART.	<i>ISBT 128 Standard Technical Specification (ST-001) Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)</i>
Product Code [Data Structure 003]	To uniquely identify a product intended for human use and encode whether or not the product has been divided.	<i>ISBT 128 Standard Technical Specification (ST-001)</i>
Expiration Date and Time [Data Structure 005]	To provide the expiration date of the product.	<i>ISBT 128 Standard Technical Specification (ST-001)</i>
Compound Message [Data Structure 023] If two-dimensional (2-D) symbols (Data Matrix) are used.	To encode multiple data structures into a single 2-D symbol.	<i>ISBT 128 Standard Technical Specification (ST-001) Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)</i>

Additional data structures that may also be useful include:

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>
Single European Code [Data Structure 038]	To encode the Single European Code (SEC) as described in the EU Commission Directive 2015/565.	<i>ISBT 128 and the Single European Code (SEC) (ST-012)</i>

## 4 Delivery Mechanisms

Data structures can be delivered using two-dimensional (2-D) symbols (Data Matrix) and linear bar codes (Code 128).

Data Matrix is strongly recommended for reproductive tissue and cell products since 2-D symbols have the advantage of allowing a great deal of information to be encoded into a very small amount of space. An imaging scanner must be used to read them.

When multiple data structures are combined in a 2-D symbol, they shall be encoded as a compound message using the Compound Message [Data Structure 023].

Facilities implementing Data Matrix shall follow the technical specifications and guidance found in the *ISBT 128 Standard Technical Specification* (ST-001) and the *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014).

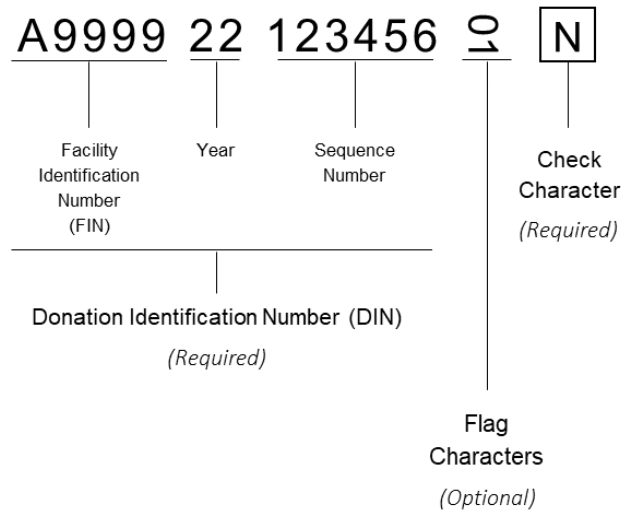
For backward compatibility, the Standard continues to permit the use of linear bar codes (Code 128).

## 5 Label Text

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

### 5.1 Donation Numbering

Figure 4 Elements of the Donation Numbering



Donation numbering is comprised of:

- 1) The required Donation Identification Number (DIN), which identifies:
  - the Facility Identification Number (FIN),
  - the nominal year in which the DIN was assigned, and
  - the sequence number within the given year for the facility identified by the FIN.
- 2) The optional Flag Characters that can be used to discriminate between identical donation numbers in different places (e.g., donor record label, test tube label). The Flag Characters should not be used to identify product divisions. When the default value (00) is used, the Flag Characters do not have to be printed.
- 3) The required Check Character that is used to verify the accurate manual entry of the DIN.

For additional information on these elements, consult the following documents:

- *ISBT 128 Standard Technical Specification (ST-001)*
- *Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)*

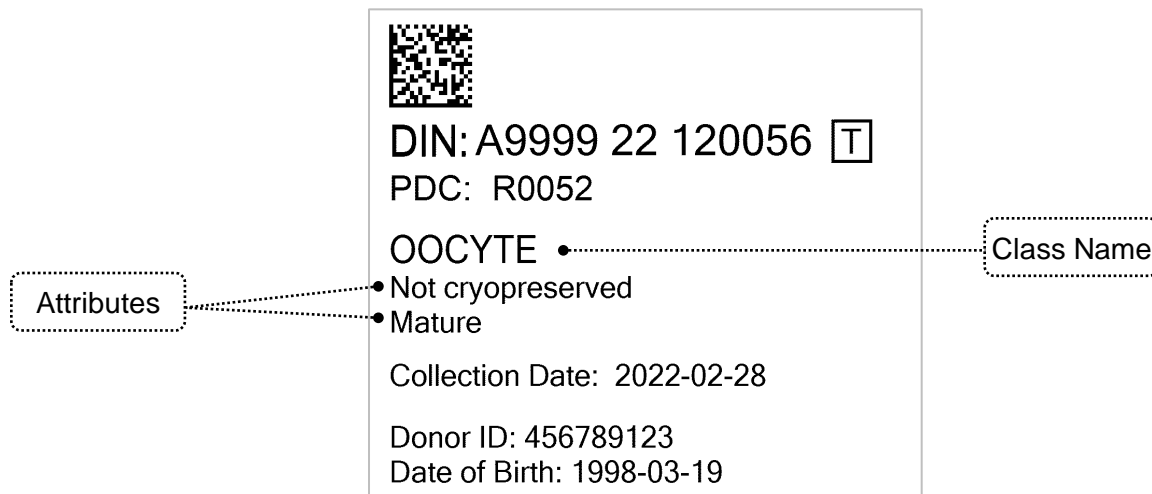
- *Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points During Processing and Distribution (IG-010)*

## 5.2 Product Descriptions

Text corresponding to the Product Description Code (PDC), Class Name, and Attributes (except default Attributes) shall be printed on the label unless space does not permit.

- The text does not have to match exactly the product description found in the ISBT 128 Product Description Code Database. It may vary but should convey the same product information.
- 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, the Class Name will be in larger print than the Attributes. See Figure 5.

Figure 5 Relative Text Size of Class Name and Attributes



### 5.3 Dates and Times

Dates shall be printed in compliance with ISO 8601-2004 extended numeric format [YYYY]-[MM]-[DD], or in the format [DD] [MMM] [YYYY].

For example, using ISO 8601-2004, September 27, 2022, is represented as 2022-09-27.

In the format [DD] [MMM] [YYYY], the day shall be numerical; the month shall be alphabetical using a three-letter abbreviation, and the year shall be a four-digit numerical representation. For example, September 27, 2022, is represented as 27 SEP 2022.

Times shall be printed based on a twenty-four-hour clock with a colon placed between the hours and minutes. When the default time of 23:59 is encoded, the time does not have to appear as text.

Examples of acceptable text for dates and times are shown below.

**2022-06-25 15:15** or **25 JUN 2022 15:15**

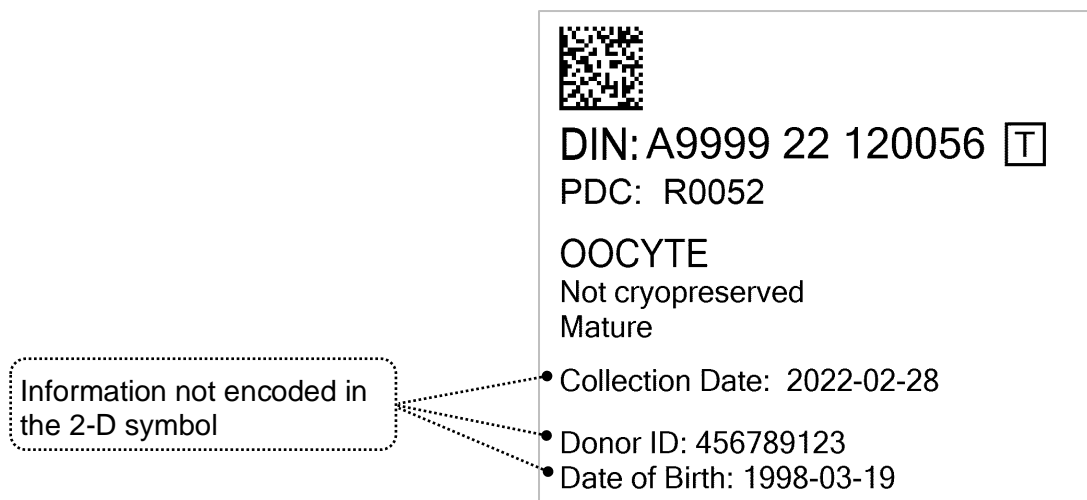
### 5.4 Text Not Associated with Electronically-Readable Information

Facilities may add text not associated with electronically-readable information where space permits, and there is a need.

The placement of this information is not standardized internationally but may be standardized nationally.

An example of a label containing information that is not associated with electronically-readable information is shown in Figure 6.

Figure 6 Text Not Associated with Electronically-Readable Information

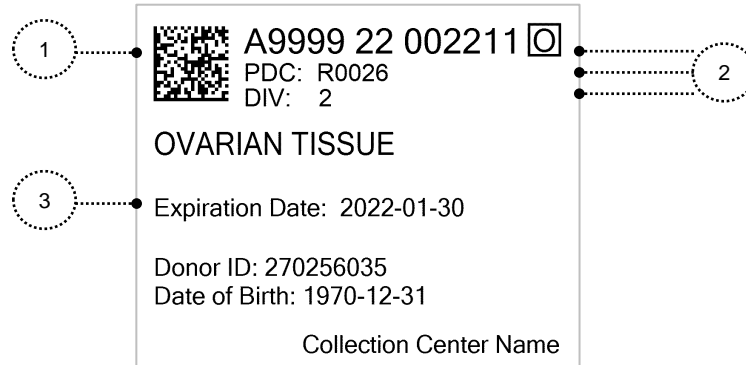




## 6 Label Examples

The following labels are provided as examples only. National regulations and appropriate standards must be consulted to ensure full compliance with requirements.

Figure 7 Product Label with 2-D Symbol



1 The 2-D symbol encodes the following information:

**=+03000=A99992200221100=<R0026002&>0220302359**

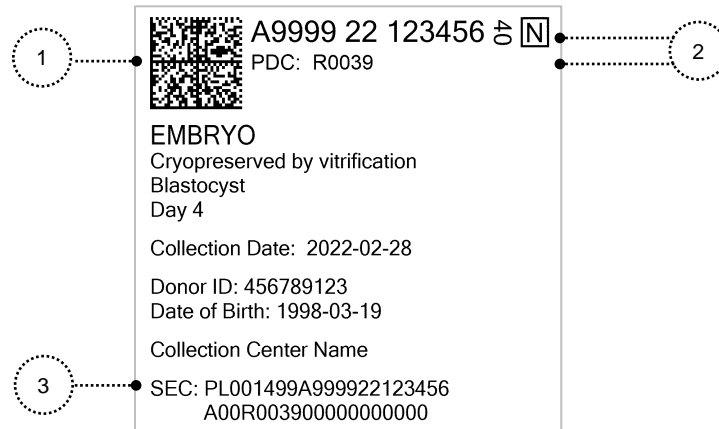
- =+03000 represents the Compound Message [Data Structure 023]  
=+ are the data identifiers  
03 indicates that three data structures are encoded in the 2-D symbol  
000 indicates that the data structures are not encoded in a specific order in the string
- =A99992200221100 represents the Donation Identification Number [Data Structure 001]  
=A are the data identifiers  
A999922002211 is the DIN and 00 (default) are the Flag Characters
- =< R0026002 represents the Product Code [Data Structure 003]  
=< are the data identifiers  
R0026 is the Product Description Code (PDC) and 002 is the Division Code
- &>0220302359 represents the Expiration Date and Time [Data Structure 005]  
&> are the data identifiers  
0220302359 represents the expiration date 2022-01-30 and expiration time 2359 (default)

2 Eye-readable donation numbering, PDC, and Division Code:

- The donation numbering comprises the DIN (A999922002211) and Check Character “O” (the default Flag Characters “00” are not printed)
- The Product Description Code “R0026” preceded by the text “PDC:”
- The Division Code “2” (leading zeros may be omitted) preceded by the text “DIV:”

3 When the Expiration Date is encoded, it shall appear in eye-readable text (the default expiration time 2359 is not printed).

Figure 8 Product Label with Electronically-Readable Single European Code (SEC)



1 The 2-D symbol encodes the following information:

**==+03000=A99992212345640=<R0039000&,4PL001499A999922123456A00R00390000000000**

- ==+03000 represents the Compound Message [Data Structure 023]  
==+ are the data identifiers  
03 indicates that three data structures are encoded in the 2-D symbol  
000 indicates that the data structures are not encoded in a specific order in the string
- =A99992212345640 represents the Donation Identification Number [Data Structure 001]  
=A are the data identifiers  
A999922123456 is the DIN and 40 are the Flag Characters
- =<R0039000 represents the Product Code [Data Structure 003]  
=< are the data identifiers  
R0039 is the Product Description Code (PDC) and 000 (default) is the Division Code
- &,4PL001499A999922123456A00R0039000000000000 represents the Single European Code [Data Structure 038]  
&,4 are the data identifiers  
PL001499A999922123456A00R0039000000000000 is the SEC

2 Eye-readable donation numbering and PDC:

- The donation numbering comprises the DIN (A999922123456), Flag Characters (40), and Check Character (N)
- The Product Description Code “R0039” preceded by the text “PDC:”

3 When the Single European Code (SEC) is encoded, it shall appear in eye-readable text.